



Addis Ababa University
School of Graduate Studies

**MARKETING CHALLENGES AND PROSPECTS OF
INNOVATIVE MULTINATIONAL PHARMACEUTICAL
COMPANIES: THE CASE OF ETHIOPIA**

BY: SAMSON TADESSE MOLLA

MAY, 2015
ADDIS ABABA, ETHIOPIA

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MULTNATIONAL PHARMACEUTICAL COMPANIES:
THE CASE OF ETHIOPIA**

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**A THESIS SUBMITTED TO ADDIS ABABA UNIVERSITY, SCHOOL OF
COMMERCE IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF MASTER OF MARKETINGADMINISTRATION**

MAY 2015

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DECLARATION

I, the undersigned, declare that this thesis is my original work, prepared under the guidance of Dr Yassin Ibrahim (PhD). All sources of materials used for the thesis have been duly acknowledged. I further confirm that the thesis has not been submitted either in part or in full to any other higher learning institution for the purpose of earning any degree.

Name

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Addis Ababa University, Addis Ababa

May, 2015

ENDORSEMENT

The thesis has been submitted to Addis Ababa University, School of Commerce for examination with my approval as a University advisor.

Advisor

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May 2015

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Acknowledgment

First and foremost, my grateful thank goes to my advisor Dr Yassin Ibrahim for his encouragement, guidance and support from the initial to the final level.

Lastly, I offer my regards and blessings to all of those who supported me in any respect during the study, particularly those who were direct participants of the study.

Above all, my greatest thanks and gratitude to the almighty God, for thee gave me the strength and perseverance to endure this task.

Abstract

Objectives: The aim of this study is to investigate the marketing challenges and prospects of innovative multinational pharmaceutical companies operating in Ethiopia.

Method: The study design was descriptive study conducted from February 2015 to May 2015 in Addis Ababa. The research used primary data from all the managers of the existing Innovative multinational companies towards the Ethiopian pharmaceuticals market opportunities and prospect in ensuring their companies future existence through semi structured interview question and self administered questionnaires. In addition, the study covers challenges with regards to product registration, government import regulations, supply chain and distribution, counterfeit products and generic product competition as the main factors to investigate the research question.

Findings: The available 12 country managers, 8 marketing managers and 4 Key account managers and 12 senior medical sales representative of the existing 12 Innovative Multinational pharmaceutical companies in Ethiopia were invited to participate in the study and all of them has responded giving the response rate of 100%. The result showed that the major driving force for the marketing activity of these companies is due to the acclaimed rapid economic growth of the country. These companies have disease areas of cardiology and metabolism as a future growth potential market unlike previously in which infectious disease was a major focus for their marketing activity. Product registration challenge and generic product competition are the major challenge for all the participants. All managers responded that counterfeit product in not a major challenge unlike other African countries.

Conclusion: The empirical result showed that Innovative Multinational pharmaceutical companies operating in Ethiopia currently view the country as a ripe market potential to expand their marketing activity better than the neighboring countries. Basically rapid population growth, the acclaimed double digit economic growth with the increase in modern health care seeking behavior of the society and the increase in prevalence of cardiometabolic diseases are the major driving force for the marketing activity of these companies. On the other hand, in the process of trying to avail their product in Ethiopian market: Product registration, foreign currency allocation, import regulation, low cost generic products competition and distribution system failure are considered to be prominent system related challenges faced by the multinationals.

Key Words: Pharmaceutical Industry, Emerging Markets, Innovative Multinational Pharmaceutical Company, Generic Pharmaceutical Companies

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List of Acronyms

API	Active Pharmaceutical Ingredient
AU	African Union
BRICMT	Brazil, Russia, India, China, Mexico, and Turkey
CAGR	Compound Annual Growth Rate
CBO	Congressional Budget Office
FDA	Food and Drug administration
FMHACA	Food, Medicine and Health Administration and control Agency
GDP	Gross Domestic Product
HIV/ADIS	Human Immuno Deficiency Virus/Acquired immune deficiency syndrome
IMPC	Innovative Multinational Pharmaceutical Companies
NCE	New Chemical Entities
PFSA	Pharmaceutical Fund and Supply Agency
R & D	Research and Development
SSA	Sub-Saharan Africa
UNECA	United Nation Economic Commission of Africa
WHO	World Health Organization

CHAPTER ONE

1. Introduction

1.1 Background of the Study

The global pharmaceutical industry looks like the epitome of a modern, matured industry that has found a comfortable way to make profits in billions of dollar. It is a global, hi-tech and has the ultimate customer. In addition, developed countries healthcare budgets are also a fortune for the industry. However, it is characterized by highly risky and lengthy research and development (R & D) processes, intense competition for intellectual property right, stringent government regulations and powerful purchaser pressures.

The origins of modern pharmaceutical industry can be traced to the late 19th century, when dyestuffs were found to have antiseptic properties. Roche, Ciba-Geigy and Sandoz started as family dyestuff companies based in Switzerland which moved to synthetic pharmaceuticals and eventually became global players. Penicillin was a major discovery for the emergent industry and during the 1940s and 1950s, R&D became firmly established with in the sector. The industry expanded in the 1960s benefiting from significant new discoveries with permanent patent protections. Regulatory controls on clinical development and marketing were light and healthcare spending boomed as economies prospered. (1)

In the late 1960s and early 1970s, two important developments that defined the directions of the global pharmaceutical industry became apparent. Firstly, the Thalidomide tragedy (where the drug given for pregnant women caused birth defects in newborns) led to much tighter regulatory controls on clinical trials, greatly increasing drug development costs. Secondly, enactment of legislations to set a fixed period on patent protection, typically 20 years from initial filing as a research discovery led to the appearance of “Generic” medicines. The impact of generic entry is illustrated by Bristol Myers Squibb’s Glucophage, (a brand for metformin) which generated US sales of \$2.1billion in 2001. Following loss of the patent in January 2002, brand sales plunged to \$69m for the first quarter. The introduction of generics, however, was very beneficial for society: valuable medicines became extremely cheap. Indeed, health economists have estimated that the social returns from pharmaceutical R & D exceed that appropriated by firms by at least 50 to 100 per cent. (2)

From the year 1998 to 2005, the global pharmaceutical sales showed more than a double increase from \$298 billion to \$602 billion. The average growth during these periods was strongest in North America (12.6% per year) compared to 9.3% in Europe and 2.9% in Japan. North America accounts for the largest proportion of the world's pharmaceutical market (45%) followed by Europe (including the UK) which accounts for 23% of the total global sales. Australia represents 1% of the global pharmaceutical market and the rest of the world including Africa, Asia (excluding Japan), Latin America and the Oceania altogether take 21%. France, Italy and Poland are the three leading countries in terms of the expenditures on pharmaceuticals. France and Italy each spent an average of 1.9% of their GDP on pharmaceuticals during the 2002 to 2007 fiscal years. (2)

The combination of economic strength and an expanding middle class is already driving a demand for medicines across Africa. Emerging markets have long been regarded as the “promised land” of the pharmaceutical industry. They are expected to amount to nearly a third of the global pharmaceutical market by 2016, and it is anticipated that they will play a vital role in sustainable growth in the industry. With huge populations, increasing prosperity, and improving longevity (albeit at differing rates), these are markets is very attractive to those companies suffering from the stagnation of mature markets, patent expirations, and increased regulatory hurdles. (3)

By 2016, pharmaceutical spending in Africa is expected to reach US\$30 billion. This value is driven by a 10.6% compound annual growth rate (CAGR) through 2016, second only to Asia Pacific (12.5%) and in line with Latin America (10.5%) during this period. (4)

A study jointly published by the Federal Ministry of Health of Ethiopia and the World Health Organization (WHO), publicized that, before five years, the allocated drug budget of Ethiopia was inadequate as revealed by a very low per capita government drug budget of ETB 1.60 (\$0.18 by the then exchange rate). This was indicated to be the lowest even by the sub-Sahara African standards and the WHO's recommendation of \$ 1.00. But until recently, Ethiopia used to put high tax burden on pharmaceutical raw materials imported from abroad which now seems to

have eased a little bit. Though compiled data on most of the pharma-economics are rare, it can, however, be said that the country doesn't have a developed pharmaceutical industry, but only few and small factories which mainly manufacture generic products using a commissioned master formula developed elsewhere. These factories produce some 25-30% of the essential drugs that the health sector of the country needs. The remaining 70-75% of the country's medicines market has been left vacant for imported products, principally for the low cost generics from micro-drug factories from Asia, mainly India and China. (5)

1.2 Statement of the Problem

The pharmaceutical industry has always been of interest to economists as a large and internationally competitive industry. Recently, it has come under policy scrutiny as a component of a much-debated health care system, with proposals ranging from preserving the current status of the industry to full price controls on pharmaceuticals. To understand the implications of various proposals, it is important first to understand the market environment in which the industry operates. In Ethiopia, out of fifty giant innovative multinational pharmaceutical companies, twelve of them are operating i.e. Pfizer, Novartis, Jonson and Jonson, MSD, Sanofi, Roche, AstraZeneca, GSK, Bayer, NovoNordisk, Merck KGa and Sandoz Pharmaceuticals.

The attractive pharmaceutical market of emerging economies, including viable economic growth, untapped pharmaceutical market, the increase non communicable disease burden (e.g. diabetes, hypertension etc..) and the increase health awareness of the society has favored these companies to invest tremendous amount of capital on their human resources, research and development and distribution channels. Even though these companies are investing heavily in developing countries with hope of future, they claim various marketing challenges like delayed product registration process, strong generic product competition, Indian and Chinese companies with lower prices, poor supply chain system of local agents and counterfeit products importations. (5)

There is no previous research conducted on this topic. So, the subject of this paper is identifying the problems affecting the marketing activity of innovative multinational pharmaceutical companies operating in Ethiopia and examining their influence on the prospects of these

companies. As a pioneer research on Innovative multinational pharmaceutical companies in Ethiopia, these research will also looks in to different marketing prospect of the countries pharmaceutical sector which not only give an insight for the existing corporate companies about the future market to ensure their long term stability but also attract other competitive innovative Pharmaceutical companies to invest in our Country. This may also give benefit to government regulatory organs to know the Ethiopian pharmaceutical market environment and can easily made actions based on the recommendation of the study.

1.3 Objective of the Study

1.3.1 General Objective

The main objective of the study is to identify the marketing challenges and prospects of innovative multinational pharmaceutical companies operating in Ethiopia.

1.3.2 Specific Objectives

- ✓ To assess the challenges of product registration, import regulation and supply chain system for innovative multinational pharmaceutical companies in Ethiopia.
- ✓ To determine the level of impact of generic competition and counterfeit product on the marketing activities of the innovative multinational pharmaceuticals
- ✓ To identify the major marketing opportunities for innovative multinational pharmaceutical companies in Ethiopia.

1.4 Research Questions

1. What are the marketing prospects that attract the companies to invest in Ethiopia in the future?
2. What are the major market opportunities the companies are currently capitalizing on?
3. What are the major marketing challenges faced by the companies?
4. What are the negative impacts of the marketing challenges in these companies?

1.5 Scope of the Study

The study has incorporated all innovative multinational pharmaceutical companies that are operating in Ethiopia. All of these companies have been working in Addis Ababa as a result the interviewee and the respondents are geographically located in Addis Ababa. To meet the objectives of the study, descriptive method of analysis was employed.

The study conceptually was only bind on the challenges and prospects of innovative multinational pharmaceuticals on their marketing activities since commencing their business in Ethiopia which encompasses from product registration to collection of credit invoices.

The study has assessed the opportunities (various demographic, population sizes, economic, disease burden) as well as the challenges (regulatory, registration and supply chain issues) of these innovative multinational pharmaceutical companies operating in Ethiopia using the data collection tool during the study period.

The study was tailored utilizing the response of country directors, Key Account Managers, Marketing Managers and Senior Medical Sales Representatives. All the information was collected in 2015.

1.6 Significance of the study

A limited research was conducted on the Ethiopian pharmaceutical sector and the paper opens the door for the future researchers and it can be used as a reference.

The research has also analyzed problems affecting marketing activities of innovative multinational pharmaceutical companies. So, it shows managers the main variables that affect

profitability and helps them to concentrate on the variables that significantly affect company's profitability.

The research results can be used by other pharmaceutical companies as a source of insight about the pharmaceutical marketing prospects and challenges of the Ethiopian market which would have great impact on the economic growth, pharmaceutical coverage and accessibility, enhance employment rates, research and development.

For local government and regulatory authorities, the recommendation parts would give them a chance to assess their policy impact in facilitating the smooth marketing activities.

1.7 Organization of the study

The study was organized in the following ways. The first chapter has discussed introduction/background to the study, statement of problem, objective of the study, significance of the study scope of the study, limitation of the study and organization of the study. The second chapter has discussed review of related literatures from both theoretical frame work and empirical findings. The third chapter has discussed research design and methodology including methods of data analysis. Chapters five has presented analysis and discuss the data and chapter six will stipulate findings and recommendation of the study.

1.8 Definition of Terms

- **Innovative Multinational Pharmaceutical companies:** are pharmaceutical companies manufacturing a branded molecule that has a trade name and is protected by intellectual property or patent, produced and sold only by the company holding the patent. (26)
- **Generic Pharmaceutical companies:** are pharmaceutical companies manufacturing a drug product that is comparable to a brand/reference listed drug product in a dosage form, strength, quality and performance characteristics and intended use after the expiry of intellectual property or patent. (26)
- **Emerging markets:** is a country that has some characteristics of a developed market but does not meet standards to be a developed market. This includes countries that may be developed markets in the future or were in the past. (4)

CHAPTER TWO

2. Review of Related Literature

2.1 Understanding Pharmaceuticals Industry

Pharmaceuticals play a vital role in maintaining the health of people and ensuring their productivity in all areas of life. In their effort to maintain a healthy way of life people invest a large proportion of their wealth to acquire effective pharmaceutical products manufacturers, distributors and retailers.

The primary function of the research-based pharmaceutical corporations is to create value by discovering and producing effective medicines, vaccines and services that improve health and well being of people by pharmaceutical products sold in markets at a profit. These products increasing shareholder's values as well as significantly affect the quality and protection of life in places where the services are better located. (6)

In the past 60 years, innovation and technology have impacted global health. According to the Human Development Report 2010, growth in life expectancy that took over 300 years to achieve in developed countries has been secured by developing countries in just half a century, thanks largely to innovations in medicine and other public health interventions. (6)

Intellectual property has played a key role in this progress. Discovering and developing a new drug, conducting clinical trials and gaining regulatory approval can cost around US\$1 billion. Less than 1% of the compounds examined in pre-clinical stages are cleared for testing in human beings, and only 22% of compounds entering clinical trials successfully reach development stage and regulatory approval. Without patents, it is estimated R&D outlays would be reduced by 64%, jeopardizing the well-being of people and the innovation process itself. Despite challenging business conditions, the industry undertakes investments that are considerably more risky than those in other high-technology sectors. By investing billions of dollars and thousands of scientist-hours, it pushes the limits of science, improves global health and contributes to the prosperity of society. (7)

As the Pharmaceutical industry matures, it faces a multiple of new challenges: the growth of generics, a slowdown in new blockbuster drugs, increased oversight from regulatory bodies worldwide. Today, the cost of developing a single drug amounts to over USD 1.3 billion compared to USD 138 million in 1975. This ten-fold increase reflects the various technical, regulatory and economic challenges facing R&D on the pipelines. (8)

Despite multiple challenges facing the multinational pharmaceutical companies, they are involved in the support of health care development by way public-private partnerships. They have reliable accesses to pharmaceutical outputs, sales percentage and employment in the industry. In a number of cases, international corporations and foundations have contributed drugs or products free of charge to help in disease eradication. For example: SmithKline Beecham has made a US\$500 million commitment to WHO of its drug albendazole, used to treat lymphatic filariasis (elephantiasis) are therefore able to change society and their environment tremendously. (9)

This chapter has presented a brief industry description and will now try to see trends in the pharmaceutical industry with the emphasis on emerging market for innovative multinational pharmaceutical companies.

2.2 Emerging Markets and their Opportunities

The global pharmaceuticals market is worth US\$300 billion a year, a figure expected to rise to US\$400 billion within three years. The 10 largest drugs companies control over one-third of this market, several with sales of more than US\$10 billion a year and profit margins of about 30%. Six are based in the United States and four in Europe. It is predicted that North and South America, Europe and Japan will continue to account for a full 85% of the global pharmaceuticals market well into the 21st century. (9)

Emerging markets have long been regarded as the “promised land” of the pharmaceutical industry. They are expected to amount to nearly a third of the global pharmaceutical market by 2016, and it is anticipated that they will play a vital role in sustainable growth in the industry. With huge populations, increasing prosperity, and improving longevity (albeit at differing rates),

these markets is very attractive to those companies suffering from the stagnation of mature markets, patent expirations, and increased regulatory hurdles. (5)

The emerging markets account for an estimated 20% (or roughly \$190bn) of global spending on medicines today, according to IMS data. Moreover, growth in emerging markets is projected to be stronger than elsewhere (12 – 15% CAGR between 2012 -2016 compared with 1 – 4% CAGR in developed markets)with spending set to nearly double by 2016. (10)

However, although these regions offer huge untapped potential, they display a wide diversity in their stages of development, particularly with regard to their healthcare infrastructures. For this reason, there can be no “one-size-fits-all” approach to emerging markets. Even among the three main clusters of markets—the BRICMT economies (those of Brazil, Russia, India, China, Mexico, and Turkey); second-tier countries such as those of Southeast Asia; and finally Africa here are local idiosyncrasies that make bespoke approaches to these markets essential. (3)

Like other African nations, Ethiopia bears a disproportionate burden of disease, for example, 75% of the world’s HIV/AIDS cases and 90% of the deaths due to malaria. Still many people suffer from tuberculosis and many others are affected by infectious diseases that cause substantial burden of morbidity and mortality. The extreme impact of infectious diseases is largely felt in Sub-Saharan Africa (SSA). Ethiopia being located in this region the existing disease profiles are more or less closely related. Despite infectious diseases being major public health problems in these areas , currently other non-communicable diseases observed in the industrialized countries, like cardiovascular disease, diabetes and cancer are also taking predominance pictures now a days. Thus non-communicable diseases are increasingly becoming prominent across the rest of the continent in the light of demographic changes taking place at the moment. Chronic non-infectious diseases are predicted to overtake dominance as the leading causes of death in Africa by 2030. (11)

In 2001/ 02 G.C, the total Ethiopian government drug fund allocated was about 104 million ETB (US\$ 12.1 million) which was approximately 19% the recurrent government health budget and represents a per capita drug budget of ETB 1.6(US\$ 0.18). This is considered to be very low as

compared with the target set by HSDP I (US\$ 1.25) and WHO's recommendation of US\$ 1.00. According to PASS, the total drug expenditure of the Ministry of Health in 2002 G.C. was estimated at ETB 257.9 million (USD 30 million) representing a per capita drug expenditure of ETB 3.8 (US\$ 0.44). No reliable data is available on the drug expenditure of the private sector and other sectors. According to the National Bank of Ethiopia, the total value of import of "*medical and pharmaceuticals*" in 2001/02 G.C was ETB 421.3 million (US\$ 49 million). However, this category includes non-drug items as well and the value for drugs alone is lower than this figure. (5)

Even though, there are no updated figures on the contribution of each source although the National Health Accounts exercise in 1995/ 96 indicated that the private expenditure on drugs accounts for the largest share of the total estimated drug expenditure in the country. It is expected that, the Ethiopian pharmaceutical market to witness growth rates of slightly over 14%, to reach an approximate value of just under USD 1 billion in the year 2018. (5)

2.3 Summary of challenges faced by Pharmaceutical Companies operating in Ethiopia

The Ethiopian pharmaceutical market growth rates are expected to be significantly higher than the overall growth of the global pharmaceutical market. It is expected to have a compound Annual Growth Rate (CAGR) of about 5%. Although the Ethiopian pharmaceutical market holds great potential, the market itself poses many challenges. Unpacking Market Challenges Ethiopia has a highly price sensitive market. The affordability of pharmaceuticals is generally limited for the vast majority of the population. As most pharmaceutical products are supplied by the government, inexpensive and quality medicines are the number one factors considered during the issuing of tenders. High price sensitivity within the market increases competition and supports the demand for low-cost products. Generic pharmaceutical companies from China and India are able to leverage on their economies of scale advantage and reduce the price of their medicines, while local and other international pharmaceutical companies often find it challenging to do the same. (5)

Pricing is highly unregulated within the market. Supplier mark-ups are uncontrolled and the consumer ends up paying unreasonably high prices for pharmaceutical products. This lack of

price control within the supply chain restrains the growth of the pharmaceutical market by limiting the access of essential medicines to the population. Although a number of infrastructure improvements have been made in recent years, challenges for conducting an efficient business operation in Ethiopia prevail. Inadequate road networks disrupt the effective transportation of finished products as well as the distribution of raw material. Communication networks are also often interrupted and unpredictable. Local manufacturers often face the burden of shortages in power supply, therefore resulting in disrupted manufacturing operations. (27)

Another significant challenge faced within the Ethiopian market is related to the subject of currency. Ethiopia currently faces shortages of foreign currency. The issue of opening Letters of Credit, for the processing of international business, poses challenges as only selected sectors of the economy is prioritized. This adversely affects the purchase of pharmaceutical product or raw material from international markets there by influence the progress domestic market. Ethiopia presents a highly regulated business environment and, more specifically, strict regulations within the pharmaceutical sector pose many challenges. Distributors also suffer the consequence of not gaining access to the use of government credit system; hamper them to provide constant supply of pharmaceutical products to relevant retailers. This creates a negative perception towards suppliers within the retail industry. (27)

Weak administration boards often lead to delays in product registration. The listing of products could take up to 2 years before reaching the shelves of retailers. Marketing of pharmaceutical products forms an essential element of generating brand promotion and awareness. Social marketing is often used as an effective tool for creating awareness of healthcare issues, such as family planning and HIV/AIDS. In comparison to various other African countries, Ethiopia's marketing dynamics are seemingly different. For effective marketing of products, marketing material should be country specific. Ethiopians relate to advertising that represents their respective culture. The use of inappropriate marketing material may be unfavorable for the promoted brand. Additional challenges existing within the market are the poor labor skills and the slow adoption of new technologies. Although the Ethiopian government has embarked on various initiatives to promote skills development in the country, specialized skills within the pharmaceutical sector are limited. Technology applications are inadequate, thus limiting the advancement of novel concepts and innovation within the market. Local manufacturing accounts

for only 20% of the pharmaceutical demands of the country. The mega Pharmaceutical manufacturing industries in Ethiopia include Addis Pharmaceutical Factory (APF) and Ethiopian Pharmaceutical Manufacturing Factory (EPHARM) who are also competing to larger share of the market available by government tenders. Domestic manufacturers are at a constantly in struggle to coup with popular demands. However due to the lack of specialized skills and technology, their ability to maintain basic manufacturing standards, does limit them to control government tenders. Although these challenges remain to existent and known to hinder growth of many pharmaceutical companies, the impact of these challenges on the market is falling. This implies that Ethiopia has high potential for many opportunities. Large multinational pharmaceutical companies, such as GlaxoSmithKline (GSK), AstraZeneca and MSD, have already managed to gain a firm footing, featuring prominent roles in both the public and private sectors. (12)

2.4 Some Findings of Related Studies

Improving global health is a multi-faceted challenge due to the many barriers preventing access to quality care. Without proper infrastructure, having best medical initiatives are useless. Without political commitment, the funding for infrastructure and capacity building will not be available. The past ten years has witnessed a renewed engagement to find solutions. The pharmaceutical industry plays a bigger role in this aspect extending from innovating and developing new drugs to the markets and creates business models for emerging economies.

A study conducted to identify Problems Facing the Pharmaceutical Industry in Philadelphia, Pennsylvania indicated four major challenges facing the complex Pharmaceutical industry. These include the decline in the discovery, approval and marketing of new chemical entities (NCE) with fewer and fewer blockbuster drugs making it to the market, competition from generics drugs, regulatory pressures and the weak growth in the US market (the largest market) and therefore the need to explore other markets. (13)

Generic drugs have always been a big challenge for the established big Pharmaceutical companies. Big Pharmaceutical companies spend many years and millions of dollars (approximately \$802 million estimated by the Congressional Budget Office, CBO) from discovery to product launch. In 1976 the estimate was \$137 million dollars and by 1990 it had

increased to \$445 million dollars. These companies are able to take advantage of their hard work and investments while their patents are in effect, but as soon as these patents expire, the generic drug makers are able to undercut the big Pharmaceuticals profit margin within 6 months by producing lower cost, and in most cases very effective alternatives. (5)

The expanding presence of Asian generic manufacturers in Africa has seen the proportion of pharmaceuticals being imported from India and China more than double in value terms in recent years. According to global import and export data, India accounted for 17.7% of African pharmaceutical imports in 2011 (up from 8.5% in 2002) and China for 4.1% (up from around 2.0% in 2002). (4)

Price pressure is aggravated by domestic competition, as local companies typically receive support from their governments, a phenomenon also often seen in public tenders across emerging markets. This situation is further exacerbated by the fact that local companies are typically generics manufacturers that will also benefit from the approaching patent cliff. (14)

Reports of counterfeit pharmaceuticals in Africa indicate a wide variety of detrimental effects. In addition to those in public health, these include lost revenues to firms that might otherwise be used to develop newer and better products, lost taxes to governments responsible for public health, additional costs firms and governments incur to protect supply chains from counterfeit products, resulting disincentives to foreign investment, and consequent loss of jobs and economic opportunities. Sales of counterfeit drugs take away from the sales of legitimate drugs. (15)

The degree of government regulation of the pharmaceutical industry also determines profitability. Each successive federal government administration regulates the pharmaceutical industry to a different degree. Some countries, such as Canada and Germany, have price controls, or caps, on pharmaceuticals sold in their borders. Also, the U.S. government and the FDA exert a great deal of control over pharmaceutical advertising and the "claims" of what a particular drug can and cannot do. Complying with the strictures of these regulating bodies costs pharmaceutical companies millions of dollars per year. According to the Cato Institute, 85 percent of the cost of

pharmaceutical development goes to complying with FDA regulations, which amount to a tax on investing in biomedical research. (16)

2.5 Conceptual Framework of the study

The main objective of the study is to identify the marketing challenges and prospects of innovative multinational pharmaceutical companies that are operating in Ethiopia. This study will focus on the parameters from literature review and factors included from researcher's perspective to assess the research objectives.

The study conducted by Mattiahs (2013) clearly state that huge population growth, increasing prosperity and improving economic development seen in emerging market like Africa is very attractive to those Innovative multinational pharmaceutical companies suffering from the stagnation in of mature markets, patent expirations and increased regulatory hurdles. Another research by Abdella (2012) showed that the disproportionate disease burden seen in developing countries increases the attractiveness of emerging market for Innovative multinational pharmaceutical companies through having wider product portfolio. The researcher specified the scope of the research in observing Economic development, population growth, and increased disease burden and societies health awareness as an opportunity for innovative multinational pharmaceutical companies to enter and invest in Ethiopia.

The study conducted by Robert (2004), pointed out that regulatory pressure including product registration process affects the long term viability of Innovative Multinational Pharmaceutical Companies. Though there are no studies in countries like Ethiopia, long and tedious product registration and regulatory issue disfavors Innovative Multinational Pharmaceutical Companies which limit their growing capacity in these markets. Another point discussed as a challenge for Innovative Multinational Pharmaceutical Companies in this study is that the fierce competition from generic products. Low cost generic products manufactured in the country or imported from India and china are able to leverage their economies of scale advantage to dominate in an emerging market while Innovative Multinational Pharmaceutical Companies often find it challenging to the same. Another challenges faced by Innovative Multinational Pharmaceutical Companies in an emerging market like Ethiopia is the challenge of counterfeit products which

resulting disincentives to foreign investment and consequent loss of jobs and economic opportunities. (12)

As synopsis, the study conceptually was only bind on the challenges and prospects of innovative multinational pharmaceuticals on their marketing activities since commencing their business in Ethiopia which encompasses from product registration to collection of credit invoices. Hence, the study has assessed the opportunities (various demographic, population sizes, economic, disease burden and modern health seeking behavior of the society) as well as the challenges (registration, regulatory and supply chain issues) of these innovative multinational pharmaceutical companies operating in Ethiopia using the data collection tool during the study period.

CHAPTER THREE

3. Research Methodology

This chapter discusses the design used, sample size and sampling technique employed in addition to methods to collect data and how that data was analyzed.

3.1 Study Area

The study was conducted in Addis Ababa city administration, which has 10 Sub Cities and 99 Kebeles, covers an area of 540 square kilometers. According to 2007 population census, the projected density for year 2011/2012 is 3038096, Addis Ababa serve as, a seat of the African Union (AU) and the United Nations Economic Commissions for Africa (UNECA).

As a Capital city, Addis Ababa is the center of the country's trade activities including the pharmaceutical market. Hence, this study area is selected since Addis Ababa is residence for the existing Innovative Multinational pharmaceutical companies in the country.

3.2 Study Design

The aim of the study is to identify problems facing multinational pharmaceutical companies' operating in Ethiopia. Because of the study needed deep research, the researcher adapts descriptive method having both qualitative and quantitative data.

Using both quantitative and qualitative data, benefits to have the validity of inquiry result. Secondly, by using qualitative data researcher can get elaboration, illustration and clarification for the result found in quantitative data.

The study populations are the top level managers of the existing twelve innovative multinational pharmaceutical companies in Ethiopia. The study was carried out from February 2015 to June, 2015.

3.3 Sample size and Sampling Technique

Roscoe 1975 proposed sample size larger than 30 and less than 500 are appropriate for most researches but in this case a census data was collected on the 12 Innovative multinational pharmaceutical companies. A census data is collected because there are only 12 Innovative multinational pharmaceutical companies with a total of 24 managers and senior medical representatives.

All managers were considered in the data collection while the 12 senior medical sales representatives were purposively selected to represent their respective company's sales force.

Due to the fact that these companies have confidentiality policies inhibit the involvement of employees on sales and medical representative post, the study was focused on the management post respondents. If the employees are included in the study the response will be biased since they have no access and information to most of the policy related information of these companies. Thus, the study has given emphasis to managerial post respondents.

3.4 Data Source and Collection method

The study has employed both primary and secondary sources of data. The former was collected through interviews of the country managers of the innovative multinational companies using semi structured set of questions and structured self-administered questionnaire to collect data from marketing and Key Account managers and senior medical sales representatives of the companies. The later source of data was collected from different book, journals bulletins, etc.

The researcher has developed its own questionnaire in order to cover different types of questions concerning the challenges and prospects of the pharmaceutical market. A pretest was conducted in two of the multinational companies i.e. MSD and GSK to ensure not only the validity of the instrument but also assess the relevance and alignment of the questionnaire with the external interaction policy of these companies.

3.5 Data Analysis and presentation

A semi structured interview questions was applied for the qualitative information gathering. For quantitative data that was collected through questionnaires, it was analyzed manually and presented by tables. Summarization as a qualitative analysis was used to present the response of the interview.

3.5 Ethical consideration

The research paper conducted with full of ethical manner and without any ethical limitation The name/s of a writer/s quoted well on the research paper as a reference, when graphs, quotations, definitions and some data's are taken from the journal, researches and books. Finally, interpretation and conclusion do not biased and harm any participants' since their answers were not to be released to anyone and any information they provide was kept confidential and only was used for academic purpose.

CHAPTER FOUR

4. Result

After carefully analyzing the results obtained from the questionnaires and interview responses the following data were obtained. Each data was analyzed manually due to the limited number of pharmaceutical companies present in the country.

4.1 Demographic Data

A total of 36 respondents who hold management positions and Medical sales representative and management post in the innovative multinational pharmaceutical companies were included in the study among whom 28 of them were males and only 8 of them were females. Among the respondents 8 of them were marketing, 12 of them were medical sales representative and 4 of them were key accounts managers. The 12 country managers were met for semi structured interview questions. All the available Country managers, Marketing Managers and Key Account managers have responded to this study. In some companies since there was only one country manager a medical sales representative was selected to be included in the study. The management structure in these multinational companies comprises commonly of one country manager and medical representatives or one country manager, one line manager and medical representatives.

There were 21 master degree holders and 15 Bachelors in Pharmacy (Bpharm) degree holders. Among the 12 innovative multinational pharmaceutical companies, 6 of the companies have more than 10 employees, 5 of the companies have 5-10 employees and 1 of the company (Roche Pharma) has less than 4 employees. The number of employees these companies have is very small as compared to the entire pharmaceutical industry employee number as a study done by United Nations Industrial Development Organization INDSTAT Indicated that in Ethiopia in 2009 the pharmaceutical industry employed about 1,437 employees with a total payment of 1,167,480 USD.

All the companies have import and distribution office in the country. Eight of the companies operated through three local importers, three of the companies have two local import agents. And one of the companies operates using sole local import agent.

4.2 Basic Information

Among the 12 innovative multinational pharmaceutical companies operating in Ethiopia 8 of these companies operate through local import and distribution agent offices while 4 of the companies have their own branch office in the country.

While 3 of the company's focus on private pharmaceutical market in delivering their pharmaceutical products and service the remaining 9 companies capitalizes on both private and public or tender based business from the pharmaceutical funds and supply agency (PFSA).

Table 4.1:- Product acceptability and competitive position of respective companies

S.No	Description	Response Rate description				
		V. Poor	Poor	Good	V. Good	Total
1	Product Acceptability	0	0	7(29.1%)	17(70.9%)	24(100%)
2	Competitive Position	1(4.2%)	0	5(20.8%)	18(75%)	24(100%)

From table 4.1 we can see that 70.9% & 75% of respondents believe that their company have very good product acceptability with their customer and very good competitive position respectively, while the other 29.1% & 20.8% believe their product acceptance is good and good competitive position respectively. One of the respondents believes the competitive position of the company is very poor due to limited registered product portfolio and one directional marketing activity focusing on product differentiation and also intense challenge from generic competitors.

Table 4.2 :- Focus population group by income for the marketing activity

S.NO	Focus Population group by Income	Frequency (%)
1	High Income	5 (41.7%)
2	Higher Medium Income	2 (16.6%)
3	Middle Medium Income	5 (41.7%)
4	Lower Medium Income	0 (0%)
Total		12 (100%)

Five of the twelve innovative multinational pharmaceutical companies have products with high prices that focus on serving high income population group; seven of the twelve companies focus their marketing activity on serving higher and middle medium income as well as high income population. Amazingly none of the companies focuses on lower medium and low income population as a focus of their marketing activity.

4.3 Market Information

4.3.1 Response Related to Market Opportunities

Economic and Population Growth

In an effort to find out the major driving force behind the multinational companies market presence and investment in Ethiopia, Among 12 country managers, 2 of them, believe that the major driving force for their companies marketing activity is due to the economic growth of the country while 1 believe the increase in disease burden and political stability seen in the country has majorly contributed to his company’s market activity. The rest 9 country managers said the combined reasons of economic growth and increased disease burden was perceived as a source of growth and market opportunity.

The same majority confirmation response level is maintained from the result of the instrument for Intermediate level managers and medical sales representatives.

Table 4.3 - Response on major driving force for the company’s marketing activity

S. NO	Driving force for marketing activity	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Total
1	Population Growth	0	0	0	7	17	24
2	Economic growth	0	0	0	2	22	24

Further deep, the country managers responded that their company has affiliated business consultants who forward country data regarding the current economic, business and political status of the country. Ethiopia currently is view as a lucrative business heaven by their company since in majority of the region even if business growth rate is there the level is lower as

compared to Ethiopia. The companies also believe that the return of investment is higher in Ethiopia as compared with neighboring countries. One of the participant noted that for a gross sales of 2.5-3 million USD the companies are investing as small as 40,000-50,000 USD comparatively an investment of 200,000-300,000USD is required to gross a slightly higher 4 million sales in Kenya. Thus with a small amount of investment higher level of return can be gained in Ethiopia. The companies also believe that the pharmaceutical market of Ethiopia is not saturated yet which brings a very good opportunity for these companies to secure a first mover advantage. For example in our neighbor Kenya there might be around 25 generic products for a single branded product while in Ethiopia a maximum of 5 generics for a single brand exist. Also the level of class of molecules for various disease areas in narrows which enables these companies to introduce new products to the market even if these products have lost patent and are outdated in the western countries they still get significant market share in Ethiopia.

Disease Burden and Company’s Product Portfolio

All of the respondents strongly agree on selection of their company’s product in accordance with the country’s disease burden.

Table 4.4:- Disease area for future growth

S.No	Disease area for future growth	Frequency
1	CV and Metabolism	10 (41.6%)
2	Infection	4 (16.6%)
3	Oncology	2 (8.3%)
4	Respiratory	6 (25%)
5	Others	2 (8.3%)
Total		24 (100%)

These innovative multinational pharmaceutical companies have already existing products that they are capitalizing on but also there are product areas which they are looking forward from their production portfolio and market experience in other markets which they believe will contribute to their future competitive position.

Table 4.4 depicts quantitative response from intermediate level managers and medical sales representatives on various disease areas which are believed to become the source of future

growth. Among which Cardiovascular and metabolism takes the higher frequency by 41.6% while respiratory follows by 25%.

All country managers believe that there is a current increase in modern health care seeking behavior of the population which will positively impact their marketing activity. Their attitude up on this subject was also reflected quantitatively from the intermediate level managers and medical sales representatives' response. As depicted in table 5, 50% of the intermediate level managers and medical sales representatives only agree on the subject while 16.67% strongly agree that the society has modern health seeking behavior, none of the respondents didn't disagree with the statement claimed.

Patient Awareness in Seeking Modern Health Care

Table 4.5:-Modern health care seeking behavior of Ethiopian population

S.No	Ethiopian population has well established Health care seeking Behavior	Frequency
1	Strongly Disagree	0 (0%)
2	Disagree	0 (0%)
3	Neutral	8 (33.33%)
4	Agree	12 (50%)
5	Strongly Agree	4 (16.67%)
Total		24 (100%)

Up on depth discussion with country managers on the major weakness with regard to Ethiopian pharmaceutical market, the respondents pointed out that “out of the pocket money” market dynamic is major weakness. They also mentioned that almost all patients pay out of pocket except few who have insurance schemes and since due to higher product prices of these companies' patient coverage and business level is limited.

4.3.2 Response related to Market Challenges

Product Registration

All country managers agreed on the challenges they face in their marketing activity starts from tedious product registration at FMHACA. The same is claimed in quantitative results from intermediate managers and medical sales representatives, that there is high rate of product registration challenge significantly affecting their marketing activity and product introduction.

Long document review period was the frequent product registration challenge with highest frequency; complex document requirement also follows with lack of procedural transparency contributing to the product registration challenge. And last but not the list low personnel capacity of FMHACA was mentioned as one of the challenges in product registration.

Among the 24 quantitative analysis respondents 12 of them commented it takes 12 to 24 months for product registration while 8 of them said it takes their company <12 months to register a product's the remaining 4 commented that they are unlucky enough to get their products registered in less than 24 months time.

Import Regulation and Custom Clearance

The respondents mentioned the following as Import regulation challenge from customs authority to import pharmaceuticals: Foreign currency allocation and banking system, No supplier credit system, Bureaucratic procedures and extended paper work, Document discrepancy and Lack of structural clarity.

As a result, the companies are forced to stay out of stock in the market for long period of time and even get their products near to the stated expiry dates. One of the respondents had faced serious challenge in market due to getting their injectable product almost near to its expiry date due to custom clearance. Hence, all respondents agreed on government intervention in giving high attention for pharmaceutical sector is essential in availing their product on time.

Table 4.6:- Import challenges once the products are shipped from country of origin

S.No	Import regulation challenge	Frequency (%)
1	Long clearance lead time	12 (50%)
2	Long shipment lead time	2 (8.4%)
3	Document discrepancy	10 (41.6%)
4	Other	0 (0%)

Table 4.6 shows import challenges once the products have been shipped from site of production 50% commented that there is a long clearance time at the port of entry while 41.6% of respondent commented that they face document discrepancy between the requirement in the customs office and the multinational manufacturer.

Distribution System

Table 4.7:- Distribution system of pharmaceutical products

S.No	Level of distribution System of Agent	Frequency
1	Poor	0 (0%)
2	Moderate	8 (33.3%)
3	Good	12 (50%)
4	Excellent	4 (16.7%)
Total		24 (100%)

The pharmaceutical distribution of their agent was rated Good by 50% of respondents while rated moderate by 16.7% of respondents.

All the managers also agree on challenges in supply chain of their products in to the market. They mentioned that the credit system of wholesalers and retailers is affecting their business turnover. They claim the market is spoiled by some unethical wholesaler and retailers in not paying their credits on time affects their agent's working capital. Their agents are selecting their good wholesalers and retailers in distributing the products which in turn arises conflict of interest with the innovative pharmaceutical multinational companies with major objective of availing their product in wider scope. They suggest on pharmaceutical importers in enforcing and implementing the same credit length for wholesalers and retailers which make them believe that

the supply chain will behave if they are treated in the same manner with all the importers they come across with in doing their business.

They also made a remark on poor financial resource, poor infrastructure and sustainability and poor forecasting and supply chain maintenance systems as distribution system challenges.

Counterfeit Products

All 12 companies' managers responded that counterfeit products are not a major challenge in Ethiopia even though 4 of the companies have come across counterfeit products of their trusted brands in regional markets, which they appreciate governments strict policy and quick response on counterfeit products.

Table 4.8:- Government regulations on counterfeit products.

S.No	Government regulation of counterfeit product	Frequency
1	Poor	3 (12.5%)
2	Less Stringent	7 (29.2%)
3	Stringent	14 (58.3%)
4	Very Stringent	0 (0%)
Total		24 (100%)

Table 4.8 shows the response with regard to government regulation on counterfeit products. Most respondents (58.3%) indicated that the government has a stringent regulation on counterfeit products while 12.5% of the respondents believe that the regulation of counterfeit products is poor.

Generic Product Competition

All respondents in both qualitative and quantitative analysis indicated that generic product competition is also a major challenge for their activity.

Table 4.9:- Impact of Generic product competition

S.No	Impact of Generic product competition	Frequency
1	Weak	0 (0%)
2	Moderate	6 (25%)
3	Strong	15 (62.5%)

4	Very Strong	3 (12.5%)
Total		24

62.5% of the respondents commented that they face a strong marketing challenge from these companies. 25% of the companies rated the generic competition as moderate.

Frequently responded challenge from all innovative multinational pharmaceutical companies' regarding generic competition the availability of low priced Indian products. Especially on Indian companies which introduces products even before the expiry of the patent right of the molecule, which is still owned by the innovative multinationals pharmaceutical companies. This factor combined with unethical promotional activity with use of unapproved (false) information and provision of gimmicks and kickbacks challenges innovative pharmaceutical multinational companies marketing activity.

As synopsis, due to challenges of foreign currency allocation and the bureaucratic system of document validation and clearance at the customs authority, the companies have shifted their distribution hub to Kenya i.e. products manufactured in USA or Europe will be shipped directly to Kenya and then supplied to Ethiopia from Kenyan. And due to the focus of these companies and the growth of business in Ethiopia, the Kenyan's are doing the best they can not to let Ethiopia take the regional lead hence inter region competition between Ethiopia and Kenya has arose. This is exemplified by some companies becoming stock out in market for more than six months time period due to delays in shipment from Kenya and document discrepancy.

CHAPTER FIVE

5. Discussions

In this part of the study results will be evaluated and discussed in elaborative and meaningful way.

5.1 MARKET OPPORTUNITIES

Population Growth

Ethiopia is currently one of the fastest developing countries and is viewed as a source of ripe opportunity for pharmaceutical companies as well as other business ventures. The participants of the study who are Managers and Senior Medical sales representatives of the innovative multinational pharmaceutical companies responded about the major attractive factors that interest the companies to invest in Ethiopia include large market size, rapid economic growth and potential plus the rapid population growth. Some of the managers also commented that the company's product portfolio match with the disease pattern of the country and political stability of the country being the driving factors for their activity. These factors are not only existing in Ethiopia but also in the entire emerging market as indicated by Emerging economies are characterized by high levels of GDP growth, relative to the US and Europe.

Demographically, the African continent represents the fastest expanding marketplace. Its 600 million people are growing at an average annual rate of 3 percent, compared to 0.5 percent in developed countries. (4) The results indicate the combined increase in population growth and double digit economic growth in Ethiopia is a very attractive future prospect for these companies. They also believe the latter reason accompanied by the increase in disease burden of therapeutic areas like cardiology and metabolism and Respiratory was a favorable opportunity for most company's future marketing activity. All the three factors have a positive impact on the current and future marketing activities of the multinational pharmaceutical companies. Each of these factors is discussed in depth below.

Economic Growth

The relationship between pharmaceutical industry and the economic environment is best described within a ‘fact of life’ – the unlimited demand for health care is confronted with limited resources for its funding. Economic environment is defined by the changes in revenues and changes in the structure of expenditure as Dickov (2011) puts it. In addition to revenue, the researcher point out that economic environment is defined by the stage in the business cycle of an economy, by inflation and unemployment rates, and by resource availability. While others argue on population’s purchasing power and price of capital as the determinants of economic environment. In view of the complex nature of economic environment, its key feature is that it affects the availability of all product categories, including pharmaceuticals, i.e. the availability of health care. (17)

In 2013, Africa maintained an average growth rate of about 4%, this comprises positively to 3% for the global economy with Ethiopia having 8.1% economic growth as indicated by Investment Opportunities in Pharmaceutical Sector. (18) As the economy of a country increases the purchasing power of people and the health coverage is believed to increase. However, 50% of the innovative multinational pharmaceutical companies operating in Ethiopia are focusing on the middle and high income population group due to high product prices. As argued by Mckinsely There is growing numbers of middle-class consumers in at least 16 countries with emerging economies. They are home to nearly 2 billion people who spend a total of \$6.9 trillion every year. In the next 10 years, 80% of economic growth is expected to come from what is called “the emerging markets”. (19)

Hence, society’s purchasing power increases accompanied by modern health seeking behavior this will increase the market share as well as sales volume of the multinationals products. Amazingly these companies are not focusing on serving the low income population group which is left entirely to be served by the generic foreign manufacturers and Local factories.

Patient Awareness in Seeking Modern Health Care

50% of respondents rating are intermediate, though the current modern health care seeking behavior is not advanced majority with. The interview results also indicated these companies also believe the dramatic increase in modern health care seeking behavior and the expansion of

primary health care service by the Ethiopian government and increasing diseases burdens of Chronic illnesses that require higher care and follow up will impact their marketing activity positively. Since as modern health care seeking behavior increases people will look forward into visiting modern health institutions on which the multinationals will strength their promotional activities to get prescriptions of their branded products which in turn will increase their sales volume becoming a good prospect for continued business activity.

Disease Burden

Cardiometabolic diseases like hypertension, diabetes are increasing at an alarming rate in Ethiopia. This increase in chronic disease is clearly stated herewith in 2008, more than 31 million people died from four leading chronic, non communicable diseases: heart disease, cancer, respiratory disease, and diabetes. Close to half of these deaths are estimated to be premature. (20) This increase in disease burden combined with the already existing infectious disease and respiratory problems like Asthma are the major disease areas identified by the respondents to be the future growth drivers for the innovative multinational pharmaceutical companies. Especially chronic illnesses like hypertension and diabetes for which patients have to take medications for life will ensure product loyalty by patients once the patients are started on a specific brand manufactured by the innovative multinational pharmaceutical companies. Nearly 80 percent will occur in low- and middle-income countries, where these chronic diseases claim around 80 percent more lives than do the total of all infectious causes. Over the past decade, rises in chronic diseases have been most greatly concentrated in developing countries and, in the case of diabetes, have outpaced some of the original Global Burden of Disease's "pessimistic scenario" forecasts. (21)

5.2 MARKETING CHALLENGE

When these innovative multinational pharmaceutical companies are trying to capitalize on the existing marketing opportunities they are faced with challenges that threaten to hinder their marketing activity. The study participants have identified five major marketing challenges these are product registration challenge, import regulation regulations, supply chain and distribution system challenge, generic competition, and counterfeit products.

Product Registration

The primary step before any pharmaceutical company could market its product is acquiring of product market authorization license through the product registration process in FMHACA. This process is not viewed as a simple stroll in the park but a challenging process. All the participants of the study indicated that they face a significant product registration challenge. Only 33.3 % of the respondents commented the fastest document review period being <1 year but the vast majority 50% commented it takes 1-2 years to register a product while the remaining 16.7% believe it takes more than 2 years. The results show the primary contributing factor behind the delayed product registration is due to long document review period combined with the low personnel capacity of FMHACA, and lack of procedural transparency. Long document treatment period by regulatory agents and long and inflexible procedures are also mentioned as a challenge in registering new pharmaceutical products in low income countries. (22) Due to this factor these companies are struggling to register their blockbuster products which in turn minimize their market potential and competitive advantage.

Import Regulation

The other marketing challenge raised by the participants of the study was import regulations. Once the products get market authorization by FMHACA the challenge of import regulation come to sight. Among the import challenges foreign exchange allocation and lack of supplier credit system was a major challenges for all 24 respondents of the study. The respondents commented that there is a long waiting period to get a foreign exchange; it takes a minimum of 1 month to a maximum of 3 month to get foreign currency once documents are supplied to the bank.

They also believe if supplier credit systems exist they will be able to bypass the long waiting period for the foreign currency since they can directly import their products without prior payment and can pay back once they get the foreign exchange.

The other import regulation challenge mentioned was import challenges at the port of entry once the products are shipped from site of production. Long clearance time at the customs port was the major challenge with 50% frequency. The respondents believe that the over busy scheduling and low capacity of the customs authority contributed to the long clearance period of the pharmaceutical products. They even pointed out that sometimes long awaited products get

damaged, stolen or expire at the customs authority before they can be cleared from the authority to be marketed.

75 % of the 12 company's country managers commented that it takes an average of 4 months to clear their product from port and an average of 3-6 month for ESL to deliver products from site of manufacture. If the products are delivered through Ethiopian Airlines the delivery is fast but it takes an average of 3 weeks to clear items from customs authority with a lengthy and non transparent procedure.

The other contributor factor for the import challenge was document discrepancy and requirement with the Ethiopian customs authority and the overseas manufacturer with a 41.6% frequency. They commented that the multinational manufacturer document requirement in other countries including our neighboring countries is very different from Ethiopia, not only different but also keeps on changing frequently and there is no clear direction and format as to what requirements and margin of error is acceptable with the customs authority.

Distribution System

The distribution system pharmaceuticals were also identified as one of the marketing challenge for the multinationals activity. Fifty percent of the respondents rated the distribution system of pharmaceuticals of their agents as Good. Also 33.3% of the participants rated it moderate. The reasons behind the challenges in distribution system was mentioned as poor infrastructure of distribution channels, credit based sales system of pharmaceuticals, and poor forecasting and demand maintenance systems of wholesalers and pharmacies. Common problems in developing countries in supply and distribution of pharmaceuticals include poor supply chain management system, stock pilfering, insufficient human resource, and limited financing resulting in chronic stock outs. In resource-poor settings where public services fail to meet demand, the private and voluntary sectors are increasingly being called on, prompting some policy makers to consider private mechanisms as alternatives to state-run drug procurement and distribution systems .(23)

Counterfeit Products

While counterfeit medicines in wealthy markets are a growing concern for physicians and law-enforcement agencies, their prevalence pales in comparison to their penetration of less developed markets. According to the World Health Organization (WHO), 25 per cent of all medicines in developing countries are counterfeit. In some countries, the prevalence is far higher: A recent

survey by the WHO of seven African countries found that between 20 and 90 per cent of all anti-malarials failed quality testing. These included chloroquine-based syrup and tablets, whose failure rate range from 23 to 38 per cent; and sulphadoxine / pyrimethamine tablets, up to 90 per cent of which were found to be below standard. (24)

Amazingly all participants of the 12 multinational companies responded that counterfeit is not a major challenge in Ethiopia which was a contradictory result when compared against other studies in various African countries which conclude that counterfeit is a major challenge in the continent. But even though the respondents commented counterfeit products are not a major challenge three of the companies commented on the interview that they have come across counterfeit products of their major sales brands in regional markets especially one of the country manager commented that a 150000 USD worth counterfeit product was caught in Dessie Market by the collaborative action of FMHACA and the federal police.

The other result was 58.3% of the respondents believe the government regulation of counterfeit product is stringent while 29.2% of them believe it's less stringent, the remaining 12.5 % believe the government regulation of counterfeit products to be poor stringent.

Generic Product Competition

Generic companies are companies which does not introduce new or innovative products but manufacture products already created by the innovative multinational pharmaceutical companies. Some European generics abide by the patent right law therefore they will not introduce their products until the patent right of the company expires. But other European as well as all Indian companies do not follow patent right laws, hence ends up introducing competitive products before the expiry of the patent right in countries where there are no patent protection laws for pharmaceutical products, the case in our country.

All respondents commented that they face a strong challenge from generic companies, 62.5% of them are facing strong challenge and the remaining 25% are facing intermediate competition from these companies. Although the global shares of exports from India and China in value terms are relatively modest, they play an important role in pharmaceutical trade for low-income countries, especially for generic medicines. In 2009, low-income countries imported more than 30% of their pharmaceuticals from India. Lower-middle-income countries with some

manufacturing capacity also buy many of their “active pharmaceutical ingredients” (APIs) from China, accounting for more than 20% of their total imports of intermediate goods. (25)

Even though the marketing opportunity for these multinationals still exists the challenge from low price generic is still one real threat that they need to focus on as a forecast data shows in the IMS Institute for Healthcare Informatics that the pharmaceutical market will reach nearly USD 1,200 billion by 2016, an increase of nearly USD 250 billion from the USD 956 billion recorded in 2011. This growth is coming mainly from market expansion in the leading emerging countries and from generics. Global brand spending is forecast to increase from USD 596 billion in 2011 to USD 615–645 billion in 2016. Global generic spending is expected to increase from USD 242 billion to USD 400–430 billion by 2016, of which USD 224–244 billion of the increase is from low-cost generics in emerging markets. (26)

The final hallmark of many emerging markets, where growth in generics is expected to drive much of the increase in pharmaceutical expenditure, is government industrial policy designed to support domestic manufacturers. The increase in generic consumption is increasingly being supported by government policy, which seeks significant savings to health budgets by encouraging patients and doctors to use generics rather than originator brands. Brazil’s Generic Medicines Policy of 1999 has resulted in generics now having over 60% of market share by volume; with high acceptance even among middle class patients.¹⁷ South Africa also has an important generics market. Some emerging markets, including China, India, Brazil, Russia, and South Africa are also keen to promote and sustain a thriving generics industry in their own countries, seeing the value of a knowledge-intensive, export-orientated industry to the wider economy. This is leading governments to favor local producers, through procurement policy and industrial policy that involves multinationals agreeing technology transfer to local producers in exchange for access to markets. (26)

The major competitive force behind the generic companies identified were

Low prices:- since these companies are not facing product development cost, stringent regulatory cost, research and development cost as well as post marketing surveillance cost they can lower their product prices at a level the multinationals will have no hope of competing in price bases. These companies introducing different brand of the multinationals product at a

lowest cost and since the benefit of the products is already established by the multinational company they immediately start to take the market share since still majority of the population is low income.

Unethical promotional Activity:- the participants of the study commented that the promotional activity of the generic companies especially Indian companies is unethical use the use of off label discussion, which involve use of product for unapproved use, promoting of products to end users at pharmacies and use of unapproved (false) information which is not supported by an clinical trial or international guidelines.

Provision of Gimmicks and Kickbacks:- these companies provide various gimmicks which force the physicians to prescribe their products. For example the respondents commented giving of laptops, coffee mugs, and cash for holidays, pens, pads and promotional item is becoming a common promotional activity by these companies. They also sponsor good prescribing physicians for a vacation overseas to create a loyal customer.

Control of retail pharmacies and wholesalers:- the respondents also pointed out that generic companies provide a commission payments varying from 10-15 % of the total purchase of their product which is forcing pharmacies and wholesalers to stock large quantities of the generic products while pushing away the innovators brand.

6. SUMMERY, CONCLUSION AND RECOMMEDATION

6.1 Summary of Major findings

Among the respondents who hold management positions only 3 were females. Only 4 of the twelve innovative multinational pharmaceutical companies operate through their regional head office while the rest use local agents. The major driving force for the marketing activity of these companies is due to the acclaimed rapid economic growth of the country. These companies have disease areas of cardiology and metabolism as a future growth potential market unlike previously in which infectious disease was a major focus for their marketing activity. The major focus population groups for the marketing activity of the multinational companies are the high and middle income population group combined. None of these companies have low income population group as a potential target due to high prices of the products they provide. Product registration challenge and generic product competition are the major challenge for all the participants. All managers responded that counterfeit product in not a major challenge unlike other African countries

6.2 Conclusion

Innovative Multinational pharmaceutical companies operating in Ethiopia currently view the country as a ripe market potential to expand their marketing activity better than the neighboring countries. Basically rapid population growth combined with the acclaimed double digit economic growth with increasing middle income population is the major driving force for the marketing activity of these companies since their innovative products, country of origin and product cost makes their product expensive than generic counter parts to be affordable by the general population. Therefore these companies believe as economy of a country improves high and middle income population also increases thus proportion of people who can afford their product also increases.

The increase in modern health care seeking behavior combined with the increase in prevalence of some diseases like hypertension, diabetes, respiratory and oncology in the population is view as a great opportunity to be capitalized by these multinationals pharmaceutical companies. Since the

treatment modality for these diseases are expensive and lifelong these disease areas are major research areas and source of competitive advantage for the companies.

As the results indicate in the process of trying to avail their product in Ethiopian market Product registration challenge process from FMHACA is the major deterring factor for the marketing activity of the multinationals with delayed product registration time and document review period. Foreign currency allocation, import regulation and distribution system failure are considered to be prominent system related challenges faced by the multinationals.

Once their product enters the country Low cost and unethical promotional activities supported by provision of gimmicks is considered a major challenges for the marketing activity of the multinationals from generic producers especially sources from China and India.

Contrary to other African countries challenge from Counterfeit products are not considered as a major challenge by these companies.

6.3 RECOMMEDATIONS

Based on the finding of this study concerning marketing challenges and prospects of multinational pharmaceutical companies in Ethiopia; the following suggestions and recommendations were made so that they will overcome the challenges and be able to exploit opportunities that are out there in the market

Currently the marketing activities of the innovative multinational pharmaceutical companies are focused toward middle and high income population group, since this group of people can be able to afford their products. I strongly recommend the government's price subsidy policy to be revised by the PFSA (Pharmaceutical funds and Supply Agency) or concerned body on the inclusion of price subsidy for innovative pharmaceutical products. Hence, the general population will be able to get quality and innovative products from these companies at an affordable price and at the same time these companies maximize their sales and profits.

The FMHACA needs to facilitate the product registration process by shortening document and product review periods, increase their workforce to facilitate the registration process and reduced bureaucracy so that new products can be introduced to the market immediately and also existing

products can have a re-registration license once the five year market authorization is over. This is also an open research area for interested researchers to identify the system and procedural challenges of FMHACA and ways to improve the registration process.

Document requirement, procedures and import processes are strongly recommended to be clearly implemented by having a clear set standard of document requirements, evaluation process and consistent duration of review so the import process and regulation can be facilitated for the smooth marketing of their products.

The level and impact of counterfeit products needs to be thoroughly investigated by a collaborative action of FMHACA and government agencies in identifying potential sources of counterfeit products by undertaking post marketing surveillance of products that are introduced to the market. The researcher strongly recommend FMHACA to conduct a random testing of products from pharmacy shelves especially on fast moving products in order to pick out products that are counterfeit and also defects in quality of products from the multinational as well as generic companies in the country.

The problems with banking system and foreign exchange allocation need to be addressed for the pharmaceutical products because currently there are serious shortages in critical medicine due to queuing for the foreign currency allocation. Therefore by selectively prioritizing product ranges those are vital for the health care by a collaborative action with MOH the government can give priorities so that the supply of vital and necessary pharmaceutical products can be insured for the benefit of the population.

Patent right protection of pharmaceuticals needs to be implemented in Ethiopia by FMHACA and regulatory authorities which will inhibit the registration and market introduction of generic products before the expiry of the patent right of the multinational innovative companies product so as these companies can introduce new products without fear of immediate generic low priced competition

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Appendix I

Semi-structured Interview Questions for Country Managers

Part I : General Information

Name of Company_____.

Country of Origin_____.

1. Gender

Male Female

2. Educational Level

Bpharm/BSC Masters Phd

Other _____(Specify)

3. Number of Employees that are working under your supervision

=<4 5- 10 >10

4. Number of approved pharmaceutical Products in your company

<10 10- 15 16- 20 >20

5. Number of local agents representing your company

1 2 3 4

Part II: Basic Information

Questions related to market opportunities

6. What do you think about Ethiopian Pharmaceutical market?
7. Please describe about the opportunities of Ethiopian pharmaceutical market?
8. What is the strength of the Ethiopian pharmaceutical market?
9. What is the weakness of the Ethiopian pharmaceutical market?
10. What do you think as treats in Ethiopian pharmaceutical market?

Questions related to market challenges

11. What are the major challenges faced by your company in its marketing operations?
12. What are the major challenges regarding **products registration**? What do you suggest to tackle these problems?
13. What are the major problems you face regarding **banking system and import regulation**? And your suggestion for improvement?
14. What is the effect of **products shipment and custom clearance** in your marketing activities and your suggestion?
15. How do you evaluate the performance of importers, wholesalers and retailers in your **products distribution** process?
16. Is there any **counterfeit product** in the market? Do you think it is affecting your company revenue? What solution do you suggest for these problems?
17. How do you evaluate the **competition with generic products**? What are your mechanisms to counteract this competition?

Appendix II

A Self Administered Questionnaire on Challenges and Prospects of Innovative Multinational Pharmaceutical Companies: In the Case of Ethiopia

Dear Respondent,

First of all I would like to thank you for your valuable cooperation. This research focuses on the challenges and prospects of innovative Multinational Pharmaceutical companies operating in Ethiopia. Your answers will not be released to anyone and any information you provide will be kept confidential and will only be used for academic purpose.

N.B

- **You can give more than one answer**
- **Please fill a thick mark (√) in the check box provided for your answers.**

Part I : General Information

Name of Company_____.

Country of Origin_____.

1. Gender

Male

Female

2. Educational Level

Bpharm/BSC Masters Phd

Other _____(Specify)

3. Position

Marketing Manager KAM Medical Representative

4. Number of approved pharmaceutical Products in your company

<10 10- 15 15- 20 >20

Part II: Basic Information

1. How do you rate your products availability

Very Poor Poor Good V. Good Excellent

2. Which market segments are you primarily exploiting on?

Government Hospitals & Pharmacies Private Hospitals & pharmacies

Both

Others _____.(Specify)

3. Which distribution channel is your company primarily focuses on?

Government distribution channel Private distribution channels

4. How do you rate your company's competitive position in Ethiopian market?

Very poor Poor Good V. Good

5. Which Income group of the population is the main target for your company?

Lower Medium Middle Medium Higher Medium High

Part III. Market Information

3.1 Questions related with Challenges

6. How do you rate challenges of **Product Registration** for your company?

High Moderate Low

6. A) what are the most common product registration challenges?

6. B) how long the product registration process requires?

Less than 6 months 7 to 12 month 3 to 24 months > 24 month

7. Is there any **import regulation that challenges** your products marketing? If “Yes”

Please describe-----
-----.

8. How do you rate the impact of **banking system and regulations** with respect to import of your products?

No impact Less impact Moderate impact High impact

9. How do you rate the challenges associated with **shipping and clearance** of products?

No challenge Less challenge Moderate challenge High challenge

9. A) what challenges do you face with shipment and custom clearance

Long clearance lead time at ports Long shipment lead time
 Documents discrepancy Others? Please Specify-----

10. How many importers do you have for **supplying and distributing** your company’s product in to the market?

1 2 3

10. A) how do you rate the distribution system of your importers?

Poor Moderate Good Excellent

10. B) What are the major challenges that you face with your importers?-----
-----.

11. How do you rate the impact of **Counterfeit Products** on your revenue?

No impact Less impact Moderate impact High impact

11. A) How do you evaluate government regulations towards counterfeit products?

Poor control Less stringent control Stringent control Very stringent control

12. How do you rate the impact of **Generic Product Competition** on your company’s revenue?

No impact Less impact Moderate impact High impact

12. A) what marketing activities of competing generic pharmaceutical companies affect your company's revenue? -----

3.2 Questions related to market opportunity

13. **Population growth** of the country has a good impact on Pharmaceutical market growth.

Strongly Disagree Disagree Neutral Agree Strongly Agree

14. IMPC has engaged in commensuration of product selection to the country based on the **country's disease burden**.

Strongly Disagree Disagree Neutral Agree Strongly Agree

15. Ethiopian population has well established modern **health seeking behavior**.

Strongly Disagree Disagree Neutral Agree Strongly Agree

16. **Economic growth** of the country can be taken as criteria to enter in to Ethiopian market.

Strongly Disagree Disagree Neutral Agree Strongly Agree

17. Which disease area do you believe to contribute to your company's future growth portfolio?

CV and Metabolism Infection Oncology Respiratory

Others -----

THANK YOU VERY MUCH FOR YOUR COOPERATION.