Exploring the conditions for the development and growth of the pharmaceutical industry in KwaZulu-Natal

by

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DECLARATION

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13 September 2023

Neliswa W Dlamini

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Prof. Krishana K Govender

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DEDICATION

This dissertation is dedicated to my late husband.

ACRONYMS AND ABBREVIATIONS

AfDB	African Development Bank
AHS	Africa Health Strategy
API	Active pharmaceutical ingredient
APP	Annual Performance Plan
AR	Annual Report
ARNS	African Regional Nutrition Strategy
AU	African Union
BP	Business Plans
CEO	Chief Executive Officer
DDI	Domestic Direct Investment
DOH	Department of Health
DTIC	Department of Trade and Industry Competition
DTP	Dube Trade Port
EFPIA	European Federation of Pharmaceutical Industries and Associations
EU	European Union
FDI	Foreign Direct Investment
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
GVA	Gross Value Added
IDZ	Industrial Development Zone
IFPMA	International Federation of Pharmaceutical Manufacturers and Association
IMS	International Medicine Statistics
IP	Intellectual Property

IPAP	Industrial Policy Action Plan
IQVIA	International Quality and Value Institute Advisors
KZN	KwaZulu-Natal
MCEP	Manufacturing Competitiveness Enhancement Programme
MTSF	Medium-Term Strategic Framework
NDP	National Development Plan
NHI	National Health Insurance
PESTLE	Political, Economic, Sociological, Technological, Legal and Environmental
PGDS	Provincial Growth and Development Strategy
PMPA	Pharmaceutical Manufacturing Plan for Africa
R&D	Research and Development
SADC	Southern African Development Community
SAERRP	South African Economic Reconstruction and Recovery Plan
SAPHRA	South African Health Products Regulatory Authority
SDG	Sustainable Development Goals
SEP	Single Exit Price
SEZ	Special Economic Zone
SA	South Africa
STCHPDC	Specialized Technical Committee on Health, Population and Drug Control
USA	United States of America
US	United States
WHO	World Health Organisation

ABSTRACT

Evidence from the literature suggests that PESTLE and Porter's Five Forces theoretical frameworks are fundamental when studying the growth dynamics of the pharmaceutical healthcare sector. Various studies of the pharmaceutical industry suggest that the sector is critical for economic growth, access to affordable healthcare, and addressing socioeconomic challenges. Recently, public healthcare in South Africa encountered numerous challenges in terms of the non-availability of vaccinations to deal with the COVID-19 pandemic. This was due to a lack of manufacturing capabilities, resulting in overreliance on imported vaccinations at that time. Therefore, this study argues that there is a competitive advantage that favours imported manufactured products such as vaccinations. This study aimed to critically analyse the growth dynamics of the pharmaceutical sector by looking at the conditions for development, limitations that are linked to regulations and contribution to economic growth in the province of KwaZulu-Natal. Using a qualitative research design method, the study collected data by conducting interviews with key players in the private sector and government. The study participants were from Xylomed Pharmaceutical, Ensemble Manufacturers, Dube Trade Port, and the Department of Economic Development, Tourism and Environmental Affairs. The analysis reveals that there is minimal interest from the government to grow the sector as is evident in the poor regulatory framework aimed at promoting and growing the sector. Subsequently, the KwaZulu-Natal province is struggling to attract foreign investment. The province is not optimally leveraging opportunities provided by foreign investment and capital, which is proven to address socioeconomic challenges. Also, the study discovered that sectorial long-term vision necessitates a skills development plan that is related to sector demand and addresses socioeconomic challenges. Thus, the framework and policies must be linked to this strategy to achieve aggregate productivity growth in the KwaZulu-Natal province. In addition, this study argues that the government's responsiveness to the pharmaceutical sector necessitates an agile approach in capacitating the industry players and strengthening coherence. The primary implication for this enquiry is that the socioeconomic challenges will persist, resulting in the country relying on foreign aid to grow the sector. Even though the study had limitations regarding the cases reviewed and the scope, it is the researcher's view that it would provide a much-needed practical and theoretical lens for future similar studies.

Keywords: economic growth, long-term vision, pharmaceutical sector, socioeconomic challenges, sustainable environment.

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CHAPTER 1: INTRODUCTION TO THE STUDY

1.1 Introduction

The medicine needs of South Africa (SA) are primarily being met by imported generic medicines and, to a lesser degree, locally manufactured generic medicines. These changes, combined with a volatile and sometimes uncertain regulatory environment, have led to interesting dynamics and changes within SA's pharmaceutical manufacturing industry (Naude & Luiz, 2013). Thus, the study aims to critically analyse the growth dynamics of the pharmaceutical sector by examining the conditions for development, limitations associated with regulations and contribution to economic growth in the province of KwaZulu-Natal (KZN). This chapter introduces the study, gives a background to it and outlines the research questions, objectives, scope and delineation of the study. Furthermore, this chapter emphasizes the significance of the study as well as the overall structure of the dissertation.

1.2 Background of the study

Horner (2022) indicates that the majority of pharmaceutical manufacturing facilities are in the Gauteng Province, with a large number located in the City of Johannesburg. This is supported by Rogerson (1998), who states that according to worldwide trends, high-technology manufacturing in SA is heavily concentrated in Gauteng. The Gauteng province is regarded as the most populous province in SA, with an estimated population of 15.4 million (Stats SA, 2021). The province boasts the highest gross state product and per capita, as well as the greatest number of hospitals (99), of SA's nine provinces (Stats SA, 2021). The Department of Health (DOH) annual report for 2020-2021 states that the KZN province is currently estimated to have a population of 11.5 million with about 74 hospitals affiliated with clinics (KZN DOH, 2022).

The pharmaceutical industry can be defined as an industry that discovers, develops, manufactures and sells drugs for use as medication. Defining the illness of the patients is not part of the industry's mission. It falls within the scope of the Healthcare sector (Jakka & Rossbach, 2013). Potential, investments in its

elementary processes or value chains contribute to job creation and the establishment of new companies (Horner, 2022).

As part of socioeconomic development, ensuring access to Healthcare is critical for the SA government, and it forms part of the developmental goals. Therefore, certain measures have been considered to ensure the reduction of drug prices and the use of generic drugs, to ensure that medication becomes accessible to those who need it more. For instance, the Minister of Health, through the Pricing Committee determines an annual percentage increase in Single Exit Price (SEP) that is uniformly applied to all products. In exceptional circumstances (e.g., raw material cost increases), the Minister of Health may permit ad hoc price increases under Regulation 9 of the Medicines Act 18 (Moeti et al., 2023).

The literature relevant to this study emphasises the great potential of the bioeconomy for sustainable development towards the achievement of the SDGs (Dietz et al., 2018). The Department of Science and Technology through its policy called the Bio-Economy Strategy and the Department of Trade and Industry Competition (DTIC) in the Industrial Policy Action Plan (IPAP) 2018/19-2020/21, continues to support developments in the broader bioeconomy (DTIC, 2019/20). These are some of the positive policy measures supporting this industry and are part of the National Development Plan (NDP).

Scholars such as Harrison and Rodriguez-Clare (2010) contend that Trade and Industry policies are established to support the sector's growth and development. In SA the Government uses various policies as a support measure, to stimulate the growth of various sectors such as the pharmaceutical sector and position them in the world economy. Such initiatives are driven by the realisation of understanding that innovation, reconstruction, and development are the main drivers of the knowledge absorption process. These strategies are therefore supported by the development of Special Economic Zones (SEZs) in KZN, where there is the Richards Bay Industrial Development Zone (IDZ) and the Dube Trade Port (DTP) SEZ. The primary aim of developing these zones is to allow export production to take place and provide production flexibility. Such programmes are employed to promote Foreign Direct Investment (FDI) and export commodities (DTIC, 2019/20).

While policies and infrastructure seem to favour the development of various sectors, this study will focus on the development of the pharmaceutical industry in the province of KZN, more especially, the conditions for industrial development and employment growth in high-tech industries, taking into consideration that job creation is the result of economic growth of any sector.

Incidents such as the COVID-19 pandemic have accelerated interest in healthcare, hence the importance of this study. Starr (2017) argues that the Healthcare sector assists an economy's most valuable factor of production, which is aligned with the national Government plans. Some findings by researchers indicate that while the private sector has a wider range of products, the public health system uses the most consumable products such as vaccines, bandages, and pain management drugs in general. Peres et al. (2019) indicate that infectious disease treatment accounts for more than half of the overall pharmaceutical spending in the public health sector, where spending is mostly on consumable products.

The SA government has shown keen interest in the local manufacturing of drugs to stimulate investment, jobs, and affordable drugs (Horner, 2022). Researchers therefore argue that high-tech industry plays a critical role in the overall economy but a comprehensive industrial strategy has to be implemented in consultation with the entire local manufacturing industry for both industrial and government objectives to be achieved in a coordinated manner (Naude & Luiz, 2013). Similar to the case of National Health Insurance (NHI), a coordinated manner could lead to a similar outcome, as it is still under negotiation at the policy phase, and such policy impacts economic growth. However, alignment is key.

State structures play a significant role within the framework of integrating the organisations within the specific sector/industry. It is the state policy that regulates the configuration of the industry. This therefore assists in profiling the economic system (Glasmeier, 2017). The policies on their own may not yield the results as expected. Hence, the critical element of developing an innovation strategy needs to be monitored. The strategy needs to be centred around two elements the consumer demand model and the supply model within the sector or industry.

The KZN province has the largest and busiest shipping terminal in the Port of Durban, commonly called Durban Harbour. This port handles up to 31.4 million tons of cargo each year and is the fourth largest container terminal in the Southern Hemisphere, handling approximately 4.5 million twenty-foot equivalent units (TEU) in 2019 (KZN Treasury, 2022).

Veitch (2017) indicates that the pharmaceutical industry concentration of registered pharmaceutical companies per province is as follows:

- Gauteng - 60
- Western Cape Province - 15
- KZN Province - 9
- Free State - 1
- Eastern Cape - 3
- North West - 1

Considering the top three provinces, KZN is at the bottom, with nine companies, which many may argue is a matter of concern, as job creation is at a critical state for KZN, as announced by the Premier of the Province, in his State of the Province Address in February 2022 (Cubai, 2022).

It is against the above background that this research aims to explore the growth sector dynamics in comparison with the other provinces, assess the need to employ any diversification measures for the pharmaceutical manufacturing sector in KZN and understand the impact it may have on economic growth and employment generation.

1.3 Research problem

Recently, researchers have shown an increased interest in the pharmaceutical industry as an economic development stimulator. For example, Tolley Jr (2019) argues that globally, everyone has the right to access healthcare. The same is enshrined in the Constitution of the Republic of SA Act 108 of 1996, Chapter 2, section 11, which states that everyone has the right to life. Furthermore, Section

27(a) stipulates that everyone has the right to access health services, so there should be an effort made to provide the required basic healthcare facilities (hospitals, physicians, equipment, innovation, and infrastructure). Much of the research on conditions for the development and growth of the pharmaceutical industry is descriptive and fails to give clarity on why the industry is characterised by a lack of investment and skills, stagnant economic growth, income, and a lack of strong policy direction. The pharmaceutical industry in SA is lagging behind policies and cannot influence the growth of the pharmaceutical industry and its impact on economic growth and development. Thus, little is known about how the pharmaceutical sector can influence the economic development and growth of KZN, and it is not clear what factors influence the conditions for development in relation to addressing issues of social-economic challenges, unemployment, equality, and poverty. Thus, this study seeks to explore the conditions for the development and growth of the pharmaceutical industry in KZN.

1.4 Research Aim and Objectives

By drawing from the Political, Economic, Sociological, Technological, Legal and Environmental (PESTLE) analysis and Porter's Five Forces theoretical framework, the study aimed to critically analyse the growth dynamics of the pharmaceutical healthcare sector by looking at the conditions for development, limitations that are linked to regulations and contributions to economic growth in the province of KZN. Therefore, to achieve this, the study was guided by the following research objectives:

1. To critically explore how the high-tech pharmaceutical industry sector influences economic growth in KZN.
2. To investigate the conditions for development and employment growth of the high-tech pharmaceutical sector in KZN.
3. To examine the dynamics of growth and development linked to the healthcare sector in ensuring sustainable growth of the sector.

1.5 Research questions

The study was guided by the following research questions:

1. What influence does the high-tech pharmaceutical industry sector have on economic growth and development activities in KZN?
2. What are the conditions for the development and employment growth of the pharmaceutical sector in KZN?
3. How are the dynamics of growth and development linked to the healthcare sector in ensuring the sustainable growth of the sector?

1.6 Significance of the research

There has been a restructuring of the global pharmaceutical industry since the early 1990s (Malerba & Orsenigo, 2015). This restructuring happened in pharmaceutical production and manufacturing, which resulted in the development of “centres of excellence” where companies focus their production and manufacturing activities on a selected number of countries. In line with this, Nielsen et al. (2017) believe that such decisions regarding choosing the destination of choice are driven by countries that value the combination of skills, geographic location, and provisions of government investment and incentives that the country provides This aligns with the framework of the Sustainable Development Goals (SDGs) that provide the framework of indicators and goals which are designed to guide national implementation of sustainable development by 2030. Therefore, this exploratory study sought to gain a comprehensive understanding of the conditions of development and growth of the pharmaceutical industry in KZN.

This study's significance is borne out of the impact and influence that the pharmaceutical industry has on economic growth and development, particularly in developing countries such as SA. Thus, this study has the potential to ignite the impetus for the KZN government to place more emphasis on and assign adequate resources to promote the sector.

1.7 Justification of the study

High levels of youth unemployment, stagnant economic growth, a lack of robust industrial policy, and many other challenges are prevalent in the KZN economy. The pharmaceutical industry has been viewed as the sector with the potential to generate infrastructure, jobs, technology, innovation, easy access to medications, and, most importantly, to address social and economic challenges. Therefore, this study will be useful in the KZN province, which is crippled by such challenges.

1.8 Dissertation structure

Chapter 1 presents an overview and gives the background of the study. The research objectives, research questions and research problem are stated.

Chapter 2 reviews relevant literature in a continental, African and SA context in relation to the phenomenon under investigation. The focus of the chapter is to unpack the objectives of the study, by looking at the economic impact of the pharmaceutical industry. Also, analysing direct and indirect contributors to the economy by the pharmaceutical industry - e.g. to GDP and other relevant issues such as how innovation and technology influence economic growth, global market dynamics, and impact on the pharmaceutical industry.

The chapter also looks at the support structures and logistics that are needed to support growth such as factors that will attract investment, the skills needed in developing a high-tech pharmaceutical workforce and how the regulatory environment helps support the growth of the pharmaceutical sector. Additionally, the chapter discusses the infrastructure needed for the pharmaceutical industry and what has been the contribution of innovation to grow the pharmaceutical sector.

Chapter 3 discusses the methodology applied in the study, including research philosophy, research design, data collection, sampling method, data analysis and ethical considerations.

Chapters 4 and **5** present the data collected from interviews and document analysis. The various themes and subthemes that emerged are discussed in **Chapter 5**.

Chapter 6 concludes the study. Recommendations are made and the limitations of the study are noted.

1.8 Chapter summary

This chapter introduced and gave a comprehensive background to the study. It outlined the research problem and highlighted the aims and objectives of the study. Lastly, the justification of the study and its significance was addressed, followed by the structure of the study.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter reviews relevant literature on the conditions for the development of the pharmaceutical industry and employment growth. In addition, the chapter reviews the pharmaceutical industry, its sustainable growth and its transformation. The status of the pharmaceutical industry in Africa is discussed, followed by an overview of the pharmaceutical industry: a case for SA, and the KZN development strategy. Finally, the chapter gives an overview and analysis of the PESTLE and Porter's Five Forces frameworks that underpin the study.

2.2 Pharmaceutical industry and sustainable growth

The growth and sustainability of the pharmaceutical industry can be described as achieving a more massive economy, by producing the volume of goods which accounts for Gross Domestic Product (GDP). For instance, Mensah (2019) argues that in advancing economies, development and growth have acquired prominence as the development of these economies strives for a better life for all. The author highlights that the procedures and objectives of development are subject to popular and democratic decision-making.

Economic development encompasses a wide range of actions aimed at establishing and sustaining a strong local economy. This includes improved economic well-being and quality of life for communities (Ahmed et al., 2018). Similarly, Audretsch et al. (2020) argue that economic development initiatives focus on retaining existing businesses, fostering growth and expansion, looking into novel ways to attract new start-ups, fostering employment creation, and encouraging company expansion.

The agenda of sustainable growth is also a priority for global communities. Thus, the international community has about 17 developmental goals they need to achieve by 2030. In 2015, more than 190 leaders committed to 17 SDGs (Rashed & Shah, 2021). Out of the 17 goals targeted, the 3rd goal of the SDGs is to achieve universal health coverage (Good health and well-being), including financial risk protection, access to quality essential healthcare services, and access to safe, effective, quality, and affordable essential medicines and vaccines for everyone (Royston et al., 2020).

The 8th goal of the SDGs is to promote inclusive and sustainable economic growth, employment, and decent work for all (Decent economic growth). Lastly, the 9th goal aims to build resilient infrastructure (Industry innovations and infrastructure), that will promote sustainable industrialisation and foster innovation. These are the three goals that are part of the united framework, which are linked to the pharmaceutical industry.

Despite these developments in sustainable development, Fankhauser and Jotzo (2018) argue that economic growth, climate action and social development are dependent more on investments made in the infrastructure, technological progress, and sustainability of industrial development.

DiMasi et al. (2016) describe the pharmaceutical industry as a collection of companies that manufacture ethical drugs and a wide range of consumable products. Furthermore, scholars such as Sharma et al. (2021) argue that the pharmaceutical industry is going through the internalization phase, with substantial opportunities for growth. Therefore, an environment comprised of a solid healthcare system is an important pillar for every socioeconomic development process, as well as a sound enabling policy environment for the pharmaceutical industry.

2.3 The transformation of the pharmaceutical industry

Empirical studies have shown that innovative activities contribute to economic growth or economic progress (Hysa et al., 2020; Maradana et al., 2017). Exploring how the high-tech pharmaceutical industry sector influences economic growth, the study unpacked the transformation phase of the pharmaceutical industry.

The pharmaceutical industry's roots may be traced back to apothecaries and pharmacies that provided traditional medicines as far back as the 1880s, referred to as the Middle Ages. During this time, the sole purpose was to provide a spectrum of therapies based on centuries of indigenous knowledge that was not founded on science; such development coincides with the development of the pharmaceutical industry (Barrett, 2022; Dutfield, 2020). A variety of social, cultural, and technological changes that influenced pharmaceutical discovery, development, and manufacture occurred in the late 19th and early 20th centuries. One of the most significant shifts came when universities began to push their faculties to form a more coherent understanding of current material and available information (Barrett, 2022).

During this period, in realising the opportunities of economic gains presented by the pharmaceutical industry, countries such as Switzerland, Germany, the United States of America (USA) and the United Kingdom (UK) emerged as the leaders who spearheaded the pharmaceutical industry as part of their strategy to stimulate the economy and drive sustainability in their respective countries, while Japan, South Korea and Israel became major sites for advanced biomedical research. China and India remain the significant producers of active pharmaceutical ingredients (APIs) that they make under contract for western firms, both originator and generic companies (Barrett, 2022)

Apart from discovering, developing and selling medicine, this industry always seeks to find ways of shaping or changing the policies, laws and regulations that affect it through various associations (Goodman, 2020). Barrett (2022) further reports that the industry transformation coincides with its transformation of regulation, which is characterised by regulatory oversight. Scholars such as Dutfield (2020) and Hourd et al. (2021) are of the view that the pharmaceutical industry invests a lot of resources in getting the legal and regulatory outcomes they desire. Part of it is pursuing governments, that what is good for the research-based pharmaceutical industry, is consequently good for the country.

2.4 The pharmaceutical industry in a broader context

2.4.1 The Global Strategy and Plan of Action

The 2030 Agenda for Sustainable Development Global Strategy and Plan of Action by the World Health Organisation (WHO) undertook a series of studies in relation to the local production of pharmaceutical products and the transfer of technology to assist developing countries (WHO, 2021).

WHO (2021) submits that the aim of the Global Strategy and Plan of Action on public health, innovation, and intellectual property (IP) must foster a fresh perspective on innovation and enable access to medicines, as well as support needs-driven essential health Research and Development (R&D) aligned with the objectives of the 2030 vision.

The International Federation of Pharmaceutical Manufacturers and Association (IFPMA) (2017) argues that a research-based pharmaceutical industry plays a vital

role in developing new medicines and vaccines to prevent and treat diseases and improve the lives of patients worldwide.

The IFPMA further states that by investing billions of dollars and thousands of scientific hours, it pushes the limits of science, fosters medical progress, and contributes to the prosperity of society (IFPMA, 2017). Notwithstanding this, global generic medicine demand in the last 20 years has seen an increase in the production of generic drugs and this shift is notable in developing economies such as Asia, India and China (Naude & Luiz, 2013).

These developing countries had no access to affordable medicine. Malefane (2020) examined the strategic position of developing countries in relation to local production. The author found that the strategic position taken by various governments in developing countries is to protect the local manufacturers from competing with imported medicine by providing high tariffs on imported medicines and incentives such as tax incentives when manufacturers export medicines.

The majority of global pharmaceutical sales originate from developed markets. For example, Akhtar (2013) indicates that the majority of global pharmaceutical sales originate from the US, European Union (EU), and Japan, and together they account for over 80% of the global market. Akhtar further indicates that global pharmaceutical sales have grown from US$ 334 billion in 1999 to US$ 773 billion in 2008, and further to US$ 776 billion in 2009, and nearly US$880 billion in 2011 (Akhtar, 2013). The US is the dominant pharmaceutical market, accounting for approximately 45% of global pharmaceutical sales, followed by Europe at 24% and Japan at 11% (Akhtar, 2013).

As per International Medicine Statistics (IMS) Health Inc. the highest regional global pharmaceutical sales were in North America with a 40.3% share in the year 2008, followed by Europe (32%) Asia, Africa, and Australia (11.8%) (Akhtar, 2013). A recent report by the European Federation of Pharmaceutical Industries and Associations (EFPIA) (2021) shows that this position has not changed much. This report further argues that developed markets still dominate the industry.

Figure 1 gives a global sales breakdown by region. It shows that in North America, the US and Canada accounted for 49.1% of world pharmaceutical sales in 2021,

compared to 23.4% in Europe. According to the International Quality and Value Institute Advisors (IQVIA) (2022), 64.4% of sales of new medicines launched during the period 2016-2021 were on the US market, compared with 16.8% on the European market, which is part of the top five markets. The EFPIA Report (2021) reports that the world pharmaceutical (prescription) market is worth $1,256,863 million as of 2021.

Figure 1: Breakdown of global sales by region

Source: EFPIA (2021)

2.4.2 Economic impact

Previous studies on the direct and indirect contribution to the economy by the pharmaceutical industry indicate that in industrialised countries, there is a consistent link between companies' performances and intellectual capital utilisation, which includes human capital, IP and structural capital (Chowdhury et al., 2019). Economic gain that involves intellectual capital efficiency is considered as the crucial factor in sustainable growth. These authors further affirm their argument that countries that succeed in innovation are able to determine their future growth and sustainability.

Horner (2022) indicates that a cornerstone of the pharmaceutical industry is the IP system, providing pharmaceutical companies with a system that allows them to recoup the costs of R&D through selling licensed drugs.

Moll (2019) reports that the economic and social footprint of the pharmaceutical industry in Europe demonstrates that the pharmaceutical industry invests most of its revenue in R&D, which is the main driver of the sector. Hence, the countries that invest in R&D have high-quality intellectual capital disclosure. Such countries have a better prospect of innovation, strategic management, attracting investment, higher productivity and improved market performance (Chowdhury et al., 2019).

Akhtar (2013) and Glasmeier (2017) define the concept of “Health” as both a cause and effect of economic development, and the pharmaceutical (High-tech) industry is especially recognized in the United Nations Millennium Development Goals as an actor that can contribute to economic development.

These authors argue that the pharmaceutical industry is classified as one of the most high-tech and capital-intensive industries. Simply put, it is considered the “lifeline” industry because its products play a crucial role in the remedy for those who need it most. In the overall economics perspective, Moll (2019) asserts that the industry forms part of Gross Value Added (GVA), through indirect, direct and induced economic impact.

According to Ostwald et al. (2020), economic impact analysis revolves around GVA, which is defined as output (at basic prices) minus intermediate consumption (at purchaser prices). It is a measure of the contribution to GDP made by an individual producer, industry, or sector. The sum of GVA over all industries or sectors, plus taxes on products, minus subsidies on products yields the GDP (Ostwald et al., 2020).

Ostwald et al. (2020) review *The Global Economic Impact of the Pharmaceutical Industry Report*. They make an argument on the economic impact created by the pharmaceutical industry. What these authors are saying is that the global pharmaceutical industry’s economic impact is twofold:

- First, through the production of pharmaceutical products, the industry contributes directly to world GDP and supports a high number of employees.
- Second, through its economic activity, the global pharmaceutical industry supports additional value creation and employment through its dependence on global supply chains.

These indirect economic effects, as well as economic effects induced by private consumption, are the global pharmaceutical industry's economic spillover effects (Ostwald et al., 2020). Additionally, industrialisation, infrastructure and urbanisation derived from industries that drive innovation, such as the pharmaceutical industry, are known to have positive impacts on economic development (Maradana et al., 2017; Xu & Li, 2022). Based on evidence from European countries, these authors argue that to enhance per capita economic growth, government methods/policies promoting innovation must be prioritised. Given the likelihood of reverse or bidirectional causality in some circumstances, policies that improve per capita economic growth (such as strategies to grow investment) would be preferable for bringing more innovation to the economy (Yang & Usman, 2021).

2.4.3 Employment effect

Previous studies indicate that pharmaceutical companies provide abundant job opportunities in their representative countries and to the local citizens (Ahmed et al., 2021). Thus, such companies are continuously in a contest to find knowledgeable employees with specific skills that can help them attain their financial objectives and provide value to their firms (Abualoush et al., 2018; Moll, 2019). The majority of these jobs are skilled jobs, in the fields of academia, clinical science and R&D. All of them combined contribute to maintaining a high level of knowledge base.

It is worth noting that the pharmaceutical industry has a distinctive way of generating economic opportunities in the form of indirect job opportunities. Such opportunities are derived from industries linked to the sector, which are the pharmaceutical logistics element, sales representatives and retailers (pharmaceutical) and wholesalers, and also direct opportunities in the form of skills, knowledge transfer and FDI (Ahmed et al., 2018).

Economic development capital that provides infrastructure support to improve employee performance is referred to as structural capital, whereas the capital employed is the final component of intellectual capital (Xu & Li, 2022). The transfer of technology is essential for economic development as it assists countries in the acquisition of knowledge. Moreover, a sector such as the pharmaceutical industry is centralized to understanding the processes, equipment-related knowledge and innovative industrial products, and it forms part of investing in knowledge

(Chowdhury et al., 2019). Additionally, process manufacturing for the pharmaceutical industry involves activities such as milling, granulation process, coating, and tablet pressing. All these processes are regarded as high-innovation technology which requires a skilled and semi-skilled workforce (Ahmed et al., 2018).

Many of the reviews analysing the pursuit of competitive advantage and accelerating economic growth argue that technology transfer contributes to overall economic growth by decreasing the reliance on imports, improving the local workforce, and increasing the reliability of supply (Chowdhury et al., 2019). Such attempts assist developing countries in attracting investment and improving market conditions, thus making it feasible for these countries to collaborate with developed countries. Xu and Li (2022) report that in most cases of the pharmaceutical industry, the collaborations are influenced by regulations and policies which are driven by national governments. Ahn et al. (2020) and Zuo and Lin (2022) are of the view that government support encourages companies to work with various partners, which contributes to diversified ecosystems.

Figure 2 below depicts a comparison between employment in the pharmaceutical industry and employment in the field of R&D, which has increased significantly over the years.

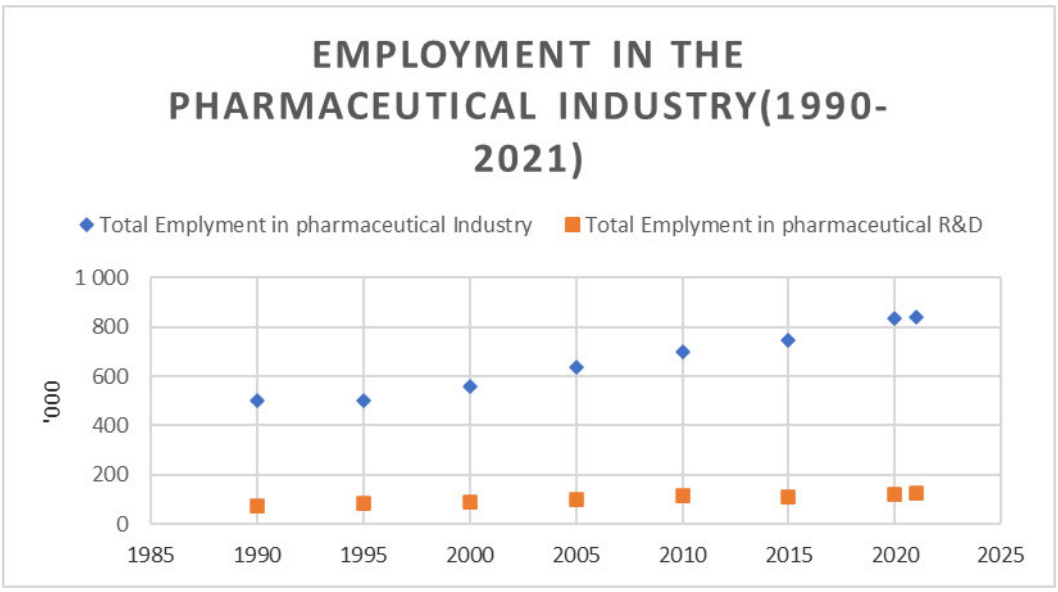

Figure 2: Employment in the pharmaceutical industry vs R&D (1990-2021)

Source: EFPIA (2021)

The above figure indicates that in 2021, total employment created in the pharmaceutical industry is estimated at 840 000 and employment in R&D is estimated at 125 000.

2.5 Status of the pharmaceutical industry in Africa

The following section discusses the conditions of development and employment growth for the high-tech pharmaceutical sector. The discussions involve unpacking the health strategies adopted by the African Union (AU), which are aimed at fostering the development of the pharmaceutical sector in Africa.

The AU developed the first Africa Health Strategy (AHS) for 2007-2015, which was endorsed by the 3rd Conference of African Ministers of Health. The strategy was adopted in 2008 (African Union, 2012). Furthermore, the AU Specialized Technical Committee on Health, Population and Drug Control (STCHPDC) also made recommendations that suggest there must be a revised Africa Health Strategy, which will be implemented from 2016 to 2030.

The AHS policy framework is based on a variety of regional and global health policy commitments. Agenda 2063 “The Africa We Want" and the 2030 Agenda for Sustainable Development, including the SDGs, are two of the most important. Other policy frameworks reinforced by AHS 2016-2030 include the sexual and reproductive health and rights continental policy framework, which extended to the Maputo Plan of Action (2016 to 2030), the Pharmaceutical Manufacturing Plan for Africa (PMPA), the African Regional Nutrition Strategy (ARNS) 2015-2025, the various AU Abuja commitments, calls, and declarations aimed at combating AIDS, tuberculosis, and malaria in Africa, and the Catalytic Framework to End AIDS and Tuberculosis by 2030, in addition to the Global Strategy for Women, Children and Adolescent Health (African Union, 2016).

The AU report emphasises that the AHS 2016-2030 is to provide strategic direction to Africa’s member states in their efforts to create better-performing health sectors, by recognising the existing continental commitments and addressing key challenges confronting efforts to reduce the continent's disease burden, primarily by drawing on lessons learned and capitalising on existing opportunities. Its strategic orientations necessitate cross-sectoral collaboration, proper resources, and leadership to

promote execution and guarantee effective responsibility for results (African Union, 2016).

2.5.1 Overview of the pharmaceutical industry in Africa

African Union (2016) indicates that in addition to pandemics, Africa is faced with a significant and growing non-communicable disease burden. These diseases are major public health issues and such diseases are projected to increase over time, and intervention strategies need to be in place. Despite these non-communicable diseases in the sub-Saharan region, acute funding shortages and competing interests of industry players remain a significant challenge in the health system (Juma et al., 2019). The competing interests that were highlighted by these authors are for example, tobacco and alcohol.

Recent studies projected these estimates as 60 million people with hypertension, 1 million cases of cancer annually and 18.6 million people with diabetes (Charlson et al., 2018; Murray, 2022). Notwithstanding these narratives, the WHO Report (2015) indicated that Africa could be on the brink of economic takeoff, such as China 30 years ago and India 20 years ago.

2.5.2 Industry size and participant analysis

The PMPA report by the AU stated that the African pharmaceutical market accounts for a small portion of the global pharmaceutical industry. Industry Outlook Research report titled ‘African Pharmaceutical Market’ highlighted that Africa is the only pharmaceutical market where high growth is still achievable, given the size of the market (Signé, 2018).

Signé (2018) found that in 2017, the value of Africa’s pharmaceutical industry jumped to USD$ 28.56 billion, compared to USD$ 5.5 billion a decade earlier. The author further reported that growth is continuing at a rapid pace, indicating that the Africa market will be worth USD$ 56–70 billion by 2030.

This creates the opportunity for multinationals and pharmaceutical companies to seek new sources of growth as developed markets stagnate, while patients will also gain access to medicines previously unavailable on the continent. (Signé, 2018).

New sources of growth, as reported above, could bring opportunities of collaboration for the developing countries and contribute to economic growth.

The AU comprises 55 countries, each one with relevant differences in terms of health systems and pharmaceutical manufacturing capacity. According to Ussai et al. (2022), there were around 600 pharmaceutical manufacturers in Africa by 2020, with 80% of them concentrated in eight countries: Egypt, Algeria, Morocco, Tunisia, Nigeria, Ghana, Kenya, and SA. Only four nations had more than 50 manufacturers, while 22 unfortunately had no domestic manufacturers. Around 25% of the 600 were multinational or global companies.

2.5.3 Market dynamics

In most developing countries, industrialisation has started to show some progress (Signé, 2018). The author opines that such development is an indication that the manufacturing revolution is imminent. Based on facts and trend analysis, the Pharmaceutical Sector Development in Africa report by Lartey et al. (2018) provided an analysis of the market drivers, which are factors influencing the demand for the pharmaceutical healthcare sector. The authors indicated that there are three main drivers of increasing urbanization—capacity (skill), supportive business environment and industry. According to (Ahmed et al., 2021) recent studies that are re-investigating the pharmaceutical industry factors, indicate that while they agree with the Lartey et al.'s (2018) views relating to the drivers, they believe that over and above supportive business environment and skills capacity, proactive eco-innovative environmental strategies are currently the main driver for a sustainable environment (Ahmed et al., 2021).

The AU's PMPA report of 2012 report identified two factors that contribute to the sector growth—economic and medical factors. Economic factors are population growth, healthcare expenditure, investment in Healthcare and disposable income. Medical factors are growth in pandemics, improving health insurance, an ageing population, and lifestyle diseases.

The PMPA report suggests that Africa's pharmaceutical markets are expanding in all segments, with prescription medications expected to increase at a compound annual

growth rate of 6.5% between 2017-2030, generics at 10%, over-the-counter medicines at 7.1%, and medical devices at 12.1% (Goldstein & Lee, 2020).

Table 1 below is an analysis of the market share of pharmaceutical companies in Africa.

Table 1: Analysis of companies' market share in Africa

Company name	Country of origin	Market share (%)
Adcock Ingram	SA	12.1%
Novartis	Swiss-American	11.5%
Merck & Co.	USA	9.7%
Johnson & Johnson	USA	8.8%
Pfizer	USA	8.8%
Sanofi	French	7.4%
Bayer	Germany	7.1%
Roche	Switzerland	6.9%
Aspen	Australia	5.21%
Cipla	India	5.0%

Source: Goldstein and Lee (2020)

According to Holt et al. (2015), 37% of African consumers are concentrated in 30 cities, with more consuming households than Australia and the Netherlands combined.

Addressing supply and distribution challenges, building stronger teams and forging partnerships are the "to win strategies" as global pharmaceutical companies need local business partners like manufacturers, packaging companies and distributors to help them navigate the continent's many markets. Widely varying consumer preferences, price points, manufacturing, and distribution infrastructures is something that needs to be explored.

2.5.4 Pharmaceutical manufacturing in Africa

The reviewed literature associated with market dynamics and industry size for the pharmaceutical industry in Africa indicates that industrialisation in Africa is imminent. The below section discusses the policies and strategies for the pharmaceutical

production sector in Africa, to address the infrastructure and accessibility needed for this industry.

Research commissioned by the United Nations Industrial Development Organisation (UNIDO) shows that the economics of pharmaceutical production are highly complex (Russo & Banda, 2015). The pharmaceutical industry is regarded as highly capital-intensive and access to capital is a significant hindrance, according to the report. Russo and Banda (2015) further highlight that there are various sources and mechanisms by which companies can access capital, such as foreign direct investment and equity debt, however, for this engagement to be successful is purely dependent on the dynamics of the pharmaceutical manufacturing system in a country.

Banks (2022) reports that African leaders have committed to create an enabling environment where every individual on the continent may be able to optimise their development potential, which allows more entrepreneurs to partake in the sector.

The PMPA report highlights that the context within which pharmaceutical manufacturing operates is determined by stakeholders such as trade associations and national medicines regulators, which include various ministries like Health, Finance, and Industry and Trade. They all form part of the system as stakeholders.

Akhtar (2013) reports that in the case of India, the government has been involved in growth and development of the pharmaceutical industry since the late 1980s, and ever since, the industry has flourished at an accelerating rate.

Steele et al. (2020) opine that policies, plans and legislation are necessary to create a pharmaceutical industry that is self-sufficient in medicine and medical supplies, which also involves medical devices. It requires political commitment and thought leadership at the highest level. These authors conducted a survey during the pandemic phase in Ethiopia, Kenya, Liberia, Mali, Nigeria, Sudan, and Tanzania and it was acknowledged that the government assisted in enhancing local pharmaceutical manufacturing. Without such commitment, the national production of pharmaceuticals will not flourish (Steele et al., 2020).

Governments in the respective countries within the AU have an important role to play. Strengthening domestic pharmaceutical systems involves strengthening the building blocks of health systems, which include laws, governance, regulatory systems and policies, innovation, R&D, manufacturing, and trade; financing; human resources and information (Ussai et al., 2022).

Buse and Hawkes (2015) argue that success in realising the agenda requires a paradigm shift by ensuring leadership for intersectoral coherence and coordination. Serem (2016) reports on the overall objective of the African Development Bank (AfDB) Group, which is to support economic development and social progress of African countries by promoting investment of public and private capital in projects and programmes designed to reduce poverty and improve living conditions. Combating poverty is at the heart of AfDB's efforts to assist the continent to attain sustainable economic growth (Serem, 2016).

AfDB's position on an overall strategy for the African pharmaceutical sector—to meet investment targets, all relevant public and private players which are development finance institutions, regional economic communities, governments, pharmaceutical companies, private equity funds, and banks on the continent—have to be mobilised, considering their specific and comparative advantages (AfDB, 2021).

The AfDB responded to the call from the AU. According to AfDB (2021), the AfDB has taken a leadership role in consolidating Africa's aspirations into a continental Africa 2030 Vision and Action Plan to close the policy gap for African countries, and regional development communities, to provide an integrated platform for dialogue and financing for a strong pharmaceutical sector. AfDB (2021) highlighted that for unlocking the potential of Africa's manufacturing industry, they propose a sustainable strategy for the industry that consists of well-balanced necessities, which are self-sufficiency and the ability to respond to anticipated growth for non-communicable diseases, and increased R&D capacity to address continental competitiveness (AfDB, 2021).

The AfDB report entails a clear vision and a clear mandate to implement a pathway toward the new order, strengthening the maturity of the pharmaceutical industry, boosting local production capacity, and encouraging market and regulatory

conditions to fund the growth of Africa's local pharmaceutical industries (AfDB, 2021). This report further indicates that an estimated USD$111 billion will be provided by 2030. The sum of USD$11 billion will be to develop the industry and $100 billion to develop the supporting infrastructure and this will be done to support the continental vision (AfDB, 2021).

2.6 An overview of the pharmaceutical industry: A case for South Africa

The following section gives an overall view of the SA pharmaceutical industry—size, local production strategy and policies that regulate the sector.

Mackintosh et al. (2015) argue that SA is the most industrialised economy on the continent, and is a key player in facilitating the industrialisation of the region, primarily within the Southern African Development Community (SADC). These authors elaborate on SA's advanced capital markets, large corporates, established development finance institutions (DFIs) and the depth of its industrial and engineering capabilities have the potential to play a critical role in uplifting the region.

Since the IPAP was first introduced in 2007 to promote structural transformation and diversify the SA economy, pharmaceuticals have been a priority sector under the more sector-focused industrial policy that SA has pursued.

The pharmaceutical sector was one of the four main sectors in the original IPAP, along with chemicals and plastic manufacturing, and it has continued to receive special emphasis in successive revisions. Horner (2022) is of the view that this has assisted the sector in qualifying as eligible for preferential access to government investment incentives and procurement for advancing manufacturing.

The concept of economic development is based on industrialization, in particular, the expansion of element manufacturing (De Gobbi, 2022). It is then not surprising that the SA government has shown keen interest in the local manufacturing of pharmaceutical products to stimulate investment, jobs, and affordable drugs (Horner, 2022), which confirms that the government has both health and industrial interest in the Pharmaceutical sector.

The SA government has attempted to create an enabling environment for the pharmaceutical sector to develop, with two departments dedicated to the sector: the DOH and the DTIC (Horner, 2022).

The SA government further implemented the policy known as National Drug Policy Number 27 of 1996 to address equity in essential drug distribution and its main objectives include drug availability, accessibility, and quality of drugs. This confirms the government's commitment to the growth of the pharmaceutical sector and the local manufacturing of essential drugs is one of the National Development Goals (Horner, 2022).

2.6.1 South African Industry Size

Horner's (2022) report indicates that although SA is the largest manufacturer and supplier of pharmaceuticals in sub-Saharan Africa, it is highly reliant on imported products. The Department of Trade, Industry and Competition (DTIC) estimates that imports represent more than two-thirds of pharmaceutical sales and that generic medicines account for in the region of 40% of pharmaceutical sales.

This report further highlights that with sales of generics growing twice as fast as patented drugs, generic sales are expected to surpass patented drug sales by 2027, which then opens more opportunities for either FDI or Domestic Direct Investment (DDI) (Signé, 2018).

2.6.2 Local Production Strategy

Aspen Chief Executive Officer (CEO), Stephen Saad, reported that at the beginning of 2021, the suspension of exports from India delayed the rollout of SA's national vaccination programme, bringing into sharp focus the need for self-sufficiency. The COVID-19 pandemic underscored the critical societal role performed by the pharmaceutical sector and the importance of reducing SA's reliance on imports (Veitch, 2022)

The World Health Organization (WHO) (2017) asserts that local production of pharmaceuticals and medical technology products are of strategic importance to the government, which aims to reduce the country's reliance on imports.

Consequently, countries such as China have policies that promote the local production of pharmaceutical products and protect public health, which has put them in the position where they are referred to as world factories, apart from their lower manufacturing cost (Naude & Luiz, 2013). Investing in pharmaceutical manufacturing capacity could create a substantial number of jobs and potentially improve access to medicines (Naude & Luiz, 2013).

Available literature mostly indicates that governments throughout the world support high-technology industries, implying that the industry plays an empirical role as an economic driver (Asher & Novosad, 2017).

South African Economic Reconstruction and Recovery Plan (SAERRP) interventions are in pursuit of the NDP goals. Some of the interventions include the programme to drive industrialization through a localization strategy, which seeks to achieve strategic objectives such as reducing the proportion of imported intermediate and finished goods, improving the efficiency of local producers and developing export competitive sectors that can expand the sales of SA-made products on the continent and beyond (Department of Trade Industry and Competition [DTIC], 2020).

Contrary to what the government is planning, Naude and Luiz's (2013) Industry Analysis of Pharmaceutical Production in SA, claimed that it would have been easy to establish a pharmaceutical manufacturing plant by merely contracting the production to an existing manufacturer with spare capacity, which is also known as "contract manufacturing". The process comes with its advantages and disadvantages. On the other hand, the view taken by Gautam and Pam (2016) is that the benefit of economies of scale global manufacturing outweighs any potential incentives for local production (Horner, 2022).

Naude and Luiz (2013) listed the following obstacles that the local pharmaceutical manufacturing industry must overcome:

- **Manufacturing capacity**

Anyakora et al. (2017) assert that pharmaceutical companies need to invest in both facilities and quality management systems to achieve Good Manufacturing Practice (GMP) compliance. GMP is a system that consists of processes, procedures and documentation that ensures that the manufacturing of products, such as food,

cosmetics, and pharmaceutical goods, is consistent and controlled according to set quality standards (De Gobbi, 2022; WHO, 2015).

According to Naude and Luiz (2013), the United Nations (UN) confirms that even though there is increased investment and operating cost involved in setting up a GMP facility, it does not mean that the international standard of production cannot be competitive. The successful set up of an academic GMP facility requires striking a unique balance between commercial and academic priorities. Naude and Luiz (2013) base their point of view on the costs. They made a comparison with Asian manufacturing plants and found the unit costs of the local factories were five times higher. The authors further report that economies of scale lead to a loss of competitiveness in terms of prices of locally produced medicines when compared to imports (Naude & Luiz, 2013).

- **South African Drug Policy**

Since 1994, the SA government has introduced various policies. The Minister of Health appointed a Drug Policy Committee to establish the NDP, which has three objectives: health, economics, and national development. The aims of developing the committee are the rationalization of pharmaceutical services, a pricing plan for drugs used in the private and public sectors, a plan for testing and evaluating drugs, and strategies for increasing the use of generic drugs. Naude and Luiz (2013) opined that such moves or shifts from the government side have an impact on local manufacturers in terms of profitability for production.

- **Skills shortage and pharmaceuticals knowledge sector**

The PMPA suggests that the system requires specialised skills in several disciplines, including pharmacy, chemistry, engineering, and life science management (strategy, financial operations, logistics and commercial law). Naude and Luiz (2013), in an industry analysis report on the pharmaceutical industry, highlighted that government focus on primary health has diminished the focus on tertiary health care, citing the decline in SA government funding of tertiary education in universities.

2.6.3 Policies and regulations of the sector

2.6.3.1 Enabling policies

De Gobbi (2022) reports that governments are responsible for developing policies and laws that regulate the operation of the pharmaceutical industry. Moreover, a government's ability to provide incentives for producers and, where necessary, impose sanctions on them, determines the overall efficiency of the sector (De Gobbi, 2022).

Expansion of the private sector within the pharmaceutical industry has resulted in a call for stronger regulation to promote high quality and price competitiveness. The pharmaceutical sector has a broad range of regulatory activities and includes factory licensing, product registration, quality monitoring, pharmacovigilance, and IP oversight. All of these regulations are to ensure efficacy, safety, quality and access to essential medicines intended to protect human and animal health and safety and the environment (De Gobbi, 2022).

Although not explicitly addressed in many publications, Criscuolo et al. (2022) argue that policy and compliance uncertainty appear to have a negative impact on innovation. Their argument is based on the fact that multinational corporations or companies delay investment and thus innovation decisions. In contrast to their argument, they are also of the view that flexible regulations tend to stimulate innovation by increasing the implementation freedom for businesses to develop cost-effective and appealing solutions.

Across Africa, a plethora of policies have been put in place to overcome some of the hurdles relating to the development of the pharmaceutical sector, such as the National Drug Policy, Medicine Regulation Policy and Pharmaceutical Procurement Policy. The South African Health Products Regulatory Authority (SAPHRA) strategic plan 2021-2025 report refers to the NDP, Vision 2030 NDP as the blueprint for the SA government that aims to eliminate poverty and reduce inequality by 2030. The NDP focuses on providing quality healthcare for all (SAPHRA, 2020). Implementation of the NDP is translated into the Medium-Term Strategic Framework (MTSF) 2019-2024.

However, with all the regulations aimed at overcoming various hurdles in the Pharmaceutical and Agricultural biotechnology sectors, issues of IP have remained the centre of discussion amongst various scholars who are of the view that Trade Related Property Rights (TRIPS) agreements are not in favour of the developing countries (Richards, 2020). This author further implies that economic evidence relating to the impact of such agreements on export performance, economic growth and FDI indicates that developed countries are in a position to exert their political power and economic power over developing countries. SA is not immune to the above policy uncertainties that seem to be prevalent in the sector (Brandl et al., 2019; Richards, 2020).

2.6.3.2 Defining the policies

- **National Drug Policy**

The policy was adopted in 1995 and endorsed by WHO to promote access to safe, quality medicine. This policy was purely adopted to serve the healthcare needs of all South Africans. The Review Policy and Strategies for the pharmaceutical sector in Africa (2019) refer to the policy as a policy that promotes local production of essential medicine, which is critical for the development of the pharmaceutical manufacturing industry.

- **Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)**

This Act provides for the control of medicines and scheduled substances by controlling the registration of medicines and other medicinal products to ensure their safety, quality, and efficacy. The Act was amended in 2004 to regulate the price at which manufacturers sell medicinal products in the private sector. The government firmly believes in equality and the SEP is to ensure transparency and prevent overcharging.

- **The Pharmacy Act, 1974 (Act No. 53 of 1974)**

Regulates the trade in pharmaceuticals and defines the responsibilities of pharmacists.

2.6.4 KZN Development Strategy

The KZN Industrial Development Strategy (2020-2025) focuses on identifying and executing interventions that will maintain and expand current firms or existing

businesses as well as attract investment in new business in the province, as stated in their strategic plan report (KZN Strategic Plan, 2020-2025). The provincial five-year plan includes various sectors that have been identified as priority sectors, which are agri-processing, automotive, chemicals and pharmaceuticals, metal and wood products, maritime, tourism, transport, and logistics. These sectors form part of provincial strategic pillars which are the industrial economic hub, maritime, aerotropolis tourism, environmental management, and radical economic transformation (Economic Development Tourism and Environmental Affairs [EDTEA], 2022).

Inclusive economic growth is listed as a strategic objective for KZN in a revised Provincial Growth and Development Strategy (PGDS) for 2035. This strategy focuses on more labour absorption, increased competitiveness to grow the production base, withstand international competition, raising net exports, growing trade as a share of the global economy, and improving the composition of trade, as well as improved support to a variety of businesses, including small businesses, by lowering regulatory burdens or costs of doing business (EDTEA, 2022).

Through the EDTEA, the vision of the KZN Province alludes to the “Attainment of radically transformed growing, inclusive, innovative, and sustainable economy, thereby optimizing employment” (EDTEA, 2022). The Department has on its own adopted MTSF, which aims at addressing the issues of unemployment, achieving a more capable state and driving an inclusive economy.

2.7 PESTLE analysis framework

This study is underpinned by PESTLE and Porter’s Five Forces model as a conceptual framework.

Francis Joseph Aguila, a general management and strategic planning scholar, developed the PESTLE framework as a tool to conduct environmental scanning (Aguilar, 1967). Over the years, the tool has been enhanced to adapt to changing business environments by adding environmental and legal factors by author Arnold Brown of life science (Yüksel, 2012).

Saltamarski (2021) reports that external factors are important in the decision-making process where strategic management is concerned. The PESTLE analysis is

regarded as a mandatory method that analyses the factors relevant to any sector's environment. It gives information that allows organisations to predict a situation, influence decisions and develop competitiveness (Matovic, 2020). Yüksel (2012) refers to strategic analysis as the first basic stage of strategic management that involves current factors relevant to the environment in which companies operate (Yüksel, 2012). Therefore, theories have a significant impact on understanding certain events. For example, Frederickson et al. (2018) claim that to grasp what we are doing or studying, we need a framework or structure to understand the consequences, causes, and decisions in the simplest terms and hence we need a theory to guide us. Frick and Rodríguez-Pose (2023) opine that three main factors drive the investment, being political stability within a country's business environment, labour costs and government support. Furthermore, the cost of energy and general infrastructure plays a vital role in influencing the investment decision. While this research aims to analyse the factors that influence the functioning and development of the pharmaceutical sector, the researcher employed the PESTLE framework to assess the factors linked to the framework as a potential influence on economic and employment growth.

The PESTLE Framework is made up of the following factors:

- **Political**

These factors determine the extent to which a government influences the economy or a certain industry (Rastogi & Trivedi, 2016). There are few empirical studies on sector development and economic growth and in most of them, the question raised by these scholars is how government policy matters in the manufacturing sector development (Minniti, 2008), which also involves sectors like pharmaceutical industries. Asher and Novasad (2017) argue that companies rely on governments to provide various services, starting from tangible public infrastructure to intangible institutions like the rule of law. The quality and efficiency of this service provision is a primary predictor of income differences across countries.

Government willingness to support is important in creating the sustainability of the pharmaceutical industry (Chan et al., 2018). The current study highlights the enabling policies that regulate this industry and which are embedded within the NDP

through the DTIC, Minister of Health and Economic Development and Environmental Tourism Affairs Department, at the provincial level.

FDI plays an important role in local economic development (Zhang et al., 2019) and the SA Government encourages FDI, opining that it is necessary to support the country's growth and development objectives (Sunde, 2017). Görg et al. (2020) report that there is growing consensus that private rather than public investment is required to generate long-term prosperity on the African continent, particularly through the creation of long-term sustainable employment. FDI and DDI are thus critical in stimulating much-needed economic growth and development. Perera (2017) reports that the political environment is significant in a country's operational risk, especially where FDI is involved.

The political environment determines the extent to which government and government policy impact an organisation or a specific industry. Policy and stability are the main factors although some authors also include fiscal and taxation policies (Perera, 2017). When analysing the PESTLE analysis framework, there is a need to ask what government policies, political elements, or groups could benefit or disrupt the success of your business. Therefore, this is relevant to this study in ascertaining the political influence on industry development and growth in the province.

- **Economic**

Economic factors are determinants of an economy's performance that directly impact a company and have resonating long-term effects (Rastogi & Trivedi, 2016). Authors such as Sabir et al. (2019) make arguments in both theoretical and empirical literature, which show that economic prosperity is associated with significant inflows of FDI into a country. Sunde (2017) investigated the theories of FDI, various economic variables that influence FDI, the effects of economic integration on the movements of FDI, and the benefits and costs of FDI.

A country's performance relies solely on economic factors (Perera, 2017). Economic factors include income level, age structure, disposable income from the country, employment rate, inflation rate, and education level. Perera (2017) opines that all this needs to be assessed before making an investment decision and the unfavourable could mean that the industry is unattractive. On the level of education,

Yüksel (2012) believes that high levels of education in a country will provide employers with a healthy pipeline of potential employees, which will also contribute to the competitiveness of the country.

For the current study, information on economic impact factors will assist in decision-making for the KZN province.

- **Social and Cultural**

The sociological factor takes into consideration all events that affect the market and community socially (Rastogi & Trivedi, 2016). Trade openness and economic growth openness are viewed as the drivers of economic growth, which are linked to the ethics structure of an individual culture (Malefane, 2020).

The business environment is likened to the traditional and cultural values of the country. Perera (2017) reports on the importance of adapting to the values which may lead to better performance, contribute to higher productivity and achievement of desired growth targets. The social and cultural factors are not paramount, especially after the Cannabis industry has been legalised. It involves traditional healers who are linked to traditional and cultural values.

- **Technological**

These factors pertain to innovations in technology that may affect the operations of the industry and the market favourably or unfavourably (Rastogi & Trivedi, 2016). Technical variables take into account the rate of technological innovation and development that may have an impact on a market or business. The pharmaceutical sector is R&D-driven, as indicated in the recent study by Kamiike (2020). Kamiike (2020) reports on the case of the Indian pharmaceutical sector, and how it gained its production self-sufficiency and became one of the largest drug exporters in the world since the late 1980s, till today. The findings of Kamiike (2020) indicate that it was due to a shift in focus and investment in R&D that was the major shift that India applied, which therefore put them in a greater competitive position.

Schuhmacher et al. (2016) report that the pharmaceutical industry is more of a technical competency industry, and R&D efficiency can increase the competitive advantage. It is then relevant to emphasise technology transfer, which is the process whereby technology is shifted from one location to another to be applied to a final

product (Varley, 1994). According to De Gobbi (2022), technology transfer can occur within a country, from one sector or firm to another, or the transfer may be from one country to another.

- **Legal**

Certain laws affect the business environment in certain countries, while there are certain policies that companies maintain for themselves.

Perera (2017) believes that adhering to legal consequences can derive a strategic advantage. This will also ensure that the industry or company is ethically directed and promotes the concept of ethics in the sector.

The SAPHRA is a regulatory body that is tasked with monitoring, evaluating, inspecting and registering all health products (Moeti et al., 2023). Healthcare is one sector that is exposed to more inter-governmental interference because of its nature. Zaboli et al. (2016) found that such interventions and oversights have frequently been justified by economic theories of healthcare market failure and the vital role of pharmaceuticals in public health. Issues of red tape should not be a hindrance to sectorial growth. The current study might not be able to ease any of them, however, highlighting them might be of use to other researchers in future.

- **Environmental**

These factors include those that influence or are determined by the surrounding environment. Environmental factors of the business environment include climate, weather, geographical location, global changes in climate, environmental offsets, ground conditions, ground contamination and nearby water sources (Rastogi & Trivedi, 2016).

Perera (2017) describes it as an ecological or natural concern in business and refers to global warming, the industry's average carbon footprint and environmental pollution concerns, which are very close to the pharmaceutical Industry. The use of energy-efficient eco-friendly systems in manufacturing is what normally guarantees a competitive advantage, as it reduces associated costs of the sector.

Issues related to environmental impact are at the centre of the sector, and again, highlighting the issues around it might assist future researchers.

The PESTLE analysis framework enables an organisation to conduct a thorough analysis of multiple external environment elements. This is achieved through data collection on the political environment and economic developments, allowing organisations to have a better grasp of how to adapt their strategic management and decision-making processes to the environment around them.

2.8 Porter's Five Forces Model Framework

Porter's Five Forces model assists in analysing the pharmaceutical industry attractiveness for the province.

While most authors indicate that local production is of strategic importance to the government, investment in pharmaceutical manufacturing capacity could create jobs and potentially improve access to medicine. Determining the competitive intensity and attractiveness of the industry is important, however, formulating strategy and understanding the competitive landscape could be the starting point.

Michael E Porter, of Harvard Business School, developed Porter's Five Forces model. It is a strategic tool used for assessing and evaluating the competitive strength and position of the business (Porter, 2008). Bruijl and Gerard (2018) are of the view that the origins of Porter's Five Forces concept may be traced back to industrial economics or industrial organizational theory. Market structure influences the behaviour of market contributors and the industrial organisation method assumes that the attractiveness of an industry in which an organization participates is defined by the market structure (Bruijl & Gerard, 2018).

The current study undertakes an analysis of the competitiveness of the pharmaceutical sector. In doing so, it examines the role of the pharmaceutical industry in job creation opportunities to eradicate poverty and expand economic activities.

Maresova and Kuca (2014) argue that Porter's Five Forces analysis can help organizations determine how patterns will influence industry rivalry and how organizations can position themselves for progress.

Goyal (2020) discusses the benefits of using Porter's Five Forces model and reports it is a model that views external analysis by moving away from using the SWOT

analysis approach, allowing companies to focus on their reaction, to change the external environment. Furthermore, the framework is interlinkable with PESTLE to assist in understanding and leveraging on dynamism.

2.8.1 Elements of Porter's Five Forces

Porter's Five Forces Industry Analysis framework distinguishes the following five elements:

- **Threat of new entrants**

It is not necessarily the actual entry of new competitors but the threat of new entrants to the industry that drives competition and impacts the industry's profitability (Mathooko & Ogutu, 2015). Factors include economies of scale, the capital-intensive nature of the industry, absolute cost advantages, access to distribution channels, government policy surrounding new entrants and potential retaliation or fallouts. The higher the threat of entry of new competitors, the lower the attractiveness of the industry.

- **Bargaining power of supply**

The framework tries to explore the impact of the bargaining power of the industry's suppliers and how much they can force the industry to share the benefits of value creation through this bargaining power. Mathooko and Ogutu (2015) state that in industry analysis, suppliers are defined as those organizations or individuals that provide the materials, information or knowledge to allow an organization to produce its goods and/or services. The higher the bargaining power of the suppliers, the lower the attractiveness of the industry.

- **Threat of substitution - the cost of change**

This is defined as an attempt to understand to what extent there is a possibility of the industry's output, manufactured product or the delivered services being substituted by some other category of products or services. As such, the threat of substitute is high if the substitute provides a cost-effective trade-off compared to the original product. According to Mathooko and Ogutu (2015), the higher the threat of substitutes, the lower the attractiveness of the industry.

- **Intensity of competitive rivalry**

This includes a number of factors, for example, the growth rate of the industry, the ratio of cost structure to the value-added cost of over-capacity, the impact of brand and its conversion to sales, switching costs, information flow, Information sharing complexity, diversity of competing businesses and last but not the least exit barriers. The higher the intensity, the lower the attractiveness of the industry.

- **Bargaining power of buyers**

This refers to the pressure that customers/consumers can put on businesses to get them to provide higher quality products, better customer service, and/or reduce prices. Mathooko and Ogutu (2015) believe that buyer power is needed, given that many buyers do not purchase in large volumes, relative to the size of a single vendor. The higher the bargaining power of the customer, the lower the attractiveness of the industry.

The identified weaknesses of Porter's Five Forces, such as its deficiency in quantifying the external factors, limits quantitative results, for the overall impact of the factors. Mathooko and Ogutu (2015) report that the government can exert legitimate influence in any given industry. Thus, the current study finds both frameworks useful as they expand the researcher’s knowledge of the problem under investigation. The framework may assist the industry and its shareholders in guiding the strategy and vision in decision-making by looking at all sector areas and identifying the best route for creating the optimal value of the sector. Consequently, the KZN province will benefit from this study by critically analysing the conditions of development and growth of the pharmaceutical industry, not only by conducting a tougher analysis but also by the impact of decision-making that might contribute to sector development and its growth.

2.9 Chapter summary

This chapter gave an overview of the pharmaceutical sector, its potential economic impact (direct and indirect impact) and its contribution to economic expansion and job creation. With regards to strategy, the chapter draws from the AU strategies that direct all its members of state in prioritising the pharmaceutical sector with an emphasis on the role of leadership, and the local economy as the element of economic drive and creating a sustainable economy.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

The chapter describes the chosen methodology and research design for the study, by elaborating on the sampling method, data collection and analysis. This chapter comprises various sub-sections, namely research paradigms, research philosophy, research design, research approach, research site, study population, sample size, recruitment strategy, data collection methods, data quality control, data analysis, and ethical considerations for the study.

3.2 Research philosophy

Worldviews or paradigms are described by Kivunja and Kuyini (2017) as a “collection of beliefs that direct action shared by scientists in agreement about how problems are to be understood to give a perspective or interpretation of the research data.” Similarly, Aliyu (2015) reports that “methodologies make an implicit and explicit assumption about the nature of the world and knowledge.” The authors confirm that it has been traditional to call particular combinations of assumptions paradigms, which is a way of thinking or school of thought.

In this study, it is believed that philosophical assumptions are what guide the researcher. This study's philosophical assumption is similar to and shared by authors such as Vasileiou et al. (2018) who argue that the philosophical assumption must be what guides the researcher before attempting to undertake the study. The selection of a research philosophy emerges from understanding which point of view seems to be the reality as perceived by the researcher. Moreover, Vasileiou et al. (2018) provide three philosophical assumptions—ontology, epistemology, and axiology, which are discussed below.

Ontology describes assumptions made by the researcher, to believe that something that makes sense to them is real, a sense of reality or existence, and what is believed to be factual or exists. Epistemology describes how the researcher came to know something, how they knows the truth or reality (nature of valid knowledge).

Axiology refers to the ethical issues demonstrated by the researcher, understanding what is considered to be right or wrong relating to the research being conducted.

3.3 Research paradigm

There are a variety of definitions for research paradigms. Kivunja and Kuyini (2017) define it as abstract beliefs and principles that shape the researcher's world as it is projected, and how the researcher interprets and also acts within that perceived world. Furthermore, it is projected as a lens through which a researcher examines the methodological aspect to determine the research methods that will be used and how data will be analysed (Kivunja & Kuyini, 2017). The research paradigms are grouped into main taxonomies, namely positivism, pragmatism and interpretivism and are discussed below.

3.3.1 Positivism paradigm

The positivism paradigm under objectivism epistemology is a methodological philosophy in quantitative research, it applies the methods of natural sciences to discover the study of social science (Pham, 2018). Park et al. (2020) concur, adding that ontologically, positivists believe that there are facts that can be proven, and the reality is the same, up until it is measured and proven. The current study is not classified as a natural science study, therefore, this worldview may not be applied to it as a scientific method of investigation.

3.3.2 Pragmatism paradigm

Pragmatism as a research paradigm refuses to get involved in contentious metaphysical concepts such as truth and reality. Instead, it accepts that there can be single or multiple realities that are open to empirical inquiry (Creswell & Clark, 2017). Different from positivism, it gives a researcher the possibility of choosing an acceptable research method from a wide range of qualitative or quantitative approaches (Kaushik & Walsh, 2019).

3.3.3 Interpretivism paradigm

This study is underpinned by the interpretivism paradigm. In this paradigm, the truth and knowledge are subjective as well as historically and culturally contextual and are dependent on people's experiences and interpretations of those experiences (Park et al., 2020). Contrary to positivists, who commonly accept only one correct answer,

interpretivism tends to be more inclusive since it embraces diverse points of view from individuals as the single phenomenon might have multiple interpretations (Thanh & Thanh, 2015). Understanding the individual and their interpretation of the world around them is prioritized in this process. As a result, the Interpretivist paradigm's central assumption is that reality is socially produced or constructed (Kivunja & Kuyini, 2017).

In this study, the researcher is under the assumption that the study participants are experienced and hold high positions in their respective institutions. It is assumed that they are knowledgeable about the phenomenon under investigation and also that they are credible. Furthermore, Vasileiou et al. (2018) argue that worldviews are better understood when examined considering their ontological, epistemological, and axiological foundations.

- **Ontology of interpretivism**

Interpretivism is concerned with knowledge and truth which are subjective and based on a variety of elements such as culture history, context and lived experience (Kivunja & Kuyini, 2017). Ontologically, this study presumes that the actuality or reality of conditions for development, and its limitations, are linked to regulations and conditions for economic growth in the province of KZN, which is the phenomenon underpinning the study.

- **Epistemology of interpretivism**

Epistemology describes how the researcher came to know something, how they know the truth or reality (nature of knowledge) (Kivunja & Kuyini, 2017). The epistemology will emphasize the nature and origin of knowing and the construction of knowledge, therefore, this study presumes that the participants selected for the interviews understand that the sector growth dynamics are linked to conditions of development, and the regulations guiding the sector in the province of KZN.

- **Axiology of interpretivism**

The axiology of interpretivism refers to the ethical issues demonstrated by a researcher, understanding what is right or wrong as the researcher (Kivunja & Kuyini, 2017). In terms of axiology and consistency with interpretivism, perceptions are determined by time and space of what is wrong or right in relation to conditions

for development and its limitations, which are linked to regulations and conditions for economic growth in the province of KZN. Therefore, this study assumed that the participants' lived experience and knowledge of sector growth dynamics are linked to conditions of development and the regulations guiding the sector in the province of KwaZulu-Natal.

3.3.4 Research philosophies utilised in this study

The study is exploratory. Multiple perspectives and visions of truth are what the study aims to explore. Alharahsheh and Pius (2020) argue that the adoption of the interpretivism paradigm can provide an in-depth understanding of certain contexts such as factors influencing a certain development, through the collection and interpretation of qualitative data. The interpretivist philosophy requires a small sample size, to be interviewed in depth to understand their perceptions and complexities around this study based on their experience. Interpretivism is considered different from physical phenomena because of human complexities, social realities, and circumstances. Therefore, this study applied interpretivism philosophy.

3.3.5 Research paradigms adopted by this study

The interpretive paradigm emphasises social context and human complexity as to how people understand the phenomenon (Rashid et al., 2019). Research respondents use their own words while relating their experiences and beliefs. The research questions seek to explore what elements need to be aligned or collaborated, which will perhaps contribute to the sector development growth in question.

3.4 Research design

This study adopted the principles of a qualitative research design. According to Creswell and Creswell (2017), a research design is a strategy and procedure that spans options from larger assumptions, describing information, and gathering techniques. Furthermore, it is viewed as a framework that provides guidance, and prior data collection, which then assist the researcher in achieving the research objective (Humphries, 2017). There are three types of research design—quantitative, mixed method and qualitative.

3.4.1 Quantitative research design

Queirós et al. (2017) state that quantitative research emphasises systematic empirical investigation using statistical and mathematical techniques to capture the data. These techniques seek to obtain accurate and reliable measurements that are allowed by statistical analysis. Creswell and Creswell (2017) emphasise that the approach therefore examines unbiased theories by exploring correlations among variables. The approach is constructed upon the positivist paradigm and believes that there are facts that can be proven where reality is the same, up until it is measured and proven, through the quantitative method.

3.4.2 Mixed-method research design

Mixed methods design studies involve the use of both qualitative and quantitative data in a single project. It represents an alternative methodological approach to traditional qualitative or quantitative research approaches. Mixed methods research capitalizes on the strengths of both qualitative and quantitative research while mitigating their weaknesses to provide an integrated comprehensive understanding of the topic under investigation (Halcomb & Hickman, 2015).

3.4.3 Qualitative research design

This study employed a qualitative research design. A qualitative technique is described by Creswell and Creswell (2017) as a technique that is intended to unpack and understand a complex reality and the meaning of action in a given context. Thorogood and Green (2018) state that questions such as how, why, and what of the phenomenon are what the technique seeks to answer or establish. Due to that, qualitative research often uses interviews that are structured or semi-structured. Language (as participants use their own words while relating to their experience), whether written or spoken, is normally used as data in qualitative research, however, images, videos, and other forms of behavioural records may also be used or considered (Haven & Van Grootel, 2019). These interviews generate qualitative data that tends to be inductive, that is not non-numerical data or qualifiable (Forman et al., 2008).

Moreover, the approach enabled the researcher to understand issues by investigating and analysing them in their context and the significance that humans

assign to them. Its rational generated meaning, purpose or reality from the opinions and experiences of participants, the techniques presented an opportunity for the researcher to acquire the unknown facts and real-life events as they are experienced (Asenahabi, 2019).

3.4.4 Research design adopted by the study

This study used the strength of qualitative design because it allowed the researcher to unpack and understand the complexity of the phenomenon under investigation. Qualitative research design was relevant to the study, and its use was necessitated by the nature of the phenomenon under investigation and its complexity. The utilisation of this design allowed the researcher to observe the behaviour, to acquire knowledge and experience from the individuals who are experts and have experience and understanding of the phenomenon under investigation.

3.5 Research strategy

This study adopted a case study approach as a research strategy. Forman et al. (2008), describe research strategy as an overall plan of research (qualitative, quantitative, and mixed method) including the process in which the research is conducted in the research design. The qualitative technique was chosen for the investigation, which is an inductive philosophical premise (Rashid et al., 2019). The inductive approach provides a framework for data analysis that can produce reliable and valid findings for the case study. The case study approach allowed the researcher to gain an in-depth understanding of the phenomenon and capture the context from the responses.

3.6 Research sites

This investigation was conducted in the eThekwini Metropolitan, which is the largest district municipality in KZN Province. Through this process, the first enterprise (private sector) selected to participate in this study was Megrotex (Ensemble Manufacturers) which is located in Pinetown. The second enterprise was Xylomed Pharmaceuticals in La Mercy. Thirdly, the public institution selected for the study was the DTP (SEZ) located in La Mercy. Lastly, the government institution mandated for the development and promotion of the pharmaceutical sector, the Department of Economic Development, Tourism and Environmental Affairs (EDTEA), in Pietermaritzburg.

3.7 Population

The population of this study comprised 2 160 individuals—1 200 (EDTEA); 80 (Dube Trade Port); 800 (Xylomed Pharmaceuticals); and 80 (Magrotex Pharmaceuticals).

3.8 Sample

Purposive sampling was used in this study to select 7 participants (see Table 2 below). Etikan (2016) describes purposive sampling as a non-random technique that does not need underlying theories or a set number of participants. This means that the study focused on gathering data from people who have knowledge and experience in the field. The researcher engaged only with companies that are on the ground and one that is in the process of putting a new manufacturing plant on the ground, which is a new project in the province. The study sample included an investment specialist, a Director of Sector Development, as well as executive directors of two pharmaceutical companies based in KZN.

Table 2: Sample size breakdown

Division/Organisation	Population	Sample size
Economic Development, Tourism and Environmental Affairs	1200	2
Dube Trade Port (Entity for EDTEA)	80	1
Xylomed Pharmaceutical	800	2
Magrotex Pharmaceutical Supply (Ensemble Medical Manufacturers)	80	2
Total	2160	7

3.9 Data collection method and description of the instrument

Data collection is a process of acquiring and quantifying information (McCusker & Gunaydin, 2015). There are two types of data—primary and secondary data.

i. Primary data (first-hand data)

ii. Secondary data (already available/ documents)

The data collection instruments in social science research are interviews, focus group discussions, surveys, and document analysis (Creswell & Creswell, 2017). For this study, interviews and document analysis were employed.

3.9.1 Interviews

Being an exploratory study, the data collection method was in the form of structured in-depth interviews with open-ended questions that gave the context and reflections of the respondents. Adhabi and Anozie (2017) describe an interview process as a discourse in which the researcher attempts to learn more about the phenomenon under investigation, posing questions to individuals to elicit information. The study followed a structured interview process, where open-ended questions were prepared by the researcher and posed to the respondents. From the response, follow-up questions were asked, which gave the researcher enough time to explore a subject as it was discussed. Before the interviews, the researcher shared the interview questions with the participants who had confirmed and discussed the context in preparing them for the recorded session.

Interviews were conducted with the Executive Manager of the Pharma portfolio at Dube Trade Port, the CEOs of Xylomed Pharmaceutical and Magrotex Pharmaceutical Supply (Ensemble Medical Manufacturers), as well as the Director of Pharma Sector Development at the Department of Economic Development, Tourism and Environmental Affairs.

Exploring the views, experiences, and beliefs of individuals participating in the sector was the main purpose of the research. The type of data collection tool chosen for the study allowed the researcher to probe further to unlock the information that perhaps the respondent might withhold knowingly or unknowingly.

In this study, the interview questions were aligned to address the study objectives. However, they were presented differently to private companies and government departments, simply because private and government have different mandates for participating in this sector. The mandate for the government is to facilitate, promote and develop economic growth, whereas private companies invest in their destination of choice and generate their revenue. Their contribution to the sector is aligned with the government strategy, which is to create jobs, develop skills and eventually

contribute to economic development. In the main, each existence is dependent on the other, hence their views and experience were significant in the contribution of the study outcome.

In terms of the interviews that were conducted, the study focused on the pharmaceutical sector, therefore within the Department a sector specialist and HOD were targeted for the study, based on the knowledge they have. For the private companies, knowledgeable individuals, such as the CEOs or the directors, were approached. These respondents were purposively selected to achieve the objectives of the study.

3.9.2 Document analysis and archives

Document and archives are secondary data regarding the phenomenon under investigation. This assists the researcher in reviewing the literature to comprehend the phenomenon under evaluation. In this study, secondary data from relevant extant literature was used to gain an in-depth understanding of the matter under investigation. Documents such as the Annual Performance Plan (APP), Annual Report (AR), Business Plans (BP), and financial statements from companies and departments were used.

3.10 Data analysis and presentation

3.10.1 Thematic analysis

For this study, the data analysis technique employed was thematic analysis. According to Vaismoradi et al. (2013), thematic analysis is a technique for detecting, analysing and interpreting patterns (or themes) in qualitative data. Some scholars such as Javadi and Zarea (2016) refer to it as a set of techniques used in analysing textual material and revealing themes emerging from the study field notes during the interview process (transcription), political documents and videos.

The main goal of thematic analysis is to identify themes and use the themes to address the research questions. According to Nowell et al. (2017), trustworthy qualitative research requires rigorous thematic analysis to produce insightful findings. These authors outline and discuss the approach of conduction, a trustworthy thematic analysis in the section below.

- **Phase 1: Familiarising yourself with your data**

It is critical that researchers engage themselves in the data to become acquainted with the breadth and depth of the content, and archiving the raw data provides an audit trail (Nowell et al., 2017). This phase involves repeated reading and analysis of raw data, searching for patterns and meanings. The researcher studied all the responses from the respondents in the interviews, to comprehend the meaning of what they were conveying.

- **Phase 2: Generating the codes**

Qualitative coding is a process of reflecting, identifying the important sections of the raw data, and indexing them as they relate to the theme (Nowell et al., 2017). In this phase, the specific statements from the interviews were analysed and categorized into specific themes, which were linked to the phenomenon under investigation. Numbers and keywords were used. The researcher allocated codes to the themes.

- **Phase 3: Searching for themes/classify response**

This stage entails categorising and organising all possibly relevant coded data extracts into themes (Braun & Clarke, 2006; Nowell et al., 2017). In this phase, the researcher goes through all the transcript notes from the interviews and segments the raw data into main themes and subthemes without abandoning any of the data. A miscellaneous category of data may be created for data that might not align with the created codes (Nowell et al., 2017).

- **Phase 4: Reviewing themes**

Determining a coherent pattern is critical in this phase (Nowell et al., 2017). For this study, a cross-case analysis was conducted on the pharmaceutical companies to determine the commonalities in their experiences in the developing phase pre-operation and beginning the process of the initiating phase. The researcher also cross-cased responses from the government sectors to identify common themes.

- **Phase 5: Naming themes**

In this phase, data may have overlapping themes. It is then important for a researcher to determine the impact that data makes on the selected theme as this will assist in the credibility of findings (Nowell et al., 2017). The researcher analysed

and refined the data to ascertain the fit in the determined themes, by proofreading the transcripts and listening to the recordings.

- **Phase 6: Producing the report**

This step includes a write-up of theme analysis, which should be logical, coherent and non-repetitive (Nowell et al., 2017). These authors emphasise trustworthiness and the audit trail. In achieving this, data must support the main points, and for credibility, all reports need to be discussed, even if the points do not necessarily correspond with the themes. For this study, it was important to analyse the themes and understand what the themes revealed in answering the research questions for the study, thereafter creating the case study.

3.11 Ethical considerations

3.11.1 Trustworthiness and credibility

Resnik (2015) defines ethics as a code of conduct that distinguishes between acceptable and inappropriate behaviour. There are various reasons why the researcher must act ethically, one of which is to minimize the misrepresentation of data, which is why the respondents must be equally attentive to the ethical concerns (Resnik, 2015).

Ethical considerations for this study were addressed by the researcher before presenting the research proposal to the University's Ethics Committee. On approval, the study proceeded. Permissions were obtained from the participating companies. All respondents were notified that participation was voluntary, that all information would remain confidential and that their anonymity was guaranteed. Furthermore, participants were informed that they could withdraw from the study at any time without suffering any prejudice. Before the interviews, the questions were shared with respondents to give them enough time to deliberate on those questions before the interview. An introductory letter was also shared with the respondents, indicating that their participation was purely voluntary and informing them of the objectives of the study.

In the current study, trustworthiness and credibility were applied accordingly, using the reflective journal and triangulation method. During the interviews, secondary data, including auditors' reports, annual reports and feasibility studies were used in

the verification of facts. The study was carried out in strict accordance with research guidelines and research findings will be characterised by consistency, truth value, neutrality, and applicability.

3.12 Limitations

It must be noted that every study has limitations. In this study, the response rate was well maintained, however, where executive members were not available, the researcher was referred to an appropriate substitute person within the same department, who was most capable of responding to the interview questions relating to the study.

3.13 Chapter summary

This chapter discussed the methodology employed in the study. It stated the research paradigms, followed by the research philosophy. The chapter also addressed the research design underpinning the study, the research approach, the research sites and the study population. The sample size and its appropriateness were addressed, followed by the recruitment strategy adopted in the study. The data collection methods, data quality control and data analysis were explained. Lastly, the ethical considerations and limitations of the study were discussed.

CHAPTER 4: DATA PRESENTATION AND ANALYSIS

4.1 Introduction

This chapter presents the primary data collected through interviews, and secondary data from documents, and archives. The purpose of the study was to critically analyse the growth dynamics of the pharmaceutical healthcare sector by looking at the conditions for development, limitations that are linked to regulations, and contribution to economic growth in the province of KZN. To achieve this, this study was guided by the research objectives and questions, as reflected in Table 3 below.

Table 3: Research objectives and questions

Research objectives	Research questions
1. To explore, how the high-tech pharmaceutical industry sector influences economic growth activities in KZN.	1. What influence does the high-tech pharmaceutical industry sector have on economic growth and development activities in KZN?
2. To investigate the conditions for development and employment growth of the high-tech pharmaceutical sector in KZN.	2. What are the conditions for development and employment growth of the pharmaceutical sector in KZN?
3. To examine the dynamics of growth and development linked to the healthcare sector in ensuring sustainable growth of the sector.	3. How are the dynamics of growth and development linked to the healthcare sector in ensuring the sustainable growth of the sector?

To critically analyse the growth dynamics of the pharmaceutical industry, the above research objectives linked to the research questions allowed the researcher to look at the conditions for development, limitations that are linked to regulations, and contribution to economic growth in the province of KZN.

4.2 Recap on the use of thematic data analysis

The researcher used the following steps in data analysis;

- **Phase 1: Familiarising yourself with the data**

The researcher studied all the responses, transcribing the recorded data from the face-to-face interviews into a written format to facilitate analysis of the data. This assisted the researcher in understanding the meaning and context of the respondents and this process allowed the researcher to identify emerging patterns from the responses.

- **Phase 2: Generating the codes**

The researcher thereafter identified the important sections from individual data, which included the notes that were taken during the face-to-face interviews. Codes were allocated to themes, representing the main themes and subthemes using numbers and keywords.

- **Phase 3: Searching for themes/classify responses**

The researcher studied the transcribed notes from the interviews and categorised and organized the raw data into main themes and subthemes, without abandoning any of the data. The researcher was under the assumption that abandoning some of the data may render the study results invalid. Categories may be created for data that might not seem to be aligned with the created codes.

- **Phase 4: Reviewing themes**

The researcher identified coherent patterns, which is critical in this phase. Therefore, the cross-case analysis was conducted to identify the common themes within the collected data.

- **Phase 5: Naming themes**

In this phase, the researcher observed overlapping themes. As a result, it became critical for the researcher to determine the impact that the data made on the selected theme. This assisted the researcher in ascertaining the criticality of the findings. The researcher analysed and refined the data to fit in the determined themes, by proofreading the transcripts to ensure quality and accuracy.

- **Phase 6: Producing the report**

This step included the write-up of theme analysis, which was logical, coherent and non-repetitive.

The researcher emphasised trustworthiness and credibility. The researcher ensured that achieving this must support the main points, and for credibility, all reports needed to be discussed even if the points did not necessarily correspond with the themes.

In closing, the researcher opted not to utilise an academic software tool like NVIVO. This was necessitated by the researcher's need to comprehend the meaning and the context of the respondents. Therefore, the researcher wanted to get a clear picture and understanding of the data to comprehend their knowledge and experience about the phenomenon under investigation. The researcher believes that the use of tools might have disallowed participants from revealing some of the realities of their experiences.

4.3 Demographic data

The primary data was collected from face-to-face interviews. Table 4 below reflects the demographic data of the interviewees.

Table 4: Demographic data of the interviewees

Participant	Research participants	Race	Gender	No. participants	Participant coding
Dube Trade Port	Sector Specialist	African	Female	1	GMM1
Magrotex	Director	Indian	Male	1	PMM2
	CEO	Indian	Male	1	PMM3
KZN EDTEA	Sector Specialist	African	Male	1	GMM4
Xylomed	CEO	African	Male	1	GMM5
Total number of interviewees			Female	Male	
			1	4	5

4.4 The study site/location

This study had two distinct sites in the province of KZN. These were the uMgungundlovu District Municipality and eThekwini Metropolitan District. The eThekwini Metropolitan is the economic hub of the province, while the uMgungundlovu District Municipality is the administrative capital of the province. The following section provides an overview of KZN, eThekwini Metropolitan, and uMgungundlovu District Municipality.

4.4.1 Geographical location of KZN province

Figure 3 is a map of the province of KZN, which stretches from the borders of Mozambique and Swaziland to Port Edward. It covers 93,450 km^2, equivalent to 7.7% of SA's total land area, and has the country's second-largest population despite having the third-smallest land area. The province is one of the nine provinces in SA.

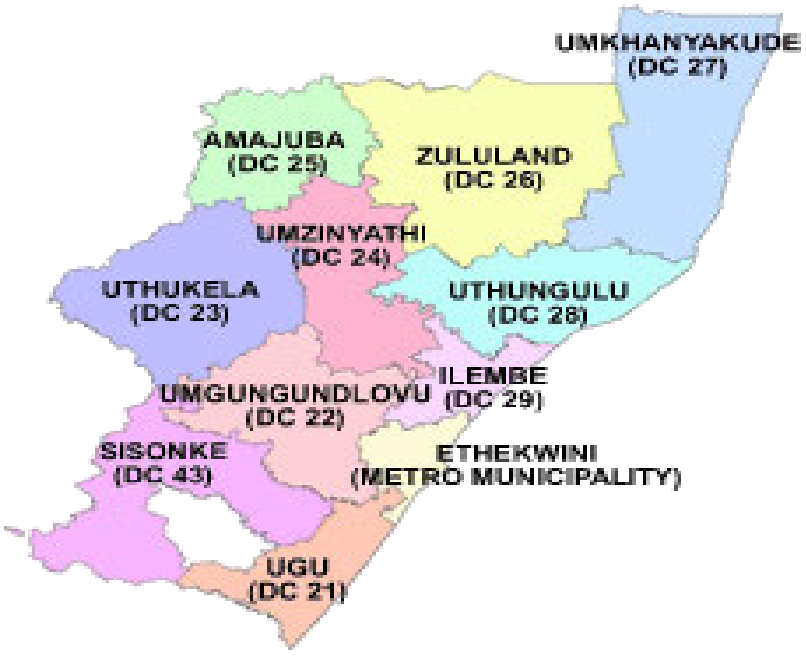

Figure 3: Map of KZN province

Source: Trade and Investment KZN (2022)

Figure 4 below depicts a map of eThekwini Metropolitan area, while Figure 5 shows a map of the uMgungundlovu District Municipality.

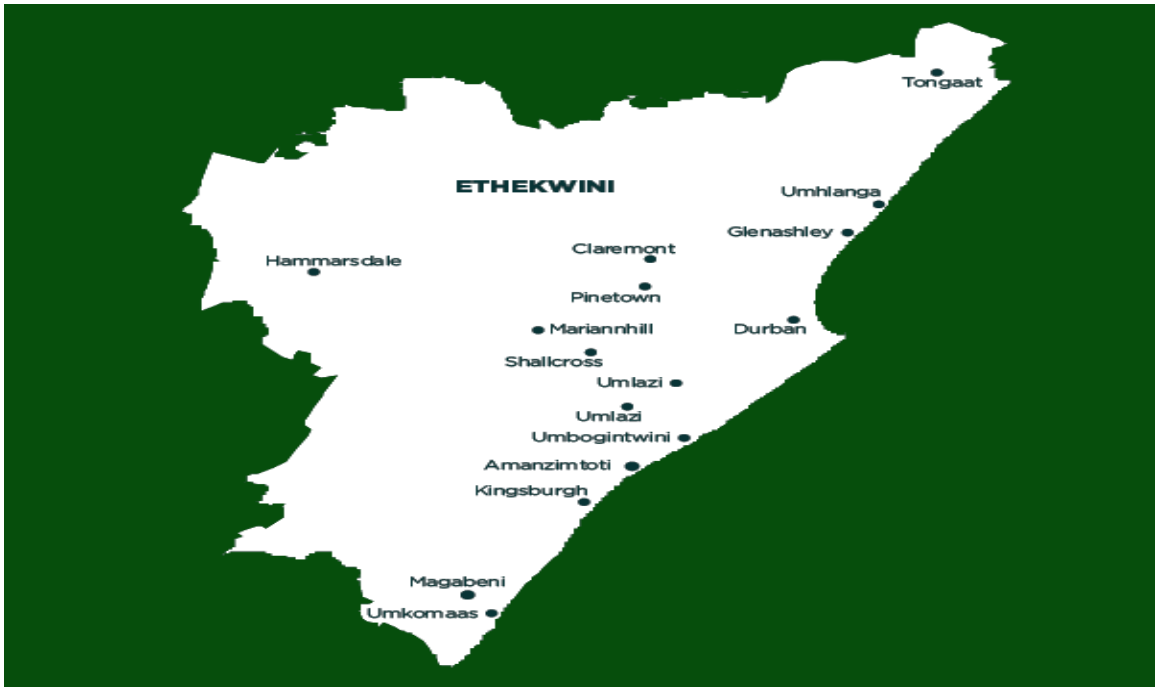

Figure 4: eThekwini metropolitan district map

Source: eThekwini Municipality (2023)

The Integrated Development Plan (IDP) states that the eThekwini Municipality is a Category A municipality found in the SA province of KZN. eThekwini is the largest city in this province and the third-largest city in the country. Its land area is comparatively larger (2 556km²) than that of other SA cities.

Figure 5: uMgungundlovu District Municipality

Source: Trade and Investment KZN (2022)

Figure 5 above is a map of uMgungundlovu District, also regarded as the administrative district of the province. The district comprises 14 local municipalities. The main city in the area is Pietermaritzburg, which is both the capital city and the legislative capital of KZN. It is an important industrial, timber, dairy and agricultural hub that has a modern, sophisticated infrastructure with easy access to airports, the N3 arterial, and railway stations. Its land area is 9 513km².

4.5 Themes and subthemes

4.5.1 Relationship between objectives of the study, research questions, interview questions, themes, and subthemes

Table 5 below is a matrix that shows the relationship between the objectives of the study, research questions, interview questions, themes, and subthemes.

4.5.2 Relationship between themes and theoretical framework

Table 6 below depicts the relationship between the themes, subthemes and the theoretical framework.

Table 5: Emerging themes from research objectives and research questions

Research objectives	Research questions	Interview questions	Themes	Subthemes
1. To explore, how the high-tech pharmaceutical industry sector influences economic growth activities in KZN	1. What influence does the high-tech pharmaceutical industry sector have on economic growth and development activities in KZN?	In your view, how do you see the pharmaceutical industry, fostering growth and development in the province of KZN? (Overview) Private sector support, in conditioning industry policies and regulation. How do you think the private sector contributes to sector development? This may include the incentives and policy advocacy relating to the sector.	R&D (Tech) Industrial policies	Inadequate investment initiatives Lack of collaboration Difficult conditions for business
2. To investigate the conditions for development and employment growth of the high-tech pharmaceutical sector in KZN.	2. What are the conditions for development and employment growth of the pharmaceutical sector in KZN?	Government support, such as industry policies and regulation how do you think they contribute to sector development? This may include the incentives relating to the sector. Given the high employment rate in the province of KZN, do you think the sector can make any contribution to assist in the space? If the answer is yes, how? Skills Shortage, could this be an issue for the pharmaceutical sector in KZN or not? How can this be improved and retained within the sector?	Government support (Environmental) Shortage of skills (Social and Political)	Review and evaluation Misalignment of available skills

3. To examine the dynamics of growth and development linked to the healthcare sector in ensuring sustainable growth of the sector	3. How are the dynamics of growth and development linked to the healthcare sector in ensuring the sustainable growth of the sector?	In your opinion, are financial constraints a hindrance in ensuring that companies comply with regulatory mandates such as GMP or is it just the lack of knowledge in most of the small enterprises? In your opinion, what role can academic institutions and government play, in assisting the development of the pharmaceutical sector? How can R&D and technological investment assist in the growth of the pharmaceutical growth to increase the sector knowledge?	Government responsiveness to pharmaceutical industry needs	Lack of government coordination

Table 6: Relationship between the themes, subthemes and the theoretical framework

Research Objectives	Interview questions	Themes	Sub Themes	Theoretical Framework
1. To explore, how the high-tech pharmaceutical industry sector influences economic growth activities in KZN	In your view, how do you see the pharmaceutical industry, fostering growth and development in the province of KZN? (Overview)	R&D (Tech)	Inadequate investment initiatives	Technological factors Economic factors Threat of new entrants
	Government support, such as industry policies and regulation how do you think they contribute to sector development? This may include the incentives relating to the sector.	Industrial policies (Political &Legal)	Lack of collaboration Difficult conditions for business	Political and legal factors Environmental factors
2. To investigate the conditions for development and employment growth of the high-tech pharmaceutical sector in KZN.	Government support, such as industry policies and regulation how do you think they contribute to sector development? This may include the incentives relating to the sector. (Elaborate)	Government support	Lack of sector long-term vision	Environment factors and Legal factors Political factors

	Given the high employment rate in the province of KZN, do you think the sector can make any contribution to assist in the space? If the answer is yes, how? Skills Shortage: could this be an issue for the pharmaceutical sector in KZN or not? How can this be improved and retained within the sector?	Shortage of skills	Misalignment of available skills	Social and cultural factors Social and cultural factors Political factors
3. To examine the dynamics of growth and development linked to the healthcare sector in ensuring sustainable growth of the sector.	In your opinion, are financial constraints a hindrance in ensuring that companies comply with regulatory mandates such as GMP or is it just the lack of knowledge in most of the small enterprises? In your opinion, what role can academic institutions and government play, in assisting the development of the pharmaceutical sector? How can R&D and technological investment assist in the growth of the pharmaceutical growth to increase the sector knowledge?	Government responsiveness to pharmaceutical industry needs		Economic factors Environmental factors Legal factors Technological factors

The section below discusses the interlinkage between research objectives, questions, interviews, and the framework.

As discussed in Chapter 2, the study is founded on the PESTLE analysis framework developed by Francis Joseph Aguila, a general management and strategic planning scholar, to conduct environmental scanning (Aguilar, 1967). Over the years, the tool has been enhanced to adapt to changing business environments by adding environmental and legal factors by author Arnold Brown of Life Science (Yüksel, 2012). The PESTLE analysis is regarded as a mandatory method that analyses the factors relevant to any sector environment and gives information that allows organisations to predict the situation, influence decisions and develop competitiveness (Matovic, 2020). Yüksel (2012) refers to strategic analysis as the first basic stage of strategic management that involves current factors relevant to the environment where companies operate.

As illustrated in the matrix in Table 6, the link between the theoretical framework, research objectives, and field questions posed to the interviewees is demonstrated. Additionally, the emerging themes and subthemes that emerged from the empirical data are also reflected in the matrix in Table 6.

The following section discusses the themes and subthemes that emerged from the study.

4.6 Influence of innovation and technology on pharmaceutical industries' economic growth activities in KZN

The primary research objective of the study was to explore how the high-tech pharmaceutical industry sector influences economic growth activities in KZN. In this research objective, various themes emerged. The initial theme that emerged was *R&D and Industrial Policies*. The subthemes that emerged from this themey are *inadequate investment initiatives*, a *lack of collaboration,* and *difficult business conditions.* During the interviews, the interviewees were asked about their comprehension and views on the influence of the pharmaceutical industry and other related questions. The section below presents the interviewees' responses, which are supported by the body of knowledge.

4.6.1 Research and Development (R&D)

The concept of health is defined as both a cause and effect of economic development. As such, the sector generates and is expected to continue producing profitable economic activities. Speaking from a broader economic viewpoint, the industry forms part of GVA through indirect, direct economic, and induced economic impacts that are considered impact analysis. As discussed in Chapter 2, R&D in the pharmaceutical industry covers three areas of activity—basic research, applied research and experimental development. Combined, the purpose is to discover and generate new knowledge, ultimately providing solutions to problems. Therefore, it contributes to human development in addition to stimulating economic growth by providing infrastructure and supplying services.

The following remarks show the respondents' comments to the question: "In your view, how do you see the pharmaceutical industry fostering growth and development in the province of KZN?"

Participant 5 stated:

> *"The Biotech and Pharma industry can grow to become one of the most important pillars of the economy in KZN and at the Dube TradePort SEZ regional economies, if not the crucial driver of the national economies."*

Participant 1 said*:*

> *"We expect that the contribution to the regional economy could reach levels as high as 40% of the economy and establish an economically significant pharma cluster that will need a significant eco-system."*

Participant 5 stated:

> *"We will provide economic impetus for the region and the population, and as a major investor, will contribute to the fiscus, as well as will benefit the country by being a producer of high-quality medicines at a cost-effective price level and as an R&D Science Centre for KZN*

Province. The associated income streams impact KZN in a variety of ways."

Similarly, another interviewee, Participant 4, stated:

"The pharmaceutical sector can contribute more when it comes to job creation and improve the GDP. In KZN we need to work very hard to support this sector because it is showing that in other provinces like Gauteng and Eastern Cape where most of these big pharmaceutical companies are at, for us we need to support and make this sector part of the province."

In conclusion, the pharmaceutical sector can contribute to economic growth, investment, and GDP. Interestingly, this aligns with the respondent's view on the influence of the pharmaceutical sector on economic growth. The perspectives of the interviewees suggest that Biotech and the Pharma industry can grow to become one of the most important pillars of the economy.

The interviewees' views demonstrate that the sector has the potential to provide economic impetus for the region and its population. Additionally, the interviewees are of the view that the sector can contribute to the production of high-quality medicines at a cost-effective level and as an R&D Science Centre for KZN Province. Notwithstanding this, for the province of KZN to achieve these milestones, the interviewees believe that this sector is not given priority by the government, thus the direction of resources, effort, and government is misplaced, ignoring the fact that the pharmaceutical sector has the potential to influence and create a positive impact on economic growth.

4.6.2 Inadequate investment in sector development

Innovation generates new industries, which then generate new employment and markets, it also contributes to the expansion of already existing markets, all of which contribute to societal growth. As discussed in Chapter 2, the pharmaceutical industry is one of the most technologically intensive industries, and R&D investments play an important role in economic growth. Furthermore, this requires a sustainable (long-term) strategy that balances necessities such as self-sufficiency and the ability to respond to anticipated growth in non-communicable diseases while also increasing

R&D capacity to address competitiveness. A clear vision will contribute towards strengthening the industry's maturity, boosting local production, and enabling the market and regulatory conditions that will encourage funds to invest in local production.

Participant 1 stated that:

> *"There is an opportunity to increase the sector in KZN, perhaps not only particular in KZN, but this might also be addressed at a national level to increase the overall growth of the sector which will increase the GDP of the country."*

Participant 5 revealed that:

> *"The manufacture of Pharmaceutical Products is dependent on various factors: a well-qualified workforce, state-of-the-art production plants and goods and services from other sectors, such as basic chemical components, energy and consulting or financial services."*

In summary, the sector requires enough resources that assist in balancing the state of self-sufficiency and the ability to respond to anticipated growth.

4.6.3 Lack of collaboration

An evaluation of pharmaceutical manufacturing in Singapore linked it to sustainable development (Carpenter, 2021), established that the Singapore government is committed to sustainable development, which is targeting all the sectors of the economy, with particular reference to manufacturing. The study by Carpenter (2021) further demonstrates that the major commitment to greenhouse, and the reduction of gas emissions, has yielded positive results. However, the author claims this commitment was challenging considering that the country has limited natural resources.

Notwithstanding government commitment to pharmaceutical manufacturing, Carpenter (2021) finds that the private sector has taken the lead from the government, particularly the pharmaceutical manufacturing sector which is a core industry sector, and the private sector has also contributed significantly to the

sustainable development of the country. This commitment by the private sector has ensured that there is availability of shared technology, joint funded initiatives, government-private sector pharma innovation initiatives, and joint programmes of action that are solution-driven with the purpose of moving closer to sustainability of the pharmaceutical sector of the future.

Furthermore, on a similar theme Participant 4, stated:

> *"Neliswa, a willingness for the government to partake in this sector is there, however, a transformation needs to happen, industry is still dominated by the major player."*

Participant 1 said that:

> *"Government need to be stringent on procuring locally manufactured goods, and be able to protect the local manufacturers, the imports are the one that makes it so difficult for local manufacturers to strive, it is very difficult to compete with the international prices, and the costs on manufacturing are very high."*

In conclusion, the government needs to align with the private sector, which is the main contributor to this sector, and drive its development. The mid-point would not necessarily mean overlooking the policies; however, the sector has high barriers to entry such as R&D expenditures, legal obstacles, et cetera. External forces cannot be seen as an additional burden to development; however, solution-driven decisions need to emerge.

4.6.4 Industrial policy

Altenburg and Rodrik (2017) define industrial policy as government actions that are used to structure the sector. When countries implement industrial policies, they are often faced with competing objectives, such as securing sustainable economic growth, maintaining financial and fiscal stability, and establishing "national champions." Sector-specific regulations, including burdensome regulation and procedures, and difficult barriers, may hinder the development of and slow the sector growth, which may have negative outcomes, and make the business environment unfavourable, as discussed in Chapter 2.

In discussions on a similar theme, Participant 5 stated:

> *"The Provincial Government of KZN can 'de-risk' the pharmaceutical projects for all investors and new potential investors. We believe that these challenges can easily be overcome with the assistance of the KZN Provincial Government. The obstacles identified are the following and are by no means limited to these; Inadequate regulatory frameworks, perceived political instability, policy incoherence and a debilitating shortage of capacity."*

4.7 Conditions for development and employment growth of the pharmaceutical industry in KZN

The second research objective of the study was to explore the conditions of development affecting the sector growth and the conditions of employment relating to the pharmaceutical sector in KZN. Concerning the questions related to this research objective, various themes emerged. The initial theme that emerged is *Government Support* and *Shortage of Skills*. The subthemes that emerged from both these themes are *Shortage of skills, Inadequate resources,* and *Misalignment of available skills.* The interviewees were asked about their understanding and views on the influence of the pharmaceutical industry, and other related questions. The below section reflects the interviewees' responses to the interview discussions on the same theme, wherein they were asked "Government support, such as industry policies and regulation, how do you think they contribute to sector development? This may include the incentives relating to the sector."

Participant 5 stated:

> *"The KZN Provincial Government must envisage that their support and encouragement to produce value-added products for the export market will increase FDI and lay the basis for more rapid industrial development. The KZN Provincial Government procurement systems must give preference to local pharmaceutical companies and offer advanced payment of up to 30% of the value of orders to any local manufacturer."*

Participant 1 responded:

"Government must provide various kinds of support to the local pharmaceutical industry during the initial phase to promote import substitution, export growth, transfer of technology and job creation and to increase the production of essential medicines to improve access."

Participant 3 revealed:

"The development of the KZN Provincial local pharmaceuticals manufacturing sub-sector has been very much limited in terms of production capacity, technology acquisition, creation of employment opportunity and investment. Most of the local manufacturers are not compliant with international GMPs, and no single product has been prequalified by WHO."

4.7.1 Government support

Songling et al. (2018) proposed that government organisations should formulate strategies that will enhance the growth and survival of industries. These authors also emphasised the fact that every industry plays a critical role in economic growth, especially in an emerging market. This is useful for this study as it provides a general view of the government's support, not only related to the pharmaceutical sector but in any industry as long as it contributes to sustainable development. As highlighted in Chapter 2, relating to the PESTLE analysis framework, political factors determine the extent to which a government may influence the economy or a certain industry (Rastogi & Trivedi, 2016)

Participant 1 stated:

"Government support is important in the short to medium term to encourage growing pharmaceutical industries in developing countries to become competitive and to channel their growth in accordance with the objectives of health policy."

Participant 5 responded:

"Government has a role to play, in making the conditions conducive to the potential investors that apply across the board, however, in

particular for this sector we have various challenges, to report one is the public procurement system that needs to follow PMFA, which is honestly against the local production, we have been engaging with National Treasury on it, which is designating the local product, the example they will always give us for an example; you see this 'urine bag', we have been procuring it with R3.00, how much do you think it will cost from a local supplier and the answer is R9.00'. Another typical example, Neliswa, is the case of Biovac, I'm sure you are aware of it as it recently happened, which was an issue of compliance."

This indicates that there is a lack of sector long-term vision by the KZN Government. It also supports the argument that political strategies influence the business environment and competitiveness of the players. Nonetheless, external forces such as government involvement in regulatory agencies and reimbursement guidelines have a significant impact on this particular sector.

4.7.2 Shortage of skills

Essentially, development funds or resources must be increased to create jobs. Additionally, while economic growth is seen as beneficial to job creation, growth must occur in sectors with the potential to absorb labour on a large scale similar to pharmaceuticals. As discussed in Chapter 2, the pharmaceutical sector is like a knowledge and skills-imparting institution, which are pillars of economic development.

Interviewees were asked on the same theme, "Skills shortage, could this be an issue for the pharmaceutical sector in KZN if the answer is yes, what role can academic institutions play, in assisting the development of the pharmaceutical sector?"

The following remarks were made by Participant 5:

"Yes, KZN definitely has an issue for Pharmaceutical Manufacturing in KZN Province, actually we will request that the KZN Provincial Government support the Industry through a "New Skills Development Support Program" in the form of funding a UKZN Degree & Diploma Programmes that will ensure that the PHARMA

Industry has a continuous supply of skilled Local employees from the surrounding regions furthermore, KZN Provincial Government need to support a "New Herbal Farming Techniques and Practices Support Program" that will incentivise Farmers to grow the medicinal herbs required by the PHARMA Industry for its Phyto-Pharmaceuticals Products."

Another respondent (Participant 1) revealed:

"Neliswa, while most of the sectors are vulnerable when it comes to availability of skills, the province itself has a high unemployment rate, however, we believe that as a government, we need to participate as an intervention to assist. Maybe again it's not the issue of shortage of skills, but it's the issue of not doing skills audit, from the national level. I'm saying this because we have universities that produce graduates that possess such high skills but when it comes to job placement, they are misplaced, and some are not being absorbed in the right positions."

This data analysis demonstrates that while there is an acknowledgement of a skills shortage in the province of KZN, it is evident that misalignment of the current availability of skills is also an issue that needs to be looked at.

4.8 Growth dynamics and development linked to the Healthcare sector in ensuring the sustainable growth of the sector.

The third research objective of the study was to examine the growth dynamics and developments linked to the pharmaceutical sector in ensuring the sustainable growth of the sector. Again, the theme that emerged was, "Government responsiveness to pharmaceutical industry needs."

4.8.1 Government responsiveness to pharmaceutical industry needs

Government sector extension and R&D work is essential for the growth of the sector. However, it is impeded by inadequate and limited resources, red tape, and multidimensional requirements. Furthermore, there is a need for the public sector to encourage the participation of the private sector and other stakeholders in the pharmaceutical industry.

One of the interviewees (Participant 5) stated that:

> *"Yes, there are significant financial constraints in current Good Manufacturing Practice Regulation and Pharma Product registration regulatory fees. At a minimum, Current Good Manufacturing Practice Regulation compliance registration fees can cost as high as ZAR5 million for a single company and no financial institution in RSA would be willing to finance the same. Furthermore, most established Pharma companies have lobbied the SAHPRA to raise Product registration fees as a way of capacitating the regulator, but the unintended result is that these fees are way beyond the reach of emerging pharmaceutical companies."*

Participant 4 revealed:

> *"It is difficult or rather unfair to expect that industries can sustain themselves on their own, it's our mandate as government to ensure that we create an environment that will enhance the environment in partnership of cause for the betterment of us all. Remember Neliswa the issue of sustainability doesn't only focus on industries; however, the academic institutions play a critical role in feeding the industries, without academic institutions industries will suffer, and as a government, we need to account."*

The data analysis of this objective demonstrates that public–private partnerships have the potential to provide sustainable development that cuts across all sectors, which will need to be supported by the leadership, which in this case, is the KZN government.

4.9 Chapter summary

This chapter revealed that there are various obstacles that the sector is facing, while the pharmaceutical sector in KZN has the potential to influence growth activities that contribute to economic growth. The primary data indicates that there is a great need for discovering and generating new knowledge, despite limitations, pertaining to industrial policies, inadequate investment initiatives, and a lack of collaboration. Furthermore, the conditions of development and employment growth necessitate

government support with various strategies for the sector to be sustainable. The interviewee responses presented in this chapter reveal that while there may be a shortage of skills, the currently available skills are misaligned with what the sector requires. Lastly, the data further demonstrates that sector dynamics have an impact on growth and development. This can be traced back to government responsiveness in the pharmaceutical sector, which is due to a lack of coordination of activities in the province of KZN.

The following chapter discusses the findings and recommendations, under each research objective discussed.

CHAPTER 5: DISCUSSION

5.1 Introduction

This chapter discusses the key findings of the study, using the study themes in relation to existing literature and related to previous studies. This chapter uncovers the growth dynamics of the pharmaceutical sector by looking at conditions for development and employment growth, thus limiting the sector's contribution to economic growth in the province of KZN.

1) To critically explore how the high-tech pharmaceutical industry sector influences economic growth in KZN.
2) To investigate the conditions for development and employment growth of the high-tech pharmaceutical sector in KZN.
3) To examine the dynamics of growth and development linked to the healthcare sector in ensuring sustainable growth of the sector.

5.2 Research & Development influence on economic growth

The initial research objective of the study was to explore how the high-tech pharmaceutical industry sector influences economic growth activities in KZN. The findings illustrate that the pharmaceutical sector has the potential to contribute to economic growth, investment, and GDP in KZN. The perspective deduced from interviewee responses, suggests that the biotech and pharmaceutical industries have the potential to become one of the most important pillars of the economy. This resonates with the findings of Agénor and Neanidis (2015) on the evaluation of innovation, public capital, and growth. In their study, Agénor and Neanidis (2015) established that the knowledge economy provides opportunities for the creation, application, and dissemination of innovative goods, thereby creating an environment in which people can become active innovators and entrepreneurs. In the same manner, this is also supported by Pece et al. (2015), from an empirical analysis of innovation and economic growth in Central Eastern Europe countries. These researchers argue that sustainable growth of an economy is influenced by its country’s innovative potential. Furthermore, the authors demonstrated that the availability of both internal and external funding influences the positive economic

growth of the country. These authors further argue that FDI increases the possibility of knowledge transfer and technological process improvement, which therefore influences the conditions of sector development.

The study found that the sector requires adequate resources to assist in balancing the state of self-sufficiency and the ability to respond to anticipated growth. This gave rise to the subtheme of inadequate *investment initiatives discussion.* Interviewee's perspective indicated that there is an opportunity to increase the sector growth in KZN, perhaps not only in KZN but at a national level to increase the overall growth of the sector, which will increase the GDP of the country.

This resonates with the findings of Aghmiuni et al. (2020), on the assessment of factors affecting innovation policy in biotechnology. The authors found that the government needs to set aside a portion of its budget mainly for biotechnology and development to encourage innovation and prepare for the modern era of globalisation. The interviewees are of the view that enhancing R&D investment activities requires a substantial investment and the size of the investment required is a hurdle for them in conducting such activities. This finding aligns with McGlacken et al. (2018) who found that while in the last decade R&D investment remained low for multinational companies in Ireland due to contract manufacturing, it was government responsiveness that ensured the country remained at the forefront of API manufacturing. Their government felt that they needed to position themselves as a global hub for process innovation and consequently, Science Foundation Ireland (SFI) was established to fund applied research in science, engineering, and mathematics to encourage innovation in the country.

Tawfik et al. (2022) opine that pharmaceutical innovation is a system that includes governments and policymakers, regulatory bodies, educational institutes, R&D organizations, entrepreneurs and pharmaceutical companies. Therefore, industry growth can only occur within a sustainable environment, and sustainability can only be claimed through its stakeholders (Tawfik et al., 2022). This led to the subtheme of *lack of collaboration* among stakeholders having similar interests in seeing sector growth. Empirical evidence has over the years shown the benefits of collaboration, which aligns with McGlacken et al. (2018) who established that trust, inclusivity and commitment to mutual benefit are some of the factors that contributed to the success

of Syndissertation and Solid-State Pharmaceutical Centre (SSPC) in Ireland. Similarly, Gutiérrez and Macken-Walsh (2022) established that sustainable sector growth requires strong collaboration across the value chain.

5.2.1 Industrial policy influences the pharmaceutical sector development

The general view from the private sector interviewees is that the lack of comprehensive policy and institutional framework has led to the declining demand for innovative products. Pecchia et al. (2020) report that in the 1990s, the European regulatory framework evolved to protect European manufacturers from unsustainable competition from foreign manufacturers. The authors further conclude that there is a critical need for an evidence-based framework, which will prioritise internal stakeholders. Furthermore, regulatory policy will ensure that regulations are in the best interests of the public and will enhance economic growth through knowledge transfer and improved technological processes.

This view aligns with Cherif et al. (2022). These researchers report that the presence of effective government institutions, a favourable business environment and investment climate, and credible macroeconomic policies all contribute to the emergence of new, modern sectors. These authors report that from the 1970s to the mid-1990s, Norway used aggressive policies to stimulate the growth of its oil service industry, resulting in the emergence of a high-tech and successful oil service cluster that had not previously existed. These policies included oil companies interfering in tenders to benefit local firms and laws requiring oil companies to conduct half of their R&D in Norway (Cherif et al., 2022). However, the common view held by the interviewees is that the SA government lacks technical capabilities and understanding in championing and leading the policy direction of such a sector. The industry players should be the ones to develop policies aimed at promoting the pharmaceutical sector to harness the benefits thereof (job creation, infrastructure development, and R&D).

The current study found that the unsustainable competitive environment needs to be managed from the provincial government side, which leads to the subtheme discussion of *difficult conditions for business*. In the main, the respondents attribute this to stringent procurement policies that make it difficult for local manufacturers to compete. The respondents believe that for local manufacturers to compete, they

need to be protected from the influx of sub-standard imported products. One interviewee made an example of Biovac vs Cipla vaccination for COVID-19, in a recent case. The study found that conditions of business in KZN are not as favourable to local manufacturers as they should be. Government marketing programmes should encourage the private sector to purchase and consume locally manufactured pharmaceutical products to make the conditions more favourable to conducting business.

This demonstrates that the government is a leading player in influencing growth activities related to the pharmaceutical sector's growth in developed countries, whereas, in undeveloped countries, the private sector continues to play a critical role in influencing economic growth related to the sector's development. This implies that activities such as R&D require full participation from both the private and public sectors, with the private sector having the skills and providing the knowledge and skills transfer to partner with the government. The government will have to enable conditions, such as unlocking Foreign Direct Investment, which will enhance economic activity and boost local production. The government must also allow the private sector to lead the evidence-based policy framework for the sector to realise a better outcome of dynamic issues at hand and improve the policy coherency within the sector. This will assist them in realising the maximum impact that the sector aims to achieve. The following section discusses the findings of the second objective of the study, which is “to investigate the conditions for development and employment growth of the high-tech pharmaceutical sector in KZN”.

5.3 Insufficient government support in enabling the conditions of development of the pharmaceutical sector

The second research objective of the study was to explore the conditions of pharmaceutical sector development and employment growth in KZN. The study established that while many factors have contributed to the underdevelopment of the local pharmaceutical manufacturing sector, one of the most significant gaps that have been identified is a lack of sectorial long-term vision that is aligned with KZN and the country's ambitious goals of economic and social development. The study established that there is a compelling case for government support for industrial innovation, which necessitates the development of strategies to facilitate the implementation process. Such strategies are documented in the NDP 2030, which is

the overall plan for the country. The NDP, in summary, indicates that the government will work with all sectors to understand how they contribute to the implementation and, in particular, to identify any barriers that prevent them from fulfilling their roles.

This necessitates a focus on identifying and overcoming the barriers to achieving the outcomes, including the need to strengthen the local government's ability to fulfil its developmental role. Moreover, the consensus among the participants (primarily from the private sector) is that while there is support from the government, the industry is generally characterised by conditions such as institutional loopholes (with reference to SAPHRA, DTIC, and NDoH) that seem to paralyse the sector. Unfortunately, this highlights once again the policy coherence issues. Fourie (2018) asserts that coherence between the development policies of recipients and providers of development assistance is required for sustainable development, which contributes to conditions of development. Likewise, during the interview, one participant stated that they believe that the KZN provincial government can de-risk pharmaceutical projects so that all investors and potential new investors can gain a competitive advantage. This was regarding the centralisation approach, which is seen to be a hindrance to them as industry players.

Another interesting view is that of Casiano Flores et al. (2021) who argue that governance assessment frameworks are significant for a unique complex environment because they allow the identification of bottlenecks and propose solutions to identify the challenge. These authors also suggest fit-for-purpose and other related frameworks. It is apparently to re-evaluate the best ways to position the sector in KZN but will necessitate an agile approach from the KZN leadership in spearheading this sector's development and enabling favourable conditions.

Enabling conditions refers to prioritising financial support. With government financial support, established firms can receive financial assistance from a variety of institutions, including internal funds, banks, financial institutions, and, in some cases, just normal investors. However, in many countries, governments have taken on the responsibility of providing financial assistance to both new and established businesses as a form of retention strategy (Songling et al., 2018). This study found that such effort has a significant impact on making the conditions of development more conducive. For instance, in SA, government assistance places its focus on

programmes that promote and support domestic manufacturing and R&D through their programmes such as the Technology and Human Resources for Industry Programme (THRIP) and the Support Programme for Industrial Innovation (SPII), as stated in the DTIC report. Wentzel and De Hart (2015) believe that incentives are intended to attract investment to stimulate economic growth, however, for the effective implementation of these incentives, classifications in categories such as promoting specific investment incentives, encouraging investment in capital assets, and reducing the company's fiscal burden are also important.

Cherian et al. (2021) conclude that the formulation of the Pharma Bureau by the Indian government to facilitate investment for ensuring faster statutory approval has contributed to facilitating timely approvals. Furthermore, these authors argue that this is even though cluster developers and participants may be granted tax-free status, and tax-free status allows the cluster developers and participants to set up and reduce production costs. It is therefore notable that sectorial long-term vision necessitates an agile approach from all stakeholders, thus alignment and commitment to visions by industry players, policymakers and the government are significant to enable the conditions for sector development. This will contribute to the culture on which the sector is formulated, which the KZN government will have to lead in enabling the conditions of development of the pharmaceutical sector.

5.3.1 The negative effects of skills shortages on employment growth

The findings of this study established that for the province of KZN to accomplish the development of the pharmaceutical sector, there must be a clear set of models, which filters through their education systems and will allow development to succeed. This is supported by Zhu et al. (2018) who argue that the educational options available to ordinary people determine a country's progress and prosperity. These authors explain that education does not only prepare people to understand and deal with the complexities of economic growth but also acts as a lever for its growth. This viewpoint is consistent with that of the study participants whose perspective was that a skills shortage affects productivity and also reduces knowledge capacity. The interviewees believe that academic institutions have an impact on the development of entrepreneurship and innovation, which is required in the pharmaceutical sector. Authors such as Brunello and Wruuck (2021) define the skills shortage as a process

where the accessible labour market does not offer employers the skills they require. One of the respondents, when asked about the contribution that this sector can make in reducing the unemployment rate, expressed that while there is a willingness from employers to capacitate their employees with the relevant skills required, the reality is that the process comes with economic cost. This resonates with the views of Santos (2020) who reports that firms that collaborate with universities and research institutes can innovate more radically.

This brings us to the subtheme discussion of *skills misalignment and its effect on employment growth.* Brunello and Wruuck (2021) argue that the impact of skills misalignment may not only result in a high rate of absenteeism but may also increase the frequency of job turnover. This resonates with the concerns expressed by the respondents that the responsibility of capacitating the sector with relevant skills must be shared between the provincial government, employers, and academic institutions at a provincial level. In this regard, one of the participant's responses was that they are requesting that the KZN Provincial Government use government policy & regulations to enhance the BPharm, BSc Biochemistry, and BSc Pharmacology Degree Programmes of local universities to be more focused on pharmaceutical production quality assurance and quality control as well as introducing Pharm Tech Diploma Programmes to ensure availability of appropriately skilled labour. Also, the provincial government should institute scholarships and bursary programmes for young local residents.

Contrary to the respondents' views, a survey conducted by Naude and Luiz (2013) found that government funding for universities has decreased over the last decade, as discussed in this study's literature review, which is a barrier to establishing sustainable pharmaceutical production in SA. This means that local governments must commit to funding programmes such as human capital development to ensure aggregate productivity growth and a competitive environment for the pharmaceutical and medical devices industry. This may be accomplished by the implementation of framework policies that encourage better location of existing skills and education policies that increase skills, which would result in an effective supply of skills.

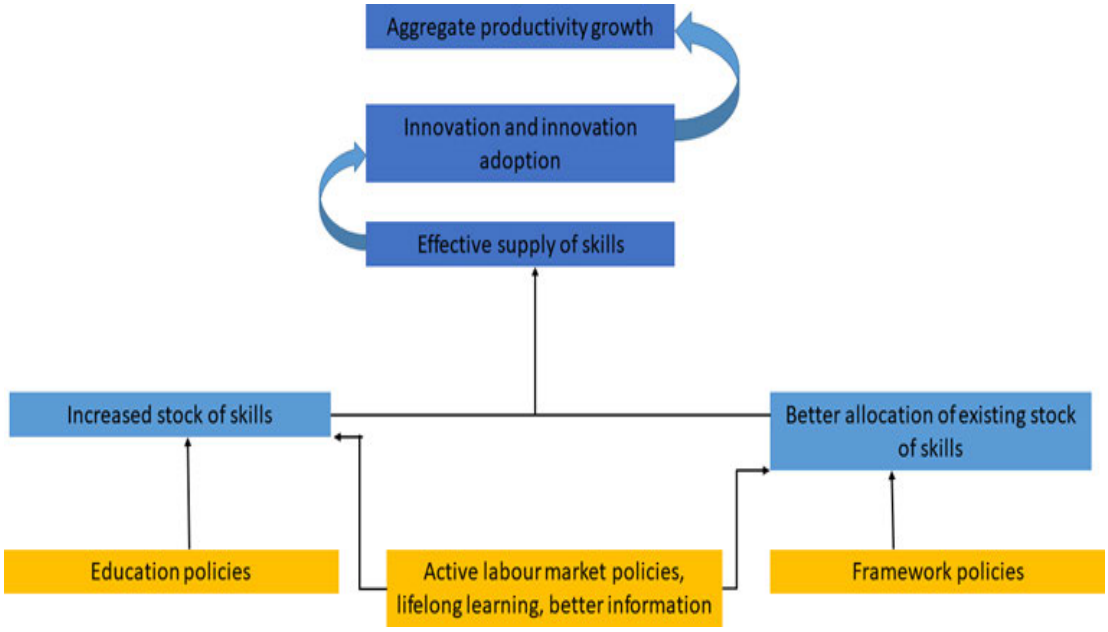

Figure 6: **Connecting skill development and overall productivity**

Source: Brunello and Wruuck (2021)

SA industry policies emphasise localization (capacitating local industry) as an economic driver, as articulated by the DTIC, thus the framework policies and education policies must be linked to this strategy, which will achieve aggregate productivity growth. For these reasons, commercially sustainable methods must be employed by the provincial government in KZN to create a suitable workforce pool that the sector needs for the province to be competitive.

5.4 Government responsiveness to the pharmaceutical sector

The third research objective was to examine the dynamics of growth and development linked to the pharmaceutical sector in ensuring sustainable growth of the sector in KZN. The study determined that re-capitalization of most facilities can achieve the quality of production that will determine product acceptance. Surprisingly, the participants' view, in particular the private sector, of government responsiveness was rather negative, arguing that there is a lack of comprehensive policy and institutional framework for them to operate in, as well as a very indistinct strategic plan. The respondents raised concerns about significant financial constraints in current GMP regulation and regulatory fees for pharma product registration. Furthermore, GMP compliance registration fees for a single company

can cost as much as ZAR 5 million, which no financial institution in SA would be willing to finance, thus greatly limiting access to capital.

According to one of the respondents, most established pharmaceutical companies have lobbied the SAHPRA to reduce product registration fees to capacitate the Regulator, as these fees are prohibitively expensive for emerging pharmaceutical companies. Haldane et al. (2021) opine that government decisions shape healthcare infrastructure, regulations, and guidelines, limiting access to medication and treatment, health coverage, and financing. Similarly, Mailu et al. (2018) contend that due to a resource disadvantage, no project venture is capable of implementing any superior competitive project idea, simply because ideas will remain just that— ideas— while there are no resources to put them into motion. Contrary to this view, Donegan et al. (2021) argue that economic development scholars have widely criticized incentive programmes and the authors believe that deals made by multinationals through the awarding system raise some concerns. Moreover, when these multinationals fail to perform, the impact is felt in job losses. A surprising perspective from one of the interviewees suggests that a lack of analytical capacity to access investment funds leads to poor implementation to grow the sector.

The study found that in terms of responsiveness by the government relating to establishing and enabling the pharmaceutical sector, it is based on the government's commitment to providing incentives related to the sector, such as the Manufacturing Competitiveness Enhancement Programme (MCEP), Innovation and technology funding, and the 12i tax allowance incentive, all administered by the DTIC. Furthermore, regarding regulations, there are a plethora of policies that are in place to unlock some of the hurdles relating to the sector, such as the National Drug Policy, Medicine Regulation Policy, and Pharmaceutical Procurement Policy. SAPHRA's strategic plan 2021-2025 refers to the NDP Vision 2030 as the blueprint for the SA government that aims to eliminate poverty and reduce inequality by 2030. The NDP focuses on providing quality healthcare for all (Chapter 10), as is highlighted in Chapter 2 of this study.

Responsiveness in this study refers to the practice of ensuring that governments and their agencies serve their constituents in a helpful and responsible manner. Linde and Peters (2020) argue that when people perceive government to be responsive to

their demands and wishes, a "buffer" of support grows. When this buffer of support grows, it may ultimately increase the scope for governments to make decisions that people perceive as not being in accordance with their short-term interests, that is, non-responsive but responsible decisions."

5.5 Chapter summary

This chapter summarized the findings of the study in relation to existing literature and related previous studies. Firstly, this chapter revealed that growth activities such as R&D in the pharmaceutical sector must be characterized by a firm ecosystem collaboration that includes policymakers, regulatory bodies, academic institutions, entrepreneurs, and pharmaceutical companies to contribute to the economic growth of KZN. The conditions of development and employment growth necessitate government support with various strategies that create a sustainable environment, which involves a sectorial long-term vision that is aligned with KZN's ambitious goals of economic and social development. Local governments must commit to funding programmes such as human capital development programmes to ensure aggregate productivity growth and a competitive environment for the pharmaceutical industry. Lastly, this chapter established that the government's responsiveness to the pharmaceutical sector necessitates an agile approach in capacitating the industry players, which can create a buffer of support and ultimately increase the scope for the government to make decisions that will influence the conditions of the development of the pharmaceutical sector in KZN.

CHAPTER 6: RECOMMENDATIONS AND CONCLUSION

6.1 Introduction

Following the discussions presented in Chapter 5, this chapter concludes the study, summarising the key findings linked to the research aim and research questions. Additionally, this chapter suggests recommendations that are based on conclusions, reviews the limitations of the study and proposes opportunities for future research.

6.2 Summary of research objectives and research questions

The study intended to critically analyse the growth and development of the pharmaceutical healthcare sector by looking at the conditions for development, limitations that are linked to regulations and contribution to economic growth in the province of KZN. The core challenge underpinning this research study was to investigate the extant body of knowledge, which indicates that the dependency on imported medicine is exceptionally high. KZN has adopted the national strategy of pharmaceutical sector growth and its long-standing regulatory policies. There have been insufficient studies conducted on conditions of development and growth of the pharmaceutical industry in KZN and this is the gap in knowledge that the study attempted to fill.

Economic development encompasses a wide range of actions aimed at establishing and sustaining a strong local economy. This includes improved economic well-being and quality of life for communities. Its initiatives focus on retaining existing businesses, fostering growth, investigating novel ways to attract new start-ups, fostering employment creation, and encouraging company expansion.

Table 7 below summarises the research objectives and research questions of this study.

Table 7: Summary of research objectives and research questions

Research objectives	Research questions
1. To explore, how the high-tech pharmaceutical industry sector influences economic growth activities in KZN.	1. What influence does the high-tech pharmaceutical industry sector have on economic growth and development activities in KZN?
2. To investigate the conditions for development and employment growth of the high-tech pharmaceutical sector in KZN.	2. What are the conditions for development and employment growth of the pharmaceutical sector in KZN?
3. To examine the dynamics of growth and development linked to the healthcare sector in ensuring sustainable growth of the sector.	3. How are the dynamics of growth and development linked to the healthcare sector in ensuring the sustainable growth of the sector?

6.3 Summary of findings, general conclusions and recommendations

6.3.1 Research Objective 1: To explore how the high-tech pharmaceutical industry sector influences economic growth activities in KZN

The first research objective of this study was to explore how the high-tech pharmaceutical industry sector influences economic growth activities in KZN

Objective #1: Aim

The study sought to explore how innovation and technology in the pharmaceutical industry sector influence economic growth in KZN. Moreover, the study intended to ascertain the views of this study participants in relation to Industrial policy in influencing the pharmaceutical sector and its development.

Objective #1: Major findings

The study findings illustrate that the pharmaceutical sector has the potential to contribute to economic growth, investment, and GDP in KZN. The study found that the pharmaceutical sector requires sufficient resources to assist in balancing the state of self-sufficiency and the ability to respond to anticipated growth and as a result, this leads to adequate investment initiatives. However, the study determined that all this is dependent on the availability of resources, which can be harnessed and leveraged by various stakeholders of the sector. Unfortunately, in the case of KZN, there seems to be a lack of collaboration among stakeholders with similar

interests in seeing the sector grow. This is a result of issues of mistrust, and exclusivity as well as a lack of commitment from stakeholders who stand to gain mutual benefits. Therefore, the growth of the sector is hindered by these dynamics in KZN.

Furthermore, the study also established that there is a lack of comprehensive policy and institutional framework in KZN. The study argues that this leads to a decline in demand for innovative products. One of the interesting findings of the study suggests that the goal of regulatory policy is to ensure that regulations are in the best interests of the public and impact economic growth through knowledge transfer and improvement of technological processes. In addition, the study uncovered that in KZN there is minimal interest from the government to grow the sector as is evident in the lack of or sub-standard regulatory framework aimed at promoting and growing the sector. Subsequently, the KZN province is struggling to attract foreign investment in this sector and in turn, the province is not optimally leveraging on opportunities provided by foreign investment and capital, which is proven to address socioeconomic challenges.

The results of this study show that the unsustainable competitive environment needs to be managed from the provincial government's perspective to improve overall business conditions. These results align with the respondents' views, that for local manufacturers to compete, they need to be protected from the influx of sub-standard imported products. Also, the government marketing programme needs to encourage the private sector to purchase and consume locally manufactured pharmaceutical products to make conditions favourable to conduct the business. It is therefore recommended that the KZN government shift their focus from direct involvement to creating a favourable environment for the local manufacturers. Furthermore, this study argues that the KZN government must allow the private sector to lead the evidence-based policy framework for the sector to realise a better outcome of dynamic issues at hand and improve the policy coherency within the sector. This will assist them in realising the maximum impact that the sector aims to achieve.

6.3.2 Research Objective 2: To investigate conditions for development and employment growth of the high-tech pharmaceutical sector in KZN

The second objective of this study was to explore the conditions of pharmaceutical sector development and growth in KZN.

Objective #2: Aim

The research intended to explore the conditions of pharmaceutical sector development and growth in KZN. Moreover, this research wanted to obtain the perspectives of the study participants in relation to skills shortages, misalignment to government long vision on SA ambitious goals.

Objective #2: Major findings

The findings demonstrate that there is a lack of sectorial long-term vision that is aligned with the province's and country's ambitious goals of economic and social development. The KZN government needs to have a long-term strategic vision for the pharmaceutical industry that will promote policy coherence and direct government and other related stakeholders, such as academic institutions, towards common sustainable development objectives. Thus, enabling conditions also refer to prioritizing financial support, infrastructure, and regulatory approval. Previous studies on ease of doing business established that in many countries, governments have taken on the responsibility of providing financial assistance to both new and established businesses as a form of a retention strategy. In some cases, these countries go to the extent of formulating the Pharma Bureau, to facilitate investment and ensure faster statutory approval, thus removing restrictions that may hinder economic growth, job creation, and an enabling environment.

Furthermore, the study discovered that sectorial long-term vision includes a skills development plan that is related to sector demand and addresses socioeconomic challenges. SA industry policies emphasize localization (capacitating local industry) as an economic driver, as articulated by the DTIC, thus, the framework policies and education policies must be linked to this strategy to achieve aggregate productivity growth.

It is for these reasons that this study suggests that commercially sustainable methods must be employed by the provincial government of KZN to lay the

foundation for creating a suitable workforce pool that the pharmaceutical sector needs for the province to be competitive. Such efforts must be implemented in collaboration with academic institutions, policymakers, and industry players who are committed to the vision of enabling conditions for the development of the pharmaceutical sector.

6.3.3 Research Objective 3: To examine the dynamics of growth and development linked to the healthcare sector in ensuring sustainable growth of the sector

The third objective of this study was to examine the dynamics of growth and development linked to the pharmaceutical sector in ensuring sustainable growth of the sector in KZN

Objective #3: Aim

The research intended to establish the dynamic of growth and development linked to the pharmaceutical sector in ensuring sustainable growth of the sector in KZN. Moreover, this research wanted to obtain the perspectives of the study participants in relation to Government responsiveness to pharmaceutical industry needs, and of government coordination strategies that relates to the sector.

Objective #3: Major findings

The study determined that re-capitalization of most facilities can achieve the quality of production that will determine product acceptance. Similarly, the study discovered that government responsiveness towards the pharmaceutical sector was rather negative, with participants arguing that there is a lack of comprehensive policy and institutional framework within which they can operate, as well as a very indistinct strategic plan for attracting investment and fostering innovation.

This study argues that the government's responsiveness to the pharmaceutical sector necessitates an agile approach in capacitating the industry players and strengthening coherence, which can create a buffer of support and ultimately increase the scope for the government to make decisions that will influence the conditions of the development of the pharmaceutical sector in KZN.

6.4 Recommendations to address the objectives of the study

6.4.1 Recommendation for Research Objective 1: KZN government must provide technical support to the private sector R&D to influence economic growth in KZN province

The study revealed that when a pharmaceutical company opens a new site or expands an existing one, which is also referred to as business expansion, this leads to numerous orders for regional companies from other sectors (secondary effect), such as the purchasing of land, development and preparatory work, the construction of new buildings or the installation and fitting of production facilities and laboratories.

A specific and effective scientific R&D support programme by the KZN Provincial Government through policy and regulation, as well as funding mechanisms from the KZN Provincial Government, will support a “New Herbal Farming Techniques and Practices Support Programme” that will incentivise farmers to grow the medicinal herbs required by the pharmaceutical industry for its Phyto-Pharmaceuticals Products.

6.4.2 Recommendation for Research Objective 2: Government must create an enabling environment for development and employment creation in the pharmaceutical sector

The KZN Provincial Government must consider supporting the industry in the form of providing funding for a “skills development support programme” and collaborating with local universities to ensure that the pharmaceutical industry has a continuous and steady supply of skilled local employees from the surrounding regions.

The KZN provincial government should consider initiating a collaborative policy advocacy programme that will be inclusive of industry players to address some of the challenges associated with the current policies, which seem to hinder industry players, and come up with progressive inclusive decisions.

6.4.3 Recommendation for Research Objective 3: Government must develop a framework to ensure stakeholder inclusiveness and positive government responsiveness to the pharmaceutical sector

The study established that all provinces have the potential to foster innovation and attract FDI. However, the innovation ecosystem can be nurtured through various enabling conditions such as financial, political stability and the regulatory framework

that protects and incentivizes industry players. Therefore, KZN province should include the industry players that are involved in this sector, such as academic institutions and the private sector. The agility of responsiveness by the KZN provincial government to the reported matters will not only assist in enabling the conditions for development but because of the nature of this sector in terms of its potential to drive economic activities, will promote economic growth and contribute to job creation, from which KZN will benefit.

6.5 Recommendations for future research

This study was exploratory and did not attempt to provide conclusive answers to the research questions, even though it aimed to provide insight into the conditions of development and growth in the pharmaceutical industry in KZN. The potential local economic impact on the pharmaceutical industry needs to be quantified by future studies. This will enable the KZN provincial government leadership to arrive at more informed decisions in the significant sense of enabling the conditions of development, thereby enabling the innovation ecosystem to be formulated in the province of KZN. Lastly, due to time and financial constraints, the views of the indigenous medicine (manufacturing) sector were not included in this study; hence its role in medicine manufacturing in SA is a sector that has potential on its own and its contribution to the GDP needs to be assessed and incorporated.

6.6 Limitations of the study

The following limitations of this study are acknowledged.

Amidst a number of scholarly works that have investigated the development of the pharmaceutical sector, this enquiry scope was limited to the conditions of development and growth of this sector particularly in Kwa-Zulu Natal. Furthermore, this study excluded the medical device companies that form part of the healthcare industry because the sampling was based on pharmaceutical companies only, which it is hoped will provide a fair evaluation based on the matter that was investigated.

The DOH did not respond on time for the interviews, hence the researcher could not interview any of the HODs from the DOH. This, therefore, limited the study in getting the views from the department on sector policy formulation, the environment and its implication on the domestic manufacturing industry and the growing trade deficiency.

Furthermore, in some companies, the participants knew the researcher very well and could have withheld some of their personal in-depth experiences. The questions were open-ended and, in some cases, the respondents got a chance to vent on what seemed to be personal to them.

On a final note, the overall, body of knowledge concerning the phenomenon under investigation is not extensive. So, to say the most available knowledge is on the medical side, with not much focus on economic spin-off contributing to this sector.

6.7 Conclusion

This chapter evaluated the study and how it aligned with the scope and study objectives. The study identified a minimal interest from the government to grow the sector, as is evident in the lack of or sub-standard regulatory framework aimed at promoting and growing the sector. Subsequently, the KZN province is struggling to attract foreign investment in this sector. In addition, the province is not optimally leveraging on opportunities provided by foreign investment and capital, which is proven to address socioeconomic challenges. Secondly, the study discovered that sectorial long-term vision necessitates a skills development plan that is related to sector demand and addresses socioeconomic challenges. Hence, the framework and education policies must be linked to this strategy to achieve aggregate productivity growth in the KZN province. Thirdly, this study argues that the government's responsiveness to the pharmaceutical sector necessitates an agile approach in capacitating the industry players and strengthening coherence. The study recommends that the government of KZN should consider a support programme for scientific R&D through policy and regulation, as well as funding mechanisms. Lastly, the KZN provincial government should consider initiating a collaborative policy advocacy programme that includes industry players to address some of the challenges associated with the current policies that seem to hinder industry players and reach progressive inclusive decisions.

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APPENDICES

APPENDIX A: INTERVIEW GUIDE

Interview Guide - Open-ended Questionnaires

Exploring Conditions for Development and Employment Growth in the Pharmaceutical Industry in KZN

1. Pharmaceutical industry and sustainable growth

1.1 In your view, how do you see the pharmaceutical industry, fostering growth and development in the province of KZN? (Overview)

1.2 In your view, do you think the government is seeing any potential in this sector? Yes/No

1.3 Government support, such as industry policies and regulation how do you think they contribute to sector development? This may include the incentives relating to the sector. (Elaborate)

1.4 Given the high employment rate in the province of KZN, do you think the sector can make any contribution to assist in the space? If the answer is yes, how?

1.5 Skills Shortage, could this be an issue for the pharmaceutical sector in KZN or not? How can this be improved and retained within the sector?

1.6 In your own opinion, what role can academic institutions play, in assisting the development of the pharmaceutical sector?

1.7 Public sector procurement, in your own opinion does it cater for local production?

1.8 In your own opinion, are financial constraints a hindrance in ensuring that companies comply with regulatory mandates such as GMP or it is just the lack of knowledge in most of the small enterprises?

1.9 Researching and developing new drugs is a lengthy and costly process, in your view does this contribute to the sector development?

1.10 KZN has experienced climate-change-related shock, how do view this as a hindrance in the pharmaceutical sector

1.11 How can R&D, and technological investment assist in industrial growth?

Government Department questions

1.1 In your view, how do you see the pharmaceutical industry, fostering growth and development in the province of KZN?

1.2 As the government, do you think the sector has the potential to dominate in the province, if the answer is yes how?

1.3 Government support and industry policies and regulation how do you think they contribute to sector development? This may include the incentives relating to the sector and any regulation that protects and guides the sector.

1.4 Given the high employment rate in the province of KZN, do you think the sector can make any contribution to assist in creating jobs? If yes, are there any intervention from the government side?

1.5 Skills Shortage, could this be an issue for the Pharmaceutical sector in KZN or not? Any intervention from the government side?

1.6 In your own opinion, what role can academic institutions and government play, in assisting the development of the Pharmaceutical sector?

1.7 Public sector procurement system, in your own opinion does it cater for local production?

1.8 Government incentives (financially or support), that can assist in sector development?

1.9 Researching and developing new drugs is a lengthy and costly process, in your own view how does this process contribute to the sector development?

1.10 KZN has experienced climate-change-related shock, how do you view this as a hindrance in the Pharmaceutical sector?

1.11 How can R&D, and technological investment assist in industrial growth?

1.12 What opportunities can the province leverage to become the leader in this sector, if there are any?

APPENDIX B: RECRUITMENT POSTER

INVITATION TO PARTICIPATE IN A RESEARCH

TITLE OF STUDY

*"*Exploring the conditions for development and employment growth in the pharmaceutical industry in KZN."

Researcher: Neliswa W Dlamini

The purpose of the study is to:

- The study intended to critically analyse the growth dynamics of the pharmaceutical healthcare sector by looking at the conditions for development, limitations that are linked to regulations and contribution to economic growth in the province of KZN

As per the invitation you are reminded to participate in the study:

-Date: May/June 2023

-Time: 10H00

-Venue: Teams /Face to face

Contact Information

To find out more about this study please contact:

- Neliswa Dlamini
- [redacted]

APPENDIX C: CONSENT TO PARTICIPATE.

Information Sheet and Consent to Participate in Research

Date: 17 April 2023

Dear Respondent's

My name is Neliswa Dlamini, I'm currently studying a Master of Commerce Leadership (MLS) degree at the University of KZN (UKZN) Master's qualification received upon completion will be at NQF level 9. The research supervisor is Profr Krishna Kistan email address is GovenderK@ukzn.ac.za.

You are being invited to consider participating in a study that involves research 'Exploring conditions for development and employment growth in the pharmaceutical industry in KZN." The aim and purpose of this research are to critically analyze the growth dynamics of the pharmaceutical healthcare sector by looking at the conditions for development, limitations that are linked to regulations and contribution to economic growth in the province of KZN. The study is expected to enroll 6-8 participants from various companies which include Xylomed, Ensemble Medical Manufacturers, Department of Trade and Investment Tourism and Environmental Affairs (Dube Trade Port). It will involve the following procedure which is the sampling method process of selecting a certain/particular targeted set of individuals to representing the population, structured in-depth interviews will be conducted face to face or online teams' method. The duration of your participation if you choose to enroll and remain in the study is expected to be an hour.

We hope that the study will create the following benefits which may not be so directed to you; conditions for development and employment growth have not yet been discussed in depth at a provincial level in the province of KZN, even though this sector is one of the priority sectors. Through this study, KZN might have an opportunity to develop new capabilities that might strengthen its competitive position. The empirical findings should provide clear directions that this sector will need to consider.

This study has been ethically reviewed and approved by the UKZN Humanities and Social Sciences Research Ethics Committee (approval number REC-040414-040).

In the event of any problems or concerns/questions you may contact the researcher at [redacted] or the UKZN Humanities & Social Sciences Research Ethics Committee, contact details are as follows:

HUMANITIES & SOCIAL SCIENCES RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus
Govan Mbeki Building

Private Bag X 54001
Durban
4000

KZN, SA

Tel: 27 31 2604557- Fax: 27 31 2604609

Email: HSSREC@ukzn.ac.za

Participation in this research is voluntary, you do not have to answer any question that makes you uncomfortable. You may choose not to take part at all. If you decide to be in this study, you may stop taking part at any time. If you decide not to be in this study or if you stop taking part at any time, you will not lose any benefits in the form of incurring penalties to which you are normally entitled.

To protect the participants, the researcher will use a coding system to protect the participants. The data will only be available to the researcher and the supervisor under no circumstances will be left unattended.

CONSENT

I _____ (Name and Surname) have been informed about the study entitled (provide details) by Neliswa Dlamini, student number 200201580.

I understand the purpose and procedures of the study intend to critically analyse healthcare sector growth dynamics focusing on the pharmaceutical industry, by looking at the conditions of development, limitations that are linked to regulations and its contribution to economic growth in the province of KZN.

I have been allowed to answer questions about the study and have had answers to my satisfaction.

I declare that my participation in this study is entirely voluntary and that I may withdraw at any time without affecting any of the benefits that I usually am entitled to.

If I have any further questions/concerns or queries related to the study, I understand that I may contact the researcher at [redacted] or email 200201580@stu.ukzn.ac.za

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

HUMANITIES & SOCIAL SCIENCES RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus
Govan Mbeki Building
Private Bag X 54001
Durban
4000
KZN, SA
Tel: 27 31 2604557 - Fax: 27 31 2604609

Email: HSSREC@ukzn.ac.za

Additional consent, where applicable

I hereby provide consent to the researcher to Audio-record my interview/focus group discussion YES / NO

_____ _____

Signature of Participant Date

_____ _____

Signature of Witness Date

(Where applicable)

APPENDIX D: XYLOMED PHARMACEUTICAL GATEKEEPER LETTER

Xylomed pharmaceuticals
Made By People, Empowered By Pride, Driven By Passion

Name of student: Neliswa Witness Dlamini

Student no: 200201580

Degree: **Master of Commerce in Leadership degree.**

The title of the proposed research is "Exploring Conditions for Development and Employment Growth in Pharmaceutical Industry in KwaZulu-Natal".

BACKGROUND

1. I am currently studying towards a Master of Commerce in leadership (MCLS) degree at the University of Kwa-Zulu Natal (UKZN). The Master qualification received upon completion will be at NQF level 9.

2. The completion of a dissertation is required in partial fulfilment of a Master of Commerce in Leadership (MCLS) degree.

DISCUSSION

1. Pharmaceutical sector in KwaZulu Natal offers significant opportunity for not only reducing the trade deficit but also increasing employment and improving healthcare. Africa Union's Review of Policies and Strategies for the Pharmaceutical Production Sector in Africa study (2020), asserts that, pharmaceutical industry in Africa has many challenges. In order to meet international standards facilities and productions practices need to improve. Which requires large capital investments, specialised expertise (skills), increased regulatory oversight, favourable business environment is all necessary for the industry to develop. The study intends to critically analyse the growth dynamics of the pharmaceutical industry by looking at the conditions for development, limitations that are linked to regulations and contribution to economic growth in the province of KwaZulu-Natal.

2. To make recommendations, that will assist in better positioning KwaZulu Natal as gateway for potential investors to Southern African Development Community Countries.

3. The research supervisor is, Dr Krishna Kistan Govender (cell no: [redacted]2 and email: GovenderK@ukzn.ac.za)

4. The deadline for dissertation submission is September 2023

9. The research will be conducted for academic purposes only and will be kept confidential by the institution.

10. There will be no reputational damage to Xylomed Pharmaceutical Company or any other stakeholders emanating from this study.

11. A copy of the final research document will be provided to Department of Economic Development, Tourism and Environmental Affairs (Investment promotion Unit) and companies involved in the research.

12. The research will be based around the investment opportunities and strategies for the pharmaceutical production in KwaZulu-Natal Province

FINANCIAL IMPLICATION

None

Please sig[redacted]

APPENDIX E: MEGROTEX MANUFACTURERS GATEKEEPER LETTER

ENSEMBLE
Medical Manufacturers PTY LTD

P.O. Box 10008, Ashwood
KZN, South Africa, 3605
Reg No. : 2014/117055/07
Vat No. : 4600187399

Tel: +2731- 700 5013/15
Fax:+2731- 700 5012
info@ensemblemedical.co.za

Name of student: Neliswa Witness Dlamini

Student no: 200201580

Degree: **Master of Commerce in Leadership degree.**

The title of the proposed research is "Exploring Conditions for Development and Employment Growth in Pharmaceutical Industry in KwaZulu-Natal".

BACKGROUND

1. I am currently studying towards a Master of Commerce in leadership (MCLS) degree at the University of Kwa-Zulu Natal (UKZN). The Master qualification received upon completion will be at NQF level 9.

2. The completion of a dissertation is required in partial fulfilment of a Master of Commerce in Leadership (MCLS) degree.

DISCUSSION

1. Pharmaceutical sector in KwaZulu Natal offers significant opportunity for not only reducing the trade deficit but also increasing employment and improving healthcare. Africa Union's Review of Policies and Strategies for the Pharmaceutical Production Sector in Africa study (2020), asserts that, pharmaceutical industry in Africa has many challenges. In order to meet international standards facilities and productions practices need to improve. Which requires large capital investments, specialised expertise (skills), increased regulatory oversight, favourable business environment is all necessary for the industry to develop. The study intends to critically analyse the growth dynamics of the pharmaceutical industry by looking at the conditions for development, limitations that are linked to regulations and contribution to economic growth in the province of KwaZulu-Natal.

2. To make recommendations, that will assist in better positioning KwaZulu Natal as gateway for potential investors to Southern African Development Community Countries.

ENSEMBLE
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info@ensemblemedical.co.za

3. The research supervisor is, Dr Krishna Kistan Govender (cell no: [redacted] and email: GovenderK@ukzn.ac.za)

4. The deadline for dissertation submission is September 2023

5. The research will be conducted for academic purposes only and will be kept confidential by the institution.

6. There will be no reputational damage to Megrotex (Ensemble Medical Manufacturing) Company or any other stakeholders emanating from this study.

7. A copy of the final research document will be provided to Department of Economic Development, Tourism and Environmental Affairs (Investment promotion Unit) and companies involved in the research.

8. The research will be based around the investment opportunities and strategies for the pharmaceutical production in KwaZulu-Natal Province

FINANCIAL IMPLICATION

None

Thanking you

[redacted]

Imraan Essack (Managing Director)

14 March 2023

APPENDIX F: ETHICAL CLEARANCE

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

19 October 2023

Neliswa Witness Dlamini (200201580)
Grad School Of Bus & Leadership
Westville Campus

Dear NW Dlamini,

Protocol reference number: HSSREC/00005164/2023
Project title: Exploring Conditions for Development and Employment Growth in Pharmaceutical Industry in KwaZulu-Natal
Amended title: Exploring the conditions for the development and growth of the pharmaceutical industry in KwaZulu-Natal
Degree: Masters

Approval Notification – Amendment Application

This letter serves to notify you that your application and request for an amendment received on 27 September 2023 has now been approved as follows:

- Change in title

Any alterations to the approved research protocol i.e. Questionnaire/Interview Schedule, Informed Consent Form; Title of the Project, Location of the Study must be reviewed and approved through an amendment /modification prior to its implementation. In case you have further queries, please quote the above reference number.

PLEASE NOTE: Research data should be securely stored in the discipline/department for a period of 5 years.

HSSREC is registered with the South African National Health Research Ethics Council (REC-040414-040).

Best wishes for the successful completion of your research protocol.

Yours faithfully

[redacted]

.....
Professor Dipane Hlalele (Chair)

/dd

APPENDIX G: GRAMMARIAN LETTER

[redacted]r

[redacted]

[redacted]g

Western Cape

22 April 2024

LANGUAGE & TECHNICAL EDITING

Cheryl M. Thomson

Exploring the conditions for development and growth of the pharmaceutical industry in KwaZulu-Natal

This is to confirm that I, Cheryl Thomson, executed the language and technical editing of the above-titled dissertation of **NELISWA WITNESS DLAMINI, student no. 200201580,** at the **UNIVERSITY of KWAZULU-NATAL**, in preparation for submission of this dissertation for assessment.

Yours faithfully

[redacted]

CHERYL M. THOMSON

Email: [redacted]

Cell: [redacted]