A COMPETITIVE ANALYSIS OF THE DRUG REGULATORY AFFAIRS REGIME IN KENYA USING PORTER’S FORCES FOR COMPETENCE POWERS

BY

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UNITED STATES INTERNATIONAL UNIVERSITY-AFRICA

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A Project Submitted to the Chandaria School of Business in Partial Fulfillment of the Requirement for the Degree of Masters in Business Administration (MBA)

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STUDENT’S DECLARATION

I, the undersigned, declare that this is my original work and has not been submitted to any other college, institution or university other than the United States International University in Nairobi for academic credit.

Signed: ___________________________       Date: ___________________________

Ajiffa Victor Labor (ID: 640855)

This project has been presented for examination with my approval as the appointed supervisor.

Signed: ___________________________       Date: ___________________________

Dr. Peter Kiriri

Signed: ___________________________       Date: ___________________________

Dean, Chandaria School of Business
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ABSTRACT

This is an empirical research on the drug regulatory affairs regime in Kenya which is a key but neglected element in Pharmaceutical business development strategy. The purpose of the research is to do a competitive analysis of the key stakeholders within the regulatory regime in Kenya using the Porter’s forces for competence powers as a guide and based on the results make recommendations for developing a competitive drug regulatory strategy for operations in the Kenya Pharmaceutical market.

The study employs the statistical analytical descriptive approach based on the literature review and fieldwork to answer the research questions. Nine (9) stakeholders have been identified and grouped into buyers, suppliers and new entrants into the drug regulatory affairs framework in Kenya. These would form the independent variables for the study and a drug regulatory strategy the dependent variable. The population of the study consisted of Pharmacists working in thirty (30) multinational Pharmaceutical and Biotech companies and the Pharmacy and Poisons Board of Kenya. The sample size studied was sixty-six (66) Pharmacists in the proportion of fifty-six (56) and ten (10) from the respective groups. The study used a questionnaire to collect data. The data was analyzed using SPSS, mean, (T) tests as well as linear regressions to determine the level of contribution of each of the stakeholders in developing a competitive regulatory strategy.

In using Porter’s forces for competence powers to do a competitive analysis of the drug regulatory framework in Kenya, the researcher found that the buyers within the framework collectively have a very strong and significant effect on creating a drug regulatory strategy. The strongest of the buyer group is the multinational headquarters and the weakest the local marketing department.

For the suppliers within the framework, the analysis of data collected for the research indicated that collectively they do not have a strong and significant effect on creating a drug regulatory strategy. The regulatory affairs professionals however who supply labour as an individual group have a very strong and significant effect on creating a drug regulatory strategy. The clinical investigators and patients that form the clinical trials both do not have an effect on creating a drug regulatory strategy.
Competitive analysis of the new entrants within the drug regulatory framework in Kenya indicated that the technological innovations in regulatory affairs are the strongest of the new entrants and the outsourcing of regulatory affairs the weakest. The three variables together proved to have a very strong and significant effect as within the drug regulatory affairs framework in Kenya.

In conclusion the findings indicated that there is a significant statistical effect for applying all three of Porter’s five forces studied on the drug regulatory framework in Kenya to create a drug regulatory strategy. Furthermore the findings indicated the ranks of competitive forces were as follows; the threat of new entrants into the regulatory framework in Kenya, the buyers and then the suppliers into the regulatory framework in Kenya.

Based on the findings of the study, the researcher recommends the need for taking into consideration the use of not only the three forces studied in this research but the entire five forces to determine the competitiveness of other functional business units within the Pharmaceutical industry. Additionally also it directs future researchers to study the opportunities and threats for each of the variables within in the drug regulatory framework.
ACKNOWLEDGEMENT

The path to the completion of this research project has been very long and full of detours; however, through it all I have always managed to keep holding on in order to complete this degree. I would firstly like to thank Dr. P.N Kiriri my supervisor for his guidance and resourcefulness. Also I would want to thank my colleagues for their continued inputs and every other individual who has shared their thoughts and ideas regarding the subject matter.

To my family and friends, I would like to say thank you for serving as a constants source of support throughout this period.

Last and most importantly to my gracious God for all that he is and all that he has done.
DEDICATION
For NJL because simply you are the best parent there is, and as always for grandma also.
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CHAPTER ONE

1.0 INTRODUCTION

1.1 Background of the Problem

In today’s turbulent and ever changing business environment, firms are struggling to achieve and maintain a competitive advantage (Yang L. and Liting, 2015). The concept of competitive advantage therefore has taken center stage in the discussions of business strategy in recent years. Porter (1998) States that “competitive advantage is at the heart of a firm’s performance in competitive markets” and continues in argument that it grows fundamentally out of the value a firm is able to create for its buyers that exceeds the firm’s cost of creating that value. Although statements about competitive advantage abound, a precise definition is elusive. However, in reviewing the use of the term competitive advantage in the strategy literature, the common theme has consistently been value creation (Rumelt & Kunin, 2003). All businesses around the world are trying to improve their efficiency and maximize their market share by optimizing the opportunities available in the market and handling arising problems and challenges. To reach these goals therefore, the managements of businesses should realize that they live within a dynamic external and internal environment which has a lot of variables that affect the company and its market value (Jaradat, Amomani, & Bataineh, 2013).

According to Thompson, Strickland, & Gamble (2009) some of these variables include a company’s resource strengths which represent its competitive assets and determine whether its competitive power in the market place will be impressively strong or disappointingly weak. Thompson, Strickland, & Gamble (2009) continued to explain that a company that is well endowed with potent resource strengths and competitive capabilities normally has a considerable amount of competitive power especially when its management team skillfully utilizes the company’s resources in ways that build sustainable competitive advantage. On the other hand, companies with modest or weak competitive assets are nearly always relegated to a trailing position in the industry in today’s uncertain and turbulent business environment.
Suikki, Tromstedt, & Haapasalo (2006), therefore have proposed that because today’s business environment is characterized by uncertainty, turbulence and inability to predict the future, businesses are required to develop new competences in order to survive. Pearce & Robinson (2008) explained that multinational industries have four features around which they shape their strategies which include; differences in prices and costs from country to country due to currency exchange fluctuations, differences in wage, inflation rates, economic factors, differences in the need of the buyers across different countries, difference in the competitors and the way they compete from one country to another and finally differences in trade rules and government regulations across different countries. The increasing challenge for managers as the market develops and competition increases therefore is to deliver a secure, long term future for their organizations (Kotler & Keller, 2010).

Several attempts have been made to explain firm’s competitiveness and precisely how they can create and sustain superior performance. Within the strategic management process for example, different frameworks have been used to evaluate the competitiveness of the Pharmaceutical industry as whole and even individual firms within the industry. Some of these framework that have been used include but are not limited to resource based view analysis, value chain analysis, SWOT analysis, PESTEL analysis, Porter’s five Forces and McKinsey 7S framework.

Hunger & Wheelen (2010) make reference to Professor Porter’s contribution to the literature of business strategy, by analyzing the business environment before and after Porter’s work. Before Michael Porter’s work for example, other researchers had sought to uncover relationships between industry structure and performance through empirical work focused on a limited number of structural variables. Today, a sub-field of economics known as industrial organization (IO) had been introduced whose immediate impact on business was limited by industrial organization economists’ focused on public, rather than private policy and by emphasis on using a short list of structural variables to explain industry profitability in a way that slighted business strategy (Ghemawat & Rivkin, 2001).

In critic to Porter’s framework for industry analysis, a survey revealed that only a few of the influences Porter flagged commanded strong empirical support (Passemard & Kleiner,
2000). However despite the fact that the five forces framework focuses on business concerns rather than public policy, it also emphasizes extended competition for value rather than just competition among existing rivals, and the simplicity of its application has inspired numerous companies as well as business schools to adopt its use (Hunger & Wheelen, 2010).

A World Health Organization report in 2014 indicates that the global pharmaceutical market is worth over 300 billion dollars a year, a figure that is expected to rise to 400 billion within three years. The ten largest pharmaceutical companies control over one-third of this market, several with sales of more than 10 billion dollars a year and profits of over 30% (WHO, 2014). The industry has been evolving profoundly in the last decade with intensive globalization, increased competitiveness and the fight for global market shares creating new challenges for companies (Kesic, 2009). These challenges as highlighted Kesic (2009) include increased competition from generic products, growing regulatory requirements and pressures for more innovative retail style communications with doctors and consumers. According to an (OECD, 2010) report, the pharmaceutical sector is a high-technology and knowledge-intensive industry with a two-tier structure. The largest firms account for the majority of the Research and Development investment in the industry and hold the majority of patents and a large number of smaller firms manufacture off-patent products under license to a patent-holder. It is heavily regulated and there are only a very few aspects of the industry that are unaffected by regulatory controls.

Government’s regulation also called Regulatory Affairs (RA) is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, telecommunication, media and banking (Sanghi & Tiwle, 2014). Braithwaite & Drahos(2000) explained that at the beginning in the late 19th and 20th century, much of regulation in the United States was administered and enforced by regulatory agencies which produced their own administrative procedures under the authority of statutes. The study continues to explain that legislators created these agencies to allow experts in the industry to focus their attention on the issue ensuring that the different industries are regulated. It explains that at the federal level, one of the earliest institutions to be established was the Interstate Commerce Commission which had its roots in earlier state-based regulatory commissions and agencies and the agencies established later
include the Federal Trade Commission, Securities and Exchange Commission, Civil Aeronautics Board, and various other institutions. These institutions vary from industry to industry and at the federal and state level.

In the health care industry, the regulatory affairs profession began to emerge as a health-related profession in the 1970s, initially in the United States. Within the biomedical/health products sector it is a relatively young, multidimensional profession that is international in scope. At its core, the Regulatory Affairs profession facilitates the collection, analysis, and communication about the risks and benefits of health products to regulatory agencies, medical care systems, and the public. Operationally, it is responsible for assuring that government obligations, market-driven demands, and evolving scientific conventions are understood and addressed by various stakeholders of the medical and healthcare system (Keramidas, 2003).

According to a (Anon, 2010), the regulatory landscape has continued to evolve in response to product safety, regulatory compliance, new technologies, improved understanding of disease states, stakeholder and customer needs and global imperatives, with new and increasing regulations, regulatory guidance and oversights. The report continues to explain that the past ten years have brought both exciting evolutions and challenging times for the pharmaceutical industry with an increasingly complex and demanding regulatory environment, creating opportunities for both the regulatory profession and the pharmaceutical industry. This evolution in the regulatory function according to the report has been driven largely by the expanding scope and global reach of the industry, global regulatory environment and intelligence, scientific breakthrough and innovation, cutting-edge technologies including e-submissions, complexity of disease area targets for development and multiple stakeholder demand for rigorous and competitive product differentiation.

The end goal drives the need for the regulatory team to meet the following objectives: deliver innovative, breakthrough regulatory strategies for the development of products and their registration, be able to more frequently anticipate the company’s success imperatives, be proactive and forward thinking; provide timely, comprehensive and robust global regulatory guidance, understand the biopharmaceutical environment and regulatory actions on precedents and utilize such regulatory intelligence, to forge new
standards to deliver more predictable outcomes, increase focus on building and strengthening relationship with regulatory authorities to provide timely expert input into product development, manufacturing and registration (Braithwaite & Drahos, 2000).

1.2 Statement of the Problem

According to Porter (1985), industry structure is determined by five competitive forces; the bargaining power of the supplier, the bargaining power of the buyer, threat of new entrants, threat of substitutes and competitive rivalry in industry. Porter (2004) then explained that analyzing the industry in terms of the five forces would help the firm identify its strength and weaknesses relative to the actual state of competition and the combined strength of these forces determines the ultimate profit potential of an industry. The Porter’s five forces framework has been used globally and locally to analyze several industries including information and technology, finance, healthcare, tourism, agriculture, sport and entertainment to name but a few. In the pharmaceutical industry for example, studies revealed that the barriers to entry are high because companies have patent rights to protect their products, invariably have huge budgets for marketing designed to protect their brands and have significant manufacturing capabilities that are very hard to replicate. The substitute products in the pharmaceutical industry pose significant threats as they can take away demand or tie up the customers who choose to use the substitutes instead of your products. Examples would be generic brands which can substitute for original products or devices that can be substituted for pharmacological treatment, like stents in thrombo-embolic diseases. Suppliers in the pharmaceutical industry usually have some stake although not a lot as the companies generally have their own manufacturing plants so suppliers don’t dictate prices and are unlikely to threaten to take business anywhere. The buyers however can significantly influence the market particularly as the government and health authorities are constantly seeking price reduction (Chatterjee, 2007).

Most of what has been documented on Porter’s five forces analysis in the Pharmaceutical industry is for determining industry competitiveness. As far as the researcher’s knowledge was, not much had been documented on the analysis of different functional areas in Pharmaceutical business development like research and development or regulatory affairs for example. Attempts to define competitive advantage within an
industry, identifies the need for a competitive strategy specific to the enterprise and industry concerned. It should take into consideration the structure of the industry, the scope of profitability and positioning of the company (Passemard & Kleiner, 2000).

Sutherland (2014) revealed that a significant gap exists because the model has not been extensively explored in heavily regulated sectors of the economy, perhaps because of the complexities of the interactions between markets, policymakers and regulators or from a belief that regulation is a mere interference. Strategic management research on the other hand has focused on competitive markets, seeking generic models, solutions and techniques, avoiding the complications of regulation, whereas those researching regulated sectors have concentrated on changes in policies, laws, regulations and technologies, plus tactical reactions to them, paying little attention to corporate strategy.

The importance of this research is partially due to this established deficiency of published data on the subject matter. The researcher therefore addresses in this research the gap in the applicability of Michael Porter’s forces for competence powers model to functional areas in the Pharmaceutical industry with a specific attention to drug regulatory affairs regime in Kenya.

1.3 Purpose of the Study

The purpose of the study was to establish the competitive analysis of the regulatory affairs framework in the Kenyan Pharmaceutical sector using three of Michael Porter’s forces for competence powers.

1.4 Research Questions

The study was guided by the following research questions:

1.4.1 What is the strength of buyers in the regulatory framework of the Pharmaceuticals industry?

1.4.2 What is the strength of the suppliers in the regulatory framework of the Pharmaceuticals industry?

1.4.3 What is the threat of the new entrants into the regulatory framework of the Pharmaceuticals industry?
1.5 Justification of this Study

1.5.1 The Patients

This study can be important because it aims to highlight with reference to the patients using these pharmaceuticals, the role Regulatory Affairs plays in ensuring that they get access to adequate and satisfactory medicines.

1.5.2 The Multinational Pharmaceutical Companies

As multi nationals expand their operations, the real issue remains to be the need for Pharmaceutical companies to be able to demonstrate the value they bring to their patients and other stakeholders (Baines, 2010). The point that Regulatory Affairs is a key contributor to the success of Pharmaceutical Business Operations cannot be over emphasized.

The benefits of this study therefore can be directly to the Multi-national Pharmaceutical companies operating in or planning to expand their operations into Kenya to serve as a guide for them when creating a regulatory strategy.

1.5.3 The Association of Regulatory Affairs Professionals (TOPRA)/ Regulatory Affairs Professionals (RAPS)

These are the two main bodies that govern the regulatory affairs profession worldwide. The regulatory professional has to be equipped and poised to effectively guide the organization to success with a credible voice, informed strategic guidance and objective evaluation. The study can therefore be for TOPRA and RAPS, an added body of knowledge that functions as a source of reference for rational decision making in the different regions of operation.

1.5.4 Pharmaceutical Sector in Kenya

The importance of the Pharmaceutical sector has become more prominent on international agendas as health indicators have been increasingly linked with a country’s successful development. In addition also, the legal or economic issues that surround pharmaceuticals have become more complex and politicized because of increase in global trade (MSH, 2012).
To Kenya as a nation therefore it can provide an insight on the performance of the pharmaceutical sector with a specific reference to the regulation of the medicines used in the country.

1.5.5 Researchers and Academicians

For the researchers and academicians, this study can provide a basis for further research on the competitiveness of other functional groups within the Pharmaceutical industry using Porter’s forces for competence powers. The competitiveness of the functional groups across regions outside Kenya can be determined. Also because only three of the five forces of competence powers is used in this research, researchers and academicians can employ the use of threat of rivalry and substitutes within the drug regulatory framework in Kenya to determine how they influence creation of a drug regulatory strategy.

1.6 Scope of the Study

This study was done in Nairobi, Kenya. It was specifically focused on analyzing data collected from Registered Pharmacist working in regulatory affairs department as documented by the Pharmacy and Poisons Board of Kenya. The professionals selected for this study were from those working with the top thirty (30) biotech and Pharmaceutical companies worldwide based on market value in 2014 (in billion U.S. dollars) as recorded by the 2014 Financial times global 500 list. Data was also collected from Registered Pharmacists who work with the Pharmacy and Poisons Board of Kenya.

A limitation for this study was the unwillingness of the target respondents to provide the required information. The researcher mitigated this limitation by assuring the respondents of confidentiality and anonymity.

1.7 Definition of Terms

1.7.1 Drug Regulatory Affairs

This is defined as a unique mix of science and management to achieve a commercially important goal within a drug development organization (Sanghi & Tiwle, 2014).
1.7.2 Regulatory Policy

This is defined as that which is about achieving government's objectives through the use of regulations, laws, and other instruments to deliver better economic and social outcomes and thus enhance the life of citizens and business (OECD, 2010).

1.7.3 Pharmaceutical Product

This is a fundamental component of both modern and traditional medicine. It is essential that such products are safe, effective, and of good quality, and are prescribed and used rationally (WHO, 2014).

1.7.4 Multi-National Corporation

This is defined as a firm that operates in two or more countries (Hill & Jones, 2001).

1.7.5 Strategy

This is a large scale, future oriented plan for interacting with the competitive environment in order to achieve the companies objectives (Pearce & Robinson, 2008).

1.7.6 Competitive Advantage

This is defined as that strategy which when a firm implements, its competitors are unable to duplicate or find too costly to try to imitate (Volberda, Morgan, Reinmoelle, Hitt, Ireland, & Hoskisson, 2011).

1.8 Chapter Summary

This chapter provides an introduction to this study with specific highlights on the background of the study, purpose of the study and research questions. The units of analysis have also been defined in the chapter and working definitions of specific terms used in the project stated. In the background, the researcher started off by shedding light on competitive advantage as a whole and then made reference to competitiveness in the pharmaceutical industry. Regulatory affairs were identified as a strategic resource for
multinational Pharmaceutical companies as they compete for market shares and Porter’s competence model identified as the framework for use in this study. The next chapter reviews the literature of the study using the research questions already mentioned in chapter one as a guide, chapter three gives the research methodology, chapter four results and findings and chapter five conclusion, discussions and recommendations.
CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

In this chapter, the researcher gives a detailed review of the literature that serves as a basis for this study. Research questions mentioned in chapter one are used as a guide for the coverage of this chapter. In section 2.2 the researcher gives an insight into the strength of buyers in the regulatory framework of the Pharmaceuticals industry, in 2.3 the strength of the suppliers in the regulatory framework of the Pharmaceuticals industry is discussed, and in 2.4 the threat of new entrants into the regulatory framework of the Pharmaceuticals industry are discussed. A chapter summary is provided in section 2.6.

2.2 The Strength of the Buyers in the Regulatory Affairs Framework

In this section, the researcher reviews literature on the strength of the buyers in the regulatory affairs framework of the Pharmaceutical industry in Kenya.

A company’s buyer maybe the customers who ultimately consume its products (its end users), but may also be the companies that distribute its products to the end users, such as retailers and wholesalers. For example, while Unilever sells its soap powder to end users, the major buyer of its end products are supermarket chains, which then resell the products to the end users (Hill & Jones, 2001). In the healthcare industry another example of buyers would be the government and hospitals who buy in bulk and even the regular patients who buy in small quantity. Pearce and Robinson (2009), explains that the buyers can force down prices, demand higher quality or more services, and play competitors off against each other- all at the expense of industry profits.

 Buyers are powerful if they have negotiating leverage relative to the industry participants, especially if they are price sensitive, using their clout primarily to pressure price reduction. There may be distinct group of buyers who differ in negotiating leverage (Porter & Kramer, 2002). In another study, Porter (1985) describes the determinants of a
consumer group’s negotiating leverage or buying power to be categorized into issues surrounding bargaining leverage and price sensitivity.

For the issues relating to the strength of the buyers, Porter (1985) highlighted them to include the buyer’s switching costs relative to the firms switching costs, buyer information, ability to backward integrate, substitute products pull-through, buyer concentration versus firm concentration, and buyer volume. For the issue of integrating backward, for example, Porter & Kramer (2002) explain that the buyers can credibly threaten to do so and produce the industries products themselves if vendors are too profitable. Producers of soft drink and beer for example have long controlled the power of packaging manufacturers by threatening to make and at times they actually make the packing materials. In the Pharmaceutical industry, this is evident in cases where in many retail pharmacies today are venturing out into doing wholesale and distribution in an effort to directly compete with their wholesale suppliers.

The second determinant describes issues surrounding price sensitivity. For this category he highlighted them to include, the price or total purchase of the product, product differences, brand identity, impact on quality or performance, buyer profits and decision makes incentives (Porter, 1985). In discussing issues relating to the price of the purchase or total purchase the Pharmaceutical industry is described wherein buyer power is mainly associated with the large quantity buyer’s like government institutions. These institutions have considerable bargaining power with drug companies and exert strong downward pressure on drug prices. In another instance in the healthcare industry, the consumers (patients) have no choice but to buy what has been prescribed to them therefore their power is described as low in the Healthcare industry. The buyers in the Pharmaceutical industry are scattered and they as such do not wield much power in the Pharmaceutical pricing (Johnson & Whittington, 2014).

A lot has been documented on the trends in buyer strength and how they affect the activities of the buyers themselves and to a greater extent, the sellers also. In the last decades, the retailing sector, in particular grocery retailing has experienced a movement towards increased concentration. Broadly speaking, large retail chains and multinational retail companies (such as Wal-Mart, Carrefour, the Metro group) now plays a dominant role, even though the phenomenon is not uniform across countries. At the European
Union level, retailer concentration is further strengthened by purchasing alliances (operating nationally or cross border such as Euro buying or buying international group). Buyer power is also on the rise in other industries, such as automobile, health care and cable television in the United States (Battigalli, Fumagalli, & Polo, 2007). Battigalli, Fumagalli, & Polo (2007) also endorsed the concern that buyer power may stifle suppliers’ incentives to invest by showing that an increase in buyer power leads to quality deterioration. Thus an increase in buyer power does not only harm consumers and total welfare, but may turn out to be detrimental also to retailers.

For the purpose of this study, the researcher refers to the buyers in the regulatory framework of the Kenyan Pharmaceutical market to be specifically the regulatory agencies who stipulate the policies the multinational headquarters that receive data, and finally the local marketing departments responsible for the advertising or promoting the sales of the Pharmaceuticals.

### 2.2.1 The Role of the Regulatory Agencies

Government regulations and policies have a major impact on the Pharmaceutical industry. Regulations regarding new product approvals, such as conducting clinical trials, post-marketing surveillance and re-examination and pricing mechanism all have their distinguishing characteristics from one Pharmaceutical market to the other (Mortanges & Joost, 1999). It is through exercising regulatory policy that national governments as well as supra-governmental authorities such as World Health Organization (WHO) and now the World Trade Organization (WTO) are acting to disseminate more broadly Pharmaceutical products with a general concern for world health welfare and the relief of technical and trade barriers impeding world trade. National governments basically regulate in four different ways to influence the drug industry: firstly in the introduction of new products, in the pricing of drugs, in the trade of drugs; and finally in patents and trademarks (Mortanges & Joost, 1999). According to WHO (2012) on the other, the roles of the drug regulatory authority include but are not limited to ensuring that medicines are of the required quality, safety, efficacy, patients have the necessary information for rational use of medicines, medicines are appropriately manufactured, stored, distributed, dispensed, illegal manufacturing and trade are detected and adequately sanctioned, promotion and
advertising is fair, balanced, aimed at rational drug use, and access to medicines not hindered by unjustified regulatory work.

All agencies have the same objectives and obligations to safeguard public health by assessing the safety, quality, and efficacy of medicines before they are authorized for marketing. However, the structure, strategies, practices, processes, and regulatory and legal obligations in place at each agency in order to carry out a regulatory review and achieve these objectives vary considerably (Hirako, McAuslane, & Salek, 2010). In the United States of America for example, the Food and Drug Administration (FDA) is the agency charged with the responsibility of protecting the public health through the regulation and supervision of food, tobacco products, dietary supplement, prescription and over the counter drugs, vaccines, biopharmaceuticals, blood transfusion products, medical devices, and electromagnetic radiation emitting devices (ERED). The agency is empowered by the United States Congress to enforce Federal laws, which serves as the primary focus for the Agency; the FDA also enforces other laws, notably Section 361 of the public and associated regulations, many of which are not directly related to food or drugs but other aspects like regulating lasers, cellular phones, condoms and control of disease on products ranging from certain household pets to sperm donation for assisted reproduction (FDA, 2013).

In Kenya on the other hand the Pharmacy and Poisons Board is the Drug Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the Practice of Pharmacy and the Manufacture and Trade in drugs and poisons. It aims to implement the appropriate regulatory measures to achieve the highest standards of safety, efficacy and quality for all drugs, chemical substances and medical devices, locally manufactured, imported, exported, distributed, sold, or used, to ensure the protection of the consumer (Pharmacy and Poisons Board Kenya, 2015).

2.2.2 The Role of the Multinational Headquarters

The multinational corporation is a business organization whose activities are located in more than two countries and is the organizational form that defines foreign direct investment. The economic definition however, emphasizes the ability of owners and their managerial agents in one country to control the operations in foreign countries (Lazarus, 1999). They are a ubiquitous feature of today’s economy, and account for about a quarter
of global output and a third of international trade (Jensen, 2006). Their importance to economic activity increases as the global economy becomes increasingly integrated, and, notwithstanding the interruption caused by the recent financial crisis and recession, that role is likely to continue to expand (World Bank, 2010).

Multinationals vary in the way they exert control over their subsidiaries. These variations greatly determine the individual requirements of the headquarters from their respective subsidiaries. Several models have been used to describe the headquarter-subsidiary relationship. Two of such models include the global integration model and the localization model (Cheng & Cannice, 2006).

In the global integration model, also sometimes referred to as the ‘think-global, act-global’ approach, the company’s approach is predominantly the same in all countries- it sells the same product, under the same brand names everywhere, uses much the same distribution channels in all countries, and competes on the basis of the same capabilities and marketing approach worldwide (Thompson, Strickland, & Gamble, 2009). This strategic theme prompts company managers to integrate and coordinate the company’s strategic moves worldwide. It puts considerable emphasis on building a global brand name and aggressively pursuing opportunities to transfer ideas, new products, and capabilities from one country to the other. Jarillo & Martinez (1990) assessed the global integration of multinational subsidiaries by measuring the percentage of inputs that the subsidiaries sourced from their parents and their networks. The more a subsidiary relies upon its parents for supplies, the more globally integrated is the subsidiary’s operations. Similarly, global integration can also be measured by the level of centralization of research and development functions, and the subsidiary’s autonomy in selling its products to local markets or through its parents’ integrated systems (Rugman & Verbeke, 2001). Some examples of the advantages of global integration are that they minimize duplication, thus saving costs through standardization and also create efficiencies due to global economies of scale (Cheng & Cannice, 2006).

In the localization model also known as the ‘think-global, act-local’ approach on the other hand the multinationals do not standardize the business activities of their subsidiaries, and the subsidiaries therefore enjoy more freedom and autonomy than in the integrated model. This strategy entails, using the same basic competitive theme in each
country, but allowing local managers the latitude to firstly, incorporate whatever country-specific variation in product attributes that are needed to best satisfy the local buyers and secondly make whatever adjustments in production, distribution, and marketing that is needed to be responsive to local market conditions and compete successfully against local rivals (Thompson, Strickland, & Gamble, 2009). Even though this strategy has economic advantages and has worked for some companies, Andreas (2010) argues that it often backfires or hampers growth potential in many markets. Today many companies are learning that it pays to have a global product platform to reduce cost married with a local customization of products and processes to appeal to a cultural demographic.

2.2.3 The Role of the Local Marketing Departments

Kotler et al (2010), describes the marketing department as that which functions to perform a set of practices that create common rules for managing customer relation in a way that benefits the customer. Marketing role within a firm is referred to as the impact of the marketing department, relative to that of other departmental functions, on strategic decisions important for the success of the business unit or organization (Merlo, 2011). An effective marketing department therefore influences as a distinct department in situations where in their functions give them the ability to persuade others to develop, shape and implement strategies based on their advice. This definition is consistent with prior conceptualizations in the marketing literature (Homburg, Workman, & Krohmer, 1999).

In the Pharmaceutical industry, marketing refers to the business of advertising or promoting the sales of Pharmaceuticals or drugs (Brezis, 2008). The amount Pharmaceutical companies spend on marketing far exceeds what they spend on research and development. In Canada for example $1.7 billion was spent in 2004 to market drugs to physicians alone; in the United States, $21 billion was spent in 2002. Another survey in 2005 revealed that, money spent on Pharmaceutical marketing in the United States was estimated at $29.9 billion with one estimate as high as $57 billion. This is evidence that as much as the industry provides a valuable and legitimate contribution to society, it is also the business of making profits and these profits are heavily dependent on marketing (Joel & Lilia, 2010).

The dimension that Pharmaceutical marketing has taken over the years includes firstly marketing to healthcare provider which involves giving out free sample, organizing
continuous medical educational activities, use of Pharmaceutical sales representative, peer influences from key opinion leaders or colleagues, journal articles and also from public and private insurers.

The second category is Pharmaceutical marketing to the users also referred to as direct to user advertising (Brezis, 2008). Direct-to-consumer advertising informs patients potentially suffering from disease and raises their awareness of treatment options. It has grown rapidly during the past several decades and is now the most prominent type of health communication that the public encounters (WHO, 2012). According to Ventola (2011), in the United States for example there are currently several types of DTC drug advertisements one type, the “help-seeking ad,” provides only information about a medical condition and encourages patients to contact their physician but doesn’t mention a product. Another category the “reminder ad,” includes the product name; this type may provide information about strength, dosage form, or price, but it doesn’t mention the indication or make any claims. The third and most common type is the “product claim ad,” which mentions the product and its indication and includes efficacy or safety claims.

The Pharmaceutical marketing department all over the world is facing major pressures from a broad range of dynamic and powerful forces. Major healthcare legislation such as the Medicare Prescription Drug, Improvement Act of 2003, widespread criticisms of Pharmaceutical industry marketing, increasing consumer involvement in health care, calls to improve regulatory bodies’ oversight of the Pharmaceutical industry, and demands for more affordable drugs are forcing society to re-examine the way that Pharmaceuticals are developed, distributed, and financed all over the world.

2.3 The Strength of the Suppliers in the Regulatory Framework

In this section the researcher reviews literature specifically on the bargaining power of suppliers in the regulatory framework of the Pharmaceutical industry.

Suppliers are organizations, groups or individuals that provide inputs, such as materials, services and manpower, to firms in the focal industry (Peng, 2009). In another study Johnson & Whittington (2014) referred to suppliers as those who provide the organisation with what it needs to produce the product or services it offers. It ranges from fuel, raw materials, and equipment to include labour and even sources of finance. They can be
viewed as a threat when they are able to force up the price that a company must pay for its inputs or reduce the quality of the inputs that they supply thereby depressing the company’s profitability. On the other hand, if suppliers are weak, they give the company the opportunity to force down prices and demand higher inputs (Hill & Jones, 2001). Porter (2008) described powerful suppliers as those who are able to capture more value for themselves. Some of the values he mentioned in his study include, charging high prices, limit quality of services they provide and even shift costs to industry participants. The ability of a supplier to make demands on a particular company or industry depends on the power of the supplier relative to that of the company or industry in which it functions. In evaluation of the ability of suppliers to make demands on a particular company or industry, there have been several suggestions to explain the circumstances in which a supplier has the upper edge in making demands from the company or industry.

According to Schwab & Porter (2002), a supplier group is considered to be powerful if it is more concentrated than the Industry it sells to. Examples of such situations include Microsoft’s monopoly in the operating system industry coupled with the fragmentation of PC assemblers and Intel for the supply of microprocessors.

Secondly, the bargaining power of suppliers can become substantial if they provide unique undifferentiated products with few or no substitutes. For instance, for coca-cola bottlers, there is only one supplier for coke syrup. If coca-cola hikes up the syrup price, bottlers, which actually bottle, market and distribute the soda, will have to swallow these increases even if they are unable to pass the price increase on to the customers (Peng, 2009). Another example would be with pharmaceutical companies that offer patented drugs with distinctive medical benefits for special disease conditions like the cancers and other emerging incurable diseases. They have power over the hospitals, health maintenance organization and other drug buyers than the drug companies that offer me-too or generic products.

A third scenario is that, industry participants face switching costs in changing suppliers. For example, shifting suppliers is difficult if companies have invested heavily in specialized ancillary equipment, learning how to operate supplier’s equipment (as with Bloomberg terminals used by financial professionals) or have invested heavily in training employee to gain certain skills. Also difficulty may arise in situations wherein firms may
have located their production line adjacent to suppliers manufacturing facilities (as in the case of beverage companies and container manufacturers). When switching costs are high, industry participants find it very hard to play suppliers off against each other (Porter, 1985).

Finally, the fourth circumstance is in situations where in the suppliers can use the threat of vertically integrating forwards into the industry. In such situations, suppliers may threaten to become both suppliers and direct competitors of the company they supply (Hill & Jones, 2001). For example in addition to supplying shoes to footwear stores and traditional departments, Nike has established a number of Nike towns in major cities.

For the purpose of this study, the researcher refers to the following category of supplier groups with reference to how they function as key components in the regulatory framework of pharmaceuticals; the internal labour who would wire the submissions, overseas reports from the multinationals, investigators and patients who supply data.

2.3.1 The Role of Internal Labour that wire the Submissions

The internal labour market refers to that which exists within a single organization and represents its internal supply or stock of labour. In its broadest sense, the internal labour market is the mechanism by which existing employees are attributed particular roles within a firm (Grimshaw, Ward, Rubery, & Beynon, 2008).

In the regulatory affairs framework, the regulatory affairs professional is the main suppliers of labour in the regulatory framework of the Pharmaceutical industry. Regulatory affairs (RA) professionals play critical roles throughout the healthcare product lifecycle, from concept through product obsolescence. They provide strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective healthcare products to individuals around the world. Continuous evolution in science and changes in the regulatory environment, health sector and general economics shape the dynamic and expanding scope of the regulatory affairs professional. RA professionals must continually grow their knowledge and skills to be effective and to advance in their profession (RAPS, 2013).

The American occupational information center (2014) describes the functions of the regulatory affairs professional to include but not limited to coordinate, prepare, or review
regulatory submissions for domestic or international projects, provide technical review of
data or reports that will be incorporated into regulatory submissions to assure scientific
rigor, accuracy, and clarity of presentation, review product promotional materials,
labeling, batch records, specification sheets, or test methods for compliance with
applicable regulations and policies, maintain current knowledge base of existing and
emerging regulations, standards, or guidance documents, interpret regulatory rules or rule
changes and ensure that they are communicated through corporate policies and
procedures, determine the types of regulatory submissions or internal documentation that
are required in situations such as proposed device changes or labeling changes, advise
project teams on subjects such as premarket regulatory requirements, export and labeling
requirements, or clinical study compliance issues, prepare or maintain technical files as
necessary to obtain and sustain product approval, coordinate efforts associated with the
preparation of regulatory documents or submissions and prepare or direct the preparation
of additional information or responses as requested by regulatory agencies.

The Pharmaceutical and Medical Professionals (2008) in addition explains that the
Regulatory Affairs professional however offers more than just technical support to the
organizations in which they function. They are central to everything that is happening and
are therefore in the best position to have input into strategic discussions. The strategic
discussions involve a comprehensive analysis of the business in relation to the industry,
the competitors and the business environment in both the short and the long term. They
also have knowledge of the clinical data, established external relationships with key
influencer’s like the regulatory authorities- Kenya Pharmacy and Poisons Board and the
Food and Drug Administration would be specific examples, have knowledge of the
competitive environment like what is needed to get a product registered as well as an in-
depth understanding of products in the same category and emerging products/therapeutic
classes.

In Kenya the Pharmacy and Poisons Board under the Cap 244 requires that a regulatory
affairs professional is a Pharmacist with at least a Bachelor in Pharmacy degree, a
member of the Pharmaceutical society of Kenya and registered with the board to practice
Pharmacy here in Kenya (Pharmacy and Poisons Board Kenya, 2015). In other countries
for example in Europe like Germany or Denmark, much emphasis is not laid on having a
Pharmacy degree. The requirement usually is that the professional has at least a life science degree.

### 2.3.2 The Role of Clinical Investigators

In the United States and many other countries around the world, new drug products must be shown to be safe and effective before they are approved by the relevant regulatory authorities for marketing. The costs associated with the development new products are substantial and a greater percentage of that cost is on clinical testing. The clinical investigators are key players in ensuring that these trials meet the objectives for which they are designed (Paul, Gupta, Felton, Gelone, Hoover, & Gennaro, 2009). The FDA defines a clinical investigation to be synonymous with research. It refers to it as any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to a regulatory body or the results of which are intended to be later submitted to, or held for inspection by, a regulatory body as part of an application for a research or marketing permit. The United States department of Health and Human Services on the other hand defines research to be a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. The agency continues to explain that it encompasses those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, for example, Investigational New Drug requirements administered by a regulatory body (FDA, 2013). The clinical investigators therefore are individual who actually conducts a study that is under whose immediate direction the drug is dispensed to a subject. In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team (FDA, 2011).

In conducting clinical investigations of drugs, including biological products, the investigators responsibility includes but are not limited to; ensuring that a clinical investigation is conducted according to the signed investigator statement for clinical investigations of drugs, including biological products, or agreement for clinical investigations of medical devices, the investigational plan, and applicable regulations, protecting the rights, safety, and welfare of subjects under the investigator’s care and controlling drugs, biological products, and devices under investigation (FDA, 2009).
According to Baer, Devine, & Catalano (2011), clinical investigators face challenges during the conduct of clinical trials that are distinctly different from what is encountered during the routine practice of medicine. Many of these challenges stem from regulatory requirements, the Guidelines for Good Clinical Practice (GCP) and the rigorous nature of clinical trials. When conducting a clinical trial, it is important that clinical investigators successfully meet all research expectations. Although there are multiple regulatory safeguards designed to ensure the ethical conduct of research, it is ultimately the investigator's responsibility to make certain that the research is fair and equitable to study participants (Baer, Devine, & Catalano, 2011).

Investigators should meet certain qualifications of education, training, and experience to assume responsibility for the proper conduct of the research. In general, United States regulators of research for example consider individuals qualified to serve as investigators if they act within the scope of their professional licenses regarding both the functions they perform and the level of supervisory medical oversight required of them under that license (Good Clinical Practice Guideline, 2011).

2.3.3 The Role of the Patient

In a clinical research study, the patients are referred to as the real volunteers who participate in the trials in an effort to develop new treatments or medication for diseases and conditions (NIH, 2014). They are also referred to as clinical research volunteers wherein they function as subjects with no known significant health problems who participates in research to test a new drug, device, or intervention. They may be a member from the community, an investigator or other employee of the research institute, or family members of a patient volunteer. The research procedures with these volunteers are designed to develop new knowledge, and not to provide direct benefit to study participants (NIH,2012)

The needs for recruiting patients in clinical trials have been identified to include for example in situations wherein you are developing a new technique such as a blood test or imaging device, and need clinical research volunteers to help us define the limits of “normal.” In such instance, the volunteers are recruited to serve as controls for patient groups (NIH, 2014). They are often matched to real patients on such characteristics as age, gender, or family relationship and are then given the same test, procedure, or drug
the patient group receives. Investigators learn about the disease progresses by comparing the patient group to the clinical research volunteers.

According to Paul et al, (2009) patients for clinical trials are selected using an exclusion or inclusion criteria based on the phase in which the trial is in. In phase one trials for example, only healthy volunteers are generally enrolled with the exception of drug trials for the treatment of life-threatening diseases. In phase two and three on the contrary, patients with actual diseased conditions are enrolled with a goal of selecting patients who are likely to benefit from the treatment. Inclusion criteria are also used to identify patient groups specified by the trial or objective and exclusion criteria used to eliminate patients who might be harmed by treatment, not likely to survive the entire trial period due to unrelated health problems, those who should not receive the drug treatment due to allergy, concomitant illness, or a contradiction.

Unlike China and India for example, where clinical trial opportunities are widely posted in public spaces such as newspapers and university campuses, the trial recruitment process in Kenya is still largely done discreetly through local healthcare facilities and community outreach workers. For example, once a study is approved by Kenya Medical Research Institute (KEMRI) which is the state corporation in charge of clinical research in Kenya (or other mandated institutions with ethics committees) through the official channels, KEMRI will send a team of ‘data handlers’ to approach a health clinic in the targeted area and identify patients on file with the specific disease or ailment needed for the trial (Wemos, 2014). Whilst the location of patients may be a reasonably straightforward and a necessary procedure, according to Wemos (2014) the process of recruiting them and getting their official consent to participate in a trial is, as in many countries, one fraught with potential risks and ethical violations.

2.4 The Threat of New Entrants into the Regulatory Framework

In this section, the researcher reviews literature on the threat of new entrants into the regulatory framework of the Pharmaceutical industry. Microeconomics teaches that profitable industries attract new competition until downward pressure on prices has squeezed the entire economic profit from the firms. According to Porter (2002) new entrants into an industry bring new capacity, the desire to gain market share, and often
substantial resources that put pressure on prices, costs and the rate of investment necessary to compete. Particularly when new entrants are diversifying from other markets, they can leverage existing capabilities and cash flows to shake up competition as in the cases when Pepsi entered the bottle water industry, Microsoft when it entered the browser industry, apple when it entered the music distribution business and in the medical device industry when B.Braun medical entered into the infusions manufacturing industry.

In the traditional model of pure competition, additional players will enter the market until the profits are nominal; unless there are specific barriers to entry or risks (Pines, 2006). Peng (2009) explained that incumbent’s primary weapons are entry barriers, which refer to industry structures that increase the cost of entry. For instance, Airbus’s new A380 burned $12billion and Boeing’s new 787 consumed $10 billion before their maiden flights. Facing such sky-high entry barriers, all potential entrants including those backed by the Japanese, Korean and Chinese governments, have quit. In evaluation of why these potential entrants quit, Peng (2009) highlighted six structural attributes that are associated with high entry barriers.

The first is whether the incumbent enjoys scale-based advantages. The key concept here is whether the firm enjoys per unit cost reduction when they increase their scale of production. This determinant according to Pearce and Robinson (2008) deter entry by forcing the entrant either to come in on a large scale or to accept a cost disadvantage. Scale economies in production, research, service and marketing are probably the key barriers to entry in the Pharmaceutical industry (Hill & Jones, 2001). Economies of scale are found in every activity of the value chain. They can act as hurdles in distribution, utilization of sales force, and nearly any other part of a business operation. In Pharmaceutical manufacturing industry, the incumbents are protected by the risk bearing benefits of developing new drugs; to develop new drugs to treat an illness takes a considerable degree of investment and research with no guarantee of success. This can only be undertaken by Pharmaceutical companies with significant resources (Pines, 2006).

The second set of advantages that incumbents may enjoy is independent of scale. This is where for example proprietary technology like patent rights for example comes into play. It is very common in Pharmaceutical industry when innovator companies manufacture
new molecules. The new entrants have to ‘invent around’ the molecules which is costly and uncertain. Some of the costs and uncertainty attributed to research and development, clinical trials, product registration and even to a greater extent marketing of the products (Pearce & Robinson, 2008).

Peng (2009) highlights the other barriers to entry to include product proliferation which is the effort to fill product space in the manner that leaves unmet demand for potential entrants, a strategy that opinion leaders claim GlaxoSmithKline used to capitalize on their first mover advantage in east Africa, product differentiation which refers to the uniqueness of the incumbent's products that customers value, for example Roche’s avastin used in metastatic colorectal cancer which was launched in three countries in Europe in 2005 and studies revealed had up to 51% of the first line markets, the possession of additional capacity that the incumbent does not use presently and finally government policies that ban or discourage entries can also serve as a barrier.

Overall, when the risk is low, established companies can charge higher prices and earn greater profits than would have been possible otherwise. Clearly in conclusion, it is in the interest of companies to pursue strategies consistent with raising entry barriers (Hill & Jones, 2001).

For the purpose of this study, the researcher refers the use of technology in the regulatory framework, harmonization of regulatory affairs requirements in East Africa and outsourcing regulatory affairs like using contract regulatory organizations for example as new entrants into the framework in Kenya.

2.4.1 The Role of Technological Innovations

Starting in the 1980s with the first desktop computer, information technology has played an important part in global economies. Today, it plays an integral role in organizations, helping them improve processes, achieve cost efficiencies, drive revenue growth and maintain a competitive advantage in the marketplace (Basu, 2012).

Furthermore these roles can be categorized to include firstly in product developments wherein it speeds up the time it takes new products to reach the marketplace also companies can now write product requirement documents by gathering market intelligence from proprietary databases, customers and sales representative and finally,
computer-assisted design and manufacturing software can speed up decision making, while collaborative technologies allow global teams to work on different components of a product simultaneously (Basu, 2012).

The importance of technological innovations in business cannot be over emphasized. From innovations in microprocessors to efficient drug delivery systems, information technology also helps businesses respond quickly to changing customer requirements. In stake holder integration, using global 24/7 interconnectivity, a customer service call originating in Des Moines, Iowa, ends up in a call center in Manila, Philippines, where a service agent could look up the relevant information on servers based in corporate headquarters in Dallas, Texas, or in Frankfurt, Germany (Ceglowski, 1999). Public companies use their investor relations websites to communicate with shareholders, research analysts and other market participants. In process involvement, enterprise resource planning (ERP) systems for example can allow managers to review sales, costs and other operating metrics on one integrated software platform, usually in real time (Basu, 2012).

Although the initial implementation costs of technological innovations are high or substantial, the long term cost savings have proven to be worth the investment (Basu, 2012). The case of the growing importance of information technology is the same with the drug regulatory affairs as it is in other functional areas of businesses. It is significant because of the way regulations are becoming stringent and countries are blurring their borders by the day (Ceglowski, 1999). One technological breakthrough in drug regulatory affairs worth mentioning is the electronic common technical document (eCTD). It is the electronic version of the common technical document (CTD) and functions as an interface for industry to agency transfer of regulatory information. There is no difference between it and a paper-based common technical document (CTD) in terms of their organization in modules and sections or in the regional scientific, technical and clinical content requirement (Wantanabe, 2011). The advantages the eCTD according to Wantanabe (2011) includes it gives a broader scope and standardization, it is interoperable, it relieves resource burdens related to paper distribution & storage, and also facilitates life cycle management (Schmuff, 2009). Also some companies have taken a step forward to invest in regulatory compliance software like TrackWise for example that function to meet the needs of all regulatory affairs professionals providing a centralized
repository to manage global product portfolio delivering and efficient and cost effective global solution for all required regulatory tasks (Wantanabe, 2011).

2.4.2 The Role of Regulatory Harmonization

Attempts to harmonize the regulatory requirements of Pharmaceuticals are ongoing. According to the World Health Organization, countries are obligated to regulate the trade of medical products to ensure access to effective, safe, and high quality treatments. However, resource constraints make these obligations difficult to fulfill. Statistics show that 90% of African regulatory authorities lack the capacity to guarantee quality, safety, and efficacious medicinal products. As a result, needed medicines are unaffordable in low-income countries, fewer drugs are available than in the developed world like Europe and the Americas hence the costs of these inefficiencies are increase in drug prices (WHO, 2012).

The three major Pharmaceuticals market United States, Europe and Japan had drug regulatory approval systems in place that were based on the same principles, but the detailed technical requirements in each region differed. For the Pharmaceutical industry, this meant duplicating consuming and expensive test procedures and submitting different and huge (“lorry-sized”) applications to each region, making application for new drug approval considered a “nightmare” (Anon, 2010). The International Conference on Harmonization was therefore formed with an aim of harmonizing the differences in the technical requirements for the registration of new drugs. It also serves as an information exchange forum for its members and other participants. The overarching goal is to reduce time and costs for both industry and regulators in the approval process, as well as improving the health of patients by introducing high quality drugs faster to them (Handoo, Arora, & Khera, 2012).

In the East African region, the East African Community (EAC) medicines registration harmonization (MRH) was launched in March 2012 with a mandate of promoting the harmonization of medicines registration in the region, which is a key contributor to public health and leads to rapid access to good quality, safe and effective medicines for priority diseases(NEPAD, 2012). The specific objectives of the project were to implement a common technical document for registration of medicines, implement a common information management system for medicine registration, implement a quality
management system in each east African community member state’s national medicine regulatory authority, build a regional and national capacity to implement the EAC-MRH project, create a platform for information sharing on the harmonized registration system to key stakeholders and finally to develop and implement a framework for mutual recognition of regulatory decisions based on chapter 21, article 118 of the East African Community treaty (EAC, 2013).

2.4.3 The Role of Contract Regulatory Organizations

Pharmaceutical companies are seeking for more efficient ways of navigating the proliferation of new regulatory requirements and stake holder expectation in ways that support their performance objectives, sustain value and protect their brands (MRA, 2013). This has given birth to regulatory consultant agencies who give expert advice on matters including but not limited to sales and marketing compliance and risk program design (Anon, 2010).

A Contract Research Organization (CRO) is defined as an organization (commercial, academic, or other) contracted by a sponsor (in this case a Pharmaceutical company) to perform one or more of a sponsor's trial-related duties and functions. They have a clear understanding of the regulatory environment, its history, trends, current requirements, policies, and provide exemplary quality regulatory support thereby reducing unnecessary delays in the drug registration process (ICH, 2014). The services of such organizations can be extended to include biopharmaceutical development, biologic assay development, commercialization, preclinical research, clinical research, clinical trials management, and Pharmacovigilance (Barnes, 2007).

The market size of these organizations in 2007 has been estimated to be around $15 billion in 2007 with the figure expected to grow over the next ten years by 15%. Examples of some of these organizations include quintile, Covance and Icon.

2.5 Chapter Summary

This chapter provides a detailed review of the literature that serves as a basis for this study. The researcher specifically gave insights into the research questions mentioned in chapter one including the bargaining power of suppliers within the regulatory framework,
the bargaining power of the buyers within the regulatory framework, and the threat of new entrants into the regulatory framework of the pharmaceuticals industry. These objectives were operationalized in order identify the key indicators for each research question mentioned.

In the next chapter, the researcher would give a blueprint for the collection, measurement and analysis of data for this study.
CHAPTER THREE

3.0 RESEARCH METHODOLOGY

3.1 Introduction

This chapter provides a sequential account of how the research project was carried out to obtain the necessary information needed to answer the research questions mentioned in chapter one and reviewed in chapter two. The chapter is organized into five (5) sections including the research design, population and sampling design, data collection methods, research procedure and data analysis methods. A chapter summary is given at the end of the chapter.

3.2 Research Design

A research design is defined as a framework for the collection and analysis of data to answer research questions and meet research objectives providing reasoned justification for choice of data sources, collection methods and techniques for analysis (Saunders, Lewis, & Thornhill, 2012).

In this study, the researcher employed the statistical analytical descriptive approach based on literature review and field work to answer the research questions. A descriptive study is done in situations where in the researcher attempts to define a subject, often by creating a profile of a group of problems, people, or events through the collection of data and the tabulation of frequencies on research variables or their interaction; it is best used wherein the researcher wants to reveals who, what, where, when or how much (Cooper & Schindler, 2010). Also according to Cooper & Schindler (2010) descriptive study is concerned with a uni-variate question or hypothesis in which the researcher asks about the states of something, the size, form, distribution, or existence of a variable. For this study, the researcher identified nine (9) stakeholders within the drug regulatory affairs framework in Kenya and grouped them into buyers, suppliers and new entrants. These would form the independent variables for the study and drug regulatory strategy the dependent variable.
3.3 Population and Sampling Design

3.3.1 Population

A population is defined as the total collection of elements about which we wish to make some inference (Cooper & Schindler, 2010). Cooper & Schindler (2010) continued to define a population element as the individual subject on which the measurement is taken. It could be a person, an organization, customer database, or the amount of quantitative data on which the measurement is taken.

The population of this study therefore comprised of Pharmaceutical professionals working within the drug regulatory frame work in Kenya. This included both the professionals representing the interest of the multinational companies and the regulators representing the interest of the regulatory body in the case of this study, the Pharmacy and Poison Board of Kenya. Pharmacists working for thirty (30) multinational Pharmaceutical and biotech companies were sampled. The companies were selected based on market value in 2014 (in billion U.S. dollars) as recorded by the 2014 Financial times global 500 list. However in Kenya, only fifteen (15) of these multinationals have wholly owned subsidiaries. The rest operate through partnership with local distributors. According to the Pharmaceutical Society of Kenya, the companies in total employ sixty-five (65) Pharmacists and the Pharmacy and Poisons Board which is the Drug Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya employs ten (10) regulators who function to implement the appropriate regulatory measures to achieve the highest standards of safety, efficacy and quality for all drugs, chemical substances and medical devices, both locally manufactured and imported. These two sets of population elements differ in that they represent different interests within the regulatory frame work and are similar in that they are all Registered Pharmacist with the Kenyan Pharmacy and Poisons Board.
Table 3.1: An Indication of the Population Distribution

<table>
<thead>
<tr>
<th>Area of Work</th>
<th>Total Number Per Category</th>
<th>Percentage</th>
<th>Study Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multinational and biotech companies</td>
<td>65</td>
<td>86.6</td>
<td>56</td>
</tr>
<tr>
<td>Pharmacy and poisons board</td>
<td>10</td>
<td>13.4</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>75</td>
<td>100</td>
<td>66</td>
</tr>
</tbody>
</table>


3.3.2 Sampling Design

3.3.2.1 Sampling Frame

According to Saunders, Lewis, & Thornhill (2012) a sample frame is the complete list of all cases in the population from which a probability sample is drawn. The sample frame used in this research was the complete list of Pharmacists working within the regulatory framework of the Pharmaceutical industry in Kenya. This list was derived from the Pharmaceutical Society of Kenya as recorded in April, 2015.

3.3.2.2 Sampling Technique

In order to ensure a fair representation and generalization of the findings to the general population, probability sampling technique was used. Firstly, a stratified sampling technique was used to partition the population of study into sub-populations, or strata. A stratified random sampling is the probability sampling procedure in which the population is divided into two or more relevant strata (Saunders, Lewis, & Thornhill, 2012). This technique was therefore suitable to divide the sample frame (Pharmacists) based on their area of occupation into the regulators and those representing the multinationals as regulatory professionals. A simple random sampling method was then used to select the respondents from the list provided by the Pharmaceutical Society of Kenya.

Simple random sampling is a sampling method in which each member of the population has an equal and known chance of been selected (Cooper & Schindler, 2010). This method was used because it is simple, easily applied to a small population and ensures that bias is not introduced.
3.3.2.3 Sample Size

A sample size is defined as a portion of the entire population or a selection of an entire population (Cooper & Schindler, 2010). According to Hussey and Hussey (2007) factors such as variability in relation to time, costs and accuracy, estimated periods, confidence with generalization to the population, and the type of sample itself (homogeneity or heterogeneity) of the population need to be taken into consideration in determining the sample size. With this in mind, and working with a five percentile (5%) margin of error, to obtain the minimum number of Pharmacists working in the Pharmaceutical industry that would be sampled for this study, the researcher adopted the Yamane’s formula (cited in Israel, 2002) and it was as follows:

\[ n = \frac{N}{1 + N (e)^2} \]

Where \( n \) is the sample size, \( N \) is the population size and \( e \) is the margin of error.

Using this formula therefore, the minimum amount of Pharmacist working for the multinational and biotech that was sampled is fifty-six (56). For the regulators, because they are only ten (10) of them, a census was done.

3.4 Data Collection Methods

According to Malhotra & Birks (2009) depending on the nature of the information to be gathered, different tools can be used to collect data. For this research, the researcher used a self-administered questionnaire as the tool for data collection. A questionnaire is an important data collection tool in instances where the researcher wants to collect effective and efficient information within a very short time. Furthermore it facilitates easy coding of information and data analysis (Malhotra & Birks, 2009).

The questionnaire was divided into four sections. The first section focuses on gathering demographic data such as position that employee occupies in the organization, nature of the organization and number of years of work experience the second section to gain insights into the impact of the buyers within the regulatory framework in determining a regulatory strategy, the third section an insight into the impact of the suppliers within the regulatory framework in determining a regulatory strategy, and the fourth insights into the impact of the threat of new entrants within the regulatory framework in determining a
regulatory strategy. The sections each contained Likert scale type questions, open ended questions and closed ended questions. Details of this questionnaire are appended in appendix two.

### 3.5 Research Procedures

The questionnaire was developed and pretested on ten (10) randomly chosen proposed respondents. This was done in an attempt to detect the weaknesses in design of the questionnaire, errors in questions and question sequencing, instructions and skip questions (Cooper & Schindler, 2010). After this step, the necessary corrections were made and the questionnaires delivered together with a cover letter in person by the researcher or via email depending on what approach the respondent found most appropriate. The letter explained the relevance of the study and assured the respondents of confidentiality and anonymity. Details of the cover letter are also shown in appendix one.

To increase the response rate the researcher did follow-up phone calls and text messages every week. Twenty-one days were scheduled for follow-up and collecting the questionnaires. All questionnaires that were not received during that time frame were considered as non-responsive. The evaluation of the data collected was done by the researcher.

### 3.6 Data Analysis Methods

Data analysis involves decrease of accumulated data into a size that is manageable, coming up with summaries, looking for patterns and applying statistical techniques (Cooper & Schindler, 2010). Additionally, data analysis may also be referred to as the process of sifting through data and piecing together numerical evidence about the social world (Malhotra & Birks, 2009).

For this study, the researcher used content analysis to analyze qualitative data and the findings presented in a prose form. For the quantitative data, the statistical package for social sciences (SPSS version 20) was used for analysis. Using the program, the researcher applied the linear regressions, statistical t-tests and means to determine the
strength and relationship of each of the stake holders in developing a competitive regulatory strategy. Data was then presented in tables, and figures.

3.7 Chapter Summary

The essence of this chapter was to explain the plan and procedure that was followed in undertaking data collection and analysis for this research. The chapter therefore gives details of the research design, population and sampling design which included the sample size and sample technique. The researcher also justifies the choice of the data collection tool and the procedure for carrying out the research. In conclusion of this chapter, the researcher describes the methods of data analysis. The next chapter- chapter four would present the results and findings.
CHAPTER FOUR

4.0 RESULTS AND FINDINGS

4.1 Introduction

This chapter presents the findings of the primary data collected from the field using the questionnaire as a tool for collecting data. The main objective of this study was to do a competitive analysis of the drug regulatory affairs framework in the Kenya.

There are four subsections; the first presents the general information which seeks to determine the respondent’s position held in their respective organizations, the type of organization they work for, years of working experience and if in their opinion drug regulatory affairs are key to the development of Pharmaceutical business strategy. The other three subsections respectively address each of the three research questions.

Sixty-six questionnaires were distributed to the respondents and the researcher received response from forty-eight respondent only accounting for 72% of the sample size. This response rate makes the data collected from the field more representative enough to answer the research questions. The result indicated in table 4.1 gives a breakdown for response rate from each category.

Table 4.1: Response Rate

<table>
<thead>
<tr>
<th>Category</th>
<th>Target Respondents</th>
<th>Response</th>
<th>Response Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multinational and biotech companies</td>
<td>56</td>
<td>41</td>
<td>73%</td>
</tr>
<tr>
<td>Pharmacy and Poisons boards</td>
<td>10</td>
<td>7</td>
<td>70%</td>
</tr>
<tr>
<td>Totals</td>
<td>66</td>
<td>48</td>
<td>72%</td>
</tr>
</tbody>
</table>
4.2 General Information

The general information for the study sought to determine the respondent’s position held in the company, years of working experience, type of organization the respondents work for and if from the respondent’s perspective drug regulatory affairs are key to Pharmaceutical business development.

4.2.1 Position held within the Organization

These researcher sought to find out the positions the respondents held in the various organization. This was an open ended question and responses fell into the following four categories; eighteen respondents were drug regulatory affairs managers making up for 43%, twelve company Pharmacists making 28%, seven drug regulatory officers at 16 % and eleven local safety and Pharmacovigilance managers at 13%. Thus the findings indicated that majority of the respondents were drug regulatory affairs managers and the minority group was local safety and Pharmacovigilance managers. The pie chart in figure 4.1 gives an illustration of the results discussed above.

![POSITION IN COMPANY](image)

**Figure 4.1: Position in Company**

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4.2.2 Company Type

In this subsection the researcher sought to find out the type of organizations the respondents worked for. Two respondents worked for local manufacturers of Pharmaceuticals in Kenya accounting for 4%, fourteen worked for importers and distributors of Pharmaceutical products in Kenya accounting for 29%, twenty-five worked for Pharmaceutical innovator companies accounting for 52% and seven for regulatory bodies accounting for 15%. As indicated by the percentages stated above, the Pharmaceutical innovator companies accounted for the majority of the companies studied. The pie chart in figure 4.2 gives an illustration of these results discussed above.

![Company Type Pie Chart](image)

**Figure 4.2: Company Type**

4.2.3 Years of working experience

In this subsection, the researcher sought to find out specifically the years of working experience of the respondents. The findings of the study indicated that 0 to 4 years of experience were eleven respondents, 5 to 9 years were twenty-seven respondents, 10-15 were eight respondents and those who have worked for above fifteen years were only two in number. A graphical representation of these findings is given in figure 4.3.
4.2.4. Importance of Drug Regulatory Affairs to the Development of a Regulatory Affairs Strategy

In this subsection, the researcher sought to find out the respondent’s opinion on the importance of drug regulatory affairs to Pharmaceutical business development in Kenya. A likert scale question was used to determine the respondent’s responses. Twelve respondents said they strongly agree that the drug regulatory affairs are key to the development of Pharmaceutical business in Kenya and thirty-six strongly agreed on its importance. No one disagreed or strongly disagreed. The mean response for this question was 4.75. A graphical representation in Figure 4.4 below gives an illustration of these findings.

![Years of working experience](image-url)
Figure 4.4: Importance of Drug Regulatory Affairs in development of a Pharmaceutical Business Strategy

4.3 The Strength of the Buyers in the Regulatory Affairs Framework

4.3.1 The Role of the Regulatory Agency

The mean response on the likert scale for the questions asked to determine the strength of the Pharmacy and Poisons board of Kenya was 3.604 meaning that they are strong and have a significant effect on the drug regulatory framework in Kenya. The respondents suggest that the board’s requirements may not be different from other regulatory authorities within the region with a mean response of 1.583 but it still plays a very strong role in the development of a competitive strategy regulatory strategy with a mean response of 4.352. They have a strong negotiating leverage with a mean response of 4.062 for that question and are very well informed on the global trends in regulatory affairs with a mean response of 4.416. These results are indicated in table 4.2 below with an indication of the ranking of each question asked.
Table 4.2: Statements on the Strength of the Buyers

<table>
<thead>
<tr>
<th>Statements</th>
<th>Mean</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>The requirements of PPB are different from that of other regulatory authorities within the region</td>
<td>1.583</td>
<td>4</td>
</tr>
<tr>
<td>PPB has a very strong impact on the development of a competitive RA strategy in Kenya</td>
<td>4.352</td>
<td>2</td>
</tr>
<tr>
<td>PPB has a very strong negotiating leverage relative to the other industry participants</td>
<td>4.062</td>
<td>3</td>
</tr>
<tr>
<td>PPB is very well informed about global trends in the RA</td>
<td>4.416</td>
<td>1</td>
</tr>
</tbody>
</table>

4.3.2 The Role of the Multinationals Headquarters

The mean response on the likert scale for the questions asked to determine the strength of the Global Headquarters was 4.223 meaning that they are very strong and have a significant effect on the drug regulatory framework in Kenya. The respondents suggested that the Global Headquarters’ requirements vary from one to the other with a mean of 3.979; and they play the strongest role in the development of a competitive regulatory strategy with a mean response of 4.703. While they have less negotiating leverage that the Pharmacy board, they are very well informed on global trends in regulatory affairs with a mean response of 4.354 for that question. Table 4.3 below gives an indication of the results and the ranking of each question.

Table 4.3: Statements on the Multinationals Headquarters

<table>
<thead>
<tr>
<th>Statements</th>
<th>Mean</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>The requirements of the multinational headquarters vary from one to the other</td>
<td>3.979</td>
<td>3</td>
</tr>
<tr>
<td>The multinational headquarters have a strong impact on the development of a competitive RA strategy</td>
<td>4.703</td>
<td>1</td>
</tr>
<tr>
<td>The multinational headquarters have a strong negotiating leverage relative to the other industry participants</td>
<td>3.854</td>
<td>4</td>
</tr>
<tr>
<td>The multinational headquarters are very well informed about global trends in RA</td>
<td>4.354</td>
<td>2</td>
</tr>
</tbody>
</table>

4.3.3 The Role of the Local Marketing Departments

The mean responses on the Likert scale for the questions asked to determine the strength of the local marketing departments was 2.979 meaning that they do not have a strong or significant effect on drug regulatory framework in Kenya. The respondents suggested that
the local marketing department vary from one to the other with a mean response of 4.104 but their impact on the development of a drug regulatory affairs strategy is not very strong with a mean of 3.104 for that question. Their negotiating leverage is the least among the buyer groups with a mean response of 2.79. They are also according to the respondents not very well informed on global trends in regulatory affairs with a mean of 1.917 for the responses to that question. Table 4.4 gives an indication of these results and the ranking for each question asked.

Table 4.4: Statements on the Local Marketing Departments

<table>
<thead>
<tr>
<th>Statements</th>
<th>Mean</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>The requirements of the local marketing departments vary from one to the other</td>
<td>4.104</td>
<td>1</td>
</tr>
<tr>
<td>The local marketing departments have a strong impact on the creation of a competitive RA strategy</td>
<td>3.104</td>
<td>2</td>
</tr>
<tr>
<td>The local marketing departments have a strong negotiating leverage relative to the other industry participants</td>
<td>2.79</td>
<td>3</td>
</tr>
<tr>
<td>The local marketing departments are very well informed about global trends in RA</td>
<td>1.917</td>
<td>4</td>
</tr>
</tbody>
</table>

4.3.4 The Results of Linear-Regression test of each the Buyers in Drug Regulatory Framework

The table below shows the effect of each of the buyers in selecting the drug regulatory affairs strategy. The results indicate that the global headquarters of the multinationals have the strongest individual impact as a buyer on the drug regulatory affairs framework in Kenya with a t-value that reached 4.145 and significance level of 0.00 less than the significance level of 0.05 used for the study and the strength of the local marketing department has the lowest effect with a t-value of 1.055.
Table 4.5: Results of Linear-Regression test of each the Buyers in Drug Regulatory Framework.

<table>
<thead>
<tr>
<th>Regression Coefficient B</th>
<th>Computed ‘t’ Value</th>
<th>Significance Level</th>
<th>Analyzing buyer status</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.62</td>
<td>2.245</td>
<td>0.121</td>
<td>PPB</td>
</tr>
<tr>
<td>-0.145</td>
<td>1.055</td>
<td>0.325</td>
<td>Local Marketing Departments</td>
</tr>
<tr>
<td>0.265</td>
<td>4.145</td>
<td>0.000</td>
<td>Multinational Headquarters</td>
</tr>
</tbody>
</table>

4.4. The Strength of Suppliers in the Regulatory Framework

4.4.1 The Role of Internal labor (Regulatory affairs professionals)

The mean response on the Likert scale for the statements relating to the internal labor was 3.351 meaning that they have a significant but not so strong impact on the drug regulatory framework. According to the respondents, if the professionals come together they have the ability to effect a change in the drug regulatory framework with a mean response of 4.375 for that question. When asked if their services can be substituted the respondents strongly disagreed with a mean response of 0.02 they attributed this to the specific unique values of the services provided by them for which they agreed with a mean score of 4.416. The cost of switching from one professional to another had neutral views with a mean response of 3.58. Table 4.6 gives an illustration of these results discussed and a ranking for each question.

Table 4.6: Statements on the Internal labor (Regulatory affairs professionals)

<table>
<thead>
<tr>
<th>Statements</th>
<th>Mean</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>They are a total number in Kenya such that they can come together and effect a change within the RA framework</td>
<td>4.375</td>
<td>2</td>
</tr>
<tr>
<td>The services provided by them can be easily substituted</td>
<td>0.021</td>
<td>3</td>
</tr>
<tr>
<td>The services provided by them have specific unique value</td>
<td>4.416</td>
<td>1</td>
</tr>
<tr>
<td>The cost of switching from one professional to the other is very high</td>
<td>3.458</td>
<td>4</td>
</tr>
</tbody>
</table>
4.4.2 The Role of Clinical Investigators

The mean response from Likert scale questions on the statements on the clinical investigators is 2.544 meaning that they do not have a significant or strong impact on the drug regulatory framework. The respondents suggest that the clinical investigators if they come together cannot effect a change in drug regulatory affairs framework with a mean of 1.791 for that question. Their services cannot however be easily substituted with a mean response of 0.521 because they have specific unique values with a mean response of 4.541. It is also expensive to switch from one investigator to the other with a mean response of 4.125. The illustrations of these results are given in table 4.7 below with a ranking for each question asked.

Table 4.7: Statements on the Clinical Investigators

<table>
<thead>
<tr>
<th>Statements</th>
<th>Mean</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>They are a total number in Kenya such that they can come together and effect a change within the RA framework</td>
<td>1.791</td>
<td>3</td>
</tr>
<tr>
<td>The services provided by them can be easily substituted</td>
<td>0.521</td>
<td>4</td>
</tr>
<tr>
<td>The services provided by them have specific unique value</td>
<td>4.541</td>
<td>1</td>
</tr>
<tr>
<td>The cost of switching from one clinical investigator to the other is very high</td>
<td>4.125</td>
<td>2</td>
</tr>
</tbody>
</table>

4.4.3. The Role of Patients who Provide Clinical Data

The mean responses on the Likert scale for the statements on the patients who provide clinical data was 1.993 meaning that they do not have a strong or significant impact on the drug regulatory framework. The patients together cannot effect change according to the respondents with a mean response of 1.812 for that question and the services they provide cannot be substituted at a mean response 2.367. They disagreed with a mean of 2.067 that the services provided by these patients have specific unique values. The cost of switching from one patient to the next is not expensive with a response rate of 1.729 for that question. Illustrations of these results are given in table 4.8 below with a ranking for each question asked.
Table 4.8: Statements on the Patients who provide clinical data

<table>
<thead>
<tr>
<th>Statements</th>
<th>Mean</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>They are a total number in Kenya such that they can come together and effect a change within the RA framework</td>
<td>1.812</td>
<td>3</td>
</tr>
<tr>
<td>The services provided by them can be easily substituted</td>
<td>2.367</td>
<td>1</td>
</tr>
<tr>
<td>The services provided by them have specific unique value</td>
<td>2.067</td>
<td>2</td>
</tr>
<tr>
<td>The cost of switching from one patient to the other is very high</td>
<td>1.729</td>
<td>4</td>
</tr>
</tbody>
</table>

4.4.4 The Results of Linear-Regression test of each the Suppliers in Drug Regulatory Framework

Results in table 4.9 indicates that internal labor has the strongest individual impact as a supplier or supplier groups with a t value of 4.225 and a significance level of 0.00 which is lower than 0.005 used for the study. The patient group has the least impact on the regulatory affairs framework as a supplier or supplier groups with a t value of 1.555 and a significance level of 0.142.

Table 4.9: Results of linear-regression test of each the supplier groups in Drug Regulatory A in Kenya’s effect on selecting a DRA strategy

<table>
<thead>
<tr>
<th>Regression Coefficient</th>
<th>Computed ‘t’ Value</th>
<th>Significance Level</th>
<th>Analyzing threat of suppliers status</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.282</td>
<td>4.225</td>
<td>0.000</td>
<td>Internal labor</td>
</tr>
<tr>
<td>0.331</td>
<td>2.450</td>
<td>0.003</td>
<td>Clinical Investigators</td>
</tr>
<tr>
<td>-0.54</td>
<td>-1.555</td>
<td>0.142</td>
<td>Patients</td>
</tr>
</tbody>
</table>

4.5 The Threat of New Entrants into the Regulatory Framework

4.5.1 The Role of Technological Innovations

The mean response on the likert scale for statements relating to the effects of technological innovations in regulatory affairs was 4.202 meaning they have a strong and
significant impact on the drug regulatory affairs framework in Kenya. Most of the respondents strongly agreed that the capital required for the technological innovations in the regulatory affairs are high with a mean response of 4.521 for that question and with a mean response of 3.142 most of the respondents can be described as apathetic to the idea of the technological innovations. The cost of switching to these innovations however is considered high as the mean response was 4.729 and the cost advantages that the organizations using these technologies would have also high with a mean response of 4.416 for that question. Table 4.10 gives an illustration of the result discussed above and the ranking for each question asked.

Table 4.10: Statements on Technological Innovations

<table>
<thead>
<tr>
<th>Statements</th>
<th>Mean</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>The capital requirements for these innovations in technology are very high</td>
<td>4.521</td>
<td>2</td>
</tr>
<tr>
<td>The responses of incumbents to these innovations in technology are very welcoming</td>
<td>3.142</td>
<td>4</td>
</tr>
<tr>
<td>The cost of switching to use of these innovations in technology are comparatively very high</td>
<td>4.729</td>
<td>1</td>
</tr>
<tr>
<td>There are very high cost advantages for organizations that adopt these innovations in technology as they expand their operations within the region</td>
<td>4.416</td>
<td>3</td>
</tr>
</tbody>
</table>

4.5.2 The role of Regulatory Harmonization

The mean response on the likert scale for the statements relating to the effects of harmonizing regulatory affairs in East Africa was 3.775 meaning that they have a significant and strong impact on the drug regulatory framework. According to the respondents, the capital requirements for harmonizing regulatory affairs in East Africa is high and the respondents agreed with a mean response of 4.142 but they were apathetic about the harmonization of regulatory affairs in East Africa with neutral responses at 3.438. The cost to be accrued by the organizations as they switch to a harmonized Regulatory Affairs in East Africa were not considered high with a mean response of 2.979, but the respondents claim however that there are very high cost advantages for organizations as the regulatory affairs in East Africa are harmonized with a mean response of 4.541 for that question. Table 4.11 gives an illustration of these results and a ranking for each question asked.
Table 4.11: Statements on Harmonizing Regulatory Affairs

<table>
<thead>
<tr>
<th>Statements</th>
<th>Mean</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>The capital requirements for harmonizing RA in East Africa are very high</td>
<td>4.142</td>
<td>2</td>
</tr>
<tr>
<td>The responses of incumbents to harmonizing RA in East Africa are very welcoming</td>
<td>3.438</td>
<td>3</td>
</tr>
<tr>
<td>The cost accrued by organizations as they switch to meet the requirements of a harmonized RA in East African are very high</td>
<td>2.979</td>
<td>4</td>
</tr>
<tr>
<td>There are very high cost advantages for organizations as RA is harmonized when they expand their operations within the region</td>
<td>4.541</td>
<td>1</td>
</tr>
</tbody>
</table>

4.5.3 The Role of Contract Regulatory Organizations

The mean response on the likert scale for statements relating to the effects of outsourcing regulatory affairs was 2.603 meaning they have a significant but not strong impact on the drug regulatory framework in Kenya. According to the respondents, the capital requirements for outsourcing regulatory affairs was considered not high with a mean response of 2.145 and incumbents are not welcoming to the idea of outsourcing regulatory affairs with a mean response of 2.229 for that question. The cost of switching to regulatory affairs outsourcing is not considered high with a mean of 1.625 but the respondents however agreed that there are very high cost advantages to the organization when they outsource regulatory a mean response of 4.416 for that question. Table 4.12 gives an illustration of these results discussed and a ranking for each question asked.

Table 4.12: Statements on Contract Regulatory Organizations

<table>
<thead>
<tr>
<th>Statements</th>
<th>Mean</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>The capital requirements for outsourcing RA re very high</td>
<td>2.145</td>
<td>2</td>
</tr>
<tr>
<td>The responses of incumbents to these innovations in technology are very welcoming</td>
<td>2.229</td>
<td>3</td>
</tr>
<tr>
<td>The cost of switching to RA outsourcing are comparatively very high</td>
<td>1.625</td>
<td>4</td>
</tr>
<tr>
<td>There are very high cost advantages for organizations that adopt RA outsourcing as they expand their operations within the region</td>
<td>4.416</td>
<td>1</td>
</tr>
</tbody>
</table>
4.5.4 The Results of Linear-Regression tests of each the Threat of New Entrants in Drug Regulatory Affairs Framework.

The most influential category among the new entrants group was the technological innovations with a significance level of 0.000 lower than the 0.05 used for this study. The t-value was also computed as 4.225 making it the new entrant group with the strongest impact on the drug regulatory framework. Outsourcing regulatory affairs on the other hand had the lowest t-value of 0.121.

Table 4.13: The Results of linear-regression test of each the threat of New Entrants in Drug Regulatory Affairs Framework

<table>
<thead>
<tr>
<th>Regression Coefficient</th>
<th>Computed ‘t’ Value</th>
<th>Significance Level</th>
<th>Analyzing threat of new entrants status</th>
</tr>
</thead>
<tbody>
<tr>
<td>β</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.271</td>
<td>4.225</td>
<td>0.000</td>
<td>Technological innovations</td>
</tr>
<tr>
<td>0.155</td>
<td>2.920</td>
<td>0.001</td>
<td>Harmonization of RA</td>
</tr>
<tr>
<td>0.135</td>
<td>2.655</td>
<td>0.121</td>
<td>Outsourcing Regulatory affairs.</td>
</tr>
</tbody>
</table>

4.6 Relationship between Buyers, Suppliers and New Entrants in the Drug Regulatory Framework

From the results indicated in table 4.14 below, the threat of the new entrants has the strongest cumulative impact on the regulatory affairs framework with a t-value of 4.678 and a significance level of 0.000 which is lower than the 0.05 used in this study. The buyer groups are second with a t-value of 2.938 and the supplier groups according to these results have the lowest impact with a t-value of 1.096
Table 4.14: Results of Linear-Regression test of the Buyers, Suppliers and New Entrants in the Drug Regulatory Framework

<table>
<thead>
<tr>
<th>Regression Coefficient $\beta$</th>
<th>Computed ‘t’ Value</th>
<th>Significance Level</th>
<th>Analyzing Independent variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.135</td>
<td>2.938</td>
<td>0.004</td>
<td>Bargaining power of buyer/buyer groups</td>
</tr>
<tr>
<td>0.115</td>
<td>1.096</td>
<td>0.274</td>
<td>Threat of supplier/supplier groups</td>
</tr>
<tr>
<td>0.271</td>
<td>4.678</td>
<td>0.000</td>
<td>Threat of new entrants</td>
</tr>
</tbody>
</table>

4.7 Chapter Summary

In using three of Michael Porter’s forces to do a competitive analysis of the drug regulatory framework in Kenya, and a linear regression model to do an analysis of the data collected for the study, the researcher concluded that the buyers, suppliers and new entrants collectively do have an impact or effect on the selection of a drug regulatory affairs strategy. From the individual analysis of each of the independent variable, the researcher concludes that the new entrants have the strongest stand-alone impact on the drug regulatory framework followed by the buyers. The supplier group alone however cannot create an impact on selecting a drug regulatory strategy. The strongest of the supplier group was the regulatory affairs professionals. The patients and clinical investigators that form part of the clinical trials for approval of drug molecules used in Kenya did not prove to have a significant impact on the selection of a drug regulatory affairs strategy. The next chapter is on the discussions, conclusions and recommendations of the study.
CHAPTER FIVE

5.0 DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

In this chapter, the researcher provides the summary, discussion, conclusion and recommendations for this research project.

In section 5.2, a summary of the study is given, in 5.3 the findings of the research are discussed in relation the roles of each of the variables identified in chapter two, a conclusion is drawn in section 5.4 and recommendations for future research and improvement in the Pharmaceutical industry in Kenya are discussed in section 5.5.

5.2 Summary

The purpose of the study was to do a competitive analysis of the drug regulatory affairs framework in Kenya using three of Michael Porter’s five forces of competence powers. The study was guided by the following research objectives: To determine the strength of the buyers in the regulatory framework of Kenya, to determine the strength of the suppliers in the regulatory framework in Kenya and to determine the threat of new entrants into the drug regulatory framework in Kenya.

The study used the statistical analytical descriptive approach based on literature review and fieldwork to answer the research questions. Pharmacists working for thirty (30) multinational Pharmaceutical and biotech companies were sampled. However in Kenya, only fifteen (15) of these multinationals have wholly owned subsidiaries. The rest operate though partnership with local distributors. According to the Pharmaceutical Society of Kenya, the companies in total employ sixty-five (65) Pharmacists and the Pharmacy and Poisons Board which is the Drug Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya employs ten (10) regulators. This formed the population of the study. A sample size of fifty-six (56) Pharmacists working with the multinational Pharmaceutical companies was selected from the total population at 95% confidence level and 5% margin of error. For the Pharmacists working with the board, because they were ten (10) in numbers, a census was done bringing the total
sample size to sixty-six (66) Pharmacists. The sample size was selected using simple random sampling and a questionnaire was used for data collection. Mean was used to describe the responses to the questions asked to determine the strength of each sub-group under the independent variables and a linear regression analysis using statistical t-tests done to compare the strength of the independent variables against each other. The data was presented using tables and figures to give a clear picture of the research findings at a glance.

In determining the strength of the buyers within the regulatory framework in Kenya, the findings established that the multinational headquarters are the strongest of the buyer group and the local marketing departments the weakest of the buyer group. The buyers together have a strong and significant effect. They as a group ranked second with regards their effect on creating a drug regulatory strategy.

For the suppliers within the regulatory framework in Kenya, the findings established that the drug regulatory affairs professionals who provide internal labour are the strongest of the supplier group and the patients who form part of clinical trials the weakest of the supplier group. Together, they do not have a strong and significant effect on creating a drug regulatory strategy. They ranked the least with regards their effect on creating a drug regulatory strategy.

Evaluating the new entrants into the drug regulatory framework in Kenya established that technological innovations in drug regulatory affairs were the strongest new entrants and the outsourcing of regulatory affairs the weakest. The new entrants together have a very strong and significant effect. As a group they ranked the strongest of the three variables studied with regards their effect on creating a drug regulatory strategy.

5.3 Discussions

5.3.1 The Strength of the Buyers

According to Porter (1985) strong buyers influence by exerting pressure to drive down prices or increase the required quality for the same price of services that they are offered. This could consequently reduce profits in an industry. An assessment of how easy it is for buyers to increase prices indicates that if the buyer’s requirements are different from that
of others within the industry and they are well informed, they will have a strong negotiating leverage and can therefore easily influence situations to their benefits. The global headquarters of the multinational Pharmaceutical companies and the Pharmacy and poisons board of Kenya according to analysis of results from this research are strong buyers within the drug regulatory framework in Kenya. They can therefore influence the drug regulations as proposed by Porter in the five forces framework for his characteristics of strong buyers.

Some of the threat that the buyer’s face in the drug regulatory frame in Kenya include; firstly poor product safety monitoring which according to WHO (2011) greatly threatens the global health progress in poor communities with not so developed regulatory authorities; this is specifically a problem for the local marketing departments and by extension the multinational Pharmaceutical companies, secondly illegal imports through the parallel importation framework in Kenya that poses a threat for the profitability of the multinational companies and finally an under staffed not so competent regulatory authority. The strong buyers using can their clout can therefore integrate functions to mitigate some of these threats.

The reverse characters for strong buyers are true for weak buyers according to the assumptions of the Porter’s five forces framework. For this research, the local marketing departments even though Homburg, Workman, & Krohmer (1999) indicate that they function to communicate the value of the Pharmaceuticals offered by these multinational companies for the purpose of promoting or selling the drugs and consequently increasing sales and by extension the profitability of the companies, were estimated to be weak buyers within the drug regulatory framework in Kenya. This was a result of the assessments of the indicators for strong buyers within the regulatory framework. The respondents indicated that even though the local marketing department’s requirements are different from one to the other, they have a very weak negotiating leverage because they are not so well informed about trends and issues in drug regulatory affairs. This therefore remarkably reduced their strength within the drug regulatory framework. Despite their weakness as buyers, they however benefit from opportunities which include a wide variability of similar products that they market hence making their processes routine and less laborious and also greatly benefit from the huge marketing budgets they get from these multinationals.
5.3.2 The Strength of the Suppliers

The suppliers are also described as the market of inputs. Suppliers of labour (manpower) were the main focus of this research. According to Porter (1998) strong suppliers influence by exercising their power to sell their products at a higher price and thus eventually squeeze industry profits. If the suppliers force up the prices paid for their inputs, profits would be reduced. Thompson, Strickland, & Gamble (2009) assessment of strong suppliers is characterized by situations wherein they are of a total number such that they can come together and create an impact, and also in situations where they offer services that cannot be easily substituted because of certain specific unique characters that they have. The drug regulatory professionals as suppliers of labour within the regulatory framework in Kenya from the analysis of data collected for this research are considered to be strong suppliers. The respondents agree that the Pharmacists who provide labour within the drug regulatory framework, if they come together can effect significant changes in drug regulations in Kenya. Further indications of these effects are that because of their strength, they can demand for better conditions of services such as salaries and other forms of remuneration from their respective employers thereby piling pressure on them and consequently affecting their profitability.

Some of the threats that the suppliers within the drug regulatory framework in Kenya face include rigorous registration periods for specifically the regulatory affairs professionals which prevents them from meeting set deadlines, inadequate materials from companies for dossier compilation hence making their jobs almost impossible and lack of knowledge from most players within the framework in Kenya about the roles and responsibility of a drug regulatory affairs professional.

The regulatory affairs professionals according to analysis from the results of this research have the strongest individual effect among the supplier group on the drug regulatory framework in Kenya. Statistics have indicated that the Pharmaceutical industry is large and a growing market in Kenya and the regulatory professionals with the knowledge and experience are few comparatively. The demand for these suppliers within the regulatory framework in Kenya is therefore expected to eventually increase. This could also be an added advantage for the professionals.
The reverse of these characters is true for weak suppliers as proposed by the Porters five forces framework. From the analysis of data collected for the research, the clinical investigators and patients that form the clinical trials for the approval of drugs to be used in Kenya were estimated to be weak suppliers. They therefore cannot influence significantly functions within the drug regulatory framework in Kenya. Even though the respondents claim that for the patients, the services provided by them have specific unique values, their strength within the drug regulatory framework in Kenya decreased because the respondents claim that the services they provide can be easily substituted.

For the case of the clinical investigators, the services provided by them cannot be easily substituted because of the specific unique characters of these services which as an effect increased their strength. However, their strength on the other hand was significantly reduced because the respondents claim that they are not of a total number in Kenya such that they come together and effect a change within the drug regulatory framework. This is mainly because most of the clinical trials during Pharmaceutical product development for these multinational companies are done outside Kenya. The results of the research indicates that lack of capacity and inefficient systems for ensuring the clinical trials are done in Kenya is one of the factors that greatly affected the clinical investigator group and the patient’s strength within the regulatory framework in Kenya.

5.3.3 The Threat of New Entrants

According to Porter (1998) profitable markets that yield high returns will attract new entrants and this will result in many new entrants which will eventually erode profitability of firms. The drug regulatory framework in Kenya is no exception to this rule. Organizations in an effort to increase profitability would seek to make use of the new entrant into the drug regulatory framework in Kenya. According to Porter (1985) if new entrants move into an industry, they would increase market share and intensify rivalry. According to Volberda, Morgan, Reinmoelle, Hitt, Ireland, & Hoskisson (2011) strong new entrants are those for which even though their start up costs are high, would eventually prove to have very high cost advantages when utilized.

Analysis of results from data collected for this research indicates that the new entrants in the drug regulatory framework in Kenya with the exception of outsourcing regulatory affairs have a very strong and significant effect. The respondents suggest that although
both technology innovations in regulatory affairs and harmonizing regulatory affairs in Kenya have very high start-up costs, the incumbents strongly welcome these new entrants. They also agree that the long run cost advantages of these two variables are very high and if efficiently employed would greatly increase profitability of the organizations (the regulatory authority and the multinational companies) within the regulatory framework in Kenya.

The threats that these new entrants into the drug regulatory framework in Kenya face include for Harmonizing East Africa’s regulatory requirements, poor implementation guidelines hence there are no clear indications of what needs to be done and how they should be done. According to Kamla (2005) policy implementation is one of the major problems confronting developing nations as they strive for changes in doing things. This is very consistent with the findings of this research. Another problem that also prevents participating countries from realizing the full potential of this harmonization is unclear process and revenue sharing among the participating authorities. Braithwaite & Drahos (2000) indicate that the different regulatory bodies all have their own organizational mission and visions and therefore align their resources in order to achieve these objectives. This is a clear indication of why it is very difficult for the different regulatory bodies in East Africa to consolidate their actions in an effort to ensure the successful implementation of East Africa’s regulatory harmonization.

For the innovations in technology, they are faced with the threat of lack of appropriate infrastructure within in these countries that will support their full utilization. Available data, suggest that the majority of developing countries such as Kenya and many others in sub-Saharan Africa are lagging behind in the information revolution (Zhao and Frank, 2003).

Even though as documented in the literature review, several authors emphasize the relevance of outsourcing regulatory affairs, results from this research suggest that they as new entrants into the drug regulatory framework in Kenya do not have a strong and significant within the selection of a drug regulatory strategy in Kenya. This is probably due to the fact that the respondents because they were mostly regulation professionals were biased in their response to the questions.
5.4 Conclusion

The foregoing discussion shows that the applicability and significance of three of Porter’s five forces of competence powers in the analysis of competitiveness of the drug regulatory framework in Kenya is similar to that used in business entities in terms of distinct attributes and capabilities which are presented to their buyers, sellers and new entrants if they are to have a strong market and competitive position.

The Porter’s forces analysis helps organizations to understand the factors affecting profitability in a specific industry, and can help to inform decisions relating to: whether to enter a specific industry, whether to increase capacity in a specific industry, how to engage stakeholders and provides a guide for developing competitive strategies.

5.4.1 The Strength of the Buyers

The foregoing conclusion on the strength of the buyers is that when the Porter’s forces for competence power model are used to do a competitive analysis of the drug regulatory affairs framework in Kenya, they collectively have a strong and significant effect on creating a drug regulatory affairs strategy.

5.4.2 The Strength of the Suppliers

The foregoing conclusion on the strength of the suppliers is that when the Porter’s forces for competence power model is used to do a competitive analysis of the drug regulatory affairs framework in Kenya, they collectively do not have a strong and significant effect on creating a drug regulatory affairs strategy. However, the regulatory affairs professionals alone as suppliers of labour have a very strong and significant effect on creating a drug regulatory affairs strategy.

5.4.3 The Threat of New Entrants

The foregoing conclusion on the threat of new entrants is that when the Porter’s forces for competence power model are used to do a competitive analysis of the drug regulatory affairs framework in Kenya, they collectively have a strong and significant effect on creating a drug regulatory affairs strategy.
5.5 Recommendations

5.5.1 Recommendations for Improvement

5.5.1.1 The Strength of the Buyers

The recommendations for the Pharmacy and poisons board of Kenya as a buyer within the drug regulatory affairs framework in Kenya is that they use their clout to firstly pressure Pharmaceutical companies to provide higher quality submissions by increasing stringency on processes and procedures. They can also use their clout to increase post market surveillances of drugs used in Kenya thereby ensuring that the drugs are safe after use by a larger population with varied conditions.

5.5.1.2 The Strength of the Suppliers

The regulatory affairs professionals with their strength can influence changes within the regulatory frame work by coming together and forming stakeholder support groups which would function to promote activities that support their interest. They could push for extension of timelines, and even demand the required material for regulatory submission from the multinational headquarters in order to ease up on their work. These stakeholder groups can also facilitate activities that would ensure that guidelines would address ethical practices and protect theirs and their organizations interests.

5.5.1.3 The Threat of New Entrants

The recommendations for the new entrants are that for the East African Harmonization of regulatory affairs, organizations support its successful implementation and technology innovations, organization venture to use them.

5.5.2 Recommendations for Further Studies

Several other strategic management frameworks have been used to analyze competitiveness within the Pharmaceutical industry. Recommendations therefore would
be for researchers to attempt using these frameworks for analyzing the competitiveness of the different functional areas within the Pharmaceutical Industry.

For the use of Porter’s framework, the researcher only sought to employ three of the five forces on the drug regulatory department. The other two forces were not evaluated. For further research, researchers can choose to study the threat of rivalry and substitutes within the drug regulatory framework in Kenya.

Also for further research, Porter’s five forces framework can be used to determine competitiveness within the research and development of Pharmaceuticals, procurement and supply chain and even quality assurance.

The gaps in clinical trials in Kenya that resulted to the decreased contribution of the clinical investigators in Kenya and the patients for clinical trials as indicated in analysis of results for this project can also be researched on to identify areas for improvement for the entire Pharmaceutical business sector and even individual multinationals Pharmaceutical companies.
REFERENCES


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APPENDIX I: LETTER OF INTRODUCTION

QUESTIONNAIRE ON ‘A COMPETITIVE ANALYSIS OF THE DRUG REGULATORY FRAMEWORK IN KENYA USING THREE OF MICHAEL PORTER’S FIVE FORCES OF COMPETENCE POWERS’

Dear Respondent:

I am an MBA student at Chandaria School of Business United States International University- Africa conducting research on ‘A Competitive Analysis of the Drug Regulatory Framework in Kenya using three of Michael Porter’s five forces of Competence Powers’ your response to this questionnaire is crucial to successful completion of this project. Please attempt to answer all the questions by filling in the spaces provided and/or by ticking the appropriate answer that best suits your view for each question.

Your time and participation in this study will be greatly appreciated.

SECTION A: PURPOSE OF THE QUESTIONNAIRE

The purpose of this questionnaire is to collect data that will enable me to apply three of Michael Porter’s five forces of competence powers on the regulatory framework of the Kenyan Pharmaceutical industry and thus use it to make recommendations for developing a competitive regulatory strategy.

The recommendations of the findings will be shared with management of Pharmaceutical companies and other relevant stakeholders seeking to use regulatory affairs as a competitive advantage in Pharmaceutical Business development. An interview may be requested to hold a face to face or on telephone should any of the questions answers be unclear to the researcher.

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SECTION B: CONFIDENTIALITY
All the answers provided in this questionnaire will be kept confidential and all measures shall be put in place to assure this confidentiality.
I consent to be identified as the source of this feedback.
[ ] Yes [ ] No

SECTION C: CONSENT
You are encouraged to complete the questionnaire, and in the case that you do NOT wish to participate; your stand will be respected.
I consent to participate as a respondent to this questionnaire.
[ ] Yes [ ] No

SECTION D: INSTRUCTIONS
Here-in are nineteen (19) questions that can take you a maximum of (thirty) 30 minutes to respond. Kindly email your completed questionnaire to ajiffalabor@gmail.com or ajiffa@ke.betashelys.com.
APPENDIX II: QUESTIONNAIRE

SECTION E: GENERAL INFORMATION

1. Position held within the company/organization:
   ………………………………………………………………………………………………………
   ………

2. Is your company / organization a:
   [ ] Local Manufacturer
   [ ] Importer and distributor of Pharmaceutical products
   [ ] Innovator company
   [ ] Regulatory Body
   [ ] Other please specify:……………………………………………………………………

3. Years of working experience:
   [ ] 0 to 4 years
   [ ] 5 to 9 years
   [ ] 10 to 15 years
   [ ] Above 15 years

4. Drug regulatory affairs are KEY to Pharmaceutical Business development in Kenya?
   [ ] I strongly disagree
   [ ] I disagree
   [ ] Neutral
   [ ] I Agree
   [ ] I Strongly Agree
SECTION F: BARGAINING POWER OF THE BUYERS/BUYER GROUPS

The buyers within the regulatory framework in Kenya have been identified to be the regulatory agency that stipulates the policies which for the case of this study would be Pharmacy and Poisons Board of Kenya (PPB), the Global headquarters of the multinationals, and finally the local marketing departments.

5. To what extent do you agree with the following statements about PPB?

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<thead>
<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
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<tr>
<td>The requirements of PPB are different from that of other regulatory authorities within the region.</td>
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<td>PPB has a very strong impact on the development of a competitive RA strategy in Kenya.</td>
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<td>PPB has a very strong negotiating leverage relative to the other industry participants.</td>
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<td>PPB is very well informed about global trends in the RA.</td>
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6. To what extent do you agree with the following statements about the Global headquarters of the multinationals?

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<th>Statement</th>
<th>Strongly Agree</th>
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<td>The requirements of the multinational headquarters vary from one to the other.</td>
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<td>The multinational headquarters have a strong impact on the development of a competitive RA strategy.</td>
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<td>The multinational headquarters are very well informed about global trends in RA.</td>
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7. To what extent do you agree with the following statements about the local marketing departments?

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<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
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<th>Agree</th>
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<tr>
<td>The requirements of the local marketing departments vary from one to the other.</td>
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<td>The local marketing departments have a strong impact on the creation of a competitive regulatory strategy.</td>
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<td>The local marketing departments are very well informed about global trends in RA.</td>
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8. Kindly identify any threats for buyers within the drug regulatory framework in Kenya:

(i) ........................................................................................................

(ii) ........................................................................................................

9. Kindly identify any opportunity for buyers within the drug regulatory framework in Kenya:

(i) ........................................................................................................

(ii) ........................................................................................................
SECTION G: THREAT OF SUPPLIERS/SUPPLIER GROUPS

The suppliers within the regulatory framework in Kenya have been identified to be the internal labour (Regulatory affairs professionals) who wires the submissions, clinical investigators, and the patients who supply clinical data.

10. To what extent do you agree with the following statements about the internal labour (Regulatory affairs professionals)?

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<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
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<tr>
<td>They are of a total number in Kenya such that they can come together and effect a change within the RA framework.</td>
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<td>The services provided by them can be easily substituted.</td>
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<td>The services provided by them have specific unique values.</td>
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<td>The cost of switching from one professional to the other is very high.</td>
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11. To what extent do you agree with the following statements about the clinical investigators?

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<th>Statement</th>
<th>Strongly Agree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
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<td>They are of a total number in Kenya such that they can come together and effect a change within the RA framework.</td>
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<td>The services provided by them have specific unique values.</td>
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<td>The cost of switching from one clinical investigator to the other is very high.</td>
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12. To what extent do you agree with the following statements about the Patients who provide clinical data?

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<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
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<tr>
<td>They are of a total number in Kenya such that they can come together and effect a change within the RA framework.</td>
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<td>The cost of switching from one Patient to the other is very high.</td>
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13. Kindly identify any threats for suppliers within the drug regulatory framework in Kenya:

(i) ........................................................................................................

(ii) ........................................................................................................

14. Kindly identify any opportunity for suppliers within the drug regulatory framework in Kenya:

(i) ........................................................................................................

(ii) ........................................................................................................
SECTION H: THREAT OF NEW ENTRANTS

The new entrants into the regulatory affairs framework in Kenya have been identified to be, Technological innovations for example software and doing e-submissions, the East African harmonization of regulatory requirements and outsourcing regulatory affairs like employing contract regulatory organizations (C.R.Os).

15. To what extent do you agree with the following statements about Technological innovations in RA.?

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<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
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<th>Neutral</th>
<th>Agree</th>
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<td>The capital requirements for these innovations in technology are very high.</td>
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<td>The responses of incumbents to these innovations in technology are very welcoming.</td>
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<td>The costs of switching to use of these innovations in technology are comparatively very high.</td>
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<td>There are very high cost advantages for organizations that adopt these innovations in technology as they expand their operations within the region.</td>
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16. To what extent do you agree with the following statements about harmonization of RA in East Africa?

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<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Disagree</th>
<th>Neutral</th>
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<tr>
<td>The capital requirements for harmonizing RA in East Africa are very high.</td>
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<td>The responses of incumbents to harmonizing RA in East Africa are very welcoming.</td>
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<td>The costs accrued by organizations as they switch to meet the requirements of a harmonized RA in East Africa are very high.</td>
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<td>There are very high cost advantages for organizations as RA is harmonized when they expand their operations within the region.</td>
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17. To what extent do you agree with the following statements about outsourcing RA?

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<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
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<tr>
<td>The capital requirements for outsourcing RA are very high.</td>
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<td>The costs of switching to RA outsourcing are comparatively very high.</td>
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<tr>
<td>There are very high cost advantages for organizations that adopt RA outsourcing as they expand their operations within the region.</td>
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18. Kindly identify any threats for new entrants within the drug regulatory framework in Kenya:

(i)..............................................................................................

(ii)..............................................................................................

19. Kindly identify any opportunity for new entrants within the drug regulatory framework in Kenya:

(i)..............................................................................................

(ii)..............................................................................................

THANK YOU FOR YOUR TIME AND PARTICIPATION