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Barriers to Establishing Profitable and Sustainable Pharmaceutical Manufacturing Firms in Botswana

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Declaration (Signatures and Acknowledgements)

The work contained in this dissertation was completed by Bohutsana Margaret Molefi at the University of Botswana between August 2016 and December 2021 It is original work except where due reference is made and neither has been nor will be submitted for the award of any other University.

Signed.....

Date 08th DECEMBER 2021

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Dedication

This project is dedicated to my Family that is Lebotse Molefi and our twins Masego Dorah Molefi and Kagiso Molefe Molefi. A master's degree in Business Administration started as a personal dream and a journey that espoused a dream that I have for this family. My husband then embraced the dream and supported the project to its fruition. This project is not only an academic achievement, it is pregnant with hope and aspirations for this family to be successful business men and women, and the legacy would be carried down through the generations.

Abstract

Africa is believed to bear a very heavy burden of disease accounting for 25% of the world's disease statistics (Owoeye, 2014) . Modern curative care is believed to depend on the availability of medicines (World Health Organization (WHO), 2013). The African continent (including Botswana) is however dependent on pharmaceutical imports. Shortage of medicines has resuscitated the discussion on the feasibility of local production (UNDP, 2013). The few firms that attempt pharmaceutical manufacturing in Africa however, continue to close. Factors that contribute to the closure of these firms have been investigated in some African countries, there is, however, a call to conduct feasibility studies and establish why pharmaceutical manufacturing is failing in Botswana (Mhamba & Mbirigenda, 2010; Naude & Luiz, 2013; UNDP, 2016b).

The purpose of this study was to establish country specific reasons that contributed to the failure of pharmaceutical manufacturing firms in Botswana. An exploratory, cross sectional study was conducted amongst firms that operated between 1990 and 2015. Two (2) employees from management from each firm were purposely sampled. Respondents completed a questionnaire which was followed by a face to face interview. Employees from four (4) of the six (6) firms responded. The data was analysed using tables, graphs and bar charts using excel to establish patterns, frequencies, and averages.

Factors that presented as major challenges were poor access to markets, lack of finances, inadequate infrastructure and unskilled labour. The market was characterized by pharmaceutical registration delays, poor procurement policies and an unsupportive business environment. The use of expatriate skilled labour was still rampant and local professionals had inadequate skills to operate successful firms. Public Private Partnerships have not been successful; however, financial institutions seem to be risk averse regarding investment in

the pharmaceutical industry. This research calls for a review of policies to support profitable pharmaceutical manufacturing.

Table of Contents

Declaration……ii
Acknowledgements……..iii
Dedication……....iv
Abstract…….……v
Table of Contents……vii
List of Figures……x
List of Tables……xi
Acronyms/Abbreviations ……...xii
Definitions……..xiv
CHAPTER 1: INTRODUCTION……..1
1.1: Overview of Botswana…….....3
1.2: The problem Statement……..4
1.3: Research Objectives……...6
1.4: Research Questions……6
1.5: Significance of the study……6
1.5.1: Impact of the Study in Government Policy…….....6
1.5.2: Impact of the study in Curriculum……..9
1.5.3: Impact of the Study in Job Creation……..10
1.5.4: Impact of the study in pharmaceutical Research…….....10
1.6: Theoretical Framework……12
1.7: The Scope of the Study……16
1.8: Structure of the report…….....16
CHAPTER 2: REVIEW OF RELATED LITERATURE…….....17
2.1: Introduction……..17
2.2: Factors contributing to closure of pharmaceutical Manufacturing Firms…….....22
2.2.1: Raw Materials……22
2.2.2: Legislation, Policies and Regulation……24
2.2.3: Company Resources……..26
2.2.3.1: Human Resource influence on Technology Transfer…….....27
2.2.3.2: Finances……..29
2.2.4: Utilities……..31
2.2.5: Market Size……32
2.3: The Business Environment…….....33

2.4: Market Orientation…….....35
2.5: Conclusion……37
2.6: Literature Gap…….....38
CHAPTER 3: RESEARCH METHODOLOGY……41
3.1: Introduction……..41
3.2: Research Questions……..41
3.3: Research Design……...41
3.4: Research Philosophies……..43
3.5: Independent and Dependent Variables……45
3.6: Population of the Study……49
3.7: Study Sample……50
3.8: Sampling Technique……51
3.9: Data Collection Methods……..51
3.9.1 Questionnaires……51
3.9.2: Interviews……..52
3.9.3: Access……52
3.9.4: Data gathering instrument……53
3.10: Data analysis…….....55
CHAPTER 4: PRESENTATION, INTERPRETATION AND ANALYSIS OF FINDINGS……..57
4.1: Introduction……..57
4.2: Descriptives……..58
4.3: Position and Length of service……59
4.4: Factors that contributed to the closure of pharmaceutical manufacturing firms……..61
4.5: Firm Resources……62
4.5.1: Tangible Resources…….....62
4.5.2: Intangible Resources……64
4.6: Market Orientation……...67
4.7: The external Business Environment…….....68
4.7.1: The Political environment…….....69
4.7.2: The Economic environment……..69
4.7.3: The Legal Environment…….....71
4.8: Firm Performance…….....71
4.9. Conclusion……72

CHAPTER 5: DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS…….74
5.1: Introduction…….74
5.2: Summary of the findings…….74
5.2.1: Market……..75
5.2.2: Financial Policies…….,80
5.2.3: Skilled Personnel……..82
5.2.4: Infrastructure…….....83
5.3 Market Orientation and Firm Performance……...84
5.4: Recommendations……85
5.5: Limitations of the study……87
5.6: Implications of the study to theory and practice……..87
5.7 Directions for future Research……..88
5.8 Conclusion…….....88
6.0 REFERENCES…….89
Appendices……..96

List of Figures

Figure1.6 Market Orientation Environment-Performance Framework…….....13
Figure 2.6 Botswana Manufacturing Status……39
Figure 3.4.1 Variables used in the study…….46
Figure 4.2.2 Gender…….58
Figure 4.3.1 Length of service…….59
Figure 4.5.2 Availability of skilled personnel…….66

List of Tables

Table 4.2.1 Demographics: Gender and Age……..58

Table 4.3.2 Firm Descriptive……...60

Table 4.4.1 Rating of Challenges…….....62

Table 4.6 Market Orientation Implementation……68

Acronyms/Abbreviations

ARV: Antiretroviral Medicines for treatment of HIV/AIDS

AIDS: Acquired Immunodeficiency Syndrome

B.O.B: Bank of Botswana

COHRED: Council on Health Research and Development

EFTA: European Free Trade Association

HIV: Human Immunodeficiency Virus

FDA: Food and Drug Administration (America)

GDP: Gross Domestic Product

GMP; Good Manufacturing Practices

IPR: Intellectual Property Rights

LDC: Least Developed Countries

M.O.H.: Ministry of Health

N.D.B: National Development Bank

NDP: National Development Plan

NEPAD: New Partnership for Africa's Development

PMPA: Pharmaceutical Manufacturing Plan for Africa

R&D: Research and Development

SAPAM: Southern African Programme on Access to Medicines and Diagnostics

SME's: Small and Medium Enterprises

TRIPS: Trade-Related Aspects of Intellectual Property Rights

TB: Tuberculosis

UNCTAD: United Nations Conference for Trade and Development

UNDP: United Nations Development Programme

UNIDO: United Nations Industrial Development Organization

WHO: World Health Organization

N.C.E: New Chemical Entity

Definitions

Definition of Terms

Access to medicines; The proportion of population with access to affordable, essential drugs on a sustainable basis; the percentage of the population that has access to a minimum of 20 of the most essential drugs. Access is further defined as having drugs continuously available and affordable at public, private health facilities or drug outlets**.**

Communicable Disease: A disease that is spread from one person to another or from an animal to a person. The spread often happens via airborne viruses or bacteria, but also through blood or other body fluid. The terms infectious and contagious are used for communicable diseases.

Counterfeit (fake) Medicines: Medicines that are deliberately and fraudulently mislabelled giving false information about their identity or source. They may or may not have the active pharmaceutical ingredient mentioned. Both branded and generic products can be counterfeited. The ingredients in counterfeit products may be wrong in quality and quantity and may be harmful.

Doha Declaration on TRIPS: Allows a country to import or produce a patented medicine provided that the owner of a patent or copyright licenses the use of their rights. The patent owner receives a payment either set down by law or determined by arbitration.

Essential Medicines; Medicines that satisfy the health care needs of the majority of the population. They are selected for their public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness.

Generic medicines: Pharmaceutical products intended to be interchangeable with the originator product and which are usually manufactured without a license (patent) from the originator company. They have the same active ingredients as that of the brand-medicine but are marketed under the name of their active ingredient (molecule). Generic medicines are legitimate, as effective as the brand-name medicine, but much cheaper**.**

Medicines; Any substance, mixture or combination of substances manufactured, sold or presented for use in the diagnosis, treatment, alleviation, modification or prevention of disease, illness, abnormal physical or mental condition or the symptoms thereof or restoring, correcting or modifying any somatic or psychic or organic condition. Pharmaceuticals word is used interchangeably with medicines**.**

Originator products: ‘‘Those products first authorized in a given country for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety, and quality, according to requirements at the time of authorization. Originator products that are marketed by a company under the terms of a licensing agreement with the originator are defined as ‘‘Licensed Brands’’

Patent: a set of exclusive rights granted by a state to an inventor for a period of time in exchange for the public disclosure of the invention. In the case of medicines, the patent grants the Pharmaceutical Company that develops a medicine a monopoly of that drug for 20 years. This means complete control over the production, distribution and price of the drug

Pharmaceutical Manufacturing

Primary level: Manufacturing Active Pharmaceutical Ingredients (APIs) and intermediates from basic chemical and biological substances; **Secondary production** includes the production of finished dosage forms from raw materials and excipients (inactive substance**); and Tertiary level:** limited to packaging and labelling finished products or repackaging bulk finished products.

Shortage of Medicines; a situation in which the current or projected demand of a medicine at user level is inadequately met**.**

Technology Transfer: Transfer of Systematic knowledge for the manufacture of a product, for the application of a process, or for the rendering of a service, which does not extend to the transactions, involving the mere sale or mere lease of goods**.**

TRIPS; (Trade-Related Aspects of Intellectual Property Rights) is an agreement of the World Trade Organization (WTO) that sets standards and conditions for the protection of intellectual property. TRIPS require that patents are granted in member states**.**

CHAPTER 1: INTRODUCTION

Medicines are an essential need in any society. The proliferation of infectious diseases and the growing trends of non-communicable diseases attest to further and continuous need of quality medicines to maintain healthy societies. The World Health Organization (WHO) asserts that, while the quality of health care has many dimensions, one important incontrovertible fact is that modern curative and preventative care depends heavily on pharmaceuticals (World Health Organization (WHO), 2013) Availability of medicines in Africa including Botswana is however dependent upon exports especially from Asian countries, and from all over the world. Empirical work shows that firms in India, China and Brazil's product portfolios are becoming more geared towards industrialized countries (UNCTAD, 2011). These countries are considering the economic benefits of supply, and it is more profitable to supply developed countries with medicines than developing nations.

Shortages of medicines in Africa has stimulated a discussion on the rising need for local production of medicines. Unfortunately previous attempts on local production of medicines in Botswana faced a number of challenges which led to closure of a number of firms. This study seeks to establish why pharmaceutical manufacturing firms fail to thrive in Botswana.

Factors that contributed to the closure of these companies are unknown as there is inadequate information or published data that explains what could have gone wrong. Reasons for failure of pharmaceutical manufacturing firms in other African countries have been discussed, for example, Tanzania, Ghana and South Africa are reported to experience high cost of finance, import tariffs on raw materials and a stiff competition from cheap generic medicines from Asia. Similarly, a South African Study revealed that of the 16 multinational pharmaceutical manufacturing firms that operated in south Africa in 2007 only ten (10) are operating, Six (6) have subcontracted manufacturing. In total 35 firms are

believed to have closed down since 1994. (Mhamba & Mbirigenda, 2010; Naude & Luiz, 2013; UNDP, 2016b).

One of the resolutions made in a UNDP workshop for strengthening access to medicines in Botswana was that a feasibility study should be conducted to ascertain the potential for enhancing Botswana's manufacturing capacity as lack of domestic supply was believed to be a risk for sustainable supply of medicines (UNDP, 2013). Kücher, et al., (2020) posit that majority of authors on firm failure agree that it emanates from internal or external factors or a combination of both. Therefore, even though these aspects may be widely documented, they are specific and peculiar to the firm and economic environment. This study is the first attempt to establish what could have contributed to the closure of pharmaceutical manufacturing firms that opened in Botswana over a fifteen year period between 1990 and 2015.

Manufacturing is a means used by many economies to contribute to the economic development of their countries. It is believed that manufacturing success has been the path for economic growth for developed nations including England, US, Germany, Japan, and more recently, newly industrialized nations like Singapore, Korea, Taiwan and China (Motlhanka & Mapfaira, n.d). Botswana seeks to diversify its economy from diamond dependency and one of its priority areas is the health sector.

The environment in which manufacturing happens can support or inhibit financial performance of firms (Okoroafo, 1993). Since most of the pharmaceutical manufacturing firms which open in Botswana eventually close, it is imperative to establish how the business environment could be contributing to the failure and eventual closure, and what could be done to counter this trend. A report by African Union, COHRED & NEPAD (2010) stated that a show of commitment from political leaders and decision makers is fundamental to creating a conducive business environment for pharmaceutical innovation. African Union, COHRED & NEPAD, 2010).

1.1 Overview of Botswana

Botswana is a middle income country which is known for its good governance and stable economy. Botswana has favourable descriptors like "the beacon of democracy", "good governance", "Africa's miracle", "Africa's beacon of democracy", "leading diamond producer" and a "stable socio-political and economic climate"(Neba, 2012).

Botswana is a landlocked country covering an area of 582 000 square kilometres, with a small population of two million and twenty four thousand, nine hundred and four (2024904) people (Statistics Botswana, 2015a). Botswana shares borders with Zimbabwe, South Africa, Namibia and Zambia. The Capital City of Botswana is Gaborone with a population of around two hundred and thirty one thousand, five hundred and ninety two (231592) people, which is projected to reach around three hundred thousand (300000) people by the year 2022 (Statistics-Botswana, 2015). Gaborone is also the administrative centre where most of the government ministries are located.

Botswana has eight (8) tribes which are predominantly Tswana speaking. Batswana were originally farmers of crops and reared animals like cows, goats, and sheep for meat. Botswana is a beef country, which is also exported to other countries, as the second largest export revenue creator after diamonds (Government of Botswana, 2010).

Botswana is well endowed with mineral resources and these include diamonds, gold, copper, nickel, uranium, iron, soda ash and coal. Diamond mining accounts for more than one-third of GDP and for 70-80% of export earnings (Bank of Botswana, 2016). Domestically, government revenues continue to be heavily reliant on minerals, customs and excise receipts, which are susceptible to exchange rate and international market fluctuations. The country, however, recognizes the danger of overdependence on diamond exports and has attempted to diversify the economy through development of other sectors. The National Development Plan has captured the need to diversify the economy as a priority area

(Government of Botswana, 2017a). Botswana has potential to grow the tourism, beef and manufacturing sectors. Reports indicate that even the 2016 performance of the manufacturing sector shows weak performance resulting in lower exports for textiles and beef. Europe is reported to be the major source of foreign direct investment in mining (Bank of Botswana, 2016).

1.2 The Problem Statement.

Despite consistent efforts to diversify the economy and attract Foreign Direct Investment, Botswana's economy has remained heavily dependent on diamond exports, and the country's poor productivity remains a concern (Habiyarembe, 2013; Neba, 2012; Sekwati, 2011). A case in point. There have been attempts by companies to operate pharmaceutical manufacturing in Botswana and unfortunately, just with other like companies in Africa and the region, most of these firms operate at a loss and finally close business. Pharmaceutical manufacturing firms that closed between 1990 and 2015 are Jenkins Botswana, Pulo Pharmaceuticals, Pan Pharma, Latex Medical, Portfolio Botswana and Gemi Rubber. However, reasons for failure and subsequent closure are not immediately known.

Botswana is signatory to numerous bilateral and regional trade agreements including South African Trade Union (SACU), African Growth and Opportunity Act (AGOA), SACU India, SACU America, the European Union and the World Trade Organization (WTO), which should facilitate local production, trade and export, However manufacturing remains low (Bank of Botswana, 2016; BITC, 2015). There is a concern that the growing number of bilateral and regional trade agreements with major trading partners, such as the United States and the European Union, may often contain provisions that limit developing countries' use of existing flexibilities under Trade-Related Aspects of Intellectual Property Rights (TRIPS) to protect public health (Sampat & Shadlen, 2015). Restrictions such as Restrictive compulsory licensing conditions, parallel importation provisions, extended data protection and enforcing national regulatory agencies to take on national patent office oversight duties

may inhibit local production of medicines and access to affordable medicines. In some bilateral agreements they introduce TRIPS-PLUS clauses that enforce IP protection beyond the requirement of TRIPS. This has severe consequences for public health. It is believed that the gains made under the legislation will be reversed drastically if Botswana was advised to harmonize its Intellectual Property Rights laws and policies with those of the EFTA countries as these countries apply IPR laws that incorporate a range of TRIPS-plus commitments which reflect higher conditions than those under the TRIPS flexibilities (World Health Organization (WHO), 2004).

For Botswana, a country with a high prevalence of HIV/AIDS, Tuberculosis (TB), Malaria and other communicable diseases limited access to medicines can have devastating results with development of resistance to affordable first-line ARV medication, increase in drug resistance TB and resistance to Anti-Malaria drugs. The country would be reversing the strides gained with the early introduction of the antiretroviral medication which reduced HIV/AIDS deaths dramatically.

Despite its small population, Botswana has a high prevalence of unemployment as depicted in the 2011 population and housing census, unemployment stands at 18.5% (Statistics-Botswana, 2013). The Ministry of Health has shown support of commitment to diversify the economy by facilitating opportunities for partnerships and collaboration between the public, private sector and individuals to stimulate growth of the Health sector, health sector innovation and entrepreneurship. The Ministry further intends to deliver valuable and competitive solutions that support economic growth and job creation (Government of Botswana, 2014). However little has been achieved in this sector. Bank of Botswana reports reflect modest growth of 2.1%, 3.7% and 0.3% in manufacturing in the years 2014, 2015 and 2016 respectively. Pharmaceutical manufacturing can, however, be a source of employment.

This study seeks to investigate as to whether the failure of pharmaceutical manufacturing firms.in Botswana is due to an unsupportive business environment or just business failure on the part of pharmaceutical firms.

1.3 Research Objectives

- To establish factors that led to the closure of pharmaceutical manufacturing Firms in Botswana.
- To evaluate the Botswana business environment with a specific focus on pharmaceutical manufacturing policies.
- To examine the market orientation that was adopted by pharmaceutical manufacturing firms.

1.4 Research Questions

- What factors led to the closure of pharmaceutical manufacturing firms in Botswana between 1990 and 2015?
- Does the business environment in Botswana enable pharmaceutical manufacturing?
- What market orientation did these firms adopt?
- How did the adoption of the market orientation influence performance of the firms?

1.5 Significance of the Study

The contributions of this study would be of interest to policy makers in the health, trade, academics, research sectors, and the private pharmaceutical manufacturing industry.

1.5.1 Impact of the study in Government Policy

The legal and policy framework is a significant cost driver and determines accessibility of medicines. Policy incoherence has often been highlighted as an unhelpful factor for local pharmaceutical manufacturing. African Countries have been observed to fail to strike a balance between the national health policy and the industrial policy which makes local production of

medicines difficult (Kaplan & Laing, 2005). UNIDO asserts that the objectives of a national health policy may be parallel to that of an industrial policy. It is suggested that the national health policy's aim may be to improve the supply of medicines, increase the quality of medicines, lower prices of needed medicines and to produce traditional medicines. The objective of the industrial policy on the other hand is to promote domestic manufacturing so as to maximize profits, a means of creating employment, to contribute to the economic development of the country or even manufacturing for export instead of promoting self-sufficiency in medicine for the local and regional market (UNIDO, 2010).

Botswana could be experiencing a failure to strike a balance between the Industrial Property Act (IPR) and the Competition Act. Southern African Programme on Access to Pharmaceuticals and Diagnostics (SAPAM) discussion paper posits that the Competition Act, the IPR Act and the National Drug Policy are not in congruence in supporting local production of medicines (World Health Organization (WHO), 2004). The TRIPs Agreement of the World Trade Organization (WTO) protects Intellectual Property Rights. Patents, a part of IPRs, grant exclusivity of production, sale or import of medicines for a minimum of 20 years. Countries can however take advantage of the TRIPS flexibilities, which allow them to produce or import medicines for certain diseases in response to the country's public health needs without consent from the owner of the patency, even when the product is still under patency. In its Industrial Property Act (2012) Botswana captured Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities. The exclusion of Intellectual property rights issues from the Competition Act may result in anticompetitive practices going unchecked in the medicines industry. On the other hand, when Intellectual Property Rights, such as patents and data exclusivity, are included in Trade Agreements, access to cheaper generics is not easy and poor countries find it hard to access essential medicines as this hinders them from establishing their own pharmaceutical industry (World Health

Organization (WHO), 2007). This study contributes to the law and policy issues and suggests harmonization of policies in a way that promotes local production and suggests reconsideration in signing of trade agreements which take away certain rights in medicine access.

Many African countries are believed to share the same challenges in accessing safe sources of medical supplies. Some of the reasons being the lack of national expertise in procurement, non-compliance with procurement legislation and regulations (Amber & Bandenhost-Weiss 2012; Dza, Gapp & Fisher 2013). Policies that do not promote continuous procurement of locally produced medicines leads to loss of revenue and may contribute to failure of manufacturing. This study could provide information, and influence procurement practice and contributes to empowerment of procurement officers dealing with medicines.

Botswana would benefit from Multinationals companies which form partnerships with local enterprises or individuals as a way of bringing skills, knowledge and technology into the country. Botswana could expedite some agreements for bringing in experts in pharmaceutical manufacturing plants for the government. This would be a springboard for skills transfer. Botswana has a number of government laboratories which could provide support to research and development and production of medicines. Like in India laboratories can help in the development of technological skills necessary for the pharmaceutical industry. In fact a distinctive feature of the pharmaceutical industry in India has been the close collaboration between the government laboratories and the private sector. Laboratories can develop technologies on their own and offer them for sale, laboratory scale processes.

Policy incoherence is also reflected in charging tax for raw materials and other production inputs whereas finished pharmaceutical imports are not taxed in Botswana. This increases production costs which affect the selling price.

1.5.2 Impact of the Study in the Curriculum

Studies show that Pharmaceutical Production is capital-technology- knowledge-intensive driven and needs complimentary skills in the sciences in the form of engineering, biochemistry, process engineering, medical engineering, pharmaceutical scientists etc. (UNIDO, 2012). Technical expertise is believed to be absolutely critical, both in terms of sufficient numbers and appropriate skills (Kaplan & Laing, 2005). The industry requires a unique and specific set of skills, especially when one considers the range of skills required in the production, registration and marketing of medicines (Kaplan & Laing, 2005).

WHO asserts that Access to affordable and quality medicines through local production depends on the availability of scientific and technological capacity. A number of documents identify challenges to local pharmaceutical production in Africa from shortages of skilled professional personnel and point to infrastructure and skills as major determinants for technology transfer (African Union et al., 2010; World Health Organization (WHO), 2011c). This study suggests an alignment of curricula with the skills needed by Botswana industry. Courses should be complimentary to each other. It will be of benefit to introduce courses which are complimentary for pharmaceutical production. Such efforts for better matching education content and scope with public health needs will need to be supported by proactive policies and strategies to retain human resources for health research and innovation (World Health Organization (WHO), 2004). There is a need to produce professionals who are needed by the market. It is imperative to argue that careful planning is needed – at least between the health and education sectors – to ensure that appropriate human resources with the necessary skill sets will be available at country and/or regional level for the mid- to long-term.

Since there is no published data to show the Botswana situation specifically regarding pharmaceutical manufacturing, this study will contribute knowledge in this area and inform

policy on tertiary education needs in Botswana. This study is timely as Botswana has introduced Pharmacy Courses and Manufacturing courses within the county.

1.5.3 Impact of the study in Job creation

The Pharmaceutical Manufacturing Industry is considered to be one of the most profitable business sectors with an average 16.2% profit ahead of financial companies (Henry; & Lexchin, 2002) Africa is depicted as one of the emerging profitable markets for pharmaceuticals. By 2016 pharmaceutical spending in Africa was expected to reach US 30billion (SADC, 2007).

The U.S. biopharmaceutical sector is a dynamic and innovative business sector generating high quality jobs and powering economic output and exports for the US economy. In 2009 alone the sector created over 650000 direct jobs in the US (Onyango, 2014).

Ensuring profitability of pharmaceutical manufacturing firms within Botswana would provide sustainable work opportunities for the unemployed in the country. Unemployment in Botswana is at 18.5% especially amongst the educated youth (Statistics Botswana, 2012, 2015b) The pharmaceutical industry interconnectedness with other sectors and its significant investments in technology, research, and development mean that the industry's gains can have an outsized effect on the economy as a whole (Onyango, 2014).

1.5.4 Impact of the study in pharmaceutical research

Conducting literature review for this study has itself revealed that there is inadequate published data on the issue of pharmaceutical manufacturing in Botswana. Much of the local production-related literature occurs in the grey literature (World Health Organization (WHO), 2011b). This study will stimulate discussions around this topic and prompt further research on this topic.

Inadequate data on African traditional medicines indicates that research and development are not directed to the medical needs of the people of Africa. Only 1% of newly marketed medicines in the past 30 years were developed for tropical diseases or tuberculosis, yet the

existing medicines for these diseases are often toxic and resistance makes them less and less effective (SADC, 2007). As pharmaceutical companies do not consider the African market to be financially viable they do not invest in those diseases. In Africa, there is very little research and development on traditional medicine, while laboratories elsewhere are already patenting products made from them. Over 80% of Africa's natural raw materials have not been subjected to standard scientific evaluation. Furthermore, about 67% of new medicines introduced worldwide from 1981 to 2002 were derived from natural sources (African Union et al., 2010). For Africa, this situation brings a comparative advantage in the area of pharmaceutical innovation, development and production using African Traditional Medicine and the continent's rich biodiversity as raw materials of choice. This presents a unique opportunity for investment in pharmaceutical innovation in Africa.

These facts provide compelling justification for investing in biodiversity as basic raw materials for pharmaceutical innovation, development and production are available (SADC, 2007). There is a reasonable amount of evidence on pharmaceutical innovation in Africa, but no centralized repository. Knowledge on the topic is shared within the circles of specialists involved in particular steps of pharmaceutical innovation but rarely outside each specific group.

The current incentive structure is inadequate to promote research and development of medicines and vaccines. Research projects in Africa tend to be mostly financed by external sources. Most countries rely on foreign partners for research funds. These partners may, however, commission research on specific diseases or conditions which may not be of benefit to Africa (African Union et al., 2010). In America, companies have incentives for developing drugs for rare diseases and this was legislated through the orphan drug act in 1983 and similar legislation was introduced in Japan and Australia (Henry; & Lexchin, 2002).

The existing Research institutions within the country, like Botswana Institute for Technology Research and Innovation, University of Botswana, Okavango Research Institute, Botswana-Harvard AIDS Institute Partnership, National AIDS Coordinating Agency and Botswana Innovation Hub, through its centres of excellence, should work as a team towards facilitating research that will bring innovation in production of medicines. Foreign direct Investment in manufacturing is attracted when Research Institutions have specific mandates in core relevant areas of science, technology and innovation where Africa has comparative advantage (African Union et al., 2010)

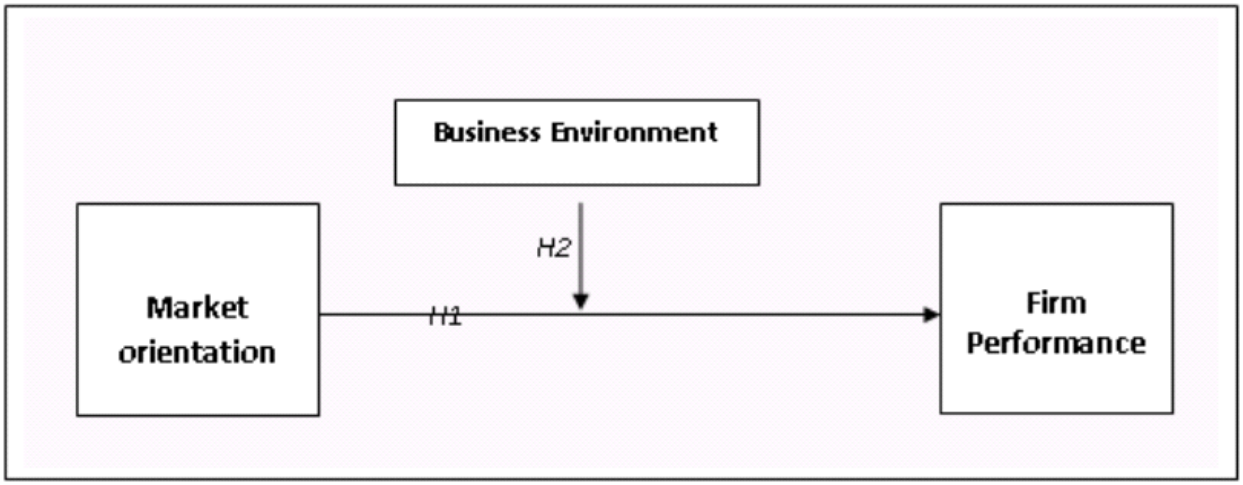
Although some researchers argue against local production of medicines for countries with small populations, other scholars suggest that Botswana should not dismiss the possibility of local production as an option, but to invest resources into a thorough feasibility study that also learns from the experiences of other countries such as Tanzania and Uganda and produce evidence-based recommendations (World Health Organization (WHO), 2004).

Botswana can take advantage of growth in tertiary institutions which provide courses in chemistry, pharmacy and manufacturing and focus on conducting local research on identifying species in our local traditional medicines which can be developed into medicines which will treat country specific diseases and diseases of the region. A repository of such information within the country will inform policy makers.

1.6 Theoretical Framework

This study adopts the Market Orientation and Firm Performance Theoretical Framework as postulated by Lagat (2012) in the Kenyan manufacturing sector study. The author sought to establish the effect of business environment on the market orientation – firm performance relationship.

Figure 1.6 Market Orientation-Environment-Performance Framework Lagat compilation (2012)



Market Orientation:

Market orientation is defined as the organization-wide generation of market intelligence pertaining to current and future customer needs, dissemination of the intelligence across departments and organization-wide responsiveness to it (Kohli & Jaworski, 1990).

Firm Performance: This refers to a measure of **performance** of a company that may not only depend on the efficiency of the company itself but also on the market where it operates. Firm performance may also be called financial stability or financial health. Financial measures that can be used in order to evaluate the **performance** of a company include revenue, return on equity, return on assets, profit margin, sales growth, capital adequacy, liquidity ratio, and stock prices, among others. In a manufacturing company, total unit sales, return on assets and inventory turnover may be key ratios to monitor.

Business Environment: The term 'business environment' connotes external forces, factors and institutions that are beyond the control of the business and they affect the functioning of a business enterprise. These include customers, competitors, suppliers, government, and the social, political, legal and technological factors etc. Thus, business environment may be

defined as the total surroundings, which have a direct or indirect bearing on the functioning of business. It may also be defined as the set of external factors, such as economic factors, social factors, political and legal factors, demographic factors, technical factors etc., which are uncontrollable in nature and affects the business decisions of a firm Lagart (2012) postulates that market–oriented organizations have a knowledge advantage over their competitors, and that this helps them to adjust to different business environments and hence achieve superior firm performance.

Market Orientation is believed to have a positive effect on business performance such as new-product success, sales growth, profitability, and return on investment. Market orientation and firm performance studies have been conducted in different countries including Japan, Germany, the United States of America and Africa (Protcko, 2014). In Ghana Akomea & Yeboah, (2011) observed that the greater the degree of market orientation, the higher the business performance.

Marketing is the process by which firms create value for customers and builds strong customer relationships in order to capture value from consumers as well (Kotler & Armstrong, 2006). Onyango (2014) posits that a basic marketing theory suggest that to maximize sales a company must position its products or services in the market in such a manner that the consumers believe they need that particular good or service and also believe the product or service is unique to them. Marketing has grown to be crucial to business success because today's customer is more knowledgeable and demands superior quality products and excellent services, to get value for his/her money. Kohli & Jaworsky (1990) assert that customer needs and expectations continually evolve over time. It is further stated that, delivering consistently high quality products and services requires ongoing tracking and responsiveness to changing market needs, which is market orientation (Kohli & Jaworski, 1990).

The Researchers further state that the more emphasis placed on customers by top management of pharmaceutical manufacturing firms, the more market oriented the firms were. By developing a customer oriented view on reshaping an organization's culture for developing superior value for customers, generation of knowledge about markets and use of that knowledge in its processes for creation of superior value. A firm that has the ability to sense and respond to market changes is believed to have the capability to sustain profitability and sustain its operations.

It is believed that a liberalized market positively influences firm performance and harsh economic environment cumulative effects include operating below installed capacities, losing business opportunities, inability to create employment, inability to complete globally and earn foreign exchange, negative impact of government policies (Barney, 1995; Okoroafo, 1993; Wangwe et al., 2014). The environment can disable positive performance. Researchers have suggested that managerial decisions may be influenced by the moderating effect of the external business environment. Some potential moderators of market orientation include market turbulence, technological turbulence, competitive intensity, market growth, and buyer power. Previous researchers have acknowledged that environmental turbulence can moderate the extent market orientation affects firm performance (Lagat 2012). Other scholars continue to highlight factors like unfair tariff regime, high cost of funds, dumping of cheap products in the market, low credit rating by financial institutions, inadequate incentive programmes by governments and multiple taxes and levies as contributors to the closure of pharmaceutical manufacturing firms in Africa (Mhamba & Mbirigenda, 2010; World Health Organization (WHO) (2011b)) Sometimes firms performance is limited by firm internal factors like inability to market themselves.

1.7. The Scope of the study

This study investigates Pharmaceutical Manufacturing Firms that operated and closed between 1990 and 2015. Firms should have operated in the Southern part of the country; the two towns of interest are Gaborone and its surrounding areas and Lobatse. Most of the manufacturing firms are located in the southern part of the country. The study limits itself to employees from closed pharmaceutical manufacturing firms only.

1.8. The Structure of the Report

This study starts with Chapter 1 which gives the introduction and background to the study, regarding barriers to establishing profitable and sustainable pharmaceutical manufacturing firms in Botswana. Chapter 2 is a review of related literature. Chapter 3 elucidates the method used for data collection and the theoretical framework. Chapter 4 is about the presentation, interpretation and analysis of findings. Chapter 5 is a discussion, conclusion, recommendation and limitations of the study.

CHAPTER 2 REVIEW OF RELATED LITERATURE

2.1 Introduction

This chapter reviews literature on the factors that have been attributed to the closure of pharmaceutical manufacturing firms, especially in Africa. One area of interest in this discussion is how domestic production of medicines influences its availability and access. Studies have been conducted which explain reasons for failure of pharmaceutical manufacturing firms in both developing and developed countries. This discussion links local manufacturing with the concept of market orientation and firm performance. Some researchers support local production of medicines while others purport that the reasons in support of local production of medicines in Africa are not convincing enough to warrant such a step.

Local production of pharmaceuticals and vaccines has been a subject of intense discussion in international, regional and national forums since the 1970s. A variety of interests – economic, legal and political economy oriented – have been responsible for varied, often contradictory, perspectives on what constitutes local production and whether or not it should be fostered. The past decade has seen a stronger emphasis on issues of local production, technology transfer and access to medicines (UNCTAD, 2011). The growing burden of diseases in Africa and shortage of medicines has stimulated discussions on this topic.

Local manufacturing can mean

- Local subsidiary of, or joint venture with, a multinational pharmaceutical company selling branded medicines in local and regional markets i.e. Glaxo-Smith-Kline, Pfizer;
- Generic manufacturer producing medicine for the local and global market;
- Generic manufacturer producing medicine predominantly for the local market;

- Locally-owned small scale manufacturing serving a small portion of the domestic market. (World Health Organization (WHO), 2011b).

Manufacturing can also happen at different levels:

Primary level: Manufacturing active pharmaceutical ingredients (APIs) and intermediates from basic chemical and biological substances;

Secondary level: Includes the production of finished dosage forms like tablets from raw materials and excipients (inactive substance); and

Tertiary level: limited to packaging and labelling finished products or repackaging bulk finished products.

Local pharmaceutical production in Africa has not yet received much support from the international community in terms of investment and technology transfer. There is a perception that Africa is not suitable for cost-effective production of quality-assured, safe medicines. Since locally produced medicines have to compete with low-priced Chinese and Indian generic products, some suggest that international procurement of inexpensive drugs is a more efficient use of funds, rather than investing in local industry. This view is supported by Kaplan & Laing (2005) who maintains that African countries lack the critical mass of industrial services and human capital required to produce quality medicines at competitive prices. Consequently, it is suggested that, local manufacturing is deemed to be more of a strategic political decision than a business decision, as from a pure business perspective, it may not be a sustainable opportunity (Kramer, Haupt, Cortzee, & Van-Boemberg, 2014). Opponents of local production further state that local production of medicines is not likely to create employment as many believe pharmaceutical manufacturing requires special skills which are lacking in Africa. Kaplan (2005) further states that local

production does not foster foreign exchange nor facilitate technology transfer as most manufacturing plants in Africa are operating at tertiary level where they are just repackaging bulk products from big international companies. Saving on Foreign exchange is not likely to happen because it is believed that in Africa, most of the inputs to pharmaceutical production like raw materials, active pharmaceutical ingredients, packaging material, the machinery and equipment used comes from outside Africa and are paid for in foreign exchange. The skills needed, technical experts and the technology used is also bought in foreign exchange and very costly.

However, shortage of medicines in Africa is coercing the continent to re-consider local production of medicines to improve access. Africa has created Fora for enabling this idea and has documents like the Pharmaceutical Manufacturing Plan for Africa and the SADC Pharmaceutical Business Plan to give direction to these engagements.

Fostering local production is however not believed to always improve access. (Dong & Mirza, 2016) purports that India's pharmaceutical industry has been successful as an exporter, but access to medicines has not always been improved for local communities. For example, first-line antiretroviral medicines are still not reaching many HIV/AIDS patients in India. It is therefore important for countries to have effective procurement and distribution processes to improve access to medicines. One researcher cautioned pharmaceutical manufacturing firms to strike a balance between desires for profit and disregarding the rights of patients to access medicines. (Henry; & Lexchin, 2002).

Africa is now the world's second fastest growing pharmaceutical market, projected to reach 30 billion USD in 2016 (Dong & Mirza, 2016). The small markets of some countries may not make pharmaceutical manufacturing viable. African countries are looking at availing the market for each other to improve economies of scale. At regional level like SADC,

countries are trying to harmonize their laws to foster trade and ease of doing business so as to avail a bigger market for pharmaceutical production (SADC, 2007).

Local pharmaceutical production can be encouraged through attracting foreign direct investment, such that knowledge-based economies may find Botswana attractive enough to invest in pharmaceutical manufacturing here, bringing the technical knowhow and spilling that knowledge to local firms.

Research indicates that theoretical literature on Foreign Direct Investment (FDI) has identified three channels of intra-industry spill-overs. The first channel is demonstration effects, when the presence of foreign firms in domestic markets encourages domestic firms to imitate directly the new knowledge or to develop their-own innovations, raising their efficiency or productivity. The second channel is labour mobility, which happens when the workers trained by MNCs move to domestic firms or establish their own business and bring with them the knowledge. The third channel is competition, when the entry of foreign firms increases competition in product markets and forces domestic firms to utilize their resources in a more efficient way (Suyanto & Salim, 2013).

Local production may also be done by local firms through use of local raw material, to conduct thorough research, characterization, development and production of local traditional medicines. Southern African Development Community (SADC) has identified the need to develop and implement a pharmaceutical programme in line with the SADC health protocol and the SADC health policy. Some of the objectives of the SADC pharmaceutical business plan includes rationalizing and maximizing the research and production capacity of local and regional pharmaceutical industry of generic essential medicines and African Traditional Medicines and establishing a regional databank of traditional medicine, medicinal plants and procedures in order to ensure their protection in

accordance with regimes and related intellectual property rights governing genetic resources, plant varieties and biotechnology (SADC, 2007).

Pharmaceutical manufacturing seems to be a challenge across sectors and across African countries.

Challenges facing the pharmaceutical manufacturing industry seem to be different in developed countries and developing countries. Findings of such studies revealed that challenges faced by developed countries include limited approval of new medicines as evidenced by a decline in the number of new chemical entities approved by Food and Drug Administration (FDA) of America, increase in generic products which reduces their profit margins, regulatory changes and political impact emanating from concerns on patient safety, global warming concerns and animal right groups (Baines, 2010).

Multinational companies continue to grow; they subcontract pharmaceutical manufacturing and move to centres of excellence across the world. Mergers and acquisitions characterize changes in multinational companies.

Failure of local production in the African region has been attributed to different reasons. The most advanced include unavailability of raw materials, lack of specialized equipment and after sales support, unreliable and costly supply of utilities and telecommunication, production below capacity, no price controls, failure to adhere to international regulatory standards, lack of skilled personnel, inadequate finance and weak legislation (Boulton, 2011; Chaudhuri et al., 2010; Fang, 2012; UNIDO, 2011; World Health Organization (WHO), 2007, 2011c)

2.2. Factors contributing to closure of Pharmaceutical Manufacturing Firms

This discussion reviews literature on the factors contributing to the closure of pharmaceutical manufacturing firms in Africa. Most of the African Countries have a history of pharmaceutical production dating back to the 70's. There is a concern about the decline and closure of firms. The differences in the economic and political environments within the continent itself indicate that the reasons for the decline in manufacturing will mostly be different, but for some reasons it will be similar. Research that has been carried out in other African countries has advanced the reasons as discussed below.

2.2.1 Raw Materials

There are a few suppliers of active pharmaceutical ingredients in the world and the majorities are now in India and China. Multinational Companies who are concentrated in developed countries and the larger emerging markets get the bigger stake of the raw material supplies. Africa on the other hand experiences unreliable supplies since the majority of the firms are small and do not operate at full capacity (Mayaki;, 2010; Owoeye, 2014). Those who argue against local production in Africa suggest that there is no reason for local production because Africa does not manufacture raw materials, in addition to that, Africa does not have a buying power and have less bargaining power than the large multinationals that are the major customers of the raw materials producers (Kaplan & Laing, 2005). It is often the case that the volume of raw materials requested by local industry is too small to justify shipment. One can argue though that this challenge presents a unique opportunity for investment in pharmaceutical innovation in Africa to Africans themselves. The overall goal of the SADC Pharmaceutical Business Plan is to ensure availability of essential medicines including African Traditional Medicines to reduce the impact of disease burden in the region. Its main objective is to improve sustainable availability and access to affordable,

quality, safe, efficacious essential medicines including African Traditional Medicine (SADC, 2007). Active Pharmaceutical Ingredients (API's) account to 60% of costs of production, High import tariffs on APIs and unfinished medicines may increase costs for local production, which is believed to increase medicine prices and affect competition with cheap generics from Asian Countries. Africa has to start acting on the issue of production of raw materials to create a platform for producing medicines at affordable prices for each region.

The argument against local production suggests that high quality, low cost medicines are not likely to be produced from the raw materials stage in countries that do not have the required market size and resources in terms of skilled people, technology and quality control (Fang, 2012; World Health Organization (WHO), 2012). Other researchers however, believe that African manufacturing of API's and FPP's might be successful for a range of moderately priced products that are no longer of high priority for Indian generic manufacturers. There are cost effective technologies that can be used for manufacturing pharmaceutical raw materials than the usual chemical synthesis, fermentation, extraction or purification of natural products from plant sources (Mackintosh, Banda, Tibandebage, & Wamae, 2015). These technologies include Leap-frogging and reverse pharmacology. These methods imply adoption of machinery, equipment and processes with higher efficiencies and lower environmental impact and this reduces API pricing by more than 70%. Reverse pharmacology is a green approach to drug discovery that takes advantage of cultural and ethno-botanical knowledge of a region to shortcut the lengthy, expensive, resource intense process used in rational drug design. Countries like Nigeria and Ghana have produced herbal and medicinal products for their region using these technologies.

2.2.2 Legislation, Policies and Regulation

Internationally, exclusivity of pharmaceutical production is protected through World Trade Organization (WTO) agreements on Trade and Related Intellectual Property Rights (TRIPS). Countries that join the WTO benefit from a reduction in tariffs when selling their goods. In return, they must guarantee protection of products and processes by granting patents (Henry; & Lexchin, 2002). Countries that sign TRIPS agreement must include protection of potencies' in their own legislation. A patency gives the owner of a product commercial monopoly for a period of twenty years for medicines. No other company can produce a similar product during the period. Several papers have argued against the implementation of TRIPS because there is a belief the TRIPS agreement may block access to affordable new medicines and vaccines, especially in developing countries (Mujinja, Mackintosh, Temu, & Wynts, 2014; Naude & Luiz, 2013; Sampat & Shadlen, 2015; Wangwe et al., 2014).

Asian Countries used to develop generic medicines for products which were still on patency until TRIPS became mandatory. There is some flexibility in the TRIPS agreement in section 31 which allows a country to produce a product which is still under patency for public health reasons without asking for permission from the patent holder. The Asian market, which is the primary exporter of medicines to Africa, has been affected by the implementation of TRIPS which affects drug supplies to Africa (Lanoszka, 2003; Sampat & Shadlen, 2015). The African Union encourages African regions to take advantage of TRIPS flexibilities to promote generic manufacturing of medicines. Although there are some other requirements like, a country has to be declared to fall into the 'Least developed Countries (LDC's)' category to be a primary beneficiary of the flexibilities, countries like Botswana do not fall into the LDC category.

Failure to meet international requirements on Good Manufacturing Practices, Good Laboratory Practices and quality, failure to qualify for WHO prequalification of African manufacturing firms has also been stated as a contributor to failure of performance. The manufacturers in general regard the quality standards and policies they are required to meet by internationally funded programmes as being as much an economic barrier as a requirement for ensuring patient safety (Boulton, 2011). International organizations in general only see quality standards as being a requirement to protect the patient.

Botswana, through the Medicines Regulatory Authority has accessible well-structured policies and guidelines for pharmaceutical manufacturing. The National Drug Policy of 2002, and the Pharmacy Practice standards of 2003, gives guidance on how pharmaceutical manufacturing in Botswana should be operated. The Medicines Registrations Guidelines and requirements for operating a manufacturing plant are accessed for free in the Ministry of Health website. Botswana is also harmonizing its medicine registration policies and requirements with other countries in the region. The Ministry of Health website has the processes needed for registration of medicines and requirements for Good Manufacturing Practices (Chaudhudri, 2007).

Government Policy should be seen to support local pharmaceutical manufacturing and protect the industry from competition from international manufacturers. There is a belief that technology transfer was often most successful where the state was actively involved in building capacity (NEPAD, 2010). The government is expected to promote Public Private Partnerships with international manufacturers to transfer skills into the country. This is actually how other Countries like India, Ghana and Tanzania started pharmaceutical manufacturing in their countries. This is possible as government can inject funds into the project as pharmaceutical manufacturing is considered a risky business and does not get credit from commercial banks. Zimbabwe Government made it mandatory to procure

certain medicines from local suppliers, and the government made a commitment to the manufacturers that their products will be consumed by the government. Zimbabwe has been successful as a generic pharmaceutical manufacturer despite her economic hardships owing to the unstable political environment. In 2012 Zimbabwe was producing 65% of medicines in their medicines list (World Health Organization (WHO), 2011d). Zimbabwe implemented a number of policies from 2008 which promoted production of medicines for HIV/AIDS, the government further bought 75% of HIV/AIDS medicines from one of the local manufacturing firms without going through a public tender (Russo & Banda, 2015). This can be implemented in Botswana to protect the pharmaceutical industry.

2.2.3 Company Resources

The Resource Based View (RBV) suggests that firm resources are an essential factor that influences competitive advantage and firm performance (Othman, Arshad, Aris, & Arif, 2015) Resources can be the strongest and weakest link to manufacturing performance. Resources are believed to include the following key constructs, resources, capabilities and competencies. Resources are divided into tangible and intangible resources (Hooley, Broderick, & Moller, 1998). Tangible resources are physical substances that an organization possesses, that is, they can be readily seen, touched and quantified such as land and buildings, plant, equipment, machinery, tools, raw materials and cash. Intangible resources are quite difficult to see, touch and quantify. Intangible resources include the knowledge and skills of employees, a firm's reputation and a firm's culture, networks and processes that are not included in normal business managerial accounting information (Kariithi & Kihara, 2017). Competence is the "ability to use resources to an acceptable level of performance ". When resources are valuable, rare, inimitable and non-substitutional, they become sources of sustainable competitive advantage and firm performance (Anggraeni, 2014). Intangible resources are more likely to generate competitive advantage and superior

performance as compared to tangible resources because they are not easily copied (Othman et al., 2015).

A capability is defined as a set of a company's processes strategically understood (Stalk, Evans, & Shulman, 1992). A capability is further defined as the ability to operate a specific configuration of an organization's set of resources (Masoud, 2013). There is an understanding that suggests that organizational capability is the ability of a firm to perform a coordinated task, utilizing organizational resources, for the purpose of achieving a particular end result (Inan & Brititci, 2015). Capabilities can also be considered as a company's latent competencies or expertise employed in organization's operations underlined with accumulated know-how (Day, 1994). Resources influence an organization's performance, resourrces are discussed below.

2.2.3.1 Human resource influence on technology transfer

Pharmaceutical Production is capital-technology-knowledge-intensive driven and needs complimentary skills in the sciences in the form of engineering, biochemistry, process engineering, medical engineers, pharmaceutical scientists etc. (Wangwe et al., 2014).

WHO asserts that access to affordable and quality medicines through local production depends on the availability of scientific and technological capacities. A number of documents identify challenges to local pharmaceutical production in Africa from shortages of skilled professional personnel, and infrastructure, as major determinants for technology transfer (COHRED & NEPAD, 2010; UNCTAD, 2011; (World Health Organization (WHO), 2011c)).

In the United Republic of Tanzania, senior management posts in the entirely private local producer are filled with overseas staff, while the middle and lower tiers of management are filled with local personnel. Firms invest heavily in training staff with low basic education,

who may struggle with the rigorous rule-following culture of Good Manufacturing Practices (GMP) (Wangwe et al., 2014).

For those who have gone through formal education, there still is a gap between the graduates and the skills needed in the market. Tanzania also has few pharmacists and chemists who need to be trained on industrial equipment and techniques, and there are few pharmaceutical technicians. Firms face high turnover of skilled staff and complain of the difficulty and cost of obtaining work permits for essential expatriates.

Still in Tanzania production is relegated to simple medicines and more technologically sophisticated pharmaceutical products like IV fluids, indictable, and more advanced antibiotics like cephalosporin's are not produced by local industries, which still lack that competence (Mhamba & Mbirigenda, 2010).

The African Business Plan suggests that African Countries should conduct an inventory of their resources, establish their needs and make informed decision in terms of what each country intends to manufacture.

BITC asserts that one of the cited market challenges in Botswana is the narrow skills base of Batswana workers (BITC, 2015). Botswana is reported to offer few experienced managers and specialists due to the small population and few opportunities for experience and training, and a number of sectors are dependent on expatriates Further to this, another report suggests that Botswana has a shortage of qualified labour and the country has relatively high labour costs compared to its competitors (BMI, 2018). There is no published information reflecting if lack of Access to technology has played a critical role in local production. Countries that demonstrated the most advanced levels of production had absorptive capacity (human skills and scientific infrastructure) that was strengthened consistently through technology transfer throughout their growth and expansion,

Furthermore technology transfer was often most successful in an environment where the state is actively engaged in building local production capacity (COHRED & NEPAD, 2010). Many developing countries simply lack the technical capacity and regulatory structures to efficiently and consistently produce high quality pharmaceutical drugs.

Technology transfer is possible where local companies enter into partnership with multinational companies. Multinational Companies however, seem to be investing in bigger emerging markets like China and India where they seem to be attracted by cheap skilled labour and economies of scale.

2.2.3.2 Finances

A report advocating for support of local production of medicines in Tanzania indicates that a significant amount of capital is needed to set up Good Manufacturing Practice (GMP)-compliant manufacturing facilities, to develop products that meet regulatory standards, and to market the products. The author added that access to the necessary investment capital, either from foreign investment or from local commercial sources, is limited, Local manufacturers, however, need access to finances at interest rates that are comparable to the rates paid by their main competitors in India.

In Ghana, for instance, a scheme has been established for majority-owned local enterprises to access loans from the Ghanaian Government, specifically for upgrading their manufacturing facilities, with an interest rate of only 12.5 percent (UNDP, 2016a). In Nigeria, one researcher reasoned that high costs of funds arising from depreciation of the Naira against major currencies, coupled with high lending rates and extreme difficulties in accessing credit for working capital, particularly by small and medium–scale industries made it difficult for firms to remain profitable (Onuoha, 2013). Botswana is believed to have high risks associated with the health and pharmaceutical sectors and this means that many

private-sector enterprises in the sectors struggle to access local debt financing. Loans are often either denied or offered with infeasible interest rates (Kramer et al., 2014). The lack of financing is considered a key constraint to economic development in the region, as without finance, businesses are unable to scale up or expand business models with a social impact.

According to a Botswana government report on economic opportunities as far back as 1982, a number of reasons were stated to be the contributing factors for inhibiting productive enterprises. These includes amongst others, but not limited to:

(a) Lack of access to financial and working capital for small- and medium-scale productive enterprises owned by citizens;

(b) Lack of industrial experience, with resulting lack of labour and management skills;

(c) Low labour productivity of low skilled and unskilled labour;

(d) Small size of the local market, obliging export in order to achieve economies of scale. (Smith, Kaplinsky, Menz, & Selabe, 1988)

It has been observed that one of the problems that SMEs often encounter in many countries is lack of institutional support for their operations. Botswana has however, come up with a number of institutions to support SMEs in the country. Despite increase in government policies and institutions directed towards supporting SMEs, the 90's did not yield the desired results in manufacturing as manufacturing was generally not successful with the failure rate between 80% and 85% with over 70% of start-up firms failing in their first 18 months and less (Gagoitseope & Pansiri, 2012).

The 2009 BIDPA study of Small and Medium Enterprises manufacturing failure reflected the following:

- Lack of information on SME programmes due to inadequate publicity of available SME programmes;

- Lack of effective implementation of programmes that are meant to support SME activities;
- Inadequate institutional support such as the administrative bottlenecks SMEs encounter when they register as companies, the need for SMEs to come to Gaborone for registration, and the general high cost of factory shells for business operations;
- The limited commercial bank financial support for SMEs which makes them solely dependent on government for support;
- The inherent government procurement policy bias towards large firms limits SMEs opportunities for business development (BIDPA & CEDA, 2009).

  The 2016 Bank of Botswana Report reflects that manufacturing contributed as little as 0.9% to the economy.

Botswana has a developed financial sector, with thirteen (13) commercial banks and 30% of the adult population having an account in 2012. The prime-lending rate for commercial banks was 11%, a minimum risk premium of 2% to 3% typically added, calculated on the combined basis of the specific venture's risk level and that of the venture's overall sector (Bank of Botswana, 2016). Citizen Entrepreneurial Development Agency (CEDA) is tasked with providing access to finance for small and medium-sized enterprises (SMEs). However, CEDA has not financed any pharmaceutical manufacturing plant (CEDA, 2012).

2.2.4. Utilities

Whilst there is an appreciation on the need to increase electricity, water and telephone tariffs to ensure commercial viability for the providers of these vital services, the increase must be gradual and consistent with the recovery of the industry. Tariffs currently being charged by some of these institutions are above the regional average. This does not bode well for the competitiveness of the local industry and has a direct impact on the cost of locally produced drugs (UNIDO, 2011).

Pharmaceutical Manufacturing plants operate under stringent environmental control. Indoor temperature, relative humidity, air change rate, room pressurization and ventilation are the most important ones. Different rooms with different floor types have different energy requirements. The white area consumes the greatest amount of energy. The production equipment is also motored through electricity.

Pharmaceutical manufacturing requirements indicate a need for few electrical interruptions if any. Countries which create special economic zones for businesses ensure that these areas have uninterrupted supply of electricity and water.

Growth outlook from ongoing issues with power generation in Botswana has been noted, but in 2013 the water and power sector declined by 30.9%, the third consecutive year of decline, which weighs on economic growth. This decline was due to dysfunctional power generating plants in the country. Despite its massive coal reserves, Botswana is reliant on South Africa for 40% of its electricity, and has been affected by rolling blackouts in its neighbour, with frequent power outages. Delays to major power station projects could create a significant drag on potential economic development (BMI, 2018)

2.2.5 Market Size

The market is a determining factor for profitability and sustainability of pharmaceutical manufacturing firms. Consumption of locally produced goods can grow the industry. There seems to be a desire by developing countries to develop the manufacturing sector, including the pharmaceutical industry in their respective countries. A number of countries seem to face difficulties in getting their goods on the shelves of local retailers. A Namibian research indicated that there is no regulation or control in-terms of importing similar products to those produced within the country. The researcher went further to say there is also unfair

trade practices within the SADC region which hinder exporting to SADC (Nambinga, 2017).

The Anticompetitive behaviours were named as inability of firms to access supply chains in new/foreign markets, regional cartels, selection of single distribution channel by a dominant firm, deceitful, misleading representations and product safety standards. Nigeria has been experiencing weak domestic demand arising from lack of consuming power and unbridled influx of cheap imports of substandard, fake and used products in the market (Onuoha, 2012)

Botswana is a geographically large country with a small, sparse population, which makes it expensive to deliver services and supplies. The SADC Pharmaceutical Business Plan however aims to address this issue by breaking down Trade barriers in the region and availing the SADC population of over 220 million as a potential market for Pharmaceuticals. The market is envisaged to avail 30 billion worth of revenues if it is positively tapped. Although Botswana is a member of SACU, and is signatory to trade agreements with the European Union and the United States, little is known of how these agreements are implemented in the pharmaceutical sector. Africa as a whole and SADC's sale of pharmaceuticals is experiencing competition from cheap Asian generic imports. Through the Abuja declaration African countries have been asked for a commitment to avail 15% of the Ministry of Health budget to procurement of medicines. Botswana has committed to this agreement. This project will unearth if the procurement practices support local manufacturing.

2.3 The Business Environment

A liberalized market is believed to positively influence firm performance and harsh economic environment cumulative effects have negative effect on the performance of businesses which can lead to firm closure. Harsh economic environment cumulative effects

may be reflected by, operating below installed capacities, losing business opportunities, inability to create employment, inability to compete globally and earn foreign exchange and negative impact of government policies (Okoroafo, 1993).

The environment can disable positive performance and other scholars continue to highlight factors like unfair tariff regime, inadequate incentive programmes by governments and multiple taxes and levies as contributors to the closure of pharmaceutical manufacturing firms in Africa (Onuoha, 2012). Onuoha (2012) further states that policy inconsistency and anomalies in customs duty, including the absurd case of a 5% increase in the duty rates of some raw materials since January 1999, while imported finished goods witnessed a corresponding reduction in duty in Tanzania made profitability in manufacturing a challenge. Scholars observed that some governments protect infant industries like in Nigeria and Ghana, where their governments stopped the import of certain products that were produced locally so as to support growth of the industries (Mujinja et al., 2014; Naude & Luiz, 2013; Olarewaju, 2012).

Many African countries are signatory to World Trade Organization (WTO) bilateral and multilateral agreements that support liberation of Trade. Some agreements are not supportive of industrialization. Developed countries were advocates for protection of infant industries by countries which were still in the process of developing their industries e.g. the manufacturing stage. Frederick List was amongst the American economists who believed that the American industry could only grow if small industries were protected from British imports. He argued that industrialization in countries with little or no experience in manufacturing will not take place according "to the natural course of things" in the face of foreign competition. In other words, in technical language, the market fails to promote the rapid industrialization of those countries. Second, since the establishment of new industries involves great risk, the producer has to be provided with extra incentives to enter the

industry. If the industry is open to foreign competition at early stages of its development, the producers will suffer and their industries will be closed (Shafaeddin, 2000). So an assurance of a local market for locally produced medicines is what Africa needs. It has been suggested that protecting industries increases the price for commodities. List argues that protection of domestic industry and the resulting monopoly would permit an eventual reduction in costs and prices allowed by the exploitation of domestic market, protected by import duties. Moreover, eventually the gradual introduction of domestic competition would safeguard the interests of consumers by exploiting economies of scale. A study conducted in Ghana indicates that there are measures that could be adopted to reduce the cost of production in the African continent. Ghana's pharmaceutical costs were compared to India and the finding indicate that the material costs were estimated to be 30 percent higher in Ghana, machinery costs 15 percent higher, factory building construction costs 35 percent higher, and power and fuel costs 50 percent higher. Given the cost disadvantages, profitability would be lower in Ghana if the volume of tablets manufactured was the same, but prices do not need to be higher to ensure viability and profitability. Ghanaian facility can enjoy the same profit margin as that of the Indian company, not by charging higher prices, but by increasing the quantity manufactured to 209 million tablets, just increasing production capacity (UNDP, 2016b). So, African countries should consider issues of national interest when signing trade agreements.

2.4 Market Orientation

The concept of market orientation has been gaining attention in the world of business since its conception in the 90's. The increase in competition and the liberation of markets has made the entire globe a village. The use of ICT has broadened consumer's markets and also increased their knowledge. Today's customer demands quality and value for their money. A business that is not knowledgeable about customer needs might soon be irrelevant (Balas,

Gokus, & Colakoglu, 2014). Market orientation is defined as the organization-wide generation of market intelligence pertaining to current and future customer needs, dissemination of the intelligence across departments and organization-wide responsiveness to it (Kohli & Jaworski, 1990).

Market Orientation is set apart from the marketing concept as it does not encourage organizations to be just outward-focused but to also disseminate the market intelligence across departments that is, throughout the organization. The concept is not limited only to the sales or marketing team; however, even the production manager should be aware of the needs of the customer. Empirical studies have shown that interdepartmental connectedness and decentralized decision making are positively related to market orientation. This concept does not support mass production. The market orientation concept goes beyond monitoring expressed customer needs only, but also analyse the competition, the regulatory, technological, legal and economic environments of the customer and the company (Connell, 2001).

Market Orientation has been studied in Europe, in the United States, in Japan, in Asia and in Africa. The concept has also been studied across sectors. In Ireland, (Connell, 2001) analysed the implementation of the market orientation concept in the printing industry and the measurement was Net Profit Margin. This study revealed that market oriented firms enjoyed greater profitability than those who were not market oriented. In Russia, market orientation was studied in knowledge-intensive companies, where market orientation was found to contribute significantly to the prediction of business performance; nevertheless, market orientation explained only 16.4% of business performance.

Market orientation and the organizational capabilities through which firms deploy their market orientation in the marketplace were believed to be important sources of competitive

advantage in a cross-industry study in the United States (Morgan, Vorhies, & Mason, 2009). The early adopters of market Orientation in business were also seen to be more profitable than the late adopters. Although the market orientation concept has been widely studied in the past two decades, the implementation of the concept was found to be lacking in the pharmaceutical industry.

Market Orientation was studied in the pharmaceutical industry in Spain. In the pharmaceutical industry, generation of a marketing intelligence would be based on the deep knowledge and an orientation towards an extensive spectrum of customers including patients, prescribers and service providers like doctors and pharmacists, and the financial contributors like medical aids (Lara & Mesa, 2006). Past studies show how pharmaceutical companies advanced reasons for the lack of implementation of the Market Orientation concept including lack of application of the concept amongst direct competitors, legal issues, reliability on conventional marketing and the lack of convincing positive effects on the company's performance amongst others. According to Akomea & Yeboah (2011) there is a void in the literature with respect to the implementation of Market Orientation in pharmaceutical manufacturing firms. The author further confirmed that the more market oriented the pharmaceutical manufacturing firms were, the more profitable they became.

2.5 Conclusion

A number of factors have been attributed to the failure of pharmaceutical manufacturing plants in Africa. These range from lack of finances to poor infrastructure, constrained skills base, failing markets and registration delays

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2.6 Literature Gap

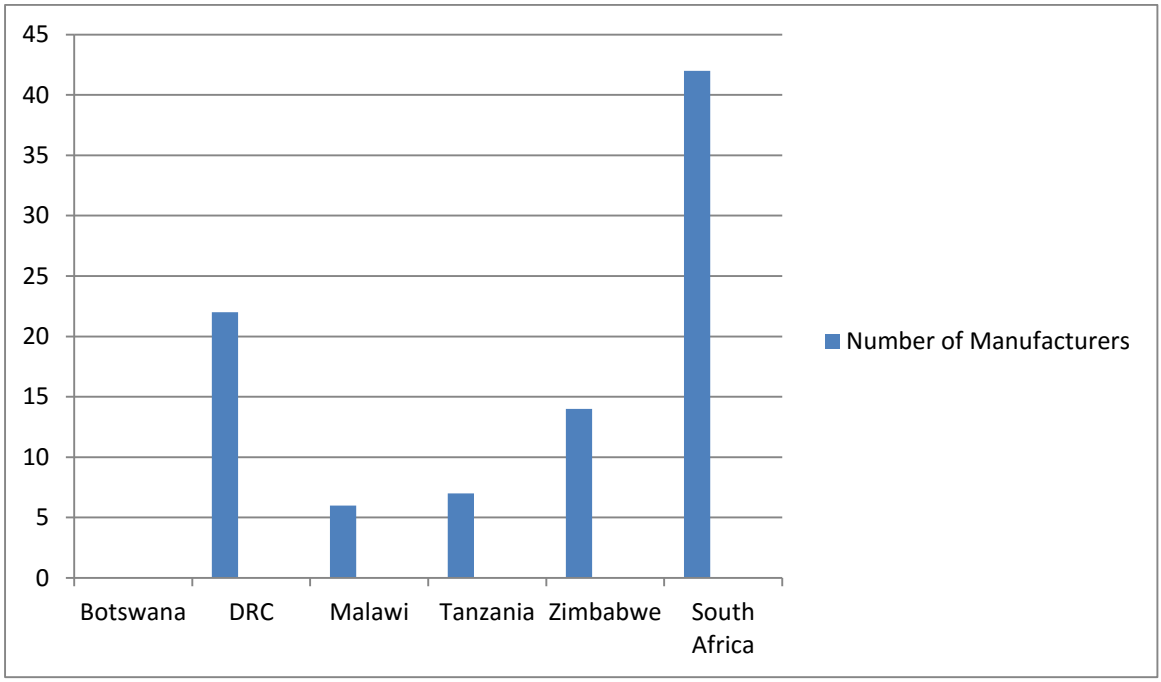
Firm performance can be influenced by how governments liberalize markets to make the environment supportive of profitable and sustainable pharmaceutical manufacturing. Firms also have a responsibility to develop a market orientation to stay competitive and therefore profitable. Countries which have done feasibility studies of the status of their environments and pharmaceutical firms e.g. Nigeria, Tanzania and Ghana have suggested how the environments can be improved to meet their country specific challenges.

There is lack of information on whether or not and under what conditions domestic production of pharmaceuticals actually makes a meaningful contribution to access and affordability of essential medicines to patients who need them most. WHO asserts that much of the local production-related literature occurs in the grey literature (World Health Organization (WHO), 2011b). The problem of limited access to information is compounded in Africa, where relevant information, especially related to traditional medicine, is kept in small circles of local experts, and seldom finds its way to a broader research community. Access to information is further hampered by poor internet access in some African countries.

Researchers advocate for feasibility studies to be done within each country to establish the need for promoting or discouraging local production of pharmaceuticals. A systematic assessment of national and regional public health needs with reference to local production of medical products with a view to generating information on the market viability and public health considerations is required.

There is inadequate published information about Botswana's pharmaceutical manufacturing's status and little is known as to whether or not Botswana's environment supports pharmaceutical manufacturing. There is lack of information regarding reasons for the closure of pharmaceutical manufacturing Firms in Botswana.

Figure 2.6 Information on Southern African pharmaceutical Manufacturing Status (World Health Organization (WHO), 2011a)



One of the observations from a local workshop suggests that the Botswana market is a low priority for manufacturers as there are insufficient incentives to attract pharmaceutical manufacturers which results in the absence of local pharmaceutical production (UNDP, 2013). There was further recommendation from the above mentioned workshop to conduct a feasibility study which will explore possibilities of local production, inform the Government on the pros and cons of local production as this requires careful legal, economic and market assessments before manufacturing. In addition to this the study will unearth possibilities for regional collaboration.

There is inadequate information on which products are on patency in Botswana to work at implementing Trips flexibilities in the country and also on which pharmaceutical products Botswana intends to prioritize for manufacturing as suggested in the SADC pharmaceutical Business Plan. If we are really moving towards promoting use of local traditional medicines

to develop medicines which will address local conditions, there should be a list of traditional medicines to refer to locally.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

This chapter outlines the plan that was used in collecting, organizing and analysing data from the respondents. It discusses the research design, the research philosophies, the instruments used to collect data and data analysis. It further lays out the most appropriate procedure and methods that the project used in carrying out this exercise.

3.2. Research Questions

I. What factors led to the closure of pharmaceutical manufacturing firms in Botswana between 1990 and 2015?

ii. Does the business environment in Botswana enable pharmaceutical manufacturing?

iii. What market orientation did these firms adopt?

iv. How did adoption of the market orientation influence the performance of the pharmaceutical firms?

3.3 Research Design

This study was an exploratory, cross sectional research. Information about the number of closed pharmaceutical manufacturing firms in Botswana is known, but little is known as to what factors contributed to the failure and ultimate closure of these firms. The study adopted mixed methods in answering the research questions by collecting quantitative and qualitative data. First a quantitative approach was taken to establish the trends and the extent of influence of the identified variables on firm performance, with the respondent ratings. A survey was conducted by administering a questionnaire followed by semi-structured interviews. A graphic rating scale was used to obtain responses from respondents. Respondents were asked to rate the extent to which a described phenomenon was a challenge to their firm on a range of 1 to ten, 1 being the least of a problem and 10 being the greatest

challenge. Quantitative studies provide data that is in numbers like the mean, median and the standard deviation. This information helped us to derive important facts from research data, including preference trends, differences between groups, and demographics. Quantitative studies' great strength is providing data that is descriptive.

The qualitative approach was meant to augment and validate quantitative findings. More importantly the study sought to get a deeper understanding of the phenomenon under study considering the critical nature of the research questions through the use of open-ended questions using the questionnaire and face to face interviews. Data from qualitative studies described the qualities or characteristics of something. Qualitative research studies can provide you with details about human behaviour, emotion, and personality characteristics that quantitative studies cannot match. Qualitative data includes information about user behaviours, needs, desires, routines, user cases, and a variety of other information that is essential in designing a product that will actually fit into a user's life. The open ended questions in the questionnaire gave information about the needs, desires, and perceptions of employees of pharmaceutical manufacturing plants.

This method was influenced by two studies conducted in the pharmaceutical manufacturing sector in Ghana and manufacturing firms in Kenya. Both studies used questionnaires in data collection and the theoretical framework was adopted from the Kenyan study. Akomea & Yeboah, (2011) studied market orientation and firm performance in Ghana's pharmaceutical industry. Lagat et al (2012) studied the impact of the external environment in market orientation- firm performance relationship in the manufacturing sector in Kenya. The Kenyan study used a semi-structured questionnaire from a random sample of managers. In South Africa and Tanzania face to face interviews were conducted from pharmaceutical manufacturing employees in management and government employees for data collection (Akomeah & Yeboah, 2011; Naude & Luiz, 2013; UNDP, 2016b). In this present study a

questionnaire followed by face to face interviews were the methods used to gather information from two employees who were in management from each pharmaceutical manufacturing firm that closed. The use of a knowledgeable source limited errors.

3.4 Research Philosophies

It is important to consider research philosophies when undertaking a study since these parameters describe perceptions, beliefs, assumptions and the nature of reality and truth (knowledge of that reality), they can influence the way in which the research is undertaken, from design through to conclusions. It is important to understand and discuss these aspects in order to ensure that approaches congruent to the nature and aims of the particular inquiry are adopted, and to ensure that researcher biases are understood, exposed, and minimized (Flowers, 2009).

The philosophy that informed this study was that of realism. Krauss (2005) asserts that realism as a research paradigm has elements of both positivism and constructivism. Realism concerns multiple perceptions about a single, mind-independent reality. Realism recognizes that perceptions have certain plasticity, and that there are differences between reality and people's perception of reality. The government of Botswana is implementing some reforms which are meant to promote industrialization in the country but the reality is that the pharmaceutical manufacturing sector is not growing.

There is a likelihood for people within the different sectors to have different perceptions about factors contributing to the failure of pharmaceutical manufacturing firms within the country. There is a reality out there about the issues at hand, and this exploratory study sought to establish the perceptions out there versus the reality so as to bridge the gap between the two and make possible recommendations that could promote positive business environment for pharmaceutical manufacturing in our country.

Realism was appropriate for this study as it accommodates both qualitative and quantitative research methodologies for researching underlying mechanisms that drive actions and events (Sekaran, 2013). Qualitative research is based on relativistic, constructive ontology which posits that there are multiple realities constructed by human beings who experience a phenomenon of interest. Positivism is seen as the way to get at the truth. Positivism believes in empirism, the idea that observation and measurement are at the core of the scientific endeavour. Positivism seeks to explain what happens in the social world by searching for regularities and causal relationships between its constituent elements. Positivism is based upon values of reason, truth and validity and there is a focus purely on facts, gathered through direct observation and experience and measured empirically using quantitative methods – surveys and experiments - and statistical analysis.

From an organizational perspective, other researchers describe the realist researcher as enquiring into the mechanisms and structures that underlie institutional forms and practices, how these emerge over time, how they might empower and constrain social actors, and how such forms may be critiqued and changed (Flowers, 2009; Krauss, 2005; Okoroafo, 1993). Realists take the view that researching from different angles and at multiple levels will all contribute to understanding since reality can exist on multiple levels.

Onuoha (2012) argues that industry or external firm factors play a more important role in dictating the influence of firm performance. On the other hand Akomea & Yeboah, (2011) suggest that firm specific (internal) factors seem to be the major determinants of the operating performance and are the main drivers for competitive advantage which is crucial for surviving economic downturn.

Firm Performance is described as the results of activities of an organization or investment over a given period of time. Firm performance is reported to be influenced by market

orientation and the appropriate utilization of company resources. The environment in which a company operates moderates these factors and therefore has an influence on firm performance.

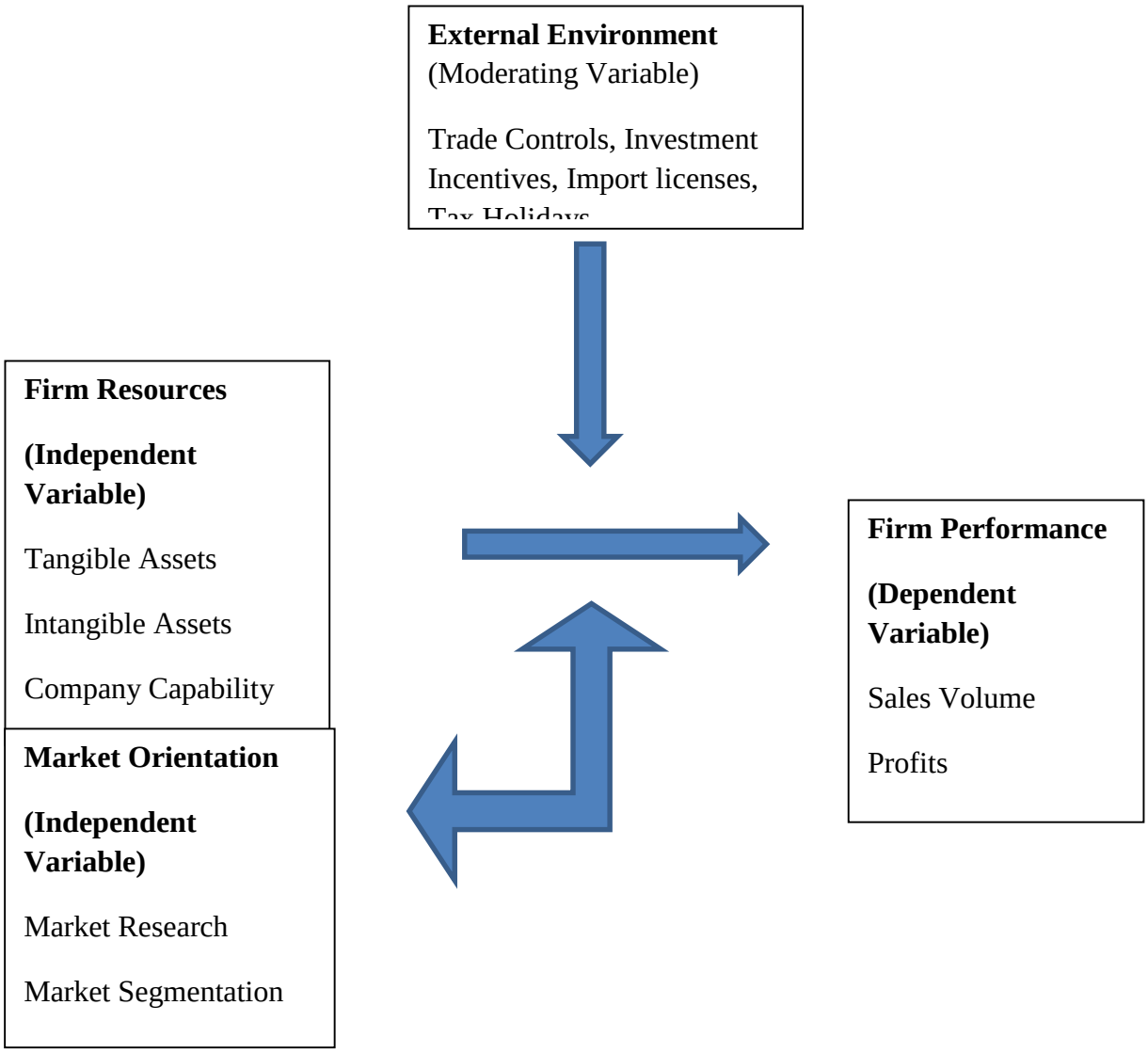
3.5 Independent and Dependent Variables

3.5.1 Dependent variable.

A variable is defined as something that varies or takes on different values (Flannely & Jawnkowski, 2014). Research aims to understand cause-effect relationships. A presumed cause of phenomena is an independent variable where as a presumed effect is a dependent variable. There are a number of attributes that describe the performance of a firm, and this includes Sales volume, Return on Investment, Sales growth rate, Market Share and Profits. This study will limit itself to three variables that is the sales volume, the profit and the Return on Investment. In this study, Firm performance is influenced by availability, proper allocation, utilization of resources and market orientation.

The conceptual framework is captured below, showing all the variables**.**

Figure 3.4.1 Variables Used in the study and the theoretical framework using the Resource Based Theory



Firm Performance. Firm Performance is viewed from subjective and objective methods. The subjective method is concerned with the performance of the firm relative to its own expectations or assessment. The objective method is concerned with absolute measurement of performance like Return on Investment, Sales and Profit (Protcko, 2014).

Sales Volume: The number or the quantity of products sold or services provided by a company in a particular period of time:

Profit: Profit is a financial benefit that is realized when the amount of revenue gained from a business activity exceeds the expenses, costs and taxes needed to sustain the activity (Hisrich, Peters, & Shepherd, 2013)

Return on Investment: Return on investment (ROI) measures the overall effectiveness on management in generating profits with its available assets. It is a ratio of income to investment (Gitman & Zatter, 2012).

Management was expected to have an idea of how the firm performed from its inception until closure regarding these parameters, and what contributed to the change in performance if there was any. The realism theory brought out the truth.

3.5.2 Independent Variables

An independent variable is presumed to have an effect on a dependent variable, it causes variation. In this study independent variables were represented by Firm Resources and the market orientation concept. Firm Resources are Tangible Assets, Intangible Assets and Firm Capabilities. The market orientation variables included market Research, Market Segmentation and product positioning. Availability, proper allocation and utilization of resources have a positive influence on firm performance. Market oriented companies are believed to have superior advantage over their competitors and are likely to have competitive advantage. This study sought to identify how these variables caused firm closure.

a) Firm Resources

(i) Tangible Assets

Tangible assets are physical assets such as land, vehicles, equipment, machinery, furniture, inventory, stock, bonds and cash. These assets are the backbone of a company but are not

available to customers. Tangible assets are at risk of damage either from naturally occurring incidents, theft or accidents.

(ii) Intangible Assets

An intangible asset can be defined as reputation, name recognition and intellectual property such as knowledge and know how. Intangible assets are the long-term resources of an entity, but have no physical existence. They derive their value from intellectual or legal rights, and from the value they add to the other assets. Intangible assets are generally classified into two broad categories: (1) Limited-life intangible assets, such as patents, copyrights, and goodwill, and (2) Unlimited-life intangible assets, such as trademarks. In contrast to tangible assets, intangible assets cannot be destroyed by fire, hurricane, or other accidents or disasters and can help build back destroyed tangible assets.

(iii) Firm Capability

Business capability is the expression or the articulation of the capacity, materials and expertise an organization needs in order to perform core functions.

(b) Market Orientation

(i) Market Research

Definition: The systematic design, collection, interpretation and reporting of information to help marketers solve specific marketing problems or take advantage of marketing opportunities (Ferrel & Pride, 2016).

(ii) Marketing strategy

A business' overall game plan for choosing a target market and the creation of a marketing mix that will satisfy the needs of the market. Strategy articulates the best use of company's resources to achieve its marketing objectives (Ferrel & Pride, 2016).

(iii) Market Segmentation: A two-step process of naming broad product markets and segmenting these markets in order to select target markets and developing suitable marketing mixes for them (Rerreault, Cannon, & McCathy, 2008).

(iv) Product Positioning: Product positioning is the process marketers use to determine how to best communicate their products' attributes to their target customers based on customer needs, competitive pressures, available communication channels and carefully crafted key messages. Effective product positioning ensures that marketing messages resonate with target consumers and compel them to take action

3.5.3 Moderating variables

External Environment

Moderating Variables consist of the external environment in which the business is operating. This includes Tax holidays, business incentives, Import tariffs and licenses, Trade controls.

3.6. Population of the study.

The population of a study according to Sekeran (2013), refers to the entire group of people, events or things of interest that the researcher wishes to investigate. In this study, all employees from closed Pharmaceutical Manufacturing plants formed the primary population of interest. Past employees within Gaborone and Lobatse were the population from which the study sample was derived. There were about six (6) manufacturing firms that operated and closed between 1990 and 2015. These firms operated mostly in Gaborone, only one (1) firm operated in Lobatse. This population was relevant to this study because they could direct the researcher to the most appropriate candidates for the study. The total population was ninety nine (99) employees from the four firms that were interviewed. Some employees however, were casual employees.

3.7 Study Sample

Any two senior management former employees who included a former managing director and/or, pharmacist from management qualified to be in the study sample, One of the employees was supposed to be a pharmacist. This study sample is comparable to similar studies carried out in Africa.

In south Africa a sample of thirteen individuals from management was targeted, three individuals from each of the three of multinational manufacturing firms, 2 individuals from a local generic manufacturing firm and two people from government (Naude & Luiz, 2013). The number of pharmaceutical manufacturing firms in South Africa was ten (10). In Ghana two senior managers from manufacturing firms were used. Nine Manufacturing firms were used in the study (Akomeah & Yeboah, 2011). In the Tanzanian study three (3) people were interviewed from the three pharmaceutical manufacturing firms. In a study of the business environment for pharmaceutical manufacturing in Nigeria a study sample size of 38 pharmaceutical companies was used (Onuoha, 2012). The difference between this studies and the current study is that whereas in the mentioned studies those interviewed were from operational firms, this study interviewed employees from closed pharmaceutical manufacturing firms.

Six (6) companies formed the target number. This sample size was based on the records available at Botswana Investment and Trade Centre. The records were for pharmaceutical manufacturing companies that were licensed as such between 1990 and 2015. It was possible to draw conclusions that apply generally to the study population using the sample mentioned above.

3.8 Sampling Technique

This study used non-probability sampling technique, specifically purposive judgmental sampling (Sekaran, 2013). The researcher was looking for expert knowledge to inform the study. It was also convenient to use employees who were available within Botswana. This sample size was based on the records available at Ministry of Trade and Industry, that is, firms that were licensed, as pharmaceutical manufacturers, operated and closed between 1990 and 2015. From the primary population of past employees**,** the study then narrowed to those in management. Management consisted of directors, factory managers, and quality assurance managers. The sample consisted of two (2) employees from management.

It seems reasonable to believe that former Directors and pharmacists who were involved in the day to day operations of the organization were best positioned to provide the information required. Directors knew the overall performance of the company; pharmacists get involved in production and link to marketing personnel who would know specific facts about the sales. One of the limitations of the study was the sample size, which was influenced by the numbers of past employees available at the time of data collection. The Firms were no longer in operation, so past employees were not readily available.

3.9 Methods of Data Collection and Justification

Different data collection techniques were used in this study.

3.9.1 Questionnaires

The study used semi-structured questionnaires to collect information from two (2) employees of pharmaceutical manufacturing firms which closed shop in Botswana, these two (2) employees were part of management. In a study of market orientation and firm performance conducted in the pharmaceutical industry in Ghana a semi structured questionnaire was developed and sent to top management.

The use of a questionnaire is an efficient data collection tool when a study is exploratory. Questionnaires have an advantage of being less expensive and less time consuming.

There was an introductory letter so as to inform the participants about the study in time.

3.9.2 Interviews

Interviewing is a useful and appropriate data collection method especially for this study which sought to establish the truth of what contributed to failure of pharmaceutical manufacturing firms in Botswana; Different types of interviewing gave the researcher opportunity of observing people's behaviour other than capturing just what they were saying. Semi-structured interviews were used on a face- to –face interaction.

In-depth face to face interviews were conducted on the same respondents who completed questionnaires, this method presented opportunities to probe interviewees to uncover underlying reasons for their responses (Akomeah & Yeboah, 2011; Sekaran, 2013). This also helped to gain insight into study questions.

Research conducted in other countries has unearthed reasons that have contributed to failure of pharmaceutical manufacturing firms, so questions that were asked in this study are informed by such(Onuoha, 2013); Naude & Luiz, 2013; Okoroafo, 1993)

3.9.3 Access.

It was convenient to gather information from managers in the pharmaceutical sector. However, all appropriate measures were taken to ensure authenticity and confidentiality of the research project. Since data was collected from individuals, ethical clearance was sought with University of Botswana Ethics Committee; introductory letters from the school of Business and a research permit from the Ministry of Health were availed so as to gain access to the participants since they were now working for different firms.

3.9.4 Research data gathering instrument.

Annexure A attached is the questionnaire that was used. The consent form is also attached.

3.9.4.1 **Reliability and Validity of the instruments used**

Instrument is the generic term that researchers use for a measurement device (survey, test, questionnaire, etc.). Instruments fall into two broad categories, researcher-completed and subject-completed, Semi Structured interviews and telephone interviews would be researcher completed whereas questionnaires sent via e-mail will be subject completed (Sekaran, 2013).

Validity of a research instrument is the extent to which an instrument measures what it is supposed to measure and performs as it is designed to perform. Questions were checked to determine if they could prompt the types of responses expected. This was done through a pilot test with a few past employees who were not in management from one of the closed firms, and were therefore not part of the sample. Information gathered was reviewed to check if it was the appropriate information that answered the research questions.

Interviewees were briefed on the subject matter prior to interviews; this helped to promote validity and reliability by enabling participants to gain an understanding of the information being requested.

The questionnaires were also reviewed by some experts like lecturers to give their inputs.

The data collection instrument was pre-tested if it consistently measures what it was intended to measure. Pretesting or pilot testing an instrument allows for the identification of sources of errors and then refinement of the instrument then focuses on minimizing measurement error.

The questionnaire was followed by a face to face interview with the same interviewee to check if their answers were consistent and the questionnaire was also administered to different individuals at the same time to check similarities and differences in the way they answered when the same content was used.

3.9.4.2 Ethical Considerations

This research was administered considering the ethics acceptable to the University of Botswana. Ethical approval was sought from the University of Botswana Ethics Board.

A research permit was then sought from the Botswana Ministry of Health. The research permit, University of Botswana support letter were presented to all the Organizations and individuals who participated in the study.

Participants of the study were given full explanation of what the study entailed, and were informed of their rights to choose to participate or to refuse participation. Research should consider respect for autonomy. Respect for autonomy considers the individual as an independent person who is able to make choices for himself/herself ("Ethical Conduct in Research: Professional Guidance," 2015). Participants have a right to self-determination and full disclosure. Giving participants complete information about the research and risks anticipated empowered them to make informed choices, importantly, the choice to participate or withdraw. Participants in this study showed their approval to participate in the study by signing a consent form.

Participants were also informed that information collected during the study would not be used in any way that is harmful to them except in fulfilling requirements of this dissertation, and their names or personal information would not be used without their consent. Identification Numbers were assigned to participants and names of participants were kept

anonymous. This was in line with research ethics which state that personal information gathered from participants should not lead to their personal identification and should not be divulged to others without the participant's consent ("Ethical Conduct in Research: Professional Guidance," 2015).

Data protection refers to the technical framework and security measures designed to guarantee that all personal data are safe from unforeseen, unintended or malevolent use. Data protection, therefore, includes the above mentioned measures with regard to access to data and the conservation of data. Also measures to assure the accuracy of the data can be included in a data protection strategy ("Ethics for Researchers, Facilitating Research in FP7," 2013).

This study included adults above 18 years of age who worked for closed pharmaceutical manufacturing plants. The study excluded vulnerable groups like children and the elderly.

Personal Biases were avoided and the researcher tried to be objective during the research process by being sensitive in the way questions were asked during interviews. The study did not cause any physical or emotional harm to participants.

Results have been presented as accurately as possible to reflect what was said and observed.

3.10 Data analysis

The data collected was analysed to assess the significance of the study by evaluating the results. Data analysis can be either quantitative or qualitative. This study adopts mixed methods in both quantitative and qualitative analysis because of the data collected through semi-structured questionnaires and face to face interviews. Quantitative methods gain their validity in the use of statistical tools; however, they often lack the capacity to explore a deeper understanding, attitudes, behaviour and process. Qualitative data analysis is defined as a process of the description, classification and interconnection of phenomena with the

researcher's concepts (Graue, 2015). The above mentioned researcher further states that quantitative research is structured by the concerns of the researcher whereas qualitative research is structured by the concerns of those who are the subject of the research. The analysis of qualitative research is believed to uncover and or understand the bigger picture by using the data to describe the phenomenon and what this means.

Data was analysed by creating tables, pie charts, bar graphs using Microsoft excel so as to establish patterns, averages, frequencies, deviation from overall patterns and extreme values. The results are presented and discussed in the next two chapters. Qualitative data from face to face interviews was summarised to put emphasis to the graphical data.

CHAPTER 4: PRESENTATION, INTERPRETATION AND ANALYSIS OF FINDINGS

4.1 Introduction

This chapter presents the findings and interprets the data. Questionnaires were sent to two participants from Six (6) closed pharmaceutical manufacturing firms that operated between 1990 and 2015. There are only six (6) recorded licensed pharmaceutical manufacturing firms that operated within that period according to Industrial affairs at the Ministry of Trade and Industry. Respondents from four (4) out of the six firms participated, questionnaires were e-mailed to them followed by face to face interviews. Respondents were asked to rate the extent to which an indicator presented as a challenge to firm performance. On a scale of 1 to 10, 1 being the least of a challenge and 10 being a challenge to a great extent. Open ended questions followed to gather more information and deeper understanding on the ratings.

The study explores influence on a variety of independent variables on firm performance of pharmaceutical manufacturing firms. This includes firm resources and market orientation. Firm resources are presented as tangible resources, intangible resources and firm capabilities while information on Market Orientation and its impact on firm performance is also presented. Further the study investigates the moderating variable on firm resources and market orientation described by the business external environment.

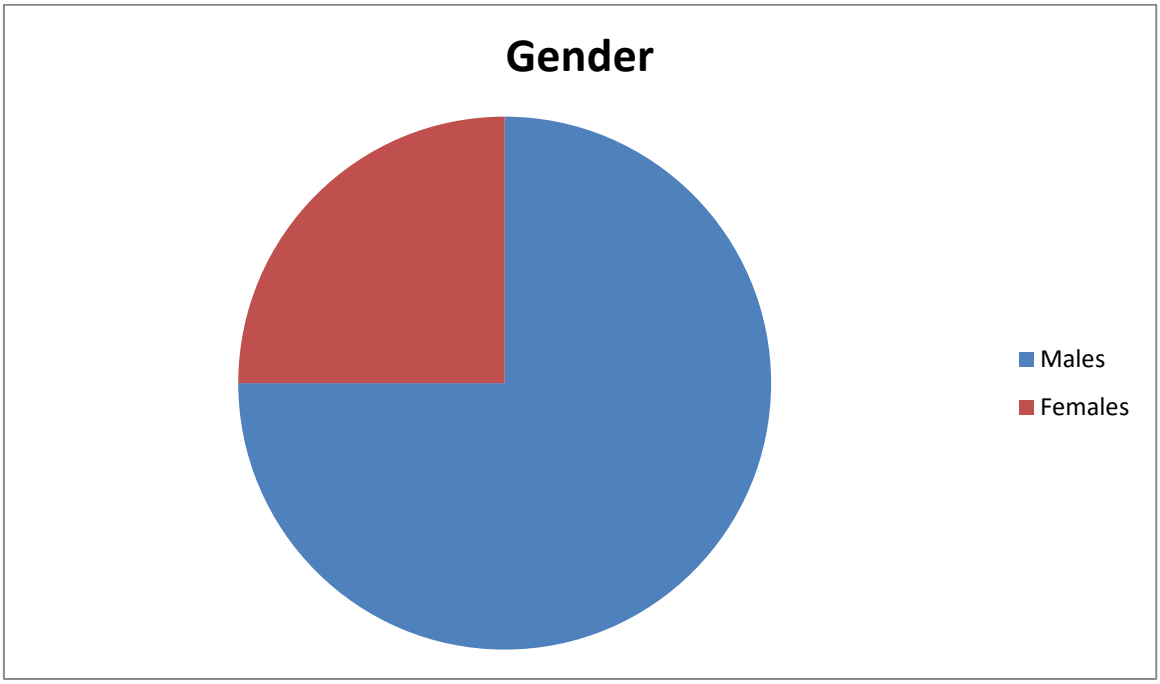
4.2 Descriptives

Table 4.2.1 Demographics: Gender and Age

Respondents	Gender	Age Category
Respondent1 1	Male	50-59
Respondent 2	Male	0-39
Respondent 3	Male	50-59
Respondent 4	Male	30-39

The age range of the respondents was between 30 and 59 at the time of the interview. Half of the respondents were in the Age group between 30 and 39, and the other half was in the age group 50- 59. The Average Age for these Managers was 32 years.

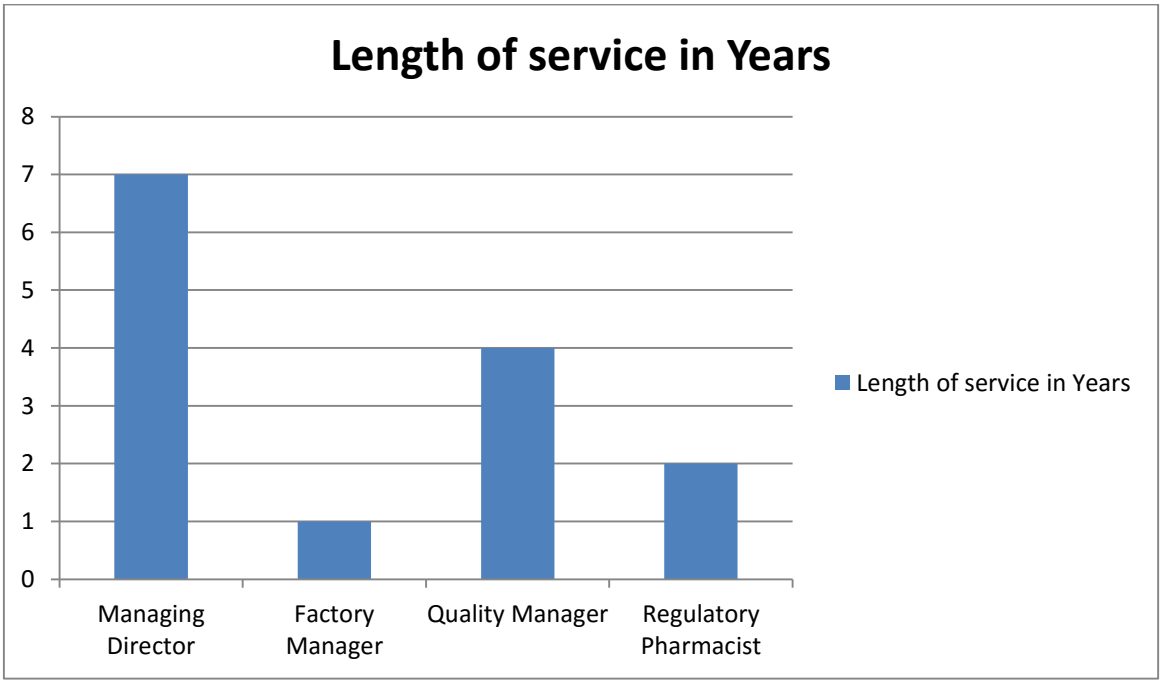
Figure 4.2.2 Gender



Three out of four of the respondents were male and there was only one female Respondent in management from the four manufacturing companies. This indicates that the majority of managers in pharmaceutical manufacturing companies in Botswana are males.

4.3. Position and Length of service

Figure 4.3.1 A bar graph showing length of service of respondents



All respondents, who are pharmacists, were in top management; among them was also a managing director who served the company for seven years. The Average length of service of the respondents was three and a half years with the least as one (1) year. Although the respondents were all in management only one of them was the owner and overall manager of the factory. The other pharmacists worked as either production pharmacists or quality control managers. The majority of firms were owned by people who were not pharmacists.

Table 4.3.2 Firm Descriptives

	Respondent 1	**Respondent 2**	**Respondent 3**	**Respondent 4**
Starting year	1992	2008	2002	2011
Year of Closure	1999	2013	2005	2015 (No sales)
Number of Employees (Size of the firm)	5	65	23	6
Place of operation	Gaborone	Lobatse	Gaborone	Gaborone
Management	Owner managed	Owner managed	Owner managed	Owner managed
Annual Turnover	1-3million pula	No information	250000 pula	No information
Manufacturing Type	Secondary	Secondary	Secondary	Secondary
Products produced	Generic medicines, cosmetics	Medical devices	Generic medicines	Generics medicines

Data was collected from pharmaceutical manufacturing companies that operated and closed between 1990 and 2015, a period spanning twenty five years. All the manufacturing plants operated in the southern part of Botswana with three (3) of the four firms based in Gaborone while one operated in Lobatse. In this period six (6) companies started and closed operations. Information was gathered from four of six of these companies. It was difficult to find employees from the other two companies, especially those who were in management who are reported to have relocated from Botswana.

The majority of the plants were producing generic medicines as opposed to branded medicine. All the four manufacturers operated as both generic medicine producers and some produced their own brands of cosmetics and herbal products. None of these plants did primary level production. These companies had a maximum annual turnover of 3 million

Pula, some were unknown, another, a minimum turnover of 250 000 Pula and one of the plants never made any sales and the turnover was P0.00.

There were differences in the way they hired their employees. Three out of four of the companies hired permanent employees with a few technical officers and the majority of employees were unskilled. The company that hired the highest number of employees had sixty five (65) employees whereas the least had only five (5) permanent staff, the rest of the employees would only be hired during the production period. The practice of acquiring casual workers was reported to be a huge cost to manufacturers, as employees lost their skills whenever there was no production and manufacturers were forced to re-train. The quickest to exit was the one that never made any sales after three years and the longest to exit operated for about seven years.

The study sought to meet the following objectives.

- To establish factors that led to the failure of pharmaceutical manufacturing firms in Botswana.
- To interrogate Botswana business environment, with a specific focus on pharmaceutical manufacturing legislation and policies.
- To establish if market orientation was adopted by pharmaceutical manufacturing firms.

4.4. Factors that contributed to the closing of pharmaceutical Manufacturing Firms.

Respondents were asked to rate the extent to which a parameter was regarded as a challenge to the firm.

Using a scale of 1 to 10, 1 being the least and 10 being the greatest challenge.

E.g. Management

1 2 3 4 5 6 7 8 9 10

Table 4.4.1 Rating of Challenges to Firm Performance.

Parameter	Average Rating
Supply of Production Inputs	5
Meeting International Standards	5.25
Management	6.23
Employee satisfaction	6.23
Equipment Maintenance	6.23
Infrastructure	7.5
Legislation and Policies	7.5
Skilled personnel	8
Market	9.5

The factors that were deemed to be the greatest challenges to pharmaceutical manufacturing and given the highest ratings were market and availability of skilled personnel. The next factors that were deemed to be a challenge also included infrastructure, legislation and policies, especially procurement policies and financial policies. Human resource issues were just above average. Supply of production inputs and meeting international standards were also just above average.

4.5 Firm Resources

The Resource Based View (RBV) suggests that firm resources are an essential factor that influences competitive advantage and firm performance (Othman, Arshad, Aris, & Arif, 2015) Resources can be the strongest and weakest link to manufacturing performance.

4.5.1 Tangible Resources

Tangible resources are normally similar especially in pharmaceutical manufacturing.

- **Land, Buildings, Machinery and Raw Materials**

In this study:

- Tangible resources in manufacturing were almost similar especially the use of similar equipment, machinery, tools, plants, raw materials and outputs.
- Physical assets were common amongst the manufacturers as none could be licensed to operate without the necessary equipment, infrastructure and processes in place.

Three out of four of the firms leased the buildings they were operating from except Company D which built a state of the art manufacturing plant which closed shop after three years before any sales were made.

All the four companies considered accessing raw materials to be a challenge but to a less extent with an average score of 5, although the raw materials were imports from India, Malaysia and South Africa. Packaging material was also coming from outside the country. The challenge was availability of finances to procure raw materials or pay suppliers if one received products on credit. The issue on charging VAT on raw materials was seen to increase production costs.

Financial Resources

Financial resources are the lifeline of operations.

In this study respondents indicated that it was difficult to get financial support to drive operations of their firms. Both commercial banks and government financial structures could not provide financial support to pharmaceutical manufacturers because they were considered as very risky operations.

Owners of firms ended up using personal finance or high cost short term finance to start their businesses. With no borrowings to drive operations, to pay salaries and suppliers, companies experienced cash flow problems and became unsustainable.

The owner of Company B who was also a pharmacist had this to say;

"Botswana Development Cooperation could only offer financial assistance if there was a foreign partner in the company"

He went on to say Pharmaceutical Manufacturing has no history in Botswana. Other respondents corroborated this belief and added that there was lack of knowledge about pharmaceutical manufacturing in Botswana and financiers did not have information about the viability of the business.

4.5.2 Intangible Resources

(i) Human Resource

It is postulated that the top major classes of resources that influence performance of pharmaceutical manufacturing firms are financial resources and human resources.

Human resource is the availability of skills, talent and know-how of employees that is required to perform the everyday tasks that are required by the manufacturing firm's strategy. Without competent people both in managerial and employee positions, manufacturing organizations will not be able to accomplish their goals (Kariithi & Kihara, 2017). This means that, the manufacturing firm will not have a competitive edge over other firms in similar industries.

(ii) **Management**

There has been an observation that the ability of a corporate organization to successfully implement business strategies solely depends on efficient use of human capital (Kwarbai & Ajike, 2016).

In pharmaceutical manufacturing production of products and production managers are key to the business.

When respondents were asked about the extent to which management and employees were a challenge to firm performance, Two out of four of the respondents considered that

management of the pharmaceutical manufacturing firms were a problem to a great extent and the other two considered that management was fine.

The reasons that were advanced for this assessment were:

- Owners of manufacturing plants who were not pharmacists by profession, were deemed to interfere with professional operations. Pharmaceutical manufacturing is a technical operation which has to meet good manufacturing practices; these owners failed to comprehend the seriousness of GMP requirements and contributed to delays in product registration, GMP certification and quality management requirements.
- The Managers also hired supervisors who had inadequate knowledge so as to take advantage of them when it comes to remuneration, as one respondent observed.
- Production pharmacists, who were citizens, did not have any experience in pharmaceutical production.
- There was also a language barrier with the managers who were from Asia and could not communicate in English.

(iii) Company Employees

Two of the respondents also considered employees to be a challenge to firm performance to a great degree whereas the other two believed employees were productive and happy. The Average rating for employee satisfaction was 6.5

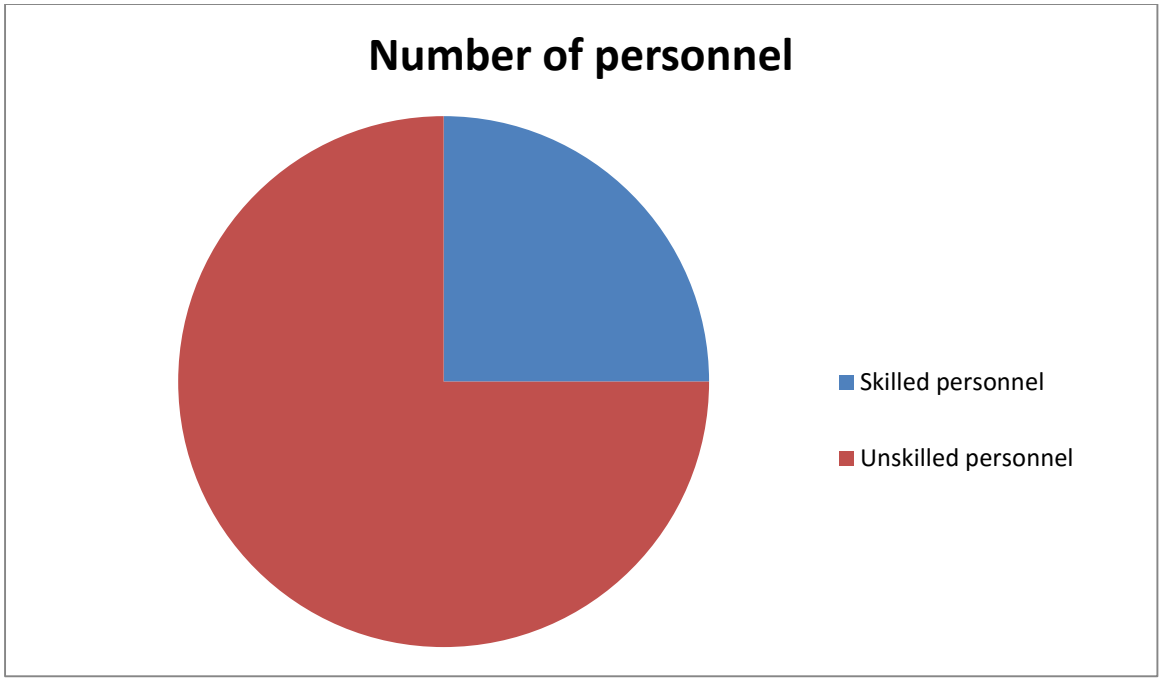
The work ethic of Batswana employees was considered to be counterproductive. There was a suggestion that Botswana labour laws promote inadequate productivity.

One respondent said "You can hardly say anything to employees in this country, because the next thing you are taken to the department of labour".

The majority of the employees in Pharmaceutical manufacturing were unskilled. Skilled labour was considered one of the greatest challenges in pharmaceutical manufacturing in

Botswana. Three out of four of the companies scored 10 for availability of skilled personnel. Skilled labour is required for production, quality assurance, equipment maintenance and operations.

Figure 4.5.2 Availability of skilled personnel



There were more unskilled personnel compared to skilled personnel.

One of the Respondents indicated that the unskilled and incompetent employees are a reflection of lack of commitment from government towards its educational policies. "The government has not ensured that the pharmacy graduates can actually operate pharmaceutical manufacturing plants. There is no collaboration between the academic institutions and pharmaceutical manufacturing industry''

Employees in pharmaceutical manufacturing firms were considered to be unhappy and dissatisfied because of low salaries.

(iv) Firm Capabilities

Capability based competitors identify their key business processes, manage them centrally and invest in them heavily, looking for a long term payback. A capability is strategic only if it begins and ends with the customer.

In this study, all respondents indicated that electricity was a challenge since pharmaceutical manufacturing requires uninterrupted electricity supply. Since there is a requirement for high usage of electricity to maintain good manufacturing practices the electricity bills were considered to be high. Internet usage was also considered to be a high cost in manufacturing. Services for continuous monitoring GMP and Quality Management Systems (QMS) could only be accessed outside the country which was not sustainable and came at a high cost for the businesses.

There was however inadequate financial resources to invest in vertical integration with international manufacturing companies.

4.6 Market Orientation

The proponents of market orientation assert that organizational success largely depends on determining the needs and wants of target markets and delivering satisfactions to those markets/consumers more effectively and efficiently than competitors do (Lagat, Chepkwony, & Kotut, 2012).

In this study a market-oriented company would have a marketing strategy which will include market intelligence generation or market research, dissemination of the market information within the company or marketing strategy and then responsiveness through product positioning.

Respondents in this study indicated that limited resources could not allow them to do anything market related.

Table 4.6 Market Orientation implementation

Parameter	Respondent 1	Respondent 2	Respondent 3	Respondent 4
Market Research e.g. Customer surveys	None	None	None	None
Marketing Strategy	None	None	None	None
Marketing Plan	None	None	None	None

Market orientation was a challenge to a great extent to all of the firms and the reason advanced was that there was no budget for implementing a market orientation concept. Access to finance was regarded as a hurdle. Marketing of pharmaceuticals was also considered to be strictly regulated and this also discouraged businesses to explore the idea.

4.7 The external Business Environment

Profit is an essential condition for the existence and survival of a firm and is critical if the owners of the firm desire to pursue the firms' goals. Business survival is, in the long run, linked to the ability to generate profit and keep a positive cash flow. Profitable companies have the ability to invest and enjoy return on investment which promotes growth and sustainability. Profitability is also believed to be influenced by firm resources and capabilities, which are internal factors. The strategic use of resources therefore has a positive impact on the performance of a firm. Management has control of resources and can allocate resources to the maximum for competitive advantage (Anggraeni, 2014).

A firm, however, does not operate in a vacuum. There is a moderating variable, which is the environment in which the firm operates. A firm's external environment has an impact on the profitability of the firm and management has no control over external factors.

The external environment consists of the political environment, the economic environment, the technological environment and the legal environment. The political landscape is crucial to the business environment as investors are interested in security, political stability, a

willingness to fight corruption, and commitment to ensure a free environment for healthy competition in the business space. A supportive economic environment has economic factors including the general economic climate influencing the market, trade rates, inflation rate, labour unemployment rate, interest rates, tax rates, tariffs, the rate of economic development, per capita domestic product and trade deficit or surplus (Chitechi, 2014). The legal environment forces include, labour law, antitrust laws, Patent laws, Procurement laws, Economic empowerment laws and regulations, occupational health & safety policies and other laws of a country or pertaining to particular business environment that industry within the business environment must with those rules.

In this study the results for the business environment are presented below:

4.7.1 Political environment

Respondents from the four manufacturers were happy with Botswana's political environment in terms of political stability and security.

4.7.2 Economic Environment

The Economic environment was considered to be inadequate in terms of business support. One of the respondents expressed appreciation for the good laws and policies in existence but lamented that there is inadequate implementation of the law, e, g production inputs for medicines are charged Value Added Tax (VAT) when imported into the country, ironically VAT is not included in the final price for medicines produced in the country and this increases production costs. The fact that Finished Pharmaceutical Products (FPP) that are imported into the country are not charged vat, which influences their reduced final price, is of great concern to local pharmaceutical manufacturers as their low prices are a serious competition to locally produced medicines.

Procurement policies and medicine registration policies were considered to have serious flaws which disadvantaged manufacturers.

One of the respondents indicated that a company she worked for built a state of the art pharmaceutical manufacturing plant in the city of Gaborone. The company existed for a period of three years without commencing any business as it awaited registration of its products by the ministry of health. Once it received the registration clearance the company missed the three year tender for central medical stores. The company could not wait for another three years for a tender for its products, so the firm was closed and sold at a great loss. The duration of the contracts were deemed to be too long and suppressed competition. This practice was believed to be caused by lack of understanding of the pharmaceutical manufacturing industry and inadequate knowledge and skills of the procurement personnel.

The market was also considered a problem to a great extent with all respondents scoring 10. With an undeveloped private sector, the Botswana government has 80-90% buying power for locally produced medicines and if procurement is inconsistent and there is no commitment from the government to buy, respondents believe manufacturing companies are doomed. The government has also the power to close borders for locally produced medicines.

There is no tax relief incentives in the pharmaceutical manufacturing businesses in Botswana compared to other countries like India. The income tax charged on firms was considered to be high at 22%.

Basic infrastructure like supply of electricity and water is crucial to pharmaceutical manufacturing. Respondents indicated that supply of consistent electricity was a challenge to a great extent. Infrastructure was given a rate of 9 and above by all respondents.

Company A which manufactured condoms indicated that frequent electricity interruptions increased manufacturing costs because the production process of condoms had to occur from start to finish without interruption, power cuts resulted in loss of all the production inputs, especially latex, since it could not be re-used.

4.7.3 The Legal Environment

Two out of the four respondents were happy with the way pharmaceutical manufacturing is regulated in the country to ensure product quality and safety. The International Good Manufacturing Practices (GMP) requirements were not considered a challenge. One of the respondents however, observed that it is important for Botswana to consider a step-wise approach in terms of the implementation of GMP requirements as they may be an impediment to infant start-ups. Developing countries could consider customizing international requirements to the local environment to make manufacturing affordable and doable for local investors.

Botswana catered for public health needs by including TRIPS flexibilities in its laws, which allows certain medicines to be produced within the country even if they are still under patency to cater for pandemics such as HIV/AIDS.

Botswana also is signatory to AGOA, SADC, SACU-European Free Trade Association Free Trade Agreement (SACU-EFTA FTA), SACU-United States of America Trade, Investment and Development Cooperation Agreement (SACU-US TIDCA) and the World Trade Organization (WTO). Respondents were happy with these opportunities, they however, were not happy with implementation of these policies, as they considered implementation to be slow. Respondents indicated facing difficulties in terms of penetrating even the SADC region.(Botswana Investment & Trade Centre; World Health Organization (WHO), 2009)

Procurement laws and policies were considered to be implemented incorrectly, bordering on corruption of procurement officers. Price reservation and the implementation of the Economic Diversification Drive were believed to be inconsistent.

4.8 Firm Performance

Performance is the organization's ability to attain its goals by using resources in an efficient and effective manner. Measuring the performance of an organization ensures that strategic

activities are aligned to the strategic plan further improving the bottom line by reducing process cost and improving productivity and mission effectiveness (Fauzi, 2010).

The most common measures of firm performance used in research are Return on Investment (ROI), profit levels, sales growth and market share. Performance can be evaluated by financial indicators depending on result outcomes, for example, sales performance, return on assets, and return on equity (Wiklund & Shepherd, 2005). Also performance is evaluated by nonfinancial indicators such as market share, perceived productivity, and consumer satisfaction compared to competitors. Firms should use both financial and non-financial measures together, as any measures alone are an inadequate tool for measuring performance, also analysts who considered both financial and non-financial measures were more accurate in their decisions and actions (Salleh, Yusof, & Saad, 2015).

In this study it was difficult to access data since the companies were closed and three out of the four respondents did not have access to firm financials statements, They were however aware of the value of the sales that were done. One of the respondents indicated that their firm received only one GPO per year to supply just once, and this was not only difficult but not supportive of business. Respondents were now actually working in other manufacturing plants.

Respondents observed that there was no guarantee that the products they produced would be purchased, so most of the manufacturers were operating below capacity. Failure of the Firms to get financial support to boost operations resulted in business failure. The most advanced challenge was failure to sell products.

4.9 Conclusion

The results show that the Market, Unskilled labour, Legislation and Policies (with emphasis on lack of financial support and poor procurement policies) and infrastructure had high ratings in terms of challenges to pharmaceutical manufacturing in Botswana. Other

challenges included inadequate skills in business management, import of pharmaceutical equipment maintenance services from outside the country and employee dissatisfaction with remuneration.

CHAPTER 5: DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

The purpose of this chapter is to summarize and provide a brief discussion of the findings. The patterns established in the findings are discussed, as a way of also establishing a link of the study objectives to the findings. The findings are compared with other similar studies conducted in Africa and the whole world. The implication of this study to practice and management is discussed. Limitations of the study and recommendations are also discussed.

All the closed pharmaceutical manufacturing firms were Small and Medium Enterprises (SMEs) considering that those firms which hired permanent employees hired less than 100 and their annual turnover was less than one million pula. These firms were started by budding entrepreneurs. Entrepreneurship is believed to be the mechanism through which economic growth takes place. However, institutional frameworks, such as the policy environment are what allocates entrepreneurial efforts toward productive and unproductive activities, by influencing the relative incentives and pay offs offered by the economy to such activities. Government policies mould institutional structures for entrepreneurial action, encouraging some activities and discouraging others (Muranda, Mphela, & Nyakunda, 2011). These researchers further state that entrepreneurs competing in a munificent environment draw from encouraging government policies, abundant financial resources, positive social attitudes and stable economic conditions to switch on their alertness to profit.

5.2 Summary of the Findings

The Objectives of the study were met since the factors that were considered to be a challenge to establishing profitable and sustainable pharmaceutical manufacturing firms in Botswana were established. The factors included the Market, Finance, Skilled Labour and Infrastructure. Legislation and Policies which were considered an impediment were also established. Market orientation was not adopted by any of the manufacturing firms.

5.2.1 Market

Most African countries which are still developing have a small private sector and therefore businesses are still dependent on governments for sale of their products. Several researchers are in agreement with this as they purport that the relatively small economic size and small markets of many African countries poses a challenge for pharmaceutical manufacturing (Bank of Botswana, 2016; Onucha, 2013; UNDP, 2013; (World Health Organization (WHO), 2009, 2011b) (Fang, 2012)). The dimension of the consumer market is essential because profits can only be attained through economies of scale. Access to pharmaceutical manufacturing market is linked to the ability of the plant to adhere to international standards before any commencement of manufacturing. Respondents were satisfied with some of the policies governing pharmaceutical manufacturing in Botswana like Good Manufacturing Practices and Quality Management Systems requirements because they were comparable to international standards. Some respondents, however, were of the opinion that the manufacturing standards required were too high for start-up manufacturers in developing countries.

It could be helpful to customize international requirements to the capabilities and ability of the country. Requirements could be implemented stepwise so as to nurture small manufacturing enterprises until they become economically capable to meet the international standards. This was a topic of interest in a conference for Africa-Based Pharmaceuticals and other Malaria technologies Manufacturers hosted in Kenya. One of the outputs for the conference was to challenge African countries to re-consider pharmaceutical manufacturing requirements. International requirement including Good Manufacturing Practices and quality standards in some quarters were considered to be an economic barrier to local pharmaceutical manufacturing. There was a recommendation to consider a stepwise approach, reward and recognition of achievement in intermediate steps towards WHO

prequalification. WHO prequalified products are internationally recognized and can open markets for export (Boulton, 2011). Developing pharmaceuticals for the region could influence harmonizing and customizing GMP requirements for the region. Accreditation of pharmaceutical Industries was also reported to be conducted by external parties at a high cost for the manufacturers as there were no local registered entities to perform such.

Access to the pharmaceutical market is also directly linked to medicines registration. Delay in registration was seen as an impediment to market access and entry, as registration period was uncertain, and could take as long as three years to register a product from a local manufacturer, with no exemption or empowerment procedures for citizen companies. The advocacy was for local products to be given priority to hasten the registration period compared to waiting with international companies just for registration. No sales of medicines can be done within and outside Botswana before registration. The turn-around time for registration of medicines should be known. It was indicated that Botswana was amongst the SADC Countries which did not indicate their turnaround time for medicine registration (Kwanjanja, 2010). Malawi had an average registration period of 3 months for HIV//AIDS medicines whereas Tanzania had an average registration period of 18months. South Africa's average registration period was 18-36 months. The envisaged harmonization of medicine registration in the region could help reduce registration turnaround time. Registration of medicine is linked to participation in government tenders which are carried out every three years. A state of the art start up manufacturing firm in Botswana closed because it waited for three years to register medicines and ended up missing the three year tender with the government.

Local manufacturers are faced with competition from similar imported medicines from the cheap Asian market. In manufacturing for instance, production inputs which are mostly imported are charged high import tariffs and vat and this contributes to increase in

production costs which are also transferred to the final finished product price. This was stated in comparison to finished pharmaceutical imports which are not charged duty and the importers then enjoy low prices. The price of the finished pharmaceutical product does not include vat, and this has contributed to unrealistic prices which are unprofitable to the local manufacturer.

Pharmaceutical Manufacturers assert that there is no protection of infant industries by the government. Products which are manufactured in Botswana were in competition with cheaper imports from Asian countries. There was no closure of borders to protect locally produced pharmaceuticals. For some products which were produced locally the government was receiving donations of the same, e.g. condoms.

These observations were legitimate because the Pharmaceutical Manufactures Business Plan has rightly observed that in other developing countries, such as China and India where there are flourishing pharmaceutical sectors, the industry is reputed to benefit from a number of policy measures including protection through tariff regimes and procurement preferences as well as direct support such as interest subsidies, export credits, cheap utilities, working capital credits and tax holidays ((African Union, 2007); UNIDO, 2012).

Respondents observed that the Botswana Investment and Trade Centre was slow in implementing the policies of reducing import tariffs and removing VAT for pharmaceutical manufacturing inputs. Other African Countries like Ghana and Nigeria have benefitted from government protection of infant industries through import bans on products which were similar to those which were locally produced. (Wangwe et al., 2014). This has led to an increase in the number of investors in pharmaceutical manufacturing in these countries and sustainable profitable manufacturing firms. Although Botswana does close borders for other manufacturers like in Agriculture e.g. when Botswana produces enough tomatoes to meet the local demand for tomatoes, the country stops the importation of tomatoes to provide a

market for those locally produced. There is however, no evidence that the same has been accorded or will be accorded to pharmaceutical manufacturing firms considering that some manufacturers are able to meet the local demand, e.g. condoms.

In Algeria and Tunisia, once a locally manufactured generic is registered, the innovator is given two years in which to commence local production of the original branded product. This means that the originator of the product was initially importing their product into the country. Once a local manufacturer produced a similar product, the innovator was expected to start production of the product locally. Failure to do this, results in a ban on importation of the finished product and the market can then only be served through a local production of the generic product.

There is an observation that local generics manufacturing companies operate in a competitive intensive, low margin, commodity-type business, where profitability and long term viability depend on economies of scale, assured demand and large markets (Coleman, Sangrujee, Zhou, & Chu, 2005). The Zimbabwean government signed a contract with a local pharmaceutical manufacturing plant and committed to buying the locally produced goods. This contributed to profit and growth such that the manufacturer was able to enter the region as a move to increase economies of scale. Zimbabwean pharmaceutical companies by the early 2000s (prior to the onset of the economic downturn) were exporting pharmaceutical drugs to South Africa, Zambia, Namibia, Malawi, Tanzania, Burundi, Rwanda, Botswana, Democratic Republic of Congo, Mauritius, Kenya, Uganda and Mozambique (World Health Organization (WHO), 2011d). So it is possible for pharmaceutical manufacturing plants in Botswana to enter the regional market.

The Expert Committee of the PMPA has undertaken an analysis of the respective size of potential markets for locally produced medicines and has come up with estimations of countries grouping to create potentially viable markets. This should facilitate the

development of pharmaceutical production at regional level, based on geographic, economic, linguistic, and other criteria (African Union, 2007). Botswana is also supported by trade agreements like South African Development community (SADC) and South African Customs Union (SACU) which fosters free trade in the SADC region.

Some Researchers argue against reduction in tariffs and import bans, as they believe that this causes manufacturers to relax and compromise on quality of products produced. In addition to that, manufacturers may enjoy monopoly and increase prices for pharmaceuticals (Kaplan & Laing, 2005). Shaafaedin (2000), however, promoted what became known as the 'infant industry' argument, which laid the first analytical argument for industrial protection as we know it in the modern sense. The Researcher quotes Frederick List, who explained that a system of protection would not give rise to monopoly, but regarded it as a 'reward' to those who risk their capital and talent to the advancement of industrialization. The notion of protection as advanced by List was based on the objective of capturing future gains by means of 'present sacrifice' (Shafaeddin, 2000; (World Health Organization (WHO), 2011b)).

Access to the market is also linked to government procurement systems since government is the largest buyer. The government has sound procurement policies which are administered through Public Procurement and Asset Disposal Board (PPADB). The government bulk buying is done through public tendering and adjudicated through PPADB and Ministerial Tender Committees. Manufacturers submitted the three year contract system for provision of pharmaceuticals is not favourable to them if their business has to be continuous, profitable and sustainable. Any start-up firm has to wait for three years to have any meaningful business, which is unrealistic.

Respondents also perceived that there is corruption amongst the procurement entities like central Medical Stores where one questioned the awarding of fifty medicinal products to one tenderer who was not even a manufacturer.

Another bottle neck to the market is the unrealistic delivery-time from procuring entities. The government uses a point system to award points to a firm; short delivery period is amongst the requirement which can help a tender to earn favourable points. This practice is also in South Africa where it is still seen as an impediment to pharmaceutical manufacturing profitability and sustainability (Naude & Luiz, 2013). The delivery terms are critical in the awarding of the tender and tenderers can easily state unrealistic delivery terms just so that they can win the tender and then fail to supply. This was considered an unfair requirement where suppliers are clumped together with manufacturers, because manufacturing in bulk and at full capacity takes a period of about three months for a product to be ready for use. Good Manufacturing Practices (GMP) dictate batch manufacturing and continuous quality tests to be done to a manufactured product up to a period of three months before it can be released. On the other hand suppliers who import the same product could have access to a product that is readily available from different manufacturers, and therefore beats manufacturer's delivery times. Firms assert that there is unrealistic delivery terms set for manufacturers, and they are blacklisted when they do not deliver within a certain period. Even as way back as 1990, firms report that there was an expectation to deliver one year products in two months.

The respondents observed that there is inadequate knowledge regarding the processes of pharmaceutical manufacturing from procurement personnel.

5.2.2 Financial Policies

All respondents assert that the financial support offered by Botswana Government and other financial institutions in support and promotion of manufacturing has not been enjoyed by

the pharmaceutical manufacturing firms in Botswana. Although Botswana government prioritizes pharmaceutical manufacturing as an investment opportunity, none of the closed firms received any funding despite attempts to source such.

Botswana imports all of its pharmaceuticals from Europe, Asia and Americas and some neighbouring countries and all of its biomedical equipment is imported. Attempts have been made to attract foreign direct investment in the area of pharmaceutical manufacturing to no avail.

According to UNDP 2016 report, International pharmaceutical manufacturing firms were reluctant to invest in building manufacturing capacities and structures in India and preferred the reliance on imports to serve the market. The report further states that this is similar to the reluctance by multinational and Indian pharmaceutical companies to invest in Africa today. It was largely as the result of such reluctance, that the Indian Government decided not only to undertake such production in the public sector, but also to initiate several other steps with the specific objective of supporting the indigenous sector and developing the industry. These measures included changing India's national policy to restrict access of international companies to the market unless they set up pharmaceutical manufacturing plants within the country. This led to technological absorption and diffusion that otherwise may not have taken place. Another major initiative of the Indian Government was to set up a number of public sector research laboratories. These contributed significantly to the development of the industry by collaborating with the private sector. In addition to this, the state development financial institutions played a significant role: term loans were provided to entrepreneurs at low rates of interest, and no separate collateral was required – the facility itself as collateral was sufficient. Most of the Indian companies that are now global enterprises started as small-scale units (UNDP, 2016b). It is important to note that most African countries including Botswana do not have policy measures in place to pressure

foreign companies in establishing local manufacturing facilities. Profitable and sustainable pharmaceutical manufacturing companies that have been set up in other African countries like Ghana, Nigeria and Tanzania were in the form of public-private partnerships. Ghana set up public pharmaceutical manufacturing firms and put in place restrictions relating to payment of import duties and a restricted import list to protect infant industries (Wangwe et al., 2014).

Funds are required to expand the growth of manufacturing firms.

Competition with cheap Asian imports causes local companies to be unable to generate large enough profits to be adequately reinvested in the company. Thus, domestic sources of funding provide the only plausible solution. However, government financial institutions and commercial banks have not been supportive of pharmaceutical manufacturing as it is deemed to be a risky endeavour. A significant amount of capital is needed to set up GMP-compliant manufacturing facilities.

5.2.3. Skilled personnel

The use of unskilled personnel even at supervisory level was seen as an impediment to progress by most of the respondents. Skilled labour was imported in most of the plants. Companies which hired local pharmacists as production pharmacists experienced a lot of problems as the local pharmacists had no experience in pharmaceutical production and this contributed to delays in meeting the requirements for pharmaceutical manufacturing. There was a need for resources to implement continuous training in these plants.

It is disturbing to note that Botswana has had active government programmes to support SMEs since the 1970s, but none of these have reached the Small and Medium Enterprises to a significant degree, particularly the manufacturing SMMEs. One of the reasons could be that there are not many appropriate or affordable financial products and business development services (BDS) for micro-businesses, which form the majority of SMEs.

The *Government of Botswana* should give incentives to experienced foreign direct investment manufacturing firms and be flexible with labour laws, as manufacturing industry needs highly skilled labour, which is not readily available in the country. Therefore, manufacturing SMMEs should be allowed to import labour with less hassles on work permit applications. Failure by the government to formulate flexible labour laws results in manufacturers migrating to South Africa where there are better incentives; this can result in many people in Botswana losing their jobs.

5.2.4 Infrastructure

Infrastructure is one of the factors raised as a bigger challenge to pharmaceutical manufacturing in this study. Infrastructure is believed to affect many aspects of business performance. Unreliable water and electricity supplies, difficulties of transport in many African countries are believed to be constant difficulties that contribute to increasing the cost of local production of medicines. (Alam, 2017). Landlocked countries are believed to have high transport costs. The median landlocked country has only 30% of the trade volume of the median coastal economy. Halving transport costs increases the volume of trade by a factor of five and improving infrastructure from the 75^{th} to the 50^{th} percentile increases trade by 50 percent (Limao & Venables, 1999). Poor industrial infrastructure and services are believed to have led to high operating costs in Tanzania (Mhamba & Mbirigenda, 2010). Infrastructure is understood to be a critical factor in the health and wealth of a country, enabling private businesses and individuals to produce goods and services more efficiently. Infrastructure is believed to contribute to economic output, and also impact unemployment. Pharmaceutical manufacturing is a controlled process and the facility uses controlled environments like air, humidity and temperature. The Heating, Ventilation and Air Conditioning (HVAC) system has been identified as the major energy consumer. Production equipment also needs continuous electricity. Huge losses can be incurred from electrical

interruption e.g. in production of condoms, the latex rubber used cannot be reused if electricity that powers the instrument is interrupted. Back up electricity is not able to power pharmaceutical manufacturing plants. Botswana has had power outages which affect pharmaceutical manufacturing (Zhang, 2008).

5.3. Market Orientation and Firm Performance

It is evident that the closed pharmaceutical Manufacturing Firms did not adopt the market orientation concept. There were no plans for generating market intelligence and using the information to generate superior products that meet the needs of the customers. Market intelligence is supposed to be spread throughout the organization; it is not only the responsibility of the marketing department (Lara & Mesa, 2006). The firms did not have a marketing strategy or a marketing plan. These are firm internal capabilities which could have led to positive firm performance. Market oriented firms have shown to have superior competitive advantage (Schalk, 2008). This is supported by Akomeah who studied the application of the market orientation concept and firm performance in Ghana's pharmaceutical industry. The study revealed that management employed technocrats and business advisory consultants to generate customer needs and then draw marketing plans for them (Akomeah & Yeboah, 2011). Management would then avail resources to drive the market orientation concept through the organization. Adoption of the market orientation was seen to maximize the firm's profitability and created a sustainable competitive advantage over rivals on the market.

It has also been observed that small firms might deem it unnecessary to adopt the market orientation concept assuming it is more suitable to larger firms. This belief is unfortunate because today the world is becoming a global village; customers are more knowledgeable and demand value for their money. So businesses might turn their fortunes around if they know that the needs of their customers help them create products needed by the market and

develop the ability to provide relevant products to the chosen target market. Market oriented companies show sales growth, return on investment and profitability.

In conclusion the firms had all odds stacked against them, with little chance for success. It was not only a highly demanding policy environment which required firms to meet rather resource consuming standards for start-ups. Penetrating markets, especially where government remains the main consumer proved a serious hiccup, while low skilled manpower and generally failing infrastructure exacerbated the challenges. Lack of access to finance made operations seriously challenging. It is also clear that all firms that eventually closed did not purposely adopt a clear market orientation, leading to wrong strategies.

On the positive side local manufacturing companies had access to production inputs although they were sourced from international markets. Policies regarding imports were deemed to be supportive to the industry. Policies governing labour issues were regarded to be satisfactory as employees did not raise issues with their working conditions. Management was also of the opinion that Botswana labour laws were too protective of employees.

5.4 Recommendations

1. It was difficult to find any published information related to the current study, either with the ministry of Trade and Industry, Botswana Investment and Trade Centre or the Ministry of Health. The government of Botswana should have a repository for research projects on the business performance of manufacturing firms, conducted in Botswana, so that they may have baseline information about different sectors to tailor make policies which best suit them and this information should be available to partners, institutions and researchers. The World Health Organization conducts assessments periodically of the pharmaceutical situation in SADC, and Botswana information seems to be lacking (World Health Organization (WHO), 2011a)

2. The office of the president should require quarterly feedback on what has been implemented regarding support given to manufacturing firms from different sectors including pharmaceutical manufacturing firms. Respondents were of the opinion that there is inadequate implementation of local empowerment policies
3. The Botswana Qualifications Authority should liaise with pharmaceutical manufacturers, Academic Institutions, Botswana Health Professions Council Botswana Investment and Trade Centre and all other business support Institutions, together with the Health Hub regarding requirements for tertiary Institutions. This is meant to create a link between academic institutions and the Industry. In this case the pharmacist training that is starting at the University of Botswana and other institutions should produce graduates who can develop the pharmaceutical industry in the country (BMI, 2018).
4. Government should raise the academic and professional levels for procurement officers. Supplies officers at B Scales are more likely to be tempted and lured into corruption than professionals. It will also be easy to assimilate continuous training and skills development.
5. A one stop facilitating office should be availed at the Ministry of Health, where all the stakeholders can support the pharmaceutical manufacturing firms and industry.
6. Ministry of Health should make a commitment to buy pharmaceuticals which are manufactured locally and close borders for those products. This is how Nigeria and Ghana developed their pharmaceutical Manufacturing sector (Wangwe et al., 2014).
7. The government should implement the special economic zones which have long been envisioned. Special economic zones ensure proper infrastructure which ensures business continuity and reduce production costs.

8. Financial Institutions, government and private sector should commit to support pharmaceutical manufacturing in Botswana. Research conducted in manufacturing sectors within Botswana reflects this as a long standing problem. Other countries reflect that government commitment in public private partnerships with multinational companies was a spring-board for pharmaceutical manufacturing growth. (Anggraeni, 2014; Neba, 2012; Sekwati, 2011)
9. There should be correct and measureable coordination between academic institutions and industry to produce synergies regarding courses which are meant to support manufacturing. Pharmaceutical production is a technology intensive based activity which needs various professionals from engineers to chemists, pharmacists, artisans. (Rahim, Atan, & Kmaluddin, 2017; UNCTAD, 2011)
10. Government should review policies for charging VAT on pharmaceutical inputs or raw materials. Increasing tariff increases the cost production and increases the ultimate price for finished products.

5.5 Limitations of the study

This study sample was limited as participants were sought from closed firms, which meant some managers have relocated from Botswana, others might have passed away. The study could have been helped by information from the owners of the closed firms too. The scope of the study was limited to the firms only and time and additional resources were needed to question the allegations against government support structures like BDC, CMS, BITC and CEDA**.**

5.6 Implication of the study to theory and practice.

Government is slow in implementing its policies for SMEs. There is perceived corruption in government procurement entities which need to be rooted out. Academic Institutions should not be concerned with producing numbers, but skilled personnel who can drive the

pharmaceutical industry. There should be vetting of Academic Institutions. Government Loans should be accorded for economic development, not in support of friendship or party partisanship. Support institutions should be led by able people who understand the need of the manufacturing industry and desire to turn around the fortunes of the industry.

5.7. Directions for future Research

This study had a limited scope but provided baseline information conducted by a local pharmacist. The project was done with limited resources and limited time. The scope of the study could be broadened to include information from institutional structures.

5.8. Conclusion

Pharmaceutical manufacturing can contribute to the economic development of Botswana and provide the much needed employment. Botswana government has the ability to support local manufacturing firms; there is need for implementation of policies.

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Appendices

Appendix A: Questionnaire……..97

Appendix B: Consent Form…….……...102

Appendix C: Ethical Approval……...105

Appendix D: Research Permit……106

APPENDIX A: QUESTIONNAIRE

Faculty of Business

Survey Questionnaire; Barriers to Establishing Profitable and Sustainable Pharmaceutical Manufacturing Firms in Botswana

PURPOSE

You are being asked to kindly participate in this research study to determine barriers to establishing profitable and sustainable pharmaceutical manufacturing firms in Botswana. The aim of this study is to find out factors that contribute to the closure of pharmaceutical manufacturing firms in Botswana. The findings of this study will inform policies in good manufacturing practices, import tariffs, tertiary curriculum and research in relation to the manufacturing sector in Botswana. Hoping that a change in policies will create a positive environment for profitable and sustainable pharmaceutical manufacturing, which will improve access to medicines and reduce unemployment in the country.

Your participation in this study is voluntary and should you wish not to continue with this survey you are free to do so. Please ask any questions on any aspect of this study that is unclear to you. This study is undertaken by a student as a requirement for a partial fulfilment of an MBA programme. This questionnaire will take 10-15 minutes

CONFIDENTIALITY

The data from this investigation will be used purely for the purpose of the study and no information will be linked to you in anyway. Your name will not appear anywhere in the questionnaire or the report that will be produced from this study. The information gathered will not be used for commercial purposes

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research participant; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the researcher, please feel free to contact the Faculty of Business, University of Botswana, Phone: Dry T.I. Magang on 355-5023, E-mail: magangti@mopipi.ub.bw

Socio Demographic Characteristics

How long did you work for the company and what was your job title?

_____

Sex Male Female

Age Categories

20-29 _____ 30-39 _____ 40-49 _____

50-59 _____ 60-69 _____ 70 - 79 _____

80-89 _____ 90-99 _____

Background of the Firm

Which year did the Pharmaceutical Manufacturing Plant start operating? _____

How many people were employed by the Firm? _____

Who owned the Firm?

100% citizen owned firm (iii) More than 51% citizen owned

Less than 51% citizen owned (iv) Multinational Firm

Was the Firm owner managed? _____

What was the annual turnover? _____

When was the Firm closed? _____

Scope of Activity

Which products were you manufacturing?

Brand Medicine (iii) Medical Devices

Generic Medicines (iv) Cosmetics

What type of Manufacturing were you engaged in?

Primary? Secondary? Tertiary

Business Operation

(Rate the extent to which the following were a challenge to your Firm.) Using a scale of 1 – 10, 1 being the least and 10 being the greatest challenge. Indicate by circling your rate

Management

1 2 3 4 5 6 7 8 9 10

Employee Satisfaction

1 2 3 4 5 6 7 8 9 10

Legislation and Policies

1 2 3 4 5 6 7 8 9 10

Supply of production inputs

1 2 3 4 5 6 7 8 9 10

Market

1 2 3 4 5 6 7 8 9 10

Infrastructure

1 2 3 4 5 6 7 8 9 10

Skilled Personnel for Pharmaceutical Manufacturing

1 2 3 4 5 6 7 8 9 10

Meeting international standards for quality

1 2 3 4 5 6 7 8 9 10

Maintaining equipment

1 2 3 4 5 6 7 8 9 10

Using the NIH competency scale below how would you rate the skills of employees from your firm?

Proficiency Level Fundamental awareness (basic knowledge) Novice (limited experience) Intermediate (practical application) Advanced (applied theory) Expert (recognized authority)

Score 1 2 3 4 5

Legislation and Policies

How would you describe the Botswana environment in terms of business support?

_____
_____

Do you think the Botswana environment was supportive to your business?

_____
_____
_____

Do you think taxes and duties structure reduced the cost of production compared to importing finished products?

_____
_____

What is your opinion about policies regulating medicines in Botswana?

_____
_____

Were your products quality certified?

_____
_____

Was your Firm GMP accredited?

_____
_____

Sales

Were you able to meet the local demand for your product, If No please explain.

_____
_____

In your opinion how did local procuring agencies/employees perceive locally produced medicines?

_____
_____

What was your annual turnover from government procurement?

_____
_____

Did you ever sell outside Botswana? If not what was the problem with supplying outside Botswana?

_____
_____

Did your Organization have a budget for marketing?

_____
_____

What proportion of your budget was dedicated for marketing?

_____
_____

Infrastructure and Capacity

(a) Was the provision of electricity sufficient and regular to your firm?

_____
_____

Was the provision of water to your organization sufficient?

_____
_____

Did your organization adopt the latest technology in manufacturing?

_____
_____

What was your capacity like? Did you manage to meet demand?
_____
_____

Inputs for manufacturing

Where were you sourcing your inputs for production from?

_____
_____

Did you experience any delivery problems?

_____
_____

What is the value of supplies that were received as a donation? (MOH)

_____
_____

Given a second chance to re-open what are the conditions you would like to see?

_____
_____

What environment do you think pharmaceutical businesses will thrive under?

_____
_____

Do you have anything else to say?

_____
_____

APPENDIX B: CONSENT FORM

Faculty of Business

INFORMED CONSENT FORM

PROJECT TITLE: BARRIERS TO ESTABLISHING PROFITABLE AND SUSTAINABLEPHARMACEUTICAL MANUFACTURING

FIRMS IN BOTSWANA

Principal Investigator: Bohutsana Molefi (MBA Candidate)

Phone number(s): 3163280// 72787312

What you should know about this research study:

- We give you this informed consent document so that you may read about the purpose, risks, and benefits of this research study.
- You have the right to refuse to take part, or agree to take part now and change your mind later.
- Please review this consent form carefully. Ask any questions before you make a decision.
- Your participation is voluntary.

PURPOSE

You are being asked to kindly participate in this research study to determine barriers to establishing profitable and sustainable pharmaceutical manufacturing firms in Botswana. The aim of this study is to find out factors that contribute to the closure of pharmaceutical manufacturing firms in Botswana. The findings of this study will inform policies in good manufacturing practices, import tariffs, tertiary curriculum and research in relation to the manufacturing sector in Botswana. Hoping that a change in policies will create a positive environment for profitable and sustainable pharmaceutical manufacturing which will improve access to medicines and reduce unemployment in the country.

. You were selected as a possible participant in this study because you have worked for a closed pharmaceutical manufacturing firm. Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.

PROCEDURES AND DURATION

If you decide to participate, you will be invited to answer questions related to the pharmaceutical firm which you worked for. A questionnaire will be sent to you, and a

subsequent interview may be held with you where clarity is needed. Filling the questionnaire may take you 12 minutes while interviews may last for 20 minutes.

RISKS AND DISCOMFORTS

The interview may cause emotional discomfort if interviewees feel they are disclosing confidential information.

BENEFITS AND/OR COMPENSATION

Your participation in this study does not attract any form of compensation. However, your participation will contribute in increasing knowledge on the conditions under which pharmaceutical manufacturing firms operate and your information may influence policy makers to improve conditions for the current and potential pharmaceutical manufacturing firms to make them sustainable.

CONFIDENTIALITY

The data from this investigation will be used solely for the purpose of this research and utmost care will be taken to protect this information. Identification numbers will be allocated to a participant and your name will not appear anywhere in the results. None of this information will be used for commercial purposes.

VOLUNTARY PARTICIPATION

Participation in this study is voluntary. If you decide not to participate in this study, your decision will not affect your future relations with the University of Botswana, its personnel, and associated institutions. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without penalty. Any refusal to observe and meet appointments agreed upon with the central investigator will be considered as implicit withdrawal and therefore will terminate the subject's participation in the investigation without his/her prior request. In the event of incapacity to fulfill the duties agreed upon the subject's participation to this investigation will be terminated without his/her consent.

AUTHORIZATION

You are making a decision whether or not to participate in this study. Your signature indicates that you have read and understood the information provided above, have had all your questions answered, and have decided to participate.

Name of Research Participant (please print) Date

_____ _____

Signature of Staff Obtaining Consent Date

(Optional)

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research participant; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of The Faculty of Business, University of Botswana, Phone: Dry T.I. Magang on 355-5023, E-mail: magangti@mopipi.ub.bw.

UNIVERSITY of BOTSWANA

Office of the Deputy Vice Chancellor (Academic Affairs)

Office of Research and Development

Corner of Notwane and Mobuto Road, Gaborone, Botswana

Pvt Bag 00708 Gaborone Botswana

Tel: [267] 355 2900
Fax: [267] 395 7573
E-mail: research@mopipi.ub.bw

Ref: UBR/RES/IRB/SOC/GRAD/095

29th January 2018

The Permanent Secretary
Ministry of Health and Wellness
Private Bag 0038
Gaborone, Botswana

RE: REQUEST FOR EXPEDITED REVIEW OF A RESEARCH PROPOSAL SUBMITTED BY MS BOHUTSANA MOLEFI.

Since it is a requirement that everyone undertaking research in Botswana should obtain a Research Permit from the relevant arm of Government, The Office of Research and Development at the University of Botswana has been tasked with the responsibility of overseeing research at UB including facilitating the issuance of Research permits for all UB Researchers inclusive of students and staff.

I am writing this letter in support of an application for a research permit by Ms Bohutsana Molefi, a master's student from Department Business Management at the University of Botswana. Ms Molefi has proposed to conduct a study titled **"Barriers to Establishing Profitable and Sustainable Pharmaceutical Manufacturing Firms in Botswana".** The overall objective of the proposed study is to establish whether the failure to establish profitable pharmaceutical manufacturing in Botswana is due to an unsupportive business environment or just business failure on the part of pharmaceutical firms. From the study findings, it is hope that the national health policy's aim may be to improve the supply of medicines, increase the quality of medicines, to lower prices of needed medicines and to produce traditional medicines.

The Office of Research and Development is satisfied with the process for data collection, analysis and the intended utilisation of findings from this research. We will appreciate your kind and timely consideration of this application.

We thank you for your [illegible] cooperation and assistance

Sincerely,

UNIVERSITY OF BOTSWANA Office of Research & Development 2018 -01- 29 P/BAG UB 00708 GABORONE TEL: +267 3552900 FAX: +267 3957573 research@mopipi.ub.bw

Dr. M. Kasule
Assistant Director Research Ethics Office of Research and Development

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REPUBLIC OF BOTSWANA

MINISTRY OF HEALTH AND WELLNESS

REFERENCE NO: HPDME: 13/18/1 **7th February 2018**

Health Research and Development Division

Ms Bohutsana Molefi
University of Botswana
Private Bag 00708
Gaborone

Dear Ms Bohutsana Molefi

PERMIT: **BARRIERS TO ESTABLISHING PROFITABLE AND SUSTAINABLE PHARMACEUTICAL MANUFACTURING FIRMS IN BOTSWANA**

Your application for a research permit for the above stated research protocol refers. We note that your proposal has been reviewed and approved by University of Botswana Review Board.

Permission is therefore granted to conduct the above mentioned study. This approval is valid for a period of 1 year effective 7th February 2018.

This permit does not however give you authority to collect data from the selected site(s) without prior approval from the management. Consent from the identified individuals should be obtained at all times.

The research should be conducted as outlined in the approved proposal. Any changes to the approved proposal must be submitted to the Health Research and Development Division in the Ministry of Health and Wellness for consideration and approval.

Furthermore, you are requested to submit at least one hardcopy and an electronic copy of the report to the Health Research, Ministry of Health Wellness within 3 months of completion of the study. Approval is for academic fulfillment only. Copies should also be submitted to all other relevant authorities.

Thank you for your cooperation and your commitment to the protection of human subjects in research.

Yours faithfully

Ms S. Mosweunyane
for /PERMANENT SECRETARY

MINISTRY OF HEALTH RESEARCH DIVISION
2018 -02- 07
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Encls: Completed Application for Research Permit
Research Proposal
Informed Consent document
Data collection tools
Comments from UB/IRB