ST. MARY'S UNIVERSITY

SCHOOL OF GRADUATE STUDIES

ASSESMENT OF CHALLENGES AND OPPORTUNITIES FOR PRODUCING PHARMACEUTICALS IN ETHIOPIA

BY

WONDWOSEN KEREMENZ

MAY, 2015

ADDIS ABABA, ETHIOPIA

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DEDECATION

This work is dedicated to my father Keremenz Agonafir

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Wondwosen Keremenz

ACRONYMS

API	Active Pharmaceutical ingredient
AU	African Union
cGMP	current Good Manufacturing Practice
DHS	Demographic and Health Survey
EPHARM	Ethiopian Pharmaceuticals Manufacturing
ETB	Ethiopian Birr
FMoH	Federal Ministry of Health
FMoT	Federal Ministry of Trade
FMHACA	Food Medicines and Healthcare Administration and Control Authority
GDP	Gross Domestic Product
GIZ	The German Federal Enterprise for International Cooperation
GTP	Growth and Transformation Plan
HSDP	Health Sector Development Program
IMS	Information Management System
KII	Key Informant interview
MDG	Millennium Development Goals
PFSA	Pharmaceutical Fund and Supply Agency
PLC	Private Limited Company
NGO	Non-Governmental Organisation
R&D	Research and Development
SEAA	Sino Ethiop Associate Africa
SEATINI	Southern & Eastern African Trade, Information & Negotiations Institute
SPSS	Statistical Package for Social Science
SWOT	Strength Weakness Opportunity Threat
TRIPS	Trade Related aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
USD	United States Dollar
USP	United States Pharmacopoeia
WHO	World Health Organization

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ABSTRACT

Local pharmaceutical production in developing countries like Ethiopia is an interest of many investors and government. This interest is mainly related to the fact that Ethiopia is a large populous country in Africa and its economy is growing continuously. The currently existing local manufacturers in Ethiopia are few in number and contributing little to the overall economy. This makes Ethiopia to be dependent on imported pharmaceuticals and even all local manufacturers are highly dependent on imported raw materials. This assessment tried to understand the strengths, weaknesses, opportunities and threats of the pharmaceutical industry in Ethiopia by reviewing relevant literatures and gathering primary data from key respondents. The assessment came up with interesting findings and recommendations like local pharmaceutical industries need to work collaboratively and centralize their procurement of raw materials to enjoy the benefits of getting good price for bulk purchase. Local manufacturers are also encouraged to improve their packaging and work to change the public perception towards local products. The government protections for local manufacturers need to be exercised very carefully so as not to compromise quality which will eventually affect their competitiveness in the global market. International proprietary agreements will force local manufacturers to focus on invention of new products to treat diseases specifically prevalent in developing countries. As invention of new products is capital and time intensive, joint ventures and partnership with multinational companies is the way forward for local manufacturers in developing countries.

***Key words**: Ethiopia, Investment, Incentives, Pharmaceuticals, Production, SWOT, TRIPS*

CHAPTER ONE
INTRODUCTION

1.1 Background of the Study

Global Pharmaceutical industries contribute significantly for the overall economy of the world. As reported by IMS Health (2007), "The Global pharmaceutical sales estimated to be US $602 billion in 2005, a growth of seven per cent from the previous year (US $550 billion)".

The pharmaceutical industry in Ethiopia is in its early stage and the contribution of the local pharmaceutical industry to the overall Ethiopian economy is explained to be minimal by Mohammed (2008) as:

> *The pharmaceutical sub sector contribution to the overall economy is minimal (contribution to GDP, foreign exchange, employment). For long period, the pharmaceutical industry was monopolized by one government organization till the current government regime came to power with free market economy in 1991 which introduced private companies with aggregate investment close to 754 million birr ($76 Million). However, the sub sector is still highly underdeveloped & dominated by few manufactures and depends on imported products. (pp.4)*

Pharmaceutical production in Ethiopia focuses on secondary manufacturing of generic drugs. This involves combination of various active ingredients and processing of bulk medicines into dosage forms. According to the health indicators of the Federal Ministry of Health (2011), there are 10 local pharmaceutical industries plus one new industry (Julphur) which makes a total of 11 of which 9 are located in Addis Ababa (Appendix B). The oldest factory is Ethiopian Pharmaceuticals Manufacturer (EPHARM) which is 50 years old and the rest 10 industries are in the business only for the past 15-20 years. Six of them are engaged in producing general human pharmaceuticals, two in intravenous fluid production, one on empty gelatin capsule production, one in liquid pharmaceutical production and one

producing both human and veterinary products. These pharmaceuticals are not engaged in producing Active Pharmaceutical Ingredients (APIs) and are using imported APIs.

Pharmaceutical market growth correlates highly with global gross domestic product (GDP) growth, population growth, an aging population, and government spending. Growth in the pharmaceutical market will be driven by increased government spending and higher demand for medicines due to rising disease burden. Generic drugs will take the lead as they are more affordable than the branded ones.

According to Frost & Sullivan (2012), most of the pharmaceutical requirement of Ethiopia is fulfilled from import mainly from India and China. With the growing number of population of Ethiopia and the high disease burden, it is expected the demand for pharmaceuticals to increase tremendously.

For Ethiopia to be self-sufficient not only in food security but also in medicines, it has to figure out on the ways of developing a vibrant local pharmaceutical industry which can supply the local demand with quality and efficacious medicines. Local production can also contribute to the national GDP by replacing the poor quality products imported at high cost of the hard-earned foreign currency.

This study assessed the environmental foundation for Ethiopian Pharmaceuticals Industry and identifies internal strengths and weaknesses and external threats and opportunities.

1.2 Statement of the Problem

Producing pharmaceuticals locally is important as it will improve the country's economy through import substitution, employment opportunity and improved shelf life of the product by decreasing the long lead time it took during importation. Local production will also guarantee quality and decrease the risk of importing substandard drugs since quality can be ensured in three different stages: raw material testing, in process testing and finished product testing.

Local pharmaceutical manufacturers are seriously challenged by imports both from the Western and Asian countries. There is a general perception that western products are better quality and Asian products are cheaper compared to local products. Those manufacturers

producing in bulk are exporting products to African countries with low price taking advantage of economies of scale.

Ethiopian pharmaceutical market is highly dependent on imports as local manufacturing industries cover only a small portion of the requirement for domestic needs. According to Mohammed (2008), Drugs manufactured locally only cover about 15 percent of the national demand. The rest is filled through import.

Despite the growing need for pharmaceuticals, local pharmaceutical products contribution to the national requirement is very low. Moreover local pharmaceutical manufacturers are facing fierce competition from imported pharmaceuticals and they are not utilizing their full capacity. This study assessed the challenges faced by local pharmaceutical industries and identifies the opportunities of producing pharmaceuticals in Ethiopia.

1.3 Research Questions

This study tried to get answers for the following research questions:

- What are the opportunities and challenges in relation to technical expertise in different areas?
- What are the opportunities regarding major incentives provided by the government to attract investors?
- To what extent do local pharmaceutical manufacturers utilize their capacities?
- Do the local pharmaceutical manufacturers fulfill international and local quality standards?
- What are the challenges that Ethiopian Pharmaceutical manufacturers facing while exporting their products?

1.4 Research Objective

General objective: To assess the challenges faced by local pharmaceuticals and identify the opportunities of producing pharmaceuticals in Ethiopia.

Specific Objectives:

- Evaluate existing capability and challenges of producing pharmaceuticals in terms of availability of experienced and educated manpower

- Evaluate existing capability and challenges of producing pharmaceuticals in terms of availability of key raw materials
- Identify basic incentives offered by the government to attract investors to pharmaceuticals manufacturing
- Assess the strengths, weaknesses, opportunities and threats of Ethiopian pharmaceutical industries.
- Examine the status of Ethiopian pharmaceutical manufacturers in meeting local and international quality standards
- Understand the challenges faced by Ethiopian pharmaceutical manufacturers associated with export of products

1.5 Significance of the Study

The result of the study will inform potential investors and existing manufacturers to identify and then propose solutions to overcome the major challenges in the pharmaceutical industry and exploit the available opportunities. 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 by other researchers and students interested to explore more in the pharmaceutical industry.

1.6 Scope of the Study

The study is limited to existing local pharmaceutical manufacturers in Addis Ababa and did not cover medical device manufacturers. As the study methodology is descriptive, it did not provide answer to the why and how part of the pharmaceutical industry situation in Ethiopia.

The scope of this study is to identify the profile of existing Ethiopian pharmaceutical industries and assess their internal and external environment so as to recommend possible solutions to utilize opportunities and overcome their challenges.

1.7 Organization of the Study

The research is organized in five chapters. The first chapter deals with the study background, problem statement, research questions, research objective, significance and scope/limitations of the study. The second chapter contains the literature review.

The third chapter is research methodology: data sources, data collection method and data analysis method. Chapter four deals with results and the final chapter five contains summary, conclusions and recommendations. References and appendices are included at the end.

1.8 Operational Definitions

Active pharmaceutical Ingredients - (API): biologically active compound(s) in a drug formulation that imparts the desired therapeutic effect. (FMHACA, 2014)

Finished product - A finished dosage form that has undergone all stages of manufacture, including packaging in its final container and labeling. (FMHACA, 2014)

Generic drug - A drug that is produced and distributed after patent expiry; a generic must contain the same active ingredients as those in the original formulation. (Frost & Sullivan, 2012)

Good Manufacturing Practice -That part of quality assurance which ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization or product specification. (FMHACA, 2014)

Pharmaceutical product - Any material or product intended for human use presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control and this includes medicines, traditional medicine, medical device, cosmetics etc. (FMHACA, 2014)

Shelf Life -The time period during which a drug product and/or drug substance is expected to remain within the approved shelf life specification, provided that it is stored under the conditions defined on the container label. (FMHACA, 2014)

CHAPTER TWO
REVIEW OF LITERATURE REVIEW

2.1 Overview of Literature Review

Different literatures about the global and Ethiopian pharmaceutical industry are reviewed and summarized in this chapter. The literatures review will start by describing pharmaceutical industry environment followed by the global and developing countries pharmaceutical market growth and the associated opportunities for pharmaceutical industries. Then, it will deal with the situations of pharmaceutical industries in Ethiopia.

2.2 Environment of Pharmaceutical Industry

2.2.1 Internal Environment

Strengths/Advantages

According to the African Union (AU) (2007), local production has the advantage of saving foreign exchange, creating jobs which will then alleviate poverty, facilitating technology transfer, stimulating exports, readily availing cheaper locally produced raw materials and improve self sufficiency in drug supply.

Geographical advantage, presence of multiple joint ventures, certain degree of skilled labor, manageable regulatory framework and investment, personal safety, investment security along with a relatively strong local pharmaceutical manufacturers' association are some of the strengths of pharmaceutical manufacturers in Ethiopia identified by Biadgleng (2009).

Weaknesses/Challenges

Decreasing R&D output, increasing R&D time, rising R&D cost, price pressure, generic competition and biotechnology are identified as challenges of global pharmaceutical

production by Amara & Aljunid (2012). .Pharmaceutical industries in developing countries that mainly manufacture with less or no R&D activities are facing different challenges related to stewardship & regulatory system, the effect of Trade Related aspects of Intellectual Property Rights (TRIPS), level of investment, market size and competition according to Amara & Aljunid (2012).

Elbeshbishi (2007) explained the TRIPS Agreement as member countries have to grant patents for a minimum of 20 years, to any inventions of a pharmaceutical product or process that fulfils the established criteria of novelty, inventiveness and usefulness. As soon as the agreement comes into force in a member country, unauthorized copies of patented drugs are prohibited, and countries that break this rule will incur trade sanctions authorized by the World Trade Organization.

2.2.2 External Environment

Opportunities

Shaw (2011) described the opportunities of global pharmaceutical manufacturing using PESLE analysis. Concerning political and economic factors, the opportunities are explained as there is growing political focus and pressure on healthcare authorities across the world, governments will be looking for savings across the board. The global economic crisis still exists yet government reports indicate that expenditures on healthcare per capital continue to grow.

Regarding social factors, Shaw (2011) indicated the increasing aging population to offer a range of opportunities and threats to the pharmaceutical industry. The trick will be to capitalize on the opportunities. Other opportunities indentified include, the problem of the increasing obesity amongst the population and its associated health risks, demanding expectations of patients and home careers as they are becoming more informed and increased public activism through the harnessing of new social networking technologies.

Shaw (2011) also mentioned technological advancements will create new business prospects both in terms of new therapy systems and service provisions specially there will be growth opportunities in: new information and communications technologies, social

media for healthcare, customized treatments, direct to patient advertising and direct to patient communications.

As there is a growing environmental agenda and the key stake holders are now becoming more aware of the need for businesses to be more proactive in this field, Shaw (2011) advised Pharmaceutical companies to see how their business and marketing plans link in with the environmental issues and utilize the opportunity to incorporate it within their Corporate Social Responsibility programmes.

According to Sabar Institute of Management (2013), Ethiopia's economy is based on agriculture, which accounts for 46% of GDP and 85% of total employment, GDP growth has remained high, per capita income is among the lowest in the world and the five-year economic plan has achieved high single-digit growth rates through government-led infrastructure expansion and commercial agriculture development.

Sabar Institute of Management (2013) further explained the opportunities for pharmaceutical manufacturers to be a heavy burden of disease mainly attributed to communicable infectious diseases and nutritional deficiencies and encouraging improvements in the coverage and utilization of the health service over the periods of implementation of Health Sector Development Programme (HSDP).

Some of the opportunities of manufacturing in Ethiopia identified by Precise Insights (2013) include: a large, young, trainable, increasingly better educated, and low-cost labor force; location advantage as Addis Ababa is already the air cargo hub of Africa, within non-stop reach of all the major destinations with new high-speed road and rail corridors being built to connect Ethiopia to the Red Sea.

Threats

According to Shaw (2011), the reduction in consumer disposable income will have an impact on those countries using health insurance models particularly where part payment is required and these economic pressures are seeing an increased growth in strategic buying groups who are forcing down prices.

The threats of producing pharmaceuticals in Ethiopia are also described by Biadgleng to include gap between lists of compounds and other ingredients for tax exemptions compared with what they import; shortage or irregular supply of electricity; and, more recently, hard currency shortage that limits the ability to import raw materials.

According to Precious Insights (2013), manufacturing is under-developed in Ethiopia – even by African standards. Some of mutually reinforcing factors mentioned by Precious Insights that have conspired to prevent the emergence of a stronger manufacturing base in the country include: an industrial structure dominated by a small number of large state-owned firms, high administrative barriers to entry for small business, including burdensome and costly procedures, resulting in a very small base of established businesses; missing markets – both in terms of industrial inputs, most of which have to be imported, and in terms of downstream local markets, which reflects the under-developed industrial sector.

Concerning legal factors, Shawn (2011) indicated that there are many regulatory and legislative restrictions in pharmaceutical industry which is exacerbated by a growing culture of litigation in many countries and stretching the legislative boundaries of patient's demanding more rights in their healthcare programmes owing to the evolution of the internet.

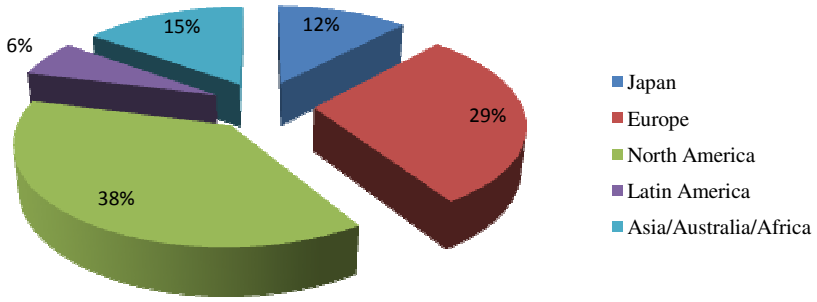
2.3 Global Pharmaceutical Industry

The pharmaceutical industry demonstrated high sales growth rate continuously according to Davidson & Greblov (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 seven and twelve per cent per year and forecasted this growth to continue between five and eight 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.

The Organization of Islamic Cooperation (OIC) (2011) described the global pharmaceutical market to be highly dominated by developed countries both in terms of production and consumption. According to the OIC report, the global market in 2010 is concentrated in North America (38%), Europe (29%) and Japan (12%) which together accounted for nearly 79% of global market. On the other hand, developing regions with a share of nearly 85% of world population, accounted for only 21% of global pharmaceutical consumption in 2010 (Figure 1). A breakdown of pharmaceutical market in developing world reveals that Asia, Australia and Africa represent nearly 15% whereas Latin America accounts for 6% of the global pharmaceutical market.

Figure 2.1 Regional Distribution of Global Pharmaceutical Market in 2010



Source: Organization of Islamic Cooperation 2011

As described by African Union (AU) (2007)

> Pharmaceutical production occurs at three levels, primary, secondary and tertiary. The primary level includes the manufacture of active pharmaceutical ingredients and intermediates from basic chemical and biological substances. Secondary production includes the production of finished dosage forms from raw materials and inactive ingredients. The tertiary level is limited to packaging and labeling of finished products or repackaging of bulk finished products. (pp.1)

2.4 Pharmaceutical Production in Developing Countries

While considering the situation of pharmaceutical market and production in Sub Saharan African (SSA) countries, their contribution is found to be minimal. The Organization of Islamic Cooperation (OIC) (2011) reported that in 2006, pharmaceutical market in SSA was valued at USD 3.8 billion, corresponding to 0.6 % of global market. According to the report, 37 out of 44 SSA countries have some pharmaceutical production and local manufacturer account for 25-30% of local demand. However, pharmaceutical production is highly concentrated among a few countries. In 2006, SSA produced US $ 1.07 billion worth of pharmaceuticals out of which more than 70% (i.e. USD 735 million) was contributed by South Africa alone.

According to the OIC (2011) report, pharmaceutical trade also remained highly concentrated in developed world which accounted for about 93 % of world exports and absorbed nearly 82% of pharmaceutical imports in 2010. As a group, developed countries are net exporters of pharmaceutical products. On the other hand, the share of developing countries in global pharmaceutical trade remained very low and they accounted for only 7% of exports and 18 % of pharmaceutical imports in 2010. As a group, developing countries are net importers of pharmaceutical products.

Even though local production seems to be advantageous because of reduced production costs (most significantly, labor costs), Elbeshbishi (2007) explained the challenge of African countries as it is not so simple in countries without industrial or environmental expertise, and it is also difficult for countries that have limited internal markets (those with small and/ or impoverished populations), which cannot benefit from the economies of scale larger countries and multinational companies enjoy.

Some of the challenges of producing pharmaceuticals in East & Southern African region are categorized by Southern & Eastern African Trade, Information & Negotiations Institute (SEATINI) (2013) in four major areas: finance, technology, infrastructure, and human resource. Financial bottlenecks include lack of working capital, lack of access to capital for recapitalization, higher financing costs and exorbitant utility tariffs. Technology constraints include high production costs related to very old plant & equipment, lack of technology, lack of integration with API suppliers & patents on medicines.

According to SEATINI (2013), infrastructure barriers include transaction & information costs including knowledge of local markets, cultures & conditions and unreliable supporting infrastructures such as electricity, water & transport. Shortage of skilled personnel & lack of training facilities for industrial pharmacy and government low accountability in proper use of aid & public funds, lack of incentives to attract & retain technical staff and weak regulation are some of human resource challenges.

Several literatures emphasize the importance of export in order to make local production more competitive. According to the AU (2007), export markets can only be achieved with innovation, competitive prices and quality. The Plan of Action advised Governments to take care of their protection in providing preference margins during public procurement through tenders as this may distort the market and local small companies may not even attempt to be competitive.

Small local drug manufacturers are facing several challenges as described by Seiter (2010)

> *Many smaller generics drug companies do business only on a national scale in their home country, sometimes even limited to a certain region within a country. Some of these companies operate with higher costs and lower quality standards than the global leaders. These companies typically buy their APIs from foreign sources and may find assessing the quality of the APIs difficult. Quality problems can also arise from poor packaging and use of insufficiently controlled excipients (inactive ingredients). Cost disadvantages for smaller national manufacturers can be attributed to limited volumes, insufficient purchasing power to secure good prices from suppliers of raw materials and APIs, bureaucratic hurdles, high taxes on imported equipment and raw materials, corruption, lack of access to financing, and other reasons related to the general business environment or specific parameters relevant for the pharmaceutical industry. (pp.21)*

Seiter also indicated the future of small local producers as targets for acquisitions and partnerships with international players because of their local market knowledge and eventually many of these companies can be expected to become parts of larger, regionally or globally operating groups.

A series of case studies conducted by UNCTAD (2011) indicate that although there is no extensive capacity, the pharmaceutical industries in less developed countries are growing and expanding their production activities by focusing in niche products and markets.

The studies mentioned an Ethiopian firm producing hard gelatin capsules and another Ugandan firm focused exclusively producing drugs for human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) and malaria as good examples.

The UNCTAD series of case studies further identified four advantages of local production in addition to their contributions to a country's industrial development, including the creation of jobs in highly relevant areas of technology. These four advantages are their contribution in ensuring lower prices of drugs and greater affordability through increasing price-based competition, filling gap for developing country economic need, produces new products that meet both local and international needs and finally through utilizing existing efficient and widespread networks and pharmaceutical supply chain, local production can enhance access by developing country populations.

The necessary care need to be undertaken while supporting local production. As clearly put by Bate (2008) supporting local production – without strengthening regulation and enforcement to ensure quality products – can have severe consequences for public health. According to Bate Local production can promote development – but only when the market prescribes it.

Producing pharmaceuticals is described by Kaplan & Laing (2005) to be a complex process that requires a reliable, high quality supply of raw materials, technical expertise and a stable supply of electricity, gas and other utilities, plus sufficient human resource capacity with scientists and expertise in pharmaceutical process and regulation. Pharmaceutical plants are capital intensive and take many years to develop and tend to be located in countries with good infrastructure, reliable utilities and access to technical expertise.

According to Kaplan & Laing (2005), there already appears to be enough capacity to produce all needed active ingredients as well as to finish bulk formulations sourced from global suppliers and increases in production can be accomplished within the present capacity of the global industry. Kaplan & Lang described the vast majority of the

manufacturing cost in the primary manufacture of active ingredients limits the opportunity for smaller local manufacturers to save costs and the fact that a developing country with manufacturing facilities is able to finish off bulk active ingredients sourced from developed or other countries at high costs may have no impact whatever on patient access to needed medicines.

Three main African health R&D challenges are described by WHO (2009) to be significant knowledge gap for diseases disproportionally affecting Africa, low degree of collaboration among African researchers and insufficient investment and ownership of R&D in and for Africa. WHO identified promising trends to help overcome these challenges to be: alignment of African research and traditional knowledge with local health priorities, local capacity in research, clinical trials, and manufacturer's willingness to collaborate, and increasing consensus around the need to boost R&D spending by governments.

According to East African Community (2011), pharmaceutical manufacturers operating from within the East Africa region generally produce at a cost disadvantage to larger generic product manufacturers internationally due to a variety of reasons including scale, expensive asset bases coupled with older technology, higher financing costs plus a lack of integration with active pharmaceutical ingredients suppliers. Other challenges identified by East African Community include shortages of skilled professional personnel and unreliable supporting infrastructure such as electricity, water and transport. On the other hand, East African Community further described the advantages of local pharmaceutical manufacture to be its benefits for the local economy such as savings on foreign exchange through import substitution, employment creation, the development of exports and increasing the access to essential medicines.

2.5 Pharmaceutical Industry in Ethiopia

Regarding the pharmaceutical industry in Ethiopia, Frost & Sullivan (2012) identified the market drivers to be: 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

According to Ethiopia FMoH (2014), Ethiopia registered an average of 8.1% growth in GDP between 2002 – 2012 and this lead to increased growth of healthcare coverage and improved access to medication.

The national health expenditure increased substantially from Birr 11.1 billion (USD 1.2 billion) nominal & USD 16.09 per capita in 2007/08 to over Birr 26.5 billion (USD 1.6 billion) nominal & USD 20.77 per capita in 2010/11, FMoH (2014).

Frost & 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 Frost & Sullivan (2012) Ethiopia is classified as the most populous country in sub-Saharan Africa and has an estimated population size greater than 84.0 million. Ethiopia contributes 1.2 per cent of the world's population. With an annual growth rate of 3.2 per cent, Ethiopia's population forecast for 2050 is estimated at 173.0 million. The increase in population size results in an increase in the number of individuals requiring health care thus increasing the demand for various pharmacological agents.

The health care coverage in Ethiopia is growing according to the FMoH (2010) indicating the number of hospitals increased from 126 to 195, number of health centers increased from 519 to 2822, number of health posts increased from 2899 to 14,416 and number of health extension workers increased from 9,900 to 33,819 between 2005 & 2010.

According to Frost & Sullivan (2012), most of the population in Africa (90 %) relied on the usage of traditional medicine to improve health conditions in past years. But recently the demand for modern medicines is increasing because of improved access and education around health care, increase in diagnostic tools, improved rural healthcare

access, and the growth of various pharmaceutical drugs for the treatment of various illness including infectious diseases, respiratory, and cardiovascular diseases.

Frost & Sullivan (2012) also mentioned market restraints as: low disposable income, weak regulations in the pharmaceutical industry, poor labor skills and slow adaption of new technologies, limited number of trained professionals in the medical field, decreased capacity of local manufacturers, and high costs of importing raw materials. In spite of the recently improved pharmaceuticals regulations, Frost & Sullivan indicated that there is a high number of counterfeit drugs circulating within the market which affects the share of genuine participants in the total pharmaceutical industry there by restraining its growth. There are efforts by the United States Pharmacopeial Convention together with the Ethiopian's Food Medicine and Health Care Administration and Control Authority (FMHACA) to reduce the burden of counterfeit drugs on the industry through conducting post-market surveillance.

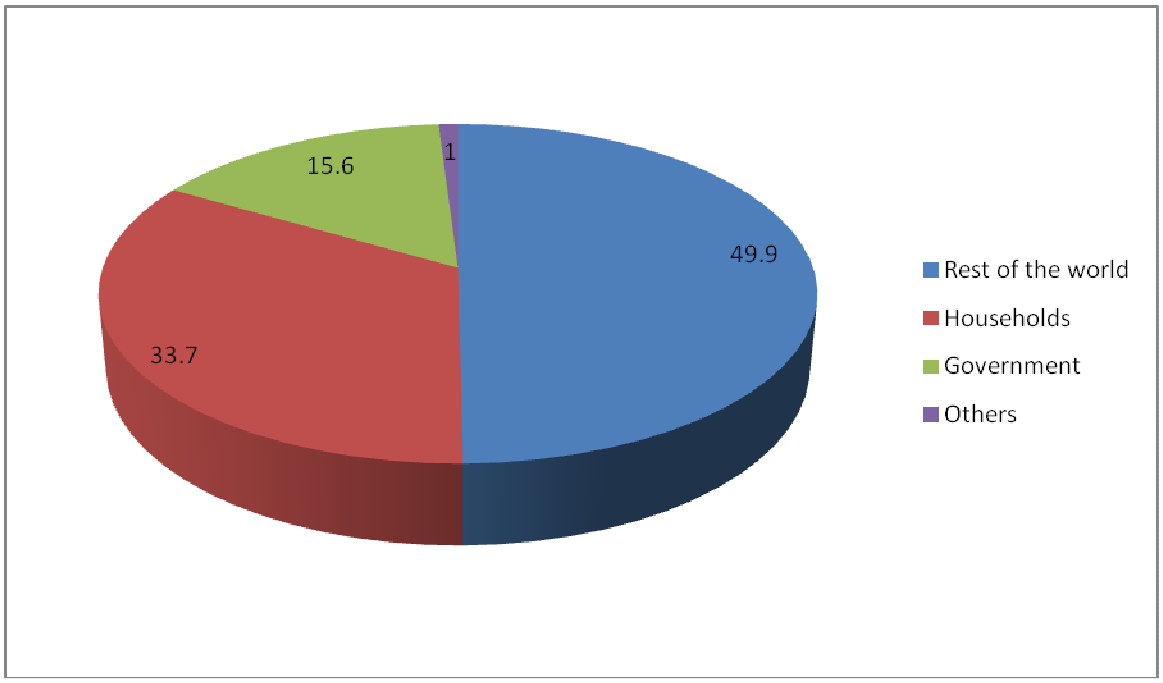
The Ethiopian government expenditure for health is indicated by Federal Ministry of Health (FMoH) and WHO (2003) as, 'Total government health budget in 2001/ 2002 G.C was 1053.2 million ETB (USD 122.5 million) and of which 549.6 million ETB (USD 63.9 million) was recurrent budget. The per capita government recurrent health budget was 8.2 ETB (USD 0.95)".

According to FMoH and WHO (2003) report, the total Ethiopian government drug budget in 2001/02 G.C. was about 104 million ETB which is approximately 19% of the recurrent government health budget and represents a per capita drug budget of 1.6 ETB. This per capita drug budget is very low as compared with the target set in HSDP I (USD 1.25) and WHO's recommendation of USD 1.00.

The major sources of finance for Ethiopian health care are indicated by FMoH (2010) to be government, households, and the rest of the world and their contribution has shown substantially increase in the past years. According to FMoH, The rest of the world (donors and international NGOs) contributed the lion's share – 50 percent of spending on health in Ethiopia in 2010/11, up from 40 percent in 2007/08, households represent the second

largest financing source, accounting for about 34 percent and government accounted for close to 16 percent. All other sources contributed less than 1 percent.

Figure 1.2: Health care financing sources in Ethiopia



Source: Federal Ministry of Health 2010

The Ethiopian market for pharmaceuticals is estimated by Groot (2012) to be 200 million USD of which 85% and all raw materials for local production is imported. Groot also indicated imported finished products from India and China are cheaper than locally produced medication since they are far ahead of Ethiopia in know-how, production capacity, quality, efficiency, logistics, marketing and sales. Some of the challenges in producing pharmaceuticals in Ethiopia mentioned by Groot include low tariffs or duties on import of end products, lack of or long waiting list for foreign currency needed for importation of raw material.

Groot (2012) also mentioned the advantages of local pharmaceutical production in Ethiopia is associated with the following factors: 80 million inhabitants, 100+ million by 2015, largest cattle population in Africa, East African trade zone, very low labor costs/ relatively well educated workforce, ongoing privatization of pharmaceutical industry, equal treatment of foreigners and substantial investments in infrastructure & utilities.

The government of Ethiopia expressed its commitment to strengthen local pharmaceutical industries in its Growth and Transformation Plan (GTP). The GTP (2010) described its objective in the pharmaceutical industry as "Enhance the capacity of existing and newly established pharmaceutical industries to substitute imported drugs and generate foreign currency earning by exporting the pharmaceutical products". The GTP identified three indicators and put targets for each. Accordingly, it plans to increase capacity utilization from 30% to 100%, domestically produced market share of pharmaceutical and medical product from 15% to 50% and income gained from pharmaceutical export trade from 1million USD to 20 million USD by 2015.

2.6 Summary

The literatures reviewed indicated that both global and local pharmaceutical market is increasing due to several factors including population and economic growth. It is also evident that Ethiopian pharmaceutical market is dependent on import and the contribution of local pharmaceutical industries to the country's economy is very low.

Government protection to local manufacturers needs to be undertaken cautiously as it may result in non competitiveness and poor quality. Strong local regulatory system together with ongoing technical support is essential to ensure quality of locally produced pharmaceuticals.

According to the above literatures, local pharmaceutical production in Ethiopia has an advantage of geographical location, presence of multiple joint ventures, manageable regulatory framework and favorable government policy. However local production also faces several challenges including cost disadvantage because they are usually small in size, insufficient raw material purchasing power and shortage of foreign currency for importing production inputs.

CHAPTER THREE
RESEARCH METHODOLOGY

3.1 Research Design

The study used descriptive method with a combination of quantitative and qualitative study technique. The methods of data collection were semi structured questionnaire and literature review which allows understanding the existing challenges and opportunities of producing pharmaceuticals in Ethiopia. Key Informant interview (KII) also allows study population to explain their challenges and opportunities without being bound by existing response choices or categories and encourage participants to talk at length about the topics. Descriptive approach is selected since it is the best method of collecting information and describing the pharmaceutical industry situation in Ethiopia as it exists.

3.2 Population and Sampling Techniques

The study was conducted in all pharmaceutical manufacturers located in Addis Ababa (9). The list of existing pharmaceutical manufacturers is summarized in Appendix B.

The study population was purposefully selected pharmaceutical industry professionals in Addis Ababa. The professionals included were from production, quality control, human resource, finance, marketing and R&D departments. From the total workers of 1545, 1198 were laborers and clerks and 347 were professionals (Appendix C). The 347 professionals were taken as sampling frame for this study and using Kregcie & Morgan (1970) sampling table, the sample size is determined to be 184. Proportional stratified random sampling technique is employed to ensure representation from different functional departments which includes production, quality control, engineering, finance, human resource, marketing and R&D. The key personnel from the pharmaceutical companies were used to gather as sufficient information as possible to understand and determine the challenges and opportunities of manufacturing pharmaceuticals in Ethiopia. In addition to the manufacturers key personnel, data's were also collected from the government regulatory authority, investment authority and ministry of trade.

3.3 Types of Data and Tools of Data Collection

The sources of data are both primary and secondary. The study used desk review of secondary documents, questionnaire and in depth interview of key informants to understand and determine the challenges and opportunities of manufacturing pharmaceuticals in Ethiopia. The documents reviewed were international and national literatures and guidelines about global and national pharmaceutical industries. The key informants were the general/plant manager, production manager or quality control manager of local pharmaceutical manufacturers.

The data collection methods were desk review for secondary data and semi structured questionnaire and interview for the primary data. The questionnaire was pre tested with three professionals working in pharmaceutical factories and as a result, minor changes in word selection and instructions were made to the questionnaire.

3.4 Procedures of Data Collection

The study addressed all existing local pharmaceutical manufacturers in Addis Ababa (9 in number). The respondents were selected using stratified random sampling method to identify the professionals working in production, quality control, engineering, finance, human resource, marketing and R&D departments. The questionnaire was distributed to all respondents and in addition 1 key informant was interviewed from each manufacturer. In addition to the manufacturers, data's were also collected from the government regulatory authority, investment authority and ministry of trade; the respondents were key personnel from public relations department.

3.5 Methods of Data Analysis

For this study, maximum effort was undertaken to maintain the quality of data; among others standardizing and pretesting of the questionnaire, and making the questions manageable and clean/understandable.

The analysis follows the procedure for qualitative thematic analysis, it begins by reading each transcript line by line to identify ideas, and attach codes and categories 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.

Statistical Package for Social Science (SPSS) software was employed to analyze and present the data's. The descriptive statistical results were presented by tables, frequency distributions and percentages to give a condensed picture of the data.

3.6. Ethical Considerations

The study did not involve any experiment on human population subjects. Procedures followed during the study were in line with the ethical standard. 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. The interview was conducted in a way that it will not compromise their privacy and confidentiality of information.

CHAPTER FOUR
RESULTS AND DISCUSSION

Ethiopian pharmaceutical manufacturers are challenged by competition from foreign countries and are highly dependent on imported raw materials. This study aims to assess the Ethiopian pharmaceutical industry situation and identify internal strengths and weaknesses and external opportunities and challenges. The study tried to address major questions like: whether the manufacturers are utilizing their full capacity, whether they have enough expertise, what government incentives are available, whether the manufacturers meet local and/or international quality standards and their challenges associated with export. The study used descriptive approach using questionnaire, in depth interview of key informants and literature review.

After developing and pretesting the questionnaire, key informants were identified, questionnaires distributed, filled questionnaires collected and in depth interview conducted. Out of a total of 184 questionnaires distributed, 173 were filled and collected (94% response rate) and 12 KIs were selected and interviewed face to face. The respondents were from local pharmaceutical industries, government and non government organizations which are Asmi Industry PLC, Cadila Pharmaceuticals (Ethiopia) PLC, East African Pharmaceuticals PLC, Ethiopian Pharmaceuticals Manufacturing PLC, Fawes Pharmaceuticals PLC, Food Beverages and Pharmaceuticals Industry Development Institute under the Federal Ministry of Trade, Food Medicines and Healthcare Administration & Control Authority (FMHACA), Julphur Pharmaceuticals PLC, Medsol Pharmaceuticals PLC, Pharmacure PLC, Sino-Ethiop Associate Africa PLC (SEAA) and United States Pharmacopoeia (USP)/Promoting Quality of Medicines. The respondents from government and non government organizations were three KIs for in depth interview.

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 Results

The results are presented under qualitative and quantitative sections. The quantitative section presented data's about annual revenue, current capacity utilization and market share of local pharmaceutical industries. The qualitative section of the result deal with availability of expertise, export experience, source of raw materials, status of quality standards, registration requirements/steps, pharmaceutical industry environment analysis and government incentives.

4.1.1 Quantitative Results

The profile of existing pharmaceutical industries indicating their annual revenue, installed capacity, currently utilized capacity and their public and private sector market share is depicted in the following table and chart:

Table 4.1: Profile of Ethiopian Pharmaceutical Industries

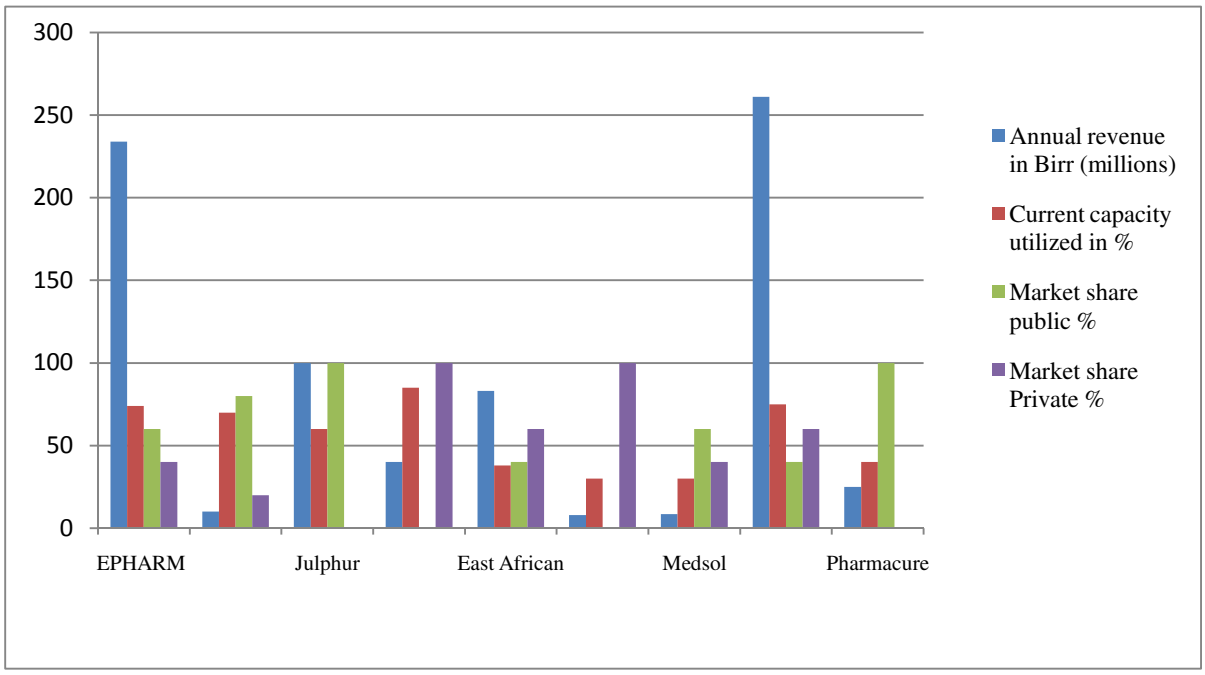
Pharmaceutical Factory	**Annual Revenue (ETB)**	**Installed Capacity/Year**	**Utilized Capacity**	**Market Share**	
				Public	**Private**
Ethiopian Pharmaceuticals Manufacturing (EPHARM)	234 million	Tablet 600 million Capsules 350 million Syrup 380,000 liter Ointment 80,000Kg Vials 11 million Intra Venous fluid 1.3 million liter Ampoules 9 million Oral powder 140,000 Kg	74%	60%	40%
Asmi Industries PLC	10.4million	100,000 first aid kits 4 million bandages 2,000 liter antiseptics	70%	80%	20%
Julphur pharmaceuticals PLC	100 million	Tablet 500 million Capsule 90 million Liquid 1 million liter	60%	100	0
Sino Ethiop Associate Africa PLC	40 million	Empty capsules 2 billion	85%	0	100
East African Pharmaceuticals PLC	83 million	Tablets 283 million Capsules 94 million Veterinary boli 47 million Veterinary sachets 12 million	38%	40%	60%
Fawes Pharmaceuticals PLC	8 million	1.2 million liter	30%	0	100
Medsol pharmaceuticals PLC	8.5 million	Syrup 1000 liter/day	30%	60%	40%
Cadila Pharmaceuticals (Ethiopia) PLC	261 million	Tablets 390 mill Capsules 264 million Liquid 14.4 million liters	75%	40%	60%
Pharmacure PLC	25 million	Intra venous fluids 5 million liters	40%	100%	0

Source: Own survey, March, 2015

The above table indicates that the revenues of local pharmaceutical manufacturers are minimal considering the huge market available in the country.

Ethiopia is highly dependent on imported pharmaceuticals and if the local manufacturers strengthen their capacity, there is high opportunity of import substitution and growth. Only three of the factories are generating annual revenue of 100 million and above. This can be achieved through fully utilizing their capacity and expansion depending on demand. Their market share is fairly distributed between public and private sectors, however there are few factories which are fully dependent on either the public or private sector and this can be an opportunity for them to explore both sectors.

Figure 0-1 Figure 4.1: Annual revenues, capacity utilization and market share



Source: Own survey, March, 2015

For better understanding of the result, the data were entered in to SPSS and by running descriptive analysis, the following descriptive statistics table is generated:

Table 4.2: Descriptive Statistics of annual revenue, capacity utilization and market share

		Annual Revenue in Birr (millions)	Capacity utilized in %	Market share public %	Market share private %
N	Valid	9	9	9	9
	Missing	1	1	1	1
Mean		85.50	55.78	53.33	46.67
Std. Deviation		97.746	21.417	37.417	37.417
Minimum		8	30	0	0
Maximum		261	85	100	100
Sum		770	502	480	420

Source: Own survey, March 2015

From the descriptive statistics table, the annual revenue of the studied pharmaceutical industries ranges from 8 to 261 million with an average revenue of 85.5 million Birr. It also showed the local industries are utilizing from 30% to 85 % of their installed capacity with an average capacity utilization of 56%. The reasons mentioned for under utilization of their capacity include: irregularity of raw material supply as they are fully dependent in imported inputs, low focus for commercial market and promotion.

Regarding the local pharmaceutical industries market share to public versus private sectors, there is a wide variation in that some are solely serving the private sector and few serving exclusively the public sector, on average the industries have 47% private and 53% public sector market share.

4.1.2 Qualitative Results

The Qualitative results are broadly categorized in the following thematic areas: availability of expertise, export experience, source of raw materials, status of quality standards, registration requirements/steps, Pharmaceutical industry situation analysis – SWOT (strengths, weaknesses, opportunities and challenges) and government incentives.

4.1.2.1 Availability of Expertise

The respondents indicate that there are no adequate experienced personnel in the areas of production, quality control and engineering. Those experienced are not well incentivized and are migrating to other sectors.

In addition to the need to have technical expertise mentioned above, some respondents also stressed the need for pharmaceutical industry management experience to comprehensively manage the industry

4.1.2.2 Export Experience

Almost all the industries are serving the local market only with no experience of export except SEAA (Sino Ethiop Associate Africa) which is specialized in producing empty hard gelatin capsules (an input for other pharmaceutical industries) is exporting to Sub Saharan African and Middle East Asian countries. This indicates that Ethiopian pharmaceutical manufacturers need to work on increasing their capacity so as to benefit from exporting to neighboring countries.

4.1.2.3 Quality Standards and Source of Raw Materials

According to the respondents, there is regulatory body mandated to inspect and certify the industries for cGMP. The regulatory authority is just starting to develop the guidelines and some of the old factories need extensive and costly renovation in order to fulfill both international and cGMP certification. The new entrants have the advantage of easily complying with the regulation as they are designed and constructed as per the requirement.

All the local industries are almost fully dependent on imported raw and packaging materials which will increase their finished product cost and become non competitive since they are buying their inputs in small quantities. This heavy relying on imported inputs also makes the industries to underutilize their capacity because of irregular supply.

Local products generally are perceived by the public to be poor quality and pharmaceuticals are no exception. In reality, because of stringent quality control at different stages (raw materials, in process and finished products) and citizenship commitment of the professionals, locally produced pharmaceuticals have relatively good quality. On the other hand, FMHACA test samples of imported products only during registration and not on consignment bases; this will give a chance for importation of poor quality products.

All the respondents agree price of pharmaceuticals is not regulated but there is a common margin trend regulated by the market which is 10 - 15% for importers/wholesalers and 25% for retail pharmacies.

Through a continuous and coordinated effort by FMHACA and partners (GIZ & USP), two industries are already qualified for PIC/S (European GMP standard) and another two are on track to be certified soon. There are also initiatives from some manufacturers working to comply for international standards like ISO and some are already qualified. These initiatives will help the local industries to comply with international quality standards which are critical and mandatory to export their products and generate more revenue and foreign currency for the country.

4.1.2.4 Registration Requirements

There are two type of registration required from regulatory authority FMHACA: factory registration and product registration. FMHACA recently developed GMP guideline and according to the guideline both local and foreign pharmaceutical manufacturers are required to fulfill the minimum standards stipulated in the guideline in the areas of quality management, sanitation & hygiene, premises, materials, personnel, production, quality control, validation, product recall and documentation. The factory GMP inspection and certification is conducted by FMHACA and so far one manufacturer is locally GMP certified; the rest are inspected and required to fulfill minimum requirements and most have got market authorization license from FMHACA.

According to the FMHACA registration guideline, the product registration requires submission of dossier including stability data and sample testing. The guideline provides recommendation on the quality, safety and efficacy information for active pharmaceutical ingredient (API) and finished pharmaceutical product that should be submitted to the Authority to support product dossiers for registration of medicines in Ethiopia. After a product is registered, its registration is valid for four years only. It is, therefore, mandatory for manufacturers to apply for re-registration by submitting the required information before the due date. Some of the manufacturers are working to register their products and some are already registered few products.

Fulfilling local registration requirement is the minimum expected of local manufacturers to stay in the market and manufacturers are encouraged to work hard and in collaboration to meet quality standards and ensure the public is provided with effective pharmaceuticals.

4.1.2.5 Internal Environment Analysis

The respondents answer regarding strengths and weaknesses of pharmaceutical industry is summarized in the below table:

Table 4.3: Strengths and weaknesses of Ethiopian pharmaceutical industries

Factors	Strengths	Weaknesses
Human resource	• Cheap labor • Bioequivalence center • Industry university linkage	• Tailored training not available • Low exposure to the industry • High turnover
Finance/ Accounting	• Tri partite system for bank loan • Joint venture	• Credit based sales • Weak financial resources • Insufficient investment level
Marketing	• Established & trusted brand names	• Low focus and budget for marketing • Limited experience
R&D	• Local herbs formulation with science & technology	• No R&D activity for new pharmaceuticals
Production	• Can avail freshly made products with relatively longer shelf life • Availability of cheap labor	• Low capacity, Less volume • Fully rely on imported inputs • Inability to use the full production capacity • Poor packaging • Duplication, most industries are producing similar type of products
Quality Control	• Stringent • Accredited FMHACA lab • No incidence of poor quality • Citizenship responsibility of professionals	• Lab equipment maintenance and calibration • Non conformity to cGMP
Engineering	• Technology transfer and expert assistance from joint venture	• Shortage of spare parts • Lack of experience on equipment maintenance • Inadequate workshop

Source: Own survey, March 2015

The table indicates that Ethiopian pharmaceutical manufacturers have the advantage of getting relatively cheap labour, initiative of university industry linkage, availing fresh products, stringent quality control and citizenship responsibility. Moreover the availability of joint venture for technology transfer and expert assistance is a good opportunity for the local pharmaceutical industries. Though stringent quality control and accredited FMHACA are considered as their strength local pharmaceutical manufacturers have a long way to go in improving their quality status to comply with cGMP and establish laboratory equipment maintenance and calibration centre.

The industries need to capitalize on the above mentioned strengths, however need to work hard in addressing their weaknesses which hinder their growth. Major weaknesses identified include unavailability of tailored training, high turnover, financial shortage, high dependency on imported raw materials and shortage of spare parts. Meeting both local and international quality standards is also a major weakness which the local manufacturers need to address so as to be able to export and increase their revenue. Regarding Engineering, the local pharmaceuticals need to work hard to improve their weaknesses on shortage of spare parts, lack of experience on equipment maintenance and inadequate workshop to become efficient and competitive.

4.1.2.6 External Environment Analysis

The following table will summarize the respondent's response regarding the opportunities and threats of producing pharmaceuticals in Ethiopia in relation to the external environment:

Table 4.4: Opportunities and challenges of Ethiopian Pharmaceutical industries

External Environment	**Opportunity**	**Threat**
Political/ Legal	• Government commitment, GTP priority • Government recognition as one out of seven pillars of the economy • Supportive institutions	• Power shortage • Low tariff rates on imported products would enable competitors to sell at lower prices • Weak regulation on price and quality of imported products • Less qualified government officials and bureaucracy
Economic	• Economic & infrastructure growth • Cheap labour • Hub of east Africa IGAD COMESA • Growth of health service	• Shortage of hard currency • Shortage of working capital • Market not stable • Continuously increasing cost of fuel, spare parts and imported raw materials. • High inflation rate
Technology	• The TRIPS agreement which allows for the exploration of patented invention • Possibility of technology transfer	• Dependency on imported spare parts and experts
Social/ Cultural	• Increased health seeking behavior • Increased health service delivery and quality of care(implementing a health insurance system), • Urbanization • Increased non communicable diseases like diabetes and hypertension • Dependency on treatment than prevention	• Low purchasing power • Peoples attitude towards local production
Demographic	• Big population with relatively high growth rate	• Competition from India & China • Dumping price • Counterfeit cheap drugs
Global	• Possibility of Joint venture • Geographic proximity to Africa and middle east Asian countries	

Source: Own survey, March 2015

Ethiopian pharmaceuticals are encouraged to exploit the opportunities identified in the above table which include strong government support in different areas, population & economic growth, possibility of joint venture, urbanization and geographic proximity. Other opportunities which need to be taken advantage of by local manufacturers include: increased health seeking behavior, increased health service delivery and quality of care (implementing a health insurance system), and increased non communicable diseases like diabetes and hypertension. However issues related to low purchasing power and public attitude towards local production might affect the market of pharmaceuticals.

On the other hand, the local industries collaboration and government support is critical to overcome identified challenges including power shortage, low tariff on imported finished products, weak regulation on price and quality of imported products, less qualified government officials and bureaucracy. Regarding the economy, shortage of hard currency, working capital, unstable market and continuously increasing cost of fuel, spare parts and imported raw materials and high inflation rate requires series attention by the government and concerned stakeholders. The global trend of dumping price and smuggling of counterfeit cheap drugs mostly from Asian countries need close follow up and strict regulation to control their import into the country.

4.1.2.6 Government Incentives

Local pharmaceuticals production is one of the government priority areas and part of the GTP. The major incentives provided by different government agencies to local pharmaceutical industries are summarized below.

The Pharmaceutical fund and supply agency (PFSA) procures products of local pharmaceutical manufacturers on the basis of advance payment provided by the National bank of Ethiopia (70%) and PFSA itself (30 %). PFSA also take local pharmaceutical products by a 25% preference during international tender and float tenders exclusively for local manufacturers on selected products.

FMHACA in collaboration with partners like WHO, GIZ and USPQPM support local industries by providing supportive supervision, capacity building to enable them fulfil cGMP requirements. Two local manufacturers are already qualified for Pharmaceutical

inspection Co operation Scheme (PIC/S) and on track to qualify for WHO GMP which will enable them to sell their products to all UN agencies. FMHACA also treats local manufacturers preferentially by putting them on fast track during plant inspection and product registration.

The Food, Beverage and Pharmaceuticals Industry Development Institute (FBPIDI) under the Federal Ministry of Trade is a newly established institute responsible to provide all round support to food, beverage and pharmaceutical industry; accelerate technology transfer; achieve sector transformation and enable the industry to be competitive internationally. The institute also plays facilitation and capacity building role for industries to comply with international cGMP.

According to the Ethiopian Investment Agency (2013), there are investment financing incentives for eligible areas including pharmaceutical manufacturing and export incentives**.** The government of Ethiopia has initiated investment financing incentives to create enabling environment for new investment project as well as for expansion activities. Development Bank of Ethiopia is providing long-term and short-term investment financing loans to projects that are given a priority by the government.

Investment fiscal incentives include customs duty exemption to all granted capital goods and spare parts worth of 15% of the total value of investment within five years from the date of commissioning the project. The imported capital goods may be transferred to another investor enjoying similar privileges. Local pharmaceuticals manufacturers have now the privilege to import all the major raw materials for pharmaceuticals inputs on zero tariffs. There is also income tax exemption as specified in the below table:

Table 4.5: Areas and period of tax exemption

Condition for profit tax eligibility	*Profit tax exemption*	*Profit tax exemption for investment made in underdeveloped regions*
An investor engaged in a new pharmaceutical manufacturing industry		
If they export at least 50% of its product	5 years	6 years
If they supply at least 75% of its product, to an investor, as an input for the production of export items	5	6
If it export less than 50% of its product	2	3
If production is for the local market	2	3
Expansion or upgrading of the above projects;		
If the expansion or upgrading increases the existing production by 25% in value and 50% of the production is to be exported	2 years	3 years

Source: Ethiopian Investment Agency (2013)

Other government supports for industries exporting their products includes: Investors with new investment project planned to export their product to foreign market after commencing production may be granted a loan up to 70% of the total investment cost. Investors planning to expand ongoing projects may be granted a loan amounting 60% of the total expansion cost if they are planning to export products obtained from the project**.**

The Ethiopian investment Agency also describes the following additional benefits for local pharmaceutical industries if they are exporting their products:

- With the exception of few products (e.g. semi-processed hides & skins) no export tax is levied on export products of Ethiopia
- Voucher scheme: A voucher is a printed document having monetary value which is used in lieu of duties and taxes paid on imported raw material. The beneficiaries of the vouchers scheme are also exporters.
- Exporters are allowed to retain and deposit in a bank account up to 20 % of their foreign exchange export earnings for future use in their operation of their enterprises and no export price control is imposed by the National bank of Ethiopia.

- Franco valuta import of raw materials is allowed for enterprises engaged in export processing.

- Exporters can benefit from the export credit guarantee scheme which is presently in place in order to ensure an exporter receives payment for goods shipped overseas in the event the customer defaults, reducing the risk of exporters' business and allowing it to keep its price competitive.

- Investors who invest in priority areas to produce mainly export products will be provided land for their investment necessary at reduced lease rate.

The different government incentives described above are very essential In attracting potential donors to the pharmaceutical industry sector and it will increase the competitiveness of existing manufacturers.

4.2 Discussion

Ethiopian pharmaceutical manufacturers are few in number and they are operating in small scale. This lower capacity production put them in a disadvantage as compared to their Asian counterparts since the later are enjoying the benefits of economies of scale like price advantage during raw material procurement and distribution of their cost to their large market.

Availability of comparatively cheap labor, commitment of individual factories and their strong association are identified as strength of the Ethiopian pharmaceutical industries. Even though local products are perceived by the public to be poor quality, in practice they demonstrated to be of high quality since they are managed by responsible professional citizens ensuring quality at different stages (raw material, in process and finished product test). One of the respondents clearly describes this situation as:

> "During my long years experience in the pharmaceutical industry, there was no incident of bad quality and severe drug reaction reported on locally produced pharmaceuticals. The professionals take the maximum care possible to ensure quality since the medicines will be eventually consumed by their relatives and citizens."

The industries specially the old ones are struggling to comply with cGMP standards and this together with their limited financial resource are hindering them from exporting and fully utilizing their capacity. The current initiative by FMHACA and partners to enable local manufacturers fulfill WHO cGMP requirement is a good opportunity which need to be wisely utilized by the local industries as it will be the way to transition to large volume production and get the benefits from economies of scale.

Ethiopian pharmaceutical industries are almost fully dependent on imported raw materials which resulted in irregular supply of inputs and underutilization of their capacity. There is shortage of experienced personnel in different technical area and comprehensive management skill found to be insufficient.

There are opportunities which can be utilized by the industries like: rapid economic and population growth, increasing and improvement of the health delivery system, urbanization resulting high prevalence of non communicable diseases.

Being the priority of the government GTP, the local manufacturers are in a better position to exploit the available comprehensive government incentives.

The local industries are facing threats including shortage of working capital & foreign currency to import raw materials, fierce competition particularly from Asian countries, smuggling of poor quality and counterfeit drugs.

The results are consistent with other studies made in Ethiopia and developing countries in that it clearly identified the major challenge of local industries to be their dependency on imported inputs whereas they have the opportunity of increasing population and economy which will increase the demand for pharmaceuticals.

CHAPTER FIVE
SUMMARY, CONCLUSIONS AND RECCOMENDATIONS

The purpose of this study is to assess the internal and external environmental situations of pharmaceutical industries in Ethiopia. The study tried to address research questions like existence of proper expertise, challenges of export, level of government incentives, status of Ethiopian pharmaceutical manufacturer's capacity utilization and their position in meeting quality standards.

The study used descriptive approach and for data collection, questionnaire, key informant in depth interview and literature review was employed.

5.1 Summary of Major Findings

The result of the study indicated that there are shortage of trained and skilled manpower in the areas of engineering and pharmacy. According to the findings, there are different types of incentives provided by the government including tax exemption, advance payment during government procurement and supportive supervision.

The study identified major opportunities to be country's economic and population growth, supportive government policy during investment, export expansion, procurement and regulation, and the available comparatively cheap human labor and challenges as dependency on imported raw materials, machineries/equipments and spare parts.

The capacity utilization of local pharmaceutical manufacturers is found to be low indicating that there is a room for growth. There is very limited export experience by the local manufacturers owing to their challenge in meeting international GMP standards.

5.1 Conclusions

The strengths of Ethiopian local manufacturers identified by the study including availability of cheap labour, industry university linkage and joint venture are very important and the manufactures need to capitalize on these strengths.

However the study participants indicated a lot of weaknesses including dependence on imported raw inputs, limited experience and limited market, which the manufacturers need to work hard to overcome these weaknesses.

The result of the study indicates producing pharmaceuticals locally have both opportunities and challenges. The local manufacturers can effectively exploit the available opportunities including the country's economic and population growth, supportive government policy during investment, export expansion, procurement and regulation, and the available comparatively cheap human labor. Attracted by the economic and population growth and associated market growth, multinational companies are showing interest to invest in pharmaceutical industry in Ethiopia and this will give a good joint venture opportunity to local manufacturers.

The threats identified are very critical and the local industries need to continue working together with the government in order to enhance their quality and competitiveness. The already available government incentives need to continue and strengthen until the local industries are able to compete with the imported products and eventually start exporting their products.

From the study results, it is evident that Ethiopian pharmaceutical manufacturers are fully dependent on imported machineries/equipments, spare parts and raw materials. This dependency leads to inconsistent supply of inputs and frequent machine downtime which contributes to their ineffectiveness. Regarding educated manpower, there is shortage of skilled and experienced personnel in areas of engineering & pharmacy and those available are not stable as there is high turnover because of low pay compared to the market.

The result of the study clearly indicates that the Ethiopian government is providing a lot of incentives through different agencies including fast track registration of products, tax exemption on imported machineries and raw materials, preferential treatment during government procurement of pharmaceuticals and tax holidays during investment. The necessary care need to be taken by the government while providing these incentives so that the quality of products is not compromised and competitiveness of local products is not affected.

Ethiopian manufacturers are struggling to meet international quality standards and only few of them fulfilled the minimum local quality standards. This is found to be a huge weakness faced by the industries which hinders them from exporting to other countries.

5.2 Recommendations

Ethiopian local industries are highly dependent on imported inputs so there is possibility of producing the inputs locally; interested investors may start from producing packing materials and additives. There is already good experience from SEAA producing the empty hard gelatin capsules to be used as an input by other local pharmaceutical industries and export to neighboring countries.

In order to generate the required experienced personnel in different disciplines, the already planned university industry linkage need to be implemented and strengthened. A central raw and packaging material sourcing and procurement will also improve the local industry efficiency through cost reduction during bulk purchase and will curb irregular supply of inputs. In addition central maintenance & calibration of production and laboratory equipments and experience/skill sharing among the local industries will have a huge positive impact on their efficiency.

The regulatory authority needs to strengthen frequent sample testing of imported products. The authority has to start testing every consignment than only during registration and conduct frequent post marketing surveillance.

Existing old local pharmaceutical industries need to learn the good joint venture experience of new entrants and actively look for partnership and integration with multinational and experienced companies so as to resolve their technology challenges and enjoy the benefits of economies of scale by producing in large volume and exporting to neighboring countries. This will also make them eligible for the comprehensive government incentives provided to exporters.

Local pharmaceutical manufacturers can do better by increasing public awareness and improving their packaging like individual syrup pack with the necessary measuring cup/spoon and educational leaflet.

Ethiopian pharmaceuticals are strongly encouraged to focus on taking the necessary measurs to comply both local and international quality standards. This is very critical in enabling them to export their products and benefit from economies of scale to increase revenue and improve effeciency.

Public perception on local products, market research and level of competition need to be further investigated. The local industries focused on producing drugs for infectious diseases and there seem to be duplication which results on unnecessary competition among them.

It is advisable to do market research for drugs treating non communicable diseases and diversify their product portfolio accordingly. Feasibility of producing APIs, additives and primary packages (what volume need to be produced to be profitable) is also another area which needs further study.

5.3 Limitations of the Study

Getting valuable figures and data's because of confidentiality was a limitation. Due to financial and time limitation, the researcher focused on Addis Ababa where most of the industries are located.

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APPENDICES

Appendix A: Questionnaire

ST. MARY'S UNIVERSITY
SCHOOL OF GRADUATE STUDIES
DEPARTMENT OF BUSINESS ADMINISTRATION

Questionnaire for assessment of challenges and opportunities of producing pharmaceuticals 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 internal and external situations of pharmaceutical industries in Ethiopia.

The information you provide will help me to better understand the situation of Ethiopian pharmaceutical industry 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.

NB: Please fill the questionnaire only if you are voluntary

Thank You

Wondwosen Keremenz

Section 1: Respondent and Organization Profile		
1.1	Name of organization	
1.2	Which department you work in the organization?	
1.3	How much is the current annual revenue?	
1.4	Does your company export products to other countries?	Yes No→**SKIP TO Q6**
1.5	What % of your revenue comes from international (export) sales?	_____
1.6	Does your company have any international/local manufacturing certificate? GMP/ISO	Yes Type _____ **SKIP TO Q8** No
1.7	Is your company GMP certified by local regulatory authority?	Yes Type _____ **SKIP TO Q8** No
1.8	What are the major challenges to fulfill international and local quality standards	
1.9	What proportion of your raw materials (inputs) are Imported/ Locally available	Imported _____ Locally available _____
1.10	Do you have competent technical expertise in areas of production, quality control/assurance, marketing and engineering?	Yes **SKIP TO Q1** No
1.11	Which expertise you lack?	
1.12	What is your current production capacity for each dosage forms?	
1.13	Are you producing with full Capacity?	Yes **SKIP TO Q14** No
1.14	What percent of your capacity are you currently utilizing?	
1.15	What % of your company's revenue comes from sales from the public sector (the government and NGOs) and the private?	Public _____ Private _____
1.16	Why do you think are local products considered inferior quality?	

<table>
<tr><th colspan="3">Section 2 Pharmaceutical Industry situation</th></tr>
<tr><td>2.1</td><td>What will be the process to obtain the regulatory approval for a manufacturing company?
How long will the process take?</td><td></td></tr>
<tr><td>2.2</td><td>What steps and datas will be required to obtain regulatory approval for a Product?
How long will the process take?</td><td></td></tr>
<tr><td>2.3</td><td>Is pricing of pharmaceuticals regulated? If Yes, how?</td><td>___ Yes
___ No SKIP TO Q5</td></tr>
<tr><td>2.4</td><td>How is the price regulated?</td><td></td></tr>
<tr><td>2.5</td><td>What incentives are available from the government to encourage local pharmaceutical industries</td><td></td></tr>
<tr><td>2.6</td><td>What are the strengths and weaknesses of local pharmaceuticals manufacturers in Ethiopia in terms of the following factors:
▪ Human Resource
▪ Finance/Accounting
▪ Marketing
▪ R&D
▪ Production
▪ Quality Control
▪ Engineering</td><td><table><tr><th>Strengths</th><th>Weaknesse</th></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td></tr>
</table>

2.7	What challenges and opportunities do you foresee for manufacturing pharmaceuticals locally in relation to the external environment? • Political/legal • Economic • Socio/cultural • Technological • Demographic and • Global	**Opportunity** / **Threat**
2.8	Which companies (countries) are your main competitors?	
2.9	What do you think are your company's major comparative advantages?	
2.10	Is there technical support like training from Government/partners for local manufacturers to increase their capacity?	
2.11	Is there preferential treatment during plant inspection and registration of products?	
2.12	Is there preferential treatment during government purchase (tender)?	
2.13	What are the incentives provided by the government for investors interested to work in pharmaceutical industry?	
Section 3 Organizational SWOT		

3. What else can be mentioned regarding your organization SWOT?

3.1. A weakness to your organization?

3.2. A strength to your organization?

3.3. An opportunity to your organization?

3.4. A threat to your organization?

Appendix B: List of pharmaceuticals manufacturing companies

S/N	Manufacturer Name	Production Type
1	Asmi Industries PLC	Surgical dressings, antiseptic disinfectants
2	Cadila Pharmaceuticals (Ethiopia) PLC	Human pharmaceuticals
3	East African Pharmaceuticals	Human & Veterinary pharmaceuticals
4	Ethiopian Pharmaceuticals Manufacturing (EPHARM)	Human pharmaceuticals
5	Fawes Pharmaceuticals PLC	Pharmaceuticals (oral liquid)
6	Julphur pharmaceuticals PLC	Human pharmaceuticals
7	Medsol pharmaceuticals PLC	Intravenous solutions
8	Pharmacure PLC	Intravenous solutions
9	Sino Ethiop Associate Africa	Empty hard gelatin capsules

Appendix C: Number of Total Employees and Sample Size

Factory	Total Employees	Clerical & laborer	Professionals	Sample Size (SS)
Factory 1	540	420	120	63
Factory 2	44	33	11	6
Factory 3	130	98	32	17
Factory 4	102	78	24	13
Factory 5	127	101	26	14
Factory 6	20	11	9	5
Factory 7	60	43	17	9
Factory 8	415	332	83	44
Factory 9	107	82	25	13
Total	**1545**	**1198**	**347**	**184**

Factory	Prod	SS	QA	SS	Eng	SS	Fin	SS	HR	SS	Mark	SS	R&D	SS	Total	Total ss	Response
Factory 1	45	25	25	13	23	12	7	4	12	5	4	2	4	2	120	63	61
Factory 2	5	3	2	1	0	0	2	1	2	1	0	0	0	0	11	6	6
Factory 3	15	7	5	3	5	3	4	2	3	2	0	0	0	0	32	17	16
Factory 4	12	5	3	2	3	2	3	2	3	2	0	0	0	0	24	13	12
Factory 5	14	7	4	2	3	2	3	2	2	1	0	0	0	0	26	14	12
Factory 6	4	2	2	1	0	0	2	1	1	1	0	0	0	0	9	5	5
Factory 7	9	4	3	2	0	0	3	2	2	1	0	0	0	0	17	9	8
Factory 8	38	20	11	6	12	6	5	3	8	4	5	3	4	2	83	44	41
Factory 9	12	5	4	2	3	2	3	2	3	2	0	0	0	0	25	13	12
Total	**152**	**78**	**61**	**32**	**52**	**27**	**31**	**19**	**36**	**19**	**9**	**5**	**8**	**4**		**184**	**173**

DECLARATION

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

_____ _____

Name: Wondwosen Keremenz Date

ENDOSEMENT

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

_____ _____

Advisor: Assistant Professor Tiruneh Legesse Date