Candidate Declaration:

Candidate Name: Osidele Mosopefoluwa Osidele

I certify that the dissertation entitled: “The study of the key challenges in the Nigerian Pharmaceutical Industry, with Emphasis on the Regulation and Quality of Medical Devices” submitted for MSc in Pharmaceutical Business and Technology is the result of my own work and that where reference is made to the work of others, due acknowledgement is given.

Candidate signature: Mosopefoluwa Osidele

Date: 13/05/2023

Supervisor name: Cecilia Vasquez-Robinet

Supervisor signature:

Date: 13/05/2023

Dedication

This thesis is dedicated wholeheartedly to my parents, whose unwavering dedication and sacrifices have shaped me into the person I am today. Their unwavering beliefs, unyielding strength, and constant prayers have instilled in me the determination to relentlessly pursue excellence.

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A STUDY OF THE KEY CHALLENGES IN THE NIGERIAN PHARMACEUTICAL INDUSTRY, WITH EMPHASIS ON THE REGULATION AND QUALITY OF MEDICAL DEVICES

Osidele, Mosopefoluwa Oluwagbeminiyi

ABSTRACT

The Nigerian pharmaceutical manufacturing sector holds significant importance for Nigeria's economy, particularly in relation to medical devices. Extensive research conducted on the Nigerian medical device industry has highlighted numerous challenges that hinder the sector's development. This study aims to investigate the challenges faced by the Nigerian pharmaceutical industry, with emphasis on the regulation and quality aspects of medical devices. Usar *et al.* (2017, p. 86-91). emphasize the weak state of pharmaceutical regulation in Nigeria, characterized by irregular inspections, inadequate enforcement, widespread violations, and resultant negative health outcomes. To structure the research process, the study adopts the Research Onion framework proposed by Saunders, Lewis, and Thornhill in 2009. The interpretivist research philosophy plays a central role in this dissertation's context. Employing a deductive research approach, the study aims to collect data and formulate a theory based on the obtained results Saunders *et al.* (2019, p. 207). A case study strategy is employed to gain in-depth understanding of the challenges, particularly in the regulatory and quality aspects, faced by the two selected medical device manufacturing firms and the regulatory authorities that restrict their performance. The research design involves a mono-method approach for data collection. The gathered data is then analyzed thematically, contributing to the overall research findings. The study reveals significant weaknesses in the current regulatory framework for medical devices, including poor implementation of guidelines, lengthy processing times, and inadequate post-marketing surveillance. Regarding challenges related to the manufacturing of high-quality medical devices, the study identifies the lack of raw materials and the unavailability of custom-made machine parts as key factors affecting the production capabilities of medical device manufacturing firms in Nigeria. Insufficient funding, policy inconsistencies, regulatory duplication, and high inspection costs are identified as factors contributing to the ineffectiveness of medical device regulation and registration. Finally, in terms of the efficacy of quality and safety management practices, the study concludes that the existing practices are inadequate in ensuring the utmost safety of the public.

Table of Contents

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

ABEC – Almaty-Bishkek Economic Corridor

MSDS- Material Data Safety Sheets

MDR- Medical Device Regulations

MDD- Medical Device Directive

EU- European Union

USA- United States of America

GHTF- Global Harmonization Task Force

AHWP- Asian Harmonization Working Party

ISO- International Organization for Standardization,

IEC- International Electro-Technical Commission

WHO- World Health Organization

GMRF- Global Model Regulatory Framework

NAFDAC- National Agency for Food, Administration and Control

SON- Standard Organization of Nigeria

FMOH- Federal Ministry of Health

IVDR- In-vitro Diagnostic Regulation

IVD- In-vitro Diagnostic devices

UDI- Unique Device Identification

BPP- Bureau of Public Procurement

NNRA- Nigeria Nuclear Regulatory Authority

GMP- Good Manufacturing Practice

MAH- Marketing Authorization Holder

ICSR- Individual case safety report

AUDA-NEPAD - African Union Development Agency- New Partnership for Africa's Development

A STUDY OF THE KEY CHALLENGES IN THE NIGERIAN PHARMACEUTICAL INDUSTRY, WITH EMPHASIS ON THE REGULATION AND QUALITY OF MEDICAL DEVICES

CHAPTER 1: INTRODUCTION

1.1 Background of the study

Although the issue of obtaining bona fide medications is a significant challenge for Nigeria's public healthcare, the country also faces additional healthcare problems related to accessing various medical devices that have not been extensively explored in academic literature. A medical device is a non-metabolic method of monitoring or enhancing patient health that affects the body. This definition encompasses a broad range of items, such as electro-medical equipment, implantable mechanical devices, diagnostic tools, and even common objects like glasses and Band-Aids (Browning, 2014, p. S28).

Medical devices play a vital role in improving patients' health and quality of life by aiding in the diagnosis and treatment of diseases. These devices range from simple to sophisticated equipment and are used in different settings, including rural clinics, specialized hospitals, and at the bedside. Because medical devices are utilized in healthcare, they are subject to stricter regulations in terms of their production and marketing (Saidi and Douglas, 2019, p. 175-185). Therefore, it is essential to outline precise specifications for the design, development, and production of medical devices to ensure that they are safe, effective, and of high quality when released into the market.

In terms of pharmaceutical care, authorities use various regulatory measures to ensure safe, effective, and high-quality pharmaceutical care (Panteli *et al.,* 2016, p. 1-122). The constant and targeted control that a public agency exercises over activities that are significant to a community might be broadly characterized as regulation (Brennan and Berwick, 1996; p. 404). The basic goals of regulation are to raise standards of performance and quality, make sure that minimum requirements are satisfied, and provide accountability for both cost-effectiveness and performance levels. Effective pharmaceutical regulation would necessitate a thorough legal and legislative framework outlining proper governance structures, regulatory technical skills, long-term funding, and performance monitoring mechanisms (Lee and Herzstein, 1986, p. 217-235).

Many countries worldwide have regulatory agencies in place to oversee the medical device industry. For instance, in the EU, the MDR of 2017 establishes the necessary standards for the design, safety, and performance of medical devices (EU, 2017). These regulations mandate that manufacturers of high-risk devices must demonstrate their safety and efficacy before they can be marketed. Nonetheless, there are limitations to pharmaceutical regulation across the world due to insufficient national capacity to carry out essential regulatory duties, with Africa being the region with the weakest capability (Kumaranayake *et al.*, 2000; Ndomondo-Sigonda and Ambali, 2011; Nayyar and Kumar, 2020).

Focusing on Nigeria, the regulatory landscape is notably inadequate, having no specific regulations or regulatory bodies dedicated to medical devices. Instead, the regulations are presented broadly to cover medicines, and related substances with a negligible addition of medical devices (Saidi and Douglas, 2019, p. 175-185). The system is marked by inconsistent regulatory inspections, poor enforcement, and widespread violations that greatly impair health services and lead to negative health consequences (Olugbenga, 2013, p. 89; Usar *et al.*, 2017) .

Given the significance of medical devices for health and wellbeing, this study aims to better understand the regulatory framework governing this sector, identify regulatory barriers, and make policy recommendations for an enhanced regulatory landscape that supports public health in Nigeria.

1.2 Overview of regulatory authorities

Different countries have regulations for approving medical devices to ensure the safety and responsibility of manufacturers. Regulatory bodies play a crucial role in ensuring that all medical devices meet the required standards, regulations, and guidelines, as there is always a risk associated with their use. It is their responsibility to authenticate all components of medical devices to protect consumers from potential health hazards.

To address the increasing need for universal medical device regulation, the GHTF was established in 1992. Originally consisting of representatives from the medical device regulatory authorities of the USA, EU, Japan, Australia, and Canada, the group expanded its membership in 2006 to include the AHWP, ISO, and the IEC (Lamph, 2012, p. 12-21).

The ISO, established in 1946 with the aim of encouraging global coordination and standardization of industrial norms, has evolved into the leading proponent and disseminator of voluntary international standards. It operates through a network of national standards institutes in 167 countries (ISO, 2022). These standards find extensive adoption at both regional and national levels, providing the foundation for the development, production, quality control, and assessment of medical devices. Governments utilize these standards to establish technical directives pertaining to health, safety, and environmental requisites in the global market, thereby aiding developing nations in acquiring valuable knowledge and optimal approaches.

Additionally, The WHO released a document titled "Medical device regulations: Global overview and guiding principles" in 2003, which acknowledged the intricate nature of the medical device industry and identified regulatory concerns. This publication offered direction to member states seeking to establish or revise their regulatory systems for medical devices (World Health Organization, 2003). The WHO consistently encourages uniformity in medical device regulation through various efforts, including the newly introduced GMRF for Medical Devices, released in 2017. The GMRF serves as a reference for countries as they develop or improve their own national regulatory frameworks for medical devices (WHO, 2017b).

These member states (Australia, Canada, EU, Japan, and USA) have established and continuously revised regulations for medical devices in their respective markets. Other countries often follow their lead and use their regulations as a reference. Moreover, if a medical device is approved by any of these regulatory authorities, it is often sufficient for registration in countries with limited resources and emerging regulatory procedures (Lamph, 2012, p. 12-21). Nonetheless, every country with a licensed pharmaceutical company has a regulatory body responsible for enforcing regulations to manage the manufacture of medical devices. The table below lists some of the countries and their regulatory agencies.

Table 1.1: Regulatory authorities around the world

Country	Name of Regulatory Authority
United States of America (USA)	Food and Drug Administration (FDA), Centre for Devices and Radiological Health (CDRH).
Ireland	European Medicine Agency (EMA), Health Products Regulatory Authority (HPRA)
Russia	Roszdravnadzor (Federal Service on Surveillance in Healthcare and Social Development, Gosstandart (Federal Agency for Technical Regulation and Metrology), Rospotrebnadoz (Federal Service for Supervision in the Area of Consumer Rights and Welfare Protection).
China	State Food and Drug Administration (SFDA)
India	Central Drug Standards Control Organization (CDSCO)
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC), Standard Organization of Nigeria (SON).
Saudi Arabia	Saudi Food and Drug Authority (SFDA)
Japan	Pharmaceutical and Medical Device Agency (PMDA), Ministry of Health, Labor, and Welfare (MHLW).
Mexico	Federal Commission for the Protection against Sanitary Risk (COFEPRIS).

Depending on whether the country imports or exports medical devices, regulatory officials are responsible for a wide range of activities. The three main phases of regulatory control are: pre-market, where it is ensured that the product will meet performance and safety standards; on-market, where it is ensured that the product will be correctly labelled and advertised; and post-market,

where it is ensured that the product will continue to be safe and effective while being used (Lamph, 2012).

1.3 International Medical Device Regulators Forum (IMDRF)

The IMDRF was established in 2011 as a voluntary group of medical device regulatory authorities from around the world. The primary objective of IMDRF is to promote international harmonization of medical device regulation, with the goal of improving patient safety and facilitating global market access for medical devices.

IMDRF has produced a number of guidelines and documents related to medical device regulation. These include guidelines for the clinical evaluation of medical devices, guidance on the use of unique device identifiers (UDIs), and guidance on the regulatory requirements for medical device software. One of the most significant documents produced by IMDRF is the Medical Device Single Audit Program (MDSAP). MDSAP is an initiative that enables manufacturers of medical devices to undergo a unified audit process satisfying the regulatory obligations of various nations, such as Australia, Brazil, Canada, Japan, and the United States. The program aims to reduce the regulatory burden on medical device manufacturers and improve the consistency and quality of regulatory audits (IMDRF, 2023).

About 11 countries have granted approval for the utilization of these guidelines, although Nigeria is not among them. Nigeria has developed its own mechanisms for regulation and has established effective pharmacovigilance practices. The country has a trio of regulatory agencies that oversee the control of medical devices, which are:

- NAFDAC
- SON
- FMOH

NAFDAC was established in 1993 under the auspices of the FMOH in Nigeria with the responsibility of regulating the manufacture, importation, exportation, advertising, distribution, sale, and use of medicines, cosmetics, medical devices, and packaged water in Nigeria.

In order to safeguard the general public's health, NAFDAC was established to guarantee the quality, safety, and efficacy of these goods (Adeyeye, 2018). As per the provisions stated in the

Act CAP F33 LFN 2004 and the corresponding guidelines, the responsibility of supervising medical devices in Nigeria rests with NAFDAC (NAFDAC, 2021). NAFDAC states that before medical devices are produced, imported, exported, promoted, sold, or distributed in Nigeria, they must first be registered (WHO, 2022).

The FMOH is responsible for the development and implementation of health policies and regulations in Nigeria (Federal Ministry of Health, 2015). The FMOH works closely with NAFDAC and other agencies to ensure the safety and efficacy of medical devices in the country. The FMOH is also responsible for the management of healthcare services, including the procurement and distribution of medical devices to public health facilities (Federal Ministry of Health, 2015).

The SON is the single statutory authority in Nigeria charged with standardizing and regulating the quality of all products. It was established by the Act No.56 of 1971 with the mandate to develop and enforce national standards for products, processes, and services in Nigeria. SON is a member of the ISO, and is responsible for ensuring that all products sold in Nigeria meet the minimum safety, quality, and performance requirements set by the agency.

Whilst these three agencies work together to regulate medical devices in Nigeria, medical device regulation is still in its infancy in Nigeria, and regulatory requirements have not yet been firmly put in place to stop the importation or use of subpar devices (Lamph, 2012, p. 12-21). The absence of stringent policies on medical devices poses a significant threat to the populace. Governments may view their prescription of these products as fulfilling their obligation to safeguard the health of citizens, however, this often leads to increased expenses for manufacturers who must comply with regulations, which they typically transfer to patients.

Therefore, it is imperative for national legislation to establish unambiguous guidelines for protecting the public and ensure that manufacturers can feasibly meet these requirements (Kedwani *et al.*, 2019, p. 609-612).

1.5 Research Purpose

The purpose of this research is to investigate the key challenges facing the Nigerian pharmaceutical industry in regards to the regulation and quality of medical devices. The study aims to provide an in-depth understanding of the current regulatory framework for medical devices in Nigeria,

identify any gaps or shortcomings in the existing regulations, and explore the impact of these challenges on the quality of medical devices available in the Nigerian market.

Additionally, the research will also assess the effectiveness of existing measures for ensuring the safety and efficacy of medical devices in the country, and suggest recommendations for improvement. Ultimately, this study aims to contribute to the ongoing efforts to enhance the quality and safety of medical devices in Nigeria and ultimately to improve the health and well-being of the Nigerian population.

1.6 Significance of the Study

The pharmaceutical industry in Nigeria is a critical sector, responsible for the production and distribution of essential drugs and medical devices needed to improve public health outcomes. Despite its importance, the industry faces several challenges that impact the quality and regulation of medical devices, including inadequate regulation and quality control, weak infrastructure, and corruption.

The use of medical devices is critical in healthcare as they play a vital role in screening, diagnosing, and treating patients. However, outdated medical devices, insufficient equipment and supplies, and limited access to high-quality and safe medical devices can significantly impact the quality of healthcare services. These challenges can limit the availability of appropriate and prioritized medical devices, thus impeding the provision of effective healthcare services (Oloko, 2022, p. 254).

While several studies have examined the challenges in the Nigerian pharmaceutical industry, none have focused specifically on the regulation and quality of medical devices. It is, therefore, necessary to fill this gap and provide and in-depth understanding of the regulatory and quality systems for medical devices in Nigeria. By conducting this study, valuable insights can be gained into the challenges faced by the Nigerian pharmaceutical industry regarding the regulation and quality of medical devices. The study will identify the root causes of the challenges and help policymakers, regulatory bodies, and industry players develop effective strategies to improve the industry's overall performance. This research can also provide a basis for future studies on the Nigerian pharmaceutical industry's challenges and opportunities, contributing to knowledge development and advancement in the field.

Furthermore, the findings of this study can contribute to improving public health outcomes in Nigeria. The regulation and quality of medical devices are critical factors that impact the safety and effectiveness of healthcare interventions. Therefore, by addressing the challenges in the Nigerian pharmaceutical industry and improving the regulation and quality of medical devices, the safety and effectiveness of healthcare interventions can be improved, resulting in better public health outcomes.

1.7 Specific Objectives

- To evaluate the current regulatory framework for medical devices in Nigeria, including identifying any gaps or shortcomings in the existing regulations.
- To investigate the impact of regulatory challenges on the quality of medical devices available in the Nigerian market.
- To assess the potential implications of these challenges on the Nigerian economy and population health outcomes.
- To evaluate the quality management practices in place in the Nigerian medical device industry.
- To assess the effectiveness of existing measures for ensuring the safety and efficacy of medical devices in Nigeria.
- To review the efforts that have been made to address these challenges in Nigeria, and evaluate the effectiveness of these efforts.
- To explore the perceptions and experiences of medical device manufacturers and stakeholders in Nigeria in relation to regulation and quality of medical devices.
- To investigate the international best practices and standards for medical device regulation and quality management, and explore how they might be applied in the Nigerian context.
- To suggest recommendations for improving the regulation and quality of medical devices in the Nigerian pharmaceutical industry.

1.8 Research Questions

- What are the current regulatory requirements for medical devices in Nigeria and how are they enforced?

- What are the major challenges facing the Nigerian pharmaceutical industry in regards to the regulation of medical devices?
- How do these challenges impact the availability and quality of medical devices in the Nigerian market?
- What are the potential implications of the challenges in the regulation and quality of medical devices on the Nigerian economy and population health outcomes?
- What measures are currently in place to ensure the safety and efficacy of medical devices in Nigeria and are they effective?
- What efforts have been made to address these challenges in Nigeria and other developing countries, and how effective have these efforts been?
- What are the perceptions and experiences of manufacturers and stakeholders on the medical devices regulation and quality in Nigeria?
- How does the medical devices regulation and quality in Nigeria compare to other countries in the region and internationally?
- What are the international best practices and standards for medical device regulation and quality management, and how can they be applied in the Nigerian context?
- What recommendations can be made to improve the regulation and quality of medical devices in the Nigerian pharmaceutical industry?

1.9 Structure of study

This dissertation comprises of five distinct chapters, each focusing on a specific aspect. The initial chapter serves as an introductory section, outlining the research's purpose, significance, aim, and objectives. The subsequent chapter involves an extensive review of existing literature, presenting the study's conceptual framework. Chapter three provides a comprehensive explanation of the research design and methodology, encompassing the overall research approach, primary data collection method, and data analysis strategy. In chapter four, the gathered primary data will be presented and analyzed, with the resulting findings being discussed. Lastly, the concluding chapter of the dissertation will offer a reflective summary of the research question, along with additional insights into the study's contributions, limitations, and recommendations for future research endeavors.

CHAPTER 2: LITERATURE REVIEW

2.1 Challenges for medical devices approval and regulation in developing countries

Given the rising life expectancy and declining fertility rates, there is a noticeable inclination towards population ageing, thereby intensifying the need for healthcare services overall and medical devices specifically. The rise in demand for healthcare services poses significant challenges for countries with subpar healthcare and educational standards, making it tough to maintain consistent growth rates. Moreover, the medical device sector and pharmaceutical industry are subject to stringent regulatory standards, and businesses operating within it must abide by the necessary laws and procedures to maintain high levels of safety and quality (Maci and Marešová, 2022, p. 71-91).

2.1.1 Poor regulatory enforcement

In the article "Mind the gap: investigating the role of collective action in the evolution of Indian medical device regulation," Kale (2019, p. 101-121) examines the development of medical device regulation in India from the perspective of collective action theory. The study highlights the drawbacks of an inadequately regulated medical device market and argues that there exists a gap between the regulatory framework and its enforcement in India, which has led to a proliferation of low-quality medical devices in the market. As a result, there is a significant risk of making poor choices when purchasing locally manufactured medical devices, which further exacerbates the problem. This, in turn, compels the country to import foreign devices, which are considerably more expensive than their domestic counterparts by up to 50%. In some medical fields, India is reliant on imports by as much as 90%, leaving foreign multinational corporations to operate under a monopoly rent. The poor regulatory enforcement not only causes India to rely on costly imports but also negatively affects the development of local technological capabilities.

On the topic of poor enforcement, Fick (2020) explored the impact of a multi-billion dollar medical device loan that the Kenyan government received from China in 2015. The loan was intended to improve healthcare in Kenya by providing state-of-the-art medical device to hospitals and clinics throughout the country. However, the article argues that the loan may not have had the intended impact, and that many of the machines provided have gone unused or are not functioning properly.

The article draws on interviews with doctors, government officials, and healthcare workers in Kenya, as well as data on the implementation of the loan. It describes how the loan was negotiated with little input from the medical community in Kenya, and how the equipment provided has not been matched with adequate training or staffing to ensure that it is used effectively. The article also raises concerns about the quality of the equipment provided, noting that some of it has been found to be faulty or unsuitable for use in the Kenyan context. Overall, the article suggests that the medical equipment loan may have been more of a political gesture than a practical solution to Kenya's healthcare challenges. It raises important questions about the role of foreign aid in addressing health inequalities in developing countries, and highlights the need for more comprehensive approaches to healthcare reform that take into account the needs and perspectives of local communities.

2.1.2 Lack of regulatory presence in start ups

According to Howard (2016, p. 281), derivative medical devices are often less expensive to produce compared to the original devices since the manufacturers do not incur the same high development costs nor do they need to provide as much clinical data. However, subsequent devices may face challenges in demonstrating product safety. Howard recommends that although more stringent regulations for new medical devices may cause delays in product launch, preventing the sale of defective devices can reduce the risk of losing public trust, and save manufacturers from reputational and financial harm (Howard, 2016, p. 267-275).

Research Contracts and Innovation (2023) highlights the success of the Technology Innovation Agency (TIA) Seed Fund, a South African government initiative that supports the development of early-stage technology companies. They focused on the experience of a spin-off company called SmartBlade, which was created by researchers at the University of Cape Town to develop a low-cost, portable ventilator for use in low-resource settings. They describe how the TIA Seed Fund provided critical early-stage funding to SmartBlade, allowing the company to develop its product and bring it to market. They also highlight the importance of collaboration between academic institutions and industry partners in the development of new technologies, citing SmartBlade's partnerships with medical device manufacturers and regulatory bodies as key to its success.

However, Scannell and Cormican (2019, p. 82) discuss the challenges of addressing regulatory limitations and highlight the case of academic spinoffs in the medical device industry as an

example of this issue. They note that compared to other forms of commercialization, academic spinoffs often face delays in addressing regulatory requirements, leading to potential issues related to safety and efficacy. The authors suggest that the solution to this problem is to include a regulatory expert in the team from an earlier stage of the development process. However, they also identify cost as a significant barrier to this approach, which may explain why regulatory experts are not typically involved earlier in the process. Furthermore, Richards and Hudson (2016, p. 1471-1476) suggest that the development of new medical products requires a significant amount of time, and regulatory bodies and governments are under increasing pressure to quickly introduce product innovations. However, the public may not fully consider the potential risks associated with new devices.

Initiatives like the TIA Seed Fund can play an important role in promoting innovation and economic growth in South Africa and other developing countries. Academic spin-offs have the potential to address local healthcare needs and create new opportunities for entrepreneurship and job creation. Hence, to accelerate the time-to-market and reduce development costs, it may be possible to create a dedicated public institution that provides timely consultations on overcoming regulatory challenges.

2.1.3 Issue of counterfeit products

Another regulatory challenge in developing countries is the issue of counterfeit products. Similar to the article by Kale (2019, p. 101-121), Glass (2014, p. 13) discusses the issue of counterfeit drugs and medical devices in developing countries in his article. The author highlights the extent of the problem and its impact on public health, as well as the reasons why these countries are particularly susceptible to counterfeit products. They also examine the existing strategies for dealing with the problem and suggests potential solutions. These authors suggest that the problem of counterfeit drugs and medical devices is a significant public health concern in developing countries. The author notes that developing countries are particularly susceptible to counterfeit drugs and medical devices due to a lack of regulation and oversight, weak supply chain systems, and a high demand for affordable medicines. They also found that traditional strategies for dealing with the problem, such as product testing and seizures, are not effective in addressing the root causes of the problem. Although both articles provide an overview of the problem of inadequate regulation, counterfeit drugs and medical devices in developing countries, its impact on public

health, and the reasons why these countries are particularly susceptible to low-quality medical devices, they do not delve into the specific challenges and issues that exist within the Nigerian context.

Hence, my study shall provide a more detailed examination of the regulatory challenges that exist in Nigeria. Additionally, I shall explore the specific challenges related to the quality of medical devices in Nigeria, such as the prevalence of counterfeit and substandard products, the challenges related to product testing and certification, and the impact of these challenges on public health. Further exploration into potential solutions to the challenges identified will also be provided in my study.

2.2 The European Medical device regulatory system

The European medical device regulatory framework is a set of laws and regulations that govern the safety and performance of medical devices sold within the European Union (EU). The framework is designed to ensure that medical devices are safe, effective, and of high quality, and that they meet the needs of patients and healthcare providers.

According to EMA (2018), the critical components of the European medical device regulatory framework include:

1. MDR - The MDR is the major law that governs medical devices in the EU. It establishes the criteria for ensuring the safety and efficacy of medical devices, along with delineating the obligations of manufacturers, importers, and distributors. The MDR replaced the previous MDD and introduced a number of significant changes to the regulatory requirements for medical devices in the EU.

2. IVDR - The IVDR is a separate regulation that governs in vitro diagnostic devices, which are medical devices used for laboratory testing of samples from the human body. The IVDR sets out requirements for the performance and safety of IVDs, as well as the responsibilities of manufacturers, importers, and distributors.

3. Conformity Assessment - The conformity assessment process is the process by which medical devices are evaluated to ensure that they meet the requirements of the MDR and

IVDR. The process includes a range of activities, such as testing, certification, and inspection.

4. Notified Bodies - Notified Bodies are independent organizations that are authorized to assess medical devices for conformity with the MDR and IVDR. Notified Bodies play a critical role in the regulatory framework, as they are responsible for ensuring that medical devices meet the required standards of safety and performance.

5. UDI - The UDI system is a system for identifying and tracking medical devices throughout their lifecycle. Under the European regulatory framework, medical devices must be assigned a unique identifier that can be used to track their use, performance, and any adverse events associated with them.

2.2.1 Classification of Medical Devices in Europe

According to EMA (2018), the classification of Medical Devices adopted in Europe is shown in the table below.

Table 2.1: Classification of Medical Devices in Europe (EMA, 2018)

Classification	Examples	Risk Level
I	Corrective glasses and frames, Manual wheelchairs, Stethoscopes, Surgical forceps	Low
IIa	Orthodontic wires, Surgical gloves, Lancets	Medium risk
IIb	Orthopedic nails and plates, Intra-ocular lens, Incubators	Medium-High
III	Pacemakers, Prosthetic heart valves, Cardiovascular sutures	High

The MDR and the IVDR are the two main regulatory documents that govern the marketing and use of medical devices in the EU. They cover all medical devices and IVDs respectively, which are marketed in the EU, including those imported from third countries. The regulations define the

criteria that devices must meet in order to be placed on the EU market, and the procedures that manufacturers must follow in order to obtain approval for their products. The criteria includes:

- Medical devices must be designed and manufactured in such a way that they do not pose undue risks to patients, users, or other individuals. They must undergo appropriate testing and evaluation to ensure their safety.
- Medical devices must perform the intended function for which they are designed and be effective in achieving their intended purpose. They must be validated through appropriate testing and evaluation to ensure their performance.
- Medical devices must be manufactured in accordance with good manufacturing practices and be of a consistently high quality. They must also be subject to appropriate quality control and quality assurance processes.
- Medical devices (IIb and III) must be supported by appropriate clinical evidence to demonstrate their safety and effectiveness. This evidence must be obtained through clinical trials or other appropriate means.
- Medical devices must undergo a risk management process that includes identification of potential risks, assessment of those risks, and implementation of measures to mitigate them.
- Medical devices must be accompanied by appropriate labeling and instructions for use to ensure that they are used safely and effectively.

The MDR and IVDR also establish a new system of classification for medical devices, based on their potential risk to patients, and introduce new requirements for post-market surveillance, clinical evaluation, and device labeling. In addition, the regulations provide for greater transparency and traceability throughout the supply chain, and establish a new centralized database for tracking medical devices on the EU market (EMA, 2018).

2.3 The African Medical device regulatory system

The WHO's report on the counterfeiting of medical products reveals indicate that around 10% of medical products circulating in several low- and middle-income African countries may be either substandard or falsified, which is expected to continue in the coming years (WHO, 2017a). This includes not only medicines and vaccines but also medical devices, which underscores their growing significance in healthcare. Despite the fact that the primary function of these devices is not pharmacological, the report emphasizes that ensuring the safety and efficacy of all medical products is crucial to protecting the health and well-being of patients, and requires a concerted effort from all stakeholders involved in their production, distribution, and regulation.

Africa presents a myriad of complex economic, political, and social realities that require careful consideration. The regulation of medical devices and IVDs in Africa, in particular, is often inadequately defined. There are significant limitations to accessing medical products, as they may not be readily available or affordable. Moreover, certain diagnostic tests require trained personnel and laboratory facilities that may not be available in many areas. The extent of regulatory oversight over medical products depends on their intended use. For instance, if a product is designed to cure, identify, or assist in the treatment of specific infectious diseases like malaria or diarrhea, regulatory authorities and help organizations typically make concerted efforts to strengthen existing regulations (Lalis, 2006).

According to Hubner *et al.* (2021, p. 136-148), there is a significant variation that exists between East, Central, and Southern Africa countries in terms of the strength and enforceability of regulations. These authors examined the state of medical device regulation in East, Central, and Southern Africa, highlighting the challenges and opportunities that exist in this evolving landscape. They emphasize the need for effective regulation to ensure the safety and efficacy of medical devices, which are increasingly being used in low-resource settings to address a range of health challenges.

Moreover, their article explores some of the emerging trends and opportunities in medical device regulation, such as the use of digital health technologies and the potential for greater harmonization of regulatory frameworks across the region. The authors suggest that increased investment and support for regulatory authorities, as well as greater engagement with industry and other

stakeholders, will be essential to ensuring that medical devices are safe, effective, and accessible to those who need them most.

Figure 2.1: Overview of Medical device regulations in ABEC countries (Lissel *et al.*, 2016, p. 4330).

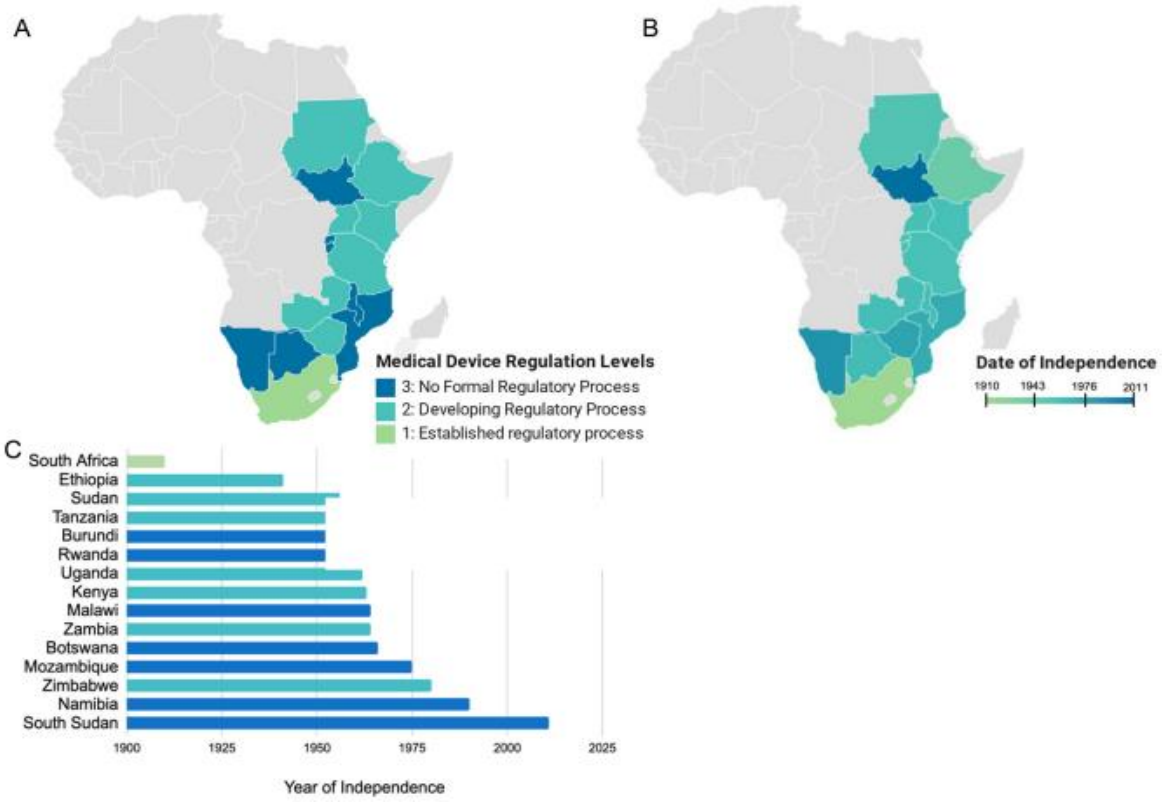
ABEC region	National Regulatory Authority	Directives / Laws	Classif. of medical devices
Northern Africa			
Egypt	Egyptian Drug Authority (EDA) - Medical Device Registration Department	93/42/EEC 2007/47/EC	Class I Class IIa Class IIb Class III
Southern Africa			
South Africa	South African Department of Health (DoH)	No. 101/1965 No. 14/2015 No. 15/1973	Class A Class B Class C Class D
Western Africa			
Burkina Faso*	Directorate General of Pharmacy and Drug Laboratories Government (DGPML)	1	1
Ghana*	Food and Drugs Authority (FDA) Ghana - Medical Device Department	Act 851	Class I Class II Class III Class IV
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)	Cap N1 L.F.N	1

Eastern Africa			
Ethiopia	Food, Medicine and Health Care Administration and Control Authority (FMHACA)	No. 661/2009 No. 9/2012 No. 12/2013	Class I Class II Class III Class IV
Kenya	Kenya Pharmacy and Poisons Board (PPB)	93/42/EEC 98/79/EC 90/385/EEC Chapter 244	Class A Class B Class C Class D
Malawi	Pharmacy, Medicines and Poisons Board (PMPB)	1	1
Uganda	National Drug Authority (NDA)	1	1
United Rep. of Tanzania	Tanzania Food and Drug Authority (TFDA)	No. I	Class A Class B Class C Class D
Zambia	Directorate of Clinical Care and Diagnostic services - Medical Equipment Unit	1	1

To ensure that medical devices marketed in Africa are safe, of acceptable quality, and perform as intended, the WHO recommends implementing legislation that defines the scope of regulation, including a clear definition of what constitutes a medical device. The ideal definition should be harmonized with the WHO's definition (WHO, 2017b).

Currently, all member countries of the College of Surgeons of East, Central, and Southern Africa (COSECSA) and South Africa have legislation in place that mandates the regulation of medical devices, with the exception of Burundi (Rugera *et al.*, 2014, p. 524), Malawi, and Mozambique (Hubner *et al.*, 2021, p. 136-148).

Figure 2.2: (A) Map of Africa showing the levels of medical device regulation in selected countries. (B) Map of Africa showing dates of country independence. (C) The level of medical device regulation is correlated to the year of independence (Hubner *et al.*, 2021, p. 139).



2.3.1 South Africa

The South African Health Products Regulatory Authority is responsible for regulating medical devices in South Africa. The regulations are defined by the Medicines and Related Substances Act of 2015, Act No.1417, the General Regulations Relating to Medical Devices and In-vitro Diagnostic Medical Devices, and the Hazardous Substances Act No. 15 of 1973. The guidelines for medical device standards are outlined in the General Information on Medical Devices and IVDs and Medical Devices and IVDs Essential Principles (South African Health Products Regulatory Authority, 2019).

IMDRF created a set of fundamental principles for medical devices, which also includes IVDs (WHO, 2017b). In South Africa, regulatory processes for medical devices require conformity to these principles, or their guiding regulatory legislation should adapt them (WHO, 2022). South Africa has three separate pieces of legislation and guidelines that closely resemble those of the IMDRF founding members. The classification of medical devices is based on their level of

invasiveness, duration of use, and other technical elements, which determine their risk level. The classification system in South Africa ranges from Class A (low risk) to Class D (high risk) as shown in Figure 1 (WHO, 2017b).

In order to comply with regulations, Class A devices necessitate the involvement of a conformity assessment body and the issuance of a declaration of conformity. Conversely, for devices falling under Classes B-D, conformity can be achieved by adhering to the essential principles and successfully undergoing assessment by a conformity assessment body, culminating in the issuance of a declaration of conformity. The process of conformity assessment may encompass clinical testing, risk management, as well as incorporating measures for quality assurance and sterility protocols (South African Health Products Regulatory Authority, 2019).

Moreover, South Africa is the only country in this analysis that has specific guidelines for regulating in vitro diagnostic devices. The regulatory framework in South Africa also includes import controls, which are crucial in countries where most medical devices are imported. In South Africa, imported medical devices account for approximately 90% of the market (Maharaj and Sunjka, 2019, p. 63-76). They also possess extensive post-market controls for medical devices, including inspections based on quality management systems procedures and guidelines, seizing devices that are unregistered or expired, reporting adverse events, and regulating labeling and advertising (Saidi and Douglas, 2018, p. 168).

2.3.2 East and Central Africa

Countries such as Burundi, Rwanda, and Mozambique have a more limited framework for the regulation of medical devices. Their legislation only mentions medical devices and definitions of medical devices in the legislative acts that establish national medicines regulatory authorities, without assigning specific guidelines for regulation (WHO, 2022).

Level 2 countries in East and Central Africa with regulatory processes that are still being developed and have not yet been fully put into practice such as Kenya and Zambia, employ a system that designates 4 levels of risk. They also have post-market controls in place, but to varying degrees. For instance, Zambia has controls for inspecting, advertising, and labeling devices, but it lacks a formal reporting system for adverse events. Rwanda is the only country with no defined regulatory

approval process for medical country that employs post-market control for all medical devices, has restrictions limited to the inspection, advertising, and labeling of these devices (WHO, 2022).

According to the WHO, the legal framework for medical devices should mandate that organizations submitting medical devices for approval within a jurisdiction must provide a declaration of conformity. This declaration confirms that the device complies with applicable laws and accredited international standards (WHO, 2017b). The conformity assessment requirements differ from country to country.

For example, Uganda requires that medical devices not licensed in one of the five founding members of the IMDRF must conform to WHO guidelines or a quality management system used in IMDRF countries (Uganda National Drug Authority, 2009). Zimbabwe is the only Level 3 country that requires conformity assessment, but only for gloves and condoms and not all medical devices (WHO, 2022). In several East and Central African countries, conformity to these principles or an adaptation within their guiding regulatory legislation is mandatory. For instance, Ethiopia's guideline for the registration of Medical devices incorporates essential safety and performance requirements for medical devices (Suleman *et al.*, 2016, p. 259).

Moreover, numerous countries mandate that medical device manufacturers, importers, and distributors must register with their respective national regulatory authorities. Registration and listing are required by all Level 1 and Level 2 countries. Zimbabwe, as mentioned before, requires registration and listing only for those who sell gloves or condoms (WHO, 2022).

Figure 2.3: Table showing the existence of Critical components of the Regulatory Process for Medical Devices in COSECSA Countries and South Africa (Hubner *et al.*, 2021, p. 140).

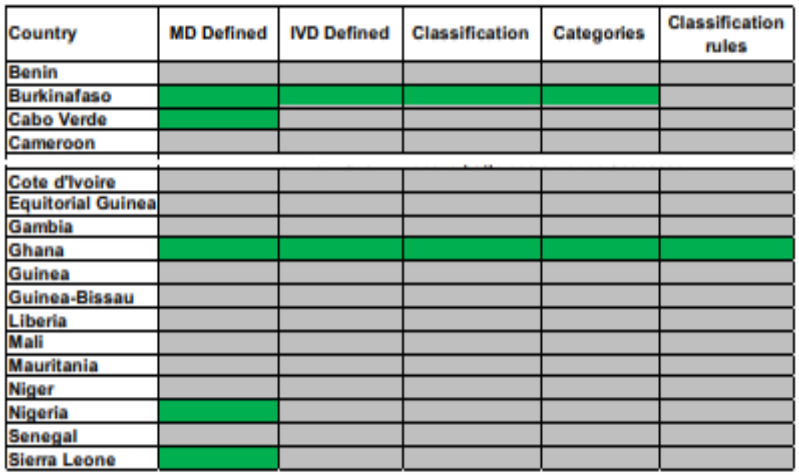
	Regulatory Complexity 1–3	Regulatory Body	Legal Framework	Medical Device Defined	Risk-based Classification System	Essential Principles	Conformity Assessment	Registration Required	Import Controls	Post-Market Controls
South Africa	1	South African Health Products Regulatory Authority	✓	✓	A–D	✓	✓	✓	✓	✓
Sudan	2	National Medicine and Poisons Board	✓	✓	A–D	✓	✓	✓	X	✓
Ethiopia	2	Food, Medicine and Healthcare Administration and Control Authority	✓	✓	I–IV	✓	X	✓	X	✓
Kenya	2	The Pharmacy and Poisons Board	✓	✓	A–D	✓	✓	✓	✓	✓
Tanzania	2	Tanzania Food and Drugs Authority	✓	✓	A–D	✓	✓	✓	✓	✓
Uganda	2	National Drug Authority	✓	✓	X	X	✓	✓	✓	✓
Zambia	2	Zambia Medicines Regulatory Authority	✓	✓	X	X	X	✓	✓	✓
Zimbabwe	3	Medical Devices Unit, Medicines Control Authority	✓	X	X	X	✓[a]	✓[a]	✓[a]	✓[a]
Botswana	3	Botswana Medicines Regulatory Authority	✓	✓	X	X	X	X	X	X
Namibia	3	Medicines Regulatory Council	✓	✓	X	X	X	X	X	X
Mozambique	3	None	X	X	X	X	X	X	X	X
Rwanda	3	Rwanda Food and Drug Administration	✓	✓	✓	X	X	✓	✓	✓
Malawi	3	Pharmacy, Medicines & Poisons Board	X	X	X	X	X	X	X	X
Burundi	3	Directorate of Pharmacies, Medicines and Laboratories	X	X	X	X	X	X	X	X
South Sudan	3	Drug and Food Control Authority	✓	✓	X	X	X	X	X	X

Abbreviation: COSECSA, College of Surgeons of East, Central and Southern Africa.
[a] Only for gloves and condoms.

2.3.4 West Africa

West African countries, on the other hand, are struggling to keep up with medical device regulation. The statistics show that only 28% and 17% of the countries in this region have established regulations and guidelines for medical devices, respectively (Ekeigwe *et al.*, 2019) . The heat maps below illustrate the state of medical devices regulatory systems in West African countries. These maps show that a large number of these countries are yet to establish proper regulatory frameworks to oversee the production, distribution, and use of medical devices. This indicates a significant gap that needs to be addressed to ensure that patients receive safe and effective medical devices that meet the necessary quality standards.

Figure 2.4: Countries with a definition and classification of medical devices (Ekeigwe *et al.*, 2019).



Country	MD Defined	IVD Defined	Classification	Categories	Classification rules
Benin					
Burkinafaso					
Cabo Verde					
Cameroon					
Cote d'Ivoire					
Equitorial Guinea					
Gambia					
Ghana					
Guinea					
Guinea-Bissau					
Liberia					
Mali					
Mauritania					
Niger					
Nigeria					
Senegal					
Sierra Leone					

Figure 2.5: Countries with legal structures – Legislation establishing NMRA and guidelines for Medical devices (Ekeigwe *et al.*, 2019).

Country	Legal Framework	Authorising Legislation	Guidelines	NRA Present	Name	Responsibilities
Benin						
Burkinafaso						
Cabo Verde						
Cameroon						
Cote d'Ivoire						
Equitorial Guinea						
Gambia						
Ghana						
Guinea						
Guinea-Bissau						
Liberia						
Mali						
Mauritania						
Niger						
Nigeria						
Senegal						
Sierra Leone						

Available Not available

According to WHO (2017b), about 40% of the countries in the African region, as defined by WHO, lack any form of regulation for medical devices. About 32% of the countries in the region have some regulations, and no data is available for the remaining 28% which are mostly from West Africa. In contrast, about 58% of all WHO member countries have regulations for medical devices. This disparity in medical device regulations between the African region and the global average is

significant and needs to be addressed, as it may result in inferior quality medical devices and restricted access to healthcare technology for patients.

In Nigeria, pharmaceutical regulation is particularly weak, marked by infrequent regulatory inspections, ineffective enforcement, and widespread violations, resulting in adverse health consequences (Usar *et al.*, 2017, p. 86-91). According to the findings of Usar and Bukar (2020, p. 11-18), the regulatory framework for pharmaceuticals in Nigeria heavily relies on administrative and bureaucratic measures, leading to unsatisfactory regulatory outcomes. Contributing factors include insufficient and occasionally overlapping legislation, instances of official corruption, inadequately trained personnel, and inadequate funding of regulatory institutions.

2.4 Differences in Medical Device legislation between Europe and Africa

The article by De Maria *et al.* (2018, p. 156-163) gives an overview of the differences between the European and African regulatory frameworks for medical devices. The article reviews the legal and regulatory environments for medical devices in Europe and Africa, and highlights the challenges and opportunities for the development of safe medical devices in these regions.

The authors conducted a literature review to gather information on the current regulatory frameworks for medical devices in Europe and Africa and found that the regulatory frameworks for medical devices in Europe are well-established and have evolved over the years to ensure the safety and efficacy of medical devices.

In Europe, medical devices are regulated by the European Union's Medical Device Regulation (MDR), which was implemented in May 2017 and fully became effective in May 2021. The MDR sets high safety and performance standards for Medical devices and requires manufacturers to undergo a rigorous conformity assessment process before their devices can be sold in the European market. The MDR also includes strict post-market surveillance requirements aimed at ensuring the continued safety and efficacy of medical devices.

Additionally, it is important to note that the new Europe MDR is significantly stricter compared to the previous version, prompting the authorities to provide a transition period of 5 additional years for its full implementation (the duration may vary based on the device classification).

However, one challenge faced is the delay in certification by national bodies, resulting in medical devices being unable to obtain certification under the new regulation as quickly as desired (Levine, 2022). That said, all countries within the EU follow the same medical device regulations, which include the MDR and the IVDR. The MDR and IVDR are directly applicable in all EU Member States, which means that they have the same legal status in all EU countries (EMA, 2018).

In contrast, medical device regulation in Africa is generally less developed, and often poorly enforced. The approval process for medical devices in Africa is prolonged, ambiguous, and primarily geared toward preventing substandard imports that pose a health risk from entering the market. Due to this, very few local companies manufacture products for the domestic and export markets (McNerney and Peeling, 2015).

Some African countries have their own medical device regulations, while others rely on regional regulations as illustrated previously. For example, the East African Community (EAC) has developed a regional harmonized framework for medical devices regulation, which aims to establish common technical standards and regulatory procedures across its member states. However, implementation of these regulations is often weak, with limited resources for enforcement and oversight (Hubner *et al.*, 2021).

De Maria *et al.* (2018, p. 156-163) identified several challenges facing the development of safe medical devices in Africa, including inadequate regulatory frameworks, limited access to funding and resources, and a lack of infrastructure and trained personnel. The authors also highlighted the importance of stakeholder engagement in the development of regulatory frameworks for medical devices. They suggested that a collaborative approach involving all stakeholders, including manufacturers, regulatory agencies, healthcare providers, and patients, is necessary to ensure the safety and efficacy of medical devices. They also proposed that international collaboration between Europe and Africa could be an effective way to address the challenges facing the development of safe medical devices in Africa.

Another difference in Medical Device legislation between Europe and Africa is the classification of medical devices. The table below shows a comparison between the European classification of Medical Devices and the African classification of Medical Devices.

Table 2.2: Comparison between the European classification of Medical Devices and the African classification of Medical Devices

	European Classification	**African Classification**
Basis of Classification	Risk-based classification system based on the intended use and potential risks of the device	Risk-based classification system based on the intended use and potential risks of the device
Classes	Class I, Class IIa, Class IIb, Class III	Class A, Class B, Class C, Class D, Class E
Criteria	Based on the duration of device contact with the body, invasiveness, and local versus systemic effects	Based on the intended purpose, risk to patients, and risk to healthcare workers
Examples of Devices	Class I: Bandages, non-invasive devices	Class A: Non-invasive devices, low-risk devices
	Class IIa: Hearing aids, pregnancy tests	Class B: Invasive devices, medium-risk devices
	Class IIb: Endoscopes, ultrasound devices	Class C: Implantable devices, high-risk devices
	Class III: Cardiac pacemakers, implantable defibrillators	Class D: Devices used in life-supporting or life-sustaining applications
		Class E: Devices with potential for misuse or abuse

Although aforementioned studies provide a broad overview of medical device legislation in Europe and Africa, they do not focus specifically on the challenges faced by the pharmaceutical industry in Nigeria. Nigeria is a rapidly growing market for medical devices and pharmaceuticals, but there are unique challenges related to regulation and quality control that need to be addressed. A study focused on Nigeria would be able to provide a more detailed understanding of these challenges, how they impact the industry and offer targeted recommendations for improvement.

2.5 The Nigerian regulatory framework and access to Quality Medical Devices

The Nigerian healthcare system faces numerous challenges, including inadequate access to safe medical technologies and devices, which has a detrimental impact on the quality of care provided

to patients. In an effort to address this issue, the Nigerian government has established a regulatory framework aimed at ensuring the accessibility and safety of medical devices in the country.

2.5.1 National Regulations on Medical Devices

The FMOH oversees all Federal health institutions in Nigeria, and is accountable for establishing health-related policies. NAFDAC is a branch of the FMOH that manages the regulation of food, drugs, and related products, including medical devices. NAFDAC's activities are guided by legislation that prohibits the manufacturing, importing, exporting, advertising, selling, or distributing of medical devices in Nigeria without proper registration in compliance with the Act or Regulations (Oloko, 2022).

To register a medical device in Nigeria, it must fulfill the defined requirements for quality, safety, and effectiveness. If the medical device is deemed unfit for its intended purpose, its registration may be revoked. NAFDAC provides guidelines for the registration of imported medical devices. Other regulatory bodies, such as the SON, BPP, and NNRA, may also be involved in verifying compliance with expected quality and safety standards.

It is noteworthy that NAFDAC, possessing the authority to establish guidelines and regulations for supervised products, maintains various regulations for the manufacture, importation, and advertising of medical devices, which include:

- Guidelines for Registration of Medical Devices in Nigeria,
- Guidelines for Registration of Imported Medical Devices in Nigeria, and
- Guidelines for Advertisement of NAFDAC Regulated Products.

These guidelines constitute the legal foundation for the production, importation, and advertising of medical devices in Nigeria, and non-compliance with these regulations results in penalties and sanctions for offending entities (NAFDAC, 2018).

2.5.2 Classification of medical devices in Nigeria

According to NAFDAC (2018), the international classification of medical devices has been adapted in Nigeria as shown in the table below;

Table 2.3: Classification of medical devices in Nigeria (NAFDAC, 2018)

International Classification	Examples	Risk Level
A	Cholesterol, uric acid test system; Surgical Instrument; Bandage, Surgical camera	Low
B	Pregnancy self-testing, Electric Hospital Bed, Surgical Lamp, Surgical Mask	Low-Moderate
C	Blood glucose self-testing, ECG, X-ray Unit, Syringe, Condom, Contact lens	Moderate-High
D	HIV Blood donor screening, Stent, Defibrillator, Pacemaker	High

2.5.3 Pre-market Approval process

For all classes above, the approval process to register a medical device in Nigeria is as follows:

1. Submit application: Designate a duly authorized representative in Nigeria to submit the application letter, registration form and other required documents.
2. Product approval meeting: After a thorough examination of the product documentation, inspection of the production facility to ensure compliance with GMP standards, and laboratory evaluation of the products, a meeting will be arranged to decide if the products meet the approval criteria.
3. Issuance of Notification: Once the meeting approves the products, the applicant will receive a registration notification followed by a Certificate of Registration valid for a period of five years.

2.5.4 List of Required Documents

- An application letter on the applicant's letterhead.
- A registration form for product registration. This form is to be printed from the NAFDAC website. Note that separate forms are required for multiple products.
- Contract manufacturing agreement (where applicable).
- Evidence of satisfactory inspection or GMP certificate for the product.

- Evidence of business registration, that is, CAC Certificate of Incorporation or Certificate of Business Name Registration as the case may be.
- Evidence of payment of registration fees.
- Evidence of registration of brand name with the Trademark Registry.
- Product labels/artwork.
- Declaration of conformity
- Description of device and intended use
- Clinical and preclinical data
- Comprehensive Certificate of Analysis. NAFDAC requires an applicant to carry out a comprehensive analysis of the product, report of which must be presented on the letterhead of the Quality Control Laboratory where the product was tested.

2.5.5 Post-Marketing Authorization Safety Monitoring of Medical Devices

There are two primary methods for post-approval monitoring of medical devices in Nigeria: Passive and Active pharmacovigilance (NAFDAC, 2018).

In Passive pharmacovigilance, individuals submit spontaneous reports of adverse events associated with medical devices to the National Pharmacovigilance Centre (NPC), including healthcare providers, consumers, and manufacturers. The NPC evaluates the information to determine if intervention is necessary. Reports may include malfunctions, injuries, or fatalities. Reporting is voluntary for healthcare providers but mandatory for MAHs and manufacturers if they become aware that one of their devices may have caused or contributed to a death or serious injury (Health Center for Devices and Radiological, 2023). The NPC has various reporting channels, including the use of yellow forms, e-reporting platforms, and a med safety app.

Active surveillance involves the active detection and reporting of adverse effects, such as through the follow-up of patients and recording of medical events. Prospective or retrospective follow-up may be used. There are two types of Active post-approval pharmacovigilance for medical devices: prospective organized clinical studies and active medical product registries (Rajan *et al.*, 2015). Additionally, the NPC is implementing a Smart Safety Surveillance (SSS) initiative to improve pharmacovigilance, particularly regarding new medicines for priority diseases.

In March 2023, AUDA-NEPAD organized a consultation for technology support in partnership with the Medicines and Healthcare Products Regulatory Agency (MHRA) through the African Union Smart Safety Surveillance (AU-3S) program. The event took place in Cape Town, South Africa, and representatives from Ethiopia, Ghana, Kenya, Nigeria, and South Africa, the five member countries, were present at the meeting (AUDA-NEPAD, 2023).

The aim of this meeting was to enhance comprehension regarding the potential for optimizing suitable technology, and also provide strategic and technical support with the aim of improving safety surveillance in the African context. Furthermore, this forum allowed participating countries to exchange their knowledge on monitoring systems for vaccines and medication, emphasizing pertinent regulations, supportive mechanisms, procedures, data exchange prerequisites, and system unification requirements.

Regardless, Nigeria's healthcare system is still inadequate and outdated, lacking modern equipment, infrastructure, and facilities. Despite the country's population reaching 180 million, access to necessary medical devices remains limited and is primarily reliant on imports. The lack of innovation in the medical device industry exacerbates the problem, resulting in inadequate diagnosis, treatment, and preventative care, leading to numerous fatalities and an upsurge in medical tourism, costing the country over $1 billion annually. Additionally, Nigeria's inability to develop or maintain medical devices is evident in its low ranking of 119 out of 127 countries in the Global Innovation Index (WHO, 2022).

In furtherance of this, Usar and Bukar (2020, p. 11-15) discuss the challenges and opportunities of pharmaceutical regulation in Nigeria. These authors evaluate the current state of regulation in the country, highlighting the major challenges faced in the regulation of the pharmaceutical industry, such as inadequate regulation and enforcement, lack of funding and resources, and the high level of counterfeit drugs. The article also addresses opportunities for improvement in the regulatory system.

2.6 Challenges to implementing Pharmacovigilance in Nigeria

After examining the ICSR database at the NPC, it was found that no adverse events linked to the use of medical devices had been reported to the Centre from 2004 to August 2020. However, the U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH) has identified the difficulties of monitoring and assessing the safety of medical devices after marketing authorization in a report titled "Ensuring the Safety of Marketed Medical Devices."

Some of these issues also apply to Nigeria, including:

- The under-reporting of adverse events in relation to medical devices. Under-reporting makes it challenging to determine the actual public health risk.
- The use of medical devices is not usually recorded in patient records by healthcare providers, making it challenging to identify the device used in adverse events.
- Medical devices do not have unique identifiers, and manufacturers regularly update their products, complicating identification.
- Medical devices are often used off-label, for patient populations or purposes not specified in pre-market testing and approval.
- Medical devices are increasingly used outside of hospitals and clinics, including in patients' homes, where non-professionals may be involved, adding complexity to diagnosis and identification of solutions.

Despite NAFDAC's requirement that no medical device should be manufactured, imported, exported, advertised, sold, distributed, or used in Nigeria without registration, Usar and Bukar (2020, p. 11-15) suggest that the Nigerian pharmaceutical industry is facing significant challenges in terms of enforcement. The author cites studies that indicate that the majority of drugs in circulation in the country are counterfeit, and that the regulatory system is inadequate to deal with this problem. They also mention the poor state of the healthcare system in the country and the lack of resources and funding for regulation.

Though in 2022, The President of the Medical Device Manufacturers Association of Nigeria (MEDMAN) and Managing Director of Jubilee Syringe Manufacturing company, Mr. Akin Oyediran, stated that sustained advocacy by his association led to the ban on the importation of substandard syringes into Nigeria by the Senate (Odey, 2022). He made this known during his

emergence as the Chairman of the Manufacturers Association of Nigeria (MAN), Cross River/Akwa Ibom state, and pledged to replicate the same advocacy to the governments of the two states in order to move the manufacturing sector forward and increase membership in the states.

In the same year, however, Oloko (2022, p. 254-264) investigated the challenges and prospects of the right to health and access to medical devices in Nigeria. The author discusses the current state of access to medical devices in the country, highlighting the major challenges faced in the provision of medical devices, such as inadequate funding, lack of resources, and poor infrastructure.

Their research suggests that the Nigerian healthcare system is facing significant challenges in terms of access to medical devices. The author cites studies that indicate that the majority of medical devices in circulation in the country are either outdated or counterfeit, and that the healthcare system is inadequate to deal with this problem. They also mention the poor state of the healthcare system in the country and the lack of resources and funding for the provision of medical devices.

Both articles by Oloko (2022, p. 254-264) and Usar and Bukar (2020, p. 11-22) have a similar focus on the challenges and opportunities in the healthcare industry in Nigeria. The article by Oloko (2022, p. 254-264) focuses on the provision and access of medical devices, while the article by Usar (2020, p. 11-22) focuses on the regulation of the pharmaceutical industry. Both articles mention the issue of counterfeit medical products and the inadequate state of the healthcare system. Both articles also note the importance of raising public awareness and the need for capacity building in terms of regulation and enforcement.

However, these articles focus more generally on the right to health and access to medical devices, and on the challenges and opportunities of pharmaceutical regulation in Nigeria, respectively, leaving a gap open for a more specific and in-depth examination of the challenges related to the regulation and quality of medical devices in Nigeria. Ultimately, my research would offer potential solutions and recommendations for addressing these challenges. This could be a valuable contribution to the existing literature on the topic, and could help to inform policy and practice in Nigeria and other developing countries.

2.7 Medical devices manufacturers in Nigeria

To effectively examine the requirements and quality of medical devices in Nigeria's pharmaceutical sector, this research will be centered on two of the leading manufacturers of medical devices in Nigeria. They are:

- **Jubilee Syringe Manufacturing Company Limited**, a syringe manufacturing company situated at Awa, Akwa-Ibom, Nigeria that was founded with the goal of manufacturing disposable syringes for medical companies.
- **Industrial and Medical Gases (IMG) Nigeria Plc**, a Nigerian company that specializes in the production and distribution of industrial and medical gases. The company was established in 1959 and is headquartered in Lagos, Nigeria.

2.7.1 Jubilee Syringe Manufacturing Company Limited

Jubilee Syringe Manufacturing Company Limited is a Nigerian company that specializes in the production of medical syringes and needles. The company was established in 2016 and is headquartered in Akwa Ibom State, Nigeria.

Jubilee Syringe Manufacturing Limited Company is the largest disposable syringe factory in Africa, boasting an annual production capacity of 350 million and a workforce of 123 employees. The company's products are extensively used in healthcare establishments throughout Nigeria and other African countries. They have a state-of-the-art manufacturing facility that uses modern technology and adheres to international quality standards to produce high-quality syringes that are safe, reliable, and affordable (Jubilee Syringe Manufacturing Company Limited, 2022). They are committed to improving healthcare in Nigeria and other African countries by providing access to high-quality medical products.

Overall, Jubilee Syringe Manufacturing Company Limited plays an important role in the Nigerian healthcare industry and is recognized for its high-quality products and commitment to improving healthcare outcomes in the country. Additionally, they make certain that full and comprehensive adherence to the HSE regulations and recommendations within the nation is upheld. Through this action, they are capable of guaranteeing that all staff members operate within a safety-conscious environment that has been implemented.

2.7.2 Industrial and Medical Gases (IMG) Nigeria Plc.

Industrial and Medical Gases (IMG) Nigeria Plc is the largest industrial, medical, and food-grade gases provider in sub-Saharan Africa. Since its establishment in 1959 as Industrial Gases Limited (IGL), the company has consistently met the needs of its customers, leading to its success in the market. The company was later renamed BOC Gases Nigeria Plc in 1997 and recently in 2021, the company changed its name to Industrial and Medical Gases Plc (Industrial & Medical Gases Nigeria, 2023a).

IMG operates a modern gas manufacturing plant that utilizes cutting-edge technology to produce high-quality gases that meet international standards. Additionally, IMG produces medical equipment such as oxygen and acetylene regulators, which are essential components in the provision of medical gases to healthcare facilities across Nigeria and other African countries. They take safety and health seriously and are committed to ensuring that its customers have access to accurate and up-to-date MSDS for all of its products. These MSDS are an important component of the company's commitment to safety and health in the workplace, providing information about the physical and chemical properties of a substance, as well as information about the potential hazards associated with its use (Industrial & Medical Gases Nigeria, 2023b).

As they produce and distribute various gases and equipment, it is important to ensure that the handling, storage, and use of these products are conducted in a safe and responsible manner. The MSDS provides critical information that helps to ensure the safe handling of these products. Ultimately, IMG play a critical role in the Nigerian healthcare industry by producing and distributing high-quality medical gases and equipment that support patient care and improve healthcare outcomes.

2.8 Conceptual framework

This portion of the thesis will elaborate on the framework underlying the study's variables. Furthermore, it will identify hidden factors discovered in other studies that can serve as indicators of the research objectives and analyze the relationships between these variables. It will also accentuate the look of the research model as well as the technique for carrying out the planned

analysis.

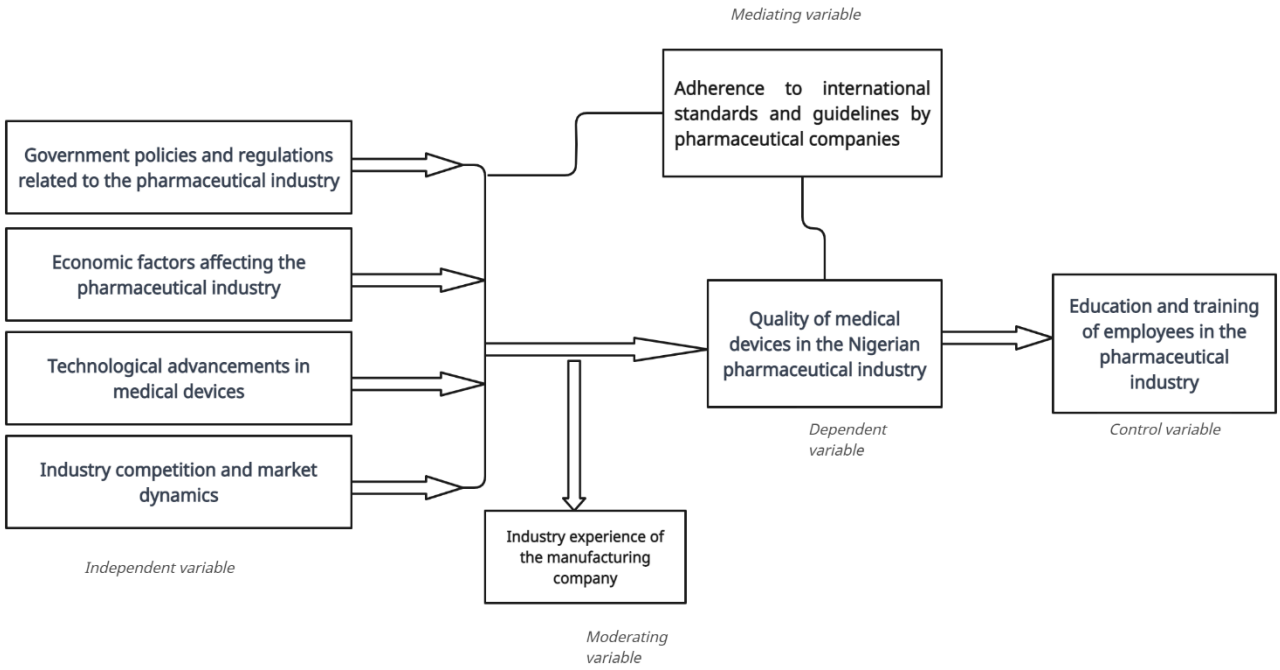


Figure 2.6: Schematic diagram of the challenges and associated variables affecting the regulation and quality of Medical devices.

Following a thorough examination of the medical device industry in Nigeria, various critical areas have been pinpointed as the challenges affecting the effective regulation and quality of medical devices. This research model segregates variables into distinct independent, mediating, moderating, and control variables that impede the quality of Medical devices, which is the dependent variable in this study.

To assess the quality of medical devices in Nigeria, the thesis will assess four elements, namely Governmental policies and regulations related to the pharmaceutical industry, Economic factors affecting the pharmaceutical industry, Technological advancements in Medical devices, and Industry competition and market dynamics. These factors are the core of the Nigerian medical device industry since, in the absence of government regulations, inferior medical devices will be released. Economic factors affecting the pharmaceutical industry can also influence the affordability and accessibility of medical devices, which can impact their quality. Technological advancements in Medical devices can improve their quality by enhancing their functionality, accuracy, and reliability. Industry competition and market dynamics can also impact the quality of

medical devices as companies strive to maintain a competitive edge by developing innovative and high-quality products. Therefore, understanding and monitoring these factors is crucial in ensuring the quality of medical devices.

Prior studies have documented specific variables referred to as moderator variables, which are acknowledged to impact core variables. Moderators ascertain and predict the strength of the dynamics of the main principal variables. In this thesis, the moderating variable is the industry experience of the manufacturing company, which determines the quality of Medical devices. Companies that have been in the industry for a longer duration have more expertise in creating safer and more effective devices. Furthermore, they will have a better understanding of the need for post-marketing surveillance and will direct their efforts towards that area.

Additionally, adherence to international standards and guidelines acts as the mediating variable, bridging the dependent variable and the independent variable. This indicates that compliance with international standards and guidelines has a substantial influence on governmental policies and regulations linked to the Nigerian pharmaceutical industry, economic factors, technological advancements in medical devices, and market dynamics. As a result, this would have a significant impact on the quality of medical devices.

Also, education and training of employees in the pharmaceutical industry serves as the control variable in this thesis. This helps infer the relationship between the main variables. It is important to have a control variable as failure to do so could lead to an inability to establish or demonstrate their non-involvement in the results. Consequently, it would be difficult to ascertain whether the outcomes were due to the independent variable or not.

Furthermore, prior literature has recorded these variables (moderators and mediating) as the limitations to the adequate quality of medical devices. Nevertheless, they overlooked the fact that all these factors shape the impact of government regulations, economic stability of the pharmaceutical industry, technological advancements, and market dynamics on the materials required for producing high-quality medical devices. Thus, for the aforementioned reason, the primary objective of this thesis is to initially ascertain the impact of government regulations, economic stability of the pharmaceutical industry, technological advancements, and market dynamics on the materials required for producing high-quality medical devices in Nigeria.

CHAPTER 3: METHODOLOGY AND RESEARCH DESIGN

3.1 Overview

In this chapter, the methodology and overall approach utilized in the research are illustrated. It is imperative for all studies to have a research approach that aligns with the objectives and allows for rational deductions. In 2009, Saunders, Lewis, and Thornhill introduced the "Research Onion," a model that assists researchers in determining a suitable research process. By working from the outermost layers to the center of the model, the Research Onion aids in selecting an appropriate research approach and allows you to flesh out on the various methodological decisions. This model forms the foundation of the current chapter and shapes its organization. This section, therefore, introduces the concept and applies it to the research design of the dissertation.

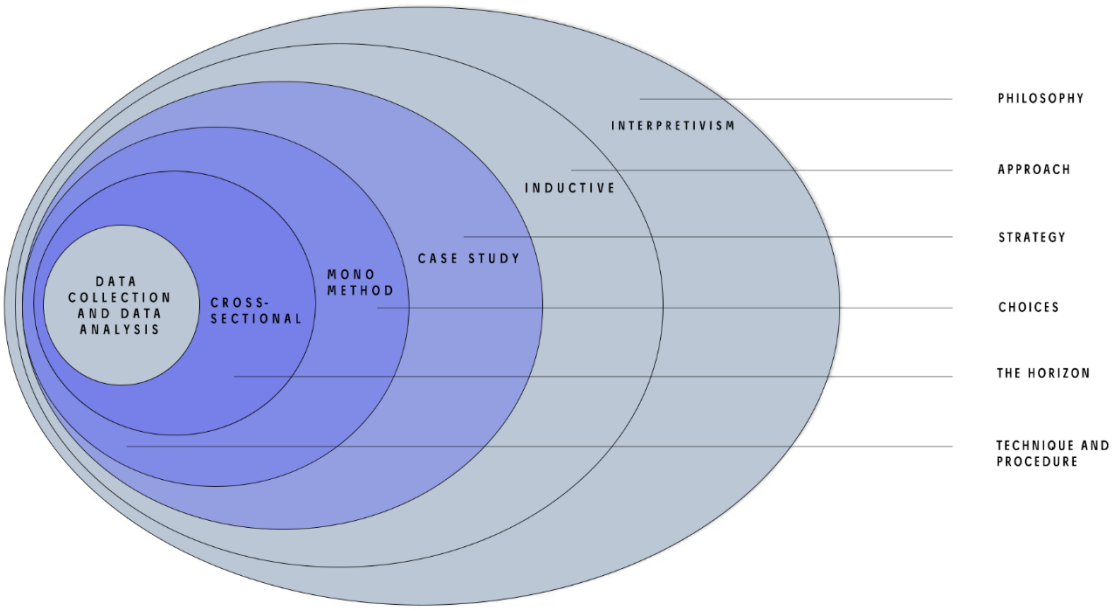


Figure 3.1: Research Onion used for this study adopted from that of Saunders *et al.* (2019, p. 207).

Beginning with the outer layer and working inward, the research philosophy will be considered first. According to Kleinberg-Levin (1988), the research philosophy refers to a researcher's fundamental belief or concept regarding the collection, interpretation, and analysis of data. This philosophy encompasses essential assumptions about a researcher's worldview, which affect the approach and methodology applied during the research process.

Saunders *et al.* (2019, p. 176) have identified five (5) main research philosophies that researchers often employ, namely positivism, realism, interpretivism, postmodernism and pragmatism. The research philosophy of interpretivism is of central importance in the context of this dissertation and will be discussed in more detail to provide a framework for the research design and analysis.

Regarding the second layer of the Research Onion model, the focus is on the research approach, which refers to the plan and methodology used in conducting the research. For this research, a qualitative research approach will be employed, which will involve gathering data through interviews. These data will be used to create and develop theories, which will then be analyzed to obtain the results. This approach follows an inductive methodology, which aims to gather data and develop a theory based on the research findings (Saunders *et al.*, 2019, p. 186).

By utilizing this approach, I will be able to achieve the research objectives and answer the research questions in a logical and systematic way. The data gathered from the interviews will be analyzed and interpreted to derive meaningful insights, which will contribute to the advancement of knowledge in the relevant field of study.

The next layer of the research onion represents the strategy of the research. The research strategy deals with a more practical aspect of the research. It describes how research can be conducted based on the study's objectives, using either experimental strategies, action, survey, descriptive, archival, case study, grounded theory or ethnography strategies (Saunders *et al.*, 2019, p. 223). For this research, a case study strategy will be used to adequately understand the key challenges in the Nigerian pharmaceutical industry, particularly in terms of regulation and quality of medical devices.

After the research strategy layer, comes the layer of research choices which involves deciding on the data collection methods. According to Saunders *et al.* (2019, p. 212), there are three (3) methods for collecting data; mono method, multiple method, and mixed method. Mono method involves using a single method, either quantitative or qualitative, for data collection. In the current research project, the qualitative method will be used for data collection.

Also, time horizon is an important part of the research design that refers to the duration over which a study is conducted. In research methodology, there are two types of time horizons: longitudinal and cross-sectional. A longitudinal study is one that spans a period of time and gathers information

from the same sample of subjects or cases at various times in the study's timeline. A cross-sectional study, on the other hand, is conducted at a single point in time, and data is collected from a sample of participants or cases at that point in time (Saunders *et al.*, 2019, p. 245). This will allow me to examine the research questions at a specific moment in time, and to compare the responses of different groups or variables.

The final layer of the research onion pertains to techniques and procedures, which involves the selection of appropriate data collection techniques and corresponding analytical approaches. This layer encompasses decisions such as questionnaire design, selection of interview partners or sample groups, among others. In this research, a series of interview questions will be crafted and the participants will be selected through snowball sampling methodology.

By using snowball sampling and referrals from existing participants, individuals who are particularly knowledgeable about the challenges facing the Nigerian pharmaceutical industry on the regulation and quality of medical devices can be identified.

These individuals can provide in-depth insights that might not be available through other research methods. Given the challenges that the industry faces, it may be difficult to identify and recruit participants through traditional means. However, by identifying a small number of key stakeholders or experts in the field, their networks can be used to identify other potential participants who might be able to provide valuable insights into the challenges facing the industry.

3.2 Research Philosophy and Approach

This study employs an Interpretivist philosophical approach. Interpretivism is a research philosophy that emphasizes the subjective meanings and interpretations that individuals give to their experiences (Alharahsheh and Pius, 2020, p. 41). This philosophy is particularly relevant for studying complex social phenomena such as the challenges facing the Nigerian pharmaceutical industry, which are likely to be influenced by a variety of contextual factors and stakeholders with diverse perspectives. An Interpretivist approach would allow me to explore the subjective experiences and perspectives of key stakeholders in the industry, such as manufacturers, regulators, and healthcare providers. Also, this would help to present solutions that will improve the regulation and quality of medical devices in Nigeria.

Additionally, the overall approach for this study is an inductive approach, hinged on an exploratory case study. An inductive research approach is characterized by the generation of new theories or insights based on empirical observations and data. This approach is particularly relevant for this research which is complex and understudied. An inductive approach would, therefore, allow me to gather rich data on the challenges faced by stakeholders in the industry and to develop new insights and theories based on that data.

Together, an interpretivism research philosophy and an inductive research approach offers the opportunity to explore the subjective experiences and perspectives of key stakeholders in the Nigerian pharmaceutical industry and to develop new insights and theories based on empirical observations and data. Ultimately, this approach would be well-suited for this research which requires a nuanced and detailed understanding of the issues at hand.

3.3 Research Strategy and Time Horizon

As aforementioned, Saunders *et al.* (2019, p. 212) identified various classes of research strategies from which scholars can select which would best suit their study.

Thus, an exploratory case study strategy will be effectively applied in this research, with the use of semi-structured interviews. The exploratory case study strategy is a research design that involves investigating a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clear.

This approach is often used to explore new or under-researched topics where little is known or when the research problem is complex and has multiple dimensions. It involves the collection and analysis of qualitative data from multiple sources, including interviews, observations, and documents. Additionally, Saunders *et al.* (2019, p. 229) suggest that the case study strategy is particularly effective in generating answers to questions concerning 'why' and 'what'. As a result, this research method is often used in exploratory and explanatory research.

To explore the challenges facing the Nigerian pharmaceutical industry regarding the regulation and quality of medical devices, a case study approach will be used to collect data from a variety of sources, including semi-structured interviews with key stakeholders such as regulators, manufacturers, and healthcare professionals, as well as document analysis of relevant policy and regulatory documents. The exploratory case study approach will allow me to examine the research

questions at a specific moment in time, and to compare the responses of different groups or variables, further allowing me to gather in-depth data on the challenges facing the Nigerian pharmaceutical industry regarding the regulation and quality of medical devices. This will then lead me to recommendations for improvements.

Furthermore, the time horizon within which data is obtained must be considered. According to (Saunders *et al.*, 2019, p. 245), cross-sectional studies look at a specific phenomenon at a certain point in time. As a result, the cross-sectional technique is implemented in this research.

3.4 Collection of Primary Data

In order to investigate the research questions and achieve the objectives of the study, it is important to gather information on the experiences, perspectives, opinions, and behaviors of individuals who have been involved in the regulation, manufacture and usage of medical devices in Nigeria, as well as those who have direct knowledge of the industry. To accomplish this, a mono method, specifically the use of a qualitative research approach, will be used to collect data.

To gather information, semi-structured interviews with open-ended questions will be utilized as a method of qualitative research. The questions will be in the format of "what," "how," and "why," and will remain open-ended in nature. Although the questions will be similar, they will be adjusted to suit each respondent's level of knowledge and experience. This open-ended approach will allow participants to communicate freely and extensively, while also enabling the researcher to delve deeper into their responses. This approach is effective in producing comparable, insightful, and precise data.

A one-on-one phone call interview will be conducted with representatives from regulatory authorities, medical device manufacturers, health care professionals and medical device users. These calls will be recorded. The interview questions would be designed to assess respondents' general knowledge of medical devices manufactured in Nigeria and the challenges they face in terms of access to good quality medical devices, as well as the effectiveness of the safety measures in place for medical devices.

In order to gather information about the current regulatory framework to show whether the products comply with legal requirements as well as to obtain information regarding the preferred medical devices to use and what potential quality factors may influence their choice, telephone

interviews would be conducted with representatives from Nigerian regulatory authorities and Medical Doctors in Nigeria.

Telephone interviews would also be conducted with Medical device manufacturers because it allows for the collection of specific, relevant information from a large number of manufacturers in a standardized and efficient manner. This will include questions about the manufacturers' experiences with the regulatory process, the quality of medical devices produced and distributed, and any challenges they have encountered in the industry. This information can then be used to identify and address any issues related to the regulation and quality of medical devices in the Nigerian pharmaceutical industry.

Telephone interviews would also be conducted with Pharmacists working in large Nigerian pharmacies. This is because pharmacists often play a crucial role in communicating complex medical information to patients in a way they can understand. This applies not only to medications but also to medical devices, many of which are available for purchase in pharmacies. In addition to this, pharmacists are also responsible for evaluating and determining the appropriate use of medications based on factors such as their effectiveness, safety, and cost-effectiveness through managing medication lists in hospitals. These skills can also be applied to evaluating other healthcare technologies, particularly interventional procedures and devices, as the methods used for evaluating these are similar to those used for evaluating medications. Users of medical devices will also be contacted, as they can vouch for the reliability and effectiveness of the various devices from the various manufacturers.

By conducting interviews with this groups of people, I would be able to identify the challenges affecting the proper regulation and quality of medical devices in Nigeria, and also gather information on the effectiveness of the pharmaceutical regulatory system in Nigeria and how it impacts the safety and quality of medical devices and ultimately, patient safety and public health. All of the data gathered from the various groups will be then combined and appropriately examined to come to a conclusion.

3.4.2 Access and Ethical Issues

The historical record of scientific and educational research shows that ethical considerations are a recurring aspect of research (Wellington, 2000, p. 2). The methods used to gather information in

research are a significant factor in shaping and restricting the research process, as well as generating ethical considerations. These ethical issues typically arise from the intricate nature of research methods in social research, including survey techniques, interview procedures, observational methods, action research, and ethnographic studies (Cohen *et al.*, 2000, p. 66). In the case of this research, interviews are employed as the primary research method, which raises access and ethical concerns.

According to Diener and Crandall (1978), informed consent is the cornerstone of ethical research practices. They described it as the process through which individuals decide whether or not to engage in an inquiry after being provided of relevant facts. Obtaining informed consent from participants is crucial, and researchers must ensure that participants understand the research objectives and what is expected of them. If a researcher fails to obtain consent or declaration from study participants, it could result in a violation of privacy under the EU data protection regulation, hence, informed consent forms will be sent to each participant in advance of the interview session to ensure compliance with their company policies and guidelines, or personal views in the case of the consumers.

Additionally, I plan to reach out to the participants via telephone calls as some of them are easily reachable and since my research takes a singular approach, conducting phone interviews is the most effective way to gather all the necessary information from them. However, this method is limited by distance due to current travel restrictions, which make conducting face-to-face interviews difficult.

Also, access to suitable research sites and participants may pose ethical challenges related to the interviewer's openness, sensitivity, and honesty. Nonetheless, it is crucial to establish trust and build relationships with respondents as rapport in the research can significantly enhance the quality of the research and serve as a source of support. Conversely, a lack of rapport may lead to negative emotions like disappointment and embarrassment (Wellington, 2000, p. 42). Consequently, throughout the research, I will maintain honesty so as to promote transparency and ethical behavior.

To ensure a cohesive research process, it is essential to follow ethical guidelines that protect participants' rights to confidentiality, withdrawal, and erasure. Hence, the privacy of the participants' data will be protected by implementing appropriate measures. Before the interview, I

will reassure the participants that all information provided will be treated confidentially and will seek permission to record the interview. Power dynamics may exist in some cases, causing participants to feel uncomfortable sharing their views due to fear of consequences. Therefore, as the interviewer, I must be aware of these power dynamics and take steps to minimize any potential harm to participants.

To further maintain confidentiality, a pseudonymous strategy will be incorporated in my research. A code will be issued to each participant, which will be used to transcribe and analyze the interview responses. These codes will be recorded during the interview and securely saved for examination. The audio recordings of the interviews will be electronically stored, password-protected, and deleted after analysis to prevent any potential breach of confidentiality.

3.5 Approach to Data Analysis

There are many ways that qualitative researchers can make sense of their data. According to (Green *et al.*, 2007 cited in Liamputtong, 2009, p. 133), researchers should initiate qualitative data analysis at the start of their research by engaging themselves in fieldwork, such as interviews, participant observation or analyzing published texts and/or documents. They should then immerse themselves in the collected data, reading and re-reading it until they are able to make sense of it. By deeply engaging with the data, researchers aim to comprehend the insights and meanings that the data holds.

On that account, two types of data analysis will be adopted in this study, which are Document analysis and Expert Interview analysis (Thematic analysis).

Document analysis is a qualitative research method that involves the evaluation of documents by the researcher in order to gain insight and understanding on a particular topic. For this study, the following steps will be employed for document analysis:

1. Identification of relevant documents: The researcher will collect relevant documents pertaining to the Nigerian pharmaceutical industry, including government policies, regulations, industry reports, and academic articles on medical device regulation and quality, as well as documents from other developed countries for comparative purposes.

2. Reading and reviewing the documents: The researcher will carefully read and analyze the gathered documents, making note of key themes, trends, and ideas that relate to the research question.
3. Acknowledgement and addressing of biases.
4. Development of relevant skills to assess the validity of the documents under review.
5. Implementation of strategies to ensure credibility.
6. Consideration of ethical issues.

This data analysis approach is an effective data analysis approach and has been selected for several reasons including;

- Access to existing data: Document analysis involves examining existing documents, reports, and records. This can save time and resources as data is already available, and can provide access to information that would be difficult to collect through other methods.
- Unobtrusive research: Document analysis is an unobtrusive research method, meaning that it does not involve direct contact with research subjects. This can reduce the potential for researcher bias and also protects the privacy of individuals and organizations.
- Rich data: Documents often contain rich and detailed data that can provide valuable insights into research questions. This can include government policies, industry reports, and academic articles, among other sources.
- Multiple sources of data: Document analysis can involve analyzing multiple sources of data, which can increase the validity and reliability of the findings. By using a variety of sources, researchers can triangulate the data, providing a more complete picture of the topic being studied.
- Replicability: Document analysis is a replicable research method, meaning that other researchers can review the same documents and conduct their own analysis. This increases the transparency and rigor of the research, and allows for the findings to be tested and validated by other researchers.

Additionally, Liamputtong (2009) provides practical tips for researchers, such as the importance of keeping detailed records, using software to manage data, and being open to unexpected findings during the analysis process. Primarily, the author describes various approaches to qualitative data

analysis, including Content analysis, Thematic analysis, Narrative analysis, Discourse analysis and Semiotic analysis.

Each approach has its own strengths and limitations. Thus, for the purpose of this research, the thematic analysis will be adopted and will serve as the basis for the expert interview analysis. Thematic analysis involves identifying and analyzing patterns, themes, and concepts within qualitative data. Given that Meuser and Nagel (2009, p. 23-24) focused on identifying thematic units or passages with similar topics to ensure a greater comparability, the expert interviews will be analyzed according to their data analysis approach. These authors discuss the following steps:

1. Transcription: The first step in the expert interview analysis will be to transcribe the interview, which involves creating a written record of the conversation, according to thematic units. This will be done manually or using computer software.
2. Familiarization: Once the interview has been transcribed, the researcher should read and re-read the transcript to become familiar with the data. This can involve making notes and highlighting important passages.
3. Coding: The next step is to code the data, which involves identifying and labeling themes, concepts, and ideas that emerge from the transcript. This can be done manually or using computer software.
4. Categorization: After coding the data, the researcher would group similar codes and themes into broader categories. This helps to organize the data and identify overarching patterns and trends.
5. Analysis: The final step is to analyze the data by interpreting the categories and themes in relation to the research question. This involves considering the implications of the findings and drawing conclusions about the knowledge produced through the expert interview.

Throughout the analysis process, Meuser and Nagel (2009, p. 23-24) emphasize the importance of maintaining transparency and reflexivity. This involves being transparent about the research process and decisions made, and reflecting on how the researcher's own experiences and biases may have influenced the analysis. It is also important for the researcher to critically evaluate the quality and credibility of the data and to consider the perspectives and opinions of the expert being interviewed.

3.6 Conclusion

This chapter has thoroughly examined the distinctions across various levels of research methodology. At this juncture, it is critical to underscore the investigation and in-depth analysis of the approaches elucidated earlier, which have been succinctly explained to reveal causal connections and will be further scrutinized in the subsequent chapter to arrive at the cogent point of this research. Throughout this study, significant emphasis has been placed on the research methodology, specifically the utilization of semi-structured interviews to obtain detailed data using the mono method. However, the information provided by the researcher will be subjected to unique interpretation to avoid complexities and facilitate the attainment of a comprehensive conclusion for the research as a whole.

CHAPTER 4: PRESENTATION AND DISCUSSION OF THE FINDINGS

4.1 Overview

In this chapter, an analysis of data and interpretation of findings obtained from interviews conducted with medical devices manufacturers, trusted partners of regulatory authorities, pharmacists from top pharmacies in Nigeria, and medical device users are presented. The aim is to offer a comprehensive analysis on the challenges of insufficient regulation and manufacture of low-quality medical devices and how to tackle these challenges. The analysis is based on the themes that emerged from the data collected during the interviews.

4.2 Findings and Discussion

4.2.1 Demographic Attributes of the Participants

In this interview, a total of eleven (11) individuals were selected for the interview process. The selected group comprised of two trusted partners of the Nigerian Regulatory authorities, three senior employees from medical device manufacturing companies, three pharmacists from large-scale pharmacies in Nigeria, and three users of medical devices. A detailed description of the demographic attributes of the participants can be found in Table 4.1.

Table 4.1: Demographic Attributes of the Participants

	Frequency	**Percent (%)**
	Gender	
Male	5	45.45
Female	6	54.55
Total	**11**	**100.0**
	Marital Status	
Single	7	63.64
Married	4	36.36
Total	**11**	**100.0**
	Age	

Less than 40 years	7	63.64
41-50 years	2	18.18
51 and Above	2	18.18
Total	**11**	**100.0**
	Educational Qualification	
HND/B.Sc.	5	45.45
Postgraduate	6	54.55
Total	**11**	**100.0**
	Work experience in firms	
Less than years	5	62.50
11-20years	1	12.50
Above 20	2	25.00
Total	**8**	**100.0**
	Experience in medical device usage	
Less than years	2	66.67
11-20years	1	33.33
Above 20	0	0
Total	**3**	**100.0**

Table 4.1 presents a comprehensive overview of the demographic characteristics of the participants involved in the interviews on the challenges of regulating and ensuring quality of medical devices in the Nigerian pharmaceutical manufacturing industry. The gender distribution among the participants reveals that out of the total of eleven individuals interviewed, 5 (45.45%) were male while 6 (55.55%) were female. These results indicate that both genders were adequately represented in the interviews, thereby ensuring gender inclusivity in the study.

The marital status of the participants indicates that 7 (63.64%) were single while 4 (36.36%) were married. Concerning the age bracket, the data indicates that only 7 (63.64%) of the participants were under the age of 40, 2 (18.18%) were between 41-50 years old, while 2 (18.18%) were aged 51 years and above. The table also highlights the educational qualifications of the participants.

Among the eleven participants, 5 (45.45%) possessed a first degree or equivalent, while 6 (55.55%) held postgraduate degrees. This finding suggests that the information provided by the participants can be deemed reliable.

Moreover, the table provides an insight into the work experience of the participants in the pharmaceutical industry. The data shows that 5 (62.50%) had less than ten years of work experience in the industry, 1 (12.50%) had between 11-20 years of experience, while 2 (25%) had over 21 years of experience. This implies that all the participants had the requisite knowledge and understanding of the industry and could provide valuable insights into the discussion.

Furthermore, the table indicates the experience of the participants in using medical devices. The data reveals that 2 (66.67%) of the participants had been using medical devices for less than ten years, while only 1 (33.33%) had between 11-20 years of experience using medical devices. These results provide an essential understanding of the participants' experience in using medical devices, which can help in assessing their ability to provide valuable insights into the topic.

4.3 Theme 1: The Regulatory framework for Medical Devices in Nigeria (Q1, Q2, Q3, Q10)

The regulatory framework for medical devices in Nigeria was critically described by the participants from the perspective of weak implementation and lack of coverage, challenges in inspection, delays in regulatory processes and need for improved communication.

The participants from the medical device manufacturing group reported that regulatory authorities conduct routine check-ups and external audits but the inspection fee is too costly. However, a partner of the regulatory authorities reported that required check-ups are not often conducted. He also added that there is insufficient manpower to inspect and schedule inspection. He, as well as other participants, identified the strength of the regulatory framework as the presence of set regulations for medical devices and pharmaceuticals, however, the poor implementation, processing times and poor post-marketing surveillance were identified as the weaknesses.

Extracts from the statements of participants are quoted as follows:

Weak Implementation and Lack of Coverage

“The regulations are on ground and are completely enacted to regulate importation, manufacture and distribution. However, in as much as the laws are available, the implementation is weak. For example, when it comes to distribution, the medicine of the good distribution practices regulations is not that robust yet compared to manufacturing Good Manufacturing Practices regulations. So, the entire supply chain is still not yet covered” **REG 1**

“Post marketing surveillance still needs to be improved. The implementation is weak because of what I will personally classify as lack of manpower, because as it is now, the structure of the regulatory body in Nigeria, focuses more on registration. The structure still lacks efficiency when it comes to monitoring when already registered products that are in the market.” **REG 1**

“NAFDAC and SON are to monitor and regulate the standard of equipment and drugs, but Nigeria is a nation that does not follow up with monitoring. So most products that come in, after the first registration they do not keep up with quality and this reduces as time goes by. Maybe because NAFDAC and SON do not keep up with monitoring and follow up on products to ensure high quality products are sustained in the market.” **PHARM 3**

Challenges in Inspection

“Implementing the regulations on ground becomes challenging. For example, there's a regulation for good manufacturing practices that states that manufacturing facilities shouldn't be visited or inspected on a regular basis, that is every six months but you find out that's in three, four years, factories are not inspected, not because they don't want to inspect but because of the lack of manpower.” **REG 1**

“THE NAFDAC and SON come for regular check to ensure that procedures are being followed.” **MANU 1**

“NAFDAC conducts quality checks to ensure what is brought it is of good quality and does not cause any harm.” **MANU 3**

“NAFDAC and SON come routinely for monitoring and look through necessary documents that have to be renewed, for example, the operating license has to be renewed every year. They visit quarterly to check that the facility meets all requirements. These two bodies guide the operation of medical devices in Nigeria” **MANU 2**

Delays in Regulatory processes

"The regulatory body is Nigeria can be very slow, it can take a while for them to conclude on their processes in order for us to get the regulatory permit. Processes that should have been finished in a week take months. When people that are meant to do their job slack, it affects the entire process and this would tell on customers as well. The longer NAFDAC took to grant us the permit, the longer customers had to wait for their products which ultimately affects the entire supply chain" **MANU 3**

"The whole process of importing raw materials can sometimes take a long time because there are a lot of protocols involved like clearance from the different agencies." **MANU 2**

"I believe the regulatory process in Nigeria can be better based on regulation, speed, perfecting the processes in place including timelines and not just NAFDAC, customs as well. This is because we have established that most raw materials come from outside the country." **MANU 3**

Need for improved Communication

"The regulatory framework is fair but can be better. One thing I can speak on is updating their materials. For example, NAFDAC has set requirements for syringe manufacturing and to update that, it will be better if a copy is sent to all companies or better yet, notify companies that requirements have been changed. Last time they came for an inspection; we were told our requirements were outdated. If they do not inform us, how do we know?" **MANU 1**

Table 4.2: Development of theme for The Regulatory framework for Medical Devices in Nigeria

Participants	Response codes	Categorization	Theme
REG 1, PHARM 3	i. Implementation is weak ii. Post-marketing surveillance is poor	Weak implementation and Lack of coverage	The Regulatory framework for Medical Devices in Nigeria
REG 1, MANU 1, MANU 2, MANU 3	Regularity of Inspection	Challenges of Inspection	

MANU2, MANU 3	Processes can be slow	Delay in Processes
MANU1	Update on materials	Need for improved communication

4.3.1 Discussion

The first objective of this study is to evaluate the current regulatory framework in Nigeria and identify any shortcomings. One key aspect of the findings is that the current regulatory framework has several gaps that need to be addressed. This suggests that there are areas where the regulatory framework is not adequately addressing the issues it is intended to regulate. Such gaps can expose the public to risks such as the availability of counterfeit and substandard drugs, which can lead to serious health consequences.

Interestingly, the study's findings are consistent with the work of Usar and Bukar (2020,p. 11-18) who also identified the weaknesses in the Nigerian regulatory framework. Their research revealed that the regulatory framework is characterized by irregular inspections and weak enforcement, which have contributed to the widespread unregulated and illicit sale of restricted products. Such issues can lead to significant public health risks and undermine the regulatory framework's ability to achieve its objectives.

Insufficient budgetary allocation was also identified as the basis for various regulatory difficulties, including lack of manpower. The connection between insufficient budget availability and poor regulatory enforcement in the private sector, which has extensive networks, has been reported in other African nations as well (Matsebula, *et al.*, 2006). The lack of manpower or shortage of personnel ultimately leads to the inability to conduct inspections and post-marketing surveillance, giving way for the production and release of subpar medical devices.

Hence, there is a major need for significant improvements in Nigeria, and Africa at large. These gaps in the current framework need to be addressed, and measures put in place to improve regulatory oversight and enforcement. By addressing these issues, the regulatory framework can better protect the public's health and safety, and ensure that regulated products meet the required standards.

4.4 Theme 2: Challenges to the Manufacture of High-Quality Medical Devices in Nigeria (Q12, Q13, Q14, Q19, Q21)

Nigeria is a developing country that heavily relies on the importation of medical devices. The manufacturing industry is facing significant challenges to the manufacture of high-quality medical devices. This theme explores the challenges to the manufacture of high-quality medical devices in Nigeria based on the responses of the participants.

Virtually all participants mentioned that Nigeria heavily relies on the importation of medical devices. The medical device manufacturers further highlight the absence of certain raw materials as a significant challenge to the manufacture of high-quality medical devices. This affects the production process and the quality of the final product. They also identified the unavailability of custom-made machine parts as a significant challenge that affects the production process and the quality of the final product. One of the pharmacists likened the use of fairly used materials as another contributing factor to the manufacture of low-quality medical devices. This practice compromises the reliability and safety of medical devices, making them unsuitable for use.

Extracts from the statements of participants are quoted as follows:

Unavailability of Raw materials and Custom-made machine parts

"Most of the raw materials needed for medical devices are not available in Nigeria. About 50-70% of the raw materials needed cannot be found in Nigeria. The major materials used in syringe manufacture are polymers which are polyethylene and polypropylene. As of this moment, we only have one manufacturer for these in Nigeria and we are not the only ones using polymers, other plastic companies use them too. Their capacity right now cannot handle all requests and that is when importation of raw materials come in". **MANU 1**

"There are some parts of machineries that are custom-made and are not readily available. The technology is Nigeria has not gone to the extent where you can go and ask for machine parts to be manufactured. This needs to be improved, not only in manufacture of medical devices but general production in Nigeria. If this can be taken care of, running costs will reduce." **MANU 1**

Limited resources and Fairly used equipment

"Most companies do not have the resources and funds to acquire new materials so they tend to source equipment in a fairly used manner. This could lead to malfunction of medical devices." **PHARM 1**

Certification challenges

"The only measure in place to ensure that products are being pushed into the market are of good quality is through routine inspections which does not happen as often as they ought to. Also, inspection of raw materials at the point of entry which is also not efficient, because when you compare the quantity of imports that come in, and the rate at which the NAFDAC lab certifies the products prior to release all the shipment ends, the ports will be jam packed. So, products are being cleared at the port of entry based on maybe historical data or if a particular brand is known to have maintained good quality" **REG 1**

Table 4.3: Development of the theme for Challenges to the Manufacture of High-Quality Medical Devices in Nigeria

Participants	Response codes	Categorization	Theme
MANU 1	i. Raw materials are not available ii. Custom-made machine parts are not available	Unavailability of raw materials and custom-made machine parts	Challenges to the Manufacture of High-Quality Medical Devices in Nigeria
PHARM 1	Companies lack resources so they tend to use fairly used materials	Limited resources and fairly used equipment	
REG 1	Backlog of products due to rate at which products come in and rate at which	Certification challenges	

	NAFDAC certifies them

4.4.1 Discussion

The third objective of this study is to assess the implication of these challenges on the Nigerian economy. These findings are similar to that of Okereke *et al.* (2021, p. 3). According to these authors, the local production of raw materials and processing equipment for the Nigerian pharmaceutical industry has been neglected, resulting in the country's dependence on India and China for supplies. This dependence has caused a hike in prices and foreign exchange difficulties, contributing to a 200% rise in the cost of imported products due to a lack of foreign exchange.

This has further have led to a decline in the Nigerian pharmaceutical manufacturing sector's capacity. Despite investing more than NGN400 billion (€793 million) in infrastructure to obtain the WHO prequalification required for foreign competition, the Nigerian pharmaceutical industry still faces challenges such as a 100% increase in the cost of importing inputs from 2014 to 2018 due to the weakness of the naira and rising logistics costs (WHO, 2022). Moreover, manufacturers are faced with increasing manufacturing costs, with energy alone accounting for 40% of overall expenditure (Pharmapproach, 2018).

Moreover, the lack of sufficient demand for locally manufactured devices may result in poor manufacturing capacity, negatively impacting previous investments in the industry. The use of fairly used materials may also create an opportunity for counterfeit and/or contaminated devices to enter into the legitimate supply chain, putting the public's lives at risk. Usar and Bukar (2020, p. 11-18) note that there is a high prevalence of fake, adulterated, and substandard drugs and devices in the Nigerian market, attributing these problems to factors such as inadequate and overlapping legislation, official corruption, poorly trained personnel, and underfunding of regulatory institutions.

4.5 Theme 3: Factors that Contribute to Ineffective Regulation and Registration of Medical Devices in Nigeria (Q9, Q10)

Medical devices are crucial for the diagnosis, treatment, and management of various health conditions. Thus, the regulation and registration of medical devices are crucial to ensure their safety and efficacy. However, in Nigeria, the process is challenging, and there are several factors contributing to these challenges.

Among these factors, the participants highlight the issue of duplicity in the guidelines established by the two main regulatory bodies in the country, which creates significant cost implications and leads to lengthy approval times during registration. This shows the disunity in the regulatory systems putting the manufacturers in a state of turmoil. The high costs associated with the clearance of raw materials and the fees charged for GMP inspection were also identified as major hurdles that impact the efforts directed towards not only the registration of medical devices, but also subsequent locally manufactured medical devices. These costs make it difficult for manufacturers to produce and register medical devices in Nigeria.

Here are what some of the participants had to say:

Inadequate Funding for Regulatory Authorities

"For medical devices, things are still picking up gradually. The major challenge of regulatory authorities in Nigeria, in particular, is funding. Most of the things that are not being done are based on the unavailability of funds" **REG 1**

Regulatory duplication

"We have to do SON and NAFDAC regulations and some of their requirements overlap. However, they have recently harmonized their requirements in the places where they are similar, which I think has helped." **MANU 1**

"The registration of medical devices is a thug of war between NAFDAC and SON as their requirements overlap and companies have to do a duplication of registration, which has its cost implications" **REG 2**

Policy inconsistencies

"Another thing is the interpretation of the regulations. This is now it's a personal experience, working over the years with the authorities. You will notice that the regulations are there but whenever there is a change in management, you tend to see a difference in the interpretation of the regulations. So some people tend to preach regulations based on their own personal understanding. For example, when a new director comes in charge of a particular directory, you tend to see new things happen in which the next director might decide to jettison so it makes it look as if that implementation is somehow lopsided." **REG 1**

Cost, Bureaucracy and Processing time

"The tariff for NAFDAC GMP inspection is on the high side, and this does not include processing and laboratory analysis. These will still have to be paid separately for GMP inspection, and there have been reports of them wanting to have an upward review of these tariffs meaning the price will increase." **REG 2**

"The cost of clearing raw materials is a challenge. There is also the cost of inspection fee, for example, if SON are to visit 4 times a year, payment is to be made 4 times a year and this payment is in 6 figures." **MANU 2**

"In Nigeria, there are a lot of processes that are not properly managed. Recently, the Nigerian government increased the tariffs meant to be paid by customs. And customs went on strike, which led to expiration of devices because customs could not check, hence, NAFDAC could not ensure its safety and quality" **MANU 3**

Table 4.4: Development of the theme for Factors that Contribute to Ineffective Regulation and Registration of Medical Devices in Nigeria

Participants	Response codes	Categorization	Theme
REG 1	Unavailability of funds	Inadequate Funding for Regulatory agencies	Factors that Contribute to Ineffective Regulation and Registration of

			Medical Devices in Nigeria
MANU 1, REG 2	i. ii.	SON and NAFDAC requirements overlap Companies have to do a duplication of registration	
REG 1	Difference in interpretation of requirements due to changes in leadership		Policy inconsistencies
REG 2, MANU 2, MANU 3	i. ii. iii.	GMP Inspection fee is on the high side Cost of clearing raw materials is challenging Increase of custom tariffs	Cost, Bureaucracy and Processing times

4.5.1 Discussion

One objective of this study is to evaluate the potential implication of regulatory challenges on the quality of medical devices. The effectiveness of regulatory bodies is significantly influenced by their funding. Adequate funding is essential for regulatory agencies to carry out their mandates effectively (Usar and Bukar, 2020, p. 11-18). In Nigeria, the funding of regulatory agencies is

often derived from fixed budgetary allocations, which may not always be sufficient to meet the regulatory needs of the agencies. This can result in regulatory agencies facing numerous challenges, including staffing shortages, inadequate logistics and infrastructural support, and limited operational resources.

Regulatory bodies require competent personnel, adequate equipment, technology, and other resources to carry out their mandates effectively However, inadequate funding results in a lack of resources and lead to reduced staff training and development opportunities. This can result in delays, reduced efficiency, and other challenges that can negatively impact regulatory effectiveness.

Therefore, policymakers must ensure that regulatory agencies are adequately funded to enable them to carry out their mandates effectively. This can be achieved through increased budgetary allocations, the implementation of cost-effective measures, and regular evaluation and review of regulatory budgets to ensure that they are sufficient to meet the needs of regulatory agencies.

A key factor contributing to the ineffectiveness of regulatory bodies is the presence of policy inconsistencies resulting from inadequate policy formulation. Ensuring the involvement of key stakeholders, clear goal definition, and effective policy articulation are critical components in determining the effectiveness of policy implementation. Research by Ensor and Weinzierl (2007, p. 355) has demonstrated that misalignment of policies with realistic goals can result in frequent shifts in regulatory direction, and unrealistic policy goals have been attributed to the failure of governments in low and middle-income countries to regulate commercial drug dealers. Furthermore, the complexity of drug and medical device regulatory agencies, often with overlapping roles, has led to fragmented policy implementation and policy failures.

Additionally, the limited utilization of health information due to inadequate integration of policy beneficiaries in the policy-making process has constrained regulatory performance in Nigeria. Thiede (2005, p. 1452) argue that mutual trust between the people and the government is crucial for the utilization of publicly provided information, but trust for the government in Nigeria is generally low. Ensuring robust policy formulation and integration of policy beneficiaries in the policy-making process is, therefore, crucial for effective regulatory performance.

Furthermore, several studies have shown that high compliance costs can have a negative impact on the effectiveness of regulatory bodies (Ensor and Weinzierl, 2007, p. 355; Kumaranayake *et al.*, 2008, p. 1). High compliance costs can create a significant barrier to entry, particularly for small and medium-sized enterprises (SMEs). SMEs may struggle to meet the costs associated with regulatory compliance, which can lead to a reduction in competition and concentration of power among larger firms. This, in turn, can result in reduced innovation, increased prices, and decreased quality of products or services.

High compliance costs can also create incentives for non-compliance or even evasion. For example, if the costs of compliance are too high, individuals or firms may choose to circumvent the regulations, which can undermine the effectiveness of regulatory bodies. Such behavior may result in a lack of trust in the regulatory system, as well as reduced accountability, both of which can further erode regulatory effectiveness.

4.6 Theme 4: The Efficacy of the Quality and Safety Management practices in Manufacturing companies (Q6, Q7, Q15, Q17, Q18)

The manufacture of medical devices is a critical aspect of healthcare delivery, as the quality and safety of these devices can significantly impact patient outcomes. Virtually all medical device manufacturers that were interviewed claimed to adhere to ISO standards such as ISO 9001:2016 on general quality management systems, ISO 13485:2015 on medical device quality management, ISO 7886 which is specified for syringe manufacture, as well as the SON and NAFDAC's established standards and guidelines on medical devices. The majority of the manufacturers also claimed to conduct system validations and develop Material Safety Data Sheets for all products. However, some manufacturers expressed challenges with implementing these practices fully, citing limited resources and capacity.

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

"For our company, we have a quality assurance department that ensures all our products are at each manufacturing step to ensure they meets specifications. If there is any deviation, the engineer on ground is informed and correction is done, that way we ensure that any product that leaves the factory is of utmost quality." **MANU 1**

“We are ISO 9001: 2016 AND ISO 13.5: 2015 certified. We have regulatory bodies in Nigeria, which are SON and NAFDAC that regulate medical devices and we are registered with both. We ensure our procedures are of the requirements and we do not deviate form set requirements. We ensure our raw materials and equipment are up to par. We try to do everything by the book because at the end of the day, every syringe we produce is a life”. **MANU 1**

“Prior to commencement of operation, the system has to be validated. The national standards are mandatory because they're the country's regulatory requirements which are the SON and NAFDAC. SON is the ISO member body for Nigeria, and NAFDAC has guidelines needed to be met. For instance, operating license which will be given only when a superintendent pharmacist has been employed. That way, the pharmacist ensures all activities are within the extent of the law.” **MANU 2**

“As a company, we have obtained specification for ISO 9001 which is for general quality management system and ISO 13.5 which is for medical device quality management, 1S0 7886 which is specifically for syringe manufacturing, as well as many other standards. Because the management of the organization is so committed to quality, they ensure that they uphold all requirements, or international standards that are applicable.” **MANU 2**

“We have to check with the MSDS and the certificates of analysis for every raw material to ensure there are no leachable substances that can negatively impact the safety of syringes for the users. ISO 7886 will also tell you physical features in terms of design that should be on this range to ensure that there is no there's clarity in terms of numbering system and graduation lines.” **MANU 2**

“We have seen both routine internal and external audits that are carried out that. So, here in the company, internal audits are conducted at least twice a year. External audits are done annually. This is done to seek compliance with requirements. We also have customer satisfaction management. Yearly, we take a sample of our customers we ask them questions about how satisfied they are with the quality of our products, what improvements would they like to be made.” **MANU 2**

“We follow ISO standards such as ISO 9001 and ISO 13485. We also show our customers these standards we follow to let them know we have quality management system in place. Also, when

materials are brought into the country. We also have quality control manager to ensure everything meets standard requirements before selling to customers in need." **MANU 3**

4.6.1 Discussion

This thesis aims to evaluate quality management practices in medical device manufacturing companies, investigate the international best practices and standards for medical device regulation and quality management, and explore how they might be applied in the Nigerian context. The use of these international standards is a step in the right direction towards ensuring the production of high-quality and safe medical devices. The establishment of local standards by regulatory bodies such as SON and NAFDAC is also commendable, as it ensures that products manufactured in Nigeria meet the required standards and are safe for use.

However, the efficacy of these quality and safety management practices by medical device manufacturing companies in Nigeria may differ from those in Europe due to several factors such as the level of infrastructure and technical expertise available, as well as the level of enforcement of regulations.

The European regulations for medical devices, particularly the Medical Device Directives and the subsequent MDR, set forth stringent requirements and standards to ensure the safety and efficacy of medical devices. The European regulations prioritize clinical evidence and require clinical evaluations for certain categories of medical devices. This ensures that devices are supported by scientific data and clinical studies before being placed on the market. Additionally, the European regulations introduce the Unique Device Identification (UDI) system, which assigns a unique identifier to each medical device, enabling traceability throughout its lifecycle (EMA, 2018). This aids in post-market surveillance, recalls, and monitoring the device's performance and safety, all of which were absent in the responses of the participants. This limits the effectiveness of post-market surveillance and device traceability

Thus, multiple benefits can be achieved by harmonizing regulations. Regulatory authorities stand to gain from enhanced expertise, increased collaboration with other regulatory bodies, and improved operational efficiency achieved through the sharing of information and recognition of regulatory decisions made by established authorities. Healthcare professionals benefit from a broader range of treatment options, enabling them to optimize patient care and management. The

biomedical industry experiences advantages such as access to new markets and an improved ability to meet regulatory requirements pertaining to device registration. Patients, on the other hand, enjoy a range of benefits including improved availability of devices, access to high-quality products that meet stringent safety, quality, and efficacy standards, and a decreased risk of utilizing unsafe devices.

Achieving harmonization requires a multifaceted approach that combines international collaboration, regulatory convergence, information sharing, capacity building, stakeholder engagement, and effective oversight. By working together towards a common goal, regulatory authorities can foster harmonized regulations that benefit all stakeholders involved in the medical device industry.

4.7 Theme 5: Suggestions and Recommendations Made by Participants (Q4, Q5, Q11, Q16, Q22)

The ninth and final objective of this study is centered on gathering suggestions and recommendations from interviewees to address the challenges that the Nigerian pharmaceutical industry faces in regulating and ensuring the quality of medical devices. The research found that the government plays a crucial role in providing long-term solutions to address some of the quality challenges affecting the manufacture of medical devices in Nigeria's pharmaceutical sector.

To address the issue of lengthy approval times and other challenges arising from lack of communication on updated SON and NAFDAC guidelines to medical device manufacturers, the regulatory bodies should ensure that they update and inform manufacturers promptly on any changes in guidelines. This would require effective communication channels and regular training programs for manufacturers. Participants also identified poor pharmacovigilance as a gap in the regulatory framework in Nigeria. To address this issue, NAFDAC and SON should focus more on pharmacovigilance as it ensures the safety of the public. This would require more investment in the necessary resources, including personnel and technology, to improve monitoring and reporting of subpar devices.

Additionally, it was suggested that an oversight body should be established to ensure that NAFDAC and SON are fulfilling their roles in regulating medical devices effectively. The body should have the power to monitor compliance with guidelines and regulations and ensure that

public safety is prioritized. The body should also be adequately funded to carry out its mandate effectively. It was also revealed that there are very few locally manufactured medical devices in Nigeria. To address this issue, the government should invest more in new technology for medical devices. This would not only improve healthcare but also boost the country's economic status. This would require partnerships with local and international stakeholders, including manufacturers and investors.

4.8 Conclusion

In conclusion, the Nigerian pharmaceutical industry is facing several challenges that are affecting the production of high-quality medical devices. The heavy reliance on the importation of medical devices due to the unavailability of raw materials and custom-made machine parts, poor implementation of certain regulatory guidelines, high costs associated with the clearance of raw materials, and fees charged for GMP inspection, are major hurdles. These challenges have contributed to the production of low-quality medical devices and compromise the safety and efficacy of medical devices, making them unsuitable for use. The use of international standards such as ISO standards and the establishment of local standards by regulatory bodies are commendable steps towards ensuring the production of high-quality and safe medical devices. However, more needs to be done to address the challenges facing the Nigerian pharmaceutical industry and to ensure that medical devices manufactured in Nigeria meet the highest standards of quality and safety.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 Overview

This chapter outlines the theoretical significance of the research, as it pertains to the study's defined objectives. It also highlights the potential practical applications and limitations of the research, while suggesting areas for further investigation in the future.

5.2 Contributions

5.2.1 The Regulatory framework for Medical Devices in Nigeria

The findings of this study provide critical insights into the regulatory framework for medical devices in Nigeria, highlighting several shortcomings that need to be addressed to ensure the safety and efficacy of medical devices in the country. The participants' perspectives shed light on key areas of concern, including regulation and enforcement, testing and certification, and post-marketing surveillance.

One of the significant issues identified is the high cost associated with routine check-ups and external audits conducted by regulatory authorities. This financial burden poses a challenge for medical device manufacturers, potentially limiting their compliance with regulatory requirements. Additionally, it was reported that the required check-ups are not consistently conducted due to insufficient manpower and scheduling issues within the regulatory authorities. Such irregularities in inspections and weak enforcement can contribute to the unregulated and illicit sale of restricted products, posing serious health risks to the public. These issues are further exacerbated by insufficient budgetary allocations.

To address these issues, it is crucial to implement measures that enhance the regulatory framework's ability to achieve its intended objectives. This includes improving the implementation of regulatory guidelines, strengthening post-marketing surveillance, and ensuring that regulatory authorities conduct regular and thorough inspections. The findings from this study underscore the significance of regulatory oversight, enhancing enforcement mechanisms, and implementing robust quality control measures to ensure that regulated medical devices meet the required standards. These improvements are vital not only for Nigeria but also for other African nations, where similar challenges have been observed, aiming to create a more robust and effective

regulatory framework that safeguards public health and promotes the availability of safe and effective medical devices.

5.2.2 Challenges to the Manufacture of High-Quality Medical Devices in Nigeria

Information on the challenges to the manufacture of high-quality medical devices in Nigeria have not been sufficiently researched. This study has made significant contributions to the subject matter within the Nigerian pharmaceutical industry. There is no doubt that existing literature has paid more attention to the challenges of pharmaceutical regulation (Usar and Bukar, 2020, p. 11-18), counterfeit medical devices (Glass, 2014, p. 11-22) and medical device regulation in Africa (Saidi and Douglas, 2019, p. 175-185). This study has contributed more to the body of knowledge by highlighting some of the challenges associated with the manufacture of high-quality medical devices in Nigeria based on the interviews conducted.

It was established that the scarcity of essential raw materials directly affects the production process and compromises the quality of the final product. Additionally, the unavailability of custom-made machine parts further hinders the manufacturing process, leading to difficulties in producing high-quality medical devices. Furthermore, participants highlighted the use of fairly used materials as another contributing factor to the production of low-quality medical devices. This practice not only compromises the reliability and safety of the devices but also makes them unsuitable for use.

Factors such as inadequate legislation, official corruption, poorly trained personnel, and underfunding of regulatory institutions contribute to these problems, calling for comprehensive reforms in the regulatory framework and enforcement mechanisms. Addressing these challenges will contribute to the sustainable development of the Nigerian healthcare system and safeguard the well-being of its population.

5.2.3 Factors that Contribute to Ineffective Regulation and Registration of Medical Devices in Nigeria

This study provides some factors that contribute to inadequate regulation and registration of medical devices in Nigeria. Very limited studies show the issues that contribute to ineffective regulation and registration, however this study has been able to identify some of these factors including inadequate funding, regulatory duplications, policy inconsistencies, and cost,

bureaucracy and processing times. This study has also looked at the economic and social impact of these inadequacies.

By focusing on this under-researched area, this study provides a valuable contribution to the literature and enhances our understanding of the challenges and opportunities in ensuring proper regulation and registration of medical devices in this sector. In order to maintain regulatory effectiveness, regulatory bodies must ensure that compliance costs are reasonable and proportional to the desired regulatory outcomes. This can be achieved through careful policy formulation, effective implementation, and regular review and evaluation of regulatory requirements.

5.2.4 The Efficacy of the Quality and Safety Management practices in Manufacturing companies

Previous studies primarily focus on topics such as knowledge management, performance management, and competitive intelligence in the medical device manufacturing industry. However, there has been limited attention paid to evaluating the efficacy of quality and safety management practices in these companies. To address this gap in the literature, this study conducted interviews with key stakeholders to identify and explain shortcomings in existing quality and safety standards for medical device manufacturing companies.

This study goes beyond previous research by specifically evaluating the application of international best practices and standards in the Nigerian context. By examining the efficacy of these practices and considering factors such as infrastructure, technical expertise, and regulatory enforcement, this study provides a comprehensive understanding of the challenges and opportunities in ensuring high-quality and safe medical devices in Nigeria.

Furthermore, by emphasizing the importance of harmonizing regulations, the study highlights the potential benefits for regulatory authorities, healthcare professionals, the biomedical industry, and patients. Through its multifaceted approach and recommendations for collaboration, convergence, and stakeholder engagement, this study offers valuable insights for policymakers, industry stakeholders, and researchers seeking to enhance the regulatory landscape and improve patient outcomes in the Nigerian medical device sector.

5.3 Limitations of the Research

This study focused on a selected pair of medical device manufacturing companies in Nigeria, with one of them operating primarily in Europe but still having a branch in Nigeria to comply with local regulations. The participation of these companies was justified by their adherence to Nigerian guidelines for registration and sale. However, the study's scope was limited as only three (3) employees in total from the manufacturing firms and three (3) pharmacists from different pharmaceutical companies, were interviewed. To enhance generalizability, future research should broaden its scope by incorporating more medical device manufacturing companies, pharmacists, and medical device users who predominantly utilize devices manufactured in Nigeria.

The study solely relied on interviews as a data collection method, which restricted the exploration of diverse perspectives from individuals working in various pharmaceutical companies and the medical device industry across Nigeria. Therefore, future investigations may adopt a mixed-method approach to gather a wider range of opinions and facilitate informed decision-making in addressing the regulatory and quality challenges of medical devices.

Another limitation arose from difficulties in getting responses from the Nigerian regulatory authorities. Nevertheless, interviews were conducted with a trusted partner specializing in Food and Drug regulatory affairs, compliance, regulatory intelligence, submissions, strategy, labelling, facility cGMP audits for biopharmaceuticals, medical devices, diagnostics, cosmetics, agrochemicals, food, and nutraceuticals companies in the West African Sub-region. Although only two individuals participated in this interview, their responses demonstrated a commendable level of knowledge on the discussed subject matter.

5.4 Directions for future research

The primary objective of this research was to conduct a comprehensive exploratory analysis of the topic. To extend the current understanding, future research endeavors could investigate the impact of post-market surveillance on counterfeit medical devices.

Furthermore, in the present study, qualitative data were gathered using interviews. However, future research should incorporate a mixed-method approach that utilizes both questionnaires and in-

depth interviews. This method could provide additional insights that can assist companies in overcoming challenges related to the regulation and quality of medical devices in Nigeria.

Additionally, future research could aim to develop a practical model that can be empirically tested in both emerging and established economies. Such an approach would help determine the model's effectiveness in diverse economic contexts and identify areas for improvement. Furthermore, future research could investigate the economic approaches for assessing regulatory impact in the medical device industry.

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APPENDIX

Codes

REG 1, REG 2- Trusted partners of regulatory authorities

MANU 1, MANU 2, MANU 3- Medical device manufacturers

PHARM 1, PHARM 2, PHARM 3- Pharmacists

USER 1, USER 2, USER 3- Medical device users

Interview questions

Representatives of Regulatory authorities	
Q1	What do you see as the strengths and weaknesses of the current framework?
Q2	Are there any gaps or shortcomings in the existing regulations that you have identified?
Q3	How do you assess the effectiveness of the existing measures for ensuring the safety and efficacy of medical devices in Nigeria?
Q4	What efforts have been made to address the challenges in the regulation of medical devices in Nigeria?
Q5	Are there any plans to address the identified gaps or shortcomings in the current regulatory framework?
Medical device manufacturers	
Q6	How do you ensure the safety, efficacy, and quality of the medical devices you manufacture in Nigeria?
Q7	What quality management practices do you have in place to ensure that your medical devices meet regulatory requirements and international standards?
Q8	What markets do you provide medical devices to?
Q9	Have you faced any regulatory challenges in Nigeria in the past? If so, what were they, and how did you address them?
Q10	How do you perceive the current regulatory framework for medical devices in Nigeria?
Q11	Do you have any suggestions for improving the regulation and quality of medical devices in Nigeria?
Pharmacists	
Q12	What is your experience with the quality of medical devices available in Nigeria?
Q13	Have you encountered any issues with the safety or efficacy of medical devices used in your practice?
Q14	Are these medical devices mostly imported?
Q15	How do you ensure that the medical devices you use are safe and effective?
Q16	How do you think the current regulatory framework for medical devices in Nigeria can be improved to ensure better patient outcomes?
Medical Device Users	
Q17	Have you ever used a medical device made in Nigeria? If so, what was your experience with it?

Q18	How do you ensure that the medical devices you use are safe and effective?
Q19	Are these medical devices mostly imported?
Q20	How accessible are these medical devices?
Q21	Have you ever encountered any issues with the safety or efficacy of a medical device you used in Nigeria?
Q22	Do you have any suggestions for improving the regulation and quality of medical devices in Nigeria?