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Exploring Conditions for Development of the Pharmaceutical Industry in KwaZulu-Natal, South Africa

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Abstract: Various studies of the pharmaceutical industry suggest that the sector is critical for economic growth, access to affordable healthcare, and addressing socio-economic challenges. Recently, public healthcare in South Africa encountered numerous challenges such as the non-availability of vaccinations to deal with the COVID-19 pandemic. This was due to inter-alia, the lack of manufacturing capabilities resulting in overreliance on imported vaccinations. This study aimed to critically review the growth dynamics of the pharmaceutical healthcare sector in KwaZulu-Natal (KZN) province in South Africa, by analysing the conditions for the development and growth of the sector. By using a qualitative research design, data was collected from the key players in this sector by conducting five (5) in-depth interviews with purposively selected individuals from the industry. The analysis reveals that there is minimal interest from the government to grow the sector since there is a poor regulatory framework and the KZN province is thus struggling to attract foreign investment in this sector. It also became apparent that a sectorial long-term vision necessitates a skills development plan related to sector demand and addressing socioeconomic challenges. The framework and policies must be linked to this strategy to achieve aggregate productivity growth in the province. Furthermore, the government's responsiveness to the pharmaceutical sector requires an agile approach to capacitate the industry players and strengthen coherence. The primary implication of this inquiry 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 would provide a much-needed practical and theoretical lens for future similar studies.

Keywords: pharmaceutical sector; economic growth; socioeconomic challenges

1. Introduction

South Africa's medicine supply is primarily being met by imported generic medicines and, to a lesser degree, locally manufactured generic medicines. This, combined with a volatile and sometimes uncertain regulatory environment has led to interesting dynamics and changes within South Africa's pharmaceutical manufacturing industry (Naudé & Luiz, 2013).

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The pharmaceutical industry is defined as an industry that discovers, develops, manufactures, or produces, and sells drugs for use as medication. Defining the illness of the patients is not part of the industry's mission, but 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 (The Pharmaceutical Industry Report, 2019). As part of socio-economic development, ensuring access to health care is critical for the South African government, and it forms part of the UN Sustainable Developmental Goals. Therefore, certain measures have been put in place to ensure the reduction of drug prices and use of generic drugs, to make sure 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 SEP (Single Exit Price) that is uniformly applied to all products (www.sahpra.org.za).

The literature emphasises the great potential of the bioeconomy for sustainable development toward the achievement of the SDGs (Dietz, Börner, Förster & Von Braun, 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 2018/19-2020/21, continues to support developments in the broader bioeconomy (www.thedti.gov.za). These are some of the positive policy measures supporting this industry and are part of the national development plan.

Researchers such as Harrison and Rodriguez-Clare (2010) contend that trade and industrial policies are established to support the sector's growth and development. This is supported in South Africa since the Government uses various policy measures, to stimulate the growth of various sectors such as the pharmaceuticals sector, and position themselves 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 (SEZ) in Kwa-Zulu Natal (KZN), there is Richards Bay Industrial Development Zone (IDZ) and 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 programs are to promote Foreign Direct Investment (FDI) and export commodities (www.thedtic.gov.za).

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 Kwa-Zulu Natal, 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. The Covid-19 pandemic 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 so aligned with the national government plans (Starr, 2017).

Some 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. For example, the 2019 Lancet Report by Peres, Macpherson, Weyant, Daly, Venturelli, and Mathur, indicates that infectious disease treatment accounts for more than half of the overall pharmaceutical spending in the public health sector, where mostly that spending is mostly in consumable products (Peres et. al, 2019).

The South African 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

industries play a critical role in the overall economy. However, 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 (Naudé & Luiz, 2013). Similar to the case of National Health Insurance (NHI), a coordinated manner could lead to a similar case that is still under negotiation at the policy phase, and such policy impacts highly this 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 result as expected, hence the critical element of developing the innovation strategy needs to be monitored. The strategy needs to look into two elements, that will be the consumer demand model and the supply model with the sector or industry.

The Department of Health (DOH) annual report 2020-2021 states that, the KwaZulu Natal province is currently estimated to have a population of 11.5 million with about 74 hospitals affiliated to the clinics (www.kznhealth.gov.za). The Kwa-Zulu Natal (KZN) province also has the largest and busiest shipping terminal in the Port of Durban, commonly called the Durban harbour. According to the latest report "KZN *Economic Review, 2022*" 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 (TEU) *twenty-foot equivalent unit* in 2019. The Who owns Whom, (2019) indicates that the Pharmaceutical Industry concentration of companies's profile per Province is as follows:

- Gauteng - Sixty (60) registered pharmaceutical companies;
- Western Cape Province – Fifteen (15) registered pharmaceutical companies;
- KwaZulu Natal Province – Nine (9) registered pharmaceutical companies;
- Free State – One (1) registered pharmaceutical company;
- Eastern Cape – Three (3) Registered pharmaceutical companies;
- Northwest – One (1) registered pharmaceutical company.

Job creation is at a critical state in the KwaZulu Natal province, as announced by the Premier of the Province, in his *State of the Province Address, February 2022* (www.kznonline.gov.za). The purpose therefore is to explore the growth sector dynamics in comparison with the other provinces and also assess if there is need to look at diversification of the pharmaceuticals manufacturing industry on the types of final products they produce and assess the impact it may create to economic growth and the employment generation.

Globally, everyone has the right to access healthcare and in South Africa, and this is enshrined in the Constitution of the Republic of South Africa Act 05 of 2005. Chapter 2 section 11 which states that everyone has a right of life and section 27(a) stipulates that everyone has the right to access health service in this process, there should be an effort to make required or basic healthcare facilities (hospitals, physicians, equipment, innovation, and infrastructure) available (www.sahrc.org.za).

In an attempt to make the required and basic healthcare available, the role of the pharmaceutical sector is critical, because it is a fundamental base of healthcare and economic sustainability. Akhtar (2021)

reports that the Indian Pharmaceutical industry is one of the world's largest and most developed, ranking fourth in terms of volume and thirteenth in terms of value. Furthermore, the study indicates that India accounts for an estimated 10% of global production and 2% of world markets in pharmaceuticals and has over the years made significant progress in infrastructure development, technical capability and enhance production with a wide range of pharmaceutical products. There is an increasing interest and investment in R&D and the industry provides employment to almost 29 million people. The contribution of pharmaceutical sector in India's GDP is 2% and 12% of manufacturing sector GDP (Akhtar, 2021).

Schneider, Schulze, Bentrop and Paunescu (2010), argue that the industrialisation process in Singapore involves innovation which is also an efficient industrial development tool that sustains economic growth. Schneider et. al. (2010) argue that in the Singaporean experience, the sector is driven by innovation hence it is classifies as a high-tech skill sector. Significantly, Schneider et. al. (2010) established that it is important to understand technological and economical variable that influence the creation of a successful projects that will generate income and growth. The pharmaceutical industry in South Africa is characterised by a lack of investment and skills, stagnant economic growth and income, and lack of strong policy direction (Naudé & Luiz, 2013), which implies that South Africa is lagging behind. Policy direction has the capacity to influence the growth of the manufacturing industry, of which the pharmaceutical business is a component. Chenoy, Ghosh and Shukla, (2019) suggests that manufacturing has the potential to emerge as one of the high-growth sectors, provided that stakeholders are focusing on developing right skills (Chenoy, et. al, 2019).

Historically, there has been restructuring in the global pharmaceutical industry since the early 1990s (Malerba & Orsenigo, 2015). This restructuring happened within pharmaceutical production and manufacturing, which has then resulted in the development of "centres of excellence", where companies focus their production and manufacturing activities in a select number of countries. Researchers such as Nielsen, Asmussen and Weatherall (2017), are of the view that such decisions that leads to choosing the destination of choice are driven by Weatherall mostly three elements which researchers have observed a strong positive association which are a right combination of skills, a beneficial geographic location in the world market and the provision of government investment incentives to companies (Nielsen, et. al, 2017). This, coupled with the global trend towards mergers and acquisitions (M&A), has led to these companies becoming more cost effective and profitable (Naudé & Luiz, 2013).

In light of the above, this study aims to critically analyse the growth dynamics of the pharmaceutical healthcare sector by exploring the conditions for development, the limitations that are linked to regulations, and contribution to economic growth in the province of KwaZulu Natal. By drawing on PESTEL analysis and Porter's theoretical framework, 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 KwaZulu Natal. To achieve this, the study was guided by the following research objectives:

- To explore, how the high-tech pharmaceutical industry sector influences economic growth activities in KwaZulu Natal;
- To investigate the conditions for development and employment growth of the high-tech pharmaceutical sector in KwaZulu Natal;

• To examine the dynamics of growth and development linked to the healthcare sector in ensuring sustainable growth of the sector.

2. Research Methodology

An interpretive research paradigm and qualitative research design which emphasise the social context and human complexity as to how people understand the phenomena (Rashid, et. al, 2019), was adopted. A qualitative technique is described by Creswell (2014) as a technique that's intends to unpack and understand a complex reality and the meaning of action in a given context. The approach enabled the researcher to understand issues by investigating and analysing them in the participant's own context and the significance that humans assign to them (Asenahabi, 2019).

This study was conducted in eThekwini Metropolitan, which is the largest district municipality in KwaZulu Natal Province as well as the economic hub of the province. By using purposive sampling, three of the largest pharmaceutical enterprises and government institutions based at the Dube Trade Port (SEZ) were purposively selected to participate in this study. Furthermore, the government institution mandated for development and promotion of pharmaceuticals sector, Department of Economic Development, Tourism and Environmental Affairs (EDTEA), was also selected. Table 1 below reflects a breakdown of the sample.

Table 1. Sample Distribution

Division/Organisation	Population	Sample Size		Data Collection tool
			Purposive	Interviews
Economic Development, Tourism and Environmental Affairs	1200	2	2	2
Dube Trade Port (Entity for EDTEA)	80	1	1	1
Xylomed Pharmaceutical	800	2	2	2
Magrotex Pharmaceutical Supply (Ensemble Medical Manufactures)	80	2	2	2
Total	**2160**	**7**	**7**	**7**

Source: Developed by the Researchers

Since this was an exploratory study, data collection was through structured in-depth interviews using open-ended question (Adhabi & Anozie, 2017). Interviews were conducted with the Executive Manager, Pharma portfolio at Dube Trade Port, followed by interviews with the CEOs of Xylomed Pharmaceutical and Magrotex Pharmaceutical Supply (Ensemble Medical Manufactures), as well as the Director of Pharmacy Sector Development at the Department of Economic Development, Tourism and Environmental Affairs. Furthermore, documents such as Annual Performance Plans (APP), Annual Reports (AR), Business Plans (BP), Financial Statements from companies and department were analysed.

Thematic analysis was used to analyse the qualitative data since it is recommended by several researchers (Vaismoradi, Turunen & Bondas, 2013; Javadi & Zarea, 2016). The main purpose of thematic analysis is to identify themes and use the themes to address the research questions. According to Nowell, Norris, White & Moules (2017) trustworthy qualitative research requires rigorous thematic analysis in order to produce insightful findings.

The study is founded on the PESTEL 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 (Yüksel, 2012). PESTEL analysis is regarded as a mandatory method that analyses the factors relevant to any sector environment and gives information that allows organisation to be able to predict the situation, influence the decision and develop competitiveness (Matovic, 2020). Yüksel 2012, refers to the strategic analysis as the first basic stage of strategic management that involves current factors relevant to the environment where companies operate (Yüksel, 2012).

3. Findings

The data was collected using a face-to-face interviews and Table 2 below reflects the demographic data of the interviewees.

Table 1. Demographic data of Research Participants

Participant	Research participants	Race	Gender	Number of 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	5	
			1	4		

Source: Developed by the researcher

Figure 1 is a matrix which shows the relationship between the themes, sub-themes and the theoretical framewor

Research Objectives	Interview questions	Themes	Sub Themes	Theoretical Framework
1. To explore, how the high-tech pharmaceutical industry sector influences economic growth activities in KwaZulu Natal	• In your view, how do you see the pharmaceutical industry, fostering growth and development in the province of KwaZulu Natal? (Overview)	Research and development (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 polices (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 KwaZulu Natal.	• 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 Factor
	• Given the high employment rate in the province of KwaZulu Natal, 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 pharmaceutical sector in Kwa-Zulu Natal or not? How can this be improved and retained with in the sector?	Shortage of skills	Misalignment of available skills	Social and cultural factors Social and cultural factors Political factor
3. To examine the dynamics of growth and development linked to the healthcare sector in ensuring sustainable growth of the sector	• In your own opinion, are financial contains hindrance in ensuring that companies comply with regulatory mandate's such as GMP or it just the lack of knowledge in most of the small enterprises? • In your own opinion, what role can academic institution 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		Economics factor Environmental factor Legal Factors Technological Factor

Figure 1. Interconnection between the Research Objectives, Interview Questions and Theoretical Framework

Source: Developed by the researcher (2023)

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

3.1. The Influence of High-Tech and Pharmaceutical Industries on 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 in KZN. The initial theme that emerged was *Research and Development and Industrial Policies*. Furthermore, the subthemes that emerged from both of these themes respectively are *inadequate investment initiatives*, a *lack of collaboration,* and *difficult business conditions.* During the face-to-face interviews, the interviewees were asked about their views on the influence of the pharmaceutical industry. The section below presents the interviewees' responses, which are supported by the body of knowledge.

4. Research and Development

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 Gross Value Added (GVA) through indirect, direct economic and induced economic impacts that are considered as of impact analysis. As discussed R&D in the pharmaceutical industry covers three areas of activity; basis research, applied research and experimental development, combined it purpose is discover and generate new knowledge, ultimately providing solutions to problems. Therefore, it contributes to human development in addition stimulating economic growth by providing infrastructure and supplying services.

The following remarks shows the respondents' comments with respect to the question: "In your view, how do you see the pharmaceutical industry fostering growth and development in the province of KwaZulu Natal?". The following remarks were made by Participant 5.

"*The Biotech and Pharma industry can grow to become one of the most important pillars of the economy in KwaZulu Natal 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 percent 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 a Research and Development (R&D) Science Centre for KZN Province. The associated income streams impact KZN in a variety of ways".

Similarly, Participant 4 stated that:

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

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 a 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-will is misplaced, ignoring the fact that the pharmaceutical sector has the potential to influence, a create positive impact on economic growth.

4.1. 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, the pharmaceutical industry being one of the most technologically intensive industries and R&D investments play an important role towards 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 indicated 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 will assist in balance the state of self-sufficiency and ability to respond to anticipated growth.

5. 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. Carpenter (2021) further demonstrates that the major commitment to green house, and the reduction of gas

emission, has yielded positive results. However, the author contents this challenges 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 government, particularly the pharmaceutical manufacturing sector which a core industry sector, and the private sector have also contributed significantly to 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 a purpose of moving closer to sustainable of the pharmaceutical sector of the future.

Participant 4, stated that:

"*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'* (GMM4, 2023).

Participant 1 said that:

"*Government need to be stringent on procuring local manufactured goods, and be able to protect the local manufacturers, the imports are the one that makes it so difficult for local manufactures to strive, it is very difficult to compete with the international prices, and the costs on manufacturing are very high'* (PPM2, 2023).

It is apparent that the government needs to align with the private sector, which is the main contributors 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.

5.1. Industrial Policy

Altenburg and Rodrik (2017), define industrial policy as government actions that are used to structure the sector. When counties are implementing 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 regulation including burdensome regulation and procedures, and difficult barriers may hinder the development therefore contributes to a slow pace of sector growth, which may have negatives outcomes, and make the business environment unfavourable.

In line with the above theme, Participant 5 stated that:

"*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*" *(GMM5).*

5.2. Conditions for Development and Employment Growth of High-Tech and 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. The initial theme that emerged is Government Support and Shortage of Skills. Furthermore, the subthemes that emerged from both these themes respectively are shortage of skills, Inadequate resources, and misalignment of available skills. The section below 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". The following remarks were made by Participant 5.

"*The KZN Provincial Government must envisage that their support and encouragement to produce value-added products for the export market will increase foreign direct investment 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 stated that:

"*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 good manufacturing practice (GMP), and no single product has been prequalified by WHO".

6. Government Support

Songling, Ishtiq, Anwar & Ahmed (2018), found that government organisations are to formulate strategies that will enhance the growth and survival of industries. Furthermore, these researchers emphasise the fact that every industry plays a critical role in economic growth, especially in an emerging market, this is then useful for the study as it provides a general view of the government's support not only related to the pharmaceutical sector however in any industry as long as it contributes to sustainable development. With respect to the PESTEL analysis framework, political factors, determine the extent to which a government may influence the economy or a certain industry (Rastogi & Trivedi, 2016).

One of the interviewees Participant 1, stated that:

"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, revealed:

"Government *has a role to play, in making the conditions conducive to the potential investors that applies across the board, however in particular for his sector we have various challenges, to mention 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 to you think it will cost from local suppler and the answer is R9.00*" *other 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".*

6.1. Shortage of Skills

Essentially, development funds or resources must be increased in order 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. The following remarks were made by Participant 5.

"Yes, furthermore, KZN definitely be 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 and UKZN Degree & Diploma Programs that will ensure that the PHARMA Industry has a continuous supply of skilled Local employees from the surrounding regions furthermore, KZN Provincial Government 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 have the high employment rate, however we believe that as government we need to participate as an intervention to assist. May be again it's not the issue of shortage of skills, but it 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 at the right positions".

The findings imply 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.

6.2. Government Responsiveness to Pharmaceutical Industry Needs

The pharmaceutical sector extension and R&D are essential for the growth of the sector; however, it is impended 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 pharmaceutical industry.

One of the interviewees (Participant 5) stated that:

"*Yes, there are significant financial constraints in cGMP and Pharma Product registration regulatory fees. At a minimum, GMP 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 of 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 government we need to account*".

Therefore, the data analysis under this objective demonstrates that, PPP has a potential to provide a sustainable development that cut across all the sectors, which will need to be supported by the leadership, in this case it will be the KZN government.

6.3. Research and Development Influencing Economic Growth

The primary research objective of the study was to explore, how the high-tech pharmaceutical industry sector influences economic growth activities in KZN. The perspective deduced from interviewees, suggest that the biotech and pharmaceutical industries have the potential to become one of the most important pillars of economy. This resonates with the findings of Agénor and Neanidis (2015), on evaluation of Innovation, public capital, and growth. In their study they 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. On the same manner, this is also supported by Pece, et. al. (2015), an empirical analysis of innovation and economic growth: in Central Eastern Europe countries, 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 positive economic growth of the country. Moreover, these authors arues that FDI increases the possibility of knowledge transfer and technological process improvement, this therefore influences the conditions of sector development.

The study found that the sector requires enough resources that will assist in balance the state of self-sufficiency and ability to respond to anticipated growth; as the results this leads *inadequate investment initiatives.* Interviewee perspective indicated that, there is an opportunity to increase the sector growth 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". This resonates with the findings of Aghmiuni et. al. (2020), on assessment of factors affecting innovation policy in biotechnology, author's found that state government need to set aside a portion of its budget mainly for biotechnology and development, in order to encourage innovation and prepare for the modern era of globalisation. Whilst the interviewees are of the view that, enhancing the R&D investment activities requires substantial amount of investment and such amount is the hinderance for them in conducting such activities. This finding is similar to the one shared by McGlacken, Hayes, Maguire, O'Halloran

and Hodnett (2018), on Industry–Academia Partnership. These researchers stated that, while in the last decade R&D investment remained low for multinational companies in Ireland due to contract manufacturing, it was their government responsiveness which has led to this country to remain in the forefront of API manufacturing, where their government felt that they needed to position themselves as a global hub for process innovation, consequently a 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), stated that, pharmaceutical innovation is a system that includes governments and policymakers, regulatory bodies, educational institutes, R&D organizations, entrepreneurs, and pharmaceutical companies. Therefore in order for the industry growth it needs to be within the sustainable environment, and sustainability can only be claimed through its stakeholders (Tawfik, et. al, 2022). Therefore, this result, leads to the findings of lack *of collaboration (Subtheme),* among stakeholders having similar interests in seeing the sector growth. Empirical evidence has over the years shown the benefits of collaboration, this finding is similar to the one shared by McGlacken, et. al. (2018), established that issues of trust, and inclusivity as well as, commitment to mutual benefit are some of the factors that contributed to the success of Synthesis and Solid-State Pharmaceutical Centre (SSPC) in Ireland. Similarly, Gutiérrez and Macken-Walsh (2022) Ecosystems of collaboration for sustainability-oriented innovation: the importance of values in the agri-food value-chain, author's established that sustainable sector growth, in their opinion, must be characterized by a strong ecosystem of collaboration across the value chain.

6.4. Industrial Policy Influences the Pharmaceutical Sector Development

A general view from the private sector interviewees is that the is a lack of comprehensive policy and institutional framework which is leading to the decline demand of innovative products. Pecchia, Piaggio, Maccaro, Formisano and Ladanza (2020) on, the inadequacy of regulatory frameworks in time of crisis and in low-resource settings: personal protective equipment and COVID-19, cited 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 evidence based framework, which will prioritised the internal stakeholders (Pecchia et. al, 2020). This view concurs with those of Cherif, Hasanov, Spatafora, Giri, Milkov, Quayyum, Industrial Policy for Growth and Diversification: A Conceptual Framework (2022) the author's cited 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. In their argument these authors mentioned that in the 1970s and until 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). In contrast to this, the common view held by the interviewees is that government lack technical capabilities and understanding in championing and leading the policy direction of such sector. the industry players should be the ones to develop policies aimed at promoting pharmaceutical sector with a purpose of harnessing benefits thereof (job creation, infrastructure development and R&D etc.).

This study found that the unsustainable competitive environment needs to be managed from the provincial government side, which leads to subtheme discussion of *difficult conditions for business.* In the main, the study respondents attribute this to stringent procuring polices that's makes it difficult for local manufactures compete. *The study participants are of the opinion that in order for local manufactures to compete, the need to be protected from the influx of below standard import products. For example, one interviewee made and an example of Biovac vs Cipla vaccination for Covid 19 recent case.* The study found that conditions of business in KwaZulu Natal are not as favourable to local manufactures as they should be. Government marketing program are to encourage the private sector to purchase and consume locally manufactured pharmaceutical products make the conditions favourable to conduct the business. In essence, this demonstrates that the government is a leading partner 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 activities related to the sector's development. This implies that activities such as research and development require full participation from both the private and public sectors, private sector having the know-how skills in the sector by providing the knowledge and skills transfer to partner with the government, where the government will have to enable conditions, such as unlocking foreign direct investment which will enhance the economic activity and boost local production. Government must also allow the private sector to lead the evidence-based policy framework for the sector in order to realise a better outcome of dynamic issues at hand and improve the policy coherency within the sector, as found in this study. This will therefore assist them in realising the maximum impact that a sector aims to achieve. The following section will discuss findings of the second objective of the study: investigate the conditions for development and employment growth of the high-tech pharmaceutical sector in KwaZulu Natal.

6.5. 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. It became apparent that, while many factors have contributed to the underdevelopment of the local pharmaceutical manufacturing sector, one of the most significant gaps that has been identified is a lack of sectorial long-term vision that is aligned with the provinces' and 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 National Development Plan 2030 (NDP), which is the overall plan for the country. The development plan in summary indicates that the government will work with all sectors to understand how they contribute to implementation and, in particular, to identify any barriers that prevent them from fulfilling their roles. Therefore, this necessitates provinces focusing on identifying and overcoming the barriers to achieving the outcomes, including the need to strengthen local government's ability to fulfil its developmental role. Moreover, the general consensus among the participants (primarily from private sector) is that, while there is support from government, however 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 then highlights once again the policy coherence issues. Fourie

(2018) Aligning South Africa's National Development Plan with the 2030 Agenda's Sustainable Development Goals: Guidelines from the policy coherence for development movement, asserts that coherence between development policies of recipients and providers of development assistance is required for sustainable development which therefore contribute 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 new potential investors can gain a competitive advantage, this was in reference to centralisation approach which seen to be hinderance to them as industry players.

Another interesting view is the one of 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, additionally these author's suggested fit-for-purpose frameworks and other related frameworks. Arguable it is apparent to re-evaluate the best ways to position the sector in the province of KZN however it will necessitate an agile approach from the KZN leadership in spearheading this sector's development and enabling favourable conditions. Enabling conditions also refers prioritising financial support with government financial support, establishing 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). The study found that such effort has a significant impact on making the conditions of development more conducive; for instance, in South Africa, government assistance places its focus on programs that promote and support domestic manufacturing and R&D through their programs such as the Technology and Human Resources for Industry Programme (THRIP) and the Support Programme for Industrial Innovation (SPII), as stated in the DITC report. Wentzel and De Hart (2015), argued 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), report that India's road to independence in manufacturing active pharmaceutical ingredients focus on essential medicines. These researchers concluded that the formulation of the Pharma Bureau by the India government, to facilitate investment for ensuring faster statutory approval has contributed to facilitate timely approvals. Furthermore, these researchers argue that this is regardless of the fact that, cluster developers and participants may be granted tax-free status consequently tax-free status allows the cluster developers and participants to setup and reducing production cost in that process. 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 government is significant to enable the conditions for sector development. This will therefore contribute to the culture that the sector is formulated on, which the KZN government will have to lead in enabling the conditions of development of the pharmaceutical sector.

6.6. The Negative Effects of Skills Shortages on Employment Growth

The findings of this study revealed that, for the province of KZN to accomplish development of the pharmaceutical sector, there must be a clear set models that will allow the development to succeed, which filters through their education systems. This is supported by the work of Zhu, et. al. (2018) with evidence from central China. The authors argue that the educational options available to ordinary people determine a country's progress and prosperity. Furthermore, the above researchers explain that education cannot only prepares people to understand and deal with the complexities of economic growth, but it also acts as a lever for its growth. This viewpoint is consistent with that of the study participants, their perspective deduced that skills shortage effects the level of productivity and also reducing the knowledge capacity, as the results, they believe that academic institutions have an impact on the development of entrepreneurship and innovation which is required in the pharmaceutical sector. Researchers such as Brunello and Wruuck (2021) define the skills shortage as, process where the accessible labour market does not offer the employers the skills they require. One of the respondents when asked about the contribution that this sector can make in reducing the unemployment rate, he expressed that, while there is a willingness from employers to capacitate their employees with relevant skills required, the reality is that that process on its own comes with its economic costs. This resonates with the views of Santos (2020) where he echoed that firms that collaborate with universities and research institutes can innovate more and more radically.

A review of the literature reveals that the impact of skills misalignment, may not only results in high rate of absenteeism but also it may also increase the frequency in changing of jobs. This resonates with the concerns expressed by the respondent 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 participants responses was that they are requesting that, the KZN Provincial Government to use Government Policy & Regulations to enhance the local universities: BPharm, BSc Biochemistry, BSc Pharmacology Degree Programs to be more pharmaceutical production quality assurance and quality control oriented as well as introducing Pharm Tech Diploma Programs to ensure availability of appropriately skilled labour in addition for provincial government to institute a scholarship and bursary programmes for young local residents.

Contrary to the participants' views, a survey conducted by Naudé and Luiz, (2013) found that is that government funding for universities has decreased over the last decade, as this was discussed in this study's literature review, and this is a barrier in establishing a sustainable pharmaceutical production in South Africa. As a result, local governments must commit to funding programs such as human capital development to ensure aggregate productivity growth and the competitive environment for pharmaceutical and medical devices industry. Therefore, this may be accomplished by framework policies that are put in place, that encourage better location of existing skills and education policies that increase skills, resulting in effective supply of skills.

South African industry policies put emphases in localization (capacitating local industry) as an economic driver, as articulated by Department of Trade, Industry and Comparation (DTIC), thus the framework polices and education polices must be linked to this strategy, to achieve aggregate productivity growth. It is therefore for these reasons that, a commercially sustainable methods must be employed by provincial government in KZN, to create a pool of suitable workforce that the sector needs to in order for the province to be competitive.

6.7. 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. It was evident 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's, 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 respondent raised concerns about significant financial constraints in cGMP and regulatory fees for Pharma Product registration. Furthermore, GMP compliance registration fees for a single company can cost as much as ZAR 5 million, and there is no financial institution in RSA that can be willing to finance, thus making access to capital limited.

According to the participants, most established pharmaceutical companies have lobbied the SAHPRA to reduce product registration fees in order to capacitate the regulator, as these fees are prohibitively expensive for emerging pharmaceutical companies. Haldane, et. al. (2021) Government decisions shape healthcare infrastructure, regulations, and guidelines, defining access to medication and treatment, health coverage, and financing. Similarly, (Mailu et. al, 2018) Strategy implementation and organizational performance in the pharmaceutical industry in Kenya, contend that, at a resource disadvantage, no project venture is capable of implementing any superior competitive project idea, simply because ideas may simply remain ideas while there are no resources to put them into motion. Contrary to this view, Donegan, Lester, and Lowe (2021) striking a balance: A national assessment of economic development incentives reveals that economic development scholars have widely criticized incentives programs; furthermore, authors believe that the deals made by multinationals through the awarding system raise some concerns; moreover, when these multinationals fail to perform, their impact is felt on job losses. Surprisingly perspective deduced from the interviewee, suggest that lack of analytical capacity to access investment funds leading to poor implementation to grow the sector.

It was established 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 the incentives related to the sector, such as the Manufacturing Competitiveness Enhancement Programme (MCEP), Innovation and technology funding, and the 12i tax allowance incentive (the window period has expired), all administered by the Department of Trade, Industry, and Competition. Furthermore, regarding regulations, there are a plethora of policies that are put 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 National Development Plan, Vision 2030 NDP, as the blueprint for the South African government that aims to eliminate poverty and reduce inequality by 2030.

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), responsiveness, support, and responsibility: How democratic responsiveness facilitates responsible government argues that when people perceive government to be responsive to their demands and wishes, a buffer "of support grows; therefore, 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."

7. Conclusion and Recommendations

The study revealed that, when a pharmaceutical company opens a new site or expands an existing one, this leads to numerous orders for regional companies from other sectors (secondary effect), such as, the purchase 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 research and development (R&D) support program" by the KZN Provincial Government through policy & regulation as well as deliberate funding mechanisms KZN Provincial Government to support a "New Herbal Farming Techniques and Practices Support Program" that will incentivise farmers to grow the medicinal herbs required by the pharmaceutical industry for its Phyto-Pharmaceuticals Products.

The KZN Provincial Government should consider supporting the industry in a form of proving funding for "skills development support program" and to collaborate with local universities to ensure that pharmaceutical industry has a continuous and steady supply of skilled local employees from the surrounding regions.

The KZN provincial government to consider initiating a collaborative policy advocacy programme that will be inclusive of industry player to address some of the challenges associated with the current policies that seem to hinder the industry players and come up in progressive inclusive decisions. This 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 and political stability and the regulatory framework that protects and incentivizes industry players. Therefore, for KZN province, it includes the industry players that are involved in this sector, academic institutions and the private sector. Thus, the agility of responsiveness by the KZN provincial government to the mentioned matters will not only assist in enabling the condition of development; however, because of the nature of this sector in terms of its potential to drive economic activities, this will promote economic growth and contribute to job creation, which KZN will benefit from.

The study was exploratory in nature, and it did not attempt to provide final and conclusive answers to the research questions, even though it aimed to provide insight into the conditions of development and employment growth in the pharmaceutical industry in KwaZulu-Natal. The potential local economic impact that can be derived from the pharmaceutical industry needs to be quantified by future studies; this will, therefore, affirm the KZN provincial government and enable the leadership to arrive at more informed decisions in the significant sense of enabling the conditions of development and, thus, enabling the innovation ecosystem to be formulated in the province of Kwa-Zulu Natal.

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