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Challenges of Entering New Pharmaceutical Markets in Nigeria and Ghana

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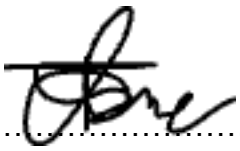
A thesis presented to the Faculty of Commerce, Law and Management, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Business Administration.

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DECLARATION

I, Thato Motshoane, hereby declare that this research article titled ‘Challenges of entering new pharmaceutical markets in Nigeria and Ghana’ is of my own creation. I have cited and acknowledged all ideas and concepts that I have come across. This serves as my partial submission to the University of the Witwatersrand, Johannesburg, for the Master of Business Administration degree requirements. This thesis was not previously submitted to another University for an assessment or a degree.



……..

Thato Sebabatso Motshoane

Signed at Johannesburg

27 February 2024

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ABSTRACT

Background: The pharmaceutical market is renowned for its stringent regulations and continuous production of superior drugs and products intended for human consumption. This study investigates the regulatory landscape of two African countries, namely Nigeria and Ghana, and the challenges of entering these economies as a result of the absence of regulatory harmonisation. The goal is to establish a regulatory framework that will facilitate the introduction of novel medicines and medical supplies into the market.

Method: The research methodology employed involved the collection, processing, and evaluation of empirical evidence. The chosen strategy was qualitative research.

Results: Entering new or foreign pharmaceutical market requires careful consideration, planning, and abiding by the regulatory requirements of the respective countries. Sustained prosperity will be guaranteed by enhancements in quality control and partnerships with local distributors and manufacturers. Partnering with local consultants who are familiar with the regulatory landscape, as well as local laws and policies is crucial. Lastly, it is important to be familiar with regulatory requirements from NAFDAC and the FDA to ensure ongoing compliance with evolving regulations.

Conclusion: Improving the local pharmaceutical market in both countries encourages the entry of foreign international pharmaceutical corporations, thus stimulating the economy of both nations. Local pharmaceutical companies in Ghana and Nigeria can strengthen their competitive edge by increasing barriers to entry. This can be achieved by raising the calibre of goods produced, increasing operational effectiveness, lowering production costs, and engaging in local innovation initiatives. Locals should maximize local government subsidies while utilizing the local context, including the nation's culture and consumer base to their advantage.

Key words: Ghana, Nigeria, challenges, entrance, opportunities, pharmaceutical, regulation, government, counterfeit, new, foreign, policies, production and local.

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LIST OF ACRONYMS

API	Active Pharmaceutical Ingredients
FDA	The Food and Drugs Authority
PCN	Pharmacists Council of Nigeria
SSA	Sub-Saharan Africa
SA	South Africa
NAFDA	The National Agency for Food and Drug Administration and Control
PCN	The Pharmacists Council of Nigeria

CHAPTER ONE: INTRODUCTION

1.1 Background and Context of Study

The present study aims to investigate the challenges of entering new pharmaceutical markets. The study explores the realities of two African countries, namely, Nigeria and Ghana. The researcher explores the regulatory landscape and the challenges of entering these economies due to the absence of regulatory harmonisation. The study seeks to establish a regulatory framework that simplifies the introduction of novel drugs and medical supplies to the market.

The pharmaceutical sector is widely recognised as one of the most meticulously regulated sectors, producing consistently high-quality drug products intended for human consumption (Lawrence & Kopcha, 2017). These products are designed to achieve the desired pharmaceutical therapeutic effects for the treatment of a broad spectrum of illnesses (Berg, 2019). Only a few countries in sub-Saharan Africa — Kenya, Nigeria, and South Africa —have a somewhat large industry, with numerous corporations manufacturing goods for their own markets and occasionally exporting to neighbouring nations (Azevedo & Azevedo, 2017).

According to Conway (2019), local producers should participate in a small portion of the value chain. The majority of them are producers of drug products, meaning they buy active pharmaceutical ingredients (APIs) from other producers and blend them into completed tablets, syrups, creams, capsules, and other forms of finished medication. In sub-Saharan Africa, up to a hundred factories are confined to the packaging industry, where they buy pills and other completed pharmaceuticals in large volumes and repackage them into packs intended for consumers (Abbott & Dukes, 2009). There are only three generating APIs — two in South Africa, and one in Ghana — and neither of them are heavily involved in research and development. Pharmaceuticals are essential to population health and well-being (Usar & Bukar, 2020). They can, however, be poisons, and drug tragedies like the thalidomide incident and other less publicised instances of drug harm serve as a constant reminder of the necessity of pharmaceutical monitoring and oversight. Thus, in the context of pharmaceutical care, policymakers typically use a variety of regulatory levers to

balance consumer access to safe, effective, and inexpensive medicines (Panteli et al., 2016).

1.1.1 South Africa's Pharmaceutical Industry

Government policies, the current state of the economy, and the evolving needs of the domestic market are driving the rapid evolution of the pharmaceutical industry in South Africa. The dominant framework of globalisation is also a component of this mix of forces. To create pharmaceutical products, the South African biotechnology industry requires funding. Developing nations had difficulty obtaining COVID-19 related pharmaceutical items from wealthy nations throughout the pandemic, especially during vaccination roll-outs, as developed nations prioritised their own populations (Uctu & Eksteen, 2022). As a developing nation, South Africa requires prosperous pharmaceutical endeavours. The biotechnology industry is the area where the majority of medical research is required and where production, trials, and less strict restrictions may be more readily applied (Montague & Oosthuizen, 2010). South Africa imports 70% of its pharmaceuticals. Imports drive up prices, particularly when the rand depreciates against other currencies in response to international trade.

Market access continues to be the largest obstacle facing South African pharmaceutical companies. The government's rigidity on pricing and the high level of regulation in South Africa have made effective price competition difficult, thereby impeding patient access to novel medications (EyeForPharma, 2015).

Although local pharmaceutical production is well-established on a regional basis, South Africa still significantly depends on pharmaceutical imports to meet domestic demand for specific drugs (Horner, 2022). Increasingly, Chinese and Indian manufacturers of generic medications are eyeing South Africa as a springboard into the continent's quickly expanding economies. Nonetheless, local drug manufacturers enjoy a competitive edge since they are well-positioned to gain from government programmes aimed at bolstering the home market because of their local presence. Some Indian companies, such as Cipla and Lupin, have operations in South Africa in order to profit from this.

The pharmaceutical sector in South Africa is the most lucrative in sub-Saharan Africa, despite its relatively small size globally. Pharmaceutical sales in South Africa were estimated at US $3.428 billion in 2018 (Research, 2019). Sales of generic drugs were projected to reach US $1.251 billion in 2018. Over time, their market share is expected to increase due to single-exit pricing, the expansion of middle-income populations, and an emphasis on cost control (Research, 2019). Although HIV/AIDS remains the leading cause of death, the most popular therapies in terms of money (as opposed to volume) are those for heart disease and hypertension (Research, 2019). Due to apartheid's legacy of a divided health system (Africa, 1996, as cited in Horner, 2022), the pharmaceutical sector in South Africa is heavily influenced by the public sector, accounting for approximately 31 percent of the just over $3 billion US industry in 2017 (Foundation, 2018).

1.1.2 Nigeria's Pharmaceutical Industry

According to Statista (2022), Nigeria has a population of 216.7 million, possibly making it the largest domestic market in Africa. Infectious and non-infectious diseases afflict a sizable section of the populace, yet their purchasing power is limited due to the extreme poverty. The size of the pharmaceutical market in Nigeria is estimated to be substantially different. According to Statista (2022), the Manufacturers' Association of Nigeria (PMG-MAN) Pharmaceutical Manufacturing Group projected that the yearly value of the pharmaceutical and healthcare goods industry would exceed US$ 2 billion. According to estimates, the market for over-the-counter (OTC) medications is approximately US$ 900 million, and the market for prescription (P&T) ethical medications is around US$ 500 million. The Nigerian market for biological products, such as insulin, interferon, vaccines, and other items, is estimated by PMG-MAN to be worth roughly US$ 100 million. Related lifestyle and healthcare products bring in an additional $500 million or more (Find Source).

According to the prognosis, the pharmaceutical industry in Nigeria is anticipated to expand at a 9.1% compound annual growth rate (CAGR), with a projected value of $5.3 billion by 2024 (Lodha International Lodha Pharma Group, 2021). Until the middle of the 20th century, affluent individual entrepreneurs or multinational pharmaceutical corporations supplied completed medicinal products to numerous developing African

nations, including Nigeria (Lodha International Lodha Pharma Group, 2021). The local manufacture of processing equipment and raw materials was not given enough attention. However, this trend has shifted, and several crucial factors — like locally produced dosage and processing equipment — are receiving increased focus. Currently, Nigeria imports a significant amount of dosage forms from Brazil, Europe, China, India, and the United States. However, the government is working to support regional manufacturing (Lodha International Lodha Pharma Group, 2021).

The Nigerian pharmaceutical industry is confronted with a number of challenges. One of the main issues is the unfair competition from foreign goods and international corporations. Furthermore, several medications with herbal origins circulating in the country need to be standardised (Lodha International Lodha Pharma Group, 2021).

1.1.3 Ghana's Pharmaceutical Industry

The government's intentions to implement universal healthcare would help Ghana's pharmaceutical sector to grow in the upcoming years. However, cost-cutting measures would likely result in a slower rate of expansion for the industry. In the long run, local generic medication manufacturers should find more opportunities as efforts to stimulate the industry pay off. If COVID-19 causes a protracted disruption, it could have a detrimental effect on Ghana's access to and cost of medications.

Ghana's pharmaceutical sales were USD 589 million in 2019, with projected statistics indicating growth to USD 620 million in 2020. In the future, revenues are predicted to expand at a 9.8% compound annual growth rate (CAGR) to reach USD 941 million by 2024. Sub-Saharan Africa boasts several pharmaceutical markets with double-digit growth rates. The significant rise in medicine sales in these regions is mostly attributed to higher volume consumption in the generic medications subsector.

The Ghanaian government, like many other African nations, has emphasised the need to increase local pharmaceutical production over the next ten years. Colonial rule in Africa negatively impacted the growth of local pharmaceutical industries in countries such as Nigeria, Ghana, and South Africa negatively (Azevedo & Azevedo, 2017). For example, under British rule in Nigeria, the focus was primarily on extracting natural resources rather than developing healthcare facilities. This left Nigeria dependent on

imported medicines with little local production even after independence. Similarly, during British colonial times in Ghana, the priority was gold extraction rather than healthcare development (Azevedo & Azevedo, 2017). This led to Ghana's reliance on imported drugs and a weak local pharmaceutical industry.

In South Africa under British, Dutch, and later apartheid rule, pharmaceutical facilities mainly served the white minority population. They had access to advanced medical supplies and imported drugs, while the black majority struggled to acquire affordable medicines. This unfair system benefited multinational drug companies over local makers (Azevedo & Azevedo, 2017). The legacy of colonial policies in these countries is a continued dependence on imported medicines, underdeveloped local production, and challenges with regulation and affordable access. Overcoming these deep-rooted issues requires major investments in facilities, training, and reform to allow domestic pharmaceutical manufacturing. Understanding this colonial history is key to addressing the current barriers to building strong, self-sufficient pharmaceutical industries in Nigeria, Ghana, and South Africa.

1.2 Research Conceptualisation

1.2.1 Research Problem Statement

The African subregion is highly dependent on the importation of pharmaceuticals and raw materials for the production of pharmaceuticals, particularly in rural areas (Akande-Sholabi & Adebisi 2020). These rural areas consistently experience delays in accessing imported medicines and locally manufactured drugs due to their geographical inaccessibility. Furthermore, any alterations in supply chain logistics or changes in importation policies can lead to medicine shortages, exacerbating the problem of limited access to essential medications.

The availability of drugs in these areas is contingent upon supply chain logistics, which are subject to fluctuations in demand and supply (Adebisi, Umah, Olaoye, Alaran & Sina-Odunsi, 2020). Although there is little evidence to support the idea that African governments are actively working to guarantee universal access to medications, the necessity for reasonably priced and easily available therapies is acknowledged (Nations, 2017; Organization, 2022).The affordability of medications, an integral

component of access, is closely linked to drug prices and the economic capacity of end-users. Since Africa's independence, there have been ongoing challenges with local production of medical supplies. Regarding Nigeria and Ghana, there is a need for the South Africa pharmaceutical market to enter their markets to address the problem of drug shortages.

1.2.2 Research Questions

The study's questions are detailed below:

What are the challenges of entering new pharmaceutical markets in Nigeria and Ghana?

- What are the regulatory frameworks in Nigeria and Ghana?
- What are the proposed future strategies for improving the challenges of entering new pharmaceutical markets in Nigeria and Ghana?

1.2.3 Research Objectives

The research objectives of the study are detailed below:

- To identify the challenges of entering new pharmaceutical markets in Nigeria and Ghana.
- To determine the regulatory framework in Nigeria and Ghana.
- To offer recommendations to overcome the challenges of entering new pharmaceutical markets in Nigeria and Ghana.

1.3 Defining of the key terms

- **1.3.1 Regulation**

Regulation is the continuous and targeted control that a public body exercises over activities valued by society. Within the field of healthcare, it encompasses any external pressures or regulations that enforce behavioural norms beyond the scope of medical practice or administration. Broadening access to high-quality pharmaceutical devices in low- and middle-income nations requires efficient regulatory regimes that are harmonised to global standards.

As a result, disputes over the ownership, distribution, and marketing of medical products have turned the pharmaceutical industry and its governance into a significant source of conflict (Pezzola & Sweet, 2016). A recent study that examined industrialised countries demonstrated, at the very least, the shortcomings of the regulatory framework in several pharmaceutical markets. Research by Olsson et al. (2010) indicates that the public supported the pharmaceutical regulatory bodies in fewer than half of the world's least developed countries.

- **1.3.2 Emerging market**

According to Bank (2006), the goal of categorising countries so that others could quickly gather information and categorise countries of interest, has affected our definition of emerging markets. In terms of socioeconomic, cultural, and regulatory elements, emerging economies greatly depart from the assumptions of theories developed in the West. They provide an engaging learning environment where one can learn more about marketing science and practise, challenging our preconceived notions. Marketers are starting to see past the negative connotations associated with typical emerging market stereotypes. When attempting to explain how context influences business performance in emerging markets, institutional theory is the most effective (Peng et al., 2008).

1.4 SIGNIFICANCE OF THE RESEARCH STUDY

Nigeria's pharmaceutical market is subject to stringent regulations governed by agencies such as the National Agency for Food and Drug Administration and Control (NAFDAC). Understanding and complying with registration requirements, quality standards, labelling regulations, and pricing policies are essential for market entry. Undoubtedly, the recent economic downturn in Nigeria had a significant impact on the cost and availability of high-quality raw materials for the pharmaceutical manufacturing sector, which in turn hindered the ability of local pharmaceutical companies to manufacture their products locally. Therefore, it is undeniable that the nation's current emphasis on industrialisation and the support of domestic manufacturing sectors like the pharmaceutical industry is a step in the right direction towards lowering its reliance on crude oil.

Ghana's pharmaceutical market is regulated by the Food and Drugs Authority (FDA), which oversees the registration, importation, manufacturing, distribution, and marketing of pharmaceutical products. Understanding and complying with regulatory requirements, including registration procedures, quality standards, labelling, and pricing regulations, are essential for market entry. Understanding cultural beliefs, healthcare-seeking behaviour, and socioeconomic factors influencing consumer preferences is essential for successful market entry. Tailoring marketing strategies, product formulations, and packaging to align with local preferences and needs can enhance acceptance and adoption.

Given the study's goals, the South African pharmaceutical industry will benefit from this research in terms of understanding the challenges of entering the Ghana and Nigeria markets.

1.5 DELIMITATIONS, LIMITATIONS & ASSUMPTIONS OF THE STUDY

1.5.1 Delimitations

Global companies continue to face challenges in gaining a home ground advantage, such as conducting interviews with local Nigerian and Ghanian stakeholders. Research conducted solely through telephone, emails, and virtual meetings might not always yield the best results. Outdated studies of global companies that entered the Nigerian and Ghanian markets may not be relevant, as circumstances have changed over time. The business landscape before the pandemic and lockdown differs from the post pandemic era, with new laws and policies potentially being implemented. Identifying the right stakeholders (Regulatory department and the department of Health) in Nigeria and Ghana for interviews may present a challenge.

1.5.2 Assumptions

The researcher can better illustrate the significance of a study by using assumptions (Corbin & Strauss, 2007). The assumptions underlying this study include the following:

- This study applies to the pharmaceutical markets in Ghana and Nigeria, which will be evaluated in this study.
- The relationship between different variables will be evaluated in this study.

- The adapted interview research instrument is relevant to the pharmaceutical industry and the participants in this study.
- Participants will be able to assess the challenges of entering new pharmaceutical markets in Nigeria and Ghana.

CHAPTER TWO: LITERATURE REVIEW

2.1 Pharmaceutical Production Sector in Africa

Africa's pharmaceutical sector accounts for a relatively small fraction of the global pharmaceutical industry. In 2007, the International Finance Corporation (IFC) projected that Africa, excluding North Africa, accounted for less than 0.6% of the global pharmaceutical industry (IFC, 2007). This market was projected to be worth $934.8 billion in 2017 and was predicted to increase at a rate of 5.8% to reach $1.17 trillion in 2021 (The Business Research Company, 2023). Health technology company, Quintiles IMS Health, predicted that in 2014 the African market was worth about $24 billion, and by 2020, it may be worth between $40 billion and $65 billion (Holt et al., 2015). For instance, the Cameroonian market was projected to be worth $36 million in 2016, Ghana's market to be worth $600 million, Kenya's market to be worth $1.2 billion, Morocco's market to be worth $2 billion, Nigeria's market to be worth $3 billion, and South Africa's market to be worth $5 billion. Nevertheless, there has not been a commensurate rise in local manufacturing capacity to keep up with the development in pharmaceutical markets (United Nations Economic Commission for Africa, 2020).

Table 2.1: Countries supplying medicines to Cameroon, Ghana, Kenya, Morocco, Nigeria, and South Africa (2015/16)

Country	1st supplier	2nd supplier
Cameroon	India	China
Ghana	India	China
Kenya	India	United Kingdom
Morocco	Local	France
Nigeria	India	China
South Africa	India	Germany

Source: Data from key informant interviews. Information on Nigeria collected during the programme validation exercise.

Over 70% of medications are imported, according to data acquired during the exercise's nation visits. Only Morocco, out of Cameroon, Ghana, Kenya, Morocco, Nigeria, and South Africa, has a domestic pharmaceutical industry that meets more than half of its needs (UNECA, 2020).

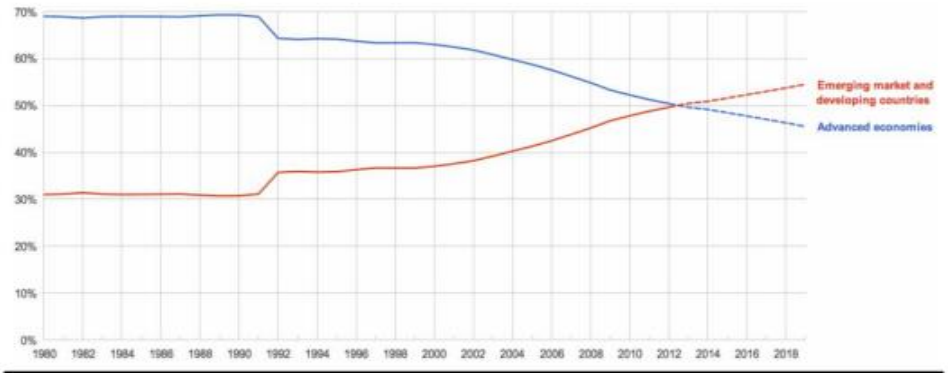
Table 2.1 illustrates how access to pharmaceutical products in the majority of African countries is skewed towards importation rather than manufacturing. There is ample evidence that the manufacturing sector is crucial to the development of developing nations' economies. Manufacturing, which is not limited to medicines, can significantly boost a nation's economy by increasing productivity, promoting reach and development, and encouraging future investments (UNECA, 2020).

2.2 Theoretical foundation

2.2.1 Institutional theory

Institutional theory was used to explain how South Africa can enter these two markets. Emerging markets have been major players in the global economy during the past ten years, and by the end of 2014, their purchasing power is expected to surpass that of the world GDP (Figure 2.1) (Davis & Marquis, 2005). Although managers and investors are very interested in the rapid rise and development of nations like China, India, Brazil, and South Africa in the twenty-first century, our ideas have not kept up with this quick pace of change (Davis & Marquis, 2005).

Figure 2.1 World GDP Trends for Advanced and Emerging Market Economies.



Source: *International Monetary Fund, April 2014 World Economic Outlook Database.*

According to Institutional theory, “organizations implement business practices because doing so enhances their legitimacy” (DiMaggio & Powell, 1983). This idea can offer insightful information on the adoption of newly developed tools and practices. Decisions about "green" sustainable activities and environmental management can be explained by institutional theory, which takes into account changes in legislation, technological advancements, and cultural values (Tate et al., 2012). Although institutional theory is widely acknowledged as one of the most well-known methodologies in organisational research today (David & Bitektine, 2009; Greenwood et al., 2017), there are significant disagreements among academics concerning the fundamental assumptions about how social norms and expectations impact organisations, as well as the referents of key concepts.

2.3 Models that explain how South Africa can enter the Nigeria and Ghana markets

Generally, the most developed, diverse, and productive economy in Africa is found in South Africa. An obvious choice for American businesses looking to enter the Sub-Saharan African market is South Africa, which boasts one of the most business-friendly environments on the continent. Growing populations and rising levels of consumption are two of the main factors propelling the pharmaceutical industry's expansion, which is why emerging markets like South Africa have the highest growth rates. According to McKinsey (2018), health care spending is increasing disproportionately with rising household income. By 2020, the pharmaceutical sector in Africa is projected to be valued between USD 40 billion and USD 65 billion per year. In Sub-Saharan Africa, South Africa continues to be the largest pharmaceutical market.

2.4 To identify challenges of entering new pharmaceutical markets in Nigeria and Ghana

2.4.1 Limited pharmaceutical industries and high costs of raw materials

A major barrier to the ease of access to medications is the scarcity of drug manufacturing businesses in Africa in comparison to the high cost of raw materials. Disappointingly, Africa produces only 3% of the world's pharmaceuticals (Bright et al., 2021) despite having 11% of the world's population and carrying 24% of the world's

disease burden (Ahen & Salo-Ahen, 2018). According to a 2019 McKinsey analysis, there are only about 375 drug-producing industries in Africa, predominantly in the northern region, for the continent's 1.1 billion inhabitants (McKinsey, 2019). Nine out of 46 countries contain a significant concentration of people from sub-Saharan Africa (McKinsey, 2019). When compared to China and India, which have 10,000 and 5000 pharma makers, respectively, providing for 1.1 billion people, this number is quite insignificant (McKinsey, 2019).

Nigeria, South Africa, Ghana, Kenya, and Zimbabwe possess industrial potential that could be leveraged for the manufacture of pharmaceuticals to meet local or international market demand, according to a 2005 World Bank study (World Bank, 2022). However, the study warned that this potential is at risk of depletion if the costs of expanding local manufacturing capacity are substantial or if the quality of the products is inadequate (WorldBank, 2022). The accessibility of unprocessed materials, particularly active pharmaceutical ingredients, which are the main substances used in the creation of pharmaceuticals, has a significant impact on both the cost of production and the quality of drugs produced. The majority of the equipment and raw materials required to produce drugs in Africa are imported, which raises production costs considerably (Ekeigwe, 2019). As a result, enterprises are compelled to rely heavily on imports and consequently bear exorbitant costs.

2.4.2 Weak regulatory systems

Pharmaceutical supply chains suffer from inadequate regulatory frameworks in several countries in Sub-Saharan Africa (SSA). The issue of low-quality medications in the pharmaceutical supply chains is a serious one, in addition to being a challenge in and of itself. Up to 90% of national drug regulatory organisations in Sub-Saharan Africa are unable to carry out their basic regulatory duties in an efficient manner (Giralt et al., 2017b).

2.4.3 Lack of government investment in pharmaceutical sector

Drug access is impacted by the general government's indifference and lack of political will, encapsulated by a persistent lack of investment in healthcare (Adebisi et al., 2020). The lack of financial support for manufacturers, high taxes imposed on the pharmaceutical industry, heavy research and development funding requirements, and

generally insufficient funding for healthcare all point to a severe lack of incentives to support local manufacturing of pharmaceuticals (Adebisi et al., 2020). Furthermore, in many African regions, the Primary Health Care Policy and other existing programmes are not being implemented adequately (Organization, 2018).

In Africa, government funding for healthcare is incredibly inadequate (Public Financing for Health in Africa: from Abuja to the SDGs, 2020). A substantial portion of the populace is unable to obtain insurance services due to the appallingly inadequate coverage of the programmes. As a result, there is an unsettlingly large un-pooled source of payment for medical services and goods, including public out-of-pocket spending, which can make up as much as 70% of all health expenditures in the region (Adebisi et al., 2020).

2.4.4 Unfavourable Manufacturing Conditions

Africa primarily uses small plants with low yields and capability for drug production (Ekeigwe, 2019). This restricts the ability to make enough tablets in the case of solid dosage forms, for example, to realise economies of scale and reduce overall production costs. African producers must create half a billion tablets annually, according to a McKinsey estimate, in order to compete on price with India (McKinsey, 2019). Nevertheless, the current lack of manufacturing capacity frequently results in high drug costs and deters local drug production. Furthermore, high electricity costs, regular power outages, and other infrastructure problems like inadequate logistics and transportation systems further impair the productivity and efficiency of manufacturing facilities (Ekeigwe, 2019).

2.4.5 Circulation of fake and counterfeit medicines

A further significant issue that needs to be addressed is the growing prevalence of fake and counterfeit medications. Counterfeit medications are those that are deliberately and deceitfully mislabelled about their identity and/or origin (Organization, 1992). According to a WHO study, 42% of medical product counterfeiting and substandard cases worldwide have been found in Africa alone (WHO, 2017).

2.4.6 Lack of effective pricing and price regulations

A non-binding framework called the Pharmaceutical Manufacturing Plan for Africa aims at "pursuing, with the support of our partners, the local production of generic medicines on the continent," was approved by the 55 members of the African Union in 2007. Still, a significant chunk of Africa's impoverished population lack access to healthcare due to the high cost of necessary medications (Organization, 2017). Regularly used generic medications, such as paracetamol, can cost up to 30 times as much in Zambia, Nigeria, Senegal, and Tunisia as they do in the UK and the USA (Cameron et al., 2009). Furthermore, a large number of African countries are unable to control or monitor prescription drug pricing; consequently, they are paying more than international accords for essential prescriptions (Cameron et al., 2009). For instance, the Sudanese drug regulatory agency permitted the importation of medications 10 times more expensive than the worldwide reference price (Lucero-Prisno et al., 2020). Many people in developing countries are currently unable to afford treatments for chronic illnesses due to ineffective laws and regulations governing pricing. This has led to private sector pharmacy prices continuing to be higher than global rates (Cameron et al., 2009).

2.4.7 Patent issues and limited investment on research and development

Access to medications in Africa is hampered by patent access restrictions and the incapacity of regional producers, researchers, and scientists to obtain patents. Due to inadequate investment in research and development, the pharmaceutical industry in many African countries are not producing new medications at their best. Due to insufficient support for innovation, the majority of African countries have high rates of disease burden (Bigdeli et al., 2013). Research has also shown that African governments find it difficult to fulfill their obligations to research and development, resulting in limited types of research and insufficient application of the research that is conducted (Ekeigwe, 2019).

2.5 To determine the regulatory framework in Nigeria and Ghana

Policies and laws governing the pharmaceutical industry's operations are created by governments in every nation on the planet. The overall efficiency of the sector is also determined by a government's capacity to offer incentives to producers and, when required, enforce sanctions on them (Cohen, 2000). Pharmaceutical regulation

encompasses a wide range of operations, including product registration, pharmacovigilance, quality monitoring, factory licencing, and intellectual property control. Its purpose is to safeguard the environment, human and animal health, and safety, ensuring the effectiveness, safety, quality, and accessibility of necessary medications. Nonetheless, three primary categories of general pharmaceutical regulations that control drugs, pharmacy employees, and medications, respectively, oversee the pharmaceutical industry globally.

Regulation is the process by which the government consciously manipulates factors like quality, quantity, and price to control or influence the actions of actors or individuals (Kumaranayake et al., 2000). The following sections provide an overview of current regulations in Nigeria and Ghana, highlighting characteristics, strengths, and weaknesses of the two national systems.

Legal and Policy Framework for Pharmaceutical Regulation in Nigeria

Global pharmaceutical regulation is hampered by the incapacity of nations to carry out essential regulatory functions, with Africa exhibiting the least capacity (Ndomondo-Sigonda & Ambali, 2011). Any country with inadequate pharmaceutical regulations risks exposing drug users to potentially dangerous medications, inferior and counterfeit goods, and encouraging the illogical prescribing of pharmaceuticals (Doua & Van Geertruyden, 2014). Lack of competent and skilled enforcement personnel, insufficient funding, and poor legal and regulatory frameworks have all been attributed to regulatory shortcomings. According to (Lowe & Montagu, 2009), drug regulations and policies are crucial to regulatory processes and should be comprehensive, incorporating every facet of pharmaceutical practice. Regulatory bodies depend on them to have the authority and capacity to perform crucial regulatory functions. Nigeria has notably lax pharmaceutical regulations, which are marked by sporadic regulatory inspections, lax enforcement, widespread violations, and unfavourable health consequences (Usar et al., 2017). Causative issues have included underfunding of regulatory organisations, official corruption, weak and frequently overlapping legislation, and inadequately qualified personnel (Esimone et al., 2001).

Nigeria has several legislative and policy tools to govern and manage the pharmaceutical sector. These highlight the government's broad commitment to

ensuring people have access to safe, effective medications and that they are used appropriately. They consist of:

National Drug Policy 1990: The objectives of this policy are to enhance access to reasonable, safe, effective, and inexpensive medications as well as their appropriate usage for all Nigerians. Additionally, it seeks to support the sustainable growth of local produce of essential medicines.

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Poisons and Pharmacy Act, Cap 366 of 1990: The Act governs how medications and medical supplies are compounded, distributed, marketed, and dispensed in Nigeria.

Food and Drugs Act Cap 150 of 1990: This forbids the sale of specified medications, foods, cosmetics, equipment, and medications in conjunction with certain medical problems. It also forbids the import, export, distribution, and sale of specific medications. In addition, it outlaws spreading false information about drugs and the production of food and medications in filthy conditions.

Counterfeit and Fake Drugs (miscellaneous provisions) Act, Cap 73 of 1990: This Act prohibits the country from producing, importing, distributing, or selling any illegal, phoney, adulterated, or counterfeit medications. Additionally, it forbids anyone from selling pharmaceuticals in public marketplaces without the regulatory authority's consent.

Pharmacists Council of Nigeria, Decree 91 of 1992. The decree established the Pharmacists Council of Nigeria (PCN), which establishes and maintains a register of individuals certified to practise pharmacy and specifies the minimum level of knowledge and expertise needed by applicants to become registered members of the pharmacy profession. Additionally, it mandates the PCN to create and oversee the pharmacists' code of conduct, as well as oversee and manage pharmacy practice in all its forms.

National Agency for Food and Drug Administration and Control Decree No. 15 of 1993: The agency oversees the manufacturing, marketing, distribution, sale, and

usage of medications, foods, cosmetics, medical equipment, bottled water, chemicals, and devices. It also regulates and controls imports and exports.

Drugs and Related Products (Registration) Decree No. 19 of 1993: It is against the law to manufacture, import, export, advertise, sell, or distribute medications, medicine goods, cosmetics, or medical devices without first registering them. Additionally, it specifies clinical trials, the registration process, and the circumstances under which certificates of registration may be suspended or revoked (Health, 2005). The latter is responsible for establishing standards, registering and licencing pharmacy graduates, and managing facilities and professional practice. On the other hand, NAFDAC is in charge of licencing manufacturing facilities, regulating import and export, inspecting manufacturing facilities and distribution routes, controlling drug promotion and advertising, marketing authorization, product quality monitoring, pharmacovigilance, quality control, and managing drug-related clinical trials (National Agency for Food, 2011).

Legal and Policy Framework for Pharmaceutical Regulation in Ghana

The Ghanaian Food and Drugs Authority (FDA), a relatively well-established drug regulatory authority, and an open economic policy are two advantages that the country's pharmaceutical sector has over those of its neighbours. Ghana's establishment of a more stringent regulatory environment, including its own drug-testing facilities as part of its post-marketing surveillance strategy, is encouraging for global drug manufacturers. Although this is positive for investor sentiment and compares positively to other pharmaceutical markets, Ghana's drug regulatory framework still needs stronger policy enforcement and a tighter supply chain.

The registration and inspectorate section is in charge of reviewing applications for medicine registration before medical products are registered. The Public Health Act's safety-monitoring and clinical trials division guarantees the security of products under regulation. The government of Ghana has been able to assist domestic pharmaceutical manufacturers and restrict foreign direct investment (FDI) in recent years due to the establishment of a more stringent regulatory framework. In Ghana, the process of registering drugs takes six to eighteen months, which is not excessively long compared to other African nations. However, due to poor purchasing power and

high financing costs, FDI and returns are severely constrained. Local pharmaceutical manufacturers have also begun modernising their facilities to comply with global Good Manufacturing Practice (GMP) guidelines.

Within the Economic Community of West African States (ECOWAS), a regional pharmaceutical regulatory body has been proposed by the Pharmaceutical Manufacturers Association of Ghana (PMAG) to improve access to medications and to foster the expansion of pharmaceutical companies. Nevertheless, regional harmonisation is still a long way off due to lax drug laws and lax border controls in other ECOWAS member states. Respecting Trade-Related Aspects of Intellectual Property Rights (TRIPS) will draw foreign pharmaceutical companies seeking to enter into joint ventures or licencing arrangements in Ghana. This would ultimately enable pharmaceutical producers to export larger quantities of drugs both inside and outside of West Africa.

Medications, vaccines, and medical devices are examples of medical products, and are essential parts of any country's healthcare system. As part of their national duty to safeguard public health and safety, national medical regulatory authorities (NMRAs) must be established to ensure the availability of high-quality, safe, and effective medical products (Ndomondo-Sigonda et al., 2017). The food and drugs authority (FDA) Ghana is the National Medicines Regulatory Authority legally mandated by Parts 6, 7 and 8 of the Public Health Act 2012 (Act 851) to safeguard the safety, quality, and efficacy of medical products in Ghana. The Food and Drug Authority (FDA) Ghana is the National Medicines Regulatory Authority legally mandated by Parts 6, 7, and 8 of the Public Health Act 2012 (Act 851) to ensure the efficacy, safety, and quality of medical products in Ghana. The mission of FDA Ghana is "to protect the health and safety of people in Ghana and to be a global centre of excellence for food and medical product regulation" (Ghana, 2012).

- Drug Evaluation and Registration Department

In order to register medical items, applications for medication registration must be evaluated by the Drug Evaluation and Registration Department. A list of the department's accomplishments is shown below:

- Over the previous 16 years, a well-regulated system for the registration of medicinal products has been developed to guarantee uniformity in operations and regulatory judgements regarding all applications for medication registration.
- A competent committee for dossier evaluation exists within the department, and examines every section of the dossiers that are filed for registration. Currently, two assessors are part of the WHO Prequalification Assessment Team. At the moment, the department is assisting with the harmonisation of the West African Health Organization (WAHO).
- The agency maintains a thorough set of guidelines to regulate product names, product attributes, and patient information leaflets. This is closely monitored to make sure that information about the product provided to patients and medical professionals is accurate. To prevent prescription errors, brand names and colour schemes for products are also regulated.
- The department has a mechanism in place to guarantee that applications are monitored following registrations. This includes keeping track of modifications to applications for registration.

▪ Herbal Medicine Department

In order to register herbal medicines in Ghana, applications for registration of dietary supplements and herbal medicines must be evaluated by the Herbal Medicine department (Asase, 2023). The department's accomplishments are listed in full below:

- Enhancements have been made to the packaging of herbal medicine sold in pharmacies.
- The manufacture of herbal medicinal products has been enforced in designated facilities with basic GMP for herbal medicine facilities.
- More than 300 producers of herbal medicines and practitioners of traditional medicine have been trained in GMP and registration requirements for impromptu preparations.
- Training has been provided on the establishment of a regulatory framework for the regulation of herbal medicines to officials of National Drug Regulatory Authorities from several African nations (Asase, 2023).

Propositions for South African (SA) pharmaceutical firms

Propositions for South African pharmaceutical firms to take advantage of regulatory frameworks in Nigeria and Ghana include:

- Harmonisation of Regulations

SA pharmaceutical firms could advocate for the harmonisation of regulatory requirements between Nigeria, Ghana, and other West African countries. Harmonisation would streamline the registration process for pharmaceutical products across borders, reducing barriers to market entry and facilitating trade within the region.

- Regulatory Compliance Assistance

SA pharmaceutical firms could offer expertise and support to local manufacturers in Nigeria and Ghana to help them navigate regulatory compliance requirements. This could include assistance with product registration, quality assurance, Good Manufacturing Practice (GMP) standards, and pharmacovigilance activities, enhancing local capacity and competitiveness.

- Market Access Partnerships

SA pharmaceutical firms could establish partnerships with local distributors, wholesalers, and healthcare providers in Nigeria and Ghana to expand market access for their products. Collaborating with local partners who understand the regulatory landscape and market dynamics can help SA firms overcome entry barriers and effectively penetrate the market.

- Advocacy for Regulatory Reforms

SA pharmaceutical firms could engage with regulatory authorities in Nigeria and Ghana to advocate for reforms that promote transparency, efficiency, and innovation in the regulatory process. This could involve proposing reforms to streamline registration procedures, expedite approvals, and enhance regulatory oversight while maintaining safety and quality standards.

- Investment in Local Manufacturing

SA pharmaceutical firms could consider investing in local manufacturing facilities in Nigeria and Ghana to strengthen their presence in the region and address supply chain vulnerabilities. Investing in local production would enhance product availability,

reduce dependency on imports, create employment opportunities, and contribute to the expansion of the local pharmaceutical sector.

These propositions highlight opportunities for SA pharmaceutical firms to leverage the regulatory framework in Nigeria and Ghana to expand their market presence, enhance regulatory compliance, and foster sustainable growth in West Africa. By addressing research gaps related to regulatory frameworks and market dynamics, SA firms can develop strategic approaches to capitalise on emerging opportunities and contribute to the advancement of healthcare delivery in the region.

2.6 Conclusion

It is impossible to guarantee optimal health, well-being, and an adequate healthcare system without reliable access to medical resources. It is evident that new pharmaceutical companies seeking to enter the African market face many obstacles, and it is important for the continent to address these challenges as it works to improve its healthcare systems and achieve universal health coverage. Using specialised procedures and nationally appropriate tactics, African governments and national health authorities must prioritise activities and initiatives aimed at enhancing access to medications.

In this regard, as observed from the above literature, the study aims to identify challenges of entering new pharmaceutical markets in Nigeria and Ghana. The regulatory framework for both countries was also explained in detail.

CHAPTER THREE

METHODOLOGY

This chapter focuses on the research design, approach, and methodology utilised to gather and analyse data to meet the study's goal. It describes the research population, sample, and sampling method, providing a systematic approach to gathering information necessary to answer the research question and address the stated research issue. The qualitative research approach was employed to acquire qualitative data from the chosen case study. Additionally, this chapter outlines and discusses the study design, approach, and methodology used. It also covers the research population, sample, and sampling procedure, the instruments used for data collection and analysis. Finally, the chapter details the ethical issues considered in the study.

3.1 Philosophical Assumptions

According to Saunders (2016), a philosophical assumption is defined as the researcher's system of beliefs and assumptions regarding knowledge generation. These include presumptions regarding human comprehension (epistemological presumptions), research realities (ontological presumptions), and the degree to which a person's personal opinions influence the research process (axiological presumptions). The study is grounded in the two research philosophies of positivism and phenomenology (Creswell & Poth, 2016).

3.1.1. Research Paradigm

In order to understand the realities of the study participants, this study adopted interpretivism as a research paradigm. Interpretivism assisted the researcher to gain a deeper understanding of the individual meanings and contribution of the participants (Alharahsheh & Pius 2020; Davies & Fisher, 2018). The interpretivist paradigm involves considering individuals' subjective, real-world experiences and viewpoints (Alharahsheh & Pius 2020). Furthermore, it examines how humans experience reality (Davies & Fisher, 2018), predicated on the idea that different people might interpret the same experience differently, and that each person's version of that experience is reality.

3.2 Research methodology

A methodical approach to problem-solving in research is known as research methodology. It can be thought of as a science that studies how scientific research is conducted (Kothari, 2019). There are three types of research approaches, which are quantitative, qualitative, and mixed method approaches. A qualitative approach was chosen for this study and is discussed next.

3.2.1 Qualitative approach

The primary goal of qualitative research is to comprehend the social reality of individuals, groups, or cultures. Denzin and Lincoln (2005) define qualitative research as an approach that utilises a naturalistic method seeking to understand phenomena in context-specific settings, such as real-world settings, where the researcher does not attempt to manipulate the phenomena of interest. Qualitative research methods were useful for this study because the researcher aimed to gather data from the perspective of the sampled participants.

3.3 Research Design

Research design is defined as the procedural plan that is used by researchers to answer questions accurately and reliably (Creswell & Poth, 2016). The process that researchers employ to provide precise and reliable answers to questions is known as the study design (Leavy, 2017). A research design involves making and communicating decisions regarding the proposed study design, including how the information is collected from identified respondents, how the respondents are selected, how the collected information is analysed and how the results are communicated (Leavy, 2017). There are five generic research designs, namely: cross-sectional, longitudinal, case study, comparative, and experimental.

The researcher used exploratory research, which mainly utilised a qualitative research method. Swedberg (2020) argues that exploratory research is a methodology that examines research questions which have not previously been researched in depth. Since the research questions of this study have not been examined before, an exploratory research design was considered appropriate for this study. Furthermore, the selected research design was necessitated by the nature and type of data to be

collected and the problem statement to be addressed. To provide a thorough understanding of these issues and explain the extent to which challenges associated with entering new pharmaceutical markets in Nigeria and Ghana can be overcome, the research problem identified in this study necessitates a thorough examination of the issue under consideration and a scientific exploration of themes.

Exploratory research is carried out when there is a lack of information available regarding a phenomena or a problem that has not been precisely characterised (Swedberg, 2020). It aims to study the research issue at different depths, rather than to offer definitive answers to the research questions. Consequently, its focus is on addressing novel issues for which there has been little to no prior research (Brown, 2006). Exploratory research, even in the worst scenario, establishes the initial research design, sampling strategy, and data collection technique and serves as the foundation for more definitive research (Singh, 2007).

3.4 Sampling Approach

Sampling is a process which utilises data provided by a small representative group to draw conclusions about entire populations (Martinez-Mesa et al., 2016). Smaller samples are thereby used to determine results for entire populations. There are two types of sampling techniques: probability and non-probability (Sekeran & Bougie, 2016). In non-probability sampling, the likelihood of choosing a certain element within the population is not known. To guarantee that all significant demographic groupings are represented in the sample, the population is stratified prior to sample selection.

3.4.1 Probability sampling

Sekaran and Bougie (2013) state that probability sampling entails participants in the recognised population having a known chance (also referred to as a nonzero chance) of being nominated in the sample. According to Denscombe (2014), probability sampling takes place when every unit in the population has a known and equal chance of being selected for the sample.

3.4.2 Non-probability sampling

According to Sekaran and Bougie (2013), non-probability sampling entails the participants in the group not having a known or fair chance of being nominated as part of the sample. Non-probability sampling comprises seven techniques, namely:

- Convenience or accidental sampling: members are chosen according to availability.
- Purposive sampling: associates of a group are decisively pursued.
- Modal instance sampling: associates have the utmost commonality in a defined group and consequently are desired.
- Expert sampling: associates perceived to be of high quality are elected for participation.
- Proportional and non-proportional quota sampling: associates are verified until precise scopes of certain sorts of data are attained or until enough data in different categories are collected.
- Diversity sampling: members are globally selected throughout the possible types of responses to capture all opportunities.
- Snowball sampling: members are sampled and afterward entreated to help in identifying other members to sample and this process continues until enough samples are gathered (Creswell & Poth, 2016).

This research embraced the purposive sampling, where the sample group is targeted to have specific attributes. Purposive sampling is a type of non-probability sampling that involves representatives of the subject population who meet certain practical criteria, such as ease of access, geographical proximity, availability of specific moments or willingness to participate in research purposes (Maree, 2007). As a result, purposive sampling utilized because the sample was relevant to the study and are likely to provide key insights as well as contribute to important results. In this study, ten participants were sampled.

3.5 Data Collection

The research utilised a qualitative approach where in-depth interviews were conducted with individuals from the target population to address the research questions (Creswell

& Poth, 2016). Additionally, dense case studies were conducted through archival studies of documents, from which research themes and theories were inductively developed. The study used semi-structured interviews as a tool to gather the data. Interviews are a common technique for collecting data. Open-ended questions were designed and handed to participants (Denzin & Lincoln, 2005). The research was conducted via Microsoft Teams due to differences in the countries. The respondents who participated in completing the questions were assured that their responses would remain anonymous. The permission letter was granted by Organon South Africa, Roche Nigeria and Pharma Symbiosis Nigeria and Ghana respectively. Data was collected in South Africa because Organon South Africa distributes medication in Nigeria and Ghana. It was important for the researcher to understand how Nigeria and Ghana facilitate this distribution process in order to identify whether it is ideal to expand Organon in these two countries.

The Microsoft Teams individual interview questions were divided into two sections. The interview was divided into three categories including the following sections: socio-demographic characteristics of respondents, questions for the Organon South Africa, challenges of entering new pharmaceutical markets in Nigeria and Ghana, the regulatory framework in Nigeria and Ghana, and recommendations to overcome challenges.

3.5.1 South African respondents

As per the Standard Operating Procedure of the organisation, the line manager was informed about the research study. HR and the compliance director were emailed to request permission to conduct interviews with respondents from the organisation. This was followed with presentation to the Managing Director requesting a letter of permission from the organization. An email was sent to respondents seeking their consent to participate in the study, after which Microsoft Teams meeting were scheduled with respondents.

Characteristics of Respondents

Respondents were asked to provide the following demographic information by ticking the appropriate response as indicated in Table 3.1.

Table 3.1 Demographic: South Africa

1. Age	Below 26	
	26-35	2
	36-55	2
	56-65	1
	Above 65	
2. Gender	Female	3
	Male	2
	Other	
3. Year of experience	Under 5 years	1
	6 - 9 years	1
	10 - 15 years	
	16 - 20 years	2
	21 - 25 years	1
4. Position in the organisation	Regulatory affairs	3
	Commercial	1
	Compliance	1

3.5.2 Ghana and Nigeria respondents

The second section was for participants from Ghana and Nigeria. The aim was to understand the challenges of entering the market according to knowledgeable participants in Ghana and Nigeria. For participants from Ghana and Nigeria, data were collected through calling, emailing, or directly messaging potential respondents with a link to the Microsoft Teams interview. Potential respondents were identified via LinkedIn based on their profiles in the regulatory and commercial fields of the pharmaceutical industry, or through referrals. This method was chosen as it allowed easy access to potential respondents. The process involved requesting a letter

granting permission from the organisation, followed by an email seeking consent from respondents. Thereafter, a Microsoft Teams meeting was scheduled with the consenting respondents.

Respondents were asked to provide the following demographic information by ticking the appropriate response as indicated in Table 3.2 and Table 3.3.

Table 3.2 Demographic: Ghana

1. Age	Below 26	
	26-35	1
	36-55	1
	56-65	
	Above 65	
2. Gender	Female	1
	Male	1
	Other	
3. Year of experience	Under 5 years	1
	6 - 9 years	
	10 - 15 years	
	16 - 20 years	1
	21 - 25 years	
4. Position in the organisation	Regulatory affairs	
	Commercial	2

Table 3.3 Demographic: Nigeria

1. Age	Below 26	
	26-35	
	36-55	3
	56-65	
	Above 65	
2. Gender	Female	1
	Male	2
	Other	
3. Year of experience	Under 5 years	
	6 - 9 years	
	10 - 15 years	1
	16 - 20 years	2
	21 - 25 years	
4. Position in the organisation	Regulatory affairs	1
	Commercial	2
	Compliance	

3.5.3 Research Instrument/Interview Guide

This study opted for semi-structured interviews as an instrument for data collection. The interview questions were divided among participants from Organon South Africa, Nigeria, and Ghana. Organon South Africa is a subsidiary of a multinational pharmaceutical company headquartered in the United States. Their main priorities are developing and distributing women's health medications under well-known brands, including those for asthma, dermatology, cardiovascular disease, pain management, and respiratory conditions.

To guarantee there is no conflict of interest, the researcher is currently employed at Organon South Africa. The researcher made it a point not to contribute to or interrupt employees while they were speaking, allowing them to express their opinions without

interference. Since employees are required by the firm's code of conduct to act in the employer's best interests, the researcher ensured that the employees spoke from their own professional experience rather than relying solely on the corporation's viewpoints. The instrument consisted of three sections and a total of seventeen questions, designed to answer the research questions and address the research objectives. The interview questions for this study are attached as Appendix C.

Table 3.4 below shows the three sections, themes, and data that the researcher intended to collect. These questions covered the work experience of the participants, the challenges of entering the Ghanaian and Nigerian markets, and the regulatory frameworks in Nigeria and Ghana.

Table 3:4 Themes section

Section	**Themes**	**Information required from the Respondents**
1	Level of experience	Researcher seeks to establish level of experience of the participants at Organon South Africa, Ghana, and Nigeria
2	Challenges of entering Ghana and Nigeria markets	In this section, the researcher seeks to establish the understanding of the challenges in entering Ghana and Nigeria markets
3	Regulatory framework in Nigeria and Ghana	The section, researcher seeks to establish the relevance of Regulatory framework in Nigeria and Ghana

3.6 Data Analysis

Data analysis is the process by which researchers take the data they have gathered and turn it into information that can be used to discuss the study's goals (Kumar, 2018). This study gathered qualitative data, which was transcribed and coded. In order to assist with answering the research questions of the study, a thematic analysis was utilised to categorise and arrange the field notes and transcripts. According to Lune

and Berg (2016), data analysis involves a “careful, detailed, systematic examination and interpretation” of collected data to “identify patterns, themes, biases and meanings”. According to Bryman (2016) a thematic analysis entails identifying themes in the data that are subsequently applied to address the research questions directed by the analytical framework and the literature review.

3.7 Ethical Considerations

A collection of values that guide study designs and methods are known as ethical considerations in research. These guidelines include collecting informed consent, assuring that participants will not suffer harm, safeguarding participants' identities and confidentiality, and confirming that consent has been granted (Cader, 2016). In this study, ethical norms regarding the voluntary nature of participation and the freedom of individual employees to opt out were respected and upheld. Information and data were gathered specifically for this academic research. The following ethical issues were addressed in this study:

3.7.1 Ensuring participant give informed consent

A participant grants their voluntary participation in a research study by signing a legal document known as informed consent. Not only is informed consent a necessary component of ethical research involving human subjects, but may also be seen as its cornerstone. The ideas of autonomy and respect for individuals provide the philosophical foundation of informed consent. Enough information about the study is provided to participants so they can decide whether or not to engage in the study voluntarily and rationally and provide their informed consent. This information includes:

- The purpose of the study
- Study procedures
- Information on their right to decline or withdraw
- Potential risk, discomfort or negative impacts
- Whom to contact for questions

In this study, the participants were provided with a letter informing them that their participation is voluntary and that all necessary steps were taken to protect their identity.

3.7.2 Ensuring that no harm comes to participants

The research study should not harm participants. The researcher must follow ethical guidelines and ensure that participants are not placed in situations where their participation could put them in danger. Physical and psychological harm are two different ways to describe harm. No harm came to participants because the questions were asked in a way that did not cause physical or emotional harm. The questions asked in the interview were structured carefully, making sure that no offensive terms were used.

3.7.3 Ensuring that permission is obtained

It is important for a researcher to obtain permission to collect data for the study, in this case, from the Organon South Africa, after the approval of the proposal. The researcher requested permission from the company to conduct the research. The letter of permission is attached as Appendix D. Obtaining ethical approval demonstrated that the researcher has adhered to the accepted ethical standards of a genuine research study.

3.7.4 Ensuring confidentiality and anonymity

Separating or altering any identifiable personal information that participants may have contributed from the data is referred to as maintaining confidentiality. Details were provided about what happens to any personal data collected during the study. The researcher has an obligation to protect the privacy of the information provided by the participants. This obligation requires researchers to put measures in place to preserve participant confidentiality at every turn of the study process. Anonymity is the state in which researchers are unaware of the identity of specific participants. In this study, the participants' confidentiality was protected by not including their names in any of the paperwork. The researchers sought to assure participants that every effort is made to ensure that the information they submit cannot be linked to them in reports, presentations, or other forms of distribution.

CHAPTER 4: ANALYSIS OF DATA AND INTERPRETATION OF RESULTS

This section presents, examines, and discusses the empirical results of the primary data gathered from the semi-structed individual interviews that were conducted for ten pharmaceutical employees in Nigeria, Ghana, and Organon in South Africa Organon. The first section provides socio-demographic data of the participants and the final section discusses the themes that emerged regarding the challenges of entering new pharmaceutical markets in Nigeria and Ghana.

4.1 Response Rate

Table 4.1 outlines the number of participants in the study, indicating that all the participants that were sampled for the study were successfully interviewed by the researcher.

Table 4.1 Response rate

	Frequency	**Percentage**
Responded	10	100
Not Responded	0	0
Total	**10**	**100**

The researcher interviewed 10 participants from three African countries, namely, Nigeria, Ghana and South Africa. All the participants were able to share their experiences, as demonstrated by 100% participation in the study by the sampled participants.

4.2 Demographic Information

The research sample was identified by collecting demographic data, which included the respondent's age, gender, years of experience, and position within the business.

4.2.1 Gender of Respondents

A discussion of the gender analysis findings can be found below.

Table 4.2 Gender of respondents

South Africa	Females: 3	Males: 1
Ghana	Females: 1	Males: 1
Nigeria	Females: 2	Males: 2

Gender	**Frequency**	**Percentage**
Female	5	50
Male	5	50
Total	**10**	**100**

Five of the ten respondents were men, and the other five were women. As such, both genders were equally represented in the study, therefore, the study was not gender biased.

4.2.2 Age distribution

A discussion of the age analysis findings can be found below.

Table 4.3 Age of participants

	Frequency	**Percentage**
Under 26	0	0
26-35	3	30
36-55	6	60
56-65	1	10
Above 65	0	0
Total	**10**	**100**

Table 4.3 indicates that 60% of the participants were in the 36- to 55-year-old age range. Of the total number of respondents, 30% belonged to the age range of 26–35, 10% to the age range of 56–65, and 0.00% to the age groups under 26 and above 65 years. The findings indicate that the research did not include all age groups of

employees, which is a disadvantage as the views of employees under the age of 26 and above 65 years are not represented in the study. Therefore, the findings of the study only represent the views of participants between the ages of 27 to 64 years.

4.2.3 Years of experience

A discussion about the findings regarding the number of years of experience can be found below.

Table 4.4 Respondents year of experience

	Frequency	**Percentage**
Under 5 years	2	20
6 - 9 years	1	10
10 - 15 years	1	10
16 - 20 years	5	50
21 - 25 years	1	10
Total	**10**	**100**

As displayed in Table 4.4, the majority of participants (50%) had between 16 to 20 years of work experience. Participants with 5 years of working experience made up 20%. Participants with 6 to 9 years of working experience comprised 10%. Participants with 10 to 15 years of working experience, and those with 21 to 25 years of working experience each comprised 10%. The abovementioned indicates that a significant segment of the participants possess adequate professional expertise to furnish pertinent data regarding challenges of entering new pharmaceutical markets in Nigeria and Ghana. Thus, the information gathered is quite dependable because the data were gathered from respondents with sufficient work experience.

4.2.4 Respondents departments

The information below provides the background information of departments that respondents are assigned to within their organisations.

Table 4.5 Respondent departments

	Frequency	**Percentage**
Regulatory affairs	4	40
Commercial	5	50
Compliance	1	10
Total	**10**	**100**

As indicated in Table 4.5, 50% of the respondents are in the commercial department, followed by 40% in the regulatory affairs department, and the remaining 10% in the compliance department. This distribution reflects diverse perspectives in the responses, informed by the activities of the respective departments. Based on the results, it can be observed that the pharmacy has a tall hierarchical organisational structure within each department. This has resulted in respondents being diversified across various departments within the organisation.

4.3 Data Analysis and Interpretation of Findings

Data was presented in themes and sub-themes to address the objectives and goals of this study in relation to the study participants' responses.

4.3.1 Objective 1: To identify challenges of entering new pharmaceutical markets in Nigeria and Ghana.

The first objective of the study was concerned with identifying the challenges of entering new pharmaceutical markets in Nigeria and Ghana. The presentation and interpretation of the research findings are discussed in this subsection in relation to the challenges of entering new pharmaceutical markets in Nigeria and Ghana.

4.3.1.1 Theme 1: Various Challenges of entering new pharmaceutical markets in Nigeria and Ghana

Sub-Theme 1.1: Local pharmaceutical market in the country

Local pharmaceutical market was identified as the reason that has led to challenges for new pharmaceuticals entering the market. This was highlighted during the research process. The following views were expressed by Gab01:

Stagnation of local market: *"The Nigerian pharmaceutical market has remained stagnant at $1.5 billion to $2.5 billion, despite its potential to hold 30 to 40 percent of the African pharma market given new policy interventions*. *Nigeria has a low level of local production of quality assured, low-cost pharmaceuticals to meet national needs. This affects the accessibility and affordability of medicines for the population, especially the poor and rural areas."*

Essential resources: *"Nigeria heavily depends on other countries for essential resources, such as raw materials, equipment, and technology. This makes the country vulnerable to supply chain disruptions and price fluctuations."*

Quality and regulation of products: *"Ghana faces issues related to the quality and regulation of pharmaceutical products, such as substandard and falsified medicines, weak enforcement of standards and laws, and inadequate infrastructure and human resources."*

Low level of local produce of essential medicines: *"Ghana has a low level of local production of essential medicines, especially vaccines and biologics, which are mostly procured through donor-funded programs or international organizations. Ghana imports about 80% of its pharmaceutical products, mainly from India and China, making it dependent on foreign sources and vulnerable to price fluctuations and supply disruptions."*

The above quotations from Gab01 highlight how Nigeria and Ghana are both heavily reliant on imported medicines and medical devices, leaving them open to changes in the price of these products as well as to supply chain interruptions. The Nigerian and Ghanian pharmaceutical markets are further hampered by the combination of high reliance on medical imports and inadequate regulatory enforcements.

Sub-Theme 1.2: Foreign pharmaceutical companies benefit from expansion into the market

Foreign pharmaceutical companies can benefit from expanding into the Ghanaian and Nigerian market in several ways. Some of the potential benefits were highlighted during the research process. The following views were expressed by Gab02:

Quality and affordable medicines: *"Accessing a large and growing population of consumers, who have increasing demand for quality and affordable medicines. Nigeria*

has the largest population in Africa, with about 200 million people, and is expected to grow to 400 million by 2050 and Ghana has a population of about 30 million people, and is expected to grow to 50 million by 2050.

Economic development: "*Contributing to the public health and economic development of the country, by providing essential medicines, creating jobs, transferring technology, and enhancing capacity. Nigeria faces a high burden of infectious and non-communicable diseases, and has a low level of health expenditure per capita."*

National policies and incentives: "*Taking advantage of the national policies and incentives that support local production and reduce import barriers, such as the Ghana Pharma Industrial Park. This is a project that aims to provide a conducive environment and incentives for local and foreign investors to set up pharmaceutical manufacturing plants in Ghana."*

Gab02 highlights that by filling the growing need for accessible, high-quality medications, promoting economic growth, and utilising favourable national regulations and incentives to encourage domestic production, international pharmaceutical businesses can reap the rewards of expanding into Nigeria and Ghana.

Sub-Theme 1.3: Legal and compliance requirements are needed prior to entering the market

Legal and compliance requirements were identified as the reasons that have led to challenges for new pharmaceuticals entering the market. This was highlighted during the research process. The following views were expressed by Gab03:

Requirements: *The requirements are to follow the guidelines and standards of the Nigerian Investment Promotion Commission (NIPC), which is the agency that promotes and facilitates foreign investment in Nigeria*.

Corporate Affairs Commission: *Registering with the Corporate Affairs Commission (CAC), which is the primary agency that governs the formation and maintenance of companies in Nigeria. Obtaining approval from the National Agency for Food and Drug Administration and Control (NAFDAC), which is the regulatory body that oversees the quality and safety of pharmaceutical products in Nigeria*.

Registrar General's Department: *Registering with the Registrar General's Department, which is the primary agency that governs the formation and maintenance of companies in Ghana. Complying with the tax laws and regulations, such as the Income Tax Act, the Value Added Tax Act, and the Customs Act. Adhering to the labour and immigration laws and regulations, such as the Labour Act, the Immigration Act, and the Ghana Investment Promotion Centre Act*.

Gab03's remarks describe the rigorous legal and compliance procedures, which include registering with many agencies, receiving regulatory licences, and abiding by tax, labour, and immigration regulations, making it difficult for new pharmaceutical businesses to enter the Nigerian and Ghanaian markets.

Sub-Theme 1.4: Current regulatory challenges of entering the market

Regulatory challenges were identified as a reason that has led to challenges for new pharmaceuticals entering the market. This was highlighted during the research process. The following views were expressed by Gab04:

Weak regulatory capacity and oversight: *The identified challenges of entering the market are the weak regulatory capacity and oversight of the National Agency for Food and Drug Administration and Control (NAFDAC), which is the main body that* oversees the quality and safety of pharmaceutical products in Nigeria and Ghana.

Following the guidelines and standards: *Following the guidelines and standards of the Nigerian Investment Promotion Commission (NIPC), which is the agency that promotes and facilitates foreign investment in Nigeria*.

Inadequate legislation: *The inadequate and often overlapping legislation, which creates confusion and uncertainty for investors and manufacturers. The official corruption, which undermines the effectiveness and credibility of the regulatory system and creates opportunities for illicit trade and practices.*

The issues highlighted above by GABO04 reduce the efficacy of regulations and cause uncertainty among investors, while also discouraging potential investors.

Sub-Theme 1.5: Problems that modern pharmaceutical companies encounter when entering new emerging markets

Problems that modern pharmaceuticals experience were identified as the reasons that have led to challenges for new pharmaceuticals entering the market. This was highlighted during the research process. The following views were expressed by Gab05:

Culture: *Understanding local cultures, languages, and healthcare practices as it is crucial for pharmaceutical companies to effectively market and distribute their products in Nigeria and Ghana. Failure to address these cultural nuances hinders market penetration.*

Evolving regulatory frameworks: *Pharmaceutical companies often encounter complex and evolving regulatory frameworks in emerging markets like Ghana and Nigeria. Navigating these regulations related to drug approval, pricing, and distribution can be a significant challenge. Navigating these regulations, obtaining necessary approvals, and ensuring compliance can be time-consuming and costly.*

Inadequate infrastructure: *In many emerging markets, including Nigeria and Ghana, inadequate infrastructure such as transportation, storage facilities, and healthcare systems can pose significant challenges for pharmaceutical companies in distributing and delivering their products effectively. Accessing remote areas and establishing efficient distribution networks can be difficult due to poor road networks and limited access to healthcare facilities in Nigeria and Ghana. This can impact the timely delivery of pharmaceutical products.*

Counterfeit products: *The prevalence of counterfeit pharmaceutical products in emerging markets like Nigeria poses a significant threat to the reputation and market share of legitimate pharmaceutical companies. It also undermines patient safety and public health.*

All of these factors highlighted by Gab05 impede efficient distribution and market penetration.

Sub-Theme 1.6: Government policies foster the development of the pharmaceutical sector

The challenges of entering the pharmaceutical sector often intersect with government policies that either facilitate or hinder the development of the industry. This was

highlighted during the research process. The following views were expressed by Gab06:

Foster the development : *The Ghana government polices foster the development by embarking on infrastructure projects, such as the Agenda 111 hospital project, to improve accessibility to health care and boost the number of medical staff across the country. These investments are expected to enhance pharmaceutical services.*

National Health Insurance Scheme: *The introduction of the National Health Insurance Scheme has significantly improved access to health care in Ghana. It provides insurance coverage for essential health services, including pharmaceuticals. This policy has facilitated better healthcare delivery and increased demand for medicines.*

Collaborations: *In Nigeria there is collaborations between the government, private sector, and international organizations drive investment, technology transfer, and capacity building in the pharmaceutical sector. Public-Private Partnerships support initiatives such as drug research and development, technology transfer, and healthcare training programs.*

Local production policies: *Nigeria has policies that encourage local pharmaceutical production. By promoting local manufacturing, the government aims to reduce dependence on imported drugs and enhance self-sufficiency. Implementing policies such as preferential procurement for locally manufactured drugs and providing support for local manufacturing capacity building can promote domestic pharmaceutical industry growth.*

All these factors mentioned by Gab06 assist in supporting local production and manufacture.

Sub-Theme 1.7: Local producers successfully compete with import

The challenges of entering the pharmaceutical sector, particularly for local producers aiming to compete with imports, are multifaceted and often deeply intertwined with various factors. The following views were expressed by Gab07:

Adherence quality assurance standards and compliance requirements: *Nigeria Local producers should prioritize adherence to stringent quality assurance standards and regulatory compliance requirements to ensure that their products meet safety, efficacy, and quality benchmarks. Investing in Good Manufacturing Practices (GMP) and obtaining certifications from regulatory authorities such as the National Agency for Food and Drug Administration and Control (NAFDAC) enhances credibility and consumer trust in local pharmaceutical products.*

Some medications that are exempted from importation: *In Ghana, the government has also introduced a policy where there are some medications that are exempted from importation. It promotes products that the local manufacturers. In addition, local producers should strive to optimize their production processes, minimize production costs, and achieve economies of scale to offer competitive pricing compared to imported pharmaceuticals. Streamlining operations, negotiating favourable supplier contracts, and adopting efficient manufacturing practices help reduce production costs and improve cost competitiveness.*

Gab07 highlights that Nigerian and Ghanaian local production can effectively compete with imports by upholding quality standards, securing the required certifications, and taking advantage of government initiatives

Sub-Theme 1.8: Government invests in the pharmaceutical sector

The challenges of entering the pharmaceutical sector are interconnected with the level of government investment and support in the industry. This was highlighted during the research process. The following views were expressed by Gab08:

Regulatory oversight: *The Nigerian government invests in pharmacies through regulatory oversight to ensure compliance with standards and regulations. The government establishes and enforces regulatory frameworks governing the pharmaceutical sector to ensure the safety, quality, and efficacy of medicines. Agencies such as the National Agency for Food and Drug Administration and Control (NAFDAC) oversee drug registration, licensing of pharmacies, and compliance with pharmaceutical standards.*

Research and development (R&D): *The government invests in research and development (R&D) initiatives to support innovation and the development of new pharmaceutical products. Funding may be allocated for research grants, collaborative research projects with academic institutions, and innovation hubs focused on addressing local healthcare challenges.*

Implementation of regulatory frameworks: *The government in Ghana invests in pharmacies through the implementation of regulatory frameworks such as the Pharmacy Act, which governs the establishment and operation of pharmacies. Investing in regulatory agencies and enforcement mechanisms strengthens drug regulatory systems, enhances compliance with pharmaceutical standards, and fosters consumer confidence in pharmacies and pharmaceutical products.*

Gab09 highlights how all the above-mentioned factors aid in generating frameworks to guarantee compliance and safety.

4.3.2 Objective 2: To determine the regulatory framework in Nigeria and Ghana

The second objective of the study was concerned with determining the regulatory framework in Nigeria and Ghana. The presentation and interpretation of the research findings are discussed in this subsection in relation to the regulatory framework in both countries.

4.3.2.1 Theme 2: Regulatory framework in Nigeria and Ghana

Sub-Theme 2.1: Supportive and safe regulations for the pharmaceutical sector

The regulatory framework significantly impacts the development of a supportive and safe pharmaceutical sector in both Ghana and Nigeria. The following views were expressed by Gab09:

Adequate resources and funding: *Allocate adequate resources and funding to regulatory agencies such as the Food and Drugs Authority (FDA) in Ghana and the National Agency for Food and Drug Administration and Control (NAFDAC) in Nigeria. Enhance the capacity of regulatory agencies through training programs, technology upgrades, and recruitment of qualified personnel.*

Inspections: *Implement cGMP (current Good Manufacturing Practices) inspections for pharmaceutical manufacturing facilities*. *Enforce strict quality control measures for pharmaceutical products, including rigorous testing of active ingredients, stability testing, and batch release inspections. Implement risk-based inspections and surveillance systems to detect and prevent the circulation of substandard and counterfeit medicines in the market.*

Streamline processes: *Simplify and streamline drug registration and approval processes to expedite the introduction of safe and effective medicines to the market. Establish clear timelines, transparent procedures, and online platforms for drug registration and regulatory submissions to improve efficiency and reduce administrative burdens.*

Gab09 highlights that adequate funding and resources, along with stringent quality control and inspections, allow for a favourable pharmaceutical sector in Ghana and Nigeria.

Sub-Theme 2.2: Four major challenges of entering new pharmaceutical markets in order of priority

Four major challenges may make it more difficult for new pharmaceutical companies to enter the markets in Ghana and Nigeria. The following views were expressed by Gab10:

Key challenges: The 4 major challenges in Nigeria are as follows:

- ***Regulatory Hurdles****: Navigating complex and evolving regulatory requirements for pharmaceutical products can be a significant challenge. This includes obtaining product registration and complying with local laws and regulations.*
- ***Infrastructure and Distribution****: Limited infrastructure and distribution networks in Nigeria can pose challenges for pharmaceutical companies in ensuring efficient and reliable supply chains and reaching remote areas.*
- ***Market Access and Competition****: Accessing the market and competing with established local and international pharmaceutical companies can be a major hurdle, especially in a market with diverse consumer preferences and purchasing power.*

- ***Quality Control and Counterfeiting****: Ensuring the quality and authenticity of pharmaceutical products in a market with a history of counterfeit drugs presents a significant challenge for new entrants.*

Key challenges: These are the 4 major challenges in Ghana:

- ***Regulatory Hurdles****: Navigating complex and evolving regulatory requirements can pose a significant barrier to entry for pharmaceutical companies in Ghana. This includes obtaining product registration and complying with local laws and regulations.*
- ***Market Access and Distribution****: Establishing efficient distribution channels and ensuring widespread market access for pharmaceutical products can be challenging due to infrastructural limitations and geographic disparities within Ghana.*
- ***Quality Control and Compliance:*** *Maintaining high standards of quality control and compliance with international pharmaceutical standards while adapting to local requirements is a crucial challenge for new market entrants in Ghana.*
- ***Competitive Landscape****: The pharmaceutical market in Ghana is competitive, with both local and international players vying for market share. Understanding and effectively competing within this landscape is a significant challenge for new entrants.*

Sub-Theme 2.3: Government policy or policies hinder(s) or make(s) new market production and distribution processes more difficult

Several government policies or regulatory challenges may hinder or make it more difficult for new pharmaceutical companies to enter the markets in Ghana and Nigeria. The following views were expressed by Gab11:

Government policies hindrance: *Major government policies hindrance are the lengthy and cumbersome regulatory approval processes for new drugs and pharmaceutical products can significantly delay market entry and increase costs for new companies. Lack of clarity in regulatory guidelines and inconsistent enforcement may further complicate the approval process, making it challenging for new companies to navigate regulatory requirements.*

High tariffs: *Restrictions on the importation of raw materials and pharmaceutical products can increase production costs for new companies. High tariffs on imported pharmaceutical products may disadvantage local producers, making it challenging for them to compete with cheaper imported alternatives and access international markets.*

Weak enforcement intellectual property: *Weak enforcement of intellectual property rights laws and inadequate protection for patents, trademarks, and proprietary formulations may discourage investment in research and innovation. New pharmaceutical companies may hesitate to invest in new drug development or technology transfer if they cannot secure adequate protection for their intellectual property, leading to a lack of innovation and market competition.*

Gab11 noted that high import tariffs, ambiguous regulatory approval procedures, lax enforcement of IP rights, and other government policies in Ghana and Nigeria impede the growth of new pharmaceutical companies by driving up costs, making it difficult to enter new markets, and discouraging innovation.

CHAPTER 5: DISCUSSION OF FINDINGS

5.1 Introduction

The purpose of this chapter is to analyse and discuss the results presented in Chapter 4. Each chapter compares these results with the relevant supporting literature on the challenges of entering new pharmaceutical markets in Nigeria and Ghana, as presented in the Literature Review section of this report. This study aimed to collect additional insights to add to the existing knowledge around the challenges of entering new pharmaceutical markets. This chapter discusses the findings in Chapter 4 in light of the literature review, addressing each research question to ensure the findings of both question 1 and 2 are thoroughly discussed.

5.2 To identify challenges of entering new pharmaceutical markets in Nigeria and Ghana.

The aim of this question was to identify the challenges of entering new pharmaceutical markets in Nigeria and Ghana. This involved exploring the current state of the pharmaceutical sector, with a particular focus on the current and future challenges in Nigeria and Ghana. This process entailed evaluating the challenges and opportunities of entering African countries.

5.2.1 Local pharmaceutical market in the countries

The respondents revealed that pharmaceutical challenges in the region stem from several factors, including low levels of local production of essential medicines, issues related to the quality and regulation of pharmaceutical products, and the countries' vulnerability to supply chain disruptions and price fluctuations. This finding supports (Ekeigwe's, 2019) observation that in Africa, raw materials and equipment needed for drug production are mostly imported, contributing significantly to the cost of production. Thus, industries are compelled to rely heavily on imports, thereby incurring excessive expenditures.

5.2.2 Foreign pharmaceutical companies benefit from expansion into the market

The respondents revealed that if pharmaceuticals did not face challenges, foreign pharmaceutical companies would benefit from the expansion into Nigerian and Ghanaian markets. This outcome is supported by (Adebisi et al., 2020) there is a significant shortage of incentives promoting the local manufacture of medicines as is evidenced by inadequate funding of research and development, lack of financial

support for manufacturers, heavy taxation levied against pharmaceutical industries, and overall inadequate healthcare budgetary allocation. Additionally, there is an inadequate implementation of existing policies, such as the Primary Health Care policy, in many African regions (Organization, 2018).

The implications for foreign pharmaceutical companies of not benefiting from expansion into Ghana and Nigeria will result in losing the competitive edge and market share to other foreign or local players who can overcome the challenges and tap into the opportunities in these markets.

5.2.3 Legal and compliance requirements are needed prior to entering the market

The respondents revealed that pharmaceutical challenges are caused by extensive laws and regulations. This findings support (Doua and Van Geertruyden, 2014) who state that the regulatory weakness has been attributed to a lack of adequate and trained enforcement staff, insufficient budgets, and inadequate regulatory and legal frameworks

The implications of having extensive legal and compliance requirements for entering the pharmaceutical industry in Ghana and Nigeria are significant. Companies must invest significant resources in compliance and regulatory affairs to ensure that they meet the requirements of the regulatory authorities.

Overall, while the legal and compliance requirements for entering the pharmaceutical industry in Ghana and Nigeria can be extensive, they are designed to ensure that companies operate with integrity and transparency, and that the products they manufacture are safe and of high quality.

5.2.4 Current regulatory challenges of entering the market

The respondents revealed that pharmaceutical challenges are caused by the weak regulatory system. This finding supports those of (Giralt et al. ,2017b) who found that 90% of national drug regulatory bodies in SSA are unable to effectively discharge their basic regulatory functions. In addition, certain unfair government policies for pharmaceutical companies and pharmaceutical machinery manufacturers also act as roadblocks to the growth of the pharmaceutical industry.

Implications of having regulatory challenges are that it could lead to a number of negative implications for the pharmaceutical industry in Ghana and Nigeria. For example, companies may be able to enter the market without meeting the necessary quality and safety standards, which could lead to the production of substandard or counterfeit drugs. This could have serious implications for public health, as patients may be exposed to harmful or ineffective medications

5.2.5 Problems that modern pharmaceutical companies encounter when entering new emerging markets

Modern pharmaceutical companies face a range of challenges when entering new emerging markets in Ghana, including regulatory, infrastructure, market access, intellectual property, cultural, and pricing-related hurdles. Understanding and effectively addressing these challenges is crucial for successful market entry and sustainable operations in the Ghanaian and Nigerian pharmaceutical market. This outcome supports (Deloitte, 2014) who stated that underdeveloped regulatory processes present challenges for businesses and manufacturers of new medical devices interested in entering the African market. These challenges can have a significant impact on the ability of modern pharmaceutical companies to enter new emerging markets. Companies that are unable to navigate these challenges effectively may struggle to establish themselves in these markets and achieve profitability.

5.2.6 Government policies foster the development of the pharmaceutical sector

In both Ghana and Nigeria, the development of the pharmaceutical sector can be fostered through various government policies aimed at promoting investment, innovation, access to medicines, and regulatory compliance. This finding supports (Cohen, 2000) who stated that all the governments of all countries worldwide are responsible for developing policies and laws that regulate the operation of the pharmaceutical industry.

5.2.7: Local producers successfully compete with import

Local producers in both Nigeria and Ghana can successfully compete with imports in the pharmaceutical sector by implementing various strategies tailored to their specific market dynamics and challenges. This finding supports (Ekeigwe , 2019) that in Africa,

raw materials and equipment needed for drug production are mostly imported, contributing significantly to the cost of production. Thus, industries are forced to rely heavily on imports and thereby incur excessive expenditures. By adopting these strategies and leveraging their unique strengths and capabilities, local producers in Ghana and Nigeria can enhance their competitiveness and capture a larger share of the domestic and regional pharmaceutical markets, contributing to economic growth and healthcare accessibility.

5.2.8: Government invests in the pharmaceutical sector

In both Ghana and Nigeria, governments may invest in pharmacies and the pharmaceutical sector through various mechanisms aimed at promoting access to healthcare services, ensuring the availability of essential medicines, and supporting local businesses. This outcome is in disagreement with (Adebisi et al., 2020), who indicated that the prevailing government apathy and lack of political will encapsulated by a consistent lack of investment in healthcare affect people's access to drugs. By implementing targeted investments and supportive policies, governments in Ghana and Nigeria can strengthen the pharmaceutical sector, improve access to essential medicines, and enhance the overall quality of healthcare services for their populations.

5.2.9 Conclusion on the challenges of entering new pharmaceutical markets

Both Nigeria and Ghana have sizable and rapidly growing populations, which present a significant market for pharmaceutical products. The increasing population size, growing middle class with disposal income, coupled with rising healthcare awareness and a growing demand for healthcare services, creates opportunities for pharmaceutical companies to expand their market presence and reach a larger customer base.

Despite the attractive opportunities, several challenges must be considered when expanding pharmaceutical operations in Nigeria and Ghana, including:

Nigeria and Ghana have complex and evolving regulatory frameworks governing the pharmaceutical industry, including registration requirements, quality standards, labelling regulations, and pricing policies. Navigating regulatory hurdles and ensuring compliance with local regulations can be time-consuming, costly, and challenging for pharmaceutical companies. Both Nigeria and Ghana face infrastructural limitations,

including inadequate transportation networks, unreliable power supply, and limited access to healthcare facilities in rural areas. Infrastructural challenges can impact the distribution, storage, and delivery of pharmaceutical products, leading to supply chain disruptions and operational inefficiencies. Despite improvements in healthcare infrastructure, access to healthcare services remains limited in many parts of Nigeria and Ghana, particularly in rural and underserved areas. Affordability of pharmaceutical products is also a significant concern for many consumers, limiting their ability to access essential medicines and healthcare services.

Local pharmaceutical companies in Nigeria and Ghana can enhance their competitive edge by ensuring stringent compliance and quality standards; implementing robust quality control measures throughout the manufacturing processes; investing in modern manufacturing facilities, distribution networks, and logistics infrastructure to improve operational efficiency and reduce production costs; and upgrading technology and adopting automation to enhance productivity, reduce waste, and ensure consistent product quality.

Locals need to raise entry barriers for internationals by making use of competitive intelligence activities such as monitoring competitor activities and analysing market trends. Since foreigners lack the local context and have limited knowledge of the language, culture, and customs of the country, customer needs, and preferences they can begin by innovating locally. Enhancements can be made to the companies and to products' branding, ensuring that they address issues or concerns locally so that locals can relate to the product and the company. Lastly locals need to form local strategic partnerships with IT firms and maximise government subsidies e.g., local preferential procurement.

5.3 To determine the regulatory framework in Nigeria and Ghana

The aim of this question was to determine the regulatory framework in Nigeria and Ghana. This was done by exploring the current state of the pharmaceutical sector with further emphasis on the current and future state of pharmaceuticals in Nigeria and Ghana's regulatory framework. This entailed an evaluation of the regulatory framework in Nigeria and Ghana.

5.3.1: Supportive and safe regulations for the pharmaceutical sector

Developing supportive and safe regulations for the pharmaceutical sector in Ghana and Nigeria requires a comprehensive approach that addresses various aspects of regulation, enforcement, and oversight. This finding supports Sastry (2014) who found that these regulatory processes are stringent with excellent safety standards. However, according to (Sorenson & Drummond 2014), these processes are expensive and may be prohibitive to non-profit organisations or local device developers in Africa. In addition, the regulatory processes of high-income countries are not designed to meet the needs and safety issues present in Africa. By implementing these measures, Ghana and Nigeria can work towards developing supportive and safe regulations for the pharmaceutical sector, ultimately ensuring the availability of quality and safe pharmaceutical products for their populations.

5.3.2 Four major challenges of entering new pharmaceutical markets in order of priority

This finding supports (Ekeigwe, 2019), who found that in Africa, raw materials and equipment needed for drug production are mostly imported, contributing significantly to the cost of production. Thus, industries are forced to rely heavily on imports, thereby incurring excessive expenditures. In addition, (Giralt et al. 2017b) stated that weak regulatory systems in many SSA countries impact negatively on the pharmaceutical supply chains. This is not only a challenge in itself, it also gives rise to a critical problem of poor quality medicines in the pharmaceutical supply chains.

5.3.3: Government policy or policies hinder(s) or make(s) new market production and distribution processes more difficult

Several government policies can hinder or make it difficult for new pharmaceutical companies to enter and operate in Ghana and Nigeria. This outcome is supported by (Ndomondo-Sigonda and Ambali 2011), who argued that globally, pharmaceutical regulation is constrained by limited national capacities to undertake core regulatory roles, with Africa demonstrating the weakest capability. Weak pharmaceutical oversight in any country exposes drug users to potentially harmful medicines, sub-standard and counterfeit products, and promotes the irrational prescription of pharmaceuticals. According to (Doua and Van Geertruyden 2014), the regulatory weakness has been attributed to a lack of adequate and trained enforcement staff,

insufficient budgets, and inadequate regulatory and legal frameworks. These policies can collectively create a challenging environment for new pharmaceutical companies in Ghana and Nigeria, impacting their ability to innovate, produce, and distribute new drugs effectively.

5.3.4 Conclusion regulatory framework in Nigeria and Ghana

Entering the pharmaceutical market in Nigeria and Ghana requires careful planning, adherence to regulatory requirements, and a commitment to quality and compliance to ensure long-term success and impact in the region. New entrants need to consider seeking legal counsel familiar with pharmaceutical regulations in Nigeria and Ghana to navigate the complexities of registration, compliance, and other legal requirements. Additionally, they need to partner with local distributors, manufacturers, or consultants who are knowledgeable about the regulatory landscape and can facilitate market entry and ensure compliance with local laws and regulations. Finally, they need to keep abreast of changes in regulatory requirements and updates from NAFDAC and the FDA to ensure ongoing compliance and adaptability to evolving regulations.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

This section draws conclusions about the findings in response to the three research questions posed, provides an indication of the implications of the study, and then concludes with recommendations to stakeholders and recommendations for future studies.

6.1 Summary

The research focused on evaluating challenges of entering new pharmaceutical markets in Nigeria and Ghana. The research questions posed were twofold: 1. “What are the challenges of entering new pharmaceutical markets in Nigeria and Ghana?” and 2. “What are the regulatory frameworks in Nigeria and Ghana?” The current research was based on understanding and complying with registration requirements, quality standards, challenges, labelling regulations, and pricing policies, which are essential for market entry.

The research methodology that was employed was the collection, processing, and analysis of empirical evidence. A qualitative research strategy was chosen for the study, and a comparative case study design was utilised. A 17-question interview schedule was used to collect answers from respondents. Semi–structured interviews were utilised in the research as they provided for open-ended questions. The research was done via MS Teams due to the difference in the countries. The respondents who participated in answering the questions were assured that their responses would remain anonymous. The permission letter was granted by Organon South Africa, Roche Nigeria and PharmaSymbiosis Nigeria and Ghana respectively. A total of ten respondents who are knowledgeable of the pharmaceutical sector were chosen for the research. Consent was received prior to recording the interviews, and assurances were given that the respondents’ identities would remain anonymous throughout the data gathering process. Recorded interviews were transcribed and the transcribed data was coded and further analysed. The reliability, validity, and limitations of the research were checked.

Key findings suggest that modern pharmaceutical companies face a range of challenges when entering new emerging markets in Ghana, including regulatory, infrastructure, market access, intellectual property, cultural, and pricing-related

hurdles. Understanding and effectively addressing these challenges is crucial for successful market entry and sustainable operations in the Ghanaian and Nigerian pharmaceutical markets. This outcome supports (Deloitte, 2014), who asserts that underdeveloped regulatory processes present challenges for businesses and manufacturers of new medical devices interested in entering the African market. These challenges can have a significant impact on the ability of modern pharmaceutical companies to enter new emerging markets. Companies that are unable to navigate these challenges effectively may struggle to establish themselves in these markets and achieve profitability. All other possible solutions, such as complex and evolving regulatory frameworks governing the pharmaceutical industry, including registration requirements, quality standards, labelling regulations, and pricing policies; ensuring high-quality standards and compliance with regulatory requirements is crucial for building trust among consumers and healthcare professionals; investing in modern manufacturing facilities, distribution networks, and logistics infrastructure that can improve operational efficiency and reduce production costs; and collaborating with international pharmaceutical companies, research institutions, and regulatory agencies can provide local companies with access to expertise, resources, and markets will need to be carefully considered.

6.2 Recommendations

- **Current regulatory challenges of entering the market**

The weak regulatory system can be addressed by allocating sufficient funding and resources to regulatory bodies, such as the National Agency for Food and Drug Administration and Control (NAFDAC) in Nigeria and the Food and Drugs Authority (FDA) in Ghana; enhancing the capacity of regulatory agencies through technological updates, while implementing regular training programs for employees; and lastly implementing stringent quality assurance procedures for pharmaceuticals, such as thorough active ingredient testing, stability assessments, and batch release inspections.

- **Local pharmaceutical market in the country**

Establishing standardised, innovative, and economical manufacturing and production procedures will guarantee high-quality drugs and packaging at affordable rates, which will reduce the high imports. This will therefore result in drugs and essential

medicines being accessible to populations living in rural and impoverished areas, while satisfying the national demand.

- **Government invests in the pharmaceutical sector**

This can be addressed by reducing import taxes on pharmaceuticals to help companies compete and stimulate foreign investment; introducing government initiatives that foster new pharmaceutical entrance e.g., reduced corporate tax and more government subsidy; and the local governments investing in pharmaceutical drug research and development.

- **Supportive and safe regulations for the pharmaceutical sector**

The approval process can be expedited by improving the clarity of regulatory guidelines and enforcing them consistently, which will make it simpler for new businesses to comply with regulatory requirements. To increase productivity and lower administrative costs, establish precise deadlines, transparent processes, and online platforms for drug registration and regulatory submissions.

Global or emerging pharmaceutical corporations should collaborate with the national and subnational health authorities in their respective nations. Emerging pharmaceutical corporations should be able to partner with national health insurance scheme of the two countries, to have their medication listed as of their essential medicines/ drug list.

- **Government policy or policies hinder(s) or make(s) new market production and distribution processes more difficult**

This can be addressed by allowing flexible intellectual property rights on generic medicine production within the two countries, thereby growing the number of the various drugs that can be distributed and made available; collaborating with regional tech firms and the government to implement risk-based surveillance and inspection protocols to identify and halt the sale of subpar and counterfeit pharmaceuticals; and lastly, collaborating with the local health department on educating the public about risk or dangers of consuming counterfeit drugs. To promote foreign direct investment in local manufacturing, the local government can offer incentives that reduce the cost or risk faced by the investor.

6.3 Conclusions

This research study has addressed the research objectives as outlined in Chapter 1 of this document. To address the challenges of entering new pharmaceutical markets in Nigeria and Ghana proposed solutions were identified. The foremost challenges facing Ghana and Nigeria are evolving regulatory frameworks, Infrastructural challenges and limited access to healthcare services. Several steps can be taken by local pharmaceutical companies in Ghana and Nigeria to enhance their competitiveness in the market:

Ensuring high-quality standards and compliance with regulatory requirements is crucial for building trust among consumers and healthcare professionals. Implementing robust quality control measures throughout the manufacturing process is essential for maintaining product efficacy and safety.

Investing in modern manufacturing facilities, distribution networks, and logistics infrastructure can improve operational efficiency and reduce production costs. Upgrading technology and adopting automation can enhance productivity, reduce waste, and ensure consistent product quality.

Collaborating with international pharmaceutical companies, research institutions, and regulatory agencies can provide local companies with access to expertise, resources, and markets. Partnerships can facilitate technology transfer, knowledge sharing, and capacity building, enabling local companies to improve their product offerings and expand their market reach.

Key solutions for determining the regulatory framework in Nigeria and Ghana include:

Adhering to regulatory requirements and intellectual property laws, which is essential for gaining market approval and protecting innovations. Companies should stay updated on evolving regulations and seek legal counsel to navigate complex intellectual property issues.

Seeking legal counsel familiar with pharmaceutical regulations in Nigeria and Ghana to navigate the complexities of registration, compliance, and other legal requirements and partner with local distributors, manufacturers, or consultants who are knowledgeable about the regulatory landscape can facilitate market entry and ensure compliance with local laws and regulations.

Keeping abreast of changes in regulatory requirements and updates from NAFDAC and the FDA can ensure ongoing compliance and adaptability to evolving regulations. Prioritizing quality assurance and control measures throughout the supply chain can assist in maintaining product integrity and compliance with regulatory standards.

6.3 Limitations

A lack of recently published material concerning challenges of entering the pharmaceutical markets, particularly in Nigeria and Ghana, led the researcher to rely on outdated sources, in addition to already-existing regulations and official publications. The researcher was forced to add sources older than five years in this dissertation as a result. To understand the challenges of entering new pharmaceutical markets in Nigeria and Ghana in the absence of recent data, it makes sense that the older sources cited in this study are still valid and informative.

6.5 Recommendations for future studies

Possible further studies should address key areas such as a comparative analysis of regulatory frameworks, market entry strategies, consumer behaviour, preferences, policy and regulatory reform through further research and analysis. Stakeholders can gain valuable insights into the challenges and opportunities of entering the pharmaceutical markets in Nigeria and Ghana. This knowledge can inform evidence-based policies, strategies, and interventions to promote sustainable growth, improve healthcare access, and enhance public health outcomes in the region.

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APPENDICES

APPENDIX A: LETTER TO RESPONDENTS

To whom it may concern

Dear Sir/Madam

My name is Thato Motshoane, and I am currently studying Master of Business Administration (MBA) at the University of the Witwatersrand. The research I am conducting is on the topic "**Exploring challenges of entering new pharmaceutical markets in Nigeria and Ghana".** My supervisor is Dr Emmanuel Quaye from the Wits School of Business.

I hereby request permission to administer an interview with yourself as the identified stakeholders. The interview is anticipated to take 40 minutes. Attached for your perusal and confirmation, is the approved title registration document for the study that I intend to conduct issued by the University of the Witwatersrand. For more clarity concerning the study kindly contact me or my supervisor on below.

Thato Motshoane: 2398759@students.wits.ac.za
Dr Emmanuel Quaye: emmanuael.quaye@wits.ac.za

Regards,

Thato Motshoane

APPENDIX B: CONSENT FORM

Research Title: **Exploring challenges of entering new pharmaceutical markets in Nigeria and Ghana**

Consent to take part in research

I..…… voluntarily agree to participate in this research study.

- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study.
- I understand that I will not benefit directly from participating in this research.
- I agree to my interview being audio-recorded.
- I understand that anonymity and confidentiality cannot be guaranteed.
- I understand that if I inform the researcher that myself or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission.
- I understand that signed consent forms and original audio recordings will be retained in the possession of the researcher until the thesis has been approved by University of Witwatersrand.
- I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

I believe the participant is giving informed consent to participate in this study.

Signature of research participant *Signature of researcher*

---------- ----------

Date _____

APPENDIX C: INTERVIEW GUIDE

Section A : Demographic information for South Africa, Nigeria and Ghana participants

1. Age	Below 26	
	26-35	
	36-55	
	56-65	
	Above 65	
2. Gender	Female	
	Male	
	Other	
3. Year of experience	Under 5 years	
	6 - 9 years	
	10 - 15 years	
	16 - 20 years	
	21 - 25 years	
4. Position in the organisation	Regulatory affairs	
	Commercial	
	Compliance	

Section B : Questions for the Organon South Africa

- What are the benefits that modern pharmaceutical companies encounter when entering new emerging markets?
- What are the challenges that modern pharmaceutical companies encounter when entering new emerging markets?
- How would you describe the pharmaceutical sector in West Africa, particularly, Ghana and Nigeria?
- Can you explain the legal and compliance requirements that are needed prior to entering the Nigerian/or Ghana market?
- In your opinion what are the key regulatory challenges of entering the Nigerian and Ghanian market?

Section C : Questions for the Nigeria and Ghana participants

Challenges of entering new pharmaceutical markets in Nigeria and Ghana

- How would you describe the local pharmaceutical market in your country?
- How would the foreign pharmaceutical companies benefit from the expansion into Nigerian /Ghanian market?
- Can you explain what legal and compliance requirements are needed prior to entering the Nigerian /Ghanian market?
- In your view what are the current regulatory challenges of entering the Nigerian/ Ghanian pharmaceutical market?
- What are the problems that modern pharmaceutical companies encounter when entering new emerging markets?
- Which form of government policies foster the development of the pharmaceutical sector?
- How do local producers successfully compete with import?
- How does government invest in the pharmaceutical sector?

Regulatory framework in Nigeria and Ghana

- How can a country develop supportive and safe regulation for the pharmaceutical sector?
- In your view what are four the major challenges of entering new pharmaceutical markets in Nigeria/ Ghana in order of priority?
- What government policy or policies hinder(s) or make(s) new market production and distribution processes more difficult?

Recommendation to overcome challenges

- What are the proposed future strategies for improving challenges of entering new pharmaceutical markets in Nigeria and Ghana?

……Thank you for your participation……

APPENDIX D: PERMISSSION LETTER



PHARMASYMBIOSIS

+234 805 529 9632
info@pharmasymbiosisgroup.com
www.pharmasymbiosisgroup.com

1st December 2023

Thato Motshoane

2398759@students.wits.ac.za

Dear Thato

PERMISSION TO ADMINISTER AN INTERVIEW

I, Lanre Arokoyo herein give my consent/permission to be interviewed by you in respect of your Master in Business research titled "Exploring challenges of entering new pharmaceutical Markets in Nigeria and Ghana".

Yours faithfully

Lanre Arokoyo 1/12/2023

email: lanre.arokoyo@pharmasymbiosisgroup.com

Tel +234 805 529 9632.

Country Manager

11C, Alfred Olaiya Street, Opebi Ikeja, Lagos

Roche

Roche Products Ltd

48/50 Isaac John, Ikeja GRA

Lagos Nigeria,

5th December, 2023

LETTER OF PERMISSION TO CONDUCT MBA RESEARCH

We hereby give Thato Sebabatso Motshoane who is currently studying for a Masters of Business Administration (MBA) at the University of the Witwatersrand, the permission to conduct a research interview with two members of staff (Regulatory and Commercial) in our firm on the topic "**Exploring challenges of entering new pharmaceutical markets in Nigeria and Ghana**"

Yours Sincerely,

Ladi Hameed

General Manager

ORGANON

Organon South Africa (Pty) Ltd
(Reg. No. 2020 / 543929 / 07)
Spaces, 1st Floor
22 Magwa Crescent, Gateway West
Waterfall City Midrand
2090
Tel: +27 (0) 87 106 9655
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December 6, 2023

The MBA Director
Wits Business School
2 St David's Place
Parktown
Johannesburg, 2050

Dear Sir / Madam

APPROVAL TO CONDUCT MBA RESEARCH STUDY AT ORGANON SA (PTY) LTD

This letter grants permission to Ms. Thato Sebabatso Motshoane [Student Number: 2398759], Marketing Associate at Organon, and current MBA Part-time student at Wits Business School, to conduct her research with Organon SA (Pty) Ltd and affiliated employees.

Her research topic is titled: "Exploring challenges of entering new pharmaceutical markets in Nigeria and Ghana".

She is granted permission to collect data using a semi-structured questionnaire to interview Organon employees during the period between December 2023 to June 2024.

This permission is granted subject to any approvals of the university and research ethics committees that may be required, as well as the informed consent of the participants.

We wish Ms. Motshoane all the best with her research.

Sincerely,

Dr Abofele Khoele
MANAGING DIRECTOR
ORGANON SOUTH AFRICA (PTY) LTD

APPENDIX E: ETHICAL CERTIFICATE

Graduate School of Business Administration
University of the Witwatersrand, Johannesburg

Wits Business School Ethics Committee
Constituted under the University Human Research Ethics Committee (Non-Medical)

Ethics Clearance Certificate

Ethics protocol number: WBS/BA2398759/357
This certificate is only valid with a legitimate ethics protocol number and signed by the Researcher (below).

This certificate is only valid if accompanied by formal permission from the relevant stakeholder(s).

Project title	Challenges of entering new pharmaceutical markets in Nigeria and Ghana
Investigator / Researcher	Ms Thato Motshoane
Nature of Project	MBA (Research Article)
Decision of the Committee	Approved, provided stakeholders and participants are advised that anonymity and confidentiality cannot be guaranteed.
Issue Date of Certificate	2022-10-11
Expiry date	Date of submission of the project / research report
Chairperson	Prof Anthony Stacey ☎ +27 11 717 3587 +27 82 880 4531 anthony.stacey@wits.ac.za

Declaration by Researcher

One copy must be signed by the Researcher and returned to the Chairperson of the Wits Business School Ethics Committee.

I fully understand the conditions under which I am authorized to carry out the abovementioned research and I guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I undertake to resubmit the protocol to the Committee.

Signature

18/10/22
Date: