TABLE OF CONTENTS

Declaration ................................................................................................. i
Copyright .................................................................................................. ii
Abstract .................................................................................................... iii
Acknowledgement ...................................................................................... v
Dedication ................................................................................................... vi

CHAPTER ONE ............................................................................................... 1
1.0 INTRODUCTION ...................................................................................... 1
1.1 Background of the Study ........................................................................ 1
1.2 Statement of the Problem ........................................................................ 7
1.3 Purpose of the Study ............................................................................... 8
1.4 Research Questions ............................................................................... 8
1.5 Significance of the Study ....................................................................... 9
1.6 Scope of the Study ................................................................................. 9
1.7 Definition of Terms .............................................................................. 9
1.8 Chapter Summary ............................................................................... 10

CHAPTER TWO .............................................................................................. 12
2.0 LITERATURE REVIEW ........................................................................... 12
2.1 Introduction .......................................................................................... 12
2.2 Steps by Government to Promote Research and Development .......... 12
2.3 Government Interventions to reduce the cost of Production in the Industry ...... 16
2.4 Government Interventions to create an enabling legal framework in the Industry .......... 22
2.5 Chapter Summary ............................................................................... 26

CHAPTER THREE .......................................................................................... 27
3.0 RESEARCH METHODOLOGY ............................................................... 27
3.1 Introduction .......................................................................................... 27
3.2 Research Design ................................................................................... 27
3.3 Population and Sampling Design ........................................................... 28
3.4 Data Collection Methods ..................................................................... 30
3.5 Research Procedures .......................................................................... 31
3.6 Data Analysis Methods ....................................................................... 31
3.7 Chapter Summary ............................................................................... 31
CHAPTER FOUR .................................................................................................................. 33

4.0 RESULTS AND FINDINGS ................................................................................................. 33
  4.1 Introduction ....................................................................................................................... 33
  4.2 Demographic Information ................................................................................................. 33
  4.3 Steps by Government to promote Research and Development ...................................... 38
  4.4 Government interventions to reduce cost of production in the industry: .................. 39
  4.5 Government interventions to create an enabling legal framework in the industry .......... 45
  4.6 Chapter Summary .......................................................................................................... 52

CHAPTER FIVE ...................................................................................................................... 53

5.0 DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS ........................................ 53
  5.1 Introduction ....................................................................................................................... 53
  5.2 Summary of Findings ....................................................................................................... 53
  5.3 Discussion ......................................................................................................................... 54
  5.4 Conclusion ......................................................................................................................... 60
  5.5 Recommendation ........................................................................................................... 62

REFERENCES ....................................................................................................................... 66

APPENDICES ......................................................................................................................... 71

APPENDIX I: IMPLEMENTATION SCHEDULE .................................................................... 71
APPENDIX II: BUDGET ......................................................................................................... 72
APPENDIX III: QUESTIONNAIRE ......................................................................................... 73
LIST OF TABLES

Table 3.1: Population .................................................................28
Table 3.2: Target Population.........................................................30
Table 4.1: Gender of Respondents................................................33
Table 4.2: Designation .................................................................34
Table 4.3: Type of Company........................................................34
Table 4.4: Category of Products....................................................34
Table 4.5: Type of Products........................................................35
Table 4.6: Determinants of Product Portfolio.................................35
Table 4.7: Tender Business...........................................................36
Table 4.8: Percentage of Tender Business of Annual Sales.............36
Table 4.9: Annual Sales...............................................................36
Table 4.10: Annual Cost of Goods Sold.......................................37
Table 4.11: Type of Research......................................................38
Table 4.12: Collaboration with Research Institution or University.....38
Table 4.13: Importance of Bioequivalence (BE) studies..................39
Table 4.14: Number of employees...............................................39
LIST OF FIGURES

Figure 4.1 Spend on Raw Materials .................................................40
Figure 4.2 Spend on Packaging Materials ......................................40
Figure 4.3 Spend on Labour .........................................................41
Figure 4.4 Spend on Energy .........................................................41
Figure 4.5 Spend on Water .........................................................42
Figure 4.6 Spend on Property Tax ...............................................42
Figure 4.7 Spend on Corporate Tax ..............................................43
Figure 4.8 Spend on Property Insurance .......................................43
Figure 4.9 Awareness in changes in legislature ..............................44
Figure 4.10 Simplicity of regulatory processes ...............................45
Figure 4.11 Difficulty of regulatory processes .................................45
Figure 4.12 Regulatory costs .......................................................46
Figure 4.13 Ease of doing business through an online portal ............46
Figure 4.14 Taxation policies .......................................................47
Figure 4.15 Disposal of expired or rejected products .......................47
Figure 4.16 Significance of counterfeits ........................................48
Figure 4.17 Government measures to combat counterfeits ...............48
Figure 4.18 Significance of KIPI ....................................................49
Figure 4.19 Importance parallel importation ...................................49
Figure 4.20 Parallel importation negative effect on businesses ...........50
CHAPTER ONE

1.0 INTRODUCTION
1.1 Background of the Study

According to the World Health Organization (WHO) the health sector is defined as being comprised as people, institutions and resources integrated through a policy framework with the common objective of promoting, maintaining and restoring health. It comprises of government ministries, hospitals, other health services, and health insurance schemes, voluntary and private organizations in health, the pharmaceutical industry, drug wholesale companies and retail pharmacies. In many developing countries, private not-for-profit health care providers constitute an important part of the health system (World health organization, 2016).

The pharmaceutical industry is therefore within the larger health sector and plays a vital role in the provision of health care. Globally, the Economic Footprint of the Pharmaceutical Industry by Dennis A. Ostwald indicates that the industry has a far reaching impact on the world’s economy, with a total economic footprint of $437 billion in terms of Global World Product (GWP). For comparison purposes the GWP is estimated to be US$76 trillion therefore the sub sector accounts for 0.5%. The 10 largest drugs companies control over one-third of this market, several with sales of more than US$10 billion a year and profit margins of about 30%. The impact of this sector from an economic perspective is significant as the figures above illustrate and provides employment to over 4 million people in America, Europe and Asia throughout the supply chain from the Active Pharmaceutical Ingredient (API) manufacturer to the end consumer (Ostwald, 2013).

Governments across the world invest heavily in health; the global figure estimated to be US$7 trillion dollars. WHO recommends that each person requires a minimum of US$ 44 dollars per year on health and that most of this should be funded from pre-paid systems such as insurance and not out of pocket expenditure. Total health expenditures range from 3.95% of GDP in Equatorial Guinea to 17.85% of GDP in the United States. The importance of these figures is to indicate the variances in different parts of the
world. There is a positive relationship between the wealth and health expenditure of a country. Subsequently a positive relationship between the health expenditure and life expectancy of a country (World Bank, 2016).

From a global perspective with the biggest players being based in Europe and America are innovators therefore their main challenge is the reduction in the launches of novel drugs. With the growing resistant strains of microbes, changing patient demographics and disease patterns there needs to be a rethink by the global pharmaceutical manufacturers in terms of putting resources and infrastructure in these markets (World health organization, 2016).

Another point of concern is the stiff competition from generic manufacturers. It is estimated that from research and development to product launch to the market the Big Pharma companies spend about US$ 2.6 billion in developing a new prescription medicine that gains marketing approval, a process often lasting longer than a decade according to a study by the Tufts Center for the Study of Drug Development (Tufts Centre for drug development, 2014). Once the patent has expired the generic drug manufacturers are able to produce the same drug at lower costs and able to recover the investment faster. These drugs are equally as effective, fit for intended use, safe and affordable. With the ever increasing cost of health burden these drugs are here to stay; evidently so having already indicated the challenges being faced by governments in developing countries. This is however a glaring opportunity for pharmaceutical manufacturing in Africa (World health organization, 2010).

The pharmaceutical industry operates within a regulatory framework supported by laws of the land. The purpose of these authorities is to ensure the regulation and control of medical products such as medicines, vaccines, blood products and medical devices. They are to ensure that they protect public health. This is enforced by ensuring that medicines are of the required quality, safety and efficacy. Provide access to information on proper drug use by both health professionals and patients. These authorities are required to ensure that medicines are appropriately handled throughout the supply chain. Regulate advertising of medicines and more
importantly access to medicines is not hindered by unjustified regulatory work. These processes take time, requiring high level of expertise therefore the manufacturing companies have to abide by the set regulations. For instance it can take up to 12 months to give market authorization for a new drug molecule therefore delaying the returns on investment (Baines, 2010).

The pharmaceutical industry in Asia offers room for growth with a market size of USD 106.8 Billion of which half is Japan’s consumption. The average per capita consumption in Asia, which has a population of 3 billion people, stood at US$36 per person. In contrast with the US at US$839 and Europe at US$439, indicating room for growth in Asia. In 2004–2005, the Asian economy as a whole grew by 4.9%, compared to 3.5% in the US and a tepid growth of 1.7% in Europe. Most countries in Asia are developing economies, with the exception of Japan and the four newly industrialized economies (NIEs) of South Korea, Taiwan, Hong Kong, and Singapore. The disease profile of the developing economies is significantly different from that of the more developed economies of US, Europe, and Japan. Asia has a lower incidence of lifestyle diseases such as cardiovascular and central nervous system. The main drugs consumed are generic which are manufactured locally under government price controls in order to make them affordable to the public. The advantage for Asia is the low cost of labour which is lower when compared to the west; a qualified scientist in India will be paid four times less than in the US. Due to this European and American multinationals such as Novartis and Pfizer look to Asia to outsource drug development to reduce the cost burden of bringing a new drug to the market. The challenges being faced by Asian countries such as Japan is looking outside of the domestic market which is getting saturated. The markets are too fragmented in India and China with about 10% of the top firms having only 15% market share. This is consequently leads to very competitive environment giving rise to price wars and paper thin margins. Singapore on the other hand had a stimulus package which attracted MNCs to do Foreign Direct Investments to develop a strong Research and Development (R&D). However due to its weak local pharmaceutical manufacturing capacity realization of the benefits
from its research will be difficult. As such, Singapore needs to develop an approach to keep these companies in Singapore in order to drive a self-sustaining ecosystem, where profits earned from the sale or licensing deals of these novel drugs are reinvested in Singapore (Liew, 2006).

The Scandinavian pharmaceutical industry is comprised of Sweden, Denmark, Norway and Finland. The pharmaceutical companies focus on biotechnology and innovation with over 400 potential new drug molecules undergoing clinical trials which is markedly different from generic manufacturing in Asia. Capital raised by biotechnology and medical technology companies headquartered in Europe measured €4.29 billion and €3.23 billion in 2013, to a total of €7.52 billion. The Nordic countries raised a total of €852 million, contributing with 11.5% of the total capital raised in Europe. The Finnish pipeline is the smallest in the Nordics, about 20% of the Swedish and about 25% of the Danish in size. Most compounds, about 20%, are developed within neurology, while the rest are spread out between cancer, infectious, autoimmune, cardiovascular and respiratory disease. Another difference to note is that Scandinavian countries focus on lifestyle disease as opposed to its Asian and African counterparts. The challenges facing Scandinavian pharmaceutical industry is the global pressure to have accessible and affordable medicines by the public. Companies are required to develop a broader set of skills than those in-house, in order to be able to build multiple business models across diverse channels to serve diverse customers. These include, among others, sophisticated analytics capabilities, social media platforms, customer segmentation experience and more. The Nordic Life Sciences industry players would also like to see an increased openness from and collaboration with the pharmaceutical manufacturers and the health care industry ((EY, 2014)

There is also a growing threat from the counterfeits posing a bigger problem on public health due to the questionable quality of the product. WHO classifies these as substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products? Further to the endangering lives they lead to loss of trust in the health systems
with anti-malarials and antibiotics being the most reported SSFFC medical products. This problem is global and affects both innovator and generic medicines ranging from the most expensive such as anti-cancer drugs to pain relievers (World health organization, 2016).

From the African perspective the pharmaceutical sector is worth US$ 20.8 billion in 2013 compared to US$ 4.7 billion in 2003. which when compared with the GDP for Africa at US$ 6 Trillion therefore constituting 0.34%. Africa’s pharmaceutical industry is the fastest growing in the world and is driven by the following countries Algeria, Angola, Cameroon, Egypt, Ethiopia, Ghana, Kenya, Libya, morocco, Nigeria, South Africa, Sudan, Tanzania, Tunisia and Uganda. According to the New Partnership for Africa’s Development (NEPAD) situation analysis on disease burden Africa is not on track to meet the health millennium declaration. The key issues to be addressed are maternal mortality, infant mortality, communicable diseases such as AIDS, malaria, TB and others such as Trypanosomiasis, Schistosomiasis, Dracunculiasis (Guinea Worm) and Filariasis. Cholera, Meningitis, Ebola and Marburg outbreaks continue, while intermittent cases of Human Avian Influenza remind the continent of the pandemic threat that mutation poses. Further to this is the burden caused by non-communicable diseases such as Hypertension, stroke, diabetes, chronic respiratory disease and cancer. Malnutrition and low vaccination rates in parts of Africa poses a challenge towards a healthy Africa. NEPAD cites insufficient sustainable financial resources and the efficient allocation and use thereof, poor commodity security and supply systems and unfair trade practices favoring the rich countries, Marginalization of African Traditional Medicine in national health systems and Capacity of the private sector is not fully mobilized relevant to this study. The Kenyan government spends about 8% of its GDP on health. According to a 2005 WHO report the average expenditure was US$11 of which US$5 was out of pocket expenditure. This is far below the recommended US$44 discussed earlier. (World health organization, 2010). The Kenyan Health Sector Strategic plan is drafted in line with Vision 2030 that aims to transform Kenya into a globally competitive and prosperous country with a high
quality of life by 2030 through transforming the country from a third world country into an industrialized, middle income country. The Kenya health policy has as a goal, ‘attaining the highest possible health standards in a manner responsive to the population needs’. The policy aims to achieve this goal through supporting provision of equitable, affordable and quality health and related services at the highest attainable standards to all Kenyans (New partnership for Africa’s development, 2007).

The pharmaceutical industry consists of three segments namely the manufacturers, distributors and retailers. All these play a major role in supporting the country’s health sector, which is estimated to have about 4,557 health facilities countrywide. 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. Out of the region’s estimated of 50 recognized pharmaceutical manufacturers; approximately 30 are based in Kenya. It is approximated that about 9,000 pharmaceutical products have been registered for sale in Kenya. Kenya pharmaceutical industry exists in the larger health sector and operates with a legal framework governed by Pharmacy and Poisons Act, Cap 244, Industrial Property Act, 2001, Anti-Counterfeit Act, December 2008 and Kenya Public Procurement and Disposal Act, 2005. The regulator is the Pharmacy and poisons Board while institutional environment comprises of Federation of Kenya Pharmaceutical Manufacturers (FKPM), Kenya Association of Pharmaceutical Industry (KAPI), Kenya Association of Manufacturers (KAM), Kenya Private Sector Alliance (KEPSA), Kenya Health Federation (KHF), PPP-Health Kenya and Pharmaceutical Society of Kenya (PSK) (Export processing zones authority, 2005).

The demand for medicines in Kenya are driven by disease incidence, procurement; notably the government purchases drugs through KEMSA, exports to the East African Community through establishment of a common market and common external tariffs. Those covered under a health scheme are likely to acquire medicines than those who have to pay out of pocket. There are many challenges facing the industry from policy,
ease of doing business, high production costs, counterfeits, lack of affordable financing and parallel importation (United Nations Industrial Development Organization, 2010).

There are a number of reasons why the local pharmaceutical sector should be strengthened. The economic benefits include more local jobs and skills development for nationals, savings of foreign exchange through import reduction, facilitation of technology transfer, stimulation of pharmaceutical exports and local innovation in new treatment regimens and dosage forms (Export processing zones authority, 2005).

1.2 Statement of the Problem

In 2008 the imports were valued at US$ 277 million while exports at US$ 59.4 million. There is a trade imbalance and the figure is an underestimate considering actual spending includes donor-funded purchases of medicines and unintentional spending on counterfeits. It can be deduced that local industry has less than a 30 per cent market share. This is, however, an upper estimate of local producers’ share in the domestic pharma market. If donor-funded purchases were taken into account, the market share of local manufacturers would be substantially lower and, correspondingly, the market share of imports would be higher, since donor procurement is sourced entirely outside Kenya. The gaps are; the local manufacturers focus on simple molecules sold over the counter (OTC) product manufacturing which is already highly saturated. Inability to produce essential medicines that meet the standards for international tenders as demanded by WHO prequalification with its emphasis on manufacturing and product international regulatory compliance (Orwa, Kibwage, Keter, & Ouko, 2004). High cost of production due to high costs of energy, expensive labor, and unfavorable taxation policies of locally manufactured pharmaceutical products compared to imports from China and India (United Nations Industrial Development Organization, 2010). Absence of a local "enabling business environment", i.e. effective and coordinated incentives and support for local pharmaceutical production of essential drugs according to international pharmaceutical standards. It is difficult to access affordable credit, (Mbuvi, 2011) limited attention and support for pharmaceutical R&D, when clear
opportunities exist (PATH, 2015); lack of a harmonized regulatory processes in the EAC to facilitate business (Chemwolo, Ngoni, & Clark, 2010). There is the glaring problem of counterfeits as discussed earlier worsened by poor perception of sub-region produced medicinal products. The inability to exploit TRIPS flexibilities as counterparts in India and China have done whether by voluntary or compulsory means. Another important factor is the parallel importation of medicines which is a complex concept which allows a distributor to import and sell drugs already registered in the market ideally after having given proof that the local market authority holder has been unable to meet the needs of the market and normally at a lower cost increasing accessibility (UNIDO, 2010).

However, there has been no study done on effective government strategies for enhancing the private pharmaceutical manufacturing sector in Kenya. Therefore, this study would provide probable government interventions that could be implemented to spur growth of the industry.

1.3 Purpose of the Study

The purpose of the study is to determine the government incentives to spur growth in the pharmaceutical manufacturing industry in Kenya.

1.4 Research Questions

1.4.1 What are steps that the government can take to promote research and development?

1.4.2 What government interventions can be taken to reduce the cost of production in the industry?

1.4.3 What government interventions can be taken to create an enabling legal framework in the industry?
1.5 Significance of the Study

1.5.1 Academia and Manufacturing Sector

The economic significance include more local jobs and skills development for nationals, Savings of foreign exchange through import reduction, Facilitation of technology transfer and stimulation of pharmaceutical exports and local innovation in new treatment regimens and dosage forms.

1.5.2 Public Health Sector

The social impact includes safe, efficacious, quality, affordable medicines, improved quality of life and increased life expectancy for Kenyans

1.6 Scope of the Study

There are 3000 pharmacists registered with the Pharmacy and poisons board. Those working in the pharmaceutical industry sector are 400 who have the technical knowledge and expertise. The industries are based in Nairobi and are 36 in number. The study is projected to take a period not exceeding 12 months; targeted completion date is December 2016. The expected limitations of the study are access to data from the national regulatory body and from the distributors (importers) who are the manufacturers’ major competitors.

1.7 Definition of Terms

1.7.1 Active Pharmaceutical Ingredient (API)

An active pharmaceutical ingredient is defined in ICH Q7 as “any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product (International conference on harmonization, 2000).
1.7.2 Innovator Pharmaceutical Product

This is a product that which was first authorized for marketing (normally as a patented product) on the basis of documentation of efficacy, safety and quality (according to requirements at the time of the authorization). When a substance has been available for many years, it may not be possible to identify an innovator pharmaceutical product (World health organization, 2016).

1.7.3 Generic Pharmaceutical Product

Usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights (World health organization, 2016).

1.7.4 Market Authorization

An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality (World health organization, 2016).

1.7.5 Parallel Imports

These are imports of a patented or trademarked product from a country where it is already marketed (World health organization, 2016)

1.8 Chapter Summary

The purpose of this study is to determine effective government strategies to spur growth in the pharmaceutical manufacturing company. The research questions are the tax policies that can be implemented to increase competitiveness, what are the government interventions can be taken to reduce the cost of production in the sector and what are steps that the government can take to promote research and development. The scope of the study are pharmacists working in the pharmaceutical manufacturing and distributing companies in Kenya.
The chapters to follow are literature review will give a review of the literature related to the problem and purpose as per the research questions or specific objectives in order to ensure relevance to the research problem. Chapter three on methodology which will provide an explanation and description of the methods and procedures used in conducting the study. Chapter four on results and findings which will present and explain the data. The findings will be presented and analyzed on the basis of the research questions and specific objectives. Chapter five on Discussion, Conclusions and Recommendations which will provide recommendations are often provided for practice or improvement and opportunities for further research.
CHAPTER TWO

2.0 LITERATURE REVIEW
2.1 INTRODUCTION

The specific objectives of the study are to determine the actions that government can take to promote research and design. Secondly to determine actions the government can take to reduce the cost of production and thirdly provision of a favorable legal framework in order to increase competitiveness of pharmaceutical manufacturing within the pharmaceutical industry.

2.2 Steps by Government to Promote Research and Development

Research and development (R&D) consists of investigative activities that a business chooses to conduct with the intention of making a discovery that can either lead to the development of new products or procedures, or to improvement of existing products or procedures. Research and development is one of the means by which business can experience future growth by developing new products or processes to improve and expand their operations (Dodgson, Gann & Salter, 2008).

The pharmaceutical manufacturing sector the steps of research and development are described as discovery, commercialization, licensing and marketing. The pharmaceutical industry has been known for its creation of innovative products (Horrobin, 2001). However, the industry's innovative pipeline has dried out over the last decade. The pharmaceutical industry has unique characteristics such as a highly regulatory environment, long development cycles, and a high level of risks and costs in the R&D process. Time from discovery to marketing of a new drug requires on average 8-10 years (Ganguli, 2003).

According to the United States government accountability office (1998) there were increased costs from $16 Billion to $40 Billion on research and development but the number of new drug approvals from Food and Drug Authority have not been commensurate to the investment. The report states that there are a number of
attributable reasons. These include limitations on the scientific understanding on the translation of discoveries to safe and effective drugs, management decisions, intellectual property protections and ever changing regulatory standards. The recommendation suggested were increasing numbers of scientists who possess the skills needed to translate drug discoveries into effective new medicines. Allowing conditional drug approvals in therapeutic areas that lack adequate and effective treatment by restructuring regulation of the drug review process and shorter clinical trials using fewer numbers of patients; and altering the length of patent terms to encourage innovation. They cautioned however that this notwithstanding adequate measures to ensure safety need to be implemented along with any changes to expedite the regulatory review process.

2.2.1 Industry and Universities or research institutions partnerships

Universities and industry have been collaborating over the years primarily through funding discrete research proposed by those in postgraduate studies. With the changing global knowledge economy there is need to form strategic partnerships designed to last longer, invest more and encourage competitiveness and therefore transform the role of university role in research in the 21st century (Science business innovation board, 2012).

A report indicates that there are lessons on policy notably policymakers need to ensure a predictable, stable environment of funding and regulate on for long-term strategic partnerships to thrive. Give universities the autonomy to operate effectively, and form partnerships. The best people to decide a university’s strategy are its own board and faculty heads, not government ministries. Reward activist, collaborative universities – and encourage more to be that way. Funding incentives work: government policy should reward, or at least not discourage, universities and companies that form strong partnerships (Wilson, 2012).

The industry-university partnerships require certain core elements needed to make a partnership work well. University leadership is vital, university presidents need to make
industry-university partnerships a strategic priority and communicate the message regularly to the entire academic community. Long-term strategic partnerships with built-in flexibility work best, both parties should start with a shared vision and develop a strategy, place the right people to form and maintain relationships and create platform for dialogue and constant follow up on projects. Less emphasis should be placed on intellectual rights and measuring outcomes. Multidisciplinary approach such that university and industry experts to work together across a number of disciplines (European commission, 2011).

2.2.2 Clinical trials & Bioequivalence studies

Clinical trials are defined as a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes according to the World Health Organization. The process of drug discovery is in five stages which must be adhered to in order to launch a product successfully according to the United States Food and Drug Authority. These are namely discovery and development, preclinical research, clinical research, regulatory review and finally post market survey monitoring. Typically, researchers discover new drugs through new insights into a disease process that allow researchers to design a product to stop or reverse the effects of the disease. Testing of molecular compounds to find possible beneficial effects against any of a large number of diseases, existing treatments that have unanticipated effects and new technologies. At this stage there could be thousands of potential candidates. For development the pharmacokinetics are determined, mechanism of action, best route of administration, side effects, how it reacts to different races, its interaction with other drugs and effectiveness (Food and drug authority, 2015).

Before conducting clinical trials on humans preclinical studies must be done mainly establish the safe dose either through test tube experiments or in whole living organisms primarily animals. However the new drug molecules have to be tested in humans and therefore the need to conduct clinical trials a study plan or protocol is developed and
must determine selection criteria, how many people participate, how long the study will last, the control group, what are the parameters of interest and how the data will be analyzed. There are 4 main phases in clinical trials. Phase 1 is conducted on few people to determine safety and dosage they are healthy or those with the condition. Phase 2 is conducted with several hundreds of people to determine efficacy and side effects. Phase 3 is conducted on thousands with purpose of determining efficacy and monitoring adverse reactions. Phase 4 is conducted on thousands of those with the condition in order to determine safety and efficacy. Many new drug molecules do not make it past the second stage estimated that only a third are successful. 30% of these pass to the final stage therefore one can deduce how costly the exercise is (Food and drug authority, 2015).

The regulatory body has to review the application and approve or disapprove the use of the drug in the market. The manufacturer or researcher submits a new drug application which contains all matters from discovery to clinical trials to the national regulatory body which then gives marketing authorization. The final stage is post market survey which entails routine manufacturer inspections and surveillance of what is already in the market Therefore, the true picture of a product’s safety actually evolves over the months and even years that make up a product’s lifetime in the marketplace (Food and drug authority, 2015).

2.2.3 Funding of R&D

The costs of developing a drug is approximated to be $1 billion and therefore making it a very expensive endeavor for any manufacturing or research firm. Consequently funding opportunities should be made available. The principal investors in drug development differ at each stage. While basic discovery research is funded primarily by government and by philanthropic organizations, late-stage development is funded mainly by pharmaceutical companies or venture capitalists. The period between discovery and proof of concept, however, is considered extremely risky and therefore has been difficult to fund. Initiatives have been undertaken to overcome this funding gap through government state bodies in the US such as California Institute for
Regenerative Medicine, Texas Cancer Initiative which provide grants and loans. The Food and Drug Administration (FDA) encourages the use of Cooperative Research and Development Agreements (CRADAs) to foster public–private partnerships in targeted areas of interest to the agency (Gambrill, 2007).

There are proposed approaches to facilitate drug development which include academic initiatives as discussed under section 2.1.1. Government initiatives provision of research funding based on forecast morbidity and funding of the national drug regulatory bodies. Private initiatives such as technology transfer, new incentives for venture capitalists through tax law, academic and industry working together. A mention also that research should be geared as per the needs of the community. Four business models for drug development are described a not-for-profit pharmaceutical company, a foundation that operates a virtual company linking investors with biopharmaceutical companies, a for-profit company with a vested interest in rare diseases, and a global private-equity fund dedicated to advancing drug discovery. There needs to be a systematic manner of sharing information through a national database (Wizemann, Robinson & Giffin, 2008).

Bioequivalence studies are conducted to show that the generic drug manufactured by a company is comparable in terms of quality, safety, and efficacy to the innovator drug and therefore clinically interchangeable. A generic company ordinarily would start to manufacture after innovator patent expiration. This is required during the evaluation at drug registration by the regulatory authority in order to safeguard the public. Human volunteers are used in these studies whereby the test product and reference product are given and blood and urine tests are done. (International conference of harmonization, 2013). Bioequivalence studies are suitable for the Kenyan set up since almost all manufacturers are generic inclined.

2.3 Government Interventions to reduce the cost of Production in the Industry

Production cost refers to the cost incurred by a business when manufacturing a good or providing a service. Production costs include a variety of expenses including, but
not limited to, labor, raw materials, consumable manufacturing supplies and general overhead. Direct costs are expenses that a manufacturing company can connect to a specific product. Indirect costs are the costs associated with creating a particular product to include the price of maintaining the entire company.

2.3.1 Direct costs:
2.3.1.1 Labour

The bureau of labor statistics, a United States bureau agency indicates in a 2011 report that the highest compensated per hour in manufacturing are Australia, Canada and Belgium at greater than $54 per hour. United States was in the middle at $35 and the least compensated Philippines at $2 per hour. The pharmaceutical industry subsector was one the highest paying in US at $48 an hour the scope was Europe, America and Asia. China and India were reported separately as wages and employment do not follow the international standards (United States department of labor, 2011).

The hourly compensation of workers in china and India is $1.37 and $1.16 respectively. China employs over 90 million people in its manufacturing sector and has been growing consistently over the recent years. In order to gauge a country’s productivity one has to measure the GDP per hour worked. Australia had a GDP of $50 dollars for every hour worked, United states at $60 dollars for every hour worked while Korea had a GDP of $30 dollars for every hour worked. This means that though Australia is the best payer its returns on the dollar are not comparable to its counterparts. GDP per hour worked is one measure of labor productivity. Although it relates output to labor hours involved in its production by all persons in a country, it does not measure the specific contribution of labor or any other factor of production. Rather, it reflects the joint effects of many influences, including changes in technology; capital investment; utilization of capacity, energy, and materials; the use of purchased services inputs, including contract employment services; the organization of production; and managerial skill; in addition to the characteristics and effort of the workforce (United States department of labor, 2011).
According to the World Bank Kenya ranked equal to China in terms of productivity but lose 40% of this advantage through indirect costs. It states that Africa is not a cheap place to produce due to the institutional and physical business environment such as unreliable infrastructure, contract enforcement difficulties, crime, corruption and poor regulation. This is reflected by the fact that Africa constitutes 2% of world trade. A critical measure of any country’s competitiveness is represented by its production cost structure. The existing literature has shown the potential loss in productivity due to costs faced by firms outside their factory gates, and investors do pay attention to these costs when deciding on a site location. Compared to firms in East Asia, for example, it costs African firms 19 percent more to produce one unit of sale—a considerable competitive disadvantage. As the global crisis looms on the African continent, this finding implies that Asian firms enjoy a much higher margin to absorb price shocks than African firms, while remaining viable producers (the World Bank, 2013).

2.3.1.2 Capital

Firms around the world need credit to be able to function. A sound business environment requires an efficient financial system capable of allocating resources to their most productive uses. Yet evidence from firm-level surveys shows that the cost of finance tops the charts of firm complaints around the globe. African entrepreneurs together with Latin American and Caribbean managers complain even more than firms in all other regions. More specifically, firms in Africa pay around 7 percent more in interest rates than firms in East Asia and in South Asia. In Eastern Europe and Central Asia, the difference is 4 percent. In the main competitors such as India, Thailand, Vietnam and China, borrowing funds is up to 40–70 percent cheaper than in Africa. Furthermore, since the interest rate charged by banks could be correlated with firm characteristics, we use these data to analyze capital cost after accounting for size, industry, export orientation, ownership, collateral requirements, sales, and value of machinery. Even after accounting for these costs, firms in Africa pay around 3–5 percent more in interest rates than firms in East Asia. The inability of banks to allocate credit more cheaply is reflected in the higher bank spreads seen in Africa. This
phenomenon could be related to inefficiencies in the banking system and to lack of competition in addition to the higher risk associated with African firms. Finally, our survey data confirm that the smaller the firm, the more expensive its credit when it finally receives it. In Africa, smaller firms pay an interest rate that is 1 percentage point higher than the interest paid by medium firms and 3 percentage points above the interest paid by large firms (The World Bank, 2013).

2.3.1.3 Electricity

Electricity costs in 2006 for 48 developing countries, of which 19 are in Africa. According to these data, one kilowatt hour (kWh) of electricity for industrial use in Africa costs, on average, US$0.068. Of all the regions documented, only in South Asia is electricity costlier, although this average is really driven by the high cost in Sri Lanka (US$0.137/kWh), while in India electricity costs US$0.06/kWh. Figure 3 shows that Africa is not competitive in terms of this key infrastructure cost. Firms in East Asia pay, on average, 7 percent less than firms in Africa for electricity, but firms in India and Vietnam pay some 11 percent less and even less than this in Brazil. As always, there is wide variation within Africa. Electricity costs are as low as approximately US$0.04 in Lesotho and Botswana and as high as US$0.14 in Senegal. Finally, it is interesting once again to see that in oil rich countries electricity is 20 percent cheaper, while in landlocked countries it is 15 percent more expensive (Africa development bank group, 2013).

According to the energy regulation commission Electricity generation in Kenya is liberalized with several licensed electric power producers, distributors and transmission utilities. The net electrical energy from the power generating plants is bought by the Kenya Power and Lighting Company (KPLC) through power purchase agreements (PPAs) approved by the Commission. For industrial consumption there is a fixed rate of $170 dollars and $0.07 per kWh (Energy regulatory commission, 2015).

Available research literature on power sector reform in Africa indicates that few African decision-makers question the underlying rationale of power sector reform.
Many simply accept it as a given and concentrate on identifying measures that would expedite the reform process. This tunnel vision perspective undermines the possibility of developing more nuanced alternatives that can generate a wider range of options that reflect the region's characteristics and institutional/management capacity. This article is based on a regional study by the authors reviewing the status, challenges and prospects of ongoing and planned power sector reform in eastern and southern Africa with special emphasis on the implications for the poor. Reforms have improved generation capacity as well as financial performance in certain utilities. However, there are several challenges that reforms are yet to address. These challenges include poor performance at the transmission and distribution end, increased electrification of the poor and, increased local participation in the power sector. There is inadequate information and data on how ongoing and planned power sector reform can be modified to address the aforementioned challenges, particularly with regard to electrification of the poor. This article suggests a number of measures that could allow the poor to benefit from power sector reform (Karekezi & Kimani, 2002).

2.3.2 Indirect costs

Indirect costs are those incurred by firms in order to get what is produced to market as well as those associated with the broader environment in which they operate. The two crucial indirect costs are transport and regulation.

2.3.2.1 Transport

One important aspect in the global supply chain is represented by inland transportation costs. To be competitive it is essential to be able to move goods within a country cheaply. Africa’s geography does not help in this regard. A huge continent with a low ratio of roads per square kilometer and large distances represents a natural obstacle to competitiveness. Furthermore, Africa is the continent with the highest number of landlocked countries (two out of five landlocked countries in the world are in Africa). Not surprisingly, inland transportation costs are higher in Africa than in other regions.
It costs US$1,100, on average, to ship a typical container with imports inland; it costs US$872 for exports. This is higher than all other regions except Eastern Europe and Central Asia, where it costs US$1,141 and US$989, respectively. East Asia, South Asia, and Latin American and the Caribbean, on the other hand, enjoy a significant comparative advantage with respect to transport costs (United Nations economic and social council, 2009).

African landlocked countries pay close to one-third more in inland transportation costs than landlocked countries outside Africa (US$2,200 versus US$1,500). Those are significant costs that penalize firms in the continent. Another important aspect of transport costs is represented by port and terminal handling fees. These costs vary widely around the world, ranging from as low as US$50 to as high as US$1,000 per container. Africa not only displays the highest variation across countries (you can pay almost 10 times more in Côte d’Ivoire than in Mauritius, where these fees are only US$100), but again it remains the region with the highest average cost for both import and export handling fees (Faye et al, 2004).

### 2.3.2.2 Regulatory fees

The quality of the regulatory environment can encourage or discourage potential entrepreneurs to start a business, to expand its activity, or even to enter the formal economy. Evidence from other studies has shown that lower regulatory barriers stimulate entry into the formal sector. Whether Africa has a friendly regulatory cost environment can be answered by looking at the costs associated with three indicators: establishing a business, registering property, and dealing with customs. Starting a business in Africa is not expensive in nominal terms. The total cost of the startup procedures and the minimum capital requirements add up to approximately US$2,350. This is less than startup costs in East Asia or Eastern Europe and Central Asia, where starting a business runs around US$3,700.20 However, if we take into account the average income per capita, then establishing a company in Africa becomes
quite expensive. Finally, another important regulatory cost is that of customs clearance. In all countries, the great majority of firms import and export their inputs and goods. When exporting or importing, firms must follow the regulatory procedures enacted in each country (World health organization, 2012).

### 2.4 Government Interventions to create an enabling legal framework in the Industry

Each industry has a set of rules, rights and obligations to guide companies, governments, and citizens. The documents in the legal framework include a country’s constitution, legislation, policy, regulations and contracts. Pharmaceutical Laws and Regulation are necessary because use of ineffective or poor quality drugs can result in therapeutic failure, worsening of disease condition, resistance development to drugs by microbes and even death resulting in undermining of the whole health sector. Therefore in a bid to protect the public laws and regulation are approved by governments to establish effective national regulatory bodies. From the American perspective we have the Food and Drugs Authority and from Kenyan perspective there is the Pharmacy and Poisons Board. There is a difference between law and regulation. Laws enable governments to develop regulations that are much faster to implement and on approval bear the same power as the law itself.

#### 2.4.1 Taxation policy

Governments around the world need to provide the necessary services to ensure a good business environment. To achieve that, they levy a number of different taxes at different levels of administration. Being impossible to take all of them into account, we consider the three most common: corporate income tax, property tax, and value-added tax (VAT). Corporate tax rates vary considerably across regions, but Africa, together with South Asia, appears to be the least tax-friendly location to corporations.18 with a rate of approximately 30 percent, African firms seem to be among the most highly taxed
firms in the world. The difference with most regions, however, is not striking. In East Asia and Latin America, tax rates are 28 percent and 29 percent, respectively. Only in Eastern Europe and Central Asia are rates significantly lower, at 19 percent. The data also show a wide dispersion within each region, and especially within Africa. Botswana has the lowest corporate income tax in the world, with a 5 percent rate, while the Democratic Republic of Congo and Chad share with Bangladesh the highest rate at 40 percent. Nonetheless, corporate tax rates in Africa are similar to those in China, India, and Vietnam. Africa is the location with the highest property tax. Firms on the continent have to pay, on average, 7.5 percent of the value of the property in taxes. This is much higher than the 4.7 percent and 2.7 percent firms pay in East Asia and Latin America and the Caribbean, respectively. A similar picture emerges if we look at VAT. Africa applies one of the highest average rates at 16 percent (second only to Eastern Europe and Central Asia, with 19 percent), while VAT in all other regions amounts to 11–14 percent (Organization for economic co-operation and development, 2012).

2.4.2 Pharmacy and Poisons Act, Cap 244

The main legislation for the control of pharmacy in Kenya is the Pharmacy and Poisons Act, Cap 244. Its main purpose is to regulate the profession of pharmacy and control the manufacturing, trade, and distribution of pharmaceutical products. The provisions specific to the licensing of the manufacture of drugs for sale are contained in Part IIIA, section 35A. This provides for the license to manufacture medicinal substances, and Section 35B provides for compliance with Good Manufacturing Practices. The rule on the manufacture of drugs in Section 16 (5) of subsidiary legislation made under section 44 requires that the premises be licensed under a registered pharmacist, or one with an equivalent qualification. In the subsidiary legislation, Gazette Notice No. 147/1981, rules for registration of drugs came into operation. The fee for registration of locally produced drugs is US$ 500 compared with US$ 1,000 for imported drugs on first registration. An additional fee of US$ 4,000 is levied for GMP inspection abroad. New registration guidelines have recently been drafted and finalized. They were due to come into force at the beginning of March 2010 but were, in fact, still under consideration at
the time of publication of this report. The Federation of Kenya Pharmaceutical Manufacturers has appealed to the Ministry of Medical Services and the Pharmacy and Poisons Board to delay implementation of some sections and, in particular, the requirement for Bio-Equivalence studies until such time as Kenya has the infrastructure to deal with this aspect (CAP 244).

2.4.3 Industrial Property Act 2001

The Act provides for the promotion of inventive and innovative activities to facilitate the acquisition of technology by granting and regulating patents, utility models, technical innovations and industrial designs. In section 22, an invention is described as new and industrially applicable. It is popularly known as the “Patent Act” and, under section 60, the term of a patent is 20 years from the date of filing the application. The legislation conforms to the international protocols under WTO/TRIPS. The TRIPS flexibilities on the exploitation of the patented inventions provide for the obligations of the patent owner. This concerns importation into Kenya provided that the rights of the holder have been exhausted in the exporting country through manufacture within that country, importation into that country or otherwise. Voluntary Licensing (Sections 64-71): This is utilized for acquisition of technology or rights necessary for the manufacture of medicines. It normally starts with an interested person applying for a search at the Kenya Industrial Property Institute (KIPI). The search is intended to establish whether or not the process of manufacture and/or the drugs are patented in Kenya or elsewhere. Compulsory Licensing (Section 72-79): This measure is taken by governments to ensure that patent rights are not abused by owners or licensees to the detriment of their citizens. Governmental Use (Section 80): This is a government measure intended to safeguard public interest, in particular with regard to matters concerning national security, nutrition, health, environmental conservation or the development of other vital sectors of the national economy. The Minister for Industrialization may issue an order that a drug be imported or the process of manufacture, or any molecule or substance, be utilized by a government ministry, department, agency or other person as the Minister may designate in the order.
Intellectual property significance in technological and economic development has long been exploited by developed countries and now adopted by many developing countries. Kenya has established a national industrial property system but there is need to strengthen and upgrade existing systems. The importance of having laws governing the protection of industrial property are for the creators to benefit economically and secondly to promote creativity which in turn contributes to economic and social development. (World Intellectual Property Organization, 2004)

2.4.4 Anti-Counterfeit Act, December 2008

This Act was legislated to prohibit trade in counterfeit goods, including pharmaceuticals. The definition of counterfeiting has generated controversy because it is broad and over encompassing and includes substandard products. The emphasis in the WHO definition of counterfeit is somehow lost and a review of the revision would be well worthwhile since there is some concern that it is so broad that legitimate generic medicines could WHO definition of counterfeit medicine means one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include those with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging also be considered counterfeit. An Anti-Counterfeit Agency under the supervision of the Ministry of Industrialization is to be set up with a mandate to operationalize the Act. The impact of counterfeiting is a global effect, the industries find themselves in direct competition with the counterfeits which have evolved to be of better quality and more affordable. This leads to loss in sales. Further to this there is loss of trust by the customers when the counterfeit fails to perform to standard and blame lies with the market authorization holder. Thirdly, the cost of burden in enforcing intellectual rights is high as the aggrieved will spend resources in investigations and litigation when combating counterfeiters and may also have to spend further sums on product protection. The budget for anti-counterfeiting is rarely well defined within an organization, but spans across several departments such as marketing, human
resources, product development and legal departments. (Organisation for Economic Co-operation and Development, 1998)

2.5 Chapter Summary

This chapter describes the matters to be discussed under each research question which are industry–university collaborations, bioequivalence studies, and funding in relation to promoting research and development. Direct and indirect costs have been discussed as part of government interventions can be taken to reduce the cost of production in the sector. There are aspects of the legal framework in which the pharmaceutical manufacturing operates which can be reviewed to favor local manufacturing under CAP 244, Taxation laws, Industrial Property Act and Anti-counterfeit Act. The chapter to follow is methodology which will provide an explanation and description of the methods and procedures used in conducting the study.
CHAPTER THREE

3.0 RESEARCH METHODOLOGY

3.1 Introduction

This chapter presents the methodology that will be used in the study. It is divided into five sub-sections: research design, population and sampling design, data collection methods, research procedures and data analysis methods to be observed in the study. The purpose of the study is to determine effective government strategies for enhancing the private pharmaceutical manufacturing sector in Kenya.

3.2 Research Design

According to Keringer (1986), research design is the plan and structure of investigation so conceived as to obtain answers to research questions. It is the blueprint for fulfilling objective and answering questions. Selecting a design may be complicated by the availability of a large variety of methods, techniques, procedures, protocols and samplings plans (Cooper and Schindler, 2014).

A descriptive design will be used to establish determine effective government strategies for enhancing the private pharmaceutical manufacturing sector in Kenya. The justification for this is that the objective is find strategies for government to implement to increase the pharmaceutical sector competitive therefore A statistical study to identify patterns or trends in a situation, but not the causal linkages among its different elements. Descriptive studies (such as a cross-sectional study) help in generating hypothesis on which further research may be based. The research objectives of descriptive studies are, descriptions of phenomena or characteristics associated with subject population, estimates of the propositions of a population that have these characteristics and discovery of associations among different variables (Cooper and Schindler, 2014).
3.3 Population and Sampling Design

3.3.1 Population

Population is the total collection of elements whereby references have to be made (Copper and Schindler, 2008). According to Cooper and Schindler (2014), the target population is people, events or records that contain desired information and can answer the measurement questions and then determine whether a sample or census is desired.

The number of pharmacists working in the pharmaceutical industry comprising of both manufacturers and distributors are 400 however only 120 pharmacists work in manufacturing plants. Therefore the sampling frame and target population is 120 pharmacists working in the pharmaceutical manufacturing industry in Nairobi, Kenya.

**Table 3.1 Target Population**

<table>
<thead>
<tr>
<th>Type of Pharmaceutical establishment</th>
<th>Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multinational Manufacturers</td>
<td>12</td>
</tr>
<tr>
<td>Local Manufacturers</td>
<td>108</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>120</strong></td>
</tr>
</tbody>
</table>

Source: Researcher (2016)

3.3.2 Sampling Design

3.3.2.1 Sampling Frame

Sampling frame is defined by Pharmacy and Poisons Board (2014) as the list of elements from which a sample is actually drawn. It is a complete and correct list of population members from the government regulatory body. The sampling frame for this study is 120 pharmacists who practice in the pharmaceutical manufacturing industry.
3.3.2.2 Sampling Technique

Stratified random sampling technique will be used in the study. According to Sarandokos 2005, it is the probability sampling procedure was the target population is divided into a number of strata and a sample drawn from each stratum. The results from the study can be weighted and combined into appropriate population estimates (Cooper and Schindler, 2014). Reasons why the researcher chooses a stratified random sampling is to increase a sample’s statistical efficiency, to provide adequate data for analyzing the various subpopulations or strata and to enable different research methods and procedures to be used in different strata (Goode and Hatt, 1952).

The population will be divided into two strata; multinational manufacturers and local manufacturers.

3.3.2.3 Sampling Size

There are various ways to determine a sample size.

A sample size of 30% of target population is recommended according to Mugenda and Mugenda (2003). Secondly determining a margin of error which is more often than not less than 2.5%. Typical surveys have margins of error ranging from less than 1% to something of the order of 4%. Thirdly through confidence intervals 95% confidence intervals are typical but not in any way mandatory. In this study 30% of the population will be considered. Therefore the sample size is 40. Using the stratified random sampling formula the table below shows the distribution in different strata using the formula:

\[ n_i = \frac{N_i \times n}{N} \]

\[ n_i \] = number of establishments in the strata
\[ N_i = \text{Population size of category} \]
\[ N = \text{Overall population size} \]
\[ N = \text{Desired sample size} \]

Table 3.2 Target Population

<table>
<thead>
<tr>
<th>Type of Pharmaceutical establishment</th>
<th>Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Population</td>
</tr>
<tr>
<td>Multinational Manufacturers</td>
<td>12</td>
</tr>
<tr>
<td>Local Manufacturers</td>
<td>108</td>
</tr>
<tr>
<td>Total</td>
<td>120</td>
</tr>
</tbody>
</table>

3.4 Data Collection Methods

Data is defined by Cooper et al (2014), as the facts presented to the researcher from the study’s environment. Data collection is the process of gathering relevant data to guide in the process of answering the presented research questions.

The study will use both primary and secondary data. Primary data will be collected from the target. Questionnaires will be administered through drop and pick, email and survey monkey while secondary data will be drawn from past research findings, journal and the internet.

The questionnaires will be developed from the research questions and it will contain both open ended and closed ended questions. The questionnaires will be self-administered and shared to respondents by both pick and drop and email.
3.5 Research Procedures

A pilot test on the questionnaire will be conducted to establish its validity and reliability. A pilot test will be conducted using random sampling approach. The results from the pre-test will be analyzed using Comprehensive R Archive Network (R) and the results will be used to improve the questionnaire.

The refined questionnaires will be administered to the target population of the sampling frame elements within the respective strata under survey through self-administered questionnaires both by email and self-dropping and picking. This will ensure confidentiality, accuracy and anonymity of the respondents.

3.6 Data Analysis Methods

According to Mugenda and Mugenda (2008), data analysis is the process of giving structure and meaning to the mass of information collected. Statistical Program for Social Sciences (SPSS) will be used to interpret the data.

The quantitative data will be analyzed using descriptive and inferential statistics. General distribution which includes frequency and percentage, measures of central tendency which include the mean, mode, median, skewness and kurtosis and measures of dispersion which include standard deviation and variance will be used in descriptive analysis. While correlation will be used in inferential analysis.

The data will be presented in figures, bar graphs, histograms, tables and pie chart for easy interpretation and understanding.

3.7 Chapter Summary

This Chapter describes the research methodology that will be used by the researcher in conducting the study. The section describes the population of the study, the sampling
design and frame, the sampling technique, sample size, data collection methods and analysis by use of SPSS.

The subsequent chapter will present the results and findings of the study based on the research questions which are intended to provide the answers on the challenges faced in accessing key resources by startups in Nairobi, Kenya. The chapters to follow is results and findings which will present and explain the data. The findings will be presented and analyzed on the basis of the research questions and specific objectives.
CHAPTER FOUR

4.0 RESULTS AND FINDINGS

4.1 Introduction

This chapter presents the results and findings of the study based on data gathered from respondents. There are different sections from the questionnaire, the first section covers general information with regards to the respondent’s demographic information, the second, third and fourth covers the aspects in which this research tends to fulfil. The survey was sent online and required response from 40 respondents. This was a return rate of 100%.

4.2 Demographic Information

4.2.1 Gender of Respondents

Table 4.1 shows that majority of the respondents (57.5%) were male while 42.5% of the respondents are women.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>23</td>
<td>57.5</td>
</tr>
<tr>
<td>Female</td>
<td>17</td>
<td>42.5</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 4.1: Gender of Respondents

4.2.2 Designation in Company

Table 4.2 shows that 37.5% of the respondents are specialists in Quality Assurance which are the majority of the respondents. The second largest group of respondents are Regulatory Managers, Quality Control Managers and Company Pharmacists at 12.5% each while the Production Managers were 8%. Directors comprised of 5% of the respondents.
Table 4.2: Designation

<table>
<thead>
<tr>
<th>Designation</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Assurance Manager</td>
<td>15</td>
<td>37.5</td>
</tr>
<tr>
<td>Company Pharmacist</td>
<td>5</td>
<td>12.5</td>
</tr>
<tr>
<td>Regulatory Affairs Manager</td>
<td>5</td>
<td>12.5</td>
</tr>
<tr>
<td>Quality Control Manager</td>
<td>5</td>
<td>12.5</td>
</tr>
<tr>
<td>Production Manager</td>
<td>8</td>
<td>20</td>
</tr>
<tr>
<td>Director</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>100%</td>
</tr>
</tbody>
</table>

4.2.3: Type of Company

Table 4.3 shows the type of company where the respondents work. A majority of the companies are locally owned at 70% while 30% are multinationals.

<table>
<thead>
<tr>
<th>Company Type</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local</td>
<td>28</td>
<td>70</td>
</tr>
<tr>
<td>Multinational</td>
<td>12</td>
<td>30</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 4.3: Type of Company

4.2.4: Category of Products

Table 4.4 shows the product category make up manufactured in the different companies that the respondents work. Human medicines were the majority manufactured at 67.5 while those that manufactured only Animal Medicines were 12.5%. Those that manufactured both human and veterinary 20%.
### Table 4.4: Category of Products

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human</td>
<td>27</td>
<td>67.5</td>
</tr>
<tr>
<td>Veterinary</td>
<td>5</td>
<td>12.5</td>
</tr>
<tr>
<td>Both</td>
<td>8</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>100%</td>
</tr>
</tbody>
</table>

### 4.2.5: Type of Products

Table 4.5 shows the different product type mix that the respondents manufacture. From the total number of respondents 90% manufacture oral liquids indicating it’s the most favored formulation type. Oral liquids and topical ointments are at 77.5% and 60% respectively. Penicillins and Injectables (parenterals) were the least favorable at 32.5% and 22.5% respectively.

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Solids</td>
<td>77.5</td>
<td>22.5</td>
<td>100</td>
</tr>
<tr>
<td>Oral Liquids</td>
<td>90</td>
<td>10</td>
<td>100</td>
</tr>
<tr>
<td>Topical Ointments</td>
<td>60</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>Parenteral</td>
<td>22.5</td>
<td>77.5</td>
<td>100</td>
</tr>
<tr>
<td>Penicillins</td>
<td>32.5</td>
<td>67.5</td>
<td>100</td>
</tr>
</tbody>
</table>

### Table 4.5: Type of Products

### 4.2.6: Determinants of Product Portfolio

Table 4.6 shows the factors that drive product portfolio of the companies where the respondents work. 60% of the respondents indicated that the major determinant was market demand followed by profitability at 10%. Simplicity of manufacture and production capacity did not have much influence on what product would be introduced in a company’s portfolio at 7.5% each.
### Determinants of Product Portfolio

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profitability</td>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td>Market Demand</td>
<td>24</td>
<td>60</td>
</tr>
<tr>
<td>Simplicity of Manufacturer</td>
<td>3</td>
<td>7.5</td>
</tr>
<tr>
<td>Production Capacity</td>
<td>3</td>
<td>7.5</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>100</td>
</tr>
</tbody>
</table>

**Table 4.6: Determinants of Product Portfolio**

#### 4.2.7: Tender Business

Table 4.7 shows that 90% of the respondents work in companies involved in the tender business both governmental and non-governmental indicating that this is a reliable source of income when compared to sourced clients.

<table>
<thead>
<tr>
<th>Tender Business</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>36</td>
<td>90</td>
</tr>
<tr>
<td>No</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>100</td>
</tr>
</tbody>
</table>

**Table 4.7: Tender Business**

#### 4.2.8: Percentage of Tender Business of Annual Sales

Table 4.8 shows that a majority of the companies’ tender business account for 20-39% of their annual sales which is a significant amount.

<table>
<thead>
<tr>
<th>Percentage of Tender Business of Annual Sales</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-19</td>
<td>10</td>
</tr>
<tr>
<td>20-39</td>
<td>16</td>
</tr>
<tr>
<td>40-59</td>
<td>9</td>
</tr>
<tr>
<td>60-79</td>
<td>3</td>
</tr>
<tr>
<td>80-99</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
</tr>
</tbody>
</table>

**Table 4.8: Percentage of Tender Business of Annual Sales**
4.2.9: Annual Sales

Table 4.9 shows that a majority of the respondents worked in companies whose annual turnover is between KES 0.5 Billion and 1.0 Billion. 20-39% of their annual sales. This is a substantive source of revenue for the country and outlines the role of manufacturing companies in the growth of the economy.

<table>
<thead>
<tr>
<th>Annual Sales in millions KS</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-500</td>
<td>9</td>
</tr>
<tr>
<td>501-1000</td>
<td>13</td>
</tr>
<tr>
<td>1001-1500</td>
<td>10</td>
</tr>
<tr>
<td>1501-2000</td>
<td>3</td>
</tr>
<tr>
<td>2001-2500</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
</tr>
</tbody>
</table>

Table 4.9: Annual Sales

4.2.10: Annual Cost of Goods Sold

Table 4.10 shows that a majority of the respondents worked in companies whose annual cost of goods sold is between KES 0 to 0.4 Billion

<table>
<thead>
<tr>
<th>Annual Cost of Goods Sold in millions KS</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-400</td>
<td>11</td>
</tr>
<tr>
<td>401-800</td>
<td>10</td>
</tr>
<tr>
<td>801-1200</td>
<td>7</td>
</tr>
<tr>
<td>1201-1600</td>
<td>3</td>
</tr>
<tr>
<td>1601-2000</td>
<td>3</td>
</tr>
<tr>
<td>Unresponsive</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
</tr>
</tbody>
</table>

Table 4.10: Annual Cost of Goods Sold
4.3 Steps by Government to promote Research and Development

4.3.1 Type of Research Conducted by Companies

Table 4.11 shows that only 2.5% of the respondents work in a company that conducts only R&D of new products. 42.5% conducted product development which provides scientific justification for the formulation of already known products in the market. 30% of the respondents work in companies that conduct both types of research while 10% conducted neither of the two.

<table>
<thead>
<tr>
<th>Type of Research</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and Development</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Product Development</td>
<td>17</td>
<td>42.5</td>
</tr>
<tr>
<td>Both</td>
<td>12</td>
<td>30</td>
</tr>
<tr>
<td>Neither</td>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 4.11: Type of Research

4.3.2 Collaboration with Research Institution or University

Table 4.12 shows that 80% of the respondents worked in companies that had no collaboration with a research institution or university while a minority 5% do.

<table>
<thead>
<tr>
<th>Collaboration with Research Institution or University</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>No</td>
<td>32</td>
<td>80</td>
</tr>
<tr>
<td>Unresponsive</td>
<td>6</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 4.12: Collaboration with Research Institution or University
4.3.3 Bioequivalence (BE) studies are important for generic drug manufacturers

Table 4.13 shows that 60% of the respondents agree that BE studies are important while 32.5% disagree. Bioequivalent studies are conducted in place of clinical trials aimed to assure that the generic product is the same as the innovator. Despite the majority agreeing with this there were concerns on the delay from registration of product to market authorization, capacity in the case the center is set up locally and the cost implications.

<table>
<thead>
<tr>
<th>Bioequivalence (BE) studies are important for generic drug manufacturers</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>24</td>
<td>60</td>
</tr>
<tr>
<td>No</td>
<td>13</td>
<td>32.5</td>
</tr>
<tr>
<td>Unresponsive</td>
<td>3</td>
<td>7.5</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 4.13: Bioequivalence (BE) studies are important for generic drug manufacturers

4.4 Government interventions to reduce cost of production in the industry:
4.4.1 Number of employees
Table 4.14 shows that a majority of respondents work in companies that have not more than 400 workers. This sector demonstrates that it is a source of employment for both the skilled and semi-skilled workers.

<table>
<thead>
<tr>
<th>Number of employees</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-200</td>
<td>15</td>
</tr>
<tr>
<td>201-400</td>
<td>14</td>
</tr>
<tr>
<td>401-600</td>
<td>9</td>
</tr>
<tr>
<td>601-800</td>
<td>1</td>
</tr>
<tr>
<td>Unresponsive</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
</tr>
</tbody>
</table>

Table 4.14: Number of employees
4.4.2 Direct Costs

4.4.2.1 Raw Materials
Direct costs are costs directly linked to the manufacture of the product. On average the companies spend KES 333.2M annually on raw materials but with a wide range of KES 725M due to the significant difference in size and capacity of the factories.

![Cost of Raw Materials](image)

**Figure 4.1 Expenditure on Raw Materials**

4.4.2.2 Packaging Materials
A majority of the respondents spend KES 150M on packaging materials however the average spend is KES 218M. The high cost is attributed to the stringent quality attributes they must have especially for primary packaging materials which come into direct contact with the product.
4.4.2.3 Labour

The manufacturing industry employs a large number of personnel as indicated in the chart below. The proprietors spend on average of 121.9M annually on recurrent expenditure which has a positive impact on the economic growth of a country.
4.4.3 Indirect Costs

4.4.3.1 Energy

Energy costs are a huge concern for the pharmaceutical manufacturing companies in Kenya due to high cost per unit as compared to other equally industrialized nations as indicated in section 2.3.1.3. This is due to the frequent power outages and factories forced to use more costly alternative sources of fuel. The average spend on energy annually is KES 29.2M however this is pegged on the output of the factory as evidenced in the wide range of KES 53M.

![Cost of Energy](image)

**Figure 4.4 Expenditure on Energy**

4.4.3.2 Water

All respondents did not have reservations on the annual expenditure and deemed it justifiable. Considering that water is also a direct cost for some products for example oral liquids and parenterals which account for the most popular manufactured type of product.
The maximum that was spent on property tax which are the land rates charged by the county government were modest with the highest spend being KES 6M while on average KES 2.2M. These are the land rates charged dependent on the area and varies from county to county.

**Figure 4.6 Expenditure on Property Taxes**
4.4.3.4 Corporate Tax

The respondents are of the opinion that corporate tax rate is high at 30% of their net income as a company. As shown in the figure below it averages at KES 81.4M with the highest cashing out KES 160M to the government. A majority of the respondents worked in companies remitting taxes between KES 50-99M.

Figure 4.7 Expenditure on Corporate Tax

4.4.3.5 Property Insurance

A majority of the respondents spend between KES 10-19M to insure their factory’s infrastructure and machinery against fire, theft and destruction annually as these are their greatest assets which hold a significant amount of the companies investment. However the rates are set by the privately owned insurance firms with government or the regulator setting capping limits.
4.5 Government interventions to create an enabling legal framework in the industry

4.5.1 Legislature affecting Pharmaceutical Industry

The figure indicates that a majority of the pharmacists working in the industry are not aware of the dynamism in laws affecting their ways of working. Those that are aware constitute only 20% who then participate development of policies, guidelines, bills before they become law.

Key
1. Strongly Disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly Agree
Figure 4.9 indicates the levels awareness in changes in legislature in the pharmaceutical industry

4.5.2 Regulatory Processes

This is the processes involved in getting a pharmaceutical product from production to the market. It involves drug registration, processing permits, audits, licensing of practitioners, market surveillance of the products in the market, recalls of substandard products carried out the Pharmacy and Poisons Board. A majority of the respondents at 65% disagree that the regulator has made these processes simple.

Figure 4.10 indicates the level of agreement in the simplicity of regulatory processes

A majority indicate that the regulator has made the process difficult deliberately making it more difficult to carry out business. The significance of this is that it encourages non-compliance and subsequently corruption.
Figure 4.11 indicates the level of agreement that the regulator has intentionally made their processes difficult

4.5.3 Regulatory Costs

For each of the processes there is a set cost which a company has to pay in order to get the service done. A majority of the respondents are neutral as the fees are comparable to what is charged by the rest of the regulators in the EAC.

Figure 4.12 indicates the level of agreement that regulatory costs are prohibitive

4.5.4 Simplicity of doing Business through Technology

An online portal system where the pharmacists is able to request a service and pay via MPESA (mobile money network by Safaricom; a telecommunications company) has simplified work. Reduced physical visits to the offices and increased efficiency and 46% agree with this deduction. However 27% do not agree that the use of this technology has made things easier.
Figure 4.13 indicates the level of agreement that the regulator has made doing business easier by introduction of online portal

4.5.5 Government Taxation Policies

A majority of the respondents are of the opinion that the taxes paid are too high and should be looked into by government to reduce the cost per product and therefore able to compete with cheaper imports.

Key
1. Strongly Disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly Agree

Figure 4.14 indicates the level of agreement that taxation policies are unfavorable to local manufacturers reducing their competitiveness

4.5.6 Disposal of Expired orRejected products

Pharmaceutical waste should be disposed of in a manner that’s safe to the environment and ensuring that the waste product does not get back into the market otherwise it
becomes a liability to the company. A majority of the respondents were neutral while those that disagreed and agreed were comparable in number.

Figure 4.15 indicates the grouped responses on disposal of expired or rejected products disposed as per the recommended guideline

4.5.7. Counterfeit Medicine

A majority of the respondents indicated that counterfeits were not of concern for their companies. Counterfeited products are majorly highly marketed branded products whose budget could only be afforded by innovator pharmaceutical companies majorly multinationals. Multinationals are few as compared to local manufacturers who are generic manufacturers. This explains only 40% conceding that counterfeits are affecting their sales.

Figure 4.16 indicates the grouped responses that counterfeits are of concern to the manufacturers
Most respondents are neutral on measures taken by government to tackle counterfeiting. However there are more who agree that government is putting in place measures to combat counterfeits than those who generally disagree.

![Figure 4.17](image)

**Figure 4.17** indicates the grouped responses that the government has taken measures to combat counterfeits

### 4.5.8 Significance of Kenya Property Industrial Institute (KIPI)

From the responses below a majority of pharmacists have not had engagement with the body responsible for intellectual property in Kenya which could indicate the low level of research undertakings in the factories or lack of adequate public sensitization by KIPI.

![Figure 4.18](image)

**Figure 4.18** indicates responses that KIPI is of significance to the manufacturers
4.5.9 Parallel Importation

A majority agree that parallel importation as a concept in theory could increase accessibility of affordable healthcare to a larger population. Parallel importation affects the multinational corporations and not the local manufacturers.

**Figure 4.19 indicates responses on importance parallel importation in improving medicines access to affordable medicine**

Parallel importation in Kenya is carried out in an unregulated manner hence the majority of responses at 52.5% agreeing on its negative impact on business.

**Figure 4.20 indicates responses on the parallel importation negative effect on businesses**
4.6 Chapter Summary

The data collection was successful with 100% response rate through an online questionnaire. A majority of the respondents were male at 57% and 70% working in locally owned manufacturing companies. The human category of products emerged the top at 67.5% with Oral Liquids being the most popular type of product at 90%. Penicillins and Injectables (parenterals) were the least favorable at 32.5% and 22.5% respectively.

Market demand was the major driver of product portfolio for the companies with 90% of respondents working in companies that deal in tender business. The average annual sales turnover range was KES 500M to KES 1Bn of which 20-40% comprised of tender business and KES 81.4M corporate tax. Seventy five % of the respondents carried out research with only 5% having institutional collaboration. A majority of respondents indicated that bioequivalent studies were important and should be done by the generic manufacturers. The companies employed on average 200-400 employees. The biggest contributor to cost of goods sold were raw materials, packaging materials and energy. A majority of the respondents were not conversant with the changes in the legal framework and neutral on matters concerning taxation policies and regulatory. The respondents indicated that the regulator intentionally made regulatory process difficult however agreed that online portal has made it easier to conduct business. Surprisingly a majority of the respondents indicated that counterfeits were not of huge concern to the companies they worked on the other hand however parallel importation has negatively affected their bottom lines.
CHAPTER FIVE

5.0 DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter consists of four sections, namely summary, discussion, conclusions, and recommendations following that order. The first section provides a summary of the important elements of the study which includes the study objectives, methodology and the findings. The second section discusses the major findings of the study with regards to the specific objectives. The third section discusses the conclusions based on the specific objectives, while using the findings and results which are obtained in the fourth chapter.

5.2 Summary of Findings

The purpose of this study was to determine the government incentives to spur growth in the pharmaceutical manufacturing industry in Kenya. The study was guided by the following research objectives: steps that the government can take to promote research and development, government interventions can be taken to reduce the cost of production in the industry and government interventions can be taken to create an enabling legal framework in the industry.

This research adopted a descriptive research design. Structured questionnaires were used as the data collection tool. In this study, descriptive statistics such as frequency distribution and percentages were used to analyze the demographic profile of participants. The demographic data was tabulated using frequency and percentages.

The study revealed that the human category of products emerged the top at 67.5. % with Oral Liquids being the most popular type of product at 90%. Penicillins and Injectables (parenterals) were the least favorable at 32.5% and 22.5% respectively. Market demand was the major driver of product portfolio for the companies with 90% of respondents working in companies that deal in tender business. The average annual sales turnover range was KES 500M to KES 1Bn of which 20-40% comprised of tender business.
For the first research objective of steps by government to promote research indicates that only 2.5 % of the respondents work in a company that conducts only R&D of new products while 42.5% conducted product development. Thirty percent of the respondents work in companies that conduct both types of research while 10% conducted neither of the two; with only 5% having institutional collaboration. This points to the direction that government should focus on creating strong research collaborations between the industries and institutions in order to encourage R&D.

For the second research objective of government interventions to reduce production costs it was found the major contributors of high costs was materials, energy and taxes. In which energy was seen as an unjustifiable cost majorly because supply was not consistent and forced to use more expensive alternative source of fuel. Modest expenditure of property tax was a non-issue however the corporate tax rate was high to many respondents who felt it should be reduced downwards since manufacturing forms are a big source of employment hiring on average 200-400 employees per company.

For the third research objective on government interventions to create a favorable legal framework. A majority of the respondents pointed out parallel importation, counterfeits, insignificance of KIPI and taxation to be of concern. A majority of the respondents were not conversant with the changes in the legal framework and neutral on matters concerning taxation policies and regulatory. The respondents indicated that the regulator intentionally made regulatory process difficult however agreed that online portal has made it easier to conduct business. Surprisingly a majority of the respondents indicated that counterfeits were not of huge concern to the companies they worked on the other hand however parallel importation has negatively affected their bottom lines when compared to the previous years.

5.3 Discussion
5.3.1 Steps by Government to promote Research and Development.

From the quantitative data obtained 2.5 % of the respondents work in a company that conducts only R&D of new products while 42.5% conducted product development which provides scientific justification for the formulation of already known products
in the market. 30% of the respondents work in companies that conduct both types of research while 10% conducted neither of the two. Eighty percent of the respondents worked in companies that had no collaboration with a research institution or university while a minority 5% did. Bioequivalence studies were seen to be important by 60% of the respondents while agree 32.5% disagreed.

It is evident from the data that for achieving long term economics growth the amount of Research and Development is important. R&D leads to inventions and innovation, this improves the quality of manufacturing and updating of existing technologies. The countries that boast of prioritizing R&D by giving 3% of its GDP to the very purpose are Finland, Japan and Sweden.

Research universities in low- and middle-income countries have crucial roles to play in developing differentiated and effective academic systems, and in making it possible for their countries to join the global knowledge society and compete in sophisticated knowledge economies. Around the world, countries have recognized that research universities are key to the knowledge economy. In the United States and Britain, there was rising concern about the ability to maintain the standards of existing research universities. Germany had allocated resources to some key institutions, and Japan had funded grants. China and India has placed emphasis on creating ‘world-class’ research universities while several of Africa’s traditionally strong universities are seeking to improve their quality in an effort to achieve research university status, with assistance from external funders.

Many local manufacturers see it difficult to conduct research because it is costly to set up a minilab which is required since its operations are different from mainstream production. It would entail a recreation of miniature critical equipment used in the facility if carrying out product development. Generic manufacturers (a majority of firms found in Kenya) do not carry innovative research since that has been done by huge multinationals. They dwell on expired patents and make their own version of the medicine to push down costs and increase access. They therefore have the Active Pharmaceutical Ingredient but the process of how the drug was made is not disclosed.
after the patent is over. Generic manufacturers have then to figure out what are the excipients used and in what ratios.

Product development (PD) also takes time as stability studies have to be conducted to ensure the product can withstand the weather conditions it is marketed in. The minimum time it takes is 8 months consequently apart from it being expensive it is time consuming therefore extending time for return on investment. The human resource to conduct PD and R&D is not readily available and companies are forced to get experts from outside the country. Collaborations between universities and industries is wanting because of a myriad of factors. Universities approach to research is to protect and not to share the downside of this is that there will be no sustainable scale up of whatever invention they create because only industries have the capacity to do this. The Kenyan universities are yet to be developed to research centers and this will take time and commitment from the different stakeholders so that their role and importance begins to be realized by the industries. Multinational corporations which have local manufacturing subsidiaries do not incur the cost R&D in Kenya as they have centralized research centers in Asia, America and Europe. Therefore all that they require to do is technology transfer.

Bioequivalence (BE) studies are done to compare an already existing product in the market most often an innovator product and a generic one so as to ensure that they are equally bioavailable to the patient. That both medicines are equally safe and effective and can be used interchangeably. However this is a costly affair as it involves studying and drawing samples from human subjects over a period of time in a controlled setting or center. It is for these reasons that Kenya has not employed this practice though the regulator had stated it will be mandatory for those doing drug registration to provide BE studies before market authorization approval is given.

In view of chapter 2, it is agreeable that research is key in growth of pharmaceutical business as 90% of the respondents are involved in one type of research or the other. Though not as refined as it is in developed countries where drug discovery is the major type of research; locally it is product development. The steps of R&D are discovery, commercialization, licensing and marketing. As Kenya we are stuck at
commercialization because of lack of interface between the research institutions which come up with new products and industries which are able to scale them up which the developed countries have mastered hence the huge expenditure by multinationals in US to the tune of $16 Billion. According to the European Commission report universities should lay less emphasis on intellectual rights as a Key Performance Indicator and more on the impact the research has on the industry and the public. Both from literature review and findings the costs of research is high and therefore companies must seek out loans and grants through public private partnerships.

5.3.2 Government interventions to reduce the Cost of Production

There are direct costs comprising of raw materials, packaging materials and labor while the indirect costs are energy, water, tax and insurance. On average the companies spend KES 333.2M annually on raw materials. A majority of the respondents spend KES 150M on packaging materials however the average spend is KES 218M. The high cost is attributed to the stringent quality attributes they must have especially for primary packaging materials which come into direct contact with the product. Some of the raw materials which were strictly used in pharma were scheduled to be zero rated in order to reduce the burden of cost on the patient. It is clear we lose a lot of foreign currency due to the amount of importation on both the raw and packaging materials brought mainly from China and India.

The manufacturing industry employs a large number of personnel on average employ 250 personnel per facility. The companies spend on average of KES 121.9M annually on recurrent expenditure which has a positive impact on the economic growth of a country. Kenya pays $0.6 per hour per worker which is half the amount paid in China and India according to literature review therefore cost of labor should not be a major concern for the Kenyan manufacturer. However to effectively conclude whether Kenya's productive a study should be conducted to compare wages with the GDP. It is agreeable with section 2.3.1.1 that Kenya’s productivity is comparable to China however lose 40% of this advantage through indirect costs such as energy, corruption and poor regulation as illustrated by the findings. Manufacturing has been the path to development and has been used as the strategic achievement of rich nations over the
last several hundred years to create a high-quality manufacturing sector in order to develop national wealth and power. This is primarily because global trade is based on goods not services according to the world trade organization only 20% of world trade is in service. Therefore a country that’s able to manufacture goods its own goods are in a position to grow exponentially since it’s said that one job in manufacturing supports three others.

Energy costs are a huge concern for the pharmaceutical manufacturing companies in Kenya due to high cost per unit as compared to other equally industrialized nations in Asia who is her main competitor which pay 7% less as indicated in section 2.3.1.3. Amongst the lowest cost of electricity providers in Africa is Lesotho in comparison to Kenya they are not as industrialized. KPLC should therefore reduce its prices further from $0.07 per kWh even though this is comparable with Africa’s average of $0.068. This is due to the frequent power outages and factories forced to use more costly alternative sources of fuel. The average spend on energy annually is KES 29.2M however this is pegged on the output of the factory as evidenced in the wide range of KES 53M. The price per unit for electricity should be subsidized by government for the manufacturers so that they are able to reinvest the money to produce more and create more employment. Expenditure on water was justifiable as it is also a direct cost for some products for example oral liquids and parenterals which account for the most popular manufactured type of product. The regulatory costs are prohibitive and the government should avert this by harmonizing processes in EAC. This means that once an application is put in Kenya it is reviewed by Uganda, Tanzania and Rwanda as well as the same cost. An online portal system where the pharmacists is able to request a service and pay via MPESA has simplified work. Reduced physical visits to the offices and increased employee efficiency and 46% agree with this deduction. This is in line with section 2.3.2.2 which indicates that it is relatively cheaper to start up business in Africa costed at US $ 2350 when compared with $ 3700.
5.3.4 Government interventions to create an enabling Legal Framework.

A majority of the pharmacists working in the industry are not aware of the dynamism in laws affecting their ways of working. Those that are aware constitute only 20% who then participate development of policies, guidelines, bills before they become law. The government should ensure that there is genuine public participation of all stakeholders.

Regulatory processes involve getting a pharmaceutical product from production to the market. It involves drug registration, processing permits, audits, licensing of practitioners, market surveillance of the products in the market, recalls of substandard products carried out the Pharmacy and Poisons Board. A majority of the respondents at 65% disagree that the regulator has made these processes simple and has made it deliberately difficult. The significance of this is that it encourages non-compliance and subsequently corruption. The government should extend audits from ministries to parastatals. Another aspect is the involvement of the EACC to regularly investigate these government institutions.

On taxation property tax was modest with the highest spend being KES 6M while on average KES 2.2M. However considering that counties such as Machakos are giving land incentives “free land” the Nairobi should consider scrapping off collecting land rates from manufacturers. Corporate tax rate on the other hand was high and should be reviewed downwards with the highest tax payer cashing out KES 160M to the government. Property Insurance rates are determined by the privately owned insurance companies therefore the government can only cap rates to protect the manufacturers. Considering section 2.4.1 when Kenya is compared with east Europe and central Asia where corporate tax is much lower at 19% in Africa and Kenya it is 30% therefore putting companies operating in the latter in an unfavorable position. However in Botswana the rate is 5% the upside is that the country is not industrialized therefore not a competitor to Kenya as far as pharmaceuticals are concerned. Property tax in Kenya is low at 1% which is contrary to what is stated in the literature review at 7.5% in Africa.
The government through NEMA and ministry of environment should establish an incineration station to provide centralized cheaper disposal services of pharmaceutical waste products in a manner that’s safe to the environment and ensuring that the waste product does not get back into the market otherwise it becomes a liability to the company. Counterfeiting normally occurs in highly marketed branded products whose budget could only be afforded by innovator pharmaceutical companies majorly multinationals. The Anti Counterfeit Agency should be empowered by government through change in legislature to prosecute the counterfeiters instead of going through courts which are more often than not compromised.

From the responses below a majority of pharmacists have not had engagement with the body responsible for intellectual property in Kenya which could indicate the low level of research undertakings in the factories or lack of adequate public sensitization by KIPI? Sensitization workshops tailor made for different sectors and professionals should be done by KIPI to enhance their relevance in the country. This would be of benefit to the Kenyan pharmaceutical industry to protect its research outcomes.

A majority agree that parallel importation as a concept in theory could increase accessibility of affordable healthcare to a larger population. Parallel importation affects the multinational corporations and not the local manufacturers. Parallel importation in Kenya is carried out in an unregulated manner hence the majority of responses at 52.5% agreeing on its negative impact on business. The government should develop guidelines as per international practices to manage stakeholders into a win-win situation.

5.4 Conclusion
5.4.1 Steps by Government to promote Research and Development.

The study concludes that there are incentives that the government can undertake both short term and long-term to enable R&D, PD and BE as one of the pillars to spur growth of the pharmaceutical manufacturing industry in Kenya. Collaborations with international agencies both governmental and non-governmental that will encourage funding, technology transfer, training of local personnel and offering technical support
to Kenya. The government through coffers should set aside a certain amount of money annually to award grants to companies that indicate interest or potential to develop research in their facilities.

It is also possible to transform, though long-term Kenyan universities to be centers of excellence in research. Establishment of a BE center in Kenya might be rather immature at the moment since almost all our factories are generic based. It might cause more problems than resolve the issue of ensuring quality alone and instead increase cost of doing business.

5.4.2 Government interventions to reduce the Cost of Production

From the study it can be concluded that the cost of production in Kenya is rather high due to high cost of raw and packaging materials, energy and taxes incurred. Provided that the government takes into account tax incentive reviews, tax breaks, access to cheaper credit will allow increased liquidity to do more. It is evident that a majority of respondents work in companies where tender business; the government should promote the buy Kenya build Kenya and allocate a certain percentage of government tender business to local manufacturers

5.4.3 Government interventions to create an enabling Legal Framework.

Finally the study concludes that creating an enabling legal framework would support the growth of the industry. Taxation laws should be drafted in a manner that would enable the industry as illustrated that corporate tax of 30% was high amongst the responses. Curbing counterfeiting will promote more Foreign Direct Investments from Multinationals who fear penetrating developing country markets due to counterfeiting and parallel importation. This means more jobs, influx of foreign exchange, improved infrastructure and technology transfer.
5.5 Recommendation

5.5.1 Recommendations for Improvement

5.5.1.1 Steps by Government to promote Research and Development

The government under the ministry of trade, industrialization or education should consider providing technical support through NGO agencies such as WHO, UNIDO and both local and international universities that are centers of excellence on research. As Kenya builds human resource capacity these experts can train the readily available technical staff pharmacists, biochemists and chemists what can be learnt on the job since they already have science background. The government should also have programs where locally trained personnel are posted to world class research centers for training for a period of time and in return work in stationed areas for a certain period of time. Ensure that these collaborations are pegged to the 2030 millennium goals to promote the economy of the country.

The government through ministry of finance should have set aside a budget for research and development. Countries that have succeeded in R&D got financial support to the tune of 3% of the GDP. Kenya could start with a fund of KES 200M just for the pharmaceutical sector as from the study is was established the average spend per company was KES 5M and there are 40 registered pharmaceutical manufacturing firms. It could also consider other than operational costs fund the establishment of the PD department by equipping the labs of smaller companies with a turnover of less than the industry average which is KES 1Bn. Government could use tax incentives to reduce the cost of PD and R&D by removing tax charged on the consumables and equipment used in the labs.

The government should set up a local BE center to support the pharma industry as the only BE center in Africa is Ethiopia so as to reduce the costs as much as possible. Bioequivalence studies are not critical for all molecules but rather the newer molecules, those with compatibility issues or toxic. They should therefore have a criteria which medicines should be put through BE and not all of them as this process is expensive and will build up the cost to the patient. This therefore counteracts what the generic companies were set out to do; reduce costs of medicines. The risk mitigation for those
that are not put through BE is strict GMP. The benefits of BE is that you increase consumer confidence of the generics since they are proven comparable to innovator product.

5.5.1.2 Government interventions to reduce the Cost of Production

According to the respondents the indirect costs that were unjustifiable were energy, insurance rates and corporate tax while direct costs were packaging materials and high cost of labor. These are therefore the main points of concern where the government can target to provide incentives for the manufacturers. Both raw materials and packaging materials capacity should be built to manufacture the inputs locally since there is ready demand from the existing manufacturing facilities. This will reduce the amount of forex the country is losing, create more jobs and reduce the cost of production since ideally they should be cheaper.

Land as a factor of production is of concern whether one wants to set up a new facility or expand. Respondents indicated that availability, affordability, suitability in terms of proximity to infrastructure, personnel and industrial zoning. The government should allocate adequate land for manufacturing and zone them out accurately through ministry of lands and planning. This land could be given for free in exchange for employment provision and economic growth of the counties since national functions were devolved.

5.5.1.3 Government interventions to create an enabling Legal Framework

The government should ensure that there is genuine public participation of all stakeholders. This ensures that all loop holes are sealed by involving the practitioners themselves and get the buy in on the contents of the policy, guidelines or law and subsequent easy implementation

The government should extend audits from ministries to parastatals. Another aspect is the involvement of the EACC to regularly investigate these government institutions.
This will ensure that malpractices are discouraged and place the leaders of the institutions responsible for misappropriation of fund and abuse of office.

The Anti Counterfeit Agency should be empowered by government through change in legislature to prosecute the counterfeiters instead of going through courts which are more often than not compromised. As much as this is a problem affecting all industries its more critical for pharmaceuticals as the impact is loss of lives.

Sensitization workshops tailor made for different sectors and professionals should be done by KIPI to enhance their relevance in the country. This would be of benefit to the Kenyan pharmaceutical industry to protect its research outcomes.

The government should develop guidelines as per international practices to manage stakeholders into a win-win situation as far as parallel importation is concerned. It has been exploited by unscrupulous businessmen to import cheaper drugs in the context of lowering drug prices at the expense of those who built on the brand.

**5.5.2 Recommendation for Further Studies**

To further the work conducted by this study focus could be dwelt on the VAT imposed by government on all inputs used by the manufacturing facilities. There are products that are tax exempt where the product is not charged VAT to the consumer therefore reducing cost but the manufacturer can’t claim VAT paid on the inputs. There are products which are zero rated where VAT is charged to the consumer but the manufacturer can credit VAT used on inputs. An analysis on what would be best suited for the industry would give insight to policy makers on how the tax incentives should be structured.

The effect of parallel importation on the pharmaceutical industry and its importance to the consumer. An in-depth analysis on its advantages and disadvantages and the structures feasible to make it acceptable and sustainable for favorable outcomes for the distributors that practice it, manufacturers that oppose it currently and the consumer who benefits from it as far as cost is concerned.
A study on Kenya’s productivity can be conducted by relating the country’s GDP to hour worked to measure labor productivity. This way it will help determine whether the country has a higher return on the dollar when compared to what is paid to the worker.
REFERENCES


International Conference on Harmonisation. (2000, November 10). GOOD MANUFACTURING PRACTICE GUIDE.


APPENDICES

APPENDIX I: IMPLEMENTATION SCHEDULE

<table>
<thead>
<tr>
<th>Activity/Time</th>
<th>Month 1</th>
<th>Month 2</th>
<th>Month 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Wk 1</td>
<td>Wk 2</td>
<td>Wk 3</td>
</tr>
<tr>
<td>Questionnaire pre-testing</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Questionnaire Finalization</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Data collection</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Data Analysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chapter 4 and 5 report</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Printing and binding of the final report</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Submission of project</td>
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</table>
## APPENDIX II: BUDGET

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
<th>Unit Cost</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printing Letters</td>
<td>20</td>
<td>25</td>
<td>500</td>
</tr>
<tr>
<td>Pre-test Questionnaires</td>
<td>20</td>
<td>25</td>
<td>500</td>
</tr>
<tr>
<td>Final Questionnaires</td>
<td>120</td>
<td>25</td>
<td>3000</td>
</tr>
<tr>
<td>Report Binding</td>
<td>5</td>
<td>300</td>
<td>1,500</td>
</tr>
<tr>
<td>Research Students</td>
<td>4</td>
<td>6,000</td>
<td>24,000</td>
</tr>
<tr>
<td>Miscellaneous/Logistics</td>
<td>Lot</td>
<td>-</td>
<td>20,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td><strong>49,500</strong></td>
</tr>
</tbody>
</table>
APPENDIX III: QUESTIONNAIRE

Re: Masters in Business Administration Research

I am a postgraduate student undertaking a Master’s degree in Business Administration at United States International University. I am currently developing a management research project whose theme “Government Strategies for enhancing the private pharmaceutical manufacturing sector in Kenya.” To this end, I kindly request you to provide the requested information by filling out the attached questionnaire. The information required is purely for academic research purposes only and in no way will your name or that of your firm be implicated in the research findings. Your cooperation and quick response shall be highly appreciated.

If you require any further information, please do not hesitate to contact me on +254 721 921 843 or endambiri@gmail.com

Yours respectfully,

Esther Karimi Ndambiri
This questionnaire is meant to collect information on the “Government Strategies for enhancing the private pharmaceutical manufacturing sector in Kenya.” Kindly answer the following questions by writing a brief response or ticking in the spaces provided as applicable.

PART A: Background Information

1. Gender
   Male [ ]  Female [ ]

2. What is your position in the Company?

   ____________________________

3. What is the type of company?
   Multinational ( )  Local ( )

4. What are the category of products deal in?
   Human ( )  Veterinary ( )  Both ( )

5. What are the type of products you manufacture
   Oral Solids ( )
   Oral liquids ( )
   Topical ointments /creams ( )
   Parenteral ( )
   Penicilllin’s ( )

6. How do you determine your product portfolio? Please tick the one which is most important factor
   Profitability ( )
Market demand ( )
Simplicity of manufacture ( )
Production capacity ( )
Others (explain) ________________________________________________________________

7. Does your company deal in tender business whether governmental or non-governmental?

Yes ( ) No ( )

8. If your answer is yes in Q7; what percentage of your sales does tendering business occupy?

______________________________________________________________

Please answer the question below by giving data from the past financial year in Kenya Shillings

9. What is the average annual sales turnover of your company?

______________________________________________________________

10. What is the average cost of goods sold of your company?

______________________________________________________________

PART B: Steps by Government to Promote Research and Development

11. Which one of the following does your company conduct?

Research and development ( ) Product development ( ) Both ( ) Neither ( )

12. What is your company’s annual spend on R&D or PD in KES?
13. In regards to R&D or Product Development; does your company have a collaboration with a research institution or university?
   Yes ( )  No ( )

14. If yes how has the collaboration been of benefit to your company?
   _________________________________________________________________

15. In your opinion what can the government do to facilitate the process of product development and R&D?
   _________________________________________________________________

16. In your opinion do you think Bioequivalence (BE) studies are crucial in drug development for generic drug manufacturers
   Yes ( )  No ( )

17. Please give reason for your answer in Q22
   _________________________________________________________________

18. In the event the regulator makes it mandatory to carry out BE studies; what kind of government support would you propose to have
   _________________________________________________________________

PART C: Government Interventions to reduce the cost of Production in the Industry

19. How many employees are in your company?
   _________________________________________________________________
20. How many unskilled employees are there in your company?

____________________________________________________________________

21. Please fill in the table below by giving data from the past 2 financial years in Kenya Shillings

<table>
<thead>
<tr>
<th>Item</th>
<th>Average Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIRECT COSTS</td>
<td></td>
</tr>
<tr>
<td>Raw materials</td>
<td></td>
</tr>
<tr>
<td>Packaging materials</td>
<td></td>
</tr>
<tr>
<td>Labor</td>
<td></td>
</tr>
<tr>
<td>INDIRECT COSTS</td>
<td></td>
</tr>
<tr>
<td>Energy</td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td></td>
</tr>
<tr>
<td>Property taxes</td>
<td></td>
</tr>
<tr>
<td>Corporate tax</td>
<td></td>
</tr>
<tr>
<td>Property insurance</td>
<td></td>
</tr>
<tr>
<td>Disposal of rejected RM/FP or expired product</td>
<td></td>
</tr>
</tbody>
</table>

22. Which of the spend(s) do you feel are unjustified and give reason why

____________________________________________________________________

23. What is the biggest challenge in identification of land as a factor of production?

____________________________________________________________________

77
24. In what way can the government aid your company to reduce the burden of cost of production

PART D: Government Interventions to create an enabling legal framework in the Industry

Please rate to what extent you are satisfied with these

(1 - Strongly Disagree; 2 – Disagree; Neutral – 3; 4 - Agree; 5 - Strongly Agree)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>I am aware when there are changes in the Acts, Bills, Policies affecting the pharmaceutical industry</td>
<td></td>
<td></td>
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<tr>
<td>26</td>
<td>The regulatory processes are straight forward and simple</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>27</td>
<td>The cumulative regulatory costs are prohibitive</td>
<td></td>
<td></td>
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<tr>
<td>28</td>
<td>There is a deliberate effort by the regulator to make the regulatory process difficult.</td>
<td></td>
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</tr>
<tr>
<td>29</td>
<td>The recently introduced online portal by the regulator has facilitated the ease of doing business</td>
<td></td>
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<tr>
<td>30</td>
<td>Government taxation policies are unfavorable towards the local pharmaceutical manufacturing sector therefore making them less competitive</td>
<td></td>
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<tr>
<td>31</td>
<td>I am confident that my expired/rejected products are properly disposed as per the recommended guidelines</td>
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<tr>
<td><strong>32</strong></td>
<td>Counterfeited medicines are a huge concern for my company</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>33</strong></td>
<td>There are mitigation measures by government to combat counterfeit drugs</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>34</strong></td>
<td>The Kenya Property Industrial Institute has been of importance to my company</td>
<td></td>
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</tr>
<tr>
<td><strong>35</strong></td>
<td>Parallel importation is an important in ensuring that the public has access to affordable drugs.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>36</strong></td>
<td>Parallel importation has negatively affected business of my company</td>
<td></td>
<td></td>
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</tbody>
</table>

37. What measures do you propose the government can take to increase the competitiveness of the pharmaceutical manufacturing sector?  
........................................................................................................................................
........................................................................................................................................