ST. MARY'S UNIVERSITY

SCHOOL OF GRADUATE STUDIES

ASSESMENT ON CHALLENGES OF MULTINATIONAL PHARMACEUTICAL COMPANIES OPERATING IN ETHIOPIA

BY

Dawit Teklu

SGS/0009/2009B

January, 2019

ADDIS ABEBA, ETHIOPIA

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APPROVED BY EXAMINERS

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DECLARATION

I, the under signed, declare that this thesis is my original work, prepared under the guidance of Mohammed M (Assitant Professor). All sources of material used while working on this thesis have been duly acknowledged. I further confirm that the thesis has not been submitted either in part or in full to any other higher learning institution for the purpose of earning any type of degree.

Dawit Teklu W/Tensay _____

Name **Signature and Date**

ENDORSEMENT

This thesis has been submitted to St. Mary's University College, School of Graduate Studies for examination with my approval as a university advisor.

_____	_____
Advisor	Signature

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LIST OF ABBREVIATIONS/ACRONYMS

AMRHI	African Medicines Registration Harmonization Initiative
CBO	Congressional Budget Office
CBI	Confidential Business Information
EFMHACA	Ethiopian Food, Medicine and Healthcare Administration and Control Authority
FDA	Food and Drug Administration
IPR	Intellectual Property Rights
MNC	Multinational Companies
NBE	National Bank of Ethiopia
RSL	Remaining Shelf Life
R & D	Research and development
WHO	World Health Organization

ABSTRACT

Multinational company is a company engages in international business when it conducts any business functions beyond its domestic borders. These multinational drug manufacturing company are operating through local import agents which manage the import and distribution process of pharmaceutical products that cover a wide ranges of therapeutic area including infection, diabetes, cardio vascular and others. The General objective of the study was to assess challenges of multinational pharmaceutical companies operating in Ethiopia. The study used both primary data and secondary data that were collected through a semi-structured questionnaire, & interview for quantitative and qualitative analysis. The study found that there are five challenges facing the companies like shortage of foreign exchange, import regulation, registration, licensing and inspection and custom control. Finally from the study it can be concluded there is Insufficient of foreign exchange for importation of pharmaceutical products, weak government support for pharmaceutical importation, bureaucratic procedure and extended paper work in banks during importation, illegal competitors are involved in import and distribution to the medicine outlets, The government is lacking adequate regulatory measure/enforcement on violations of the licensing rules and the inspection procedure is lacking transparency and exposed to corruption, complex document and more than a year is required during the registration process, the custom clearance authority takes a long period of time to process the shipments, and generic drug producer with low price strategy affect the marketing activities of MNPC. Based on these findings, the study recommends that give forex priority for pharmaceutical importers, minimizing bureaucratic approaches, increase quality of service in custom and conduct a random testing of products to find counterfeit product.

Key words: multinational pharmaceutical companies, challenges, pharmaceutical marketing

CHAPTER ONE

INTRODUCTION

1.1 Background of the Study

The pharmaceuticals industry is defined as all those who contribute to the discovery, creation and supply of pharmaceuticals products and services, including prescription medicines and vaccines. The stages of the value chain include discovery research, and basic research and design (R&D), through to clinical trials, and then the manufacturing of pharmaceuticals. It includes the originator medicine sector, the generic medicine sector and the medical biotechnology sector (PISG Australia, 2009).

The global pharmaceutical industry has proved a rapid growth over the years and emerged as one of the fastest growing industries in the world. However, world pharmaceutical production and consumption is still unevenly dispersed around the world with the developed countries as the leading producers and consumers of pharmaceuticals (U.S. Department of Commerce, 2016).

The pharmaceutical industry in Ethiopia consists of three segments namely, manufacturers, distributors and retailers who actively support the Ministry of Health and other key players in developing the health sector in Ethiopia. Companies in the three segments are either large multinational corporations (MNCs), subsidiaries, joint ventures or locally owned corporations. The MNCs manufacture their products locally or import directly from designated manufacturing sites and supply the drugs directly to distributors who in turn supply the retail outlets, hospitals, government and non-governmental institutions (FMHACA, 2012).

Multinational company is a company engages in international business when it conducts any business functions beyond its domestic borders Multinational entities have played a major role in international trade for several centuries. Multinational corporations engage in very useful and morally defensible activities in third world countries for which they frequently have received little credit. Significant among these activities are their extensions of opportunities for earning higher incomes as well as the consumption of improved quality goods and services to people in poorer regions of the world. Compared to local firms, multinational corporations provide developing countries with critical financial infrastructure and enormous resources for economic and social development (Nyaboke, 2012).

There are only eight giant multinational pharmaceutical companies currently operating in Ethiopia. These multinational drug manufacturing company are operating through local import agents which manage the import and distribution process of pharmaceutical products that cover a wide ranges of therapeutic area including infection, diabetes, cardio vascular and others. These companies are investing tremendous amount of capital on their human resources, research and development office and distribution channel in recent year. This has been predominantly driven by the attractive market prospects seen in Ethiopia including viable economic growth, untapped pharmaceutical market, the increase chronic disease burden and the increase health awareness of Ethiopia population (Solomon, 2014).

Even though these companies are investing heavily with hop of future growth they are not without challenge. These paper tries to identify the challenges of multinational pharmaceutical companies operating in Ethiopia.

1.1.1 Background of Multinational Pharmaceutical Companies operating in Ethiopia

The key players of multinational pharmaceutical companies operating in Ethiopia are Novartis, AstraZeneca, Sanofi, Bayer, Novonordisk, Pfizer, Roch and Jonson and Johnson whereas (GSK and Merck) left the market.

1. Pfizer

The world's largest pharmaceutical company is Pfizer, headquartered in Connecticut, USA. The research-based company has a varied portfolio that spans many therapy areas, including immunology, oncology, neurosciences and rare diseases. Despite modest revenue growth, Pfizer had a very successful year in 2017. The company received ten FDA approvals and many of its best-selling products have many years of patent protection remaining. There was particular growth with some of Pfizer's key products, including Ibrance (60% increase), Eliquis and Xeljanz.

2. Roch

Swiss pharmaceutical company, Roche, is the 2nd biggest pharmaceutical company in the world for 2018, and employs 93,734 people worldwide. The company develops innovative drugs and

devices in a number of key indications, such as oncology, immunology, infectious diseases and neuroscience. Annual growth from the pharmaceutical segment was 12.34% and revenue from the top 3 products contributed over 40% of Roche's total revenue in 2017 ($57.37 bn). Roche's best-selling drugs also happen to be the world's top three cancer drugs: Herceptin, Avastin and Rituxan. The company looks forward to six potential drug submissions in 2018, including Actemra for rheumatoid arthritis and systemic sclerosis, and Tecentriq for various types of cancer.

3. Sanofi

In the top 3 pharmaceutical companies in the world is French pharmaceutical company, Sanofi. The company saw 4.2% revenue growth within its pharmaceutical sector, which contributes 85.44% of the company's total revenue. 25% of this revenue came from Sanofi's three best selling drugs, Lantus, an insulin injection for diabetes, Lovenox, an anticoagulant to prevent blood clots, and Aubagio, the one-daily pill to treat a form of multiple sclerosis. Sanofi also featured on the Forbes Top Multinational Performers list in 2017.

4. Johnson & Johnson

4th on the top 10 pharmaceutical list is Johnson & Johnson, a company that was established over 130 years ago and has become a staple household name thanks to popular consumer goods like Aveeno, Neutrogena and Listerine. This year, the company had a series of successes including its acquisition of biopharmaceutical company Actelion, which is expected to transform J&J's pulmonary arterial hypertension portfolio. The pharmaceutical segment enjoyed a sales increase of 8.3% of which the primary drivers of growth included best-selling drugs Stelara, Darzalex, Imbruvica and Zytiga.

5. Bayer

Bayer is one of the top pharmaceutical companies and the famous 'Aspirin' is the product of this company. Leverkusen, German based, which has more than 5000 items in its portfolio, having a motto of "Science for a better Life" and core values including integrity, flexibility, efficiency and leadership, the company has adapted to the new technologies and machineries which is helping the company to grow at this pace. Recently, Bayer has tested drones in the crop sciences and also working on it to take full utilization.

6. Novo Nordisk

It is one of a Denmark company which involved in the manufacture marketing of pharmaceutical product and service and was created in 1989 through the merger of two Danish companies. It produce equipment and medication. The company has production facilities in seven countries and affiliates or offices in 75 countries.

7. Novartis

One of the leading pharmaceutical companies in Switzerland, Novartis comfortably makes the top 10 pharmaceutical list for 2018. The company focuses on a wide range of disease areas including oncology, immunology/dermatology, neuroscience and respiratory. Despite experiencing modest revenue growth of 1.35% at the end of 2017, pharmaceutical sales remain strong thanks to drugs such as oncology success Gleevec, multiple sclerosis treatment Gilenya and dermatology drug Cosentyx which saw a significant 82% increase in sales in 2017.

8. AstraZeneca

AstraZeneca is a global research-based biopharmaceutical company, which primarily focuses on discovery, development and commercialization of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. The company sells products under the brands Atacand, Crestor, Onglyza, Nexium, Entocort, Losec, Merrem/Meronem, Carbocaine, Citanest, Diprivan, Marcaine/Sensorcaine. AstraZeneca was founded on April 6, 1999 and is headquartered in London.

1.2. Statements of the Problem

The eight MNPC operating have a representative office in Ethiopia. These companies perform their activities through local import and distribution agents. Even though the MNPC are bringing significant level of input in certain therapeutic areas their input is small compared to their capacity and product portfolio. For Example, company that have more than 100 product in their product portfolio have about 20-30 products marketed in Ethiopia. Despite of this, companies are operating at a limited capacity their existence is based on present and future marketing opportunities that need to be identified.

The insisting matter for the current study is the continuous availability of quality medicines are really exposed and there is shortage of pharmaceutical drugs in many pharmaceutical product retailer.

According to evidence showed from MNPC are importing more than 50% of country's pharmaceutical products consumption and contributes as suppliers. The domestic producers are contributing only 15% for local market. (Ethiopia Federal Ministry of Health, 2015).

These MNPCs operating in the country have a various benefits including increase job opportunity with high salary payment, research funds for public and private hospitals, flow of donations and funds for low income population who need chronic disease therapy. Despite of this, some companies like MERCK and GSK, which were previously marketing medical product in Ethiopia, have left the market other companies SANOFI and NOVARTIES are also downsize employee due to significant challenges. This study is intended to address the major challenges that are facing the multinational pharmaceutical companies.

1.3 Research Questions

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

- What are the major challenges related to foreign exchange, government support for multinational pharmaceutical companies operating in Ethiopia?
- What are the challenges related to licensing and inspection for multinational pharmaceutical companies operating in Ethiopia?
- How product assessment and registration challenges multinational pharmaceutical companies operating in Ethiopia?
- What are the challenges related to custom control for multinational pharmaceutical companies operating in Ethiopia?
- To what extent generic competition and counterfeit product challenges multinational pharmaceutical companies operating in Ethiopia?

1.4 Objective of the Study

1.4.1 General Objective

The primary objective of this study is to assess the challenges of multinational pharmaceutical companies operating in Ethiopia.

1.4.2 Specific Objectives

- To assess the shortage of foreign exchange, government support for multinational pharmaceutical companies operating in Ethiopia.

- To identify the challenges related to licensing and inspection for multinational pharmaceutical companies operating in Ethiopia.

- To identify the challenges of product assessment and registration for multinational pharmaceutical companies operating in Ethiopia.

- To determine the generic competition and counterfeit product challenge for multinational pharmaceutical companies operating in Ethiopia.

- To determine the challenges related to custom control of pharmaceutical product of multinational pharmaceutical companies operating in Ethiopia.

1.5 Significance of the Study

This study is designed to address the major challenges facing multinational pharmaceutical companies operating in Ethiopia The result of the study will inform new MNPC and existing one to identify the major challenges in the MNPCs. The result will also be an input for policy makers and regulatory body for developing regulations and guidelines. The result can also be used as reference for other researchers interested to explore more in the pharmaceutical industry.

1.6 Scope of the Study

This study focuses on the challenge facing multinational pharmaceutical companies operating in Addis Ababa, Ethiopia. The scope of the study focuses on the eight multinational pharmaceutical companies operating in Ethiopia. From the ten giant MNPC registered eight of them (Novartis, AstraZeneca, Sanofi, Bayer, Novonordisk, Pfizer, Roch and Jonson and Johnson) are currently operating where as two of them (GSK and Merck) left the market. Due to time and other constraints, the study used limited variables to assess the challenge facing multinational pharmaceutical companies and limited on descriptive statistics techniques to analyze the data.

1.7 Organization of the Study

This study is 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, and scope of the study. Chapter two contains literature review. The methodology encompassing; study design, sampling 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

REVIEW OF RELATED LITERATURES

2.1. 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.

2.2. Theoretical Literature Review

2.2.1 General Overview of the Pharmaceutical Industry

The pharmaceutical industry can be defined as a combination of processes, organizations and operations involved in the development, design and manufacture of useful pharmaceutical drugs. 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 (Aitken, 2007).

2.2.2 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.

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 (International Federation of Pharmaceutical Manufacturers & Associations, 2017).

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 (Pharmaceutical Research and Manufacturers of America, 2012).

2.2.3 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 A, 2007).

2.2.3.1 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. 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 (Boru, 2015).

2.2.3.2 Government Regulation

Differences in regulatory approval requirements can lead to duplicative testing and clinical trial requirements, delays in product approval and higher costs to MNCs. Many regulatory agencies lack adequate training and resources to review submissions in a timely and consistent manner, creating enormous backlogs, approval uncertainty and market access delays. There may also be concerns related to the security and maintenance of confidential business information (CBI), such as clinical data that must be submitted for approval (U.S. Department of Commerce, 2016).

2.2.3.3 Product Registration

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).

2.2.3.4 Custom 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 (MSH, 2012). 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 (Durgavich, 2009; MSH, 2012). 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. Medicine expiry is a major challenge in global pharmaceutical supply chains due to the long route taken through a regional distribution center before arriving at the country for use (Privett and Kopezak, 2012).

2.2.3.5 Generic Competition

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).

Patent breaking generic competition would drive price down but a big challenge for the established big pharmaceutical companies. Because big pharmaceutical companies spend many

years and millions of dollars (approximately $802 million estimated by the congressional budget office CBO) from discovery to product launch. These companies are able to take advantage of their hard work and investments while their patents are in effect, but as soon as these patents expire the generic drug makers are able to undercut the big pharmaceutical profit margin within six month by producing lower cost and inmost case very effective alternatives (peter, 2007).

For the multinational pharmaceutical companies generic drugs are the big challenge. It requires huge investment and years by large pharmaceutical industries in order to launch a product. According to Congressional Budget Office (CBO) the estimated cost was $137 million dollars which has been increased to $446 million dollars in 1990. The benefits were taken by MNCs but by affecting their patent and then they were expired. The generic drug manufacturers are able to lower the pharmaceutical profit margin within 6 months by producing lower cost products and also by producing their alternatives (Mehmood, 2016).

2.2.3.6 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).

2.3 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).

2.4. Conceptual Framework

Jabareen (2009) explain Conceptual framework as a network or a plane of interlinked concepts that together provide a comprehensive understanding of a phenomenon or phenomena. Conceptual framework provides the link between the research title, the objectives, the study methodology and the literature review. The conceptual framework adopted for this study shows that shortage of foreign exchange, government regulation, product registration, custom control, generic competition and counterfeit product challenge multinational companies. The conceptual framework of the study was based on key concepts of the study and literature review. In line with the reasoning above, the conceptual framework below is proposed.

Fig 2.1: Conceptual framework Source: Researcher own construct based on the literature review (2018)

CHAPTER THREE

RESEARCH METHODOLOGY

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 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 that MNPC are facing.

3.3. Population and Sampling Techniques

The population for this study comprised of the eight 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 eight multinational pharmaceutical companies at Addis Ababa under Food, Medicine and Healthcare Administration and Control Authority of Ethiopia (EFMHACA). The list of the companies that were covered in this study was attached as Appendix A.

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 eight MNPC and there are only 63 employees are currently working, among the eight MNPC

operating in Ethiopia six of the company has 5-10 employees, one of the companies has 19 employee and one of the company has 2 employees. Thus in order to get a comprehensive data all exiting employees are 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 manager, marketing manager, fist line manager, regulatory assistant, and medical 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 sample respondent. The questionnaire has 5 rating scale ranging from 1=strongly disagree, 2 = disagree, 3 = undecided (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 two days for analysis. The questionnaires were collected by checking the completeness of the data. An interview questions were also conducted with country manager of the MNPC. Finally the activities were accomplished by appreciating the respondents.

3.6 Methods of 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 Statistical Package for Social Sciences (SPSS version 20) to analyze the collected data. Descriptive data was analyzed and presented by using frequency counts, percentage, mean and standard deviation. 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 of MNPC 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 sample respondents on their into account that numbers a five point Likert scale 1, 2, 3, 4 and 5 represents strongly disagree, disagree, undecided (neutral), agree and strongly agree respectively. The result of the study showed that the scores of disagree have been taken to represent a variable which had a mean score of less than 2.8, the score of undecided (neutral) have been taken to represent a variable which had a mean score of 2.9 to 3.2 and the score of agree have been taken to represent a variable which had a mean score of above 3.2. A standard deviation of >0.9 implies a significant difference on the impact of the variable among respondents (Scott, 1999).

3.7 Validity and Reliability Test

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. Sanofi and Bayer to ensure the validity of the questionnaire, to assess the relevance and alignment of the questionnaire with external interaction 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. Some of the changes were related to questionnaire's terminology and repeated items.

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 25 testing variables. From the analysis the Cronbach's alpha result found from the data collected from 59 respondents for 25 questions, the overall Cronbach's alpha score is 0.990. The coefficient 0.7 is an acceptable reliability coefficient; since score of 0.990 is above the standard threshold level the questionnaire were reliable (Dawson, 2007).

To achieve reliability of the questionnaires, the Cronbach's alpha for all questions (Items) under dimension of the study objectives was calculated. The values of the reliability analysis were listed on the following Table 3.1.

Table 3.1: Reliability Statistics

No	Dimensions	Cronbach's Alpha	N of Items
1	Foreign exchange, government support	.919	5
2	Licensing and inspection	.964	6
3	Product assessment and registration	.943	5
4	Custom Control	.942	3
5	Counterfeit product and generic competition	.968	6

Source: Own survey and SPSS output, (2018)

3.8. Ethical Considerations

A letter written from St. Mary's University was taken to the respective bodies to undertake a pre survey and to assure that the study is meant to be used for academic purpose. Confidentiality and anonymity of the respondents was ensured throughout the execution of the study for participants were not expected to disclose their personal information.

The purpose and the benefit of the study and the voluntary nature of participation were discussed with each study participants, and informed verbal consent was obtained. The right of the respondents to refuse to answer for few or all questions was respected.

CHAPTER FOUR

RESULTS AND DISCUSSIONS

4.1. 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 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 eight MNPC, which are Novartis, AstraZeneca, Sanofi, Bayer, Novonordisk, Pfizer, Roch and Jonson and Johnson.

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.

4.2. 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. It also include number of employee, number of approved pharmaceutical product and number of local agents representing the company.

Table 4.2.1 Background of the respondents

S.N	Socio-demographics Characteristics	Frequency	%
1	Gender		
	Male	43	73%
	Female	16	27%
	Total	59	100%
2	Occupational position		
	Country Manager	6	10%
	Marketing Manager	9	15%
	First line manager	5	8%
	Regulatory assistant	8	13%
	Medical Representative	31	52%
	Total	59	100%
3	Educational Qualification		
	Diploma	-	-
	Bachelor Degree	32	55%
	Masters	27	45%
4	Years in current position		
	1-3 years	10	17%
	4-10 years	23	39%
	Above 10 years	26	44%
	Total	59	100

Source; Own survey, 2018

The above table shows that male respondents were about 73% while females were 27%.This shows that the positions of pharmaceutical marketing of MNPC were occupied by male pharmacists. Various occupational positions were taken in to account in the questioner this include 6(10%) country manager, 9(15%) marketing manager, 5(8%) fist line manager, 8(13%) regulatory assistant, and 31(52%) medical representative. This could support the multinational

companies in using the available opportunities and minimizing the challenges in the pharmaceutical marketing since they have direct exposure to the activities of pharmaceutical marketing.

Regarding the educational status of the respondents, 55% of the respondents were Bachelor Degree holders while the rest 45% of the respondents were graduate of Masters. This implies that the academic level of the 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.

Among the eight MNPC operating in Ethiopia six of the company has 5-10 employees, one of the companies has 19 employee and one of the company has 2 employees. The data concerning the length of service of the respondents indicates that 10 (17%), 23 (39%), and 26 (44%) have served for 1-3 years, 4-10 years, and for more than 10 years respectively. This may reveal that all of them are familiar with the system in place and are able to give reliable information about the pharmaceutical marketing. We can also learn from the data that senior employees are considered to be assigned on managerial position which is likely to motivate other employees to stay with the organization.

Table 4.2.2 Number of approved pharmaceutical product and number of local agent representing the company.

Number of approved pharmaceutical product	Frequency	Percentage	Number of local agent representing the company	Frequency	Percentage
<10 product	-	-	<3 agents	1	12.5%
11-20product	-	-	4-10 agents	7	87.5%
>21 product	8	100%	>11 agent	-	-
Total number of company	8	100	total	8	100

Even though this companies have a wide range of medicinal product only some of product lines are registered in Ethiopia. This eight MNPC have registered greater than 21 product in their product line. One of the company (Bayer) has import and distribution office in the country. 4 of the companies are operating through 3 local importers, 3 of the companies has 2 local import agents.

4.3 Data Analysis

4.3.1 Quantitative data analysis

After collection, screening, and organizing of the data gathered through questionnaire filled by different employee, the researcher came across the following finding about the challenges of multinational pharmaceutical company operating in Ethiopia. The data collected are tabulated in which it shows the frequency/number of respondents and the percentage from the total 59 sample size.

4.3.1.1 Challenges related to foreign exchange, government support

The study sought to determine the first objective of the study which was to identify challenges related to foreign exchange, government support to MNPC operating in Ethiopia. The findings are presented in the table 4.3.1.1 below.

Table 4.3.1.1 Challenges related to foreign exchange, government support

NO	Questions	Frequency	Level of agreement					Total	Statistical Comparison	
			SD	D	N	A	SA		Mean	Std. Devi
1	Getting foreign exchange is delaying the importation process	Count	-	-	-	5	54	59	4.92	0.28
		%	-	-	-	8.5	91.5	100		
2	The government is not supporting you company by foreign currency	Count	1	12	11	19	16	59	3.63	1.14
		%	1.7	20.3	18.6	32.2	27.1	100		

3	Currency devaluation is creating difficultly during importation process	Count	-	-	12	28	19	59	4.12	0.72
		%	-	-	20.3	47.5	32.2	100		
4	The foreign exchange supplied is insufficient to cover the required order size	Count	-	4	13	35	7	59	3.76	0.75
		%	-	6.8	22	59.3	11.9	100		
5	Bureaucratic procedure and extended paper work in banking system is challenging your company.	Count	-	11	6	24	18	59	3.83	1.07
		%	-	18.6	10.2	40.7	30.5	100		
	Valid N							59		
	Aggregate mean and average standard deviation								4.05	0.79
Note: Values 1, 2, 3, 4 and 5 represent strongly disagree, disagree, neutral, agree and strongly agree, respectively.										
Where: Less than 2.8 = Disagree, 2.9-3.2 = Neutral, Above 3.2 = Agree										

Source: Own survey and SPSS output, (2018)

As shown in item 1 of Table 4.3.1.1, 91.5% of the respondents illustrated that the level of difficulty getting foreign exchange for importation is high which delaying the importation process. This shows that getting foreign currency is one of the challenges in pharmaceutical marketing. The respondent (70%) confirmed that, the level of getting foreign currency is very difficult since there is no enough foreign currency from the bank for importation to cover the required order size. 60 % of the respondents responded that the level of government support to private pharmaceutical marketing is low. On this issue of currency devaluation affect importation process 18 (30.5%) of respondent strongly agree there is currency devaluation, and 29 (49%) of employees answered agree. This shows currency devaluation is creating difficultly during importation process.

The above table shows that about 70.6% of the respondents revealed bureaucratic procedure and extended paper work in banking system, it takes a minimum of one month to a maximum of three month to get forex once documents are supplied to the bank.

The average mean and standard deviation of the total items of challenges related to foreign exchange, government support related information represents 4.05 and 0.79 respectively. this shows that foreign exchange constraint and extended paper work in bank is one of the major challenges of MNPC operating in Ethiopia.

4.3.1.2 Challenges related to Licensing and inspection

In assessing the challenges related to licensing and inspection of the pharmaceutical companies, various related issues were presented for the reflection of the respondents. Table 4.3.1.2 illustrates the reflection of the respondents regarding the challenges related to licensing and inspection.

Table 4.3.1.2 Challenges related to Licensing and inspection

NO	Questions	Frequency	Level of agreement					Total	Statistical Comparison	
			SD	D	N	A	SA		Mean	Std. Devi
1	Illegal competitors are involved in import and distribution to the medicine outlets.	Count	3	8	3	27	18	59	3.83	1.16
		%	5.1	13.6	5.1	45.8	30.5	100		
2	The government is lacking adequate regulatory measure/enforcement on violations of the licensing rules.	Count	-	2	9	27	21	59	4.13	0.79
		%	-	3.4	15.3	45.8	35.6	100		
3	Illegal competitors are creating unfair	Count	2	4	11	32	10	59	3.74	0.93

	competition in marketing process	%	3.4	6.8	18.6	54.2	16.9	100		
4	Lack of standards and specifications to be applied in assessing the quality, safety and efficacy of medicinal products	Count	-	24	28	5	2	59	2.74	0.75
		%	-	40.7	47.5	8.5	3.4	100		
5	The government doesn't take appropriate regulatory measure on violations of the inspection rules.	Count	6	2	8	26	17	59	3.77	1.2
		%	10.2	3.4	13.6	44.1	28.8	100		
6	The inspection procedure is lacking transparency and exposed to corruption.	Count	2	7	21	14	15	59	3.55	1.10
		%	3.4	11.9	35.6	23.7	25.4	100		
	Valid N							59		
	Aggregate mean and average standard deviation								3.62	0.98
Note: Values 1, 2, 3, 4 and 5 represent strongly disagree, disagree, neutral, agree and strongly agree, respectively.										
Where: Less than 2.8 = Disagree, 2.9-3.2 = Neutral, Above 3.2 = Agree										

Source: Own survey and SPSS output, (2018)

Among the 59 respondent 75% of them commented illegal competitors are involved in import and distribution to the medicine outlets, and this competitors creating unfair competition in marketing process. The respondent commented that there is standards and specifications to be applied in assessing the quality, safety and efficacy of medicinal products. 72% of the respondent indicated the government doesn't take appropriate regulatory measure on violations of the

inspection rules and 50% of the respondent responded that inspection procedure is lacking transparency and exposed to corruption. From the findings as indicated in table 4.3.1.2 above, the average mean and standard deviation of the total item of challenges related to licensing and inspection represents 3.62 and 0.98 respectively, which shows that challenges related to licensing and inspection is one of the major challenges of MNPC operating in Ethiopia.

4.3.1.3 Challenges related to product assessment and registration

The third objective of the study was to assess the challenges related to product assessment and registration process. The respondents were asked to indicate their levels of agreement. The findings are presented in the table 4.3.1.3 below.

Table 4.3.1.3 Challenges related to product assessment and registration

NO	Questions	Frequency	Level of agreement					Total	Statistical Comparison	
			SD	D	N	A	SA		Mean	Std. Devi
1	There is delay in Regulatory authority to ensure that a medicinal product has been adequately tested and evaluated for safety, efficacy and quality.	Count	-	-	3	38	18	59	4.25	0.54
		%	-	-	5.1	64.4	30.5	100		
2	Less track registration and Target time frame to assess (more than a year).	Count	-	-	5	27	27	59	4.37	0.64
		%	-	-	8.5	45.8	45.8	100		
3	Complex document is required during the registration process.	Count	2	5	6	18	28	59	4.10	1.10
		%	3.4	8.5	10.2	30.5	47.5	100		
4	It takes them a long	Count	5	2	17	21	14	59	3.62	1.14

	document review period in the regulatory firm	%	8.5	3.4	28.8	35.6	23.7	100		
5	The authority has inadequate IT support to implement registration process	Count	6	18	5	28	2	59	3.03	1.15
		%	10.2	30.5	8.5	47.5	3.4	100		
	Valid N							59		
	Aggregate mean and average standard deviation								3.87	0.91
Note: Values 1, 2, 3, 4 and 5 represent strongly disagree, disagree, neutral, agree and strongly agree, respectively.										
Where: Less than 2.8 = Disagree, 2.9-3.2 = Neutral, Above 3.2 = Agree										

Source: Own survey and SPSS output, (2018)

Table-4.3.1.3, shows the respondents attitude on the activities of product assessment and registration in FMHACA. The respondent view there is delay in Regulatory authority to ensure that a medicinal product has been adequately tested and evaluated for safety, efficacy and quality. 56(94%) of them agree on the issue. Most of the respondents, 54(91%) replied less track registration and target time frame to assess (more than a year).

The result show the primary contributing factor behind the delayed product registration is due to complex document is required during the registration process 46(78%) combined with long document review period, 30(50%) of the respondent said there is lack of IT support to implement registration process the remaining 6(10%), and 18(31%) respondents replied they strongly disagree and disagree on the issue respectively.

From the findings as indicated in table 4.3.1.3 above, the average mean and standard deviation of the total item of challenges related to licensing and inspection represents 3.87 and 0.91 respectively which shows that issues related to product assessment and registration is a challenge to MNPC operating in Ethiopia.

4.3.1.4 Challenges related to Custom Control

The study sought to determine the forth objective of the study which was to determine challenges related to Custom Control and process for pharmaceutical product. The respondents were asked to indicate the extent to which challenges confront in Custom. The findings are presented in the table 4.3.1.4 below.

Table 4.3.1.4 Challenges related to Custom Control

NO	Questions	Frequency	Level of agreement					Total	Statistical Comparison	
			SD	D	N	A	SA		Mean	Std. Devi
1	The custom clearance authority takes a long period of time to process the shipments	Count	10	3	4	28	14	59	3.55	1.36
		%	16.9	5.1	6.8	47.5	23.7	100		
2	Lack of suitable material handling facilities and equipment for proper pharmaceutical products in the custom port (like cold storage).	Count	-	7	15	28	9	59	3.66	0.88
		%	-	11.9	25.4	47.5	15.3	100		
3	Poor inter-agency cooperation between law enforcing bodies and weak custom control.	Count	2	5	6	18	28	59	4.10	1.10
		%	3.4	8.5	10.2	30.5	47.5	100		
	Valid N							59		
	Aggregate mean and average standard deviation								3.77	1.1
Note: Values 1, 2, 3, 4 and 5 represent strongly disagree, disagree, neutral, agree and strongly agree, respectively.										

Where: Less than 2.8 = Disagree, 2.9-3.2 = Neutral, Above 3.2 = Agree

Source: Own survey and SPSS output, (2018)

The respondents commented that there is import challenge at the port of entry once the product is shipped from site of production. Long clearance time at the customs port was the major challenge with 42 (71%). The respondent 37 (70%) believe that there is lack of suitable material handling facilities and equipment for proper pharmaceutical products in the custom port (like cold storage) and 46 (77.5%) poor inter-agency cooperation between law enforcing bodies and weak custom control.

From the findings as indicated in table 4.3.1.4 above, the average mean and standard deviation of the total item of challenges related to custom control represents 3.77 and 1.1 respectively which shows custom control is another challenge for MNPC operating Ethiopia.

4.3.1.5 Challenges related to Counterfeit Product and Generic Competition

Table 4.3.1.5 Challenges related to Counterfeit Product and Generic Competition

NO	Questions	Frequency	Level of agreement					Total	Statistical Comparison	
			SD	D	N	A	SA		Mean	Std. Devi
1	Counterfeit product price is low when compared to the brand medications.	Count	-	20	22	12	5	59	3.03	0.94
		%	-	33.9	37.3	20.3	8.5	100		
2	Counterfeit product affects good will of the brand medication which is produced by MNPC.	Count	3	13	28	11	4	59	3.00	0.94
		%	5.1	22	47.5	18.6	6.8	100		
3	The end cost of MNPC products is expensive when compared to generic	Count	5	4	7	23	20	59	3.83	1.21
		%	8.5	6.8	11.9	39	33.9	100		

	medications.									
4	Generic drug manufactures often able to maintain low price strategy.	Count	10	3	4	28	14	59	3.55	1.36
		%	16.9	5.1	6.8	47.5	23.7	100		
5	High position of generic drugs in the market place affect brand drug products.	Count	3	21	23	2	10	59	2.91	1.13
		%	5.1	35.6	39	3.4	16.9	100		
6	Medical representatives affecting the pharmaceutical marketing by making unethical promotional activities.	Count	5	8	11	29	6	59	3.38	1.11
		%	8.5	13.6	18.6	49.2	10.2	100		
	Valid N							59		
	Aggregate mean and average standard deviation								3.28	1.11
Note: Values 1, 2, 3, 4 and 5 represent strongly disagree, disagree, neutral, agree and strongly agree, respectively.										
Where: Less than 2.8 = Disagree, 2.9-3.2 = Neutral, Above 3.2 = Agree										

Source: Own survey and SPSS output, (2018)

From the above table 4.3.1.5, we can understand that about 33% of the respondents indicated that the level of availability of counterfeit medicines in Ethiopian market is low and counterfeit product doesn't the affects good will of the brand medication which is produced by MNPC. Therefore this shows that availability of counterfeit medicines in Ethiopian pharmaceutical market could not be a major challenge in pharmaceutical marketing of MNPC operating in Ethiopia.

72% of the respondents responded that the end cost of MNPC products is expensive when compared to generic medications and also Generic drug manufactures often able to maintain low price strategy. Hence, this shows that the competition among generic pharmaceutical importers is also another challenges of MNPC operating in Ethiopia. And of course unethical intensive promotional activities of competitor companies is also another major challenge as 59% of the respondents responded. As it can be seen from Table 4.3.1.5 above, the average mean and standard deviation of the total item of inventory control techniques represents 3.28 and 1.11 respectively, which shows that average mean is neutral and the standard deviation of all variables implies that there is high variation in the responses.

4.3.2 Qualitative data Analysis

This part of the study is about analysis of qualitative data. The questionnaire was designed in such way that the respondents will be able to freely give their opinion or idea.

4.3.2.1 Interview Questions for country managers

1. What challenges are you facing in the market (From every angle)?

2. What should be done to lessen the challenges and expand the market coverage and dominance of MNPC products?

4.3.2.2 Discussion

The key informants revealed that there is lack/Insufficient of foreign exchange for importation of pharmaceutical products. They explained that the long tedious process requested by the banks is tiresome and takes long time to get foreign exchange.

The key informants also revealed that process for pharmaceutical product registration is very tough. 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 i.e.to get market authorization for a product. So, getting market authorization is super challenge for MNPC operating in Ethiopia.

The informants believe that the over busy schedule and 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. There is no separate ware house for storage of pharmaceutical products, and it is treated as other

commodities which affects the quality of the products, which directly affects marketing the product. Due to inappropriate storage the label of the products was removed and so marketing of pharmaceuticals whose label was removed was impossible. There is no pharmacist there who can handle the products professionally and communicate with the importers and understand each other. There is inconsistency by custom officers during estimation of taxes on the products, which affects the pricing the products. This directly affects the marketing of the products. There is also poor inter-agency cooperation between law enforcing bodies and weak custom control.

According to key informants, currently the availability of counterfeit drugs in Ethiopian pharmaceutical market is minimal. So, it is not a major challenge for the Ethiopian pharmaceutical marketing.

CHAPTER FIVE

SUMMARY OF FINDINGS, CONCLUSSIONS AND RECOMENADTIONS

5.1. Introduction

The final part of this research paper provides summary of the findings of the study, conclusions and recommendations for the challenges 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.

5.2. Summary of Findings

The purpose of this study was to assess the challenges 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, these challenges are facing the multinational pharmaceutical companies operating in Ethiopia:

- Lack/Insufficient of foreign exchange for importation of pharmaceutical products
- Weak government support for pharmaceutical importation
- Currency devaluation during importation process
- Bureaucratic procedure and extended paper work in banks during importation
- Illegal competitors are involved in import and distribution to the medicine outlets.
- The government is lacking adequate regulatory measure/enforcement on violations of the licensing rules and the inspection procedure is lacking transparency and exposed to corruption.
- Illegal competitors are creating unfair competition in marketing process
- There is delay in Regulatory authority (FMHACA) to ensure that a medicinal product has been adequately tested and evaluated for safety, efficacy and quality.
- Complex document and more than a year is required during the registration process.
- The custom clearance authority takes a long period of time to process the shipments
- Lack of suitable material handling facilities and equipment for proper pharmaceutical products in the custom port (like cold storage).

- Poor inter-agency cooperation between law enforcing bodies and weak custom control.
- The end cost of MNPC products is expensive when compared to generic medications and the generic drug manufactures low price strategy affect the marketing activities of MNPC.

5.3. Conclusions

Finally, from this study it can be concluded that:

- Lack/insufficient of foreign exchange, weak government support, currency devaluation, bureaucratic procedure in banks are a challenge for MNPC.
- There are illegal competitors which involved in import and distribution to the medicine outlets and the government is lacking adequate regulatory measure/enforcement on violations which affect the marketing activities of MNPC.
- There is a product registration challenge which is primary contributed by factors such a long document review period once the relevant document and sample have been supplied the fastest document review period were greater than 1 year which made the process for pharmaceutical product registration is very tough. So, getting market authorization is super challenge for MNPC in Ethiopia.
- Generic drug producer with low price strategy especially from China and India affect the marketing activities of MNPC.
- The over busy schedule and 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. There is no separate ware house for storage of pharmaceutical products, and it is treated as other commodities which affects the quality of the products, which directly affects marketing the product. There is also poor inter-agency cooperation between law enforcing bodies and weak custom control.

5.4. 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 in MNPC operating in Ethiopia:

- Due to shortage of foreign currency there are serious shortage of critical medicine and big multinational pharmaceutical are closing there representative offices, (GSK and Merck left the market) and most of the companies are downsizing employees and are on the way to close. Therefore in order to have a continuous availability of medicinal product and equipment the NBE has to increase giving priority of foreign exchange for pharmaceutical importers.
- The difficulties /long process of getting market authorization for pharmaceutical products from FMHACA have to be minimized by removing irrelevant further requests for product registration and minimizing high bureaucratic approaches.
- The document required and the procedure has to be clearly listed to process the custom clearance. In custom the product must be stored in separate room with suitable material handling facilities and equipment and treat separately from other commodities to maintain the quality of the product.
- Inter-agency cooperation between law enforcing bodies and strong custom control in border I need to control illegal pharmaceutical product.
- FMHACA needs to strengthen frequent sample testing of imported products from shelves in order to find counterfeit product.

5.5. Suggestions for Further Research

There are a few studies that have been conducted in pharmaceutical sector in Ethiopia. The researcher recommend for future researchers to conduct study by including more variables focusing on profitability and market share of MNPCs operating in Ethiopia. The registration process and custom control when importing pharmaceutical product and the strategies need to be employed to attain competitive advantage especially in the pharmaceutical industry.

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APPENDIX A: QUESTIONNAIRE

ST. MARY'S UNIVERSITY

SCHOOL OF GRADUATE STUDIES

DEPARTMENT OF BUSINESS ADMINISTRATION

Questionnaire for Assessment on the challenges of multinational pharmaceutical companies operating in Ethiopia

Dear respondent,

First of all I would like to thank you for giving your precious time to fill this questionnaire. The Purpose of this questionnaire is to gather relevant information which will inform the **challenges of multinational pharmaceutical companies operating in Ethiopia**.

The information you provide will help me to better understand the situation of multinational pharmaceutical companies and will be used as an input for completing my MBA Thesis in St Mary's University.

Therefore, I kindly request you to complete the following questions to reflect your opinions as accurately as possible and give factual information to the best of your knowledge. The information that I will get from you will be treated confidentially and will not be disclosed for third party.

Thank You

DAWIT TEKLU

Part I Demographic information of respondents

1. Gender

Male ☐ **Female** ☐

2. Educational Level

Diploma ☐ **Bpharma/ BSC** ☐ **masters** ☐ **PHD** ☐

Other (please specify) _____

3. Occupational position

Country Manager ☐ **marketing manager** ☐ **Medical Representative** ☐

Other_____

4. Years of service on the current job ----------

5. Years of service in the organization ----------

6. Number of approved pharmaceutical product

<10 ☐ **11-15** ☐ **16-20** ☐ **>21** ☐

7. Number of employees

<4 ☐ **5-10** ☐ **11-20** ☐ **>21** ☐

8. Number of local agents representing your company

<3 ☐ **4-10** ☐ **>11** ☐

Part II. Basic Information

Statements below indicate your level of agreement or disagreement

Regarding this aspect of the study respondents were required from the statements below indicate your level of agreement or disagreement. There are no correct or wrong answers. Please use the scale indicated below.

Scale indicated below: 1=strongly disagree 2=Disagree 3=Neutral 4=Agree 5=Strongly Agree

1. Foreign exchange government support	**1**	**2**	**3**	**4**	**5**
1.1 Getting foreign exchange is delaying the importation process.					
1.2 The government is not supporting you company by foreign currency.					
1.3 Currency devaluation is creating difficultly during importation process.					
1.4 The foreign exchange supplied is insufficient to cover the required order size					
1.5 Bureaucratic procedure and extended paper work in banking system is challenging your company.					
2. Licensing and inspection					
2.1 Illegal competitors are involved in import and distribution to the medicine outlets.					
2.2 The government is lacking adequate regulatory measure/enforcement on violations of the licensing rules.					
2.3 Illegal competitors are creating unfair competition in marketing process					
2.4 Lack of standards and specifications to be applied in assessing the quality, safety and efficacy of medicinal products.					
2.5 The government doesn't take appropriate regulatory measure on violations of the inspection rules.					
2.6 The inspection procedure is lacking transparency and exposed to corruption.					
3. Product Assessment and Registration					
3.1 There is delay in Regulatory authority to ensure that a medicinal product					

has been adequately tested and evaluated for safety, efficacy and quality.					
3.2 Less track registration and Target time frame to assess (more than a year).					
3.3 Complex document is required during the registration process.					
3.4 It takes them a long document review period in the regulatory firm.					
3.5 The authority has inadequate IT support to implement registration process.					
4. Custom Control					
4.1 The custom clearance authority takes a long period of time to process the shipments.					
4.2 Lack of suitable material handling facilities and equipment for proper pharmaceutical products in the custom port (like cold storage).					
4.3 Poor inter-agency cooperation between law enforcing bodies and weak custom control.					
5. Counterfeit Product and Generic Competition					
5.1 Counterfeit product price is low when compared to the brand medications.					
5.2 Counterfeit product affects good will of the brand medication which is produced by MNPC.					
5.3 The end cost of MNPC products is expensive when compared to generic medications.					
5.4 Generic drug manufactures often able to maintain low price strategy.					
5.5 High position of generic drugs in the market place affect brand drug products.					
5.6 Medical representatives affecting the pharmaceutical marketing by making unethical promotional activities.					

If you have any of unclaimed idea please

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APPENDIX B: INTERVIEW QUESTIONS

Interview Questions for country managers

1. What challenges are you facing in the market (From every angle)?

2. What should be done to lessen the challenges and expand the market coverage and dominance of MNPC products?

APPENDIX C: LIST OF MULTINATIONAL PHARMACEUTICAL COMPANIES

Company	**Country of Origin**
1. Pfizer	USA
2. Norvatis	Switzerland
3. Sanofi Aventis	France
4. Roche	Switzerland
5. Novo Nordisk	Denmark
6. Astra Zeneca	UK
7. Bayer	Germany
8. Johnson & Johnson	USA

Source: The EFMHACA database, 2018