

Prospects and Challenges in product Registration, Importation,
Distribution and Marketing of Multinational Pharmaceutical
Companies in Ethiopia: The Case of Sanofi, Novartis, Bayer,
AstraZeneca and Pfizer

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By: Abebe Misganie

Under the supervision of: Daniel Amente (PhD Candidate)

And

Gadise Amensis (Mrs)



MBA Program, Department Of Management Collage of Business
and Economics Jimma University

Jimma , Ethiopia
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Declaration

I hereby declare that this thesis “The Prospects and Challenges of Multinational Pharmaceutical companies in Ethiopia has been carried out by me under the guidance and supervision of Mr. Daniel Amente (PhD Candidate) and Gadise Amensis (Mrs)

As to my knowledge this research is original and has not been submitted for the award of any degree or diploma at any university or institutions.

Researcher’s Name

Date

Signature

Certificate of Originality

This is to certify that the project titled the Challenges and Prospects of Multinational Pharmaceutical Companies in Ethiopia is an original work of the student and is being submitted in partial fulfillment for the award of the Master's Degree in Business Administration of Jimma University.

Main Adviser's Name

Date

Signature

Co-Advisor's Name

Date

Signature

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Acronyms

MNPC	Multinational Pharmaceutical Companies
EFDA	Ethiopian Food and Drug Administration
W H O	World Health Organization
R & D	Research and Development
OTC	Over the Counter
LMIC	Low and Medium Income Countries
AMRHI	African Medicines Registration Harmonization Initiative
IPR	Intellectual Property Rights
IJPER	Indian Journal of Pharmaceutical Education and Research
FMOH	Federal Ministry of Health
IFPMA	International Federation for Pharmaceutical Manufacturers and Association
INN	International Nonproprietary Name
SPSS	Statistical Package for Social Science
MRAs	Medicine Regulatory Authorities
EPSA	Ethiopian Pharmaceuticals Supply Agency

Abstract

The pharmaceuticals industry is defined as all those who contribute to the discovery, creation and supply of pharmaceuticals products. Multinational companies are those engage in international business when it conducts any business functions beyond its domestic borders. Since countries vary in terms of their market size, growth trajectory, macroeconomic landscape, legal structure, and political complexities, multinational companies need to know the real challenges and opportunities of every country. The general objective of the study was to assess challenges and prospects of multinational pharmaceutical companies operating in Ethiopia. Since the numbers of employees in these companies are few in numbers census technique was used. The study used questionnaires and key informant interview to collect the data from 45 respondents. Data was analyzed and presented using descriptive statistics. Accordingly, the findings of the study revealed that tedious process of getting marketing authorization; serious shortage of forex allocation, bureaucratic procedure and extended paper work in banks, unethical pharmaceutical product promotion, weak government support for brand products importation and some supply chain related problems have been identified as major challenges. The study also indicated that growing population size, increased burden of non-communicable diseases, expansion of health care services, emerging middle class groups, who can afford innovative treatments and the progressive economic growth of the country as areas of opportunities for MNPCs. Based on the findings and conclusions made, the following recommendations have been given: the authority/ EFDA has to set clear time table indication for market authorization process, better forex allocation for pharmaceutical sectors from the government, strict follow up and controlling mechanism to ensure ethical pharmaceutical products promotional practice in the country and government support for multinational companies

Key terms: *Challenges, Multinationals, Opportunities, Pharmaceuticals,*

Chapter One

1.1. Introduction

This chapter outlines the background of the study to have an insight on the subject being studied and the statement of the problem that triggers this study. In this chapter the research questions and objectives have been clearly indicated for which the study has sought answers. In this chapter the importance of the study has been reflected, scope and limitation of the study have also been indicated

1.2 Background of the study

The Pharmaceutical industry is defined as the industry that involves the process of discovering, developing and manufacturing drugs by both private and public organizations. The modern pharma industry was established in 19th century after several health challenges that stimulated research in to the medicinal properties of plants, minerals and animals.

Growth and prosperity of a given nation largely depends on the health of the individuals in the society. Subsequently, the pharmaceutical industry has been identified in the United Nations' Millennium Development Goals as a major driver for the healthcare system (Shushmita et al., 2012). However, African continent has poor health indicators yet compared to other continents; this is largely because the governments of African countries have not fully addressed health challenges facing their population. One of such health challenges is lack of access to high quality medicines (Anyakora et al., 2017).

The pharma industry is the world's largest industry due to worldwide revenue of \$2.8 trillion. Pharma industry has seen major changes in the recent years that place new demand on payers, providers and manufacturers. Pharmaceuticals are considered as the most highly regulated industries worldwide (Mary et al., 2017). The pharmaceutical industry is highly complex. The technologies leading to drug discovery and development are at the peak of human knowledge. The huge size of the companies and the complexities of their processes and technologies results in many organizational and management challenges (Kolatra, 2014).

Innovation has always been the backbone and underlying strength of the pharmaceutical industry. During decades the industry has delivered multiple life-saving medicines contributing to new treatment options for several medical needs. The large pharma companies

generate the maximal revenues and spend the most in R&D activities. The industry also maintains the highest research spend as percentage of revenues versus any other industrial sector (Khanna, 2012)

Due to its exceptionally high R&D and associated costs, multinational pharmaceutical companies have seen a significant change in operating model and footprint in the last couple of decades. The current big pharma model is transitioning to that of a lean, focused company with a research footprint within key innovation bio clusters and a growing revenue stream from specialty products and biologics and emerging markets (Guatam, 2015)

The pharmaceutical industry is highly capital and technology intensive. The survival of companies in this industry is highly dependent on their R&D competence, as well as the ability to sell products, where remaining within national boundaries is not a sustainable strategy. The development potential of the pharmaceutical industry, the pace of change, high competition levels and forthcoming restructuring leave enough space for thinking about the specific aspects of pharmaceutical product marketing. The pharmaceutical market will continue to change and adapt to the new economic reality ‘...in which growth is shifting from mature markets to emerging ones (Vasiljev et al., 2010)

The Africa’s pharmaceutical market is expected to be worth \$ 60 billion by 2020. However Africa’s attractiveness lies not in its current market size, but in its rapid growth, with an estimated 9.8 percent compound annual growth rate between 2010 and 2020 (Holt et al., 2015). While the overall pharmaceutical market in Sub-Saharan Africa is growing worth USD 3.8 billion annually, the pharmaceutical manufacturing sector in Africa contributes only 20 – 30 % of the continent’s need. Thus, more than 80% of drugs sold in Africa are imported (Zahangir, 2017)

Today no African country, whatever its size and level of economic development, is entirely self-sufficient in pharmaceuticals. That’s good news for multinational pharmaceutical companies seeking new sources of growth as developed markets stagnate. It’s also good news for African patients, who have gained access to medicines previously unavailable in the continent. However, Africa is not one unified market, but 54 distinct ones, with wide gaps between countries in terms of their market size, growth trajectory, macroeconomic landscape, legal structure, and political complexities. Therefore, companies must also understand what

driving growth and what challenges they are likely to face, and how to collaboratively work with local health systems to win in this complex environment (Holt et al., 2015)

1.3. Statement of the problem

Pharma industry is intense capital and technology driven industry because of the intrinsic complexities like developmental challenges for new drugs, regulatory challenges for commercialization, huge capital requirement, longer gestation period, delay in return on investments and frequent changes in disease trends. This industry has been contributing to both human and financial health of the world (IJPER, 2017)

The introduction of innovative drugs for a given country usually has a two-fold benefit for society. First, it improves the physical and mental well-being of individuals. Second, it reduces hospitalization and other healthcare costs (IFPMA, 2017). While in developed countries growth is flat due to the prevailing healthcare challenges, emerging markets continue to grow phenomenally (Kumra, 2015). Emerging markets are expected to amount to nearly a third of the global pharmaceutical market 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, these markets are very attractive to those companies suffering from the stagnation of mature markets, patent expirations, and increased regulatory hurdles. PWC Pharma summit report (2012). Problems facing the multinational companies are increased generic competition, regulatory changes and change in disease pattern to name a few (Donald, 2010)

Even though MNPCs are key players in the health care system and economic growth of many other countries, their contribution here in Ethiopia is very limited. For Example, companies that have more than 100 products in their product portfolio have about 20-30 products marketed in Ethiopia and companies that have average of 25 employees in other many countries have only 5 -7 employees here in Ethiopia. Some MNPCs like GSK, MERCK and Johnson & Johnson have already left the market and some others like Bayer, Sanofi and Novartise have downsized their employees. As a result, there is a growing concern about serious shortage of innovative pharmaceutical products in the market, employees are losing their jobs and the country at large could not take advantages from these big pharma companies.

According to FMOH (2016) health sector is one investment potential area in Ethiopia today. Investors can take full advantage of this opportunity through direct investment or joint ventures with local investors and therefore multinational pharmaceutical companies are also counting the population size, economic growth and increasing disease burden as areas of opportunities to consider Ethiopia for their next destination.

This controversy would have been studied extensively, however from the findings of the previous studies, it was evident that little has been done with regard to challenges and prospects of MNPCs in Ethiopia. Therefore, this study sought to answer the question; what are the challenges and prospects of multinational pharmaceutical companies in Ethiopia?

1.4. Research Questions

In line with the statement of the problem the following questions are expected to be answered.

- What is the existing pharmaceutical companies marketing practice?
- What are the major challenges encountered in multinational pharmaceutical Companies operating in Ethiopia?
- What are the major opportunities to be exploited by multinational Pharmaceutical Companies operating in Ethiopia?

1.5. Objective of the study

1.5.1. General Objective

The primary objective of this study is to examine major challenges and prospects of Multinational pharmaceutical companies in Ethiopia

1.5.2. Specific Objectives

- To assess practices of pharmaceuticals companies operating in Ethiopia
- To examine challenges affecting the properly operation and functioning of multinational pharmaceutical companies operating in Ethiopia
- To investigate the prospects of multinational pharmaceutical companies operating in Ethiopia

1.6. Significance of the study

This study is designed to assess the major challenges and prospects of multinational pharmaceutical companies operating in Ethiopia. The result of the study will inform in coming MNPCs and existing ones to identify the major challenges in the market and subsequently companies can be able to formulate the best strategy that can fit in the local scenario. The result of the study can also indicate the available opportunities that would determine prospects of multinational companies in the country so that company leaders can make informed decisions about their future. The result will also be an input for policy makers and regulatory bodies' to develop workable regulations and guidelines. The result can also be used as reference for other researchers interested to explore more in the pharmaceutical industry

1.7. Scope and Limitation of the Study

1.7.1. Scope of the study

This study focuses on the challenges and prospects of multinational pharmaceutical companies operating in Ethiopia. The scope of the study focuses on the five (Novartis, AstraZeneca, Sanofi, Bayer and Pfizer) multinational pharmaceutical companies operating in Ethiopia. The geographic scope of the study is here in Addis Ababa since all of the multinational pharmaceutical companies are based in Addis. The methodological scope of the study is descriptive study design analyzed with frequency and percentages. The time scope of the study was from September 2019 to August 2020. The study focuses on multinational pharmaceutical companies due to the fact that the challenges facing multinationals may not be necessary similar to that of generic companies and since multinationals invest much higher than generics, the level of risk is also higher for multinationals. The opportunities identified for the multinational companies would have a good representation for the rest of pharmaceutical companies.

1.7.2. Limitations of the study

Due to time and other constraints, the study used limited number of variables to assess the challenges and opportunities of multinational pharmaceutical companies and limited on descriptive statistics techniques to analyze the data. The other limitation was little has been done yet in this area of research to use as a source of information

1.8. Organization of the study

This study has been organized under five chapters. Chapter one contains introduction and background of the study in addition to the statement of the problem, objectives of the study, significance, scope and limitations of the study as well as organization of the study. Chapter two contains literature review. The methodology encompassing; study design and method of analysis is discussed in the third chapter. Chapter four contains result analysis and discussion. At last, chapter five presents conclusion and recommendation.

Chapter Two

Literature Review

Introduction

This chapter reviews the literatures that are related to the subject of this study in order to gain an understanding of challenges facing multinational pharmaceutical companies. Literature was reviewed in line with the stated study objectives. The review was relay greatly on data obtained from published reference materials such as books and journals. It is organized under the following parts: theoretical literature review, empirical literature review and conceptual framework.

2.1 Theoretical Literature Review

2.1.1 General overview of Pharmaceutical Industry

The pharmaceutical industry in general is the world's largest industry due to worldwide revenues of approximately US\$2.8 trillion. Pharma industry has seen major changes in the recent years that place new demands on payers, providers and manufacturers (Mary et al., 2017). The research-based pharmaceutical industry plays a unique role in developing new medicines and vaccines to prevent and treat diseases, and improve the lives of patients worldwide. Its key contribution to global health is turning fundamental research into innovative treatments. Despite often challenging business and regulatory conditions, the industry undertakes investments that are considerably more risky than those in most high-technology sectors. By investing billions of dollars, it pushes the limits of science, fosters medical progress, and contributes to the prosperity of society (IFPMA, 2012).

The pharmaceutical industry is highly capital and technology intensive. The survival of companies in this industry is highly dependent on their research and development competence, as well as the ability to sell products, where remaining within national boundaries is not a sustainable strategy. The development potential of the pharmaceutical industry, the pace of change, high competition levels and forthcoming restructuring leave enough space for thinking about the specific aspects of pharmaceutical product marketing. The pharmaceutical market will continue to change and adapt to the new economic reality '...in which growth is shifting from mature markets to emerging ones (Stevan et al., 2010). Today's successful companies share a strong focus and a heavy commitment to marketing.

Modern marketing seeks to attract new customers by promising superior value, and to keep current customers by delivering satisfaction. To be successful, companies will have to be strongly market focused (Philip and Gary, 2001).

2.1.2 The Pharmaceuticals Marketing

The definition of Marketing; according to Philip Kotler 2012: Marketing a social and managerial process by which individuals and groups obtain what they need and want through creating an exchanging products and values with others. However, pharmaceutical marketing differs from other types of marketing because the consumer i.e. the patients are not the target audience, whereas the physicians prescribing the medicines are the target audience of the pharmaceutical companies. It is the doctor who makes the decision on behalf of the patient. Physicians are privileged with the right of recognizing the need of their patients and recommend medications for the well-being of their patients.

For many large pharmaceutical firms that sell branded drugs, the successful marketing remains the key to profitable growth. New therapies are essential in enabling pharmaceutical companies to overcome the challenge of generic substitution—the replacement of branded drugs with generic alternatives, Generic drugs enter the market at much lower prices compared with the original branded drugs they replace, as generic drugs do not need to go through the risky, costly, and lengthy process of new drug development (Ding et al., 2014).

Successful marketing depends on key issues including what the company is going to produce, how much it is going to charge, how it is going to deliver its products and services, and even how it is going to inform customers about its products and services. Traditionally, these considerations were known as 4Ps- Product, Price, Place, and Promotion. Indeed, these considerations are what determine the choice of a marketing strategy that a firm should adopt

Pharmaceutical Promotion: The World Health Organization defines drug promotion strategies as "all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs." (WHO/HAI., W. H., 2005)

Promotional strategies are communication strategies through which a company passes across the benefits of its product and services to its target customers. No matter how successfully

developed a product may be, it is worthless except its benefits are made clear and appreciated by the target customers (Uchenna et al., 2010).

Pharmaceutical companies spend large amounts of their sales dollars on promotions for two reasons; to inform and persuade. For many doctors, especially those who have been practicing medicine for a long time reported that drug promotions are major sources of new drug information which play a major role in their decision making. However, it should be noted that promotion efforts are not only confined to the prescribers, but also to the public. Pharmaceutical companies invest large sums of money promoting their products. They use a multifaceted approach to drug promotion, incorporating techniques such as hospital and office detailing by pharmaceutical representatives (Uchenna et al., 2010)

To persuade the physicians to prescribe their brands pharmaceuticals engage in marketing techniques like giving samples, gifts, sponsoring travel etc. Many countries are striving to reduce the impact of incentives on prescription behavior (Narendran and Narendranathan, 2013). Pharmaceutical marketing efforts are also problematic if they influence health professionals to prescribe drugs that are not the best choices for their patients (Napit, 2018). One central issue in the debate about the pharmaceutical industry has been whether it is primarily driven by innovation or marketing.

Pharmaceuticals price: product price is worth if only customers are willing and able to pay for it. The price must be competitive but this does not necessarily mean that it has to be the cheapest in the market. In pricing, a firm may adopt market pricing strategy, marketing skimming pricing, time based pricing, location focused pricing, customary pricing, and the common discount pricing (American Marketing Association, 1998)

Pharmaceutical pricing in middle and low-income countries (MLICs) is an important and contentious issue. Because most patients lack insurance coverage and pay out-of-pocket for drugs, pricing commensurate with income is critical to affordability (Patricia et al., 2013)

Charging different prices to different consumers is a common business practice in many industries including airlines, retail, electric utilities, textbooks, university tuition and pharmaceuticals. In the context of pharmaceutical and other health products, differential pricing (also called tiered pricing) is the adaptation of product prices to the purchasing power

of consumers in different geographical or socio-economic segments. Differential pricing could potentially be a very effective strategy to improve access to essential medicines in low and middle-income countries where most patients pay for medicines out-of-pocket and therefore cannot afford prices comparable to high income markets. In addition, a well implemented differential pricing system can lead to incremental sales for the pharmaceutical manufacturers (Adrian, 2003)

Pharmaceutical product: There are predominantly two types of pharmaceuticals: originator products and generic products. An originator product is the first version of a medicine, developed and patented by an originator pharmaceutical company (WHO, 2016). A generic product is chemically equivalent and bioequivalent to the originator product but it can only enter the market after the patent or other exclusive rights of the originator product have expired. While the originator product must go through an expensive and lengthy research and development process in order to gain marketing authorization, a generic product can enter the market once it has a proven chemical equivalence and bioequivalence to the originator product. This comparatively fast and inexpensive development process allows selling generic products for an often substantially cheaper price.

Pharmaceutical products can be classified as Original brands, Non original brands, Unbranded products and OTC (over the counter) products. Original brands are pharmaceutical products with brand names, marketed by the originator or companies, which have license to market by the originator and these products are prescription bound. Non original brands are marketed by the non-originator with brand name, many a times these products will not have patent protection and these products are also prescription bound. Unbranded pharmaceutical products are active ingredients, also called as the generic medicine, marketed as the international nonproprietary name (INN). Whereas, OTC products are other medicine with non-prescription bound and larger substance of which are the over-the-counter (Umesh et al., 2016)

2.1.3 Multinational Pharmaceutical Company

The large, global pharmaceutical companies that dominate the sector in terms of sales and market capitalization have their roots in the late 19th century, when their founders, usually pharmacists or chemists, began industrial production of synthetic drugs. Most of these drugs were derived from herbal extracts with defined therapeutic activities. Advances in chemistry and later in information technology and robotics led to a multifold increase in research productivity for the labs of drug companies, which over time developed thousands of medicines, many of which are still available today even though the originator company may have disappeared and the original brand has been replaced by generic copies. Clearly, pharmaceutical innovation, led by for-profit companies, has saved millions of lives and contributed significantly to the growth in life expectancy over the past century. The World Health Organization (WHO) recognizes through its “essential medicines” concept that a significant number of drugs are indispensable for adequately treating a wide range of life-threatening or debilitating diseases even under the most difficult economic conditions. (IFPMA, 2017).

Though the research process is long, uncertain, and expensive, the treatments that eventually result save lives and improve the health of people all around the world. Recent decades have seen enormous progress in the fight against major causes of death and disability, including cancer, HIV/AIDS, mental illness, and diabetes, as well as against numerous rare diseases. In addition, advances by companies in the biopharmaceutical sector play an important role in controlling costs of health care by reducing hospitalizations, surgeries, and other costly care. Some of the advantage of MNPC are producing a new medicines changing lives and managing health care costs, contributing strongly to the country economy despite a challenging environment, bringing medicines to patients in need, the R&D process is the road to new medicines (IFPMA, 2017).

2.1.4 Challenges of Multinational Pharmaceutical Companies

Multinational Companies which are operating in emerging markets have better chances to establish, grow and sustain since the markets in these countries are getting stronger and better year after a year. That being said Multinational Companies should not forget that these markets are highly unpredictable, unstable and less profitable. Whether they are domestic or foreign, multinational companies operating in emerging markets face a variety of complex

and multifaceted challenges. These challenges range from company specific, to country specific and global specific issues (Mohammad, 2007).

Challenges in Product Registration: As regionalized and globalized trade expands, new developments in science and medicine continue, and new technologies are introduced, there are unprecedented challenges and opportunities to ensure that regulatory systems are well-equipped to ensure the quality of medicines. Robust and effective quality assurance and regulatory systems are widely recognized as a key aspect to effectively scaling up access to medicines and health services as part of efforts to ensure universal health coverage. However, many LMICs lack adequate systems, structures, or capacity to ensure the safety, efficacy, and quality of medicines (Kaddu et al., 2018).

Access to medicines has long been and remains a challenge in African countries. The impact of medicines registration policies in these countries poses a challenge for pharmaceutical companies wanting to register medicines in these countries. The recent AMRHI (African Medicines Registration Harmonization Initiative) has increased the focus on the need for harmonization. Medicines registration regulations differ across African countries. Anecdotal evidence, based on the experience of pharmaceutical companies on progress towards harmonization is somewhat different, i.e. that country specific requirements were a barrier to the registration of medicines (Narsai et al., 2015).

Challenges in Product Importation:

Shortage of Foreign Exchange: The percentage growth of the current account deficit has been diverging through time, mainly explained by the relatively higher growth of the value of imports than the rate at which the value of exports did. Some of the reasons for the current foreign currency constraint include huge demand for strategic goods (such as petroleum), extended public investment, imported inflation, erratic foreign aid inflow, accumulated and uprising demand of non-strategic imports and poor foreign currency earning capacity (Nyaboke, 2012).

Countries continue to experience widening current account deficits and a fluctuating foreign exchange reserves. The demand for foreign currency to finance import bills of various goods has been growing from year to year, partly due to public and private investment boom: capital

goods, intermediate inputs, and consumer goods. However, the supply side for foreign currency is constrained by poor export sector performance and erratic foreign aid inflow (Boru, 2015).

Customs Control: Efficient port clearing is essential for running a well-functioning import and distribution system, especially in a landlocked country where medicines have to be transported long distances on the road. The costly consequences of port delays are highlighted in the Management Sciences for Health (2012) as “reduced shelf life, deterioration of product or packaging of the product, theft, storage fees (demurrage), longer delivery lead times, stock-outs and cash flow problems”. The importer can incur extra costs in quality testing or even disposal of temperature sensitive medicines whose qualities have been compromised (MSH, 2012).

The main causes of delays in port clearance are missing or incomplete documentation sent from supplier, poor communication between supplier and importer, inexperienced port-clearance staff and inadequate port capacity. The Remaining Shelf Life (RSL) of imported pharmaceuticals on arrival is also checked at the port against the minimum RSL set by FMHACA (2012), which is 60% for products with shelf life of three years and above and 50% for products with shelf life of two years and less; however, a RSL of 75% or above is recommended to minimize product expiry.

Challenges in Product Distribution: Gaps in local health systems and infrastructures hamper the delivery of medicines to millions of people. Access also depends on procurement practices, tax and tariff policies, mark-ups along the supply chain, and the strength of national drug regulatory authorities. Apart from being affordable and of good quality, medicines must also be safe; a system for pharmacovigilance needs to be in place. Secure supply chain management is likewise needed to protect populations from substandard or falsified medical products (WHO, 2007 – 2017)

The pharmaceutical supply chain depicts how medicinal products are delivered to patients. According to the basic supply chain model for prescription drugs, pharmaceutical companies distribute the products to wholesalers, which sell it to pharmacies. Pharmacies represent in most cases the ultimate contact to the patient / consumer. Players and their relationships in

the supply chain vary depending on product type (e.g. prescription / OTC; drug / medical device; hospital product / pharmacy product), regulatory environment and other factors. Numerous pharmaceutical supply chain variations result in significant price variability across different types of consumers and markets. (Irina et al., 2009)

Challenges in Marketing and Brand Positioning: (Kotler and Andreasen, 2006) argued that a positioning strategy is a key component of the strategic marketing planning process and is aligned with organizational goals/objectives, internal resource capabilities and external market opportunities. The marketing and brand positioning challenges of MNPCs in Ethiopia can be broadly classified as generic competition and counterfeit products.

Generics competition: In most HICs, generic copies of originator drugs can be marketed after expiry of patents and other exclusivities, subject to meeting regulatory requirements of bioequivalence and good manufacturing standards. These regulatory requirements for generic quality enable consumers/payers to treat generics as perfect substitutes for originators, which is a necessary condition for aggressive generic price competition and erosion of originator sales once multiple generics enter an originator market. By contrast, drug regulatory agencies in most MLICs admit generic copies that are marketed as functionally equivalent to the originator but are not required by regulation to demonstrate bioequivalence or meet international good manufacturing practice standards (Patricia et al., 2012).

Innovative (originator) chemically-derived drugs are developed through extensive R&D and clinical trials in both humans and animals. The innovator relies on patents, regulatory data protection and other forms of Intellectual Property Rights (IPR) to justify the investment required to bring a product to market. The U.S. patent term is 20 years, and drugs are eligible for at least five years of market exclusivity depending on the time between patent validity and U.S. Food and Drug Administration (FDA) approval. The pharmaceutical industry is heavily dependent on the development of new molecules to replace the revenue stream of older drugs that are approaching the expiration of their patent terms. Pricing of new drugs is designed to cover past and future R&D expenditure (U.S. Department of Commerce, 2016).

Generic drugs are copies of innovative pharmaceuticals that contain the same active ingredients and are identical in strength, dosage form and route of administration. In the

United States, upon either patent expiration or a successful challenge of relevant patents, a manufacturer can produce a generic drug as long as it meets FDA approval and bioequivalence standards. Generic companies typically focus on high volumes to earn profits, requiring efficient production methods and distribution chains (U.S. Department of Commerce, 2016).

Counterfeit Products: A counterfeit drug is a pharmaceutical product that is produced and sold with the intent to deceptively represent its origin, authenticity or effectiveness. It may contain inappropriate quantities of active ingredients (or none at all), may cause bodily harm, and may contain ingredients that are not on the label or be supplied with inaccurate packaging and labeling. Counterfeit drugs are a dangerous source of unfair competition and financial harm for MNPC. Counterfeits ultimately raise the price of medicines by requiring legitimate manufacturers to use considerable resources to ensure a safe supply chain for genuine pharmaceuticals. Existing government policies and enforcement efforts are often insufficient to address counterfeiting problems (U.S. Department of Commerce, 2016).

Intellectual Property (IP) Laws protect against Intellectual Property Rights (IPR) infringements. IPR violations are a serious cost to any research based pharmaceutical industry; it can also lead to issues such as counterfeiting and production of sub-standard drugs. Intellectual Property Rights of a researched molecule are protected by the patent. This patent has to be respected in order for innovative companies to keep coming up with lifesaving drugs (Mehmood, 2016).

2.1.5 Prospects of Multinational Pharmaceutical companies

The pharmaceutical industry demonstrated high sales growth rate continuously according to (Davidson and Greblow, 2005). The main reason identified by Davidson for this growth is the numerous advancements in science and technology including those in the health care industry which increased life expectancy and growing proportion of elderly people. The rapid increase of the global pharmaceutical market is also reported by (IMS Health, 2007) indicating the growth rates varying between five and eight per cent per year and forecasted this growth to continue between eight and twelve per cent over the next few years. According to the IMS , 2007 health report, the growth is both for branded and generic drugs; however brands

continue to account for the bulk of global sales by value. The report also indicated pharmaceutical industry is dominated by fifteen multinational companies

2.2 Empirical Literature Review

A study conducted in Three Major Problems Threatening Multi-National Pharmaceutical Companies Doing Business in China indicate that there are three major problems threatening multi-national pharmaceutical companies this includes policies in the areas of patents and technology transfer, commercial bribery and counterfeit products (Chow, 2017).

Another study conducted in India Opportunities and challenges for Indian Pharmaceutical companies in overseas markets showed that MNPCs are facing an increasingly challenging environment. Strict regulations of the entire medicine industry, with a focus on cost control and compliance are key components of the health care reform and put considerable pressure on MNPCs profit rates. More precisely, cost control measures, including a capped total healthcare insurance expenditure, controlled drug sales proportion and a strict centralized procurement policy, will make it more and more difficult for MNPCs to keep their overall margin at the current level (Venkataswamy et al., 2017).

Although Pakistan pharmaceutical market is growing at a steady rate but still MNCs are facing certain challenges which includes increased generic competition, Regulatory changes and political impact, unethical drug promotion, some drug makers send low-quality medicines to Africa deliberately, and shortage of raw material source is indicated in research conducted in Pakistan Challenges Faced by MNCs in Pakistan Due to Unethical Practice of National Pharmaceuticals Industry (Mehmood, 2016).

Keeping up with emerging legislation (as healthcare demands in the region increased, regulators are introducing wider and more numerous regulatory changes in order to protect the public and the industry's long-term security), restricted approach to regulatory compliance (Regulatory compliance is made harder by restricted nature of pharmaceutical companies' data, leading to missed details, deadlines and processes) and disconnect between regulator and international pharmaceutical (Development of new regulations often occurs in isolation without international companies developing sufficiently deep connections with

regulators of their target audience's host country) are the challenges indicted for MNPC operating in UAE (Pharmaceutical Regulations Summit , 2017).

Africa presents a complex, multifaceted set of markets, which are highly heterogeneous in terms of pharmaceutical growth, language and trading blocs. Consequently, the opportunities they offer are also quite variable. Understanding the nuances and navigating the challenges are key to establishing successful and sustainable operations. To date, three types of pharmaceutical industry players have a track record of success, defined as sustainable revenue-generating business operation: innovative multinational companies (MNCs), Indian and Chinese pharmaceutical companies, and local manufacturers. (IMS, 2012)

The forecasted pharmaceutical market growth in African countries has already generated interest both among companies with existing African operations and those that plan future presence. From MNCs to Indian and Chinese generics manufacturers, pharmaceutical companies from all over the world are attracted by increasing African economic strength and the potential of its emerging middle class. These factors are triggering a rising demand for healthcare services and medicines, offering a strong growth opportunity for the companies with the right sustainable business model (IMS, 2012)

The pharmaceutical industry in Ethiopia is driven by: Progressive growth of Ethiopian economy, increase in the burden of communicable and non-communicable disease, lifestyle changes such as diet and sedentary living, increasingly high population growth rate, expansion of health care coverage, improved awareness around modern medicine, and local preference of government tenders as identified by (Frost and Sullivan, 2012)

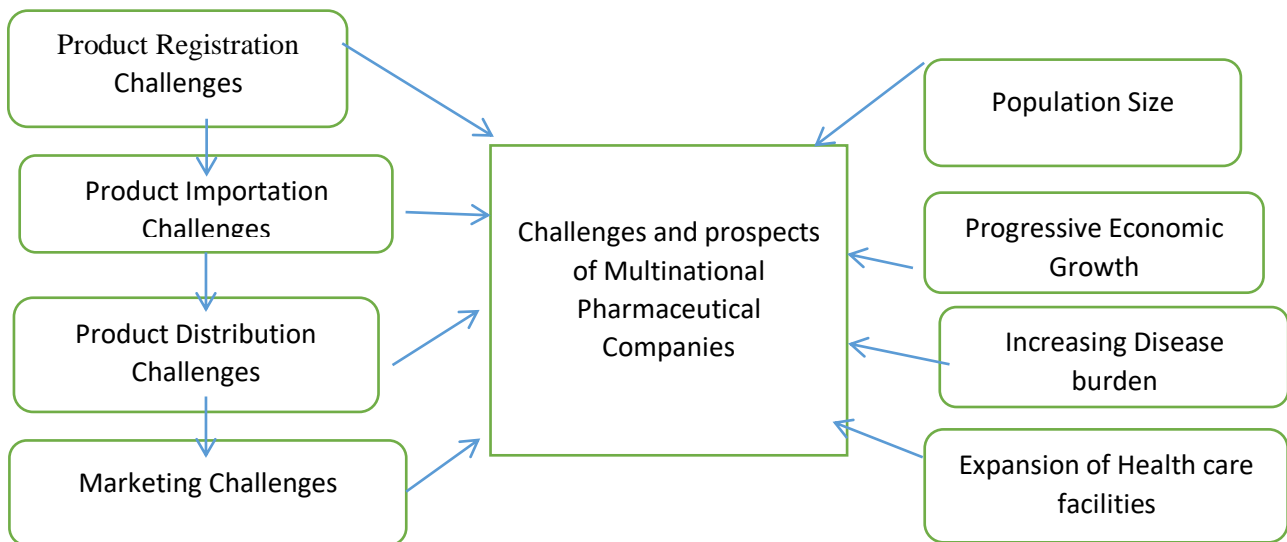
(Frost and Sullivan , 2012) described the high prevalence of infectious diseases and the rising of non-communicable diseases related to cardiovascular, diabetes, central nervous system, and cancerous tumors serves as a major driving force for the growth of the Ethiopian pharmaceutical industry. The reasons mentioned by Frost & Sullivan for the recent rise of non-communicable diseases are lifestyle changes related to the shift to Western lifestyle characterized by consumption of the Western diet and an increase in sedentary activities, increased population growth, improved diagnostic techniques as well as the expansion of specialized medical fields

According to Ethiopian Investment Commission “Increased attention to the country’s disease burden, rising healthcare coverage, and progressive population and economic growth make Ethiopia an attractive market for pharmaceuticals” • The Ethiopian pharmaceutical market is expected to grow at 15% per year to reach nearly \$1billion by 2020

2.3 Conceptual Framework

The conceptual frame work of the study is designed in the following manner, with proposition of challenges from registration to marketing of products and areas of opportunity for multinational pharmaceutical companies in Ethiopia.

Figure 1: Conceptual frame work of the study



Source: Own construct (2020)

Chapter Three:

Research Methodology

Introduction

This chapter discusses the design and approach used population and sampling techniques employed in addition to methods used to collect data and how that data will be analyzed.

3.1. Research Approach

The general objective of this research was to assess the challenge and Prospects of MNPC operating in Ethiopia. Therefore, so as to meet this objective properly a mixed approach whereby both qualitative and quantitative research approaches were employed as appropriate. The study mostly used quantitative approach to produce numerical data, but qualitative approach was also used as well to strength the quantitative data.

3.2. Research Design

The study used a descriptive research design. According to (Mugenda and Mugenda , 2003), descriptive research is used to obtain information concerning the current status of the phenomena to describe what exists, with respect to variables or conditions in a situation. Descriptive study design enables the researcher to provide an accurate and valid representation of variables that are relevant to the research question. It focuses on providing description of the state of nature or affairs, as it exists at present by way of interviews, and administering of questionnaires. Therefore, descriptive research design is adopted in this study since the researcher was intended to describe the existing challenges and prospects of MNPC in the country.

3.3. Population

A census was preferred because the multinational pharmaceutical companies operating in Ethiopia are not too many and collection of data was manageable to bridge the gap of the problem that was under investigation.

The population for this study comprised of the five MNPC found in Addis Ababa. Because of these multinational pharmaceutical companies share common characteristics and manage

various pharmaceutical products they are considered as target population for the study. There are a total of five multinational pharmaceutical companies at Addis Ababa. As to the sample size determination, 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 five MNPC and there are only 45 employees are currently working, among the five MNPCs actively operating in Ethiopia. Four of the companies have 5-7 employees each and one of the company has >15 employees. Thus in order to get a comprehensive data all exiting employees have been included in the study.

3.4. Source of Data and Data Collection Tools

The study relied on both primary and secondary data. Primary data was collected from different professionals such as Country managers, Marketing managers, Key account Managers, Product Managers, Sales Supervisors, and Medical / Sales representative. The primary source of data for this research was semi structured questionnaire and interview. Secondary data was also obtained from external sources such as reference books, journal articles and research papers related to the topics. The purpose of sourcing for secondary data was to help in the formation of problems, literature review and construction of questionnaire.

This study employed different types of data collection instruments to collect primary and secondary data. The primary instrument used to collect data was questionnaire. A questionnaire in a 5 point likert scale was used to collect data from the respondent. The questionnaire has 5 rating scale ranging from 1=strongly disagree, 2 = disagree, 3 = neutral, 4 = agree and 5 = strongly agree. The questionnaire was designed to meet the objectives of the study. A questionnaire was developed by communicating with the expert working in the industry, different literatures review and commented by advisor. However, the researcher structured it in such a way that it includes all relevant parts and information to clearly acquaint the respondents and to suit the objectives of the study in order to solicit answers that would meet the objectives.

3.5. Procedure of Data Collection

The procedure for the data collection was first the respondents are communicated to get their consent. Once their consent was known, the questionnaires were distributed by the researcher to each participant by appreciating their participation and devoting their precious time for the

research. The researcher gave the respondents the option of filling the questionnaires at their convenient time and collected after three days for analysis. The questionnaires were collected by checking the completeness of the data. An interview questions were also conducted with some respondents. Finally the activities were accomplished by thanking the respondents.

3.6. Data Analysis

Data processing is an important part of the whole survey operation. The data collected through questionnaires and observation was processed, summarized, edited, tabulated and coded to ensure completeness, consistency and accuracy. Descriptive analytical technique was used with the aid of SPSS version 20 to analyze the collected data. Descriptive data was analyzed and presented by using frequency counts and percentage. The correlation among variables have been assessed and explained. Quantitative explanations were made of quantitative data to give meaning to them as well as explain their implications. Data from qualitative method was analyzed systematically in such a way that the major issues were identified. From these, appropriate conclusions and recommendations were made from the findings of the research.

The analysis conducted on data gathered to assess the challenge and prospects of MNPCs operating in Ethiopia is presented in relation to the objectives of the study. Descriptive statistics used to analyze the data in this study was based on the responses of respondents on their into account that numbers a five point Likert scale 1, 2, 3, 4 and 5 represents strongly disagree, disagree, neutral, agree and strongly agree respectively.

3.7. Validity and Reliability

3.7.1. Instrument Validity

To ensure validity, all questionnaires were self-administered to the right persons of respondents by the researcher and only data that was collected was analyzed. To test validity of the questionnaire, a pilot study was conducted in two of MNPC i.e. Bayer and Pfizer to ensure the validity of the questionnaire, to assess the relevance and alignment of the questionnaire with communication policy of these companies. Respondents were also asked to comment on the format and wording of the questionnaire. A few changes were made to the questionnaire after a pilot study and commented by advisor.

3.7.2. Instrument Reliability

In this study, a reliability test was performed in order to see whether the study was given similar results if the same study is repeated. To ensure reliability of this study, a Cronbach's Alpha was performed as a measure to see if the study repeats the same results if the same study is performed again. The reliability of the instruments & data was established following a pre-test procedure of the instruments before their use with actual research respondents by Cronbach's Alpha.

Total numbers of questions in the questionnaire were 46 testing variables. From the analysis the Cronbach's alpha result found from the data collected from 42 respondents for 46 questions, the overall Cronbach's alpha score is 0.820. The coefficient 0.7 is an acceptable reliability coefficient; since score of 0.820 is above the standard threshold level the questionnaire were reliable (Dawson, 2007).

3.8. Ethical issues

Ethics is one of the major considerations in research. The researcher of this study is also subject to the following ethical considerations. The research work was started after getting the willingness of the stated organizations. Respondents will be clearly communicated about the objective of the research before they are asked to give their answer. There is no any physical or psychological damage to them because of the research. Respondents will not be asked about their name, race, religion, etc.

Chapter Four

Data Presentation, Analysis and Interpretation

Introduction

In this chapter of the research, the data collected from different sources are presented, analyzed and interpreted. Accordingly, the chapter deals with the demographic nature of the respondents and analysis and interpretation of the data collected. The analysis of data is processed in line with the basic research questions and objectives of the study. Thus, the chapter has two parts. The first part presents the characteristics of the respondents, the local backgrounds of the companies and some marketing information about Companies. The second part presents detailed analysis and discussion of data collected through questionnaire and information obtained from administered questionnaires and interview with key informants in the sector.

After developing and pretesting the questionnaire, key informants were identified, questionnaires distributed, filled questionnaires collected and in depth interview conducted. The respondents were from the five MNPC, which are Novartis, AstraZeneca, Sanofi, Bayer and Pfizer

Forty five (45) Self-administered questionnaires were distributed to respondents; unfortunately 3 responses from self-administered questionnaires were found to be incomplete and rejected from analysis at editing stage. The remaining 42 responses (self-administered) were analyzed using SPSS Version 20. The response rate was 93.3%. According to Mugenda and Mugenda (1999), a response rate of 70% and above is excellent.

The data from the filled questionnaires and interview notes were reviewed by reading each record line by line to identify ideas, and categorized to analyze the information gathered from the participants. Specifically the analysis followed a series of steps that include preparing and organizing the data, having an overall understanding of the data, develop categories and conducting a detailed analysis based on the data.

4.1. Demographic Characteristics of the Respondents

The first part of the questionnaire consists of demographic information of the participants. This part of the questionnaire requested a limited amount of information related to personal and professional characteristics of the respondents. Accordingly, the following variables about respondents were summarized and described in the subsequent tables. These variables include: gender, occupational position, educational status and year of experience in pharmaceutical sector.

Table 4.1: Background of the respondents

		Count	Layer N %
Gender	Male	29	69.0%
	Female	13	31.0%
Total		42	100.0%
Educational Background	Diploma	0	0.0%
	BSC	24	57.1%
	Masters	18	42.9%
	PhD	0	0.0%
Total		42	100%
Occupation	General Manager	2	4.8%
	Marketing Manager	5	11.9%
	Country Manager	3	7.1%
	Sales Supervisor	7	16.7%
	Medical/Sales Representative	19	45.2%
	Key Account Manager	3	7.1%
	Product Manager	2	4.8%
	Technical Manager	1	2.4%
Total		42	100%
Year of Experience	<5 years	5	11.9%
	6 - 10 years	17	40.5%
	11 - 15 years	14	33.3%
	16 - 20 years	5	11.9%
	> 20 years	1	2.4%
Total		42	100%

Source; Own survey, 2020

The above table 4,1 shows that male respondents were about 69% while females were 31%.This shows that the positions of pharmaceutical marketing of MNPC were mainly occupied by male professionals. Regarding the educational status of the respondents, 57.1% of the respondents were Bachelor Degree holders while the rest 42.9% of the respondents were graduate of Masters. This implies that the MNPCs positions have been occupied with highly educated professionals and the academic level of managers could help the pharmaceutical companies to make use of the available opportunities and to alleviate the challenges facing the pharmaceutical marketing in multinational companies operating in Ethiopia.

Various occupational positions were taken in to account in the questionnaire this include 19(45.2%) Medical/Sales Representatives, 7 (16.7%) Sales Supervisors, 5 (11.9%) Marketing Managers, 3 (7.1%) Country Managers and Key account Managers each. As it is indicated in table 4.1 most of the respondents have a direct involvement in the market and they do have better understanding of the market practices and challenges as well as viable mechanisms to mitigate the existing problems. This could support the multinational companies in using the available opportunities and minimizing the challenges in the pharmaceutical marketing. The data concerning the length of service of the respondents indicates that 17(40.5%), 14 (33.3%), and 5(11.9%) have served for 6-10 years, 11-15 years, and 16 -20 years respectively. This implies that majority of the respondents engaged in this study have worked in the pharmaceutical sector for a considerable time and thus they have vast knowledge which could be relied upon in the study. This indicates that most of the respondents of this study have worked for an ample time thus they were conversant with the information that the study sought, challenges and prospects of multinational pharmaceutical companies operating in Ethiopia

4.2. Local Background of the study organizations

This section of the questionnaire consists of local background of study organizations. This part of the questionnaire requested a limited amount of information related to number of employee, number of approved pharmaceutical product, number of local agents representing the company and for how long these companies have been in the country

Table 4. 2: Local Background of the Companies

		Count	Layer N %
Number of Local employees in your Company	<4	1	2.4%
	5 – 9	30	71.4%
	>15	11	26.2%
Total		42	100%
Number of Registered Pharmaceutical Products in Ethiopia	<10	0	0.0%
	11- 15	12	28.6%
	16 -20	12	28.6%
	>20	18	42.9%
Total		42	100%
Number of Local Agents Representing the Company	1	0	0.0%
	2	1	2.4%
	3	15	35.7%
	4	16	38.1%
	5	10	23.8%
Total		42	100%
For how long your Company has been Working in Ethiopia	0 - 5 yrs.	0	0.0%
	6 - 10 yrs.	3	7.1%
	11 - 15 yrs.	24	57.1%
	>15 yrs.	15	35.7%
Total		42	100%

Source: Own survey result, 2020

From the above table 4.2 it is indicated that 71.4% of multinational pharmaceutical companies operating in Ethiopia have 5– 9 employees and only 26.2% of the companies have employees more than 15. This implies despite the huge potential of multinational companies and big number of employees in other countries, the number of jobs which are created by multinational companies in Ethiopia is so limited. Even though these companies have a wide range of medicinal products only some of product lines are registered in Ethiopia. Four of these five MNPC have registered 10 -20 products in their product line and only one company has registered greater than 20 products. Four of the companies are operating through 2-4 local

importers and only one company has 5 local import agents. When it comes companies' year of presence in Ethiopia, most of the companies have been in the market for more than 10 years. Therefore the findings from table 4.2 implies that even though these companies have long years of experience in the market and wide range of products in their product catalog list they only manage to register few number of products and they have partnership only with few import agents so that companies are working at their minimum capacity and the country at large could not get benefited maximally from them.

4.3. Marketing Information

This section of the questionnaire consists of information about their existing marketing activities and competitive positions in the market. The questionnaire requested some amount of information related product acceptability, best attributes for their products, market segment they are capitalizing on, their customer target and treatment areas they are working in. Knowing the current market position of companies and areas of their primary focus would help to understand and correlate well the challenges and opportunities being presented.

Table 4. 3 Companies Marketing Information

		Count	Layer N %
Products acceptability in the market	Poor	0	0.0%
	Good	4	9.5%
	Very Good	19	45.2%
	Excellent	19	45.2%
Total		42	100%
Main attributes of your Products' acceptability	Brand Name	14	33.3%
	Product Package	0	0.0%
	Product Price	1	2.4%
	Product Quality	27	64.3%
Total		42	100%
Your company's competitive position in the market	Poor	0	0.0%
	Good	4	9.5%
	Very Good	29	69.0%
	Excellent	9	21.4%
Total		42	100%
Primary distribution outlet	Public Tender	2	4.8%

	Wholesalers	4	9.5%
	Pharmacies	19	45.2%
	Hospitals	17	40.5%
Total		40	95%
Target market segment	Public Tender	3	7.1%
	Government Hospitals and Pharmacies	0	0.0%
	Private Hospitals and Pharmacies	29	69.0%
	Private Retail Pharmacies	10	23.8%
Total		39	93%
Focus economic class of the population	Low Income	0	0.0%
	Medium Income	23	54.8%
	High Income	19	45.2%
Total		42	100%
Impact of health care seeking behavior of the society on your marketing activity	No Impact	0	0.0%
	Low Impact	3	7.1%
	Moderate Impact	28	66.7%
	High Impact	11	26.2%
Total		42	100%
Target treatment area of your company	Communicable Disease	1	2.4%
	Non Communicable Disease	15	35.7%
	Both	26	61.9%
Total		42	100%
Focus diseases for your company	Cardio Vascular and Metabolism	26	61.9%
	Infection	7	16.7%
	Oncology	9	21.4%
	Respiratory	0	0.0%
Total		42	100%
Priority disease areas for your company's future growth	Cardio Vascular and Metabolism	28	66.7%
	Infection	4	9.5%
	Oncology	10	23.8%
	Respiratory	0	0.0%

Source: Own survey result, 2020

From the above table 4.3 it is possible to see that product acceptability of multinational companies is rated as very good and excellent by 45.2% of the respondents each. This implies that there is no doubt of superior quality and better safety profile of multinational companies' product among physicians. The influential attributing factors for their products acceptability are quality and brand name as it is confirmed by 64.3% and 33.3% of the respondents respectively. The distribution outlets they are primarily using are private pharmacies and hospitals (45.2% & 40.5%) respectively. This implies that wholesalers are not keen in distributing the products of multinational companies. The chance of getting for public tender is quite low for multinational companies as only 4.8 % of the respondents confirmed public tender as an outlet for multinationals. This is because public tenders primarily focus on low price generic products so that the market segment multinational companies capitalizing on are private hospitals and retail pharmacies as it is confirmed by 69% & 23.8% of respondents respectively. The multinational pharmaceutical companies in Ethiopia have been working in both communicable and non-communicable diseases. There is a significant shift of interest to non-communicable diseases as the prevalence of cases is increasing fast. Among the non-communicable diseases cardiovascular and metabolism is found to be the primary focus of multinationals as it is confirmed by 61.9% of respondents. In addition cardiovascular & metabolism and Oncology disease areas has been indicated as area of interests for MNPCs for future growth of the companies.

4.4. Challenges of Multinational Pharmaceutical Company operating in Ethiopia

4.4.1. Challenges related to Product Registration

Data collected through questionnaire survey was analyzed with SPSS 20 to assess respondent's level of agreement on identified factors that affects product registration. The study aims to determine the first objective of the study which was to identify challenges related to product registration process to MNPCs operating in Ethiopia. Thus, various related issues were presented for the reflection of the respondents. The main factors that are assessed under this challenge are presented in the table 4.4.

Table 4. 4: Challenges related to Product Registration

Factors	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Total		$\Sigma(SA+A)$
	Layer N %	Layer N %	Layer N %	Layer N %	Layer N %	Count	Layer N %	
Complex document requirement at the authority/EFDA	2.4%	2.4%	9.5%	57.1%	28.6%	42	100.0%	85.7%
Long document or dossier evaluation period	0.0%	0.0%	4.8%	59.5%	35.7%	42	100.0%	95.2%
Lack of procedural transparency at the Authority	0.0%	7.1%	40.5%	35.7%	16.7%	42	100.0%	52.4%
Poor data recording and management system	0.0%	11.9%	38.1%	38.1%	11.9%	42	100.0%	50.0%
Low personnel technical capacity at the authority /EFDA	2.4%	19.0%	38.1%	28.6%	11.9%	42	100.0%	40.5%
Lack of objective criteria for manufacturing facility inspections and sampling	4.8%	40.5%	28.6%	16.7%	9.5%	42	100.0%	26.2%
Absence of one-window service at the authority	2.4%	19.0%	23.8%	38.1%	16.7%	42	100.0%	54.8%
Lack of digitalization and inadequate IT support	4.8%	40.5%	23.8%	21.4%	9.5%	42	100.0%	31.0%
Low Motivation or Sense of service among staffs	0.0%	11.9%	33.3%	28.6%	26.2%	42	100.0%	54.8%

Source: Own survey and SPSS output, (2020)

As shown in item 1 of Table 4.4, 85.7% (28.6 % + 57.1 %) of the respondents either agreed or strongly agreed on the requirement of complex document at the authority/ EFDA. The second item as well emphasis it further since 95.2% (35.7% + 59.7%) of respondents either agreed or strongly agreed on the long document/ dossier evaluation period at the authority. As a result, the pharmaceutical market authorization process of Ethiopia is subject to pass through lengthy and tedious registration process and therefore multinational companies are

experiencing different technical difficulties during new product registration and dossier evaluation process is found to be the main challenge of product registration process in Ethiopia. Similarly, Narsai et al., 2012 survey proved that pharmaceutical companies operating in Africa are experiencing difficulties in complying with the technical requirements of individual African markets. According to this survey it is well documented that the African MRAs are under resourced and lack skills and capacity to perform their functions adequately. These remains a common complain of people in the pharmaceutical sector since most of the documents requested by the authority during registration process are irrelevant and redundant. According to Sultan et al., 2016 the requirements for Ethiopian market authorization are: (1) the medicinal product has to be included in to national medicine list; (2) the manufacturing site has to be approved and certified for compliance with GMP either by EFDA or other recognized stringent regulatory authorities and (3) such GMP certified or waived manufacturers have to submit application for dossier evaluation and product quality assessment accompanied with application fee. However, the actual practice on the ground is not in line with the guidelines and as a result of this lengthy process the average time required to get a market authorization for a given product in Ethiopia is one and half years so that companies are getting discouraged to go through this tiresome process and hence innovative products availability issue has been remained the question of the people in our market. The above table also shows that 52.4 % of the respondents agreed on the lack of procedural transparency, and 50% of the respondents confirmed the presence of poor data recording and management system at the authority. Thus clients are requested for the same documents again and over again during market authorization process that result in unnecessary confrontation between the technical staff and their clients that ultimately damage the trust and further prolong the duration of market authorization process.

The study also shows that 40.5% of the respondents responded that there are low personnel technical capacity, 54.8 % of the respondents either agreed or strongly agreed on the absence of one window service at the authority and similarly 54.8% of the respondents confirmed low motivation and sense of service among staffs at the authority. This further confirms that not only the volume of the documents to be analysed, but also poor efficiency in data recording and personnel technical capability contribute to have lengthy product registration process in the country. However, Frost and Sullivan, 2012 strongly recommends a well-resourced, effectively functioning national medicine regulatory authority is a prerequisite for building a competitive pharmaceutical industry capable of ensuring the safety, quality and efficacy of all

medicines on the market. The implications of these challenges are few numbers of multinationals pharmaceutical companies with narrow product range have been operating in the country. From the total respondents only 31.0% agreed on the lack of digitalization and inadequate IT support at the authority, thus it implies that the authority is going digital and a good progress has been achieved in relation to IT support so technology utilization is on the right track.

One of the encouraging scores in the overall performance of the authority is the presence of objective criteria for manufacturing facilities inspection and sampling since only 26.2% of the respondents agreed on lack of objectivity in this aspect. This implies that there is a clear objective in place at the authority for manufacturing plant inspections so there are no double standards or bias in this aspect.

4.4.2. Correlations Analysis of factor that affects the product Registration

Pearson correlation method was adopted to measure the degree of relationship between variables that affects product registration. Results presented in Table 4.5 below shown that:

Complex document requirement at the authority/EFDA is highly correlated with long document or dossier evaluation period, lack of procedural transparency and low personnel technical capacity at the authority at a correlation coefficient of $R=.573$, $P=0.000$; $R=.687$, $P=0.000$, and $R=.472$, $P=.002$; respectively. That means; whenever there is increase the coefficient of one variable there is an increase of all other variables in same direction, meaning that the less complex document requirements at the authority the short document or dossier evaluation period required, the more we maintain procedural transparency and personnel technical capacity at the authority. Long document or dossier evaluation period is highly correlated with lack of procedural transparency and low personnel technical capacity at the authority at a correlation coefficient of $R=.454$, $P=.002$; and $R=.579$, $P=.00$; respectively. The positive linear relationship between indicates the more there is procedural transparency and high personnel technical capacity the short document or dossier evaluation period at the Authority.

Lack of procedural transparency is highly correlated with poor data recording and management system, low personnel technical capacity and low motivation among staffs at the authority at the correlation coefficient of $R= .497$, $P=0.001$; $R=.476$, $P=0.001$;and $R= .401$, $P=0.008$ respectively. This implies that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This means the more

personnel technical capacity and high motivated staff the high data recording and procedural transparency at the authority.

Lack of objective criteria for manufacturing facility inspection is highly correlated with absence of one window service, lack of digitalization and adequate IT support and low motivation among staff at the correlation coefficient of $R = .467, P = 0.002$; $R = .608, P = 0.000$; and $R = .549, P = 0.000$ respectively. This implies that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This means the more we maintain objective criteria for facility inspection, one window service and adequate IT support the more motivated staff at the authority

Absence of one window service is highly correlated with lack of digitalization and IT support at the correlation coefficient of $R = .519, P = 0.000$. This implies that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. . This means the more we maintain good digitalization and adequate IT support the good one window service can be provide.

Table 4. 5: Correlation Analysis of challenges related to Product Registration

Challenges Related to Product Registration		Complex document requirement at the authority/EFDA	Long document or dossier evaluation period	Lack of procedural transparency at the Authority	Poor data recording and management system	Low personnel technical capacity at the authority /EFDA	Lack of objective criteria for manufacturing facility inspections and sampling	Absence of one-window service at the authority	Lack of digitalization and inadequate IT support	Low Motivation or Sense of service among staffs
Complex document requirement at the authority/EFDA	Pearson Correlation	1	.573**	.687**	.354*	.472**	.120	.043	.299	.202
	Sig. (2-tailed)		.000	.000	.021	.002	.448	.787	.055	.200
	N	42	42	42	42	42	42	42	42	42
Long document or dossier evaluation period	Pearson Correlation	.573**	1	.454**	.377*	.579**	.075	.155	.049	.088
	Sig. (2-tailed)	.000		.002	.014	.000	.636	.327	.759	.580
	N	42	42	42	42	42	42	42	42	42
Lack of procedural transparency at the Authority	Pearson Correlation	.687**	.454**	1	.497**	.476**	.392*	.151	.220	.401**
	Sig. (2-tailed)	.000	.002		.001	.001	.010	.341	.161	.008
	N	42	42	42	42	42	42	42	42	42
Poor data recording and management system	Pearson Correlation	.354*	.377*	.497**	1	.341*	.264	.053	.231	.354*
	Sig. (2-tailed)	.021	.014	.001		.027	.091	.738	.140	.022
	N	42	42	42	42	42	42	42	42	42
Low personnel technical capacity at the authority /EFDA	Pearson Correlation	.472**	.579**	.476**	.341*	1	.359*	.214	.248	.214
	Sig. (2-tailed)	.002	.000	.001	.027		.019	.174	.113	.174
	N	42	42	42	42	42	42	42	42	42
Lack of objective criteria for manufacturing facility inspections and	Pearson Correlation	.120	.075	.392*	.264	.359*	1	.467**	.608**	.549**
	Sig. (2-tailed)	.448	.636	.010	.091	.019		.002	.000	.000
	N	42	42	42	42	42	42	42	42	42
Absence of one-window service at the authority	Pearson Correlation	.043	.155	.151	.053	.214	.467**	1	.519**	.165
	Sig. (2-tailed)	.787	.327	.341	.738	.174	.002		.000	.297
	N	42	42	42	42	42	42	42	42	42
Lack of digitalization and inadequate IT support	Pearson Correlation	.299	.049	.220	.231	.248	.608**	.519**	1	.549**
	Sig. (2-tailed)	.055	.759	.161	.140	.113	.000	.000		.000
	N	42	42	42	42	42	42	42	42	42
Low Motivation or Sense of service among staffs	Pearson Correlation	.202	.088	.401**	.354*	.214	.549**	.165	.549**	1
	Sig. (2-tailed)	.200	.580	.008	.022	.174	.000	.297	.000	
	N	42	42	42	42	42	42	42	42	42

** . Correlation is significant at the 0.01 level (2-tailed).

* . Correlation is significant at the 0.05 level (2-tailed).

4.4.3. Challenges related to Product Importation

In assessing the challenges related to Product importation of the pharmaceutical companies, various related issues were presented for the reflection of the respondents. The four main

points that are assessed under this challenge are the issue of getting Forex allocation from the government, procedural transparency being employed in different banks during forex allocation, government support for pharmaceuticals importation and issues in relation to customs clearance. Table 4.6 illustrates the reflection of the respondents regarding the challenges related to pharmaceuticals product importation.

Table 4. 6: Challenges related to Product Importation

Factors	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Total		$\Sigma(SA+A)$
	Layer N %	Layer N %	Layer N %	Layer N %	Layer N %	Count	Layer N %	
Insufficient Forex allocation from banks seriously affecting the importation process	2.4%	0.0%	2.4%	21.4%	73.8%	42	100.0%	95.2%
Banking system lacks transparency for Forex allocation	2.4%	0.0%	9.5%	40.5%	47.6%	42	100.0%	88.1%
Long queue and bureaucratic procedures at the banks	2.4%	2.4%	9.5%	54.8%	31.0%	42	100.0%	85.7%
Currency devaluation is the problem in importation	0.0%	0.0%	38.1%	42.9%	19.0%	42	100.0%	61.9%
The government policy is not supporting the importation	2.4%	7.1%	40.5%	38.1%	11.9%	42	100.0%	50.0%
Long clearance lead time at the receiving ports/ Customs	2.4%	16.7%	23.8%	45.2%	11.9%	42	100.0%	57.1%
Document discrepancy during custom clearance	4.8%	28.6%	26.2%	31.0%	9.5%	42	100.0%	40.5%
Inadequate storage facility at the customs	11.9%	11.9%	40.5%	28.6%	7.1%	42	100.0%	35.7%

Source: Own survey result, 2020

From the total of 42 respondents 95.2 % (73.8 % + 21.4%) either strongly agreed or agreed that there is insufficient forex allocation from banks and that seriously affecting the pharmaceutical importation and 88.1% (47.6% + 40. 7%) of the respondents indicated that banking system lacks transparency for forex allocation. In addition of this 85.7% of the respondents confirmed that there is a long queue and bureaucratic procedures at the banks. This shows that getting foreign currency is one of the main challenges in pharmaceutical importation in Ethiopia. From the total respondents 61.9% agreed that currency devaluation is also one of the challenges in product importation. Similarly the study conducted by Boru, 2015 confirmed that Ethiopia continues to experience widening current account deficits and a fluctuating foreign exchange reserves. The demand for foreign currency to finance import bills of various goods has been growing from year to year, partly due to public and private investment boom: capital goods, intermediate inputs, and consumer goods. However, the supply side for foreign currency is constrained by poor export sector performance and erratic foreign aid inflow. This gap between the demand for and supply of foreign currency keep on widening through time hence resulting in depletion or else fluctuation in the reserve position. This implies that shortage of foreign exchange allocation is a longstanding challenge for pharmaceuticals importation in Ethiopia.

50 % of the respondents responded that the level of government support to private pharmaceutical import is low. This implies that companies are not importing the required amount of products to meet the demand on the ground, thus frequent stock out situation is happening in the market, sometimes even for emergency or lifesaving items so that this challenge has been put the patient's life at risk. In addition when there is less supply than demand in a given market there will be price inflation that will eventually unaffordable for majority of patients. In the other dimension of product importation challenge 57.1% of respondents indicated that long clearance time at the customs port and 35.7% of the respondents agreed on the inadequate storage facilities at the customs are some of the challenges and these results in increased landing cost that will ultimately reflected on patient price and there will be high risk of product safety. Similarly the study conducted by Solomon (2014) indicated that inappropriate storage of pharmaceuticals at the customs as a result of these labels is removed and products are automatically discarded.

4.4.4. Correlations Analysis of factor that affects the product Importation

Pearson correlation method was adopted to measure the degree of relationship between variables that affects product importation. Results presented in Table 4.7 below shown that:

Insufficient Forex allocation at the Bank is highly correlated with lack of transparency, bureaucratic procedures at the banks and currency devaluation at the correlation coefficient of $R = .712$, $P = 0.000$; $R = .583$, $P = 0.000$, and $R = .397$, $P = 0.009$ respectively. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the more sufficient forex allocated the more transparent and less bureaucratic procedures can be maintained at the banks, and less currency devaluation can have.

Transparency lacking banking system is highly correlated with long queue at the banks and currency devaluation at the correlation coefficient of $R = .743$, $P = 0.000$, and $R = .411$, $P = 0.007$ respectively. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the more transparent banking system is implemented the fewer queues and currency devaluation can maintain at the banks.

Long queue and bureaucratic procedures at the bank is highly correlated with currency devaluation at the correlation coefficient of $R = .417$, $P = .006$. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the less queue at the bank the less currency devaluation.

Long clearance lead time at the receiving port is highly correlated with document discrepancy during custom clearance at the correlation coefficient of $R = .511$, $P = 0.001$. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the short clearance lead time at receiving port the less document discrepancy during custom clearance.

Table 4. 7: Correlation Analysis of Challenges related to Product Importation

Challenges related to Product Importation		Insufficient Forex allocation from banks seriously affecting the importation process	Banking system lacks transparency for Forex allocation	Long queue and bureaucratic procedures at the banks	Currency devaluation is the problem in importation	The government policy is not supporting the importation	Long clearance lead time at the receiving ports/ Customs	Document discrepancy during custom clearance	Inadequate storage facility at the customs
Insufficient Forex allocation from banks seriously affecting the importation	Pearson Correlation	1	.712**	.583**	.397**	.054	.069	.230	-.057
	Sig. (2-tailed)		.000	.000	.009	.734	.663	.143	.721
	N	42	42	42	42	42	42	42	42
Banking system lacks transparency for Forex allocation	Pearson Correlation	.712**	1	.743**	.411**	.081	.257	.252	-.237
	Sig. (2-tailed)	.000		.000	.007	.608	.100	.107	.130
	N	42	42	42	42	42	42	42	42
Long queue and bureaucratic procedures at the banks	Pearson Correlation	.583**	.743**	1	.417**	.064	.205	.199	-.323*
	Sig. (2-tailed)	.000	.000		.006	.685	.193	.207	.037
	N	42	42	42	42	42	42	42	42
Currency devaluation is the problem in importation	Pearson Correlation	.397**	.411**	.417**	1	.222	.226	.150	-.194
	Sig. (2-tailed)	.009	.007	.006		.158	.151	.343	.218
	N	42	42	42	42	42	42	42	42
The government policy is not supporting the importation	Pearson Correlation	.054	.081	.064	.222	1	.221	.113	-.213
	Sig. (2-tailed)	.734	.608	.685	.158		.160	.474	.175
	N	42	42	42	42	42	42	42	42
Long clearance lead time at the receiving ports/ Customs	Pearson Correlation	.069	.257	.205	.226	.221	1	.511**	.035
	Sig. (2-tailed)	.663	.100	.193	.151	.160		.001	.824
	N	42	42	42	42	42	42	42	42
Document discrepancy during custom clearance	Pearson Correlation	.230	.252	.199	.150	.113	.511**	1	.157
	Sig. (2-tailed)	.143	.107	.207	.343	.474	.001		.320
	N	42	42	42	42	42	42	42	42
Inadequate storage facility at the customs	Pearson Correlation	-.057	-.237	-.323*	-.194	-.213	.035	.157	1
	Sig. (2-tailed)	.721	.130	.037	.218	.175	.824	.320	
	N	42	42	42	42	42	42	42	42

** . Correlation is significant at the 0.01 level (2-tailed).

* . Correlation is significant at the 0.05 level (2-tailed).

4.4.5. Challenges related to Product Distribution

In assessing the challenges related to Product Distribution of the pharmaceutical companies, various related issues were presented for the reflection of the respondents. Since pharmaceutical products are highly sensitive molecules their storage and transportation should be in line with the product specific guideline recommendation so as to maintain the safety and efficacy of pharmaceutical products. Therefore under this challenge different points like the overall pharmaceutical supply chain management system of the country, the presence or absence of standardized storage facilities and local stock forwarding companies

have been assessed. Table 4.8 illustrates the reflection of the respondents regarding the challenges related to pharmaceuticals product distribution in the country.

Table 4. 8: Challenges related to Product Distribution

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Total		$\Sigma(SA+A)$
	Layer N %	Layer N %	Layer N %	Layer N %	Layer N %	Count	Layer Valid N %	
Poor supply chain management system in the country	0.0%	4.8%	21.4%	61.9%	11.9%	42	100.0%	73.8%
Long distribution chain and many mark-up points	2.4%	9.5%	23.8%	52.4%	11.9%	42	100.0%	64.3%
Unavailability of standardized storage facilities	2.4%	7.1%	42.9%	40.5%	7.1%	42	100.0%	47.6%
Low stock holding capacity of wholesalers and retailers	0.0%	21.4%	45.2%	21.4%	11.9%	42	100.0%	33.3%
Absence of local stock forwarding companies for regions	0.0%	11.9%	26.2%	47.6%	14.3%	42	100.0%	61.9%
Less mutual trust in credit based sales transactions	2.4%	28.6%	40.5%	16.7%	11.9%	42	100.0%	28.6%

Source: Own survey result, 2020

From the total respondents 73.8% proved that there is poor pharmaceutical supply chain management system in the country specially for the private market and 64.3% of respondents confirmed about long distribution chain and many mark-ups points along the supply chain. This could have the impact on the safety of medications especially for sensitive molecules like biological products and the presence of several mark-ups result in price increase for the end users. 47.6 % of respondents confirmed that the unavailability of standardized storage facilities for the pharmaceuticals and 61.9 % of respondents indicated that the absence of

local dedicated stock forwarding companies to reach out the regional market so that in most cases pharmaceutical products have been transported with other commodities that could ultimately compromise the safety and quality of products. From the study it is possible to see that only 28.6 % of the respondents are either strongly agreed or agreed on the less mutual trust in credit based sales that means there is reasonable trust between suppliers and wholesaler and payments are settled before their due date in the pharmaceutical sector. However, the study conducted by Solomon (2014) showed that collection of credit sales was one of the major challenges in pharmaceutical marketing of private pharmaceutical importers of Ethiopia. That means trust has been built over time between suppliers and retailers in the pharmaceutical sector and credit sales will no longer be a challenge for MNPCs operating in Ethiopia. According to the key informants, now a days most of the credit based sales transactions have been made based on the post-dated checks that further increases the trust and reduces the risk of the creditors in the pharmaceutical sector.

4.4.6. Correlations Analysis of factor that affects the product Distribution

Pearson correlation method was adopted to measure the degree of relationship between variables that affects product distribution. Results presented in Table 4.9 below shown that:

Poor supply chain management system in the country is moderately correlated with unavailability of standardized storage facilities and highly correlated with absence of local stock forwarding companies in the country at the correlation coefficient of $R=.392$, $P=0.010$,and $R=.398$, $P=0.009$ respectively. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the more we maintain the availability of standardized storage facilities and stock forwarding companies the better supply chain management can be practiced in the country.

Long distribution chain and many mark ups is highly correlated with unavailability of standardized storage facilities and moderately correlated with absence of local stock forwarding companies with the correlation coefficient of $R= .512$, $P=0.001$, and $R=.345$, $P=0.025$ respectively. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the more we maintained the availability of local stock forwarding company and standardized storage facilities the shorter distribution chain and less number of mark ups can be implemented.

Unavailability of standardized storage facility in the country is highly correlated with low stock holding capacity of wholesalers and retailers with the correlation coefficient of $R=.432$, $P=0.004$. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the more we maintain the availability of standardized storage facility the better stock holding capacity at the wholesalers and retailers.

Low stock holding capacity of wholesalers and retailers is highly correlated with less mutual trust in credit based sales at the correlation coefficient of $R=.494$, $P=0.001$. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the high stock holding capacity of wholesalers and retailers the better mutual trust in credit based sales can be maintained.

Table 4. 9. Correlation Analysis of challenges related to Product Distribution

Challenges related to Product Distribution		Poor supply chain management system in the country	Long distribution chain and many mark-up points	Unavailability of standardized storage facilities	Low stock holding capacity of wholesalers and retailers	Absence of local stock forwarding companies for regions	Less mutual trust in credit based sales transactions
Poor supply chain management system in the country	Pearson Correlation	1	.264	.392*	.293	.398**	.222
	Sig. (2-tailed)		.091	.010	.060	.009	.158
	N	42	42	42	42	42	42
Long distribution chain and many mark-up points	Pearson Correlation	.264	1	.512**	.081	.345*	.083
	Sig. (2-tailed)	.091		.001	.611	.025	.603
	N	42	42	42	42	42	42
Unavailability of standardized storage facilities	Pearson Correlation	.392*	.512**	1	.432**	.181	.279
	Sig. (2-tailed)	.010	.001		.004	.250	.073
	N	42	42	42	42	42	42
Low stock holding capacity of wholesalers and retailers	Pearson Correlation	.293	.081	.432**	1	.255	.494**
	Sig. (2-tailed)	.060	.611	.004		.103	.001
	N	42	42	42	42	42	42
Absence of local stock forwarding companies for regions	Pearson Correlation	.398**	.345*	.181	.255	1	.301
	Sig. (2-tailed)	.009	.025	.250	.103		.053
	N	42	42	42	42	42	42
Less mutual trust in credit based sales transactions	Pearson Correlation	.222	.083	.279	.494**	.301	1
	Sig. (2-tailed)	.158	.603	.073	.001	.053	
	N	42	42	42	42	42	42

*. Correlation is significant at the 0.05 level (2-tailed).

** . Correlation is significant at the 0.01 level (2-tailed).

4.4.7. Challenges related to marketing activities and brand positioning

Once the product is arrived at the warehouse of local distributors, companies will immediately mobilize their resources and get involved in different strategic marketing activities so as to have a better market share and to liquidate the stock in a soonest possible time. However different challenges related to marketing activities like aggressive competition from generic competitors, unethical marketing promotion from rivals and purchasing power of the society could be some of key challenges being presented. Table 4.10 illustrates the

reflection of the respondents regarding the challenges related to marketing activities and brand positioning.

Table 4.10: Challenges related to marketing activities and brand positioning

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Total		$\Sigma(SA+A)$
	Layer N %	Layer N %	Layer N %	Layer N %	Layer N %	Count	Layer N %	
Aggressive generic companies competition	0.0%	4.8%	9.5%	31.0%	54.8%	42	100.0%	85.7%
The market is highly dominated by generic products	0.0%	2.4%	7.1%	28.6%	61.9%	42	100.0%	90.5%
Low price strategy of generic companies	2.4%	2.4%	4.8%	38.1%	52.4%	42	100.0%	90.5%
Unethical product promotion from generic companies	2.4%	2.4%	16.7%	21.4%	57.1%	42	100.0%	78.6%
Sales driven marketing strategy of generic companies	2.4%	2.4%	9.5%	54.8%	31.0%	42	100.0%	85.7%
The big discounts being offered by local agents of generic companies	2.4%	7.1%	47.6%	23.8%	19.0%	42	100.0%	42.9%
Less government policy support for branded products	2.4%	7.1%	9.5%	45.2%	35.7%	42	100.0%	81.0%
The reputation of branded products has been affected by counterfeited equivalents	9.5%	16.7%	31.0%	33.3%	9.5%	42	100.0%	42.9%
Significant market share has been taken by counterfeits	11.9%	33.3%	38.1%	9.5%	7.1%	42	100.0%	16.7%
Weak government regulation on counterfeit products	7.1%	16.7%	11.9%	59.5%	4.8%	42	100.0%	64.3%
Low purchasing power of	2.4%	4.8%	9.5%	47.6%	35.7%	42	100.0%	83.3%

the society								
Low innovative treatment seeking behavior of the people	4.8%	11.9%	11.9%	61.9%	9.5%	42	100.0%	71.4%

Source: Own survey result, 2020

From the above table 4.10 we can see that from the total respondents 85.8% responded that there is aggressive generic companies' competition, 90.5% of respondents confirmed that the Ethiopian pharmaceutical market is highly dominated by generic products and 90.5% respondents proved that low price strategy being implemented by generic pharmaceutical companies in Ethiopia. From these findings of the study, it was established that generic companies competition has been remained the major challenge for marketing and brand positioning of branded products in Ethiopia and subsequently the Ethiopian pharmaceutical market is highly dominated by generic products. This is mainly because generic companies do not require investing huge amount of money for R&D since these companies enter the market once the patent protection and other exclusivity rights of originator companies have expired. In addition most of the generic companies working in Ethiopia are from China, India and other Asian countries with GMP prequalification licenses so that they don't require to have the same quality levels with originators so their primary focus is cost containment and appearing in the market with lower price. These findings are supported by Ding et al., 2014 that confirms generic drugs enter the market at much lower prices compared with the original branded drugs they replace, as generic drugs do not need to go through the risky, costly, and lengthy process of new drug development

The study conducted by Donald A. (2010) further indicated that Generic drugs have always been a big challenge for the established big Pharma companies because big Pharma companies spend many years and millions of dollars for new drugs discovery but as soon as these patents expire, the generic drug makers are able to undercut the big Pharma profit margin within 6 months by producing lower cost alternatives.

From the total respondents 78.6% of them either strongly agreed or agreed that there is unethical product promotion practice from generic companies operating in Ethiopia to influence the prescribing behavior of doctors in their clinical practice.

Similarly, the study conducted by Uchenna et al., 2010 in South East Nigeria showed that as much as 60% of doctors admit to being influenced by promotional strategies

Pharmaceutical companies invest large sums of money promoting their products. Multinational pharmaceutical companies subject to comply with strict business ethics principles and meet the global standards in their overall operations whereas generic companies are reluctant to do so unless the national regulatory authorities strictly monitor them. The study findings clearly indicated that there is unethical product promotion practice from generic companies to persuade the physicians to prescribe their products that leads to unfair market share and wrong choice of medications. This implies that the marketing activities of generic pharmaceutical companies working in Ethiopia are not adequately monitored or regulated.

Similarly, study conducted by Napit (2018) proved that Pharmaceutical marketing efforts are also problematic if they influence health professionals to prescribe drugs that are not the best choices for their patients.

The study conducted by Samrawit (2017) in Addis Ababa green licensed hospitals further confirmed that prescribing behaviors of physicians can be influenced by the promotional activities of medical representatives in Ethiopia.

From the study findings, it was established that 85.7 % of the respondents agreed on the implementation of volume sales strategy of generic companies and it is also accompanied by less government policy support for branded products in Ethiopia as 81.0% of the respondents agreed. The pharmaceutical policy of Ethiopia emphasizes more on the access just to match with allocated pharmaceutical budget so that almost all public tenders have been taken by generic companies since lower price bidders are always taken as a best candidate of suppliers. This implies that Generic companies are policy backed to dominate the Ethiopian market and subsequently some of multinationals pharmaceutical companies are leaving the country.

Low purchasing power of the society also the challenge for multinational pharmaceutical companies operating in Ethiopia as 83.3% of the respondents indicated. This may bring the attention of multinational pharmaceutical companies to relook in to their pricing strategy that will improve the affordability of their products. This also implies that multinational pharmaceutical companies operating in Ethiopia require employing differential pricing strategy to widen the customers' base. Similarly, the study conducted by Andrian, 2003 proved that in the context of pharmaceutical and other health products, differential pricing (also called tiered pricing) is the adaptation of product prices to the purchasing power of consumers in different geographical or socio-economic segments and a well implemented

differential pricing system can lead to incremental sales for the pharmaceutical manufacturers.

From the above table 4.10 we can understand that only 16.6 % of the respondents indicated that significant market share has been taken by counterfeited products so that the impact of counterfeited medicines in Ethiopian market is low. Similarly, the study conducted by Solomon (2014) confirmed that the level of availability of counterfeit medicines in Ethiopian market is low. Therefore this confirms that availability of counterfeit pharmaceutical products in Ethiopian pharmaceutical market is not a major challenge for pharmaceutical marketing in Ethiopia.

4.4.8. Correlations Analysis of factor that affects marketing and brand positioning

Pearson correlation method was adopted to measure the degree of relationship between variables that affects marketing and brand positioning. Results presented in Table 4.11 below shown that aggressive generic companies' competition is highly correlated with generic products market dominance and unethical product promotion practice from generic companies at correlation coefficient of $R=.639$, $P=0.000$, and $R=.395$, $P=0.010$ respectively. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the more ethical product promotion from generic companies the less aggressive competition from generic companies and lower market dominance by generic products.

Market dominance of generic products' is highly correlated with low price strategies of generic companies, unethical product promotion from generics, sales driven marketing strategy of generic companies, big discount offer by the local agents of generic companies and low innovative treatment seeking behavior of the society at correlation coefficient of $R=.543$, $P=0.000$, $R=.463$, $P=0.002$, $R=.426$, $P=0.005$, $R=.459$, $P=0.002$, and $R=.416$, $P=0.006$ respectively. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the more ethical product promotion, the higher price strategy, the less sales driven marketing strategy from generic companies, the less discount offer by local agents and the higher innovative seeking behavior of the society the less market dominance of generic products.

Low price strategy of generic companies is highly correlated with unethical product promotion, sales driven marketing strategy, big discount offer by local agents, less government policy support for brand products, low purchasing power of the society and low innovative treatment seeking behavior of the people at correlation coefficient of $R=.578$, $P=0.000$, $R= .672$, $P=0.000$, $R=.616$, $P=0.000$, $R=.515$, $P=0.000$, $R=.404$, $P=0.008$, and $R=.423$, $P=0.005$ respectively. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the more ethical product promotion, the less sales driven strategy, the higher price strategy, no discount by local agents, the higher government policy support for brand products the more innovative treatment seeking behavior of the society.

Unethical product promotion from generic companies' is highly correlated with sales driven marketing strategy, big discount offer, less government policy support, reputation damage of brand products by counterfeited products and low innovative treatment seeking behavior of the people at the correlation coefficient of $R=.544$, $P=0.00$, $R=.531$, $P=0.00$, $R=.408$, $P=0.007$, $R=.414$, $P=0.006$, and $R=.517$, $P=0.000$ respectively. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the higher government support for brand products, the less influence of counterfeited products, no discount offer by local agents, the less sales driven strategy the more ethical product promotion practice from generic companies.

Sales driven marketing strategy of generic companies' is highly correlated with big discount offer by local agents and less government policy support for brand products at correlation coefficient of $R=.740$, $P=0.000$, $R=.751$, $P=0.000$ respectively. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that higher government policy support for brand products and the fewer discounts offer by local agents the less sales driven marketing practice from generic companies.

The big discount offer by local agents of generic companies' is highly correlated with less government policy support for brand products and low innovative treatment seeking behavior of the people at correlation coefficient of $R=.612$, $P=0.000$, $R=.445$, $P=0.003$ respectively. This means that increasing the coefficient of one variable will increase the coefficient value

of other variable in the same positive direction. This implies that the higher government supports for brand products and innovative seeking of the people the less discount offer by generic companies.

Weak government regulation on counterfeit product is highly correlated with major market share by counterfeit products at correlation coefficient of $R=.446$, $P=0.003$. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the stronger government regulation enforcement on counterfeit products the lesser market share taken up by counterfeit products. Low purchasing power of the society is highly correlated with low innovative treatment seeking behavior at correlation coefficient of $R=.413$, $P=0.007$. This implies that the higher purchasing power the more innovative treatment seeking behavior of the people

Table 4.11: Correlation Analysis of challenges related to marketing activities and brand positioning

challenges related to marketing activities and brand positioning	Aggressive generic companies competition	The market is highly dominated by generic products	Low price strategy of generic companies	Unethical product promotion from generic companies	Sales driven marketing strategy of generic companies	The big discounts being offered by local agents of generic companies	Less government policy support for branded products	The reputation of branded products has been affected by counterfeited equivalents	Significant market share has been taken by counterfeits	Weak government regulation on counterfeit products	Low purchasing power of the society	Low innovative treatment seeking behavior of the people
Pearson Correlation	1	.639**	.380*	.395**	.222	.074	.066	.089	-.082	.198	.110	.118
Sig. (2-tailed)		.000	.013	.010	.158	.641	.676	.574	.606	.210	.488	.456
N	42	42	42	42	42	42	42	42	42	42	42	42
Pearson Correlation	.639**	1	.543**	.463**	.426**	.459**	.267	.249	-.094	.218	.247	.416**
Sig. (2-tailed)			.000	.002	.005	.002	.087	.112	.554	.166	.114	.006
N	42	42	42	42	42	42	42	42	42	42	42	42
Pearson Correlation	.380*	.543**	1	.578**	.672**	.616**	.515**	.358*	.238	.112	.404**	.423**
Sig. (2-tailed)				.000	.000	.000	.000	.020	.130	.478	.008	.005
N	42	42	42	42	42	42	42	42	42	42	42	42
Pearson Correlation	.395**	.463**	.578**	1	.544**	.531**	.408**	.414**	.373*	.334*	.180	.517**
Sig. (2-tailed)					.000	.000	.007	.006	.015	.030	.253	.000
N	42	42	42	42	42	42	42	42	42	42	42	42
Pearson Correlation	.222	.426**	.672**	.544**	1	.740**	.751**	.493**	.309*	.040	.327*	.279
Sig. (2-tailed)						.000	.000	.001	.046	.801	.035	.074
N	42	42	42	42	42	42	42	42	42	42	42	42
Pearson Correlation	.074	.459**	.616**	.531**	.740**	1	.612**	.414**	.263	.048	.432**	.445**
Sig. (2-tailed)							.000	.006	.092	.765	.004	.003
N	42	42	42	42	42	42	42	42	42	42	42	42
Pearson Correlation	.066	.267	.515**	.408**	.751**	.612**	1	.498**	.415**	.076	.181	.145
Sig. (2-tailed)								.001	.006	.634	.252	.359
N	42	42	42	42	42	42	42	42	42	42	42	42
Pearson Correlation	.089	.249	.358*	.414**	.493**	.414**	.498**	1	.688**	.273	-.016	.150
Sig. (2-tailed)				.006	.001	.006	.001		.000	.080	.922	.344
N	42	42	42	42	42	42	42	42	42	42	42	42
Pearson Correlation	-.082	-.094	.238	.373*	.309*	.263	.415**	.688**	1	.446**	-.091	.078
Sig. (2-tailed)				.015	.046	.092	.006	.000		.003	.565	.623
N	42	42	42	42	42	42	42	42	42	42	42	42
Pearson Correlation	.198	.218	.112	.334*	.040	.048	.076	.273	.446**	1	.061	.244
Sig. (2-tailed)				.030	.801	.765	.634	.080	.003		.700	.119
N	42	42	42	42	42	42	42	42	42	42	42	42
Pearson Correlation	.110	.247	.404**	.180	.327*	.432**	.181	-.016	-.091	.061	1	.413**
Sig. (2-tailed)				.253	.035	.004	.252	.922	.565	.700		.007
N	42	42	42	42	42	42	42	42	42	42	42	42
Pearson Correlation	.118	.416**	.423**	.517**	.279	.445**	.145	.150	.078	.244	.413**	1
Sig. (2-tailed)				.000	.074	.003	.359	.344	.623	.119	.007	
N	42	42	42	42	42	42	42	42	42	42	42	42

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

4.6. Prospects of Multinational Pharmaceutical companies operating in Ethiopia

Data collected through questionnaire survey was analyzed with SPSS 20 to assess respondent's level of agreement on identified factors that affect the prospects of multinational pharmaceutical companies operating in Ethiopia. According to respondents response under table 4.12 below, population number of a country with frequency distribution of 95.2% (38.1% +57.1%) level of agreement , sustainable economic growth with 76.2 % (14.3% +61.9%), emerging middle class group with 85.7 % (38.1 % + 47.6%), growing disease burden in the country with 92.9% (45.2 % + 47.7%), expansion of health care service in the country with 73.8% (19% + 54.8%), and growing human resource capacity of the country 73.8 % (7.1 % + 66.7%) have been identified as major factors of opportunities for multinational pharmaceutical companies operating in Ethiopia

Table 4.12: Prospects of Multinational Pharmaceutical companies operating in Ethiopia

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Total		$\Sigma(SA+A)$
	Layer N %	Layer N %	Layer N %	Layer N %	Layer N %	Count	Layer N %	
Population number of Ethiopia is an opportunity	0.0%	0.0%	4.8%	57.1%	38.1%	42	100.0%	95.2%
Sustainable economic growth of the country is really attractive for Multinationals	0.0%	0.0%	23.8%	61.9%	14.3%	42	100.0%	76.2%
Emerging middle class group and per capita health care expenditure has been increasing	0.0%	0.0%	14.3%	47.6%	38.1%	42	100.0%	85.7%
Growing disease burden in the country increases the demand for pharmaceutical products	0.0%	0.0%	7.1%	47.6%	45.2%	42	100.0%	92.9%

Expansion of the health care service in the country	2.4%	2.4%	21.4%	54.8%	19.0%	42	100.0%	73.8%
Government is determined to increase access of quality medicines	2.4%	11.9%	57.1%	19.0%	9.5%	42	100.0%	28.6%
Public procurement system favors more branded products	38.1%	47.6%	9.5%	2.4%	2.4%	42	100.0%	4.8%
Strategic location of Ethiopia is an opportunity	11.9%	2.4%	42.9%	33.3%	9.5%	42	100.0%	42.9%
Growing in ICT infrastructure in the country increases ease of doing business for Multinationals	14.3%	21.4%	42.9%	14.3%	7.1%	42	100.0%	21.4%
Human Resource capacity of the sector has been developing	14.3%	0.0%	11.9%	66.7%	7.1%	42	100.0%	73.8%
Priority being given for Pharmaceuticals in Forex allocation	11.9%	33.3%	21.4%	28.6%	4.8%	42	100.0%	33.3%

Source: Own survey result, 2020

As shown in the above table 4.12 from the total respondents 95.2% agreed that increased population size of a country is an opportunity for pharmaceutical marketing this is because as the number of people increases the demand for the pharmaceuticals also increases, however local manufacturing capacity of Ethiopia covers only 20 – 25 % of the demand so the remaining portion of the demand has been covered by imported products so it has been considered as a major opportunity for multinational companies. From the findings of the study, it was established that majority (92.9%) of the respondents confirmed the growing disease burden in the country is the second main opportunity for pharmaceutical companies. This is because of progressive life style changes in the society and fast urbanization trend, people tends to be more sedentary and there is also growing trend of European foods so the

prevalence of non-communicable diseases like diabetes, cardiovascular, cancer and mental illness is increasing.

The study done by IMS health-Africa, stated that the changing economic profile of Africa is also linked to an increased demand for chronic care drugs, reflecting a marked shift in the burden of illness towards non communicable diseases (NCDs) and Africa is expected to experience the largest increase in death rates from cardiovascular (CV) disease, cancer, respiratory disease and diabetes over the next ten years, resulting in greater demand for healthcare services and appropriate medicines(IMS- Africa, 2012).

This study has also identified it as main opportunity for Pharma companies in general for multinational pharmaceutical companies in particular because most of non-communicable diseases require innovative and new class of molecules.

85.7% of the respondents agreed on the presence of emerging middle class group and subsequent increase of per capita health care expenditure as a possible opportunity for multinational pharmaceutical companies. This implies that the number of people who can afford for quality medical care and innovative treatments are increasing in the country so that multinational companies look forward to take advantage from this target group of customers. From the total respondents 76.2% agreed on the sustainable economic growth of the country and 73.8 % of respondents indicated the expansion of health care services in the country. When there is economic development and GDP growth in a given country there is also the assumption that per capita income of individuals will grow so individual's health care expenditure and innovative treatment seeking behavior also increasing so multinationals pharmaceutical companies can take advantage of this by supplying quality and new generation products. The expansion of health care service in the country would give an opportunity for a society early diagnosis and improved access of medical care so that multinational pharmaceutical companies could take advantage of it by supplying their product and /or services.

Similarly study done by IMS health which focused on pharmaceutical market growth of African countries stated that the increasing economic strength is one of the factor which triggers the rising demand for health care and medicines and offers growth opportunity for pharmaceutical companies (IMS, 2012)

From the study findings, 28.6 % of the respondents agreed on the government's determination to increase access of branded products and it is further reflected by only 4.8 % of the respondents agreed on the public procurement policy of the country is in favor of

branded products. Annually, from the total imported products two-third of the pharmaceuticals has been brought through Ethiopian pharmaceutical supply agency (EPSA) after floating international tenders. However, as it is indicated with this study multinational pharmaceutical companies are less likely to win tenders since price is the critical factor to select suppliers in our public procurement system and it further increases the dominance of generics in our market.

On the other hand, Forex allocation is found to be the main challenge for multinational pharmaceutical companies in the private market as it is proved by only 33.3 % of the respondents agreed on priority being given for pharmaceuticals in Forex allocation. This implies that the government support both in public tender and Forex allocation could not be taken as an opportunity for multinational pharmaceutical companies operating in Ethiopia.

From the study findings, 73.8% of the respondents agreed that human resource capacity of the sector has been developing. This implies that the well availability of highly qualified and competent pharmacy professionals in the country can be considered as one of the opportunities for multinational pharmaceutical companies in Ethiopia.

4.6.1. Correlations Analysis of factor that affects prospects of multinational pharmaceutical companies in Ethiopia

Pearson correlation method was adopted to measure the degree of relationship between variables that affects prospects of multinational pharmaceutical companies operating in Ethiopia. Results presented in Table 4.13 below shown that:

Population number of the Ethiopia is an opportunity for MNPCs is highly correlated with priority requirement for pharmaceuticals in Forex allocation and moderately correlated with economic growth of the country at correlation coefficient of $R=.479$, $P=0.001$, and $R=.370$, $P=0.016$ respectively. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the higher population number the progressive economic growth and the higher demand for pharmaceuticals and hence the more priority requirement for pharmaceuticals in Forex allocation.

Economic growth of the country is attractive for multinationals is highly correlated with emerging middle class group, growing disease burden in the country, expansion of health care service, strategic location of the country, growing ICT infrastructure, developing human resource capacity and priority requirement for pharmaceuticals in Forex allocation at correlation coefficient of $R=.626, P=0.000$; $R=.477, P=0.001$; $R=.442, P=0.003$; $R=.476, P=0.001$; $R=.583, P=0.000$; $R=.422, P=0.005$, and $R=.427, P=0.005$ respectively. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that the higher economic growth and the strategic location the better human resource capacity and ICT infrastructure in the country that translates further to more emerging middle class group, higher disease burden and more expansion of health care system,

Emerging middle class group is highly correlated with growing disease burden, expansion of health care system and developing human resource capacity at the correlation coefficient of $R=.520, P=0.000$; $R=.478, P=0.001$, and $R=.647, P=0.000$ respectively. This means that increasing the coefficient of one variable will increase the coefficient value of other variable in the same positive direction. This implies that higher middle class group the more growing disease burden in response of the life style changes of the people, the further expansion of health care system and better human resource capacity development.

Human resource capacity of the sector is highly correlated with economic growth, emerging middle class group and growing ICT infrastructure at the correlation coefficient of $R=.442, P=0.005$, $R=.647, P=0.000$, and $R=.448, P=0.003$ respectively. This implies that the more economic growth in the country the higher emerging middle class group, the better human resource capacity and ICT infrastructure required.

Table 4.13: Correlation Analysis of Prospects of Multinational Pharmaceutical companies operating in Ethiopia

Prospects of Multinational Pharmaceutical companies operating in Ethiopia		Population number of Ethiopia is an opportunity	Sustainable economic growth of the country is really attractive for Multinationals	Emerging middle class group and per capita health care expenditure has been increasing	Growing disease burden in the country increases the demand for pharmaceutical products	Expansion of the health care service in the country	Government is determined to increase access of quality medicines	Public procurement system favors more branded products	Strategic location of Ethiopia is an opportunity	Growing in ICT infrastructure in the country increases ease of doing business for Multinationals	Human Resource capacity of the sector has been developing	Priority being given for Pharmaceuticals in Forex allocation
Population number of Ethiopia is an opportunity	Pearson Correlation	1	.370*	.165	.046	.304	.049	.016	-.066	.156	.063	.479**
	Sig. (2-tailed)		.016	.297	.773	.050	.757	.919	.679	.323	.692	.001
	N	42	42	42	42	42	42	42	42	42	42	42
economic growth of the country is really attractive for Multinationals	Pearson Correlation	.370*	1	.626**	.477**	.442**	.311*	.194	.476**	.583**	.422**	.427**
	Sig. (2-tailed)	.016		.000	.001	.003	.045	.217	.001	.000	.005	.005
	N	42	42	42	42	42	42	42	42	42	42	42
Emerging middle class group and per capita health care expenditure has been increasing	Pearson Correlation	.165	.626**	1	.520**	.478**	.075	.067	.273	.327*	.647**	.184
	Sig. (2-tailed)	.297	.000		.000	.001	.636	.675	.081	.035	.000	.243
	N	42	42	42	42	42	42	42	42	42	42	42
burden in the country increases the demand for pharmaceutical	Pearson Correlation	.046	.477**	.520**	1	.060	-.064	-.237	-.007	.266	.368*	.105
	Sig. (2-tailed)	.773	.001	.000		.707	.686	.131	.965	.089	.017	.506
	N	42	42	42	42	42	42	42	42	42	42	42
Expansion of the health care service in the country	Pearson Correlation	.304	.442**	.478**	.060	1	.275	.164	.362*	.283	.336*	.354*
	Sig. (2-tailed)	.050	.003	.001	.707		.078	.299	.018	.069	.030	.021
	N	42	42	42	42	42	42	42	42	42	42	42
Government is determined to increase access of quality medicines	Pearson Correlation	.049	.311*	.075	-.064	.275	1	.270	.249	.177	-.117	.142
	Sig. (2-tailed)	.757	.045	.636	.686	.078		.083	.111	.261	.462	.371
	N	42	42	42	42	42	42	42	42	42	42	42
Public procurement system favors more branded products	Pearson Correlation	.016	.194	.067	-.237	.164	.270	1	.456**	.367*	-.033	.065
	Sig. (2-tailed)	.919	.217	.675	.131	.299	.083		.002	.017	.838	.681
	N	42	42	42	42	42	42	42	42	42	42	42
Strategic location of Ethiopia is an opportunity	Pearson Correlation	-.066	.476**	.273	-.007	.362*	.249	.456**	1	.625**	.303	.181
	Sig. (2-tailed)	.679	.001	.081	.965	.018	.111	.002		.000	.051	.251
	N	42	42	42	42	42	42	42	42	42	42	42
Growing in ICT infrastructure in the country increases ease of doing	Pearson Correlation	.156	.583**	.327*	.266	.283	.177	.367*	.625**	1	.448**	.400**
	Sig. (2-tailed)	.323	.000	.035	.089	.069	.261	.017	.000		.003	.009
	N	42	42	42	42	42	42	42	42	42	42	42
Human Resource capacity of the sector has been developing	Pearson Correlation	.063	.422**	.647**	.368*	.336*	-.117	-.033	.303	.448**	1	.385*
	Sig. (2-tailed)	.692	.005	.000	.017	.030	.462	.838	.051	.003		.012
	N	42	42	42	42	42	42	42	42	42	42	42
Priority being given for Pharmaceuticals in Forex allocation	Pearson Correlation	.479**	.427**	.184	.105	.354*	.142	.065	.181	.400**	.385*	1
	Sig. (2-tailed)	.001	.005	.243	.506	.021	.371	.681	.251	.009	.012	
	N	42	42	42	42	42	42	42	42	42	42	42

*. Correlation is significant at the 0.05 level (2-tailed).

** Correlation is significant at the 0.01 level (2-tailed).

This part of the study presents correlating data obtained quantitatively and qualitatively. As it was obtained from quantitative analysis almost all key informants pointed out that process for pharmaceutical product registration is very challenging. They explained that the long tedious process requested by the regulatory body of the country is tiresome and takes long time to register a product. So getting market authorization is super challenge for MNPC operating in Ethiopia. To overcome this challenges authority should set up simplified process flows and working procedures have to be clear and transparent. Only relevant documents should be requested during registration process and there should be a clear time table for dossier evaluation period. The country should give special attention for multinational companies by incorporating a clear policy support.

The key informants also commented that there is a very series shortage of foreign exchange for importation of pharmaceutical products and the long tedious process requested by the banks. Therefore, companies are not fully utilized their potential and as a result of this a very serious stock out situations are happening in the market. The informants believe that low capacity of custom authority contributed to the long clearance period of the pharmaceutical products. At long awaited products get damaged before they can be cleared from the authority to the market that further aggravates the stock out situation and most importantly, it puts patient safety at risk. Especially the cold chain products are not properly handled at the customs because of inadequate space and absence of pharmacy professionals on the spot.

According to the key informants opinion the supply chain management system of pharmaceutical products is not adequately monitored and the local distribution system does not meet pharmaceutical products handling requirements. So pharmaceutical products have been distributed to the regional markets simply with other commodities and the drivers who are taking responsibility have no idea about pharmaceutical products' quality and safety. In most countries pharmaceutical products have been distributed with dedicated and professional stock forwarding companies, but this practice is not yet implemented locally so the government should encourage people to have these facilities in place.

The key informants also strongly commented the unethical product promotion practice being conducted by generic companies that leads to wrong choice of treatments for patients and unfair market share being taken by generic companies that will eventually affect the business of MNPCs in the market.

Chapter Five

Summary, Conclusions and Recommendations

Introduction

The final part of this research paper provides summary of the findings of the study, conclusions and recommendations for the challenges and prospects of multinational pharmaceutical companies which were drawn from the findings and discussions of the data collected by questionnaires and interview. The chapter is structured as follows: Summary, conclusion, recommendations and suggestions for further research.

5.1. Summary of Findings

The purpose of this study was to assess the challenges and prospects of multinational pharmaceutical companies operating in Ethiopia. The study was guided by research questions and the following summaries of major findings of the study are presented based on the analysis and interpretation of collected data. As per the questionnaire and key interview analysis, the following challenges and opportunities are facing the multinational pharmaceutical companies operating in Ethiopia

Among several challenges related to product registration process: Long document or dossier evaluation period and Complex document requirement at the authority/ EFDA are the two major challenges respectively. Among Challenges related to product importation process: Insufficient Forex allocation from banks and less transparent banking system for Forex allocation are the two major challenges as well

From the total variables under the challenges of pharmaceutical products distribution: Poor pharmaceutical supply chain management system in the country, Long distribution chain & many mark-up points and absence of local stock forwarding companies are the three main challenges identified. From the entire variables assessed under the challenges of Marketing activities and brand positioning: Low price strategy of generic companies & aggressive generic companies competition , unethical product promotion from generic companies and low government support for brand products are the three major challenges.

Under prospects different possible opportunities have been assessed so that increasing population number of Ethiopia is found to be the first opportunity according to the study. Growing disease burden especially non-communicable illnesses in response to life style changes in the country has rated as a second best opportunity for multinational pharmaceutical companies. Emerging middle class group and Progressive economic growth of the country have been rated as a third and fourth good opportunities for multinational pharmaceutical companies respectively.

From the interview questions respondents have mentioned that since multinational pharmaceutical companies provide high quality and best in class products, their target customers are those who can afford these innovative molecules. Therefore the presence of many international organizations like UNECA, AU, Ethiopian airlines and many NGOs in the country can be considered as an opportunity because of their health insurance offer for their staffs.

5.2. Conclusions

The study findings showed that the main challenge related to product registration is complex document requirement and subsequently long document review period. The documents which are required for product registration by the authority are very redundant and most of the required documents have no any relevance with the product being registered so in Ethiopia the fastest document review period could take an average of one and half years which made the process of getting market authorization is quite challenging for MNPCs in Ethiopia.

The findings also showed that there is serious shortage of Forex allocation from banks and there is also less transparent banking system for forex allocation at different banks. Despite the fact that pharmaceutical products are prescribed to maintain health and to save lives of patients, there is no priority being given for pharmaceuticals so companies are supposed to wait average of four months to get forex allocation after the PO has been submitted. As a result of this there is inconsistent supply of medicines and serious stock out problem in the market. Thus some MNPCs like GSK, MSD and Johnson & Johnson recently left the market and others have already downsized their staff.

The study results also indicated that the pharmaceutical supply chain management of Ethiopia is in its infancy stage yet and hence pharmaceutical products have been distributed in a substandard way. Unlike generic companies, most MNPCs especially with refrigerator

products want to meet the global safety standards throughout the distribution, however maintaining these standards in Ethiopia remain a challenge for MNPCs. In addition, a number of mark-ups at each distribution point have pushed the end price up so that MNPCs product becomes more expensive than its justifiable price.

The study findings also showed that MNPCs in Ethiopia are facing stiff competition from generic companies as generics have a very low price strategy and sales driven marketing approaches. Despite the fact that MNPC products are high quality and best safety profiles, many patients go to the generic products because of low purchasing power and information asymmetry about quality difference between generics and original brands. The study findings also confirmed that there is unethical product promotion practice from generic companies that results in biased doctors' decision on prescription whereas MNPCs follow very strict global pharmaceutical product promotion guidelines that demands only evidence based communication with HCPs. On top of that there no adequate government support for brand products in Ethiopia as MNPCs has less chance of winning public tenders.

The study results also proved that Ethiopia is a country of opportunities for MNPCs as growing population size, increasing disease burden especially non communicable illnesses and expansion of health care services have been indicated in the study as a good opportunities looking forward. The study also indicated that the progressive economic growth of the country and emerging middle class groups, who can afford innovative treatments will be a good source of business for MNPCs in Ethiopia.

5.3. Recommendations

Based on the findings and the analysis of the study, the following recommendations were suggested by the researcher to help improve the challenges faced and leverage the opportunities in MNPC operating in Ethiopia.

- As 95.2% of the respondents agreed on the insufficient forex allocation from the government, it is found to be the major finding in the product importation challenges. So that the government should improve its forex allocation for pharmaceuticals importation and priorities should be given for life saving branded items. Banks should have a list of life saving items from the regulatory authority so that they can know which products require top priority during Forex allocation.

- There should be incentive scheme for Diaspora people, who are using their Dollar account for pharmaceutical importation. The government should also widen the validation period and saving amount of retention accounts so that people with this account can import reasonably high large volume of pharmaceuticals so that the shortage can be alleviated partly.
- As 88.1% of respondents agreed on the lack of transparency in the banks system for forex allocation, banks should put in place very open and transparent forex allocation procedures
- As 95.2% of respondents agreed on the long document or dossier evaluation period and 85.7 % of respondents agreed on complex document requirement at the authority. EFDA should implement simplified and agile procedures for drug registration process. The dossier evaluation check list should be reviewed and there should be a clear time table indication for market authorization processes
- As 73.8% of the respondents agreed on the poor pharmaceutical supply chain system in the country, the pharmaceutical products distribution system doesn't meet the standards, therefore the government should set a kind of incentive scheme like duty free cars for investors to establish companies with standardized pharmaceutical products transportation facilities
- As 78.6 % of the respondents agreed on the presence of unethical product promotion practice in the country, the Ethiopian pharmaceutical products promotion practice is not well monitored and regulated by the authority/ EFDA so that there is an indication of unethical promotions from generic companies. Therefore the authority should set a follow up mechanism and there should be periodic market survey to check companies' practice on their marketing activities
- As 81 % of the respondents agreed on the less government policy support for branded products , the government should support them to sustain their presence in the country since MNPCs contribute a lot for health care system and economic growth of the country

5.4. Suggestions for Further Research

The researcher recommend for future researchers to conduct study by including more variables focusing on current market position and strategies being employed by multinational pharmaceutical companies operating in Ethiopia. This research also indicates unethical pharmaceutical promotion practice so further research is recommended to figure out its magnitude.

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Appendix



Jimma University

College of Business and Economics

Masters of Business Administration

The purpose of this questionnaire is to collect relevant data for research entitled “Challenges and Prospects of Multinational Pharmaceutical Companies in Ethiopia” for the partial fulfillment of Master’s degree in Business Administration.

Your answers will not be disclosed to anyone and will remain anonymous. I would like to assure you that any information you provide will be kept confidential and be used only for academic purpose

N.B

- No need of writing your name in the questionnaire
- You can give more than one answer when appropriate
- Please fill a tick mark (✓) in the check box provided for your answer

Part I: General Information

Name of Company_____.

Country of Origin_____.

1. Gender

Male Female

2. Educational Level

Diploma Degree /BSc Masters PhD

If other please specify.....

3. Position/Status

General Manager Marketing Manager Country Manager Sales
super^{vis}or Medical/Sales Representative Key Account Manager

4. Years of your service in the sector

< 5 years 6 – 10 years 11 – 15 years 16 – 20 years > 20
years

4. Number of local Employees in your company

<4 5- 9 10- 14 > 15

5. Number of registered pharmaceutical Products in Ethiopia

<10 11- 15 16- 20 >20

6. Number of local agents representing the company

1 2 3 4 5

Part II: Basic Information

1. For how long your company has been working in Ethiopia

0- 5 yrs 6-10 yrs 11-15 yrs >15 yrs

2. How do you rate your products acceptability in the market

Poor Good Very Good Excellent

3. What attributes of your company’s products do you think are influential in the market?

- Brand name
- Product Package
- Product price
- Product quality
- If other please

specify_____

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

Poor Good Very Good Excellent

5. Which distribution outlet you primarily use?

Public tender / EPSA Wholesalers Pharmacies

Hospitals

If other please

specify_____

6. Which market segment are you primarily capitalizing on?

Public tender/EPISA Government Hospitals & Pharmacies Private
Hospitals & Pharmacies Private Retail Pharmacies

If other please

specify_____

Part III. Market Information

1. Which economic class of the population does your marketing activity focuses on?

Low income Medium Income High Income

2. How do you rate the level of impact the health care seeking behavior of the society on your marketing activity? And Why?

No Impact low impact Moderate Impact High Impact

_____.

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3. Which treatment area does your company mainly working in and why?

Communicable diseases Non Communicable Diseases Both

_____.

.

4. Which diseases are does your company primarily focuses on?

Cardio-Vascular and Metabolism Infection Oncology Respiratory

If other please

specify_____

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

Cardio-Vascular and Metabolism Infection Oncology Respiratory

If other please

specify_____

1. Challenges in Product Registration, Importation, Distribution and In-market activities of Multinational Pharmaceutical companies operating in Ethiopia

To what extent do you agree with the following statements? Give your ratings on 5 points scale where 1- Strongly disagree, 2- Disagree, 3- Not sure, 4- Agree, 5- Strongly agree

No	1.1. Challenges in product Registration	1	2	3	4	5
1	Complex document requirement at the authority/EFDA					
2	Long document or dossier evaluation period					
3	Lack of procedural transparency at the Authority					
4	Poor data recording and management system					
5	Low personnel technical capacity at the authority /EFDA					
6	Lack of objective criteria for manufacturing facility inspections and sampling					
7	Absence of one-window service at the authority					
8	Lack of digitalization and inadequate IT support					
9	Low motivation or sense of service among staffs					

No	1.2. Challenges in product Importation	1	2	3	4	5
1	Insufficient Forex allocation from banks seriously affecting the importation process					
2	Banking system lacks transparency for Forex allocation					
3	Long queue and bureaucratic procedures at the banks					
4	Currency devaluation is the problem in importation					
5	The government policy is not supporting the importation					
6	Long clearance lead time at the receiving ports/ Customs					
7	Document discrepancy during custom clearance					
8	Inadequate storage facility at the customs					
No	1.3. Challenges in product Distribution	1	2	3	4	5
1	Poor supply chain management system in the country					
2	Long distribution chain and many mark-up points					
3	Unavailability of standardized storage facilities					
4	Low stock holding capacity of wholesalers and retailers					
5	Absence of local stock forwarding companies for regions					
6	Less mutual trust in credit based sales transactions					

No	1.4. Challenges in marketing activities and brand positioning	1	2	3	4	5
1	Aggressive generic companies competition					
2	The market is highly dominated by generic products					
3	Low price strategy of generic companies					
4	Unethical product promotion from generic companies					
5	Sales driven marketing strategy of generic companies					
6	The big discounts being offered by local agents of generic companies					
7	Less government policy support for branded products					
8	The reputation of branded products has been affected by counterfeited equivalents					
9	Significant market share has been taken by counterfeits					
10	Weak government regulation on counterfeit products					
11	Low purchasing power of the society					
12	Low innovative treatment seeking behavior of the people					

2. Prospects of Multinational Pharmaceutical companies operating in Ethiopia

To what extent do you agree with the following statements? Give your ratings on 5 points scale where 1- Strongly disagree, 2- Disagree, 3- Not sure, 4- Agree, 5- Strongly agree

No	2.1. Prospects of Multinational Pharmaceutical companies in Ethiopia	1	2	3	4	5
1	Population number of Ethiopia is an opportunity					
2	Sustainable economic growth of the country is really attractive for Multinationals					
3	Emerging middle class group and per capita health care expenditure has been increasing					
4	Growing disease burden in the country increases the demand for pharmaceutical products					
5	Expansion of the health care service in the country					
6	Government is determined to increase access of quality medicines					
7	Public procurement system favors more branded products					
8	Strategic location of Ethiopia is an opportunity					
9	Growing in ICT infrastructure in the country increases ease of doing business for Multinationals					
10	Human Resource capacity of the sector has been developing					
11	Priority being given for Pharmaceuticals in Forex allocation					



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Open ended / Interview Questions

1. According to your perspective what attracts your company to invest in Ethiopia?

2. What do you think should be done to lessen or overcome challenges that multinational Pharmaceutical companies face in the market?

3. What opportunities/ prospects do you see for multinational pharmaceutical companies operating in Ethiopia?

4. Do you believe that multinational pharmaceutical companies are taking their own competitive advantages in the market? And How?

5. What should be done to increase the market share and profitability of multinational pharmaceutical companies in Ethiopia?

6. Please mention any opinion on the issues being discussed?

Thank You Very Much for Your Cooperation.