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AN ANALYSIS OF FACTORS AFFECTING SUSTAINABLE GROWTH OF LOCAL PHARMACEUTICAL MANUFACTURING COMPANIES IN KENYA

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Submitted in partial fulfilment of the requirements for the Degree of Master of Business Administration at Strathmore University

Strathmore Business School,

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Nairobi, Kenya

June, 2018

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I declare that this work has not been previously submitted and approved for the award of a degree by this or any other University. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made in the thesis itself.

Douglas Weru

June 2018

Approval

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ABSTRACT

The purpose of the study was to analyze the factors affecting sustainable growth of local pharmaceutical manufacturing companies by determining and establishing their influence on sustainable growth of these firms in Kenya. The review of related literature identified these factors as competition, government regulations, international regulations and the cost of production. The study adopted a cross sectional research design and targeted 32 local firms registered with the Pharmacy Poisons Board in 2016. Data was collected using a questionnaire and analyzed using descriptive and inferential statistics. Pearson's correlation and regression analysis were used to test the influence of predictor variables on the dependent variable. We found that there has been increase in the number of employees in the firms since their inception (median of 6-10) to date (median 41-50) signifying growth. The study established that competition in the sector had positive effects on the growth of the local pharmaceutical manufacturers. Government regulations also favoured growth of the firms. This could be attributed to government policies aimed at enhancing growth in the sector. The study concludes that the international regulations have benefited the local firms even though they seem to favour multinationals. Further, the study concludes that the cost of production in Kenya, largely driven by cost of raw materials, energy, labour, machinery and taxes had a significant negative influence on the growth of these firms. The study recommends that government encourages competition in the sector to enhancing quality and promote use of competitive strategies thus facilitating growth. The government should introduce more policies and regulations that encourage the growth in the sector. The local pharmaceutical manufacturers should strive to adhere to international regulations inorder to access international markets for their products. Lastly government should review sector specific tariffs, lower the cost of energy, promote labour environment that responds to sustainable growth needs of local pharmaceutical manufacturers. The study was limited to the extent that it excluded the role of management and corporate culture in influencing sustainable growth of the firms.

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LIST OF ACRONYMS AND ABBREVIATION

COMESA: Common Market for Eastern and Southern Africa

FDA: Food and Drug Administration

GDP: Gross Domestic Product

HIV/AIDS: Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome

IBM: International Business Machine Corporation

ICT: Information and Communication Technology

MNC: Multi-National Corporations

NCE: New chemical entity

OECD: Organization for Economic Co-operation and Development

OTC: Over the Counter

R&D: Research and Development

SME: Small and Medium-size Enterprises

TB: Tuberculosis

UNIDO: United Nations Industrial Development Organization

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OPERATIONAL DEFINITION OF TERMS

External environmental factors: Refers to all the outside factors or influences that impact the operation of a company.

Internal environmental factors: Refers to the elements within the organization, including current employees, management, and especially corporate culture that impact the operations and growth of the company.

Growth Growth is process of increasing in physical size. In terms of firm, growth is capability to increase annual revenues by more the industry average over a sustained period. Enterprise growth is the development process that enterprises keep the tendencies of balanced and stable growth of total performance level (including output, sales volume, profit and gross assets) or keeps realizing the large enhancement of total performance and the stage spanning of development quality and level

Sustainable growth Refers to the maximum rate of growth that a firm can sustain without having to increase financial leverage or look for outside financing.

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ACKNOWLEDGEMENT

This journey of contribution to the body of knowledge would not have been possible without the support I received from my family. Thank you for walking with me through the days and nights and for editing my final work. My supervisor, Dr. John Mahasi, thank you for the intellectual discussions, the challenge and guidance. Colleagues in the Pharmaceutical industry, the Federation of Kenya Pharmaceutical manufacturers and the Kenya Association of Pharmaceutical Industry. Your interactions made it worth while and eased my research process.

Finally to the giver of life, I thank God for wealth and good health.

DEDICATION

This work is dedicated to Pam, my friend and spouse, for all the invaluable critique and mentorship. Thank you. To Sam and Kay for love, life and purpose.

Nothing good comes out of comfort.

CHAPTER ONE
INTRODUCTION

1.1 Background to the Study

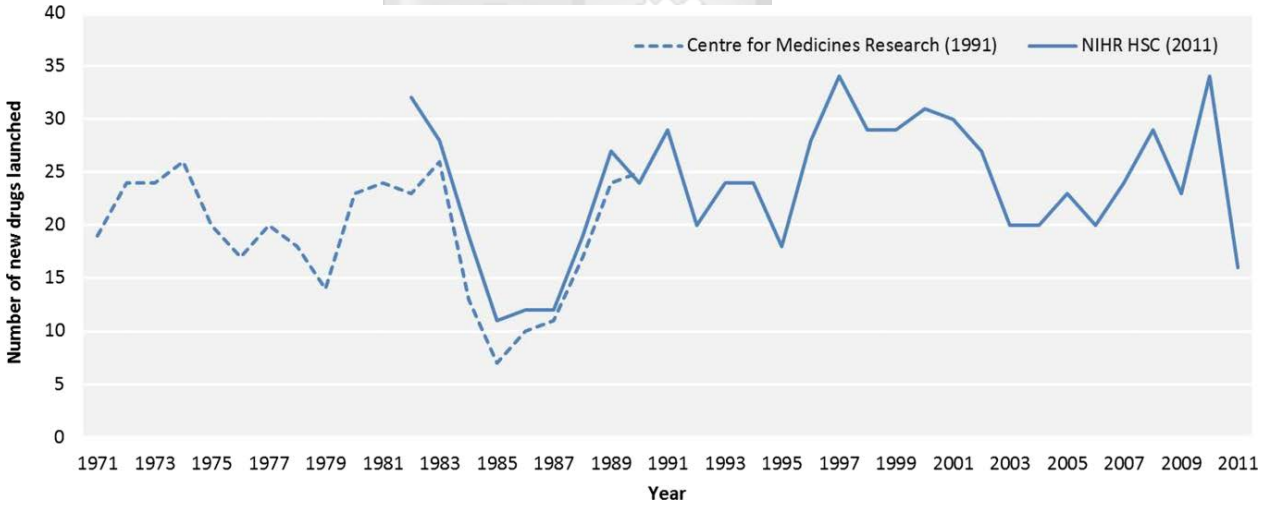
The pharmaceutical industry in Kenya like in the rest of the world is experiencing the same phenomenon that many other industries have faced in the past. Many companies have been forced to try and reinvent themselves in the face of challenges in their business environment which has had effect on their growth (Banes, 2010). It happened with the computer industry for example, International Business Machine Corporation (IBM) moving to a service model, the steel industry (outsourcing and diversification) and more recently, the technology sector with the bursting of the dotcom bubble.

One thing has become clear, only the companies that are willing to change or modify their strategies and follow that with excellent execution of these strategies will have long term success and sustainable growth (Mateev & Anastasov, 2010). For instance, in the recent past, big pharmaceuticals have resorted to strategies aimed at ensuring their survival due to the turbulent business environment. A case in point is the Pfizer buyout of Wyeth and Roche's acquisition of Genentech (Yeung, 2016). Others have pursued the path of diversification as is the case with Johnson and Johnson, Novartis or Abbot that have significant business activities outside of the traditional pharmaceutical arena engaging in areas such as consumer products, healthcare services, medical devices and medical diagnostics. Yet other companies have taken the path of focusing on the 'Emerging Markets' that are in some ways considered largely untapped potential like AstraZeneca and GlaxoSmithKline's focus on China and India respectively (Munene, 2016).

Despite increasing pharmaceutical research and development (R&D) times, costs and spending there are concerns that these increasing efforts are not being reflected in the numbers of new drugs being brought to the market (Yeung, 2016). Indeed, it is widely reported that there has been a decline in the rate of development of new drugs over recent decades (Scannell, Blanckley, & Boldon, 2012; Yeung, 2016).

Within the context of drugs, development, a new innovation is generally defined as the discovery, development and bringing to the market of a new chemical entity (NCE) 'an active ingredient that has never been previously in the market in any form'. These new entities may be relatively minor modifications of existing drugs or represent radical new breakthroughs. A plot of the IMS data (Figure 1.1) shows a decline in the NCE launches from 33 in 2009 down to approximately 16 by the end of 2011 lowest level ever since 1985. This phenomenon has not been restricted to just a few therapeutic areas or companies and is compounded by the fact that the value of the launches that have occurred are significantly less than in the years when blockbusters drugs provided significant increase in revenue.

Figure 1.1: Launch of New Chemical Entity



The local pharmaceutical manufacturing industry plays an important role of manufacturing of essential generic medicines from both a health and an economic development perspective. However, presently the industry is experiencing the same challenges that many other industries have faced in the past where many companies have been forced to try and reinvent themselves in the face of challenges in their business environment (Kinoti & Njeru, 2013).

There has been a general decline in the growth of the industry with some industry players winding up their operations and others doing something else totally different from their line of operation.

Traditionally, the healthcare industry specifically, life science sectors including pharmaceutical, biotech, and medical devices has been less exposed to fluctuations in the economy for a couple of reasons. Healthcare demand is less sensitive to economic trends, and there is no price elasticity in times of crisis, at least in European social welfare economies, which account for 35 percent of the global market. People continue to become ill and still need treatment, irrespective of global economic forces. Moreover, in times of crisis, people may be even more susceptible to stress and depression-related illnesses or diseases (Owuoth, 2010).

While the overall outlook for the pharmaceutical industry remains fairly strong, some dark clouds loom in the horizon. The growth of pharmaceutical manufacturing companies in developing countries and in the sub Saharan Africa in particular has been on the decline since the global economic crisis of 2009 (Mackintosh et al, 2016). Specifically, the smaller pharmaceutical niche players that do not yet have stable cash flows from products are experiencing difficulties with regard to their growth (Kariithi & Kihara, 2017). These companies are exposed to the challenges of globalization, dumping among others. Some of these companies are either contemplating diversification, or changing the line of business and some contemplating total shutdown. This study sought to determine the factors affecting sustainable growth of local manufacturing pharmaceutical companies in Kenya

1.1.1 Factors Affecting Growth of Pharmaceutical Companies

The reason for the decline in the growth of the pharmaceutical companies has been attributed to many factors. These include increased scrutiny and higher safety standards dictated by the Food and Drug Administration authorities, broad portfolio of early stage therapeutic products being looked at but with not much success in creating novel medicines in the vast majority of the areas, despite advances in technology and processes (Baines, 2010).

Generic drugs have always been a big challenge for the established big pharmaceutical companies which spend many years and millions of dollars from discovery to product launch, yet generic companies are able to take advantage of the hard work and investments of big R&D based Pharmaceutical forms to make generic drugs which are far much cheaper and in most cases very effective alternatives thus undercutting their profits once their patent rights expire (Ward, Martino, Simpson & Stevens, 2013).

The recent economic downturn has had an effect on the small pharmaceutical companies as most are experiencing difficulties as credit dries up. As such these companies are tackling their funding problems by reducing high cash-burn rates through radical cost cutting and aggressive working capital management which in the long run have effect on their growth. A large share of these companies unless well-funded will not survive this crisis and many will be bought by large pharmaceutical companies (Dechezleprêtre and Misato Sato, 2014). The governments and other international donor agencies such as the World Health Organizations (WHO) who are the largest spenders in the pharmaceuticals have cut their budgets on the pharmaceuticals thereby reducing the revenues of these firms (Behner, Vallerien, Ehrhardt & Rollmann, 2009). The less disposable income for customers have made the generic option more attractive to payers, insurance companies and consumers concerned with managing their costs. As a result, the generic drug makers have been making inroads in the product sales of the branded products. These factors largely influence the growth of the pharmaceutical companies (Baines, 2010).

The international regulation and lobby groups have also impacted on the manufacturing of pharmaceutical products. For instance, the concerns about global warming (the effects of manufacturing plants on the environment), animal rights groups (resistance to testing in animals) and many other groups. These groups often have not only the monetary resources but also the political connections that can make it very difficult for pharmaceutical companies to operate to their full potential in many countries and markets (Baines, 2010). Economists traditionally think environmental regulations add costs to companies and slow down productivity.

Environmental regulations may thus affect the competitiveness of the domestic industry if the stringency of policies differs across countries, putting some firms at a disadvantage to their foreign competitors (Dechezleprêtre and Misato Sato, 2014).

The pharmaceutical industry in Kenya has been going through heightened competition both locally and internationally especially from companies manufacturing generic products which have forced the prices for the products be below the production costs (Munene, 2016). The existing regulatory framework has also made it hard for pharmaceutical companies to compete favorably as they are unable to engage in traditional marketing activities of their products. The cost of production in Kenya has been a subject for debate. Kenyan manufacturers are not protected from unfair competition and besides the raw materials used in production of drugs are predominantly imported. High importation duties and the high cost of electricity among others, has led to a high cost of production. These have pushed the prices for locally manufactured products up rendering them uncompetitive in the wake of the available cheap generic drugs (Owuoth, 2010).

1.1.2 Kenya Pharmaceutical Industry Overview

The pharmaceutical industry in Kenya consists of three segments namely the manufacturers, distributors and retailers. The industry plays a major role in supporting the country's health sector, estimated to have about 4,557 health facilities countrywide. Pharmacy and Poisons Board regulates the industry. Kenya is currently the largest producer of pharmaceutical products in the Common Market for Eastern and Southern Africa (COMESA) region, supplying about 50% of the regions' market (Wilson, 2012). Out of the region's estimated 50 recognized pharmaceutical manufacturers; 32 are based in Kenya. The Kenyan market for pharmaceuticals reached US$ 558.5 million in 2016 where the total turnover for the local production hit US$ 803 million (WHO, 2016). The value addition from the pharmaceutical sector generates around US$ 62 million and amounts to 30 per cent of the Gross Domestic Product (GDP)

It is approximated that about 9,000 pharmaceutical products were registered for sale in Kenya Medical Directory, 2011 and over 16,000 with the Pharmacy and Poisons Board by 2015. These are categorized according to particular levels of outlet as general sales/OTC (Over the Counter), pharmacy only medicines, Prescription/ Pharmacist only medicines. The pharmaceutical sector consists of about 32 licensed firms which include local manufacturing companies and subsidiaries of large Multi-National Corporations (MNCs). Most are located within Nairobi and its environs. These firms collectively employ over 2,000 people, about 65% of who work in direct production. The industry compounds and packs medicinal products. Others repack formulated drugs and processes bulk drugs into unit dose packs using predominantly imported active ingredients and excipients. The bulk of locally manufactured preparations are non-sterile, nonprescription, over the counter (OTC) products (Munene, 2016).

1.2 Statement of the Problem

Many Manufacturing firms including pharmaceutical companies have relocated or restructured their operations opting to serve the local market through importing from low-cost manufacturing areas such as Egypt, South Africa and India therefore resulting in job losses (Nyabiage & Kapchanga, 2014). This is an indication that many manufacturing firms in Kenya are experiencing growth challenges with many reporting profit warnings due to challenges in the operating environment. Statistics from World Bank show that manufacturing companies in Kenya including the pharmaceuticals operating in Kenya registered stagnation and declining profits for the last five years due to a turbulent operating environment. Manufacturing sector in Kenya and pharmaceutical industry in particular contributed barely 13.6 per cent to the GDP in the year 2016 representing a 3.3 growth indicating a decline from the previous year 2015 where it had reported a 5.6 per cent growth (KNBS, 2016).

There are 32 local pharmaceutical manufacturing industries actively manufacturing generic drugs for local and export market. Despite this, the country still relies heavily on imported drugs to service the public health needs.

In 2015, the country imported $809 million worth of drugs. In the same year, donor communities spent an additional $693 million to purchase drugs for pandemic diseases including malaria, tuberculosis and HIV (WHO, 2016). The local pharmaceutical industries only managed to access 30% government and private sector spending in the pharmaceutical market and almost none from the donor communities. The foreign pharmaceutical companies are only utilizing 80 per cent of their capacity while the local firms can only manage 65 per cent of their production capacity. This is despite the fact that there exists a huge demand for pharmaceutical products in the COMESA region with Kenya only supplying 50% (Kenya Association of Manufacturers, 2013; Karuhanga, 2013). The underutilization of their production capacity means that these firms are not operating optimally and as such may not be meeting their operational costs, hence making losses. This study sought to investigate the factors affecting sustainable growth of local pharmaceutical manufacturing companies in Kenya.

Several studies have been done in Kenya on the growth of pharmaceutical companies. For instance, Ngigi, (2012) did a study on the constraints to growth of SME retail pharmaceutical enterprises in Kenya where he found that growth was influenced by entrepreneurs' demographic factors, finance, and socio-economic factors among others. Another study by Ali (2014) on corporate brand equity and firm performance in pharmaceutical industry in Kenya found that corporate reputation, firms' competitiveness, value chain activities and allocation of resources influenced organizational performance. Murule (2011) did a study on the strategic response by pharmaceutical manufacturing industry in Kenya where he found the local pharmaceutical manufacturing firms to have adopted strategies as pricing, marketing, strategic alliance and ICT. While these studies are beneficial to the researcher, none of the studies was done on the factors affecting sustainable growth of local pharmaceutical industries in Kenya, hence a knowledge gap. It was therefore this gap that the researcher sought to fill.

1.3 Objective of the Study

To determine the factors affecting sustainable growth of local pharmaceutical manufacturing companies in Kenya.

1.3.1 Specific Objectives

1. To establish the various internal and external environmental factors that affect sustainable growth of local pharmaceutical manufacturing companies in Kenya
2. To analyze the influence of these factors on the sustainable growth of local pharmaceutical manufacturing companies in Kenya

1.4 Research Questions

1. What are the various internal and external environmental factors that affect growth of pharmaceutical industries in Kenya
2. To what extent have these factors influenced sustainable growth of local manufacturing pharmaceutical companies in Kenya

1.5 Significance of the Study

This study will be beneficial to the following:

The government and policy makers in particular may gain understanding of the factors that influence sustainable growth of local pharmaceutical manufacturing companies and may therefore develop informed policies that would enhance their growth

It will assist the management of local pharmaceutical manufacturers to identify the factors hindering or promoting sustainable growth of their firms in Kenya. This may help them to design proper ways of managing threats or harnessing positive drivers so as to maximize on their productivity and profits.

The study is expected to increase the pool of knowledge by providing information on factors affecting sustainable growth of local pharmaceutical manufacturers in Kenya. Further it highlights the unresolved issues on the relationship between sustainable growth and the independent factors that require further research.

1.6 Scope of the Study

The study targeted a population of 32 local pharmaceutical industries in Kenya whose headquarters are in Nairobi.

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CHAPTER TWO
LITERATURE REVIEW

2.1 Introduction

In this chapter, we reviewed the literature that is related to the study objectives. The chapter is structured as followers: theoretical framework, competition, cost of production, international regulations and the conceptual framework.

2.2 Theoretical Framework

The study is anchored on the transaction cost theory and theory of the growth of the firm.

2.2.1 Transaction Cost Economics Theory

Transaction cost economics theory tries to explain why companies exist, and why companies expand or source out activities to the external environment. The transaction cost theory supposes that companies try to minimize the costs of exchanging resources with the environment, and that companies try to minimize the bureaucratic costs of exchanges within the company. Companies are therefore weighing the costs of exchanging resources with the environment, against the bureaucratic costs of performing activities in-house. Coase (1937) set out his transaction cost theory of the firm in 1937, making it one of the first (neo-classical) attempts to define the firm theoretically in relation to the market. A firm's interactions with the market may not be under its control (for instance because of sales taxes), but its internal allocation of resources is within a firm, market transactions are eliminated and in place of the complicated market structure with exchange transactions is substituted the entrepreneur who directs production. Transaction cost theory concentrates on the relative efficiency of different exchange processes (Tirole, 1988).

Transaction costs economics theory is frequently viewed as a subset of new institutional economics. The new trend in transaction costs is to describe firms from a new perspective based on organizational terms, as governance structures, not in neoclassical terms, as production functions.

Evidence has shown that the performance of firms which take into consideration transaction costs is better than the performance of firms which do not consider them (Macher & Richman, 2008). Furthermore, it was found that companies that follow the basic transaction costs hypothesis, (i.e. having high costs of finding and negotiating with partners), tend to use a higher degree of control (Brouthers, 2002). In addition, transaction-costs economics has recognized that the productivity of a value chain is a function of both production costs and transaction costs, and that, moreover, transaction costs are significant and have a major impact on economic efficiency Dyer & Chu, 2003). From a global sourcing perspective companies get their intermediate products from outside suppliers if the transaction costs of external purchases are lower than domestic ones. In other words, transaction costs determine the governance structure of a supply chain (Bremen, et al., 2010).

In the light of globalization, firms have to decide whether to follow a domestic or a global source to supply their needs. Furthermore, firms must consider the costs of negotiating and concluding contracts for each transaction (Coase, 1937). Those costs cannot be eliminated, but the firm can reduce them by making one contract for a longer period instead of many shorter contacts. The firm is treated as an avoider of transaction costs, i.e. of negative costs (Hardt, 2009). Williamson refers to human actors as positive transaction costs and in pragmatic methodology all of them play key roles in the transaction costs treatment of inter firm contracting (Williamson, 2008). In addition, there are vertical integration consequences, i.e. the replacement of the costs of buying and selling on the market by the costs of intra-firm transfers; the existence of vertical integration may suggest that the costs of operating competitive markets are not zero (Williamson, 2008). The idea of zero transaction costs is a fiction (Coase, 1937). Economic approaches to the study of organization and transaction costs focus on efficiency (Williamson, 2008). Therefore, the transaction costs approach is applied at three levels of analysis: first, the firm-wide level (this takes into consideration all operational activities which are related to each other), secondly, operational level, which determines activities will be done inside and outside the firm. Thirdly, human capital organizing approaches (creating harmony between interior structures and work groups).

This theory is relevant to this study as it relates to how cost implication is very important in the production system of a firm. The cost is in terms of the cost of doing business such as the taxes, electricity, raw materials among others which have a direct influence of the firms operations and eventual growth.

2.2.2 Theory of Growth of Firm

The theory of the growth of the firm advocated by Edith Penrose (1959) defines a firm as a collection of (productive) physical and human resources. According to Penrose, there is no limit to the growth of firms, it is the rate of growth that is limited in the short run but there is no limit to the size of the firm (Penrose, 1959). Growth is an administrative planning unit, the activities of which are interrelated and is coordinated by policies which are framed in the light of their effect on the enterprise as a whole. Growth in any period is nonetheless limited by the amount of available managerial attention. Managers who spend too much time focusing on the firm's expansion divert their attention from operating efficiency. This model of the firm has a central managerial discretion responsible for general policies (Penrose, 1959).

In neoclassical economic theory, cost for producing one more product is equivalent to the product price. This makes the marginal utility of the product equal to the marginal costs. In the long term within a market with free competition the optimal size of farm unit is obtained once the farmer reaches the lowest average cost for the product. The productive activities of the firm are governed by the productive opportunities as seen by the entrepreneur. The growth gets limited by the fact that the firm doesn't see opportunities for expansion, is unwilling to act upon them, or is unable to respond to them (Penrose, 1959). For a firm, the decision to search for opportunities is an enterprising decision requiring entrepreneurial intuition and imagination, and must precede the economic decision to go ahead with the examination of opportunities for expansion. Hence, the managerial competence of a firm is to a large extent a function of the quality of the entrepreneurial services available to it.

Another key concept in Penrose's theory of firm growth is that firms are composed of idiosyncratic configurations of 'resources'. These resources can play a role in ensuring durable competitive advantage if they are valuable, rare, inimitable and non-substitutable (Dierickx & Cool 1989; Eisenhardt & Martin, 2000). Examples of resources are brand names, in-house knowledge of technology, employment of skilled personnel, trade contracts, machinery, and efficient procedures (Wernerfelt, 1984). A firm can decide upon the direction of a growth project by examining the strengths and weaknesses of its existing resource base (Barney, 1986). Economies of growth may emerge from exploiting the strengths associated with the unique collection of productive opportunities available to each firm. The indivisible and interdependent nature of these resources can also be seen to add impetus to a firm's growth (Coad, 2006). In fast-changing markets, however, a firm's competitive advantage may erode if it relies too heavily on certain specific resources. In such circumstances, a firm's performance depends on its abilities to create or release resources and to reconfigure their resource portfolio. These abilities are known as 'dynamic capabilities' (Eisenhardt and Martin, 2000; Winter, 2003).

This theory is applicable to the study as it seeks to explain the importance of the management decision in terms of the growth of the firm such as the decision to invest in research and development, implementing competitive strategies to enhance firm's competitive advantage with the aim of enhancing the sustainable growth of the firm.

2.3 Factors Affecting Sustainable Growth of Pharmaceutical Firms

Pharmaceutical companies have a responsibility to their shareholders, investors, employees and patients to operate in a way that will ensure their viability for the long term. That is the only way that they will be able to continue to provide and improve the medicines that societies depend on them to produce. There exists huge opportunity for the pharmaceutical industry to meet the needs of patients in therapeutic areas, as well as and by inference the financial gains they can have in geographies that have been a focus of their business plans but have huge and diverse unmet needs. Yet, the growth of the pharmaceutical firms has been seen to be dwindling due to the changing business environment (Banes, 2010).

Various studies have linked the growth of firms to factors such as regulation change and political impact, increased competition, dumping, increasing cost of production among others (Baines, 2010; IMS, 2008).

2.3.1 Effect of Competition on Firms Sustainable Growth

Hollis (2003) compares 82 manufacturing industries in seven countries, and finds that relatively higher domestic concentration is associated with a smaller domestic share in world output and fewer net exports. Clougherty and Zhang (2008) review 433 specific airline routes between 1987 and 1992, as well as each airline's number of competitors in its home market and share of passengers on that route. They find that fewer domestic competitors lead to a decrease in an airline's market share on international routes. The number of Canadian carriers dropped from five to two between 1989 and 1991. Based on their estimation results, this reduction in domestic competition triggered an annual loss in air transport services exports of $6.5 million.

Kim and Marion (1997) find similar evidence for a positive relationship between domestic rivalry and export performance from the U.S. food manufacturing industries. The self-reported number of domestic competitors was also found to explain export intensity in six major emerging economies (the Arab Republic of Egypt, Hungary, India, Poland, South Africa, and Vietnam), as shown in Estrin and others (2008).

However, in itself, a large market share is not necessarily related to lower export performance (see an early review by Morgan 1999; and Iyer 2010). Whereas Zhao and Zou (2002) conclude that firms are less likely to engage in export activity among the 1,700 highly concentrated Chinese manufacturing and service firms they surveyed, Guan and Ma (2003) find that among 213 Chinese industrial firms, a firm's individual domestic market share is not a good predictor of export performance. Moreover, markets with larger variability in market structure tend to export more.

In Japan, Ito and Pucik (1993) find that industry's largest companies the market "leaders" have lower export ratios than market followers.

Sakakibara and Porter (2001) further measure the intensity of rivalry with market-share instability. They demonstrate that higher annual percentage changes in market share of the largest firms between 1973 and 1990 (an indication of high competitive pressures) is significantly associated with higher world export shares of that industry in the early 1990s. In short, the more competition firms perceive, the more they export. A study from Vietnam (Hiep, Nishijima 2009) builds on the World Bank Investment Climate Survey. Some 1,150 firms reported the degree of perceived domestic competition. The empirical results show that firms that reported facing some or intense competition, as opposed to no competition, have a higher share of direct exports in total sales.

The production capabilities of the Kenyan industry were confirmed during this period by the companies' role in the campaigning that led to the 2001 government decision to allow compulsory licensing of generic production of HIV/AIDS medicines, and the subsequent issuing of voluntary licenses (UNIDO, 2010). However, private importers from South and East Asia were increasingly generating price-based competition in the Kenyan medicines market as liberalization took hold. With export figures that in absolute terms remain very modest, it is essential that Kenyan manufacturers keep upgrading and also control costs in order not only to expand its foreign markets but also to keep up with increasingly demanding technological standards and cheap foreign competition that creates a serious challenge to local producers.

2.3.2 Effect of Government Regulations on Firm's Growth

Extensive empirical literature has assessed how the regulatory environment for business affects a broad range of economic outcomes at both the macro and micro levels including productivity, growth, employment, trade, investment, access to finance and the informal economy. Furthermore, firm interaction with the government, measured by government contracts and the level of regulation in the industry, is also an important determinant of the firm's performance (Mitchell et al. 1997, Grier, Munger & Roberts 1994). Several other studies reach this conclusion. Hansen and Mitchell (2000) find that government regulations are significant determinants of firms' performance.

Drope and Hansen (2006) find that interaction with government, proxied by the number of federal cases in which a firm is involved, is positively associated with the likelihood of lobbying and with the amount spent on lobbying for large firms. By contrast, Brasher and Lowery (2006) find that government regulations are weak explanatory variables for firms' performance.

The institutional school, which derived from the environment-strategy-performance paradigm, contends that a variety of external (including institutional) factors should be taken into account when companies develop and implement strategies. Institutional constraints and government intervention are particularly important for SME development (Olive, 1997; Zapalska, 2001). SME development relies on government support policies, while enhancing competitiveness is the fundamental guarantee for SME survival. Therefore, the key assignment of government support is for SME to develop competitive advantages. Skinner (1969) points out that manufacturing strategy is a powerful weapon for a company to gain competitive advantage Skinner (1969); Badri et al. (2000), through a survey on UAE manufacturing companies, state that government regulations have a positive impact on manufacturing strategy formulation (Masood & Davis, 2000).

According to Kessler (2006), regulation may affect cost and quality through prices and use of existing products. On one hand, lower regulated prices may lead to lower costs per use and therefore greater use, which may in turn lead to higher quality and lower overall costs of care. On the other hand, regulation may have unintended consequences for prices and use that mitigate or outweigh its intended benefits. Regulation may actually lead to increases in the prices of some products, which in turn may lead to lower quality and higher costs of care. In addition, lower regulated prices may reduce access to new drugs by leading firms to launch products later in regulated markets than they otherwise would, which would have similar adverse effects.

Small firms often most heavily bear the cost of regulations. From an institutional perspective, small firms are shaped by institutions, while they are constrained by the institutions as well.

Given the characteristics of small firms, small firms are far more disadvantaged compared with their larger counterparts; for example, small scale organizations in terms of financial and human capital, have minimal influence on the market, small firms do not have the power to substantially lobby the government for their preferred policies and regulations. Small firms are often in a far worse situation to their capacity to respond to regulatory requirements, compared to larger companies.

Small firms do not have in house experts to handle regulatory compliance requirements. Instead, they would rather hand over regulatory related issues to their accountants and lawyers (Adams et al. 2011). The Australian Productivity Commission (2006) has reported that most executives and senior management teams spend more than 25% of their time meeting numerous regulatory compliance requirements, which hampers them from undertaking their core businesses. Thus, small firms are bearing disproportionate regulatory costs.

Pharmaceutical regulation involves a potential trade-off between curbing costs today and having fewer drugs to treat current and future generations. Thus, the first step in examining this trade-off is estimating the effect of regulations on pharmaceutical revenues. However, there is little consensus about whether or not real-world pharmaceutical regulations have any impact on revenues. Some believe that these regulations have little "bite," especially over time, as pharmaceutical firms learn to work their way around them. Others believe that regulations have big impacts on revenues and consequently limit the pace of innovation (Wangwe, et al. 2014).

Martikainen, Kivi and Linnosmaa (2005), found that wholesale prices for newly launched reimbursable pharmaceuticals were highest in countries where manufacturers are free to set their own prices. Another study, Ekelund and Persson (2003), find that in contrast to the unregulated market in the US, prices of new drugs in all classes fall faster in the regulated market of Sweden. Finally, Danzon and Chao (2000) found a negative relation between strict price regulation and the price of older molecules.

However, they also found that generic competition is more effective in reducing prices in the US compared to more stringently regulated markets. In general, existing studies are limited by their reliance on cross-sectional variation in revenues or prices, and their resulting vulnerability to heterogeneity across countries in type of regulation and other determinants of prices.

There are some studies that address the heterogeneity problem by analyzing longitudinal data and comparing pharmaceutical expenditure before and after policies take effect. For example, Pavcnik (2002) estimated a 10–26% decrease in drug prices as a result of a reference pricing policy introduced in Germany after 1989.

Pekurinen and Häkkinen (2005) suggested that voluntary generic substitution and prescribing policies had no effect on expenditures in Finland, but that compulsory generic substitution decreased prices and led to cost savings in the first year after introduction. However, most of these studies only examine the effects of a limited range of regulations in one country or a small group of countries.

2.3.3 Effect of International Regulations on Firms' Growth

Detailed account of the history of pharmaceutical regulation can be found in Lee and Herzstein (1986), Permanand (2006), Danzon and Keuffel (2005). In brief, the regulation of pharmaceuticals evolved at the national level in response to the public health concerns (typically, urged by drug disaster that required immediate change and strengthening of safeguards) with globalization of pharmaceutical markets, some aspects of regulation, especially those concerning quality, safety and efficacy were taken to the supranational level. In short, the objectives of regulations can be summarized as including securing a reward to R&D to assure a continuous flow of innovative new medications; ensuring the safety of drugs; and controlling the quantity and enhancing the quality of drug expenditures.

The impact of international policy regulations and standards on trade has been an important global policy issue during the past decade.

Regulations and standards, in principle, are designed to facilitate production, guarantee quality of products, reduce transaction costs and enhance contestability in the market. For example, pollution standards can contribute to a clean environment, health and sanitary requirements can improve the health status in an economy, and competition policy can enhance market contestability. However, standards and technical regulations can produce serious distortions in commercial markets: international regulatory systems may deter trade and limit market entry through environmental, health or safety standards (Maskus et al. 2008).

A country's technical regulations and standards, which are often considered nontariff barriers, are of particular concern in a development context. Every country establishes their own policies and standards to deal with needs of the national industry. In this context, developing countries fall behind developed country in establishing effective standards and regulations that take international best practices into consideration. Developing countries find it difficult to develop standards that are straightforwardly acceptable by the developed nations, and they have a hard time in meeting standards and regulations set by developed countries (Prasad & Jayasuriya, 2003). Every country develops their own policies and standards for a specific product and they differ from country to country. These differences create problems for manufacturing industries, especially for major exporting countries.

A large literature has focused on how international regulations and standards impact productivity growth and trade competitiveness in both manufacturing goods and agricultural products. With respect to regulations and standards, many policy-makers suggested that international regulation may have influence the countries' decision on what to produce, whether to export, and where to export. However, empirical analyses of the impact of policy regulations and standards on exporting firms in developing countries are relatively sparse. On the other hand, compliance costs stemming from technical regulations and standards vary across industries, and depend on firm size, firm characteristics and market structure (Knut, 2012; Freund and Bolaky, 2008; Le Bas, Haned & Colombelli, 2011).

Since the initiation of economic reforms and the adoption of the open door policy, international trade and Kenya's economy have experienced dramatic growth. Kenya's integration into the global economy has largely contributed to its sustained economic growth. Some of the industries with comparative advantages began to acquire a high level of specialization, and Kenya has achieved a high growth rate of GDP, as well as an enormous inflow of hard currency and increase in employment. However, some international trade regulations are restrictive as the stakes are sometimes raised so high that the local firms cannot participate but spectate as they lack the capital required and the quality standards may not allow them. This has always locked out the local manufacturing firms in Kenya from participating in the supplies of the pharmaceuticals in the international arena (Odhiambo, 2013).

2.3.4 Relationship between Cost of Production and Firms' Growth

Cost behavior according to Asaolu and Nassar (2007) is the study of the ways in which costs vary or do not vary with the level of activity in an organization. They level of activity was described as the amount of work done or the number of events that have occurred. Drury (2005) on the other hand, also defines cost as expenses, which have been consumed in earning revenue. Profitability was however defined by Lucey (1997) as the excess of revenue over cost. In other word, profit is determined by deducting cost from revenue. This shows the linearity of profit and cost. The term "variable" and fixed cost otherwise known as indirect and direct expenses have been traditionally used in the management accounting literature to describe how costs react to changes in activity level. Short-term variable costs vary in direct proportion to the volume of activity that is, doubling the level of activity double the total variable costs. This was assumed by Fischer and Schmitz (1998) to lead to increase in profit.

Consequently, total variable costs are linear and unit variable cost is constant (Adeniji, 2011). In like manner, Horngren (2006), pointed out that a fixed cost remains unchanged in total for a given time period despite wide changes in the related level of total activity or volume.

Furthermore, Horngren et al. (2009), added that costs are defined as variable or fixed with respect to a specific cost object and for a given time. Adeniji (2011), reported that over a sufficiently long period of time, virtually, all costs are variable. During such a long period of time, contraction in demand will be accompanied by reductions in virtually all categories of costs. For example, senior managers can be relieved of their jobs, machinery may not be replaced and buildings and land may be sold. Similarly, large expansions in activity will eventually cause all categories of costs being incurred by enterprise to increase. According to Olabisi et al. (2012) Step fixed costs are fixed within specific levels of activity within a given time period. Many items of cost are fixed costs in nature within certain levels of activity i.e. relevance range exists (Asaolu & Nassar, 2007).

Horngren (2006), defined a controllable cost as any cost that is primarily subject to the influence of a given responsibility center manager for a given time period. The allocation of costs to products is in-appropriate for cost control, since the manufacture of a product may consist of different operations, all of which are the responsibility of different individual. The product cost will not therefore pinpoint costs to area of responsibility, to overcome this problem, Zengin and Ada (2010) suggested that costs and revenue must be traced to individual who are responsible for their incurrence. This system is known as 'responsibility accounting'. The centers identified by Drury (2005) are: (a) A cost centre where managers are responsible for the expenses that are under their control. (b) A profit centre where managers are accountable for sales revenue and expenses e.g. selling and production department of a company. (c) An investment centre where managers are normally accountable for sales, revenue and expenses, and also responsible for some capital investment decisions and able to influence the size of the investment.

McGlaphren (2003) cites that production costs are expenses, such as materials and labor that a company incurs in the course of producing the product to sell to consumers. In general, the lower the production cost, the higher the profit, or the amount left over after subtracting expenses from sales revenue. However, low production costs do not necessarily guarantee a high profit.

A business may have unsustainably high fixed costs, such as rent, or may cut production costs of producing an inferior product that nobody wants. A firm maximizes profit by operating where marginal revenue equal marginal costs. A change in fixed costs has no effect on the profit maximizing output or price. The firm merely treats short term fixed costs as sunk costs and continues to operate as before. This can be confirmed graphically. Using the diagram illustrating the total cost–total revenue perspective, the firm maximizes profit at the point where the slopes of the total cost line and total revenue line are equal. An increase in fixed cost would cause the total cost curve to shift up by the amount of the change (Drury, 2005).

2.3.5 Growth of the Firm

Growth has been studied in different models by several authors. The well-known growth model of Churchill & Lewis (1983) argues that a young company is usually in the survival phase. Despite the fact that there will not be growth immediately, the investing factor will show its impact in the near future. Hence, the investing factor is necessary for young companies to survive. According to the model, younger companies are less experienced and organizationally inefficient. Larger companies on the other hand have sufficient experience and are more efficient. According to Phillips & Kirchhoff (1989), young companies without growth or with negative growth are more likely to fail. Growth enables the company to add value and is a factor which strengthens the organization.

In finance, growth rate estimation of dividends, earning and price per share are important factors in determining the value of an investment or a firm. Enterprise growth can be measured in sales and profits which may give a more accurate estimation of growth. However, the entrepreneur may not give accurate figures (Liedholm *et al*, 2008) so using the measurement of employment growth becomes more practical and prudent. Several studies have used the number of employees as a proxy for the size of the firm. The growth is determined by the entrepreneurial characteristics of the entrepreneur and the enterprise characteristics, where the latter are partly determined by the environmental factors and the sector in which the business operates, (Naituli *et al*, 2006, Beccheti, *et al* 2002).

In contradiction to Ahlström's model the Gibrat's law (1931) states that the growth of a company is a random process. According to the author, the size of a company is independent from firm growth. Research by Oliveira & Fortunato (2006) found evidence for the dependency of age. Firm size and firm age as growth determinants are a prerequisite for distinguishing strong growing companies from weaker ones (Mateev & Anastasov, 2010). However, Churchill & Lewis' model (1983) indicated firm size as a growth standard, which is a measure for firm growth.

Sustainable growth is defined as the growth the company is capable of if it does not alter its capital structure (Mubeen, 2017). Sustainable growth is achieved when company is able to generate and retain earnings. Higgins (1977, 1981) developed a sustainable growth rate model where he assumes that firms can only generate new funds by either using retained earnings (internal financing) or issuing debt (external financing) but not by issuing new equity. However, he also assumes the constant leverage ratio. Though criticized by researchers such as Bivona (2000) and Ashta (2008), Platt et al (1995) supported Higgins constant leverage assumption, saying that in a situation where firms are in financial distress having restriction of issuing new debt due to existing debt burden, Higgin's Model can be applied. According to Higgins' (2008) Model of sustainable growth, when a firm is not issuing new equity to raise funds, the cash to finance growth must come from internal sources, i.e. retained earnings and new borrowings.

Sustainable growth

$$= \frac{Net\ income}{Sales} + \frac{Sales}{Total\ assets} + \frac{Total\ assets}{Shareholders'equity} + (1 - Dividend\ payout\ ratio)$$

Hence Higgins' sustainable growth rate allows only internal source and external debt financing.

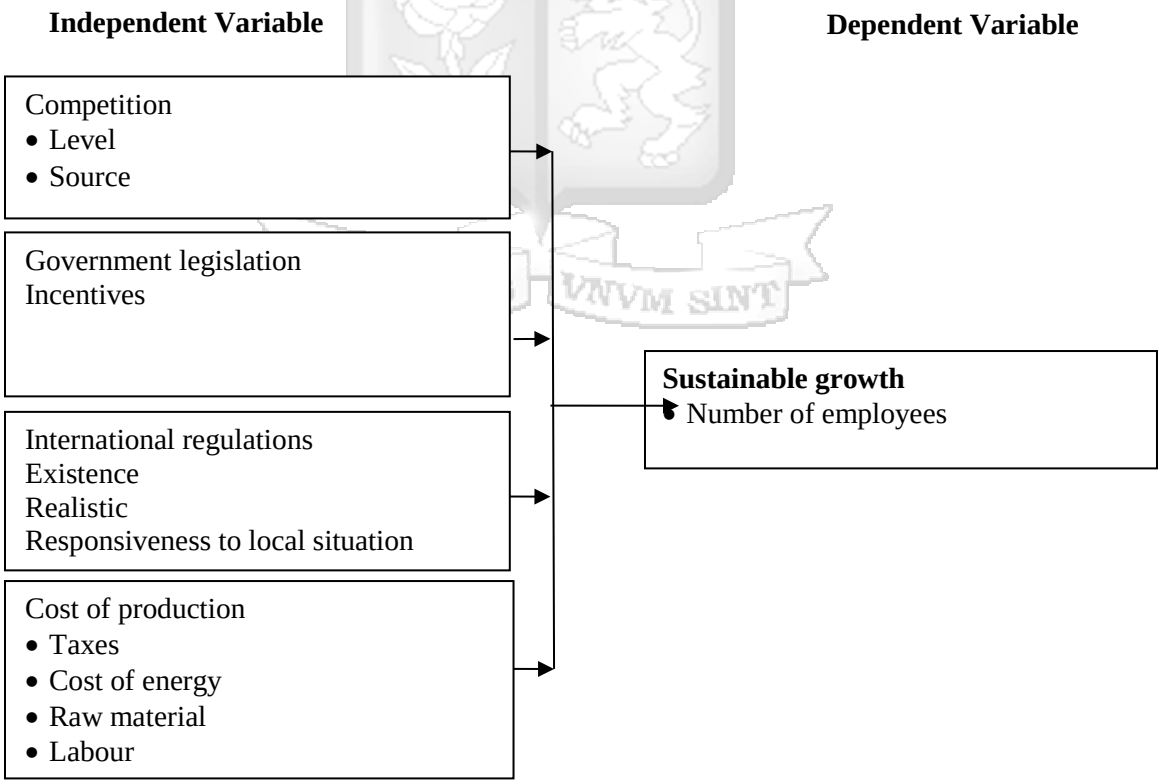
2.4 Summary of Literature and Research Gaps

The reviewed literature (Drury, 2005; Le Bas, Haned & Colombelli, 2011; Pekurinen and Häkkinen 2005; Hiep, Nishijima 2009) has revealed that the competition, the government legislation, international regulations and the cost of production have an influence on the growth of the firms. However, none of these studies were done in the developing countries hence the findings cannot be used to generalize the status in these settings. Secondly, there studies were done in other sectors and not in the pharmaceutical sector, hence a knowledge gap. This study therefore seeks to analyze factors affecting the sustainable growth of local pharmaceutical industries in Kenya.

2.5 Conceptual Framework

The conceptual framework of the study is presented in Figure 2.1

Figure 2.1: Conceptual Framework



CHAPTER THREE:
RESEARCH METHODOLOGY

3.1 Introduction

This chapter presents the methodology that is used in this study. This is presented in the following format: research design, target population, sampling technique, data collection techniques, data analysis methods and ethical considerations.

3.2 Research Design

The study adopted a cross-sectional research design, which entails collection of data on more than one case at a single point in time with one or more variables. According to Cooper and Schindeler (2003) cross sectional surveys are best applicable where the study seeks to measure the same variables across all the respondents. A cross-sectional survey design is the most appropriate for investigating the behavior under study (Mugenda and Mugenda, 2003). Many studies in the past have utilized this design in wide surveys to derive their evidence on various strategic management issues affecting the pharmaceutical industry. In this study, the researcher aimed to analyze factors affecting sustainable growth of local pharmaceutical industries in Kenya. The factors to be analyzed were competition, government legislation, international regulations and the cost of doing business.

3.3 Target Population

The target population for this study was the 32 local pharmaceutical manufacturing firms in Kenya registered with the Pharmacy Poisons Board in 2016.

3.4 Sampling Procedure and Sample Size

Due to the manageability of the population (32 local pharmaceutical manufacturers) the researcher conducted a census study in which all the elements of the population were studied. The sample size was therefore the 32 local pharmaceutical industries in Kenya.

3.5 Data Collection

The researcher used questionnaires to collect data from the respondents. According to Sapsford (2006) the advantage of using questionnaires is that they are an entirely standardized measuring instrument because the questions are always phrased exactly in the same way for all respondents. It is more efficient in that it requires less time to respond to information, permits respondents to remain anonymous in their responses and it is easy to administer (Mugenda and Mugenda, 2003). The questionnaire comprised of five sections, demographic data, competition, government legislation, international regulations and cost of doing business. The researcher then administered the questionnaires after receiving ethical approval from the University. In instances where the respondents did not have time to respond to the questions immediately, the researcher used drop and pick method. The questionnaires were left with the respondent to fill at their convenient time and return within a week. The data was collected between 19th March to 20th April 2018.

3.6 Validity and Reliability of the Instruments

3.6.1 Validity of the Instruments

To test the validity of the instruments, the researcher used expert raters and the supervisors who tested for content validity and enhance the value and content of research instrument. Content validity of an instrument is the degree to which a test appears to measure a concept by logical analysis of the items. The emphasis is on adequate coverage by the instrument of the scope implied by the topic of study. The rated findings were used to calculate content validity index (CVI) using the formula:

$$CVI = K/N$$

Where K = Total number of items in the questionnaire declared valid by both raters/judges.

N = Total number of items in the questionnaire

The study got an index of 0.743 According to Polit (2006) an instrument is considered valid if the CVI is at least 0.7. The researcher modified any items that were found ambiguous to elicit relevant information.

3.6.2 Reliability of the Instruments

The researcher pilot tested the instruments to check reliability. The researcher administered the questionnaires to the same group of persons in the pilot study after one week. The split half method was used to establish instrument reliability. Computation of the correlation between the scores was done by first splitting the tests into two halves. The tests were then be assigned odd and even number items. To compute the coefficient, the researcher used the formula:

$$Re = \frac{2r}{r + 1}$$

Where Re = reliability of the original test

r = reliability of the coefficient resulting from correlating the scores of the odd items with the scores of the even items.

Reliability was analyzed with the aid of computer software Statistical Package for Social Sciences (SPSS). The reliability was tested using Cronbach's Alpha coefficient. A high value of alpha of 0.7 and above is often used as evidence that the item measure an underlying (or latent) construct (Gliem & Gliem, R. R. (2003). The study got a value of 0.81 which is higher than the recommended, 0.7, hence the instruments were deemed reliable.

3.7 Data Analysis

The data collected was cleaned prior to analysis. This involved editing of the primary data to identify and eliminate errors made by respondents. The data was analyzed and presented using descriptive statistics such as mean scores and standard deviation to determine the distributions of the variables.

The results of analysis are presented in pie charts, tables as well as graphs. Diagnostic tests of normality, homoscedasticity and multicollinearity were conducted to validate the regression analysis model.

3.8 Ethical considerations

Ethical approval was obtained from Strathmore University Institutional Review Board

The participants who accepted willingly to take part in the study were taken through a consent form systematically for them to understand before they signed it. Participation was purely on voluntary basis.

Participant's names were not included in the data collection tool. Participants were assigned study numbers in the data collection form instead of their individual or company names. There were no direct benefits or risks pecuniary to the participants in the study.

CHAPTER FOUR

DATA ANALYSIS, INTERPRETATION AND PRESENTATION

4.1 Introduction

In this chapter, data from the field is analyzed and presented from where interpretation of the findings is given. This is done as per the objectives of the study. The findings are presented in figures and tables. A total of 32 questionnaires were given out, out of which, 30 were completed and returned to the researcher. This gave a response rate of 93.7%, which is above the recommended 31% response rate by Cooper and Schindler (2008) for social sciences.

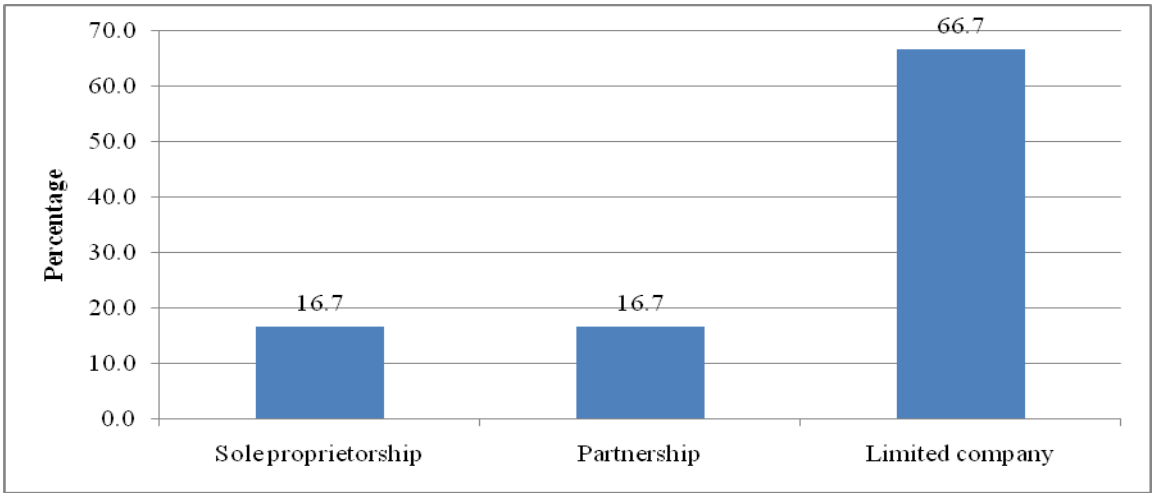
4.2 Demographic Information

The study sought to establish some demographic information concerning the respondent firms. These included the nature of the firms' registration, the type of ownership and how long they have been in operation. The findings are presented in the subsequent sections.

4.2.1 Nature of Registration

The study sought to determine the nature of the registration of the pharmaceutical companies in Kenya. The results are presented in Figure 4.1.

Figure 4. 1:Nature of Registration



The findings show that most of the firms (66.7%) were limited liability companies while 16.7% were sole proprietorships and partnerships.

4.2.2 Type of Ownership

The respondents were asked to state the type of ownership of the firms. The results are presented in the Table 4.1.

Table 4.1: Type of Ownership

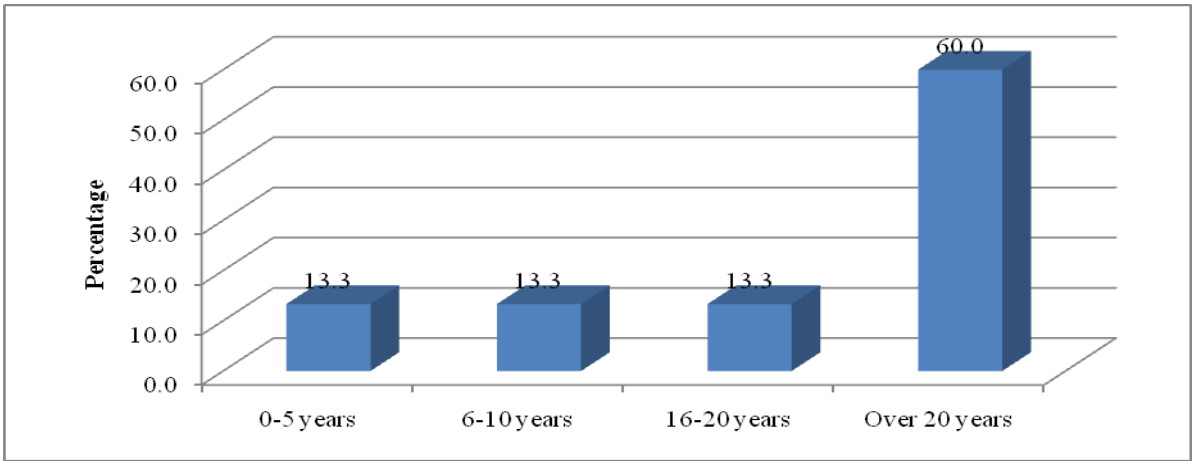
	Frequency	**Percent**
Shareholding	9	30.0
Family owned	16	53.3
Not indicated	5	16.7
Total	**30**	**100.0**

The results show that most of the firms (53.3%) are family owned where 30% are shareholding.

4.2.3 Years of Operation

The study sought to determine the number of years the respondent firms have been in operation in Kenya. The results are presented in Figure 4.2.

Figure 4. 2: Years of Operation

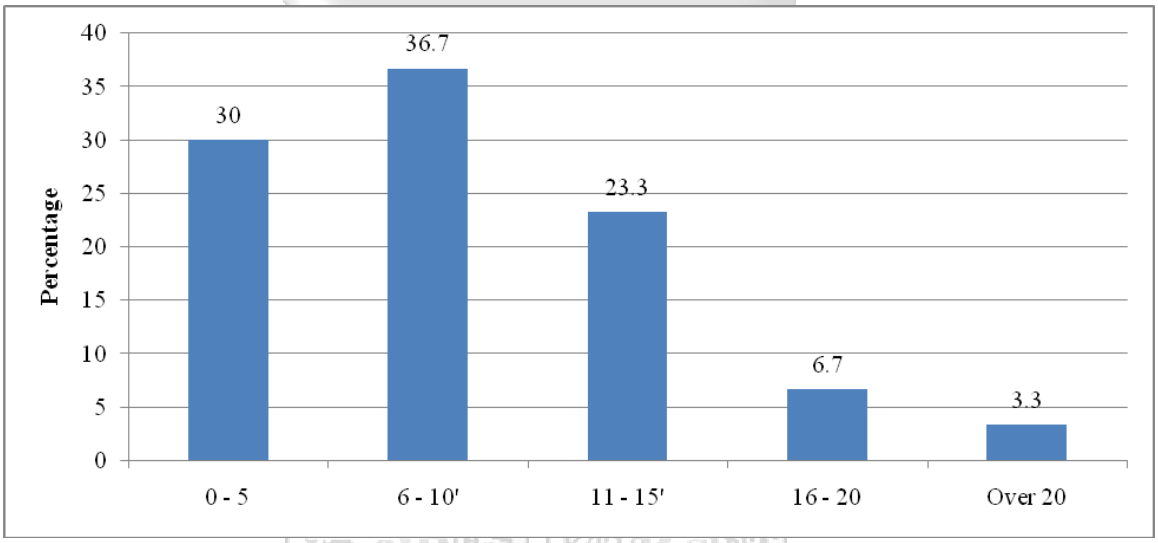


Majority of the firms (60%) have been in operation for over 20 years in Kenya. The findings also show that 13.3% of the firms have been in operation for either five years and below, 6 to 10 years and 16 to 20 years. The findings mean that most of the firms have been in operation in Kenya for several years.

4.2.4 Number of Employees at Start

The study sought to determine the number of employees at start. The findings are presented in Figure 4.3.

Figure 4. 3: Number of Employees at Start

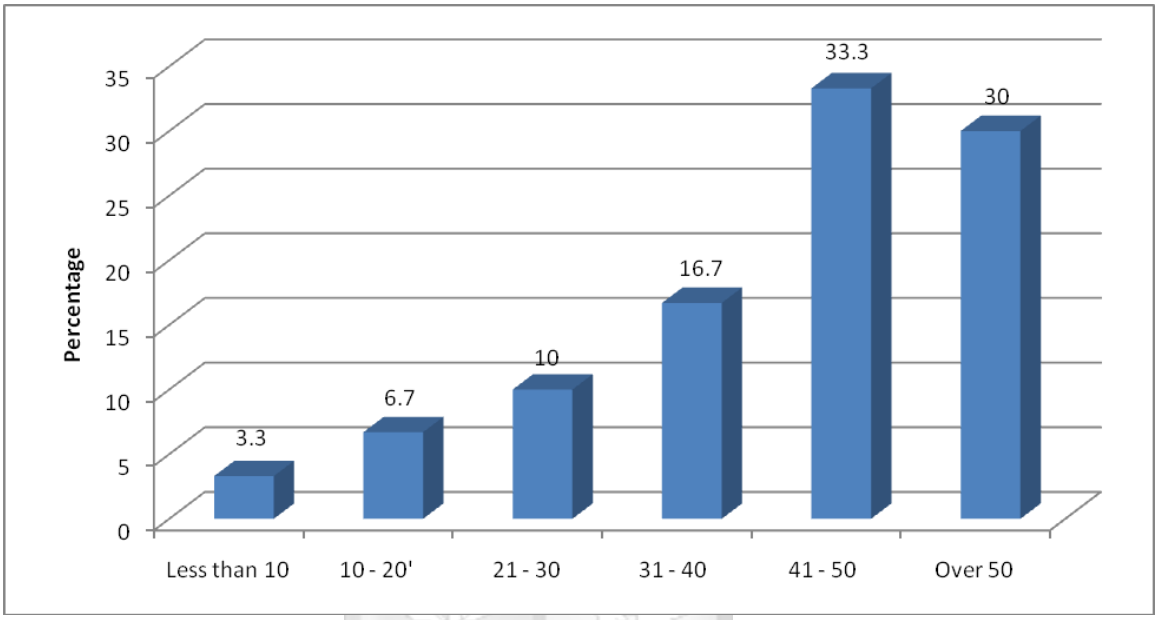


The study findings revealed that at start most of the firms has 10 employees and below as it shows that 36.7% of the firms had between 6 and 10 employees while 30% had between zero and 5 employees. The findings also show that 23.3% of the firms had between 11 and 15 employees. The results mean that most of the firms started as small companies.

4.2.5 Number of Employees at the Time of Study

The respondents were asked to state the number of employees their firms have currently. The results are presented in Figure 4.4.

Figure 4. 4: Number of Employees at the Time of Study



The study findings show that a third of the respondent firms (33.3%) have between 41 and 50 employees while 30% of the firms have over 50 employees. The results also show that 16.7% of the firms have between 31 amd 40 employees. Only 3.3% of the firms have remained at less than 10 employees. The findings therefore means that there has been growth in the pharmaceutical manufacturing firms in Kenya.

4.3 Effect of Competition on Sustainable Growth of Pharmaceutical Manufacturing Companies in Kenya

This section sought information to determine whether competition in the industry affected sustainable growth of pharmaceutical manufacturing firms in Kenya. The findings are presented in the subsequent sections.

4.3.1 Level of Competition in the Pharmaceutical Sector in Kenya

The respondents were asked to describe the level of competition in the pharmaceutical sector in Kenya. The findings are presented in Table 4.2.

Table 4.2: Level of Competition in the Pharmaceutical Sector in Kenya

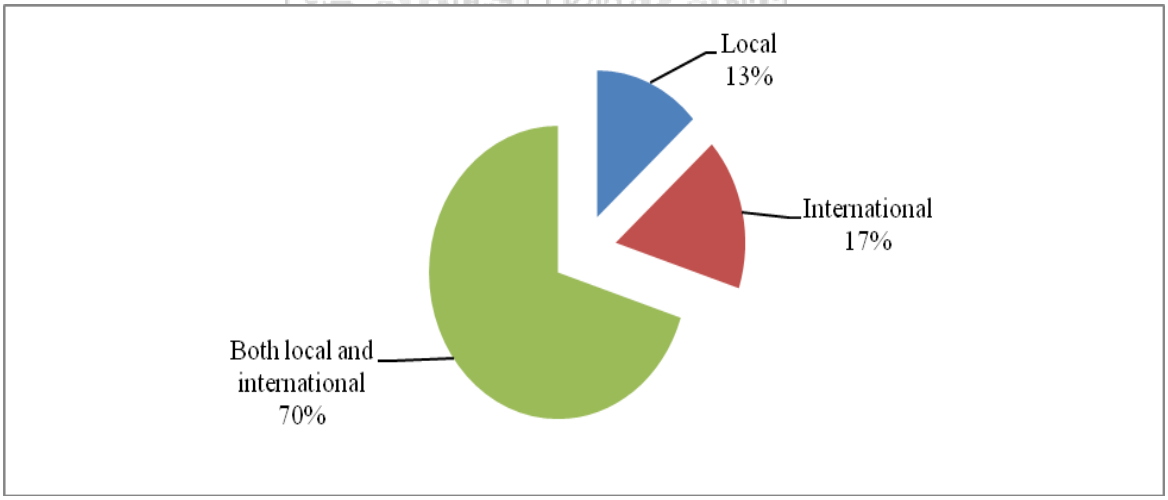
	Frequency	**Percent**
Very high	1	3.3
High	29	96.7
Total	**30**	**100.0**

The study findings revealed that majority of the respondents (96.7) described the level of competition in the pharmaceutical sector as high. The findings mean that the competition in the pharmaceutical sector is fierce.

4.3.2 Source of Competition

The study sought to determine where the competition originated from. The results are presented in Figure 4.5.

Figure 4. 5: Source of Competition



According to the results of the study, 70% of the respondents noted that the competition in the pharmaceutical sector was both local and international.

The results show that 17% of the respondents indicated that the competition was majorly international while 13% indicated that the competition was generally local.

4.3.3 Description of Competition in the Pharmaceutical Sector

The respondents were asked to state whether they agreed or not with the statements with regard to the competition in the pharmaceutical sector in Kenya. The findings are presented in Table 4.3.

Table 4.3: Description of Competition in the Pharmaceutical Sector

	Yes	**No**	**Total**
There is a lot of imported drugs	93.3	6.7	**100**
There are so many counterfeit products in the market	36.7	63.3	**100**
Generic drugs in the country has resulted to unfair competition	53.3	46.7	**100**
Business environment unfair in favor of some competitors	53.3	46.7	**100**
Market favors international companies	70.0	30.0	**100**
Local companies are not up to task in terms of competitive advantage	30.0	70.0	**100**

The study results show that majority of the respondents (93.3%) agreed with the statement that there was a lot of imported drugs in the country. The study findings further show that most respondents (63.7%) did not agree with the statement that there were many counterfeit products in the market. Most respondents (53.3%) agreed that generic drugs in the country resulted into unfair competition. According to most of the respondents (53.3%), business environment was unfair in favor of some competitors. Majority of the respondents (70.0%) agreed that the market favored international companies. However, majority of the respondents (70%) did not agree with the statement that the local companies were up to task in terms of competitive advantage or not. The study findings mean that to a large extent, the market did not favour the local manufacturing firms in terms of competition.

4.3.4 Have Coping Strategies to Counter Competition

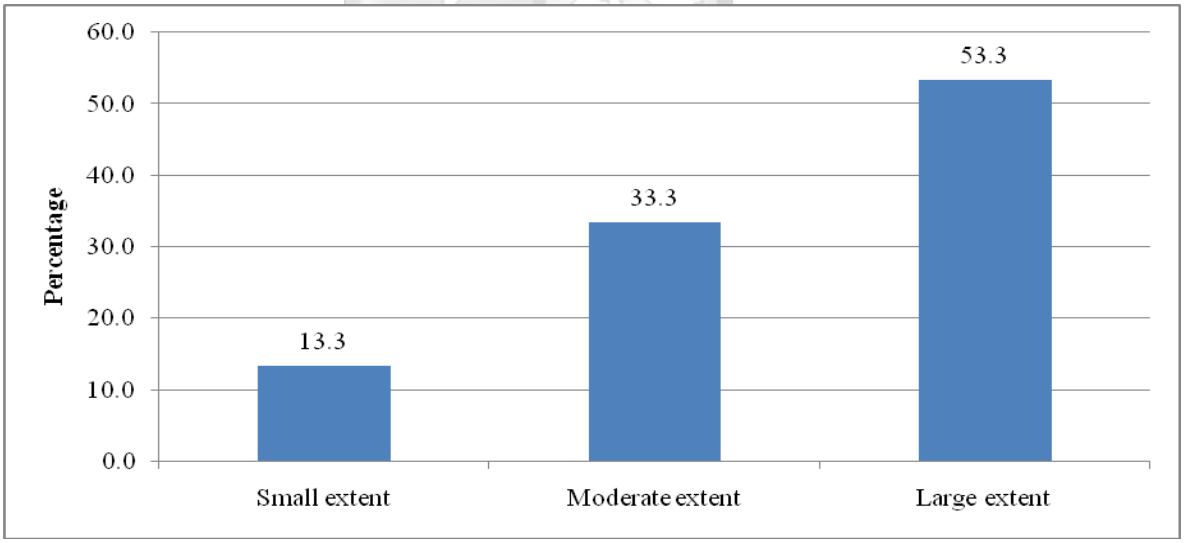
The study sought to determine whether pharmaceutical companies in Kenya had coping strategies to counter competition. The results of the study revealed that all the respondent firms had coping strategies in place to counter the competition in the sector.

Asked to explain their answers, the respondents indicated that they employed strategic sourcing of raw materials. The respondents also stated that their firms had adopted vigorous marketing and distribution systems. The firms also resorted to price reduction strategies so as to be competitive according to some respondents. The respondents further stated that one of the strategies employed to counter competition was to assure quality of their products and ensuring constant availability of the products.

4.3.5 Influence of Competition of Firms Growth

The respondents were asked to state the extent to which the competition in the sector influenced the growth of their organizations. The findings are presented in figure 4.6.

Figure 4. 6: Influence of Competition of Firms Growth



The results show that most of the respondents (53.3%) indicated that competition influenced the growth of the firms to a large extent.

Findings show that 33.3% of the respondents indicated that competition only affected the growth of the firms only to a moderate extent. The findings mean that competition influenced the growth of the pharmaceutical manufacturing firms in Kenya.

Asked to state how in their opinion competition influenced the growth of the firms, respondents indicated that competition led to the deterioration of sales volumes and margins. The respondents also indicated that due to the competition, their market share was reduced. Respondents indicated that due to the existing competition, their firms have been forced to diversify especially in the areas of therapeutic which though less competitive, require large capital and marketing budgets which may negatively affect the growth of the firms.

On the other hand, the respondents argued that competition has worked for good for their firms. Respondents stated that as a result of the competition, the local pharmaceutical manufacturing firms have had to invest in better premises, equipment and even personnel to enhance the quality of their products and hence remain competitive. The respondents also stated that the local pharmaceutical manufacturing firms have had to focus on marketing and improve on the quality of their products so as to remain competitive. From the above, it is clear that competition has had both positive and negative effects on the growth of pharmaceutical firms in Kenya.

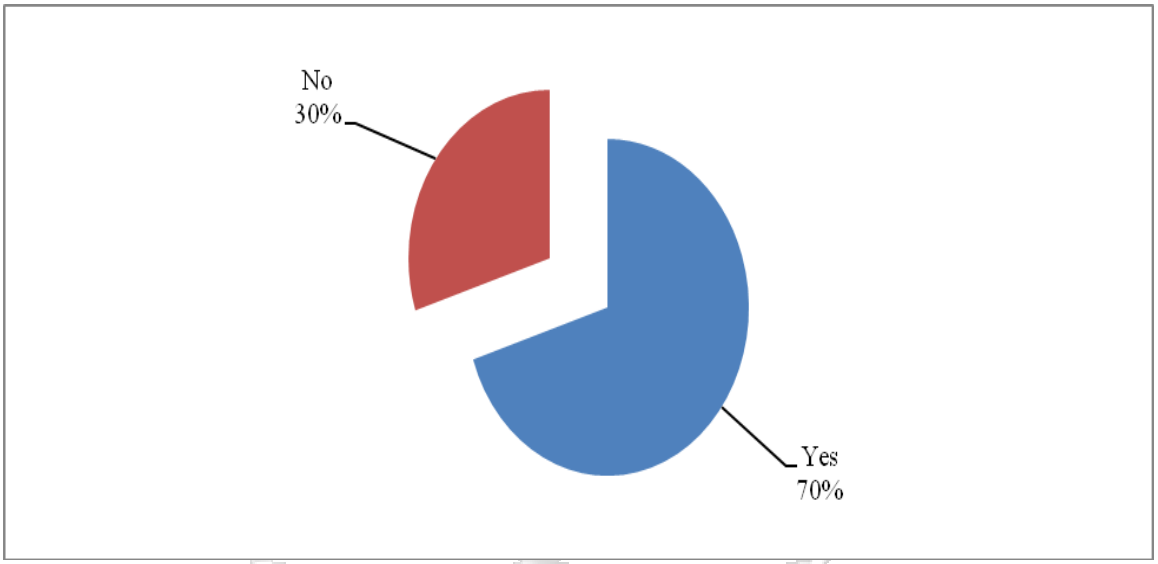
4.4 Effect of Government Regulation on Growth of Pharmaceutical Manufacturing Firms

In this section the study sought to determine the effect of government regulation on the growth of pharmaceutical manufacturing firms in Kenya. The findings are presented in the subsequent sections.

4.4.1 Awareness of Government Legislation for Growth of Pharmaceutical Manufacturing in Kenya

The study sought to determine whether the respondents were aware of any government legislation for the growth of pharmaceutical manufacturing in Kenya. The findings are in Figure 4.7.

Figure 4. 7: Awareness of Government Legislation for Growth of Pharmaceutical Manufacturing in Kenya

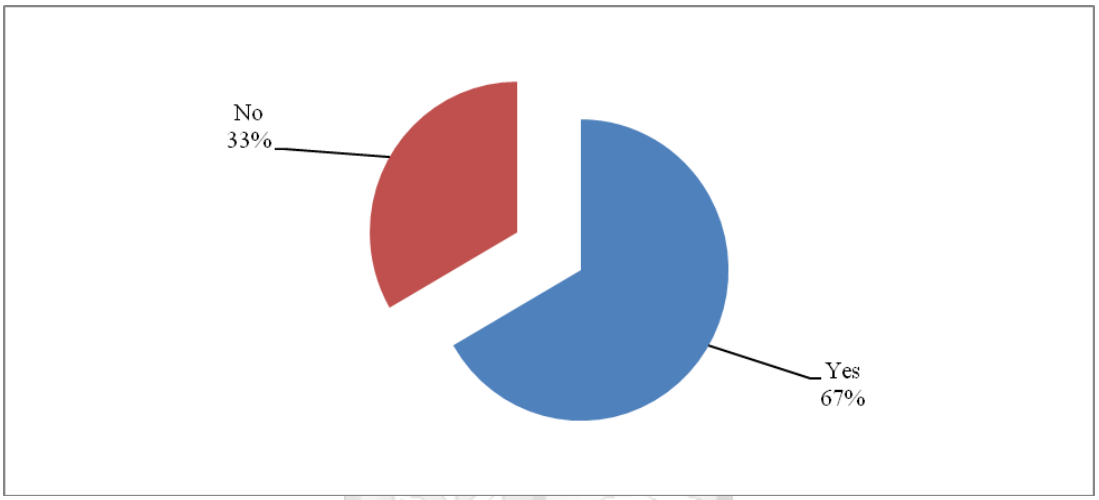


Majority of the respondents (70%) stated that indeed they were aware of existence of government legislation for the growth of the pharmaceutical manufacturing firms in Kenya. Findings however, show that 30% of the respondents were unaware of such a law. The findings mean that there exists a law regarding the growth of pharmaceutical firms and the respondents are aware of it.

4.4.2 Incentives to Local Pharmaceutical Manufacturing Firms by Government

The respondents were asked whether the government offered any incentive to the local pharmaceutical manufacturing firms to enhance their gwoth. The results are presented in Figure 4.8.

Figure 4. 8: On whether Government Offered Incentives to Local Pharmaceutical Manufacturing Firms



The study findings show that majority of the respondents (67%) indicated that indeed the government offered incentives to the local pharmaceutical manufacturing firms. According to a third of the respondents (33%), the government did not offer any incentive to the local manufacturers. The results mean that to a large extent, the government offered incentive to the local manufacturing firms.

Asked to state the incentives by the government, the tespondents stated that the government had given a 15% preference for local manufacturers in public procurement. The respondents also stated that there was a duty free importation or tax exemption of raw materials and packaging materials zero rating of VAT on packaging and other inputs among others. Respondents also stated that there was a government policy on increased local content of buy Kenya build Kenya, however, this was not fully enforced.

4.4.3 Government Legislation Aimed at Enhancing Growth of Pharmaceutical Manufacturing in Kenya

The study sought to establish the extent to which the government legislation was aimed at enhancing the growth of pharmaceutical manufacturing in Kenya. The findings are presented in Table 4.4.

Table 4.4: Government Legislation Aimed at Enhancing Growth of Pharmaceutical Manufacturing in Kenya

	Frequency	**Percent**
Small extent	12	40.0
Moderate extent	18	60.0
Total	**30**	**100.0**

Results show that most of the respondents (60%) stated that the government legislation was aimed at enhancing the growth of the pharmaceutical manufacturing in Kenya only to a moderate extent while 40% indicated that this was only to a small extent. The results mean that the efforts by the government were only felt to a small extent.

4.4.4 Government Legislation affecting Growth of Pharmaceutical Manufacturing Firms in Kenya

The study researcher to determine the extent the government legislation affected the growth of pharmaceutical manufacturing firms in Kenya. The findings are presented in Table 4.5.

Table 4.5: Extent to which Government Legislation affected Growth of Pharmaceutical Manufacturing Firms in Kenya

	Frequency	**Percent**
Small extent	5	16.7
Moderate extent	17	56.7
Large extent	6	20.0
Very large extent	2	6.7
Total	**30**	**100.0**

The results of the study show that 56.7% of the respondents stated that the government legislations had affected the growth of the pharmaceutical manufacturing firms in Kenya only to a moderate extent.

The results show that 20% of the respondents indicated that the legislation affected the growth of the firms to a large extent while 16.7% indicated that this was only to a small extent. The findings mean that the effect of the government legislation on the growth of the pharmaceutical firms is not adequate.

Asked to state in their opinion the legislations the government should put in place in order to enhance the growth of pharmaceutical manufacturing firms in Kenya, the respondents indicated that the government needed to increase duty (import duty) on pharmaceutical products which can manufactured locally.

The respondents also indicated that a specific legislation should be put in place compelling the government to source pharmaceutical products for its healthcare system locally and only procure externally, if they cannot be sufficiently produced locally. The respondents said that the government should consider removing VAT and other taxes on services and energy to the pharmaceutical firms so as to reduce the cost of production and make the local manufacturers competitive. Further the respondents stated that the government should consider setting up a fund that will enable commercial banks to lend to the pharmaceutical sector at subsidized rates.

4.5 Effect of International Regulations on Growth of Pharmaceutical Manufacturing Firms

In this section the study sought to determine the effect of international regulations on the growth of pharmaceutical manufacturing firms in Kenya. The results are presented in the following sub sections.

4.5.1 Awareness of International Regulations Governing Operations of Companies

The respondents were asked whether they were aware of the international regulations that governed the operations of pharmaceutical manufacturing companies. The findings are presented in Table 4.7.

Table 4.6: Awareness of International Regulations Governing Operations of Companies

	Frequency	**Percent**
Yes	26	86.7
No	4	13.3
Total	**30**	**100.0**

The findings show that 87% of the respondents were aware of the international regulations governing the operations of pharmaceutical manufacturing companies. The findings mean that the respondents knew of the existing international regulations with regard to the manufacturing and sale of drugs.

Asked to describe the international regulations, the respondents with the knowledge of existence of international regulations described the international regulations as being relatively friendly.

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4.5.2 Effect of International Regulations on Growth of Pharmaceutical Firms

The respondents were asked to state whether they agreed or not with the statements regarding the effect of international regulations on the growth of the pharmaceutical manufacturing firms in Kenya. The findings are presented in Table 4.8.

Table 4. 7: Effect of International Regulations on Growth of Pharmaceutical Firms

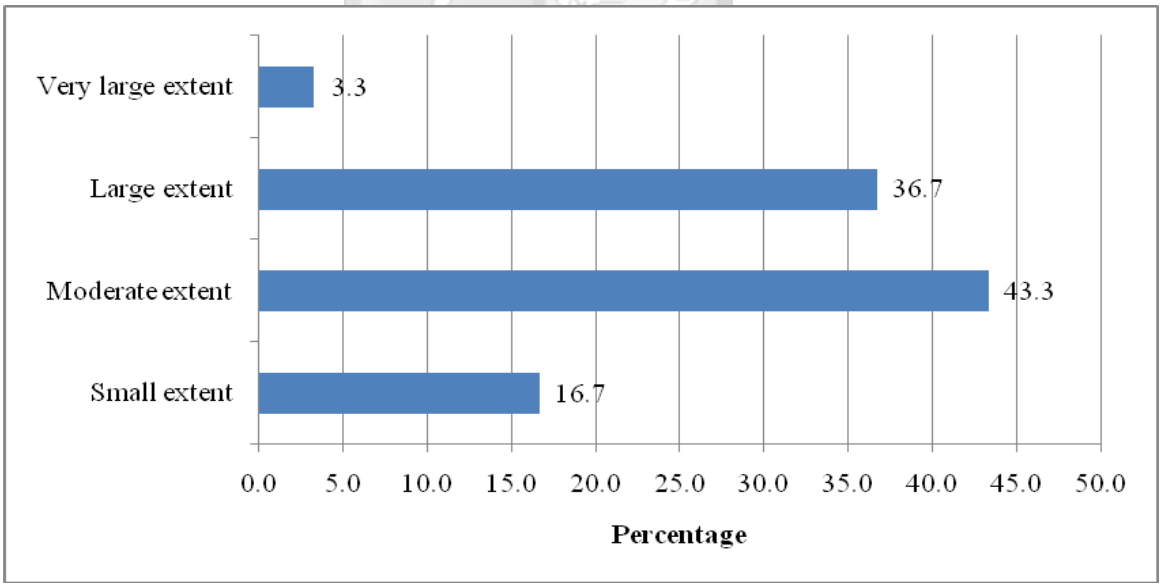
	Yes	No	**Total**
A lot of regulations with regard to international practice	90.0	10.0	**100**
A lot is demanded from local manufacturers to export	90.0	10.0	**100**
International regulations favor multinational manufacturing firms	83.3	16.7	**100**
International regulations favor dumping	26.7	73.3	**100**

The study findings show that majority of the respondents (90.0%) agreed that indeed there was a lot of regulations with regard to international practices. The results also show that majority of the respondents (90%) agreed that there was a lot of demand from the local manufacturers to export to foreign countries. 83.3% of the respondents agreed that indeed the international regulations favored the multinational pharmaceutical firms. The findings however, show that majority of the respondents (73.3%) never agreed with the statement that the international regulations favored dumping. The findings imply that the international regulations affected the growth of pharmaceutical firms in Kenya.

4.5.3 Extent to which International Laws Influenced the Growth of Pharmaceutical Firms in Kenya

The study sought to establish the extent to which the international regulations influenced the growth of pharmaceutical manufacturing firms in Kenya. The findings are presented in Figure 4.9

Figure 4. 9: Extent International Laws Influenced the Growth of Pharmaceutical Firms in Kenya



The study findings show that 43.3% of the respondents indicated international laws had influenced the growth of pharmaceutical firms in Kenya to a moderate extent.

The findings further show that according to 36.7% of the respondents, the international laws had influenced the growth of the firms to a large extent. The findings mean that the international laws have to some extent influenced the growth of the pharmaceuticals in Kenya.

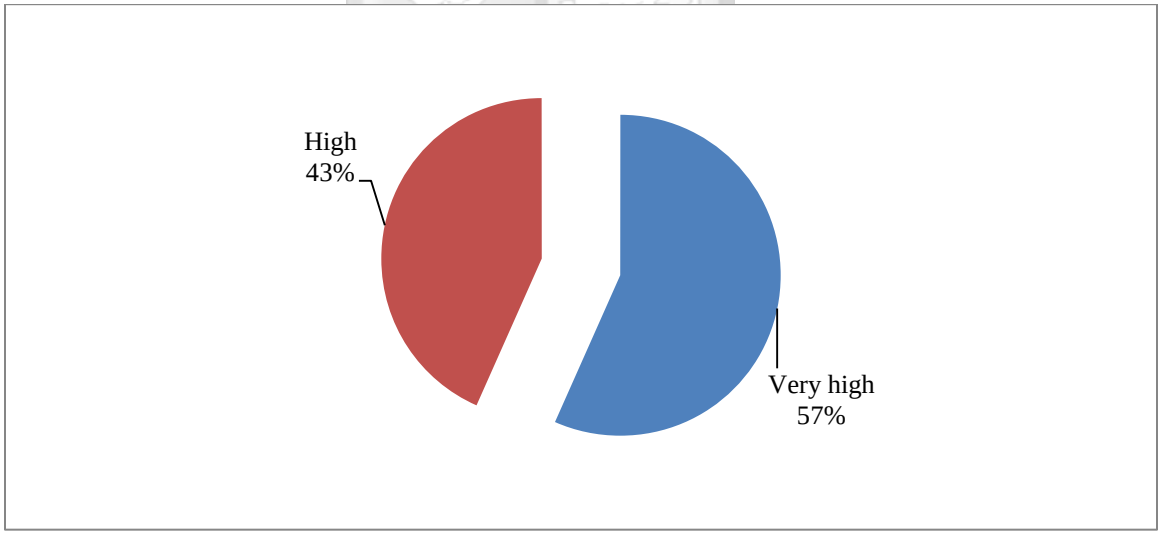
4.6 Effect of Cost of Production on Growth of Pharmaceutical Manufacturing Firms

The researcher sought to determine the effect of the cost of production on the growth of the pharmaceutical manufacturing firms in Kenya. The findings are presented in the subsequent sections.

4.6.1 Description of Cost of Producing Drugs in Kenya

The respondents were asked to describe the cost of producing drugs in Kenya. The results are presented in Figure 4.10

Figure 4. 10: Description of Cost of Producing Drugs in Kenya

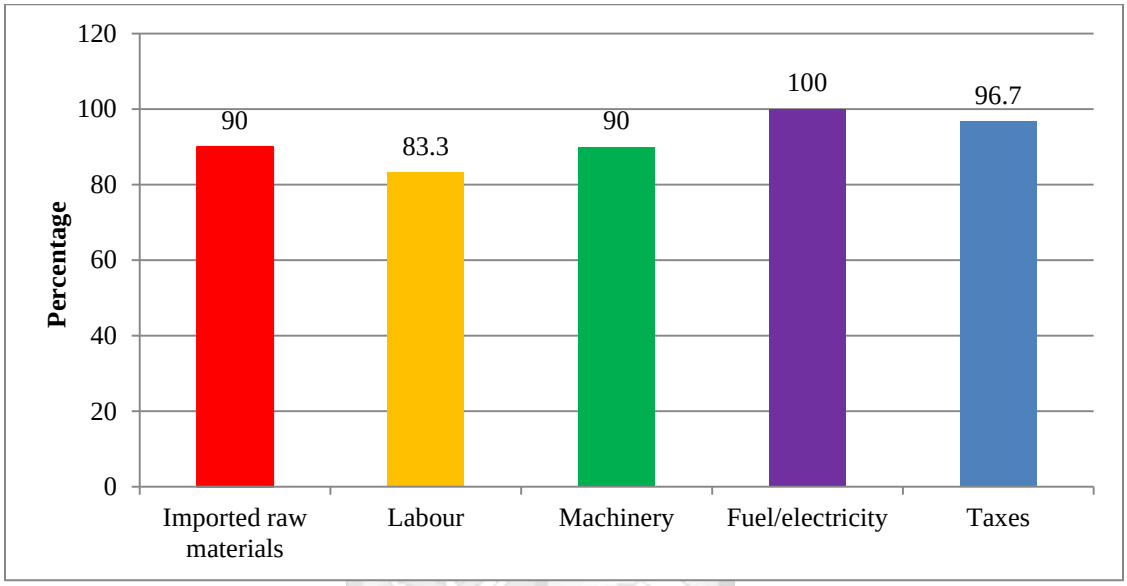


Results show that 57% of the respondents described the cost of producing drugs in Kenya as very high while 43% termed at as high. The findings mean that the cost of producing drugs in Kenya is high.

4.6.2 Drivers of Cost of Producing Drugs

The respondents were asked to indicate the main drivers of the cost of producing drugs in Kenya. The findings are presented in Figure 4.11

Figure 4. 11: Drivers of Cost of Producing Drugs



The study findings show that all the listed factors including raw material, labour, machinery, fuel/electricity and taxes were all potential drivers of the cost of producing drugs in Kenya. The results show that 90% of the respondents stated that imported raw materials and machinery drove high the cost of production. The results further show that according to 83.3% of the respondents, labour was a determinant in the cost of producing drugs. All the respondents cited fuel/electricity as a major determinant of the cost of producing drugs. Last but not least is taxes which 96.7% of the respondents named as one of the drivers to cost of production.

4.6.3 Effects of Cost of Production on Organizational Growth

The respondents were asked to state whether they agreed or not with the statements provided with regard to the effect of cost of prodicing drugs on the growth of the pharmaceutical manufacturing firms in Kenya. The findings are presented in Table 4.6.

Table 4.8: Effects of Cost of Production on Organizational Growth

	Yes	No	Total
Cost of raw material too high	83.3	16.7	**100**
Taxes levied on raw materials make production expensive	53.3	46.7	**100**
Pharmaceuticals pay government a lot of money as levies for doing business	76.7	23.3	**100**
Transportation and electricity costs are too high	93.3	6.7	**100**
Cost of production is generally too high hence high cost of local drugs	86.7	13.3	**100**

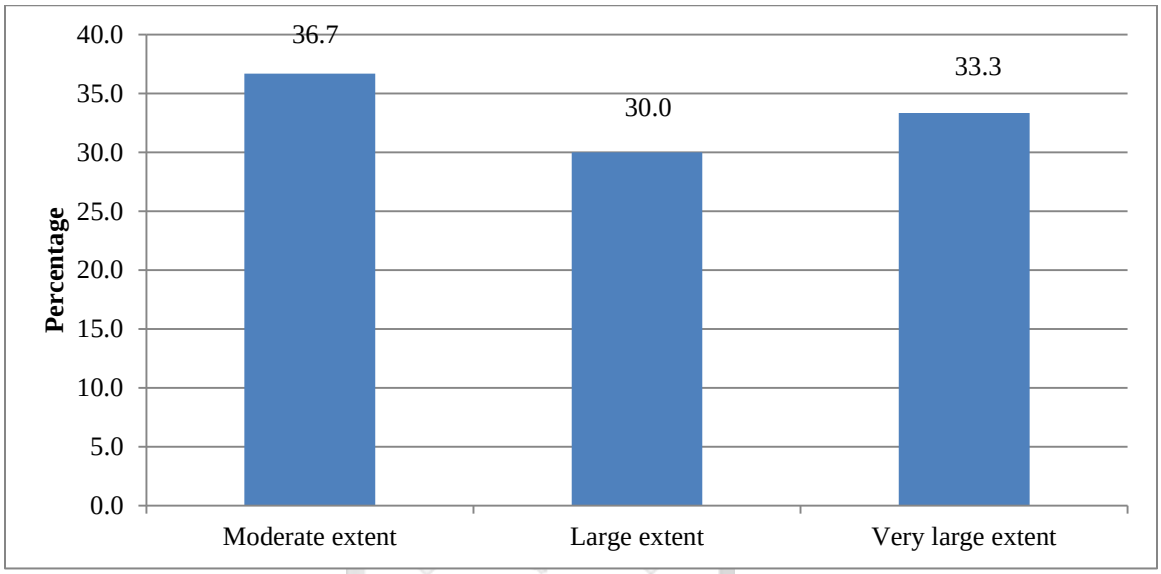
The study findings show that majority of the respondents (83.3%) agreed that indeed the cost of raw materials was high. The findings further show that most respondents (53.3%) agreed that the tax levied on the raw materials make the production expensive.

Majority of the respondents (76.7%) agreed to the statement that the pharmaceuticals pay government a lot of money as levies for doing business. The results show that 93.3% of the respondents agreed that indeed the transportation and electricity costs were too high. Last, the 86.7% of the respondents agreed with the statement that the cost of production was generally too high hence the high cost of the local drugs. From the findings of the study, inference can be made that the cost of production was high making locally manufactured drugs expensive hence less competitive when compared to imported drugs.

4.6.4 Extent to which Cost of Production has Influenced Growth of Pharmaceutical Manufacturing Firms

The respondents were asked to indicate the extent to which the production cost had influenced the growth of pharmaceutical manufacturing firms in Kenya. The findings are presented in Figure 4.12.

Figure 4. 12: Cost of Production has Influenced Growth of Pharmaceutical Manufacturing Firms



The findings show that 36.7% of the respondents stated that the cost of production had influenced the growth of pharmaceutical manufacturing to a moderate extent. A further 33.3% of the respondents indicated that the cost of production influenced growth to a very large extent while 30% indicated that it did to a large extent. The findings mean that the cost of production significantly influenced the growth of local pharmaceutical manufacturing firms in Kenya.

Asked to state how the cost of production had influenced the growth of pharmaceuticals manufacturing in Kenya, the respondents stated that due to the high cost of production, the prices of the locally produced drugs remain high and therefore cannot compete favorably with cheap drugs from giants like India who have dominated the Kenyan market and the surrounding regions. The respondents also stated that many firms have had to shut down as they have been rendered irrelevant due to the production of unaffordable drugs which cannot sell both locally and internationally.

4.7 Regression

The researcher further carried out regression analysis to establish the statistical significance of the relationship between the independent variables, competition, government regulation, international regulations and cost of production and the dependent variable, growth of pharmaceutical manufacturing firms in Kenya.

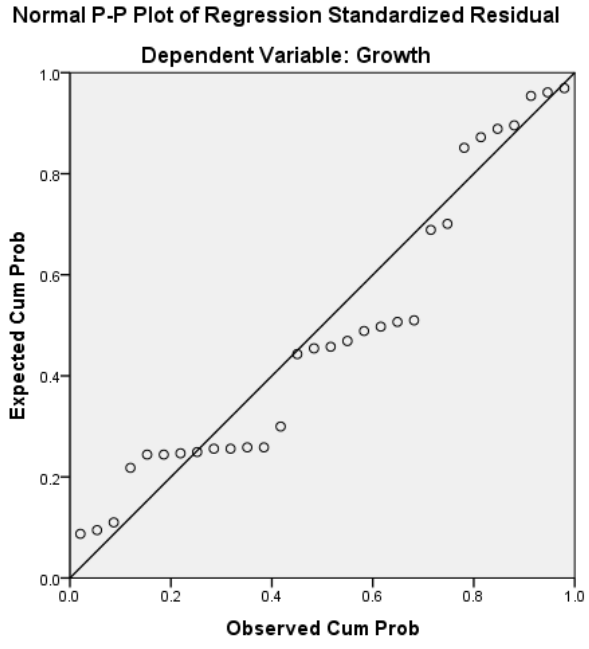
According to Green and Salkind (2003) regression analysis is a statistics process of estimating the relationship between variables. It helps in generating equation that describes the statistical relationship between one or more predictor variables and the response variable.

4.7.1 Diagnostic Tests

4.7.1.1 Test for Normality

The researcher tested for normality to check whether the test met the assumption of normal distribution using the normal predicted probability (P-P) plot to test whether the residuals are normally distributed. The findings are presented in Figure 4.13.

Figure 4. 13: Test for Normality

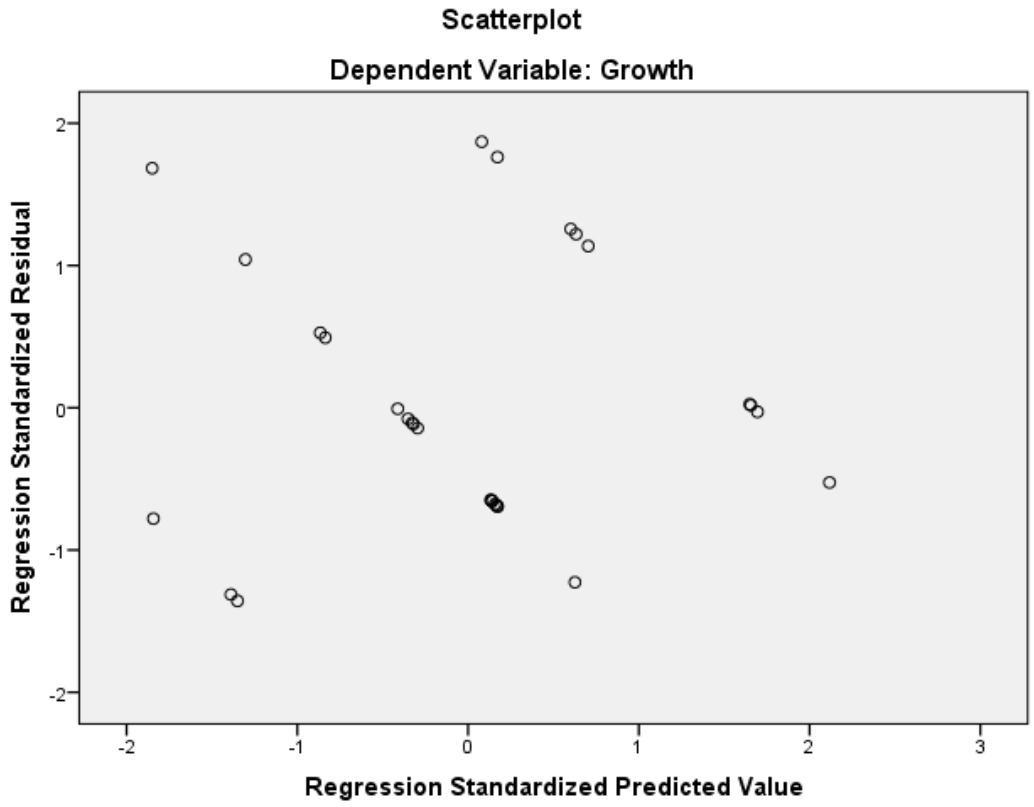


Analysis of the results show that the scatter plots follow the normality line hence the variances may be assumed to be normally distributed.

4.7.1.2 Test for Homoscedasticity

We tested for homoscedasticity of the regression to test whether the residuals are equally distributed. The findings are presented in Figure 4.14.

Figure 4. 14: Test for Homoscedasticity



Since the scaterplots are are scattered evenly, that is to the left and right of zero in the y-axis and also to the left and right of the x-axis, the distribution is said to be equal, hence the regression has passed the test of homoscedasticity.

4.7.1.3 Test for Multicollinearity

The third diagnostic test is the test for multicollinearity which refers to when predictor variables are highly correlated with each other. Since our study has multiple predictor variables, it was important to do the test. This was done using the variance inflation factor (VIF) values. The findings are presented in Table 4.9.

Table 4.9: Test for Multicollinearity

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Collinearity Statistics	
		B	Std. Error	Beta			Tolerance	VIF
1	(Constant)	.931	.583		1.597	**.023**		
	Competition	.232	.104	.291	2.228	**.035**	.899	**1.112**
	Government regulations	.221	.114	.246	1.940	**.044**	.952	**1.050**
	International laws	.729	.129	.764	5.643	**.000**	.837	**1.194**
	Production cost	-.236	.088	-.379	-2.683	**.013**	.772	**1.295**

a. Dependent Variable: Growth

The results show that since none of the VIF values is greater than 3.3, there is the absence of multicollinearity. If any VIF is equal to or greater than 3.3, then it can be concluded that collinearity is present in the model. Having satisfied these assumptions, the researcher proceeded with the regression analysis.

4.7.2 Regression Results

The regression analysis results were presented using regression model summary tables, analysis of variance (ANOVA) table and beta coefficient tables. Diagnostic tests were also performed to establish whether the assumptions of the regression including normality, homescedasticity and multicollinearity were met.

In Table 4.10, the coefficient of determination (R squared) is 0.616 which implied that 61.6% of the variation in the growth of pharmaceutical manufacturing companies in Kenya was explained by the competition, government regulations, international regulations and the cost of production.

The remaining 38.4% can be explained by other factors not included in the study. This implied that there existed a strong positive relationship between the independent variables and the growth of pharmaceutical manufacturing companies in Kenya.

Table 4.10: Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.785[a]	.616	.554	.407

a. Predictors: (Constant), Production cost, Government regulations, Competition, International laws

The ANOVA results for regression coefficients on Table 4.11 showed that the significance of the F statistics is 0.000 which is less than 0.05. This implied that there was a significant relationship between the competition, government regulations, international regulations and the cost of production.

Table 4.11: ANOVA

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	6.652	4	1.663	10.022	.000[b]
	Residual	4.148	25	.166		
	Total	10.800	29			

a. Dependent Variable: Sustainable Growth

b. Predictors: (Constant), Production cost, Government regulations, Competition, International laws

Table 4.12 presents the beta coefficients of all independent variables versus the dependent variable.

Table 4.12: Beta Coefficients

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	.931	.583		1.597	.023
	Competition	.232	.104	.291	2.228	.035
	Government regulations	.221	.114	.246	1.940	.044
	International laws	.729	.129	.764	5.643	.000
	Production cost	-.236	.088	-.379	-2.683	.013

a. Dependent Variable: Sustainable Growth

Fitted model $Y = 0.931 + 0.232X_1 + 0.221X_2 + 0.729X_3 - 0.236X_4$

The regression model was written as: Sustainable growth = 0.931 + 0.232 Competition + 0.221 Government regulations + 0.729 International regulations - 0.236 Cost of production

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CHAPTER FIVE
DISCUSSIONS, SUMMARY OF FINDINGS, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter presents the discussions and summary of the findings of the study. This is followed by the conclusions based on the findings from where the researcher has made recommendations for action. The chapter also presents limitations of the study and suggestions for further research.

5.2 Discussion of the Findings

The study established that most of the pharmaceutical firms (66.7%) were limited companies. Most of the firms were family owned and shareholding (53.3%, 30% respectively). The findings revealed that majority of the pharmaceutical manufacturing companies in Kenya (60%) have been in operation for over 20 years. The results revealed that 30% of the firms started with five employees of less while 36.7% started with between six and 10 employees. However, currently, a third of the firms have between 41 and 50 employees while 30% have over 50 employees. This is suggestive of growth in the local pharmaceutical manufacturing firms in Kenya. This is in contrast with the finding of Mackintosh et al (2016), who asserted that the growth of pharmaceutical manufacturing companies in developing countries and in the Sub Saharan Africa in particular has been on the decline since the global economic crisis of 2009.

The level of competition in the pharmaceutical manufacturing in Kenya was described as high by 96.7% of the respondents in the study. According to 70% of the respondents, the competition in the pharmaceutical sector was both local and international. Most of the respondents stated that there were a lot of imported drugs in the market (93.3%). Respondents further noted that generic drugs in the country resulted into unfair competition (53.3%). The business environment according to most respondents was unfair in favor of some competitors (53.3%), same as the market which favored international companies (70%). All the respondents who participated in the study had coping strategies in place to counter the competition in the sector.

Most respondents (53.3%) believed that competition influenced the growth of the firms to a large extent. There was a positive and significant relationship between competition and the growth of the firms. These findings are in line with Chong and Rundus (2004) and Odhiambo (2013) who noted that firms that are exposed to more competition in their domestic market are more likely to succeed in the international markets. According to them, competition opens up the eyes of the firms to look beyond their domestic markets and start looking at other markets which in the end results in a positive growth.

Most of the respondents (70%) were aware of the existence of government legislation on growth of the pharmaceutical manufacturing firms in Kenya. Majority of the respondents (67%) indicated that indeed the government offered incentives to the local pharmaceutical manufacturing firms. Respondents stated that the government had given a 15% preferential treatment for local manufacturers in public procurement tenders.

The government has exempted taxation of some raw and packaging materials used in production of pharmaceuticals. Further the government has zero rated VAT on all pharmaceutical exports. According to most of the respondents (60%), legislation was aimed at enhancing the growth of the pharmaceutical manufacturing in Kenya, but only to moderate extent. 56.7% of the respondents believe that the government legislations affect the growth of the pharmaceutical manufacturing firms in Kenya only to a moderate extent.

From the regression analysis, there was a positive and significant relationship between government regulations and the growth of the firms. These findings agree with Hunsen and Mitchell (2000) who noted that government regulations significantly determine the growth of a firm. However, the findings contradict Brasher and Lowery (2006) who argued that government regulations are weak explanatory variables for firms' performance. On the importance of the government incentives, the study findings concur with Oliver (1997) and Zapalska (2001) who noted that government interventions through incentives and subsidies are particularly important for the development of local companies.

They also argued that the development of local firms relies on the government support policies while enhancing competitiveness is the fundamental guarantee for the firm's survival.

All the respondents described the cost of producing drugs in Kenya as either high (47%) or very high (53%). The drivers of high cost of production in Kenya included raw material, labour, machinery, fuel/electricity and taxes. According to 90% of the respondents, imported raw materials and machinery drove high the cost of production. On the other hand, 83.3% of the respondents indicated that the high cost labour made the locally manufactured drugs expensive, hence less competitive. All the respondents cited fuel/electricity as a major determinant of the cost of producing drugs. According to 96.7% of the respondents, taxes was as one of the drivers to cost of production. These findings are in agreement with McGlaphreri (2003) who noted that the main drivers of the cost of production for many firms included labour and the raw materials. Most respondents noted that pharmaceuticals companies paid government a lot of money as levies for doing business (76.7%). Transportation and electricity costs were also termed as too high (93.3%). Respondents strongly agreed that the cost of production was too high hence the high cost of the local drugs (86.7%). According to majority of the respondents (63.5%) the cost of production had influenced the growth of pharmaceutical manufacturing. The results from the regression analysis revealed that there was a negative and significant relationship between the cost of production and the growth of the firms. These findings agree with Williamson (2008) who noted that the factors which increased the cost of doing business included taxes, electricity and the raw materials among others which have a direct influence on the firms operations and eventual growth.

According to the study, a majority of the respondents (87%) were aware of the international regulations governing the operations of pharmaceutical manufacturing companies. Most respondents were in agreement that there was a lot of regulations with regard to international practices (90.0%). The findings further revealed that there was a lot of demand from the local manufacturers to export to foreign countries (90.0%). International regulations favored the multinational pharmaceutical firms (83.3%).

These findings support the views of Prasad and Javasuriwa (2003) who noted that developing countries find it difficult to develop standards that are straightforwardly acceptable by the developed nations and they therefore have hard time in meeting standards and regulations set by developed countries. According to 43.3% of the respondents, the international laws moderately influenced the growth of pharmaceutical firms in Kenya. However, 36.7% of the respondents, think that the international laws had influenced the growth of the firms to a large extent. There was a positive and significant relationship between international regulations and the growth of the firms.

The study findings show that three of the four analyzed variables had a positive relationship with the independent variable except the cost of production which had a negative relationship.

The findings therefore mean that a unit change in competition will result into a 0.232 positive change in the same direction in the growth of the firms. The findings further show that, a unit change in government regulation will result into a 0.221 positive change in the growth of the pharmaceutical companies. The results mean that a unit change in international regulations will result in a 0.729 change in the same direction of the growth of pharmaceutical firms. Finally, the results mean that a unit change in the cost of production will result in a 0.236 change in the opposite direction in the growth of pharmaceutical manufacturing firms in Kenya. The findings show that all the tests were statistically significant as the p-values were less than 0.05.

5.3 Summary of the Findings

The firms experienced growth as there was increase in the number of employees over the years for all the firms that participated in the study. The study established that competition positively influenced the growth of the firms. However, most of the firms described the competition in the industry as high and further stated that there was a lot of imported drugs while at the same time, that the environment favoured their competitors.

The results revealed that the most of the respondents were aware of the international regulations guiding the manufacturing of drugs. There was a positive effect of the government regulations and international regulations on the growth of the firms in Kenya. However the effect of a unit increase in cost of production was negative growth in the local manufacturing firms

5.4 Conclusion

The study established that there has been increase in the number of employees by the firms from their inception to date. The firms have experienced an increase in the number of employees which signifies growth. The study established that there has been competition in the sector which had positive effects on the growth of the local pharmaceutical manufacturers. Government regulations also favoured growth of the local firms in Kenya. This could be attributed to government policies by aimed at enhancing growth in the sector. The study concludes that the international regulations have worked to the benefit the local firms even though they seem to favour the multinationals. Further, the study concludes that the cost of production in Kenya largely driven by cost of raw materials, energy, labour, machinery and taxes had a significant negative influence on the growth of these firms.

5.5 Limitations of the study

Literature review identifies management as a critical factor which has tremendous impact on a firm's performance and trajectory. This study neither quantified the managerial aspects nor its impact on sustainable growth. Further, determination of growth was based on employee numbers. Other constructs including financials, asset base and cost development may also be used as indicators of growth.

Modifiers of growth such as environmental considerations and inadequacy of technical expertise especially in a pharmaceuticals sector which is highly advanced in technology may play an important role. Formulation of valid constructs to analyze them and collection of reliable financial data proved difficult.

These aspects were therefore not included in the study and may explain part of the remaining 38.4% of the variation in sustainable growth of pharmaceutical manufacturing firms in Kenya that was not explained by the regression model. These may inform areas of further research

5.6 Recommendations

The study made the following recommendations

According to this study, 61.6% of the variation in the sustainable growth of local pharmaceutical manufacturers in Kenya was explained by four factors competition, government regulations, international regulations and the cost of production. These factors therefore are relevant and may be studied further.

The government should encourage competition in the sector such as by lowering barriers to entry and by providing an enabling environment for competitive strategies to thrive while maintaining sanity and ethical oversight.

The government should enhance existing regulations and introduce new ones that encourage innovativeness in the industry, protect investments, encourage growth and promote markets. Legislations on regional integration, reciprocal trade treaties, environmantal protection, market access, labour and technology transfers should be enhanced to promote sustainable growth of pharmaceutical manufacturing firms in Kenya.

Managers of the local pharmaceutical manufacturers should adhere to the international regulations so as to enhance their products competitiveness in the international markets. This will ensure sustainable growth.

Lastly, the government should review its tarrifs especially on energy, imported raw materials to lower the cost of production for the pharmaceutical manufacturing firms in Kenya. Labour relations should be regulated so as to enhance productivity protect the interests of employees and employers. There is need for reasoning even as this is happening.

5.6 Suggestions for Further Research

This study was only done on the pharmaceutical manufacturing firms in Kenya and specifically Nairobi. The study suggests that similar studies should be done in other sectors of the economy and manufacturing sector in particular with the aim of establishing the factors affecting their growth in Kenya.

Other areas of further research may include the impact of management on sustainable growth. Sustainable growth may be measured using other constructs such as financials, asset base and cost development where reliable data is available collected over a longer period of time.

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APPENDICES

APPENDIX 1: QUESTIONNAIRE

1. Nature of Firm registration:

   Sole Proprietorship [ ] Partnership [ ] Limited Company [ ]

   Other [ ] specify.....

2. Type of ownership:

   Owner-Managed [ ] Partnership [ ] Shareholding [ ] Family-owned [ ]

   Other [ ] specify……..

3. Number of years in operation

   0 – 5 [ ] 6 – 10 [ ] 11 – 15 [ ] 16 – 20 [ ] Over 21 [ ]

4. How many employees did your organizations start with? Less than 5 [ ]

   6 – 10 [ ] 10 – 15 [ ] Over 15 [ ]

5. How many employees are there currently? Less than 10 [ ] 10 – 20 [ ]

   21 – 30 [ ] 31 – 40 [ ] 41 – 50 [ ] Over 50 employees

SECTION B: COMPETITION

1. How would you describe the level of competition in the pharmaceutical sector in Kenya? Very high [ ] High [ ] Moderate [ ]

   Low [ ] Very low [ ]

2. From where does your competition originate? Local [ ] International [ ]

   Both local and international [ ] Others (specify)_____

3. State the extent to which you agree with the following statements with regard to competition in the pharmaceutical industry on a scale of 1-5 where 1=strongly disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly agree

	1	2	3	4	5
There is a lot of importation of drugs in the country					
There are so many counterfeit products in the market					
The generic drugs in the country has resulted into unfair competition					
The business environment is unfair in favour of some competitors					
The market favors the international companies The local companies are not up to the task in terms of competitive advantage					

4. Do you have coping strategies to counter the competition?

   Yes [ ] No [ ]

5. Explain your answer_____

_____

6. To what extent has competition influenced the growth of your organization?

   No extent [ ] Small extent [ ] Moderate extent [ ]

   Large extent [ ] Very large extent [ ]

7. How in your opinion, has competition influenced the growth of your firm?

   _____

   _____

   _____

SECTION C: GOVERNMENT LEGISLATION

8. Are you aware of any legislation by the government for the growth of the pharmaceutical manufacturing in Kenya? Yes [ ] No [ ]
9. a) Does the government offer incentives to local pharmaceutical manufacturing firms aimed at enhancing their growth? Yes [ ] No [ ]

   b) If yes, what are the incentives?_____

_____

_____

10. To what extent is there government legislation aimed at enhancing the growth of pharmaceutical manufacturing industry in Kenya?

    No extent [ ] Small extent [ ] Moderate extent [ ]

    Large extent [ ] Very large extent [ ]

11. To what extent has the government legislation affected the growth of pharmaceutical firms in Kenya?

    No extent [ ] Small extent [ ] Moderate extent [ ]

    Large extent [ ] Very large extent [ ]

12. In your opinion, what legislation should the government put in place to enhance the growth of pharmaceutical manufacturing in Kenya?

_____

_____

_____

_____

SECTION D: INTERNATIONAL REGULATIONS

13. Are you aware of international regulations governing the operations of the pharmaceutical manufacturing? Yes [ ] No [ ]
14. If yes, how would you describe these regulations?

    Punitive [ ] Relatively friendly [ ] Very friendly [ ]

15. State the extent to which you agree with the following statements with regard to the effect of international regulations on the growth of pharmaceutical industry in Kenya on a scale of 1-5 where 1=Strongly disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly agree

	1	2	3	4	5
There is a lot of regulations with regard to international practice					
A lot is demanded from the local manufacturers to export to foreign countries					
The international regulations favour multinational pharmaceutical firms					
International regulations favour dumping					

16. To what extent have these laws influenced the growth of pharmaceutical manufacturing in Kenya? No extent [ ] Small extent [ ] Moderate extent [ ] Large extent [ ] Very large extent [ ]
17. In your opinion, how has the international regulations influenced the growth of pharmaceutical manufacturing in Kenya?

_____

_____

_____

SECTION E: COST OF PRODUCTION

18. How would you describe the cost of producing drugs in Kenya?

    Very high [ ] High [ ] Fair [ ] Low [ ] Very low [ ]

19. What are the main drivers of the cost of producing drugs?

    Imported raw materials [ ] Labour [ ] Machinery [ ]

    Fuel/electricity [ ] Others

    specify_____

20. State the extent to which you agree with the following statements with regard to the effect of cost of production on the growth of pharmaceutical industry in Kenya on a scale of 1-5 where 1= Strongly disagree, 2= Disagree, 3= Neutral, 4= Agree, 5= Strongly agree

	1	2	3	4	5
The cost of raw materials is too high					
The taxes levied on raw materials makes production expensive					
The pharmaceuticals pay government a lot of money as levies for doing business					
The transportation cost and electricity is too high					
The cost of production is generally too high driving up the cost of local drugs					

21. To what extent has the cost of production influenced the growth of your firm?

    No extent [ ] Small extent [ ] Moderate extent [ ] Large extent [ ] Very large extent [ ]

22. In your opinion, how has the cost of production influenced the growth of pharmaceutical manufacturing in Kenya?

_____

_____

VT OMNES VNVM SINT

APPENDIX 2: APPROVAL BY SU –IRB

Strathmore UNIVERSITY

19th March 2018 SU-IRB 0181/18

Douglas Weru
P.O Box 59857, 00200
Nairobi

Email: werud08@gmail.com

Dear Douglas Weru,

REF **Student Number:** MBA/92694/16 **Protocol ID:** SU-IRB 0181/18
Title: An Analysis Of Factors Affecting Sustainable Growth Of Local Pharmaceutical Manufacturing Companies In Kenya

We acknowledge receipt of your application documents to the Strathmore University Institutional Ethics Review Committee (SU-IERC) which includes:

1. Study Proposal dated January 2018
2. Participant Information sheet and consent Form dated January 2018
3. Study Questionnaire dated January 2018
4. CV

The committee has reviewed your application, and your study *"An Analysis of Factors Affecting Sustainable Growth of Local Pharmaceutical Manufacturing Companies in Kenya"* has been granted **approval**.

This approval is valid for one year beginning **19th March 2018** until **18th March 2019.**

In case the study extends beyond one year, you are required to seek an extension of the Ethics approval prior to its expiry. You are required to submit any proposed changes to this proposal to SU-IERC for review and approval prior to implementation of any change.

SU-IERC should be notified when your study is complete.

Thank you

Sincerely,

Amina Salim
Regulatory Affairs Fellow

STRATHMORE UNIVERSITY INSTITUTIONAL REVIEW BOARD APPROVED