A Case Study Approaches to Explore the Challenges of Local Pharmaceutical Manufacturer in Ethiopia.

A Thesis Submitted to Addis Ababa University College of Business and Economics, Graduate Studies in Partial Fulfillment for the Requirements of the Degree of Masters of Business Administration, Specialization in Management.

By: Solomon Getachew

Advisor: Dr. Ethiopia Legesse

Addis Ababa University

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Declaration

I, Solomon Getachew, hereby declare that the thesis entitled ***A Case Study Approaches to Explore the Challenges of Local Pharmaceutical Manufacturer in Ethiopia*** is my own original work and has not been submitted for any degree in any other university. It is offered for the award of the degree of Master of Business Administration in Management from Addis Ababa University.

Name: **Solomon Getachew** Advisor Name: **Dr. Ethiopia Legesse**

Signature:_____ Signature:  Date: Sept. 8, 2024

Statement of Certification

This is to certify that the thesis prepared by Solomon Getachew entitled: ***Explore the Challenges of Local Pharmaceutical Manufacturer in Ethiopia: A Qualitative Study*** and submitted in partial fulfillment of the requirements for the degree of Master of Business Administration Specialization in Management compiles with the regulations of the university and meets the accepted standards with respect to originality and quality.

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Chair of Department or Graduate Program Coordinator

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Acronyms and Abbreviations

API	Active Pharmaceutical Ingredient
AHRI	Armauer Hansen Research Institute
CAGR	Compound Annual Growth Rate
CSA	Central Statistics Agency
COVID-19	Coronavirus disease 2019
DRC	the Democratic Republic of the Congo
EFDA	Ethiopian Food and Drug Authority
EIC	Ethiopian Investment Commission
EPHARM	Ethiopian Pharmaceutical Manufacturing Factory
EPSS	Ethiopian Pharmaceutical Supply Service
FBPIDI	Food, Beverage and Pharmaceuticals Industry Development Institute
FDI	Foreign Direct Investment
FGD	Focus Group Discussion
FICCI	Federation of Indian Chambers of Commerce and Industry
GDP	Gross domestic product
GMP	Good Manufacturing Practice
GTP-I	Growth Transformation Plan I
HSDP	Health Sector Development Program
ILO	International Labor Organization
LC	Letters of Credit
Manu	Manufacturer
MOH	Ministry of Health
MSH	Management Sciences for Health
NBE	The National Bank of Ethiopia
NMRA	National Medicines Regulatory Authority
NSPA-Pharma	National Strategy and Action Plan for the Development of Pharmaceutical Manufacturing
OECD	The Organization for Economic Co-operation and Development

PMPA	Pharmaceutical Manufacturing Plan for Africa
SH	Stakeholder
UNECA	United Nations Economic Commission for Africa
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development
USD	United States Dollar
WE	Working Experience
WHO	World Health Organization

Abstract

The growth of the manufacturing sector contributes to an increase in the overall factor productivity and competitiveness of the economy, with a cascading effect up and down the supply chain. Although the manufacturing sector offers a path to long-term economic progress, its expansion is not without obstacles. The current study by using the qualitative method of approach was explore the challenges faced by the pharmaceutical manufacturer found in Ethiopia. Data was collected through key informant interview and focus group discussion by enquiring different stakeholders in the industry and key personnel of the manufacturers. The study subject was identified and choose by purposive sampling. Thematic analysis was used for the transcribed interviews and FGD replies, while manual transcript analysis was also done. Based on the findings, the main challenge for domestic pharmaceutical manufacturer that are currently affecting their business are Shortage/lack of hard currency, unavailability of domestic active and inactive raw materials manufacturer, lack of sustainable financing, shortage working capital/access to finance, problem related with plant infrastructure, weak marketing structure, and lack of research and development capacity. The root cause for the mentioned challenges is mainly absence of cognizance about sector by the administration, poor coordination among different stakeholders, poor export performance made by the country. The study also explored that the methods used by the companies to tackle the above problems. Ethiopia's pharmaceutical industries are running well below their potential, and their average capacity is getting smaller over time. Various internal and external challenges can be attributed to this decline in capacity utilization.

Keywords: *Pharmaceutical manufacturer, Challenges of local pharmaceutical manufacturer, Stakeholders*

1. INTRODUCTION

1.1 Background of the study

The second-most populous nation in Sub-Saharan Africa is Ethiopia (Agency., 2016). Notwithstanding main advances in the past three periods, the people of Ethiopia continue to experience high rates of illness and death.

Ethiopia's economy is among the fastest growing in the world, with average growth over the last ten years of over 10.9%. The goal is to abolish poverty entirely and move toward being a middle-income country by 2020–2025. Growth Transformation Plan I is the document that embodies the national growth vision of the Ethiopian government, 2010–2015 (The Federal Democratic Republic of Ethiopia:, 2011).

Having access to high-quality healthcare is a critical component of every society's riches and a prerequisite for its continued growth. The provision of healthcare typically involves a range of diverse treatments aimed at preventing, treating, or managing an individual's illnesses or injuries. The medical and pharmaceutical sciences have advanced significantly during the previous centuries, with some of the most significant disruptive developments emerging in the last five decades alone. As a result, the role that pharmaceuticals play in the management and treatment of both acute and chronic illnesses, as well as in giving people access to high-quality healthcare, has continued to grow (Sven Stegemann, 2016).

Many individuals worldwide would not be able to receive the quality care they need without medicines, which are an essential component of health services. In addition to providing critical preventative therapies, vital life-saving measures, and much-needed relief from chronic illnesses, medicines also help patients live longer and have higher quality lives. Thus, achieving the best possible standard of health requires fair access to safe and reasonably priced medications. Without a functioning pharmaceutical sector, no health system could exist since pharmaceutical items and access to necessary medications are necessities.

The pharmaceutical sector, which encompasses medication development, discovery, production, and marketing, is a vital component of any healthcare system. The pharmaceutical industry's general framework for the modern age begins with drug discovery and continues through preclinical and clinical evaluations, medication manufacture, and market launch. (Lipsky and Sharp, 2001;Taylor, 2016).

Three interconnected activities comprise the complex process of pharmaceutical production: the manufacture of intermediates and active pharmaceutical ingredients; the production of finished dosage forms from excipients and active pharmaceutical ingredients; and the final wrapping of finished dosage forms or repackaging of bulk finished products. Specialized technologies, a consistent supply of superior raw materials, and a consistent supply of superior energy, water, and other utilities are needed for the entire process. Additionally, skilled workers with specialized knowledge are required.

Building a forward-thinking, long-lasting healthcare system that can handle both normal and emergency needs requires a strong foundation in the development of the pharmaceutical manufacturing industry. One such situation where having access to high-quality medical care is essential is the COVID-19 pandemic (International Finance Corporation, 2020).

The pharmaceutical industry is an essential sector for every nation since its goods directly address essential consumer demands in a crucial domain, namely health care. Undoubtedly, the worldwide market for pharmaceutical items has been growing at an exponential rate. (Muratoglu, 2017)

A global market with a compound annual growth rate (CAGR) of 4.9% and an expected value of $1.6 trillion in 2020 has resulted from growth in the pharmaceutical manufacturing industry. But getting access to affordable, high-quality medications has always been difficult for underdeveloped nations, especially those in sub-Saharan Africa (Ekeigwe, 2019). when it seems that no more than 30% of the demand for necessary medications is met by local production (Stevens and Huys, 2017).

Roughly 20% of global production was made by the pharmaceutical sector in emerging nations. Nowadays, it is much less. Few emerging nations produced active pharmaceutical ingredient, and the majority of businesses were little. Foreign subsidiaries, or those in industrialized nations, had a big impact. Approximately two thirds of all medications manufactured in the developing countries were made by foreign-owned businesses. The pharmaceutical business relied on the production of generic products under license and, to a lesser extent, production by multinational affiliates in most developing nations, but not all of them. Without a significant local investment in product creation, domestic demand was satisfied in both instances. Very few poor nations were able to begin exporting pharmaceuticals on a regular basis. Indeed, pharmaceutical preparations and finished goods accounted for about two thirds of all pharmaceutical exports. For a developing nation to

become a net exporter of pharmaceuticals, it needed to have a processing sector that could turn pharmaceutical intermediates into final goods. (Kaplan, W. A., and Laing, 2005).

In the context of fostering equal access to medications and other health innovations, the significance of local production and associated technology transfer has been emphasized more and more over the past 20 years. Many nations, especially low- and middle-income nations (LMICs), see local production as a tactic to ensure health security and enhance timely access; yet, new and persistent obstacles have surfaced. Global manufacturing capacity has been demonstrated to be insufficient to satisfy the needs for health in the face of the current COVID-19 pandemic; spreading the manufacturing of health items geographically to supplement current production chains could help address this issue (WHO, 2021).

The pharmaceutical industry is a highly knowledge-based and technologically advanced sector that is essential to the provision of pharmaceuticals and other associated goods needed to address population health needs (Muratoglu, 2017). The majority of Ethiopia's need for medications and medical equipment is met by imports from other nations. As a result, ensuring timely access to cost-effective and high-quality medical items still presents a number of difficulties. One of the top priorities in the national growth vision of the Ethiopian government is the growth of domestic pharmaceutical industry. This is stated in national strategy of Ethiopia and plan of action for the Development Pharmaceutical Manufacturing (NSPA-Pharma). The strategy plan seeks to hasten the growth of regional pharmaceutical production in order to guarantee access to important medications with guaranteed quality and support the local economy (FMoH, 2021).

There are currently 11 factories functioning in Ethiopia, but only two of them adhere to local good manufacturing practices (GMP) standards, and none of them have received international GMP certification (FBPIDI, 2020).

From a health and economic development standpoint, the domestic pharmaceutical manufacturing business is crucial to the production of necessary generic medications. But at the moment, the sector is going through the same difficulties that a lot of other sectors have gone through in the past, forcing many businesses to attempt and reinvent themselves in response to difficulties in their commercial environment. (Ireri, 2010).

Local pharmaceutical enterprises supplied $44.2 million worth of goods in 2014. Nevertheless, only 90 of the more than 380 goods on the national essential medications list may be supplied by these firms due to their constrained product portfolios. A 10% premium

is paid for the supply of 35–40% of their total output to the private sector. Ethiopia's private pharmaceutical industry is thought to be worth $100 million USD annually (MOH and MOI of Ethiopia, 2015). It is imperative that the relevant organization comprehends the regulatory compliance concerns that local pharmaceutical businesses are facing as well as the obstacles that have impeded the industry's growth thus far. Only then can it take necessary measures and offer support for the industry's further development (Tawfik et al., 2022).

There are some gloomy clouds in the distance, even if the pharmaceutical industry's overall outlook is still quite positive. Since the global economic crisis of 2009, the number of pharmaceutical manufacturing enterprises in developing nations, and particularly in sub-Saharan Africa, has decreased (Banda et al., 2016). These businesses face a variety of globalization-related difficulties, including dumping. A few of these businesses are thinking about expanding their product lines, diversifying, or perhaps shutting down completely. This investigation aimed to assess challenges faced by the domestic manufacturing pharmaceutical companies in Ethiopia.

1.2 Statements of the Problem

The pharmaceutical sector requires a lot of capital. Research and development (R and D) expenditures associated with the creation of novel medications are high, leading to significant sunk costs. Large, established multinational corporations from the US and Western Europe are the key players. However, new actors have entered the scene recently, such as local businesses from a comparatively small number of emerging nations and international corporations from China, India, and South Korea. In the pharmaceutical industries of the majority of Latin American and Caribbean nations, players from these three categories of companies can be found, albeit in different degrees (Vargas Veronica, 2022).

Due to the COVID-19 outbreak, access to medications was hampered globally, endangering the lives of several people (Badreldin and Atallah, 2021; Shuman et al., 2020). The healthcare system and pharmaceutical supply chain are impacted by high drug usage rates and inadequate local pharmaceutical production continue to be major challenges (Badreldin and Atallah, 2021).

The World Health Organization (WHO) estimates that between 20 and 30 percent of medications that are imported into developing nations are either illicit or counterfeit. The latter are unlicensed medications that are imported into the nation by unregistered businesses and people, such briefcase dealers.

One essential component of the healthcare system is the pharmaceutical manufacturing industry. In addition to being a health risk, low-quality medications cost the government and patients money. The availability of a comprehensive national Health Sector Development Program (HSDP 1997-2015), which prioritized "Strengthening of Pharmaceutical Sector," was acknowledged as one of the country's major accomplishments, according to WHO's Country Cooperation Strategy (2013) (WHO, 2015).

Due to a shortage of access to reasonably priced medications, Africans are now buying inferior and fake medications in an effort to find more economical options. Creating a local pharmaceutical industry may also generate additional income that can be utilized to fortify industry regulation, thus lowering the use of phony or subpar medications. Developing local capacity to produce medicines at lower costs would help to address this issue. If patients, particularly in Africa, had easy access to safe and effective medications for treatment, many fatalities may be avoided. There are major economic advantages to establishing local pharmaceutical manufacture in addition to health benefits. Better health is especially essential to people's productivity and lifestyles (UNECA, 2020).

Ethiopia has a high frequency of unregistered items, primarily because of supply and demand imbalances, lengthy registration processes, and a lack of foreign exchange, all of which have an impact on both domestic production and imports.

Most local pharmaceutical manufacturers only supply 20% of the local market and work below capacity. Local pharmaceutical enterprises supplied $44.2 million worth of goods in 2014. Of the more than 380 goods on the national essential medications list, only 90 are believed to be supplied by local producers due to their narrow product portfolios. Approximately 35–40% of their whole production is sold to the private sector for a 10% premium. Ethiopia's private pharmaceutical business is thought to be worth $100 million USD annually. The pharmaceutical items Ethiopian industry exported in 2014 were valued at roughly US$ 2 million, significantly less than the US$ 20 million GTP-I aim. (MOH and MOI of Ethiopia, 2015).

According to data from MOH, imports serve as suppliers and account for more than 50% of the nation's consumption of pharmaceutical items. The share of domestic producers in the local market is barely 15% (MOH and MOI of Ethiopia, 2015).

The government started enacting extensive Growth and Transformation Plans and economic policy reforms in order to create a stable manufacturing sector, with the goal of making the nation middle-income by 2025 (WB), 2015).

The contribution of local pharmaceutical products to the national requirement is quite low, despite the growing need for pharmaceuticals. Furthermore, local producers of pharmaceuticals are not operating to their full potential due to intense rivalry from foreign producers. In addition to identifying the prospects for pharmaceutical production in Ethiopia, this study evaluated the difficulties faced by the national pharmaceutical industry.

1.3 Research Questions

The following queries should be addressed in accordance with the problem statement.

- How do pharmaceutical manufacturers in various contexts perceive environmental pressure resulting from resource uncertainty?

- Why these issues have arisen in the pharmaceutical manufacturers?

- What kind of support are obtained from different stakeholders?

- How do local pharmaceutical manufacturers in various contexts use measures to lessen an unpredictable and resource-constrained environment?

1.4 The study's objective

1.4.1 General Objective

The principal aim of this investigation is to assess the difficulties with local pharmaceutical manufacturers operating in country.

1.4.2 Specific Objectives

- To evaluate the main challenges faced by the domestic pharmaceutical manufacturer

- To assess government support (different stakeholders) provided for strengthening of pharmaceutical firms with operations in Ethiopia.

- To identify the root cause of the main challenges

- To identify the mechanisms used to overcome the challenges

1.5 Significance of the Research

Producing goods locally will boost the economy, add jobs, and creates revenue from exports and preserves foreign exchange reserves. More regionally adapted goods, medications for

untreated illnesses, and increased medication accessibility will result from local manufacture. Additionally, local manufacture might provide more authority to overburdened African authorities, who are fighting low-quality pharmaceuticals occasionally produced in remote locations that are hard to watch over.

The research-driven pharmaceutical sector has the potential to be extremely important for Europe's economic recovery and for maintaining its competitiveness in the rapidly expanding global market. It is projected to have invested €39,000 million in European R and D in 2020. Approximately 830,000 people are directly employed by it, and it creates three times as many jobs overall (IQVIA, 2021).

A robust manufacturing sector helps the private sector grow, strengthening an economy's resistance to outside shocks. Furthermore, by diversifying exports and reducing imports, domestic manufacturing strengthens external accounts.

The purpose of this study is to discuss the main difficulties that Ethiopian domestic pharmaceutical manufacturers face. The study's conclusions may offer guidance to prospective new investors in the pharmaceutical industry on how to take advantage of opportunities and overcome obstacles to improve performance in the market. The outcome will also be used as a source of information by regulatory bodies and policy makers as they create rules and guidelines. The outcome will also serve as a guide for those researchers who wish to delve deeper into the pharmaceutical sector.

1.6 Scope of the Study and Delimitations

This research is centered on exploring the difficulty that domestic pharmaceutical firms with operations in Ethiopia. The study is tried to spotlight on currently active pharmaceutical manufacturers and the stakeholders to the sector. Due to saturation and other constraints, the study is not incorporated all stakeholders to the sector.

1.7 Limitation of the study

Due to certain manufacturing firms and stakeholders' refusals to participate, the study did not include participants from all pharmaceutical manufacturing companies and stakeholders in Ethiopia, which limited the scope and quality of the data gathered. The depth of the study's reach and comprehensiveness is somewhat limited by this lack of volunteer participation.

- The main obstacles the researcher encountered in carrying out this study were the dearth of empirical research in the relevant field, particularly in our nation, and the lack of sufficiently published and recorded data on the subject.
- A few study participants did not indicate that they would be willing to be recorded. This makes it challenging for the researcher to conduct a thorough analysis of the data gathered.
- The present qualitative investigation, which concentrated on important personnels or managers, gave an in-depth analysis of the issues encountered by the pharmaceutical makers. Nevertheless, it lacks data coming from lower-level staff members or technicians.

1.8 Structure of the research

The article is divided into six chapters. The first chapter includes an introduction, the study's background, a problem statement, research questions, the study's purpose, its significance, and scope. The second chapter is devoted to a study of the literature that examines research findings from national and international publications as classified by theoretical and empirical, writers, and researchers regarding the difficulties that local pharmaceutical manufacturers. In the third chapter, the researcher described the procedures used to gather, examine, and record data for the study. It also displays the selection criteria and the process used to choose the targets. The data is provided in the fourth chapter using the qualitative method of data collection, analysis, and organization following the meaning and significance of the research issues the researcher hopes to address. The examination of the data analysis with detail explanation of results based on the study questions is presented in the fifth chapter. The researcher provided the study's summary, conclusion, and implications in the sixth and final chapter.

2. REVIEW of RELATED LITERATURE

2.1 Theoretical Literature review

The creation, manufacturing, and distribution of pharmaceuticals are the main priorities of the pharmaceutical industry, which is an important field. It is essential to healthcare since it provides medications for illness prevention, diagnosis, and treatment. In order to improve patient outcomes and progress healthcare, the pharmaceutical business collaborates with other sectors and scientific disciplines, making it a complex and multidimensional sector.

2.1.1 Resource Dependency Theory

Pfeffer and Salancik first created Resource Dependency Theory (RDT) in 1978. It looks at how businesses use external resources and the methods they use to manage these dependencies. RDT holds that organizations are not independent entities but rather are a part of systems of connections with other individuals and organizations, and that these relationships are essential to their success and survival. According to the hypothesis, companies control their dependence to boost control over vital resources and lower uncertainty. This is especially important for sectors like pharmaceuticals, where alliances, regulatory approval, and resource availability are crucial for preserving competitive advantage. There is a lot of uncertainty in the pharmaceutical sector, especially when it comes to clinical trial outcomes, regulatory procedures, and the dangers of international supply chains. Uncertainty develops when companies lack control over vital resources, as RDT implies. Reliance on regulatory clearance agencies or API suppliers puts pharmaceutical firms at risk (Pfeffer, Jeffrey and Salancik, 1978).

Pharmaceutical producers use a number of tactics, in accordance with RDT's recommendations, to lessen dependency and minimize risks: Pharmaceutical businesses frequently try to steer clear of becoming overly dependent on one supplier since this could lead to a production bottleneck or risk. For instance, supply chain interruptions during the COVID-19 epidemic highlighted the necessity of having a diverse network of suppliers (Shilesh & Senthilkumar, 2019)

The Resource Dependency Theory provides important information about the external forces that pharmaceutical companies must deal with as well as the tactics they can use to control dependencies and reduce risks. Pharmaceutical firms can more effectively manage issues including supply chain disruptions, regulatory hurdles, technological breakthroughs, shortages of skilled workers, and market competition by concentrating on lowering their

dependency on vital resources and comprehending the external factors at work (Ansmann et al., 2021).

Dependency on foreign sources for essential raw materials, especially active pharmaceutical ingredients (APIs), is one of the main issues local pharmaceutical firms confront. The infrastructure and technology necessary to manufacture APIs domestically are lacking in many developing nations, despite the fact that they are essential components in medication manufacturing. These regional producers instead depend on importation from more developed nations or international companies that manage API production and distribution (Khan & Rauf, 2024 ; Pfeffer, Jeffrey and Salancik, 1978)

Capital is another essential resource that regional pharmaceutical producers frequently lack. The manufacturing of pharmaceuticals necessitates large investments in intellectual capital, such as skilled labor, as well as infrastructure. In underdeveloped nations, a lot of local pharmaceutical companies find it difficult to get the funding they need to make these investments. Due to high interest rates, limited credit availability, and underdeveloped financial markets in these nations, local businesses frequently lack the financial resources necessary to construct cutting-edge facilities or finance R&D initiatives (Kaplan, W. A., and Laing, 2005; Oliver, 1991).

In the pharmaceutical sector, regulatory agencies are essential because they establish the benchmarks for medication quality, safety, and efficacy. One of the biggest obstacles facing regional pharmaceutical producers is navigating regulatory frameworks that were frequently created with large firms in mind. For smaller, regional firms who lack the means to comply with the strict criteria, these restrictions can be expensive and onerous. Additionally, local manufacturers could also rely on outside regulatory bodies to approve their goods. For instance, in order to enter worldwide markets, local businesses in many nations are required to adhere to international standards. The ability of local businesses to expand and thrive may be hampered by their reliance on foreign authorities for market access (Ketele et al., 2022; MSH, 2012).

One of the main ideas of resource dependency theory is that multinational pharmaceutical corporations have a lot of power over local manufacturers. These multinational companies control the pharmaceutical supply chain, including raw materials, advanced technologies, intellectual property, and market access. Local manufacturers in developing nations, especially those with less access to capital and technology, rely on these larger companies for

the resources they need to produce medicines. As noted by Hillman, Withers, and Collins (2009), companies that lack access to essential resources are frequently compelled to form alliances or partnerships with larger companies in order to obtain these resources, but these alliances can frequently result in power imbalances where local manufacturers are inferior to the larger players (Hillman et al., 2009).

2.1.2 General Overview of Pharmaceutical Industry

The global economy's prosperity is significantly influenced by the biopharmaceutical sector. It is a strong industry that has supported industrialized economies and is becoming more widely acknowledged as a key industry in developing nations as well. It supports trade, investments in research and development, employment (direct, indirect, and induced), and the development of technological capability (Epifa, 2021).

Globally, the pharmaceutical industry is defined by a few dominant producers controlling a large portion of the market, fierce competition, and capital consolidation the joining of enterprises.

In terms of total research and development expenditures, the pharmaceutical industry led the globe in 2015. Over €100 billion was spent on this kind of work. (Hernández et al., 2015) . Both in terms of its organizational structure and commercial practices, this sector functions with peculiar characteristics. The industry is extensively controlled by national, regional, and international laws because of its unique characteristics. The pharmaceutical business is additionally protected by stringent patent rules and applications that guarantee enormous profits from local and global commerce, making it even further crucial in terms of country economies and multinational corporations (OECD, 2002).

There are two ways that the global pharmaceutical industry affects the economy. First, by manufacturing pharmaceutical products, the industry immediately increases the GDP of the world economy and creates many jobs. Second, the pharmaceutical industry encourages additional value creation and employment through its economic activity due to its reliance on global supply chains. Indirect economic benefits and the economic repercussions of individual consumption are both included in the global pharmaceutical industry's spillover effects on the economy (Dennis Ostwald, Marcus Cramer, Nora Albu, 2020).

The processes, businesses, and activities that comprise the pharmaceutical industry are the creation, planning, and manufacturing of potent pharmaceutical drugs. The pharmaceutical

sector uses a lot of technology and capital. Companies' capacity to sell products and conduct effective research and development are crucial to their survival in this sector, because staying indoors state borders remain non-viable business tactic. There is ample room to consider the particulars of pharmaceutical product marketing given the pharmaceutical industry's development potential, change's rapid pace, intense competition, and impending reorganization (Taylor, 2016).

Even during periods of financial crisis and economic unrest, the biopharmaceutical industry has continuously made the largest investments in research and development of any industrial sector. According to estimates, the research-based biopharmaceutical industry would have invested USD 198 billion in biopharmaceutical R and D globally in 2020. (Evaluate Pharma, 2021). The yearly spending of the biopharmaceutical industry is 8.1 times higher than that of the aerospace and defense, 7.2 times higher than the chemicals, and 1.2 times higher than the software and computer services industries, among other high-tech industries. (Sikaras and Hron, 2020).

2.2 Empirical Literature Review

2.2.1 Challenges in Pharmaceutical industry

Gaining a thorough grasp of the pharmaceutical industry's business practices is necessary to increase domestic pharmaceutical production in countries. There are legal, scientific, technical, financial, and fiscal components to the pharmaceutical industry.

In terms of both economic development and public health, the local pharmaceutical manufacturing sector is crucial to the production of necessary generic medications. But at the moment, the sector is going through the same difficulties that a lot of other sectors have gone through in the past, forcing many businesses to attempt and reinvent themselves in response to difficulties in their commercial environment. However, the obstacles that the African pharmaceutical industry must overcome to bring its facilities and production methods up to par with global standards are numerous and include high capital costs, specialized knowledge, highly skilled labor, more stringent regulatory oversight, and an all-around business climate that fosters industry growth.

A. Source of challenges in strategic planning and implementation

Strategic planning is a critical process that establishes an organization's strategic posture as well as the resources and capabilities necessary to maintain its competitiveness and flexibility in response to external changes. With the creation, application, and assessment of company corporate strategies, strategic plans guide the strategic leaders of the organization toward the accomplishment of desired future objectives. A concerted effort involving commitment from all responsible organizations, not just management, is necessary for the successful execution of a strategy. But in order to carry out the plan, management needs to make sure that the right resources, channels of command, and support systems are in place inside the company structure (Abbass F. Alkhafaji, 2011).

Up until recently, worldwide acquisition of huge quantities of medications primarily from Indian manufacturers and their import and distribution were the main focuses of international policy regarding access to important medicines in Africa. Rekindled governmental interest in the possible advantages of local pharmaceutical supply and production is now challenging this emphasis (Mujinja et al., 2014).

In Latin America and the Caribbean, pharmaceutical products have improved life expectancy and quality of life. Nonetheless, they frequently represent a considerable portion of household expenses, particularly for the impoverished and those experiencing severe medical shocks. Furthermore, as the Covid-19 outbreak has vividly shown, they are not always available. The operations of the pharmaceutical industry, a topic that has not gotten much attention in policy discussions, are related to this uneven record (Vargas Veronica, 2022).

B. Challenges of efficiency in pharmaceutical production

The results show that, on average, the Bangladeshi pharmaceutical industry's productivity increased during the 2009–2013 research period. The model's results clarify that the industry's technological innovations, brought about by the acceptance and advancement of new technological features by the enterprises, are the only causes of the marginal productivity improvement. Technical efficiency has declined overall. The pharmaceutical industry's efficiency gap is probably expanding, with less efficient enterprises relocating farther from the frontier, which is the likely cause of the efficiency decline. Although the cause of the increased performance dispersion is unknown, there are a few possible explanations (Azad et al., 2018).

With the exception of the United States, China currently has the second-largest pharmaceutical market globally. Over 5000 local producers operate in the extremely fragmented pharmaceutical business. The pharmaceutical industry in China is currently facing a number of difficulties, such as low-quality drugs, inadequate intellectual property protection, a high rate of incorrect prescriptions, a long wait for novel medications, and high out-of-pocket expenses (Mills et al., 2019).

Challenges faced by Sri Lankan pharmaceutical supply chains comprise erratic lead times and inadequate standards or norms for regulations pertaining to pharmaceutical products, inadequate temperature control in customs warehouses, underutilization of human resources, and competition from generic products manufactured abroad (Gunawardana & Herath, 2020).

Africa's pharmaceutical industry faces numerous obstacles, such as the need to modernize facilities and production methods to meet international standards (UNECA, 2020). Ten percent of consumed commodities are produced locally within the Congo's Democratic Republic (DRC), a country with a inhabitant of over 93 million individuals but just 30 local pharmaceutical businesses. Due to a lack of production capacity, China and India are now the primary suppliers of APIs and other pharmaceutical commodities. In the country, there has several obstacles in the pharmaceutical manufacturing industry, including unstable and expensive utility supplies, elevated transportation expenses, political unrest, and corruption (Okereke, 2022).

C. Challenges faced in international finance

Financing accessibility has always been a problem for LMIC manufacturers, especially those in Africa. Key development finance institutions (DFIs) believe that the pandemic has, nevertheless, brought attention to and understanding of the need for a comprehensive approach to the problem, going beyond previous efforts that may or may not have resulted in the improvements in capital access that are necessary. Given the widespread awareness of the need to increase local production capacity, the necessity of localizing financial institutions to support projects, and the increased willingness of international donors to facilitate financial support, it is possible to see the current focus on ensuring the provision of affordable capital as an opportunity (WHO, 2021).

Local pharmaceutical production has been hampered for more than 20 years by a lack of access to capital, particularly long-term financing, and foreign currency to pay for essential imports, according to studies by UNIDO (2007, 2011) and Banda (2012). Local financial institutions' ability to offer loans denominated in foreign currencies has been negatively impacted by the lack of foreign currency resulting from balance of payment deficits (Geoffrey, 2013).

Ethiopian foreign money is a limited resource, so it must be handled carefully to ensure its effective and appropriate distribution. The National Bank of Ethiopia guarantees openness in foreign exchange management and foreign currency allocation in addition to relinquishing regulations. As a result, all commercial banks must have guidelines or a procedure manual for foreign exchange management that is clear and sound and that outlines the responsibilities of each bank employee involved in a foreign exchange transaction (NBE, 2021).

Ethiopia's foreign exchange reserves fluctuate and its current account deficits are getting wider. An increase in public and private investment in capital goods, intermediate inputs, and consumer products has led to an annual rise in the need for foreign currency to finance import bills of a variety of goods. However, the weak performance of the export sector and the irregular influx of foreign aid limit the supply side of foreign currency. The difference between the supply and demand for foreign currency keeps growing over time, which causes the reserve position to either fluctuate or deplete (Lelissa, 2015).

D. Challenges in regulation

One of the global industries with the highest levels of regulation is the pharmaceutical one. The safety, effectiveness, manufacturing quality, false product claims, and illegal inducements to select a specific drug are all considered while evaluating drugs. Many nations control prices through their own healthcare and insurance systems. While open competition based on quality, safety, and price drives much of the success of products in the U.S. market, businesses operating abroad must contend with a patchwork of inconsistent laws, protectionist measures, and price controls. Both developed and developing nations are increasingly erecting these barriers. The main obstacles facing the US sector are regulatory complexity and attempts to rein in rising health care costs (International Trade Administration, 2016).

Indian pharmaceutical companies have encountered numerous challenges on multiple fronts. The drug price control order in the domestic market means that drug prices are tightly controlled, which puts significant pressure on revenues and, in turn, on costs. On the international front, threats from multinational pharmaceutical companies are becoming increasingly formidable obstacles to overcome (Festa G. et al., 2022).

Many obstacles stand in the way of Rwanda's developing a strong pharmaceutical industry, according to a situation analysis carried out by the USAID funded Rwanda Health Systems Strengthening Project. These challenges include an inadequate regulatory framework and regulatory capacity, a misalignment of industrial and health policies, a convoluted and unclear procurement process for essential inputs, and more (USAID, 2016).

The National Medicines Regulatory Authority (NMRA) frequently changes its guidelines without providing a grace period, which can cause delays in duty waivers and other regulatory approvals (Gunawardana & Herath, 2020).

In Africa, getting access to medications has always been difficult and continues to be so. Pharmaceutical companies who wish to register medications in these nations face challenges due to the impact of the rules governing medicine registration. The necessity for harmonization has gained more attention as a result of the recent African Medicines Registration Harmonization Initiative (AMRHI). The laws governing the registration of medicines vary throughout African nations. Anecdotal data suggests that country specific criteria posed a barrier to medicine registration, based on the experience of pharmaceutical corporations regarding the progress towards harmonization (Narsai et al., 2012).

A few requirements for a successful regulatory performance are the appropriate coordination of diverse regulatory operations, the availability of financial resources, and a suitable number of human resources with the necessary competency to carry out their obligations (Nyika et al., 2022).

Encouraging the development of novel medications and vaccines in nations where the pharmaceutical industry is well-established involves making sure the NRA promptly releases guidelines regarding technical data and the regulatory process. In order to ensure that

medications and vaccines can be effectively brought to market with the fewest possible delays, the National Regulatory Authority (NRA) thus supports the development of new products. This can be used in conjunction with an accelerated review and approval process for products that have already been approved and marketed in other nations (WHO, 2021).

Limited human resource capacity, poor utilization, and inadequate market authorization strategies all impede the effectiveness of drug registration. The limitations of the EFDA, conflicts of interest, and the delays in the processing of information requests are unknown to applicants. Emerging key problems include decreased application flow, market withdrawal, lengthy lead times for registration, and technical capacity deficiencies in the evaluation of biologics, biosimilars, nanomedicines, and conventional pharmaceuticals.

E. Challenges in supply chain management

The 2011 EFY Annual Performance Report from EPSA showed that 89% of the spending was allocated to pharmaceutical procurement. Nevertheless, the procurement process is hampered by issues like poor contract management, laborious approval procedures, protracted port clearance periods, and inadequate performance bond tracking systems. The Ethiopian government created a ten-year National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015–2025) with regard to purchasing from regional producers. According to this proposal, 20% of EPSA's purchases from regional producers would occur in 2015, 50% in 2020, and 60% in 2025. Nevertheless, the intended goals have not been met by EPSA or the regional producers. The 2011 EFY Annual Performance Report of EPSA states that local manufacturers' procurement share of RDF and health program procurement was 22.3%; as a result, their ability to replace the importation of pharmaceuticals fell well short of the aim (EPSA, 2020).

Brazil undoubtedly has difficult challenges in ensuring that the populace has access to safe and high-quality pharmaceutical products and in lowering the health risks related to the nation's reliance on imports of foreign API. Regulations pertaining to the control of APIs will undoubtedly continue to grow, as they have in the past, as manufacturers grow and develop their businesses. Notwithstanding the importance of national pharmaceutical manufacture in enhancing the accessibility of critical medications, local API production may not always be

possible because of the Asian major API Manufacturing countries' competitively low costs (Tonini et al., 2023).

The pharmaceutical industry in Nepal is primarily dependent on imports, which make up 69.7% of the market (or Rs. 8649 million). This reliance is vital to the industry since, in a patent-recognized import-driven economy, higher pricing might be a significant problem. Since all materials, including bulk medications and active pharmaceutical substances, are imported from outside, Nepal must move toward a self-sufficient domestic pharmaceutical industry (Gyawali and Shrestha, 2021).

Africa is heavily dependent on imported medications due to a lack of adequate domestic pharmaceutical production capability, despite the region's high need for safe, effective, and reasonably priced healthcare. Roughly 79% of all medications in Africa are imported. This raises health care costs dramatically and puts consumers at risk of a disruption in their medication supply. While most Africans still do not have guaranteed access to life-saving medications, this is nevertheless a human right. The widespread availability and affordability of important medications are hampered by lengthy lead times in overseas procurement, brittle logistics and storage capacity, and expensive transport and distribution expenses. Furthermore, many patients may not be able to afford proprietary medications for conditions like cancer, hepatitis, and multi-drug-resistant tuberculosis due to their cost (Dong and Mirza, 2016).

Pharmaceutical raw resources and product quality improvement are the biggest manufacturing challenges. Since the majority of the raw materials used to make medicine are imported, banking and financial transactions are disrupted. The development of the pharmaceutical sector depends on raising the standard of pharmaceutical product and raw material manufacture, as well as on achieving GMP certification requirements. Despite possessing the required equipment, Iran's pharmaceutical industry has encountered significant difficulties because it is not eligible for GMP regulations and its pharmaceutical manufacture is of low quality.

Ports are intricate and ever-changing regulatory and operational environments. Port efficiency can be attributed to two factors: the management of processes among various stakeholders encompassing numerous stages and the laborious manual paperwork in the port

ecosystem. The physical infrastructure's quality, capacity, and sophistication constitute one component of port efficiency. The main goal of the suggested improvements was to create dependable digital systems with improved user interfaces for bill of entry, shipping bills, cargo filing, etc., to enable timely clearances by reducing delays brought on by frequent malfunctions. It was also evaluated whether procedures across ports could be streamlined to remove redundant paperwork and processes (Mitra et al., 2021).

F. Challenges related to Human Resource Management

Employers frequently have trouble finding workers who completely understand their particular needs. Programs for human resource development aid in closing the gap between the demands of the workplace and individuals' knowledge, abilities, and attitudes. These initiatives put a strong emphasis on staff education, training, and development in order to sustain competency levels and adjust to shifting organizational needs. Dissatisfaction with HRD processes results from firms in underdeveloped nations frequently ignoring the needs of their workforce because of inadequate assessment, antiquated procedures, a lack of educational opportunities, and inadequate supervisor direction. These issues eventually cause the organizations to experience a lack of an ideal man-task relationship, employee resistance to accepting new tasks, a decline in productivity, an increase in operational errors, a decline in employee commitment and morale, and an upsurge in employee turnover.

African countries needs highly specialized knowledge, workers with specialized training, more regulatory oversight, and an overall business climate that fosters industry growth (UNECA, 2020).

Technology, product, and geographic diversification are critical for pandemic preparedness and sustainability; the hub and spoke approach might effectively satisfy manufacturers' training needs and skill development while having a significant impact on diversification. One essential element is the development of skilled human capital. Building the skills and ability of regulators and manufacturers is necessary to guarantee timely and high-quality market entrance. Technology transfer, GMP, process development, and other specific topics are covered in training (WHO, 2021).

G. Challenges of the infrastructure

A pharmaceutical company's operating space needs to adhere to a set of minimal requirements. The building should have good structural integrity and sufficient ventilation,

lighting, and temperature management. Every location where pharmaceuticals are produced, processed, or packed needs to be hygienic and free of any possible pollutants, including dust, filth, germs, and leftovers from previous drug usage (WHO, 2022).

HVAC (heating, ventilation, and air conditioning) systems provide heating and cooling for buildings that are residential, commercial, or industrial. The main purpose of HVAC systems is to keep people' interior spaces healthy and pleasant; well-designed, efficient systems achieve this with low emissions of air, water, and non-renewable energy pollutants. An HVAC system plays a critical role in a pharmaceutical facility by managing the manufacturing environment. The World Health Organization (WHO) reports that temperature, humidity, and air distribution system have a significant impact on a pharmaceutical plant's product quality (Peris, 2019).

A vital component of many pharmaceutical and life science processes is water. In the processing, formulation, and production of pharmaceutical goods, active pharmaceutical ingredients (APIs), and intermediates, water is widely employed as a raw material, component, and solvent. The quality of the water used in the manufacturing of pharmaceutical products must adhere to international standards. Systems for the manufacture, storage, and distribution of pharmaceutical water must be properly planned, built, tested, certified, and maintained to guarantee the consistent supply of water with the right quality (Gupta, 2016).

H. Government support

Many players that make up the pharmaceutical manufacturing system dictate the environment in which pharmaceutical manufacture occurs. The producers themselves, trade associations, different government ministries, national medicines regulatory authority (NMRAs), and a variety of distribution routes are some of these organizations. Institutions that train the human capital needed for this knowledge intensive industry are other important participants. The ability and willingness of businesses to produce goods that meet international standards, as well as the extent to which such production may be sustainable, are determined by the combined effect of these various actors. Ensuring that products are manufactured in accordance with Good Manufacturing Practices (GMP) should be a primary responsibility of the regulator. It should also supervise product distribution to guarantee compliance with

Good Warehousing Practices (GWP) and Distribution Practices (GDP), and monitor the market through post-marketing monitoring and pharmacovigilance. The growth and sustainability of a nation's industrial sector can be supported by a variety of government departments using the policy tools at their disposal (AUC-UNIDO, 2012).

Governments provide a variety of fiscal and non-fiscal policy incentives to encourage the production of medical goods locally. It is crucial from the perspective of public health that this support specifically attempts to increase people's access to locally made medical products in addition to encouraging industrial development. Government incentives must support the common objectives of industrial and health policies in order to accomplish this. To ensure that local industry eventually becomes competitive in the marketplace, government support must be predicated on a long-term strategy. Such assistance cannot be unending or constant. The kind of assistance and mix of incentives that governments should offer to private businesses cannot be determined by a single, set formula. It should change over time and change depending on the situation (WHO, 2021).

2.2.2 Pharmaceutical Industry in Developed Countries

Based on metrics such as production levels, imports and exports, R and D investments, and employment, the global pharmaceutical business is expanding at a rapid pace. Germany and Switzerland have the top-ranked pharmaceutical sectors in terms of exports and production volumes.

Recently, the pharmaceutical market has experienced remarkable growth worldwide. Compared to 2001, when it was valued USD 390 billion, the market was valued over USD 1.25 trillion in 2019. With 48.9% of worldwide pharmaceutical revenue coming from North America, the US continues to lead the pharmaceutical industry. But recently, several emerging countries have started to make a big difference. Economies such as those of Brazil, India, Russia, Colombia, and Egypt are examples of emerging markets. Even though Latin American countries are involved in this growing sector, their share of global profits is still rather small. In contrast, the pharmaceutical industry in China has grown at the quickest rate in recent memory (Mikulic, 2022).

Switzerland's best industry to work in is the pharmaceutical sector. Approximately 61.4 billion Swiss francs of value added were produced along the whole value chain in 2020 concerning the manufacture, research, and development of pharmaceutical products; in fact,

one out of every eleven Swiss francs earned in Switzerland was generated in this manner. The prosperity of pharmaceutical companies benefits a large number of enterprises in other economic sectors. The pharmaceutical industry's capacity for innovation has allowed it to grow significantly over the previous several decades and has made it a very competitive global market.

More than 500 pharmaceutical companies, including both domestic corporations and subsidiaries of foreign corporations, are based in Germany. After the United States, China, and Japan, Germany is the fourth-biggest pharmaceutical market globally and the largest in Europe. The pharmaceutical industry as a whole saw a 5.7% growth in revenue in 2019 to reach EUR 46.4 billion. The pharmacy segment accounted for approximately 86% of sales, with the clinic segment contributing 14%. Pharmacies sold 58.8 billion euros worth of drugs in that same year, an increase of 5.3 percent. Eighty-seven percent of these sales were made up of prescription only medications. Whereas non-prescription drugs only produced 12 percent of revenue, they accounted for half of units sold (Julia Albrecht, GTAI; Gregor Kemper, 2021) .

The pharmaceutical industry spent around € 39,600 million on research and development in Europe in 2020. Between 1995 and 2005, there was a notable movement in economic and scientific activity towards the US due to a decade of strong US market dominance; this tendency has been intensifying since 2015. Furthermore, developing economies are becoming a greater threat to Europe: the market's rapid expansion as well as the research climates in nations like China and Korea are pushing businesses and researchers away from Europe and into non-European markets. China almost tied Europe in 2021 for the newest active ingredients introduced to the global market, with 18 and 19 new compounds introduced, respectively. The US led the field with 35 new compounds out of a total of 95. The pharmaceutical market's geographic distribution and, eventually, the R and D base are probably going to steadily migrate toward rapidly developing nations. (DiMasi et al., 2016).

From 2021 to 2028, the pharmaceutical manufacturing market is expected to develop at a compound annual growth rate (CAGR) of 11.34%, from a 2020 valuation of USD 405.52 billion. The pharmaceutical sector has seen a dramatic shift with the advent of new technology and more affordable and efficient manufacturing methods. In addition, a rise in

the flow of investments in this industry has helped the market grow. (Grand View Research, 2020).

At ex-factory costs, the global pharmaceutical market was predicted to be worth € 943,667 million ($ 1,077,856 million) in 2020. With a 49.0% share, the North American market (USA and Canada) continued to be the largest market in the world, far ahead of China, Japan, and Europe. (IQVIA, 2021).

The Indian pharmaceutical business has grown significantly in the last fifty years, both domestically and internationally. When compared to 1969, they accounted for just 5% of global medicine consumption, local pharmaceuticals now account for a substantial 80% of the market in India. More significantly, over same time period, the country likewise gained a commanding presence in the world's basic pharmaceutical market, obtaining the moniker "Global Pharmacy". The Indian pharmaceutical industry contributes more than 20% of the volume of the global generics market and 62% of the world vaccination demand. Both in Republic of India and around the world, the industry has made a substantial contribution to improving public health outcomes. Among the top ten industries for decreasing the exchange imbalance besides luring in overseas direct investment, pharmaceutical industry has been considerably boosting India's economic growth. Between April 2000 and June 2020, the medicines and the pharmaceutical industry received collective overseas direct investment inflows totaling $16.54 billion USD. Additionally, the trade surplus it has been producing US$20.7 billion in pharmaceutical exports and US$2.31 billion in imports in FY204 makes it of utmost significance. The industry is 14th globally in terms of value and third globally in terms of volume, employing about 2.7 million people directly or indirectly (FICCI, 2021).

2.2.3 Pharmaceutical industry in Developing Countries

The pharmaceutical manufacturing sector has experienced tremendous expansion in recent years, as evidenced by the sharp rise in the number of Chinese pharmaceutical manufacturing firms, as well as the notable increases in industrial operational income and profit. Based on information from the China High-tech Industry Statistical Yearbook 2021, there were 8170 pharmaceutical manufacturing companies in China in 2020 that were larger than the allowed size, with 1563 of those companies being large and medium-sized. There are 2473 manufacturers of chemical medication, 1540 manufacturers of finished traditional Chinese

herbal medicine, and 909 manufacturers of biopharmaceutical products, according to industry classification (Guan et al., 2022).

The pharmaceutical industry currently produces medications for humans in 62 companies, medicines for animals in 8 companies, and 73 companies that produce Ayurvedic remedies. Through importers, 390 international pharmaceutical companies supply medications to Nepal. Pharmaceutical product import and domestic production statistics were analyzed, and it was found that the market shares of pharmaceuticals from other countries are 2%, those from India are 52%, and those from home production are 46% (Gyawali and Shrestha, 2021).

Once the initial patents expire, the pharmaceutical business mostly concentrates on producing generic versions of pharmaceuticals, with biologics and vaccines still in the early stages of development. Improvements are needed to the degree of R and D and innovation, as well as the ability to invest in and produce technology. However, in response to public health problems, the COVID-19 pandemic has been both a crisis and an opportunity, spurring improvements in the basic R and D system for vaccine development and manufacture. The government provided funding of 5,480.22 million baht, the highest drug development budget in Thailand's history, during this period of unparalleled cooperation between the public and private sectors, including international organizations. Determining how this R and D breakthrough will impact the long-term expansion of the pharmaceutical business remains a crucial challenge (Loylom Prasertsri, 2024).

600 pharmaceutical firms operated in Africa in 2020, with 80% of them focused in just 8 nations: Nigeria, Ghana, Kenya, South Africa, Algeria, Morocco, Egypt, and Tunisia. There were just four countries with over fifty firms, whereas 22 nations did not have any domestic production. About 25% of the 600 were global corporations (Ussai et al., 2022).

For years, people have debated and investigated the possibility of high-quality, affordable medications being produced nationally or locally to meet the requirements of the general public. Evidence shows that the pharmaceutical industry is crucial to the general health of its inhabitants in emerging countries (Urias, 2017).

Pandemic COVID-19 has served as sobering a prompt reminder of the significance of pharmaceuticals to human welfare. Many individuals are left behind, especially in developing nations, which is a reflection of the pharmaceutical industry's current dismal performance in various parts of the world. The majority of the medications required in Sub-Saharan Africa are imported, making the native population there incredibly susceptible to illness and other

hardships. Certain diseases are specific to Africa, therefore medications that are imported may not always be successful there. One example of this is the ineffectiveness of various COVID-19 vaccinations against specific local strains of the virus (ILO. 2022).

Africa continues to have a high rate of sickness because of substantial barriers to acquiring high-quality medications. Less than 60% of necessary medications are reportedly available in the public sector throughout the continent. This shortage is partly caused by Africa's over reliance on foreign medical supplies. There is widespread agreement that improving the continent's capacity to produce reasonably priced, high-quality medications would benefit both public health and economic growth. A business tactic that offers a roadmap for assisting the African pharmaceutical manufacturing industry and the manufacture of superior vital medications was also created in 2012. The Pharmaceutical Manufacturing Plan for Africa business plan fervently advocates for the purchase of medical goods from African-based businesses in order to increase domestic pharmaceutical manufacture and, consequently, enhance public health results. The proposal suggests using pooled procurement as a tool to encourage local manufacturers to solve maternal, newborn, and child health in addition to bolstering the supply chain management and procurement systems. The business plan for the pharmaceutical manufacturing strategy for Africa emphasizes how urgent it is to address the issues the sector is facing. The inability to obtain inexpensive financing and contemporary technology is one such issue that prevents company growth. (UNECA, 2020).

In Africa, there is an immediate need to revitalize the domestic pharmaceutical sector. Since diseases vary, medications that are effective in one area of production might not be effective in treating patients in another region into which they are imported. Even while several African nations, already manufacture pharmaceutical items, the continent still ingresses around 80% of its medicinal supplies and medicines (Byaruhanga, 2020).

The subregion of Africa is largely dependent on the importation of pharmaceuticals and raw materials for the production of pharmaceuticals. (Akande-sholabi and Adebisi, 2020; Beargie et al., 2019). In the last ten years, a number of continental and global initiatives have been launched with the aim of augmenting domestic pharmaceutical output throughout Africa, expanding the availability of vital medications, and strengthening export prospects. Among these is the Pharmaceutical Manufacturing Plan for Africa (PMPA) of the African Union (AU), which seeks to enhance Africa's capacity to manufacture reasonably priced, high-quality pharmaceuticals for all necessary medications that improve health outcomes and generate both direct and indirect economic benefits. Many international donors and

implementing organizations collaborate with developing nations to support programs aimed at enhancing local production, bolstering regulatory frameworks, and improving access to medications. Globally, developing nations could make use of the public health-related WTO TRIPS flexibility to complement and possibly replace imported medications with domestically produced ones.

African manufacturing is still very young and faces several structural obstacles. These include low productivity levels, inadequate energy and transportation infrastructure, a lack of skilled labor, and a lack of creative entrepreneurs. Lack of savings is another significant barrier, since it prevents manufacturing companies from making the kind of sizable capital investments that are required for their development.

Africa's capacity to find and develop medications that address local needs is being seriously hampered by a lack of innovative pharmaceutical companies and highly qualified pharmaceutical experts. Due to a lack of skilled workers, Sub-Saharan Africa has not been able to find and develop the medications needed to solve this issue through existing facilities and educational initiatives. Academic institutions are also ill-positioned to close the gap (Babalola et al., 2024).

With a market value estimated at $56.6 billion, Egypt is the biggest producer and consumer of pharmaceuticals in the Middle East and North Africa (MENA) area. With $400 million in exports, it is a major participant in the worldwide supply chains for pharmaceuticals, demonstrating the industry's strength and significance to the Egyptian economy. At the moment, almost 90% of the raw materials utilized in Egypt's pharmaceutical industry's production are imported. Egypt has several chances to increase its economic complexity through the pharmaceutical sector, as the industry has a reasonably high level of average complexity from a microeconomic standpoint (The African Development Bank Group, 2023).

2.2.4 Pharmaceutical industry in Ethiopia

Ethiopia has had a brief history of producing pharmaceuticals. EPHARM, the nation of Ethiopia's first pharmaceutical manufacturing facility, was established in 1964 as a joint venture between Smith and Nephew of Britain and the Ethiopian government. Israel's Teva Jerusalem replaced Smith and Nephew in 1971. The corporation was nationalized after the military overthrew the monarchial monarchy in December 1975. There are currently 15 pharmaceutical manufacturers in Ethiopia, of which nine make pharmaceuticals, one makes

empty gelatin capsules, and the remaining four make medical devices (Gebremariam et al., 2016).

The majority Ethiopian medicinal market 65% to 75% is comprised of imports, which come mostly from Belgium (13%), the Netherlands (20%), and India (22%) (Gebre-mariam et al., 2016). The majority of imports in 2019 consisted of finished items, accounting for almost 80% of all pharmaceutical products imported (Jaco Maritz., 2022). With just 11 manufacturers, 45% of which are jointly owned by foreign and local investors, there is little domestic rivalry. China has two joint ventures and one fully-owned company in Ethiopia's pharmaceutical industry, making it a growing force.

The government of Ethiopia has implemented a number of initiatives to enhance the industry. The country created a ten-year plan for the production of pharmaceuticals. By 2025, the domestic pharmaceutical market in Ethiopia might be valued more than $1 billion USD. An increasing middle-class foundation and 5.4% urbanization rate annually are predicted to fuel growth, which will increase availability of health-care (Australian Government, 2020).

The 279-hectare Kilinto Park is the first industrial park of its kind in Africa, and 136 of those hectares are used for the production of pharmaceuticals. The park is 863 kilometers from the port of Djibouti, 15 kilometers from the heart of Addis Abeba, and 10 minutes by car from Bole International Airport. In order to facilitate speedy setup, investors are given access to land that has been serviced or is ready for use (Jaco Maritz., 2022).

The Ethiopian government thinks that by encouraging and supporting the production of value-added goods for the export market, it will boost foreign exchange and create the conditions for an even faster rate of industrial development. Ethiopian government procurement mechanisms provide up to thirty percent of the order value in advance payment to local pharmaceutical producers. In certain instances, businesses are also provided with technical support and consulting services to aid in their adherence to global drug manufacturing standards. The Food, Beverage and Pharmaceuticals Industry Development Institute was established, regulatory authority was strengthened, and the foundation for laws and incentives aimed at promoting the sector's growth and investment was laid. These are examples of indirect government support. Tax-free loans up to 70% for new investments and 60% for renovation projects completed in the first five years are provided by the Ethiopian government. Furthermore, imports of capital goods are exempt from customs duties to the

extent of 100%, and spare parts up to 15% of the total value are also exempt. Local firms are given a 25% price preference and a shortened product registration period by the PFSA (MOH and MOI of Ethiopia, 2015). In technical terms, improving domestic pharmaceutical systems entails fortifying the foundational elements of health systems, such as legislation, governance, policy, regulatory frameworks, innovation, R and D, production, and commerce, as well as funding, information, and human resources.

3. METHODOLOGY

3.1. Area of Study

The investigation was carried out in pharmaceutical industry/companies which, was found in Ethiopia is situated in Africa's Horn of Africa, which is its northeastern region. Kenya borders it on the south; Somalia borders it on the east and southeast; Sudan and South Sudan border it on the west; Eritrea and Djibouti border it on the northeast. Ethiopia's latitude and longitude are between 30o N and 150o N, the Equator and the Tropic of Cancer, and 330o E and 480o E, respectively. (Ministry of Health, 2021).

3.2 Design of Research

A qualitative case study approach was employed, with the pharmaceutical manufacturing industry selected as the case for investigation.

This study was employed a qualitative descriptive study methodology to investigate the difficulties face by the pharmaceutical manufacturer and examine the role played by the different stakeholders working together with this sector. By employing observation, interviews, focus groups discussion (FGD), document analysis, and other methods to gather data from a limited number of respondents, qualitative research assists the researcher in conducting a thorough study of the data (Creswell, 2009). Both focus groups and key informant interviews were utilized to gather a detail information on the subject matter.

3.3 Sampling and Participants

A purposive sampling strategy was used in this study. A key informant interviews was conducted with individuals having positions as plant manager, production manager, and quality assurance managers who are working in pharmaceutical industries located in Ethiopia. Moreover, key informants from the supporting stakeholders Armauer Hansen Research Institute (AHRI), investment commission, government regulatory authority, pharmaceutical supply agency and bank (AHRI, EIC, EFDA, EPSS, Bank) was also purposively sampled to take part in the study.

3.4 Sample size

The interview went on until it reached a saturation point, at which time no more information could be obtained in relation to the goals of the study and the body of existing literature. Based on the saturation points, twelve participants, who have more experience in

pharmaceutical manufacturing practices and managerial position from the supporting stakeholder organizations were included in this study.

Experienced eight technical managers of the pharmaceutical industries were included in the FGD as a participant of the study.

3.5 Data Collection Technique

3.5.1 Source of data

The primary data for this study came from key personnel of the domestic pharmaceutical manufacturer using key informant interviews and FGD. In addition, to the above a key informant interview was conducted with the supporting stakeholder such as, Armauer Hansen Research Institute (AHRI), investment commission, government regulatory authority, pharmaceutical supply agency and bank (AHRI, EIC, EFDA, EPSS, Bank).

3.5.2 Data collection methods

To get qualitative information, a key informant interview (KII) was done. Key informant interviews (KII) facilitate the sharing of people's experiences and help the researcher obtain adequate knowledge on the topic of inquiry. The selection of the key informants was based on their expertise in the field, their roles, and their experiences from relevant stakeholders of sector. To conduct the key informant interview, a semi-structured interview guide was created. To enhance the interview guide, namely the interview questions, four preliminary pilot interviews were conducted. An introduction and the study's goal were given to the key informants as a guide for the interview process. In order to continue with the interview, the key informants were also asked for their permission. An interview was set up after the consent was obtained. The key informant interview involved the researcher taking copious notes and tape recording for those who expressed their willingness. An average of 45 minutes had been allotted to key informant interviews.

Focus Group Discussion was conducted to get incredibly rich qualitative data that is hard to collect through other methods on the obstacles that the pharmaceutical maker must overcome from key personnel of the companies. The data gathered from the key informant interviews was additionally confirmed and checked with the assistance of the FGDs. A semi-structured discussion guide was created to facilitate a detailed discussion. Respondents have been given a discussion guide on consent and confidentiality issues. Once the responders have given their agreement and the guide has been reviewed, the discussion was performed. The interview guide included inquiries regarding notable obstacles encountered by

pharmaceutical companies, the underlying reason for the difficulties, the type of intervention taken by the company, and any support obtaining from the stakeholders. Through meticulous note-taking, responses have been documented.

Review of pertinent documents: In order to comprehend the global experience of pharmaceutical industry, available industries in the countries, and to gather data on the challenges they faced and government support.

3.6. Data Analysis Technique

Since the study's primary goal was to investigate major challenges faced by local pharmaceutical manufacturer, primary data collection was done through key informant interviews and FGD mainly. Some of the interviews were recorded, and those that gave their permission to do so had their voices spoken. To gain an understanding of the data, the researcher replayed and listened to the recorded responses. Memoranda that had been taken throughout the interview assisted in the transcription of the data. The transcribed data was translated, and the precision of the translation was verified by carefully reviewing and re-examining the written and audio recordings of the data. After transcribing the results of the interview, the researcher grouped replies according to similarities. Themes were created by carefully piecing together a comparable line of stories. A study can be handled in three various ways whereas inductive, deductive and adductive. The primary distinction among both deductive and inductive study methodologies is that the former focus on developing new theories from the data, whereas the latter aims to test existing theories. Since this study was qualitative, a hybrid (inductive and deductive) research approach was used to examine novel ideas and test existing theories for the pharmaceutical manufacturing sector. Major themes are created by combining related themes that have been developed into subthemes. Then, in order to illustrate possible connections between themes and subthemes, the identified codes were grouped into themes using thematic maps. To guarantee coherence between the themes, coded extracts, and the complete data set, the selected themes were then examined and improved.

3.7. Ethical considerations

After proposal was approved by the advisor, the letter of cooperation was written from the College of Business and Economics at Ababa University to the study participants organizations.

Researcher made sure that there was no harm done by participating in the study during the data collecting. Since the study is qualitative and requires key informant and FGD recording responses to ensure information is captured accurately, participants were informed that the researcher would need their full agreement before interviewing them.

In an effort to investigate the challenges encountered by a domestic pharmaceutical manufacturer, the researcher adhered to confidentiality standards and made sure that participant identities remained anonymous. The researcher also informed the participants that, they were free to end the interview at any time.

My attention was naturally drawn to the ethical issues in pharmaceutical manufacture throughout this study because I am a pharmacist with years of expertise in the different pharmaceutical sector. Although I made an effort to maintain objectivity, I acknowledge that my professional beliefs influenced how I perceived the difficulties manufacturers faced. By participating in peer review and cross-referencing results with people from various professional backgrounds, I used to lessen this prejudice. In order to have a more comprehensive picture of the difficulties pharmaceutical businesses encounter, I also spoke with academics, suppliers, and industry professionals who focus on manufacturing and regulatory affairs.

4. DATA ANALYSIS

A descriptive qualitative study using thematic analysis was conducted in order to explore the challenges of domestic pharmaceutical manufacturer in Ethiopia. Key informant interviews and FGD were conducted with 12 and 8 participants respectively.

Overview pf the pharmaceutical Industry

Ethiopia's pharmaceutical manufacturing industry is essential to enhancing public health and expanding access to medications. To reach its full potential, though, further training, technology, and infrastructure expenditures are needed. Currently, eleven manufacturers produce finished pharmaceuticals in Ethiopia. Among them, Acure was established the youngest and participating in the manufacturing of the products as of now. About fifty percent of them are operating as a joint venture and out of which, 54.5% of them are established after 2000 GC. About 45.5% of them are complying with current good manufacturing practice (cGMP) requirement of the EFDA. Some of them are started exporting a few types of products to other African countries.

Table 1: Companies profile

S. No	Company	Years of establishment	Type of investment
1	Ethiopia Pharmaceuticals Manufacturing SC	1964	Local investment
2	East African Pharmaceuticals PLC	1996	Joint venture
3	Addis Pharmaceutical Factory SC	1997	Joint venture
4	Pharmacure PLC	1998	Foreign investment
5	Medsol Pharmaceuticals Manufacturing	1999	Local investment
6	Cadila Pharmaceuticals (Ethiopia) PLC	2003	Joint venture
7	Julphar Pharmaceuticals PLC	2013	Joint venture
8	Human Well Pharmaceutical Ethiopia PLC	2015	Foreign investment
9	Sansheng Pharmaceuticals PLC	2018	Foreign investment

10	Kilitch Estro Biotech private limited company (KEBPLC)	2020	Joint venture
11	Glocare Pharma Manufacturing PLC	2021	Joint venture

Source: Own Survey, 2024

The finding of the study is presented using ten main themes. The ten themes Include: source of challenges in strategic planning and implementation; challenges of efficiency in pharmaceutical production; challenges faced in international finance; challenges related to regulation; challenges in supply chain management; challenges related to human resource management; challenges of the infrastructure; root cause analysis and methods to tackle the challenges; technical assistance and support and, suggestions and area of improvements.

1. Source of challenges in strategic planning and implementation

Table 2: Thematic framework explaining the themes, sub-themes, and issues associated with the Source of challenges in strategic planning and implementation.

Themes	Subthemes	Codes (Issues)
Source of challenges in strategic planning and implementation	Challenges in strategic planning and implementation	Not implemented of strategic plan
		Not having a clear directives, rules and regulations
		Lack of clear communication and feedback system
		Lack of clear accountability

Source: Own Survey, 2024

Most of the participants were believed as a clear policy was established in 2016/2017 GC after a government was intervened based on the declining status of the sector. Even though, the government was developed a five-year national strategic plan, it was not implemented as required. The participants from the FGD group, addressed the idea as follows. *"There was a five-year of National strategic and Plan of action however, it was not implemented. This is because a clear directives, rules and regulations were not approved on how to implement the strategy".* (FGD Participant 3, WE 25 years)

The other participant from the FGD group also emphasizes about the having a well-crafted policy in the country that guided and even can transform the sector to the better status. However, due to not implemented it remains as it is. It was explained in the following quotes. *"The Trade and Industry Ministry and Ethiopian Investment Commission collaborated to create the finest policy recommendation in 2017, which was anticipated to revolutionize the subsector. But for the last seven years, the policy has not been completely implemented".* (FGD Participant 5, WE 18 years)

The study participants from the manufacturer highlighted the reasons for not implementation of the strategic plan and policy in the sector. According to their view, the main rationale is weak communication and feedback system of the different responsible organization. Moreover, lack of clear accountability among the stakeholders is the vital hindrances. Pharmaceutical strategic planning is a team effort; without open lines of communication and a quick feedback loop, the plan may devolve into a collection of unrelated projects rather than a coherent course of action.

2. Challenges of Efficiency in Pharmaceutical Production

Table 3: Thematic framework explaining the themes, sub-themes, and issues associated with the Challenges of efficiency in pharmaceutical production

Themes	Subthemes	Codes (Issues)
Challenges of efficiency in pharmaceutical production	Reduced production capacity	Operates below its actual capacity
		Exist without any growth
		Decreasing production rate
		Lack of maintenance

Source: Own Survey, 2024

The pharmaceutical industry in Ethiopia relies on importing medicines and other medical products. There are few local manufacturing companies in the sectors, only contribute less than 10% of the market. The local manufacturer also used imported raw material for their production. The current overall situation of pharmaceutical industry in Ethiopia is explained weak not that much fertile and the respondents quote illustrated as follows *"The production*

capacity was declining year by year and unable to contribute to the country with regard to GDP. From the past five years their number has not been significantly increased as expected; Only 11 Pharmaceutical manufacturers exist without any growth". [Participant 1, Manu, Male]

The production rate is a key indicator of how quickly and efficiently the manufacturer can produce drugs while satisfying stringent quality standards plus regulatory requirements in pharmaceutical sector. This rate, often quantified in units or batch per hour/day is key to meet consumer demand, optimally utilizing resources and ensuring timely availability of critical prescriptions. The majority of the study participants agreed that, from time to time the number of shifts they produced drugs are decreased. This idea found complimented with response of one study participant. *"In contrast to our former schedule, our organization now uses some shifts to manufacture the medications. This impacts our manufacturing rates currently".* [Participant 3, Manu, Male]

Pharmaceutical production is significant to the world's health since it impacts on the use of medication for various diseases. It is connected to production capacities and productivity or ensuring that inventories of required medicines are accessible to numerous people most especially in an outbreak. It also fosters public health programs as well as increases an economy manufacturing capacity and competitiveness thus affecting its affordability. However, the current practice of manufacturing in the country declining through different reason as mentioned by the study participants. One of the participants stressed his idea as follows "*Our company currently operates below its actual capacity and has low productivity levels as a result of difficult to obtain the raw materials and other recurring issues*". [Participant 5, Manu, Male]

Preventing unforeseen malfunctions and stops in production can be achieved by routine maintenance of facilities and equipment. Particularly, the nation lacks reliable maintenance and repair services for laboratory instruments and pharmaceutical equipment, despite the dire need for them. The nation's existing lack of these services causes delays, raises maintenance and repair costs, and prolongs equipment downtime, all of which have a detrimental effect on the industry's ability to compete on the whole. Reducing idle time is essential to sustaining production effectiveness. However, throughout the conversation, it was brought up that one of the reasons the country's technical equipment isn't operating as efficiently as it should be is due to the lack of technical organizations with the capacity to maintain it. One of the study participants highlighted his view as follows *"Unexpected malfunctions, which disrupt our*

operations and slow down production, are typically caused, in my opinion, by the lack of well-qualified organizations in the nation that perform pharmaceutical equipment maintenance. This not only messes with our schedules but also drives up operating expenses." [Participant 2, Manu, Male]

3. Challenges faced in International Finance

Table 4: Thematic framework explaining the themes, sub-themes, and issues associated with the challenges faced in international finance.

Themes	Subthemes	Codes (Issues)
Challenges faced in international finance	Challenges related to forex and foreign exchange rate fluctuation	Lengthy waiting list for hard currency
		Deficiency of forex
		Fluctuation of exchange rate

Source: Own Survey, 2024

The pharma sector typically manufacturing is quite different from other manufacturing sectors like garment, food and chemicals. Respondents explained the main challenge faced currently by the pharmaceutical company to manufacture the product as follows. Almost all of input materials are imported from abroad. Only packaging materials are available. Therefore, the sector requires huge amount of foreign currency.

Participants said that a significant problem facing the Ethiopian economy as a whole is the lack of foreign exchange. Even with the government's special attention to the pharmaceutical industry, it is challenging to obtain the foreign exchange required in time to purchase supplies and materials. Some of the study participant responses are illustrated in the quote as mentioned here. *"The main challenge is hard currency. As we know, pharmaceutical is high-tech industry. Almost all materials should be imported from foreign countries for local manufacturer; means huge amount of hard currency is needed. Otherwise, difficult for us to continue of manufacturing. Other challenges we faced such as lack of techniques, no stable power supply, very difficult to find chemicals and spare parts for testing and maintenance"*. [Participant 5, Manu, Female]

Other study participant also addresses, the deficiency of the foreign currency in the country hits the sector heavily. The participant in the interview touched on how fluctuations in foreign exchange rates can have a big impact on the pharmaceutical business. *"As to me, in addition of shortage of raw materials and lack of sustainable financing, a continuous increasing of cost of products due to fluctuation of exchange rate was the main challenges this time to produce pharmaceutical products in the country".* [Participant 1, Manu, Male]

As most of the study participants explained, most of the time, their company spend more of their local currency to buy the same amount of foreign goods because the majority of the materials required in the manufacturing of medications are imported. The participants stated that budgeting for future costs or profits presents difficulties for businesses, which might have an effect on long-term investments and strategic planning. The following quotes of one participant found in line with the above idea. "*The main challenges are a deficiency of foreign money needed to purchase raw materials and spare parts aimed at equipment and machines. Furthermore, there is no raw material manufacturer in the country. Even the packaging materials came from abroad. That made the issues worse for our company".* [Participant 4, Manu, Female]

The response of key informant participant is found compliment with the response obtained from the focus group discussion which is quoted as follows. During the discussion, the participant highlighted as there is long waiting queue for obtaining of the hard currency in addition to the shortage or unavailability of the forex in the country. As per the participants response, even priority is given for importer rather than the local manufacturer during the distributing of the currency. The quotes of the participants addressed as follows. *"Comparing our local pharmaceuticals industries to importers of pharmaceuticals, domestic manufacturers assert that significant production barriers result from inadequate and relative delays in foreign currency allocation. Currency waiting lists are still lengthy even after giving priority to pharmaceutical importers when allocating foreign exchange".* [FGD Participant 7, WE 26 years]

4. Challenges related to Regulation

Table 5: Thematic framework explaining the themes, sub-themes, and issues associated with the challenges related to regulation.

Themes	Subthemes	Codes (Issues)
Challenges related to	Challenges related to product	Product registration was a

regulation	registration and laboratory testing	lengthy
		Having small number of market authorized medicine
		Long product test waiting time

Source: Own Survey, 2024

Timely authorization and evaluation are necessary to provide timely access to medications. In this sense, the amount of time needed for a nation's registration procedure is crucial. On the other hand, few data exist regarding how well the registration procedure is working in many developing nations. One of the study participants view addressed as follows *"A high percentage of product registration issues have a negative impact on their marketing efforts. The most frequent problem with product registration was a lengthy document review process and laboratory testing time".* [Participant 2, SH, Female]

When compared to prior practices, nearly all participants indicated that the registration system is undergoing a thorough and hopeful change, particularly in light of the launch of the online application site and electronic information and regulatory system (eRIS). Participants do, however, report that the system continues to have serious consistency issues, both with regard to the registration timeline and decision-making. The perspectives of the participants about the scenario are shown in the following quotes. *"The main obstacles restricting the effectiveness of Ethiopia's regulatory system are the small number of authorized medications and lengthy registration waiting periods, even with the EFDA's fast track system to program medications and locally produced goods".* [FGD Participant 1, WE 15 years]

In the pharmaceutical sector, the approval procedure for medications is essential to guaranteeing the availability of safe and efficient therapies on the market. On the other hand, delays in medication testing and approval by regulatory bodies can have serious consequences for patients waiting for new treatments as well as pharmaceutical corporations. The participant of the study addressed the issue as follows. *"One of the challenges we face from the regulatory side is the delay in receiving the testing result, which in turn affects our market strategy"*. [Participant 3, Manu, Male] Regulatory bodies are frequently entrusted with examining and testing a significant number of submissions from various clients, which

could be the cause of the delay. The authority workload grows in tandem with the number of new medication applications, which could result in backlogs and longer periods of waiting to undergo testing and approval.

5. Challenges in Supply Chain Management

Table 6: Thematic framework explaining the themes, sub-themes, and issues associated with the challenges in supply chain management.

Themes	Subthemes	Codes (Issues)
Challenges in supply chain management	Challenges related to procurement and importation	Forced to quote with local currency during international competitive bidding
		Long lead time
		Unavailability of material in the country
		Discontinuing the 30% advance payment

Source: Own Survey, 2024

According to the participants issues with procurement process and supplies are the other critical challenges faced by the manufacturer. Most of the participant agreed and appreciated the significant impact of hindrance related to the procurement issue. There are issues with the procurement system that EPSS has to address. In order to increase the efficiency of local production and foster a dynamic, competitive local pharmaceutical manufacturing system, the system needs to be strengthened and support measures should be provided. One study participant explained as follows *"The procurement process affects us mostly. Despite the Foreign currency problem in the country, local industries that participate in international competitive bidding, tenders are compelled to quote in local currency, while foreign enterprises use USD or EURO. Because there is a significant delay between the date of the tender quotation and the product delivery, the periodic devaluation of the Ethiopian Birr has caused problems for local industries".* [FGD Participant 8, WE 17 years]

According to resource dependence theory, local manufacturers may be weakened by the dependency dynamic created by relying on overseas suppliers for APIs. When the most crucial production inputs are controlled by these suppliers, which are frequently big, international pharmaceutical companies, local businesses are exposed to supply disruptions, price swings, and even modifications in trade regulations. Problems to global supply chains during crises like the COVID-19 pandemic brought to light how indigenous producers in developing nations were unable to create necessary medications without access to international raw ingredients. This idea found supported by the respondents from the stakeholders explained the challenges faced the local manufacturer as follows. *"Active Pharmaceuticals and chemicals are widely imported from nations like China and India by our pharmaceutical industry this will have it is own negative impact like high-cost fluctuation, long lead time and transportation cost".* [Participant 1, SH, Male]

The purpose of the thirty percent advanced payment procedure is to help local manufacturers by giving them the money they need to pay for the beginning costs of manufacturing. This advance aids in cash flow management for manufacturers, enabling them to control labor expenses, acquire raw materials, and guarantee timely pharmaceutical manufacturing. EPSS hopes to promote a more stable and dependable local industrial environment by obtaining this advance payment. One study participant, however, refuted his theory by contrasting the previous assertion. *"Currently, the EPSS has discontinued the thirty percent upfront payment for most of the local pharmaceutical companies when awarding contracts."* [FGD Participant 5, WE 18 years]

6. Challenges related to Human Resource Management

Table 7: Thematic framework explaining the themes, sub-themes, and issues associated with the challenges related to Human Resource Management.

Themes	Subthemes	Codes (Issues)
Challenges related to Human Resource Management	Challenges of talent, retention and training of personnels	Shortage of skilled experienced personnel
		High turn over
		Lack of training

Source: Own Survey, 2024

One of the mainstays of contemporary healthcare, the pharmaceutical business, is severely lacking in qualified workers. This deficiency is a serious problem that jeopardizes patient safety, the effectiveness of drug development, and the expansion of the business as a whole. It is not merely a small annoyance. During the discussion, one of the participants highlighted the following idea, which is complimented with the above statement. *"It is getting more and harder to find qualified personnel who can operate the complex machinery we utilize in manufacturing. The company's overall operations are impacted by these problems".* [FGD Participant 3, WE 25 years]

One of the main challenges facing the pharmaceutical companies that deal with human resource management is keeping experienced staff. One of the study participants stated *"Entirely, not much has been done for managing our skilled professionals in pharmaceutical companies, and therefore, our talented and experienced professionals have always been hunted by rivals; consequently, as a result, the typical turnover rate of equipped and talented employees in our companies is high".* [Participant 2, Manu, Male] Payment is not the only factor that contributes to employee turnover; other factors include opportunities for education and more free time.

Participant 2 from the manufacturer addressed the rationale for high employee turnover rates in the pharmaceutical industry by saying, *"Pharmaceutical industries must keep up with other sectors where qualified individuals can work. Since it is a fact that pharmacists choose to work in pharmacies where they are paid more than those in the company and are required to put in less labor."*

In the pharmaceutical sector, training fulfills a number of vital purposes. First of all, it guarantees that staff members are knowledgeable about the most recent developments in technology and business practices. Second, in order to comply with strict regulatory standards, training is essential. The regulatory bodies impose strict regulations on the pharmaceutical industry. To guarantee that products are produced, tested, and promoted in compliance with legal standards, employees must be well-versed in these regulations. Sufficient training guarantees that novel treatments can be introduced to the market without difficulty and helps avert costly regulatory violations. One of the study participants complimented this view as follows. *"The regulatory environment is always changing, but companies' training initiatives don't always keep up with this. This results in gaps in the*

knowledge necessary to assemble the dossiers, which may cause drug approvals and regulatory compliance to be delayed". [Participant 2, SH, Female]

7. Challenges of the infrastructure

Table 8: Thematic framework explaining the themes, sub-themes, and issues associated with the challenges of the infrastructure.

Themes	Subthemes	Codes (Issues)
Challenges of the infrastructure	Challenges related to facilities	Problem related with plant infrastructure
	Challenges related to utilities	Malfunction or nonexistent of HVAC system
		Inadequate water purification facilities

Source: Own Survey, 2024

The study participants stated different challenges that hinder the pharmaceutical manufacturer from attaining their mission. Issues related to infrastructure, utilities like waters and air handling units, in the country are among the mentioned obstacles. Almost all participants of the study addressed the weak infrastructure in the sector as a critical deterrent observed nowadays in the country. In addition, the participants underlined as the pharmaceutical industry's support services sector has to be strengthened. A quote of participant from stakeholder and manufacturer emphasized the above statements. **"***In addition to so many obstacles, I think, problem related with plant infrastructure, weak marketing structure, and lack of research and development capacity, are the main challenge faced by the most of the pharmaceutical company"*. [Participant 3, SH, Male]

Strict environmental regulations are applied to pharmaceutical manufacturing in order to meet regulatory requirements. It is difficult to comply with these regulations in the absence of an HVAC system, putting you at risk of non-compliance and related fines. Variations in the environment brought on by the absence of HVAC systems may result in varying product quality. This has an impact on the products' quality and the health of operators. Similar opinions addressed by the study participant in the following quote. *"One of the biggest*

issues, in my opinion, is that inadequate air quality, which affects worker health and safety, is caused by poor ventilation resulting from a broken or nonexistent heating, ventilation, and air conditioning system". [Participant 2, Manu, Male]

A key component of the drug-making process is the pharmaceutical water system, which makes sure that the water used in formulations satisfies strict quality requirements. By means of rigorous validation, careful design, and compliance with regulations, these systems facilitate the manufacturing of safe and efficacious pharmaceutical goods. The participant idea elucidated as follows. *"I would say, having inadequate water purification facilities can cause contamination and uneven water quality, which impacts the dependability of our manufacturing processes".*

8. Root cause analysis and methods to tackle the challenges

Table 9: Thematic framework explaining the themes, sub-themes, and issues associated with root cause analysis and methods to tackle the challenges

Themes	Subthemes	Codes (Issues)
Root cause analysis and methods to tackle the challenges	Root cause of the challenges	Lack of awareness about the sector
		Poor coordination among stakeholders
		Poor exportation practice
		The unavailability of API manufacturer
	Potential approach	Procure the material by parent company abroad
		Export to west Africa
		Depositing the money in different banks

Source: Own Survey, 2024

According to the study participant from the manufacturer, the topic that kept coming up was that the pharmaceutical company's inability to provide services in line with their stated aim

was primarily due to hard currency problems and a lack of detailed knowledge about them from various stakeholders. The fundamental reasoning for the occurrence of the main problem always needs to be addressed in order to prevent it from the reoccurrence. Participants are explained the root cause for the main problem as follows. *"So many problems are there. I think the main root causes are like lack of awareness about the sector by the government, shortage of foreign currency, and the impact of COVID-19 pandemic and poor export performance made the country in shortage of availing foreign currency to solve the associated problems".* [Participant 2, Manu, Male]

The above statement complimented with the response of the FGD participant, which stated as below. *"From my experience, in addition to shortage of hard currency, lack of awareness about the sector from many stakeholders, poor coordination among different stakeholders deter the industry from being fruitful".* [FGD Participant 1, WE 15 years]

Importantly, the production of basic goods especially in the pharmaceutical industry such as manufacture of drugs and other healthcare products in the global pharmaceutical company is highly vulnerable to raw material availability. Absence of raw materials inside a nation leads to a domino effect sparking issues affecting the manufacturing industry as well as the community overall health and financial stability. This statement found in line with view of the study participant response, *"To the best of my knowledge, lack of API manufacturer and adequate raw materials access in our country for some reasons, is the greatest root cause of a majority of challenges faced by the company"*. [Participant 4, Manu, Female]

In contrast to the manufacturer's perspective, stakeholders' participants clarified that the primary source of the issue was the local manufacturer's inadequate capacity, which prevented it from competing with other manufacturers on the worldwide market. They did not enter the global market by meeting the requirements of international standards since they considered their current circumstances to be favorable. One of the respondents are addressed the issue as follows *"from my understanding and experience on the sector, the limited participation of international investment flowing in to the sector and unable to compete with international company due limitation in capacity utilization are the source of the challenges for pharmaceutical manufacturer".* [Participant 3, SH, Male]

The companies tried to address the current problems by using different techniques. Some of the study participant mentioned having other business which had a capacity to generate hard currency as a revenue and used it as a supplement for pharmaceutical sector. The participant

quotes explained hereafter. *"The company is exporting of cash crops as a subsidiary business and working with banks to get supplier credit for raw materials".* [Participant 2, Manu, Male]

In contrast to the aforementioned theories, the study's participants representing other manufacturers stressed that they made an effort to get the required input materials from their parent firm, which is based overseas. Additionally, they made money by exporting medical supplies. They attempted to address the issues they encountered in their daily operations by doing this. This view was echoed in the following quotes *"For hard currency, we ask the parent company to procure materials and send them to Ethiopia by Franco valuta. In addition, we try to export medicine to West Africa to earn hard currency. However, we can only use 50% (before August 2023, it was 20%), which is unfair to the pharmaceutical industry when compared to other industries such as coffee exporting. We need to import almost every material, but there is no need for coffee manufacturing".* [Participant 3, Manu, Male]

The other participant also addressed her idea by deposing their money at different banks, they increase the chance of getting more the hard currency from multiple banks as way of tackling the faced problems. Her view is explained in the following quotes. *"Fortunately, we have liquid cash in banks. Therefore, by depositing our money in some banks, we try to collect hard currency from each one based on the deposits we have in those banks. And this helps us in covering at least 15% of our annual plan".* [Participant 4, Manu, Female]

9. Technical assistance and support

Table 10: Thematic framework explaining the themes, sub-themes, and issues associated with technical assistance and support.

Themes	Subthemes	Codes (Issues)
Technical assistance and support	Technical aid	Providing training
		Giving testing priorities
	Support	Providing preference in government procurement procedures

		Bank offers subsidized loans

Source: Own Survey, 2024

Most respondents from the manufacturer agreed that as insignificant support is obtained from the different stakeholders currently in order to compete in the market. The participants from local pharmaceutical industries explained as they did not satisfied by the support gained from stakeholders. However, technical training in different relevant topics and service priority for local manufacturer is provided by organizations in order to strength their capacity. The response of one study participant explained his idea as follows *"As far as I know so many support like GMP training, medicine registration training, and local manufacturer testing priority support are obtained from EFDA, and EPSS is changing the policy for payment currency in the coming bidding, which makes 35% hard currency a letter of credit to pay local facilities".* [Participant 3, Manu, Male]

The establishment of a pharmaceutical industry necessitates the coordinated efforts of numerous stakeholders over an extended period, regardless of the number of participating enterprises. Most of the participants from the local manufacturer emphasize and agree that the stakeholders must collaborate effectively to create acceptable, doable plans that are developed, implemented, and monitored in order to guarantee that industrial development is planned and carried out appropriately. Setting up a suitable governance framework is necessary to do this. The view of study participant illustrated below. *"The government side offered some assistance. However, the support was insufficient and not provided in a coordinated manner. Because we had some liquid cash in several banks, for instance, we were receiving some hard currency. So, if you don't have that money, you might not get even something small. However, we received strong technical assistance from EFDA to obtain GMP certification by the standards and register our product. In addition, trilateral agreement between the National Bank, EPSS, and the Pharma Association are also being worked on. According to the agreement, EPSS will release a local tender. Local manufacturers will submit bids for the contract, and if their company wins, EPSS will arrange for roughly 55% of the costs associated with importing raw materials. Consequently, this initiative will result in a good improvement".* [FGD Participant 6, WE 20 years]

Different organization of the government sector had a support hand in order to strengthen the local pharmaceutical industry. The stakeholders were interviewed about the support they

provided to the local pharmaceutical manufacturer in the Ethiopia and which is illustrated by the following quotations. A priority of service is provided for local manufacturer in order to strength them. The study participant witnessed from the regulatory authority as follows *"Fast track registration and testing of their product were given in order to support them to keep alive in the market. In addition, technical support was given by participating them in different technical training on how to apply good manufacturing practice".* [Participant 2, SH, Female]

Policies of public procurement often include provisions that provide for preferences or priority of domestically produced goods in most of the developing countries. This involves the utilization of reliability features such as price coding and special encouragements with the aim of stimulating regional sectors, triggering economic growth, and ensuring the stability of national supply sources. One study participant addressed as follows *"Local pharmaceutical firms receive preference in government procurement procedures, which also include advance payments of up to 30% of order values. Moreover, technical assistance and consulting support will help them comply with international drug production standards. In addition, only products that are sufficiently produced by two or more domestic manufacturers are eligible for tenders reserved for local manufacturers".* [Participant 1, SH, Male]

Supporting in the area of problem-solving research and development is a critical activity needs to be done by the responsible organization in order to increase the performance of the domestic pharmaceutical manufacturer. The response of one participant from the stakeholder found in line with this statement. *"The development of highly skilled graduate required by the industry, strengthening the research and development activities and attracting local and foreign investment in the sector were the main support provided to the local manufacturer by our organization".* [Participant 3, SH, Male]

As part of government support provided by the bank to the local pharmaceutical industry as means of attracting new investor in the sector and supporting the of the existing facilities, one study participant addressed the following quotation. *"The Ethiopian Development Bank offers subsidized loans of up to 70% for new pharmaceutical manufacturing facilities and up to 60% for the renovation of current facilities, as well as various manufacturing and testing equipment and utilities as a means of support. Furthermore, to promote the local*

pharmaceutical manufacturing firms, the bank changed the guidelines for exporters, requiring them to use 50% of the hard currency instead of 20%". [Participant 4, SH, Female]

10. Suggestions and area of improvements

Table 11: Thematic framework explaining the themes, sub-themes, and issues associated with suggestions and area of improvements.

Themes	Subthemes	Codes (Issues)
Suggestions and area of improvements	Preference	should give priority to pharma companies
	Advantageous situation	creating a conducive environment to attract investors
	Pooled procurement	Make available basic raw materials imported in bulk from abroad
	Advance	Strengthen of regulatory bodies

Source: Own Survey, 2024

In order to address the issues that are currently being encountered as a challenge in the field of local pharmaceutical manufacturing facility, the study participants identified a number of areas that needed improvement. As per most of the study participants opinion, reserving of enough amount of the hard currency in the country is a critical activity needs to be done by the government. This is illustrated by the following excerpts: *"The government should give priority to pharma companies by availing foreign currency; providing incentives like exemption of tax for input, spare parts, and consumables, and creating a conducive environment to attract investors to establish API manufacturers in the country".* [FGD Participant 2, WE 20 years]

The majority of the study participants responded to their suggestion that the government procurement body should procure the product of the pharmaceutical manufacturer in foreign currency during a procurement tender award similar to a foreign company to ease the current problem for the local companies. One of the study participant speech marks as follows *"The government procurement agency (EPSS) should consider purchasing our products in foreign currency".* [Participant 1, Manu, Male]

The technique of pooled purchasing is, in fact, strategic, and research shows that it provides a marked number of significant benefits. It is a process whereby several business organizations pool their resources to acquire products or services. Substantially, this cooperative approach has implications for effectiveness, cost control and better procurement for both the public and private organizations. The study participant addresses the same idea "*I believe that having some of the primary and vital inputs imported in big quantities from other countries and as a result promoting the growth of the value chain and ensuring that the right knowledge and skills concerning the erection of the GMP thought is passed to the right individuals will enhance the strengthening of the industry"*. [Participant 6, SH, Male]

Professional employees are a very important asset for any given firm in the today's rapidly and competitively growing business environment. They are effective, creative and resourceful in addressing problems hence challenging, drive performance and innovation which defines success and growth of an organization. The view of one study participant found in line with this idea *"Strengthen of regulatory bodies by recruiting of more human power and skilled staffs on technical capacity. Availing of necessary resource for testing, establishing of API Manufacturer and technical equipment maintenance center in the country are a mandatory step to move forward".* [Participant 2, SH, Female]

Strengthens of the sector requires the involvement of different stakeholders in order to ensure the quality of the medications being produced, it requires many organizations and stakeholders, a multitude of locations, intricate multilevel distribution networks, and numerous national and international laws and standards that must be followed. The study participants form different stakeholders explained their recommendation in order to tackle the main challenges faced by the local pharmaceutical manufacturer. This idea found in line with the view of one study participant *"As per my view, upgrading the local pharmaceutical manufacturing industry competitiveness through the provision of appropriate policy support, internationally accepted qualification standard, strong marketing activities, and availability of highly skilled professional, promoting local and foreign investment, strengthening research and development initiative and fostering the local production of raw materials are a way forward to strengthen the domestic pharmaceutical industry".* [Participant 5, SH, Male]

5. DISCUSSION

The component of quality management known as good manufacturing practice makes ensuring that goods are manufactured and controlled in accordance with quality standards suitable for their intended use and as mandated by marketing authorization. Key qualities, such as the identity, strength, quality, and purity of drug products, are attained in part by adherence to GMP requirements. GMP's main goal is to control and reduce the risks that come with making pharmaceuticals so that the products' efficacy, safety, and quality are ensured. Reaching that goal will guarantee the greatest levels of safety, quality, and efficacy in any procedure involving the production of medical goods (WHO, 2022; MSH, 2012)

This study has provided novel insights regarding having different legal documents like policies and strategies to strengthening the sector however, implementation of this documents at ground level is not sufficient. Developing policy pieces that serve as beneficial next steps and expand upon current circumstances and regional institutional capabilities as opposed to creating a comprehensive local production policy often presents the most difficulty to policy makers. The ability of many nations to oversee, control, and monitor the manufacturing of pharmaceuticals is restricted. Policies should consider whether a nation can effectively adopt and enforce the necessary laws (MSH, 2012). Development in any sector is mostly determined by policies and practices (Adigwe, 2023).

Manufacturing and managing pharmaceuticals are a challenging task. Strong industry competition and dynamic market forces that frequently cause changes in supply and demand further exacerbate this. The increased number of medications on the market has created fierce competition for pharmaceutical companies today. The influx of new technology, growing globalization, and changing health demands have made health supply chains extremely competitive (Gunawardana & Herath, 2020; Shilesh & Senthilkumar, 2019).

African producers, who now work in tiny, disjointed marketplaces, are unable to compete with their Asian counterparts, who operate in far larger markets and can thus take advantage of economies of scale. Economies of scale enable companies to save costs by increasing production quantities (Janet Byaruhanga, 2020).

The finding of the study showed that, Ethiopia's domestic pharmaceutical production falls well short of the nation's estimated drug requirements. This finding is found consistent alongside the report of Organization for Industrial Development of the United Nations (2019) that stated, the percentage of domestic production in sub-Saharan African nations that

manufacture pharmaceuticals ranges from 10 to 30 percent. This range includes both those with a sizable pharmaceutical industry such as South Africa, Ghana, Kenya, Nigeria, and those having none at all (UNIDO, 2019). Consequently, among the most significant steps in enhancing public wellness security is lowering reliance on imports.

It is found consistent also with the study done by Obembe et al (2022) regarding stakeholders' perceptions of the effectiveness of pharmacy practice in Nigeria (Obembe et al., 2022) and with report of GCB Strategy and Research Department (2022) stated that, Ghana has been a leader in the pharmaceutical industry for over 40 years. There are currently 35 registered companies in Ghana's pharmaceutical manufacturing sector, which employs a diverse spectrum of professionals. Over 75% of the businesses are owned by business people from Ghana. However, due to insufficient resources, there is capacity underutilization (less than 55% on average). About 30% of the pharmaceuticals sold in Ghana are made locally, and the other 70% are imported. (GCB Strategy and Research Department, 2022). In contrast to other lower- and middle-income countries like Ethiopia and other African nations, Pakistan boasts a thriving pharmaceutical industry that meets seventy percent of the nation generates completed pharmaceutical items and meets its demand for medicine. that are accepted by nations in Asia, Africa, and the US, (Atif, M., Ahmad, M., Saleem, Q., Curley, L., Qamar-uz-Zaman, M., Babar, 2017).

Local manufacturers face a strong competitive challenge from imported products, which comprise more than 80% of the value of pharmaceuticals consumed in the nation. A clear aim of the Ethiopian government is to elevate the proportion of domestic production. Plans I (2010/11-2014/15) and II (2015/16-2019/20) for Growth and Transformation), as well as the Ten Years Development Plan that followed in 2021–2030, highlight the significance of local production in supplying export markets and serving as a substitute for imported goods. However, this objective was not addressed due to different obstacles so far.

The majority of the advantages of local production are outweighed by lower production facility utilization rates, unregulated supply chain structures, subpar production standards, high operating costs, and limited human resources (Conway et al., 2019). Foreign businesses now enjoy a significant competitive advantage in the pharmaceutical markets due to the local pharmaceutical industry's incapacity to adequately address local needs for innovative pharmaceuticals and low-cost generic manufacture.

Generic products reign supreme in the Egyptian pharmaceutical sector. Even with the dearth of advanced manufacturers, the industry lacks a competitive edge when it comes to quality and production level, which is considered to be below the general requirements required by the US and European markets. (The African Development Bank Group, 2023).

One of the main obstacles for the Ethiopian domestic pharmaceutical manufacturer stated by the study participants were all active pharmaceutical ingredients and other inputs used for manufacturing of the products come from abroad. This study finding is found consistent with the following reports. The health care industry is heavily reliant on pharmaceuticals, immunizations, medical equipment, and diagnostics that are created and obtained outside, particularly from China and India. This means that there is little chance for domestic learning curve development. Clearly, the majority of the equipment and raw materials imported into West Africa are used in the pharmaceutical industry. (Ekigwe, 2019*).* Under-Saharan African nations, like many more LMICs (low- and middle-income countries), hope to grow their pharmaceutical industry by encouraging access to reasonably priced, high-quality medicine. However, due to a lack of domestic production capacity, African drug manufacturers frequently import packaging, machinery, and active pharmaceutical ingredients (APIs) (Reichman, 2009).

Most of the participants illustrated the challenge of acquiring foreign currency for the purpose of importing raw materials and other necessary inputs. This indicates that purchasing pharmaceutical inputs, which support the domestic production of pharmaceutical products can be challenging when it comes to obtaining foreign exchange. This finding is complemented with the studies done by Yechalework Aynalem (2019) stated that, “shortage of foreign exchange is another hold up according to investors interviewed” (Aynalem, 2019).

Detailed analysis reveals that the rise in privately owned businesses, unofficial channels for foreign exchange inflow, population growth, and corruption will exacerbate the problems associated with the appropriate use of foreign exchange and intensify the effects of its shortage. It also reveals that the lack of foreign exchange has had a variety of negative effects on businesses, including reduced profits, employee layoffs, and a deterrent to new investment (Kebede, 2024).

The lack of foreign currency is having a significant impact on the private sector, which lowers competitiveness. Retailers, distributors, and companies that replace imports are the most impacted. Companies who are more impacted by the foreign exchange shortage are also

more inclined to turn to creative means of obtaining foreign currency. There are signs that as exports increase and more private transactions go via official channels, the lack of foreign currency may somewhat improve.

Manufacturers, even with priority status from the National Bank of Ethiopia (NBE), find it difficult to obtain foreign exchange from commercial banks. Laboratory reagents and inputs for pharmaceutical manufacturing were placed in the highest priority group for foreign currency allocation by the central bank in a directive. It is common, nevertheless, for manufacturers who have priority access to foreign exchange to hold off on opening letters of credit (LC) for longer than two years. As a result, local manufacturers submit subpar bids for the contracts that EPSS awards. When trying to compete with multinational firms that have substantial financial resources and access to international capital markets, local pharmaceutical makers in underdeveloped nations frequently encounter difficulties (Kebede, 2024; NBE, 2021). Oliver (1991) points out that firms with limited resources may use a variety of tactics to deal with reliance, like looking for partnerships or collaborations with companies that have more resources. But occasionally, these tactics might make local businesses less independent or vulnerable to outside funding.

Other challenges like shortage of skilled experienced personnel, shortage working capital/access to finance, problem related with plant infrastructure, weak marketing structure, and lack of research and development capacity, were mentioned by the participants. The study findings are found aligned with summary report from the Diagnostic Report 2020 for the Pharmaceutical Industry in Kenya emphasizes and a report of Alruthia et al., 2018 and Alrasheedy, 2020, which stated as, Local drug manufacturing can be encouraged by the Saudi Kingdom's strong regulatory framework, stable domestic economy, and free trade agreement with the Middle East and North Africa. Nonetheless, the Saudi Arabian pharmaceutical industry may face significant difficulties due to the government's tardy spending, drawn-out registration and procurement processes, a lack of expertise besides skill in medicine finding and expansion, and a nonexistence of research and development for novel drugs. The capacity of international businesses to promote a drug product at a low price is another barrier that many indigenous pharmaceutical companies in the Kingdom face.

However, the lack of qualified human resources in Ethiopia's pharmaceutical industry is a current problem. Despite the country's 11 pharmacy schools, their curricula are primarily focused on clinical pharmacy, while the industry needs industrial pharmacy specialists. A comprehensive program is required to plan and guarantee staff members' access to applicable

teaching, training received on the job and ongoing education courses, tremendous possibilities for online education. Range of services is needed, after postgraduate and tertiary level knowledge in general management and research and development to the specialized executive and practical know-how needed to manage manufacturing facilities the expertise of plant operators in operating and maintaining machinery (MOH and MOI of Ethiopia, 2015).

In order to guarantee that medications produced domestically and those imported meet the necessary quality standards, the National Regulatory Authority must have the proper number of employees, resources, and equipment. Generally speaking, some regulatory strengthening is needed in order to build a fully functional NRA (WHO, 2003).

A lengthy registration dossier review and quality control testing time were mentioned as the main challenge faced by the local industry from the regulatory side. Establishing a competitive pharmaceutical industry requires a well-resourced, efficiently operating national medicine regulatory authority that can oversee the complete value chain as well as continuously evaluate quality, wellbeing, and effectiveness of each sold medications through processes like post-marketing surveillance, manufacturing plant inspections, and dossier evaluations (Araya, 2018). By actively managing and reducing external dependencies, pharmaceutical businesses can strengthen their resilience and gain market share in a complicated and highly regulated environment.

Pharmaceutical manufacturing involves several operations that are subject to multiple regulation ranging from the inception of product development and discovery through price, market participant licensing, quality control testing, pharmacovigilance (tracking adverse effects), marketing including direct-to-consumer advertising, sales in international markets like USA by semi-specific packaging labels or routes between sectorial billing pre-ordering systems specific services consumptions. On the consumer side of things, supply chain management, purchasing agreements and procurement systems all play a role. In addition to national pharmaceutical policies, a nation's pharmaceutical market can be affected by events and changes in other domains such as trade agreements or industrial policy. The interactions among all of these things and parties, is possibly represented by consumers' access to medications (Seiter, 2010).

It is imperative to guarantee the smooth integration of the water, HVAC, and premises systems. Ensuring that buildings, the HVAC system, and water systems meet the many and

frequently strict criteria necessitates a thorough and coordinated strategy, along with strict documentation and standard adherence (Obiuto et al., 2024).

Most of the participants were not found satisfactory regarding the support obtained from different stakeholders. Establishing manufacturing facilities can still encourage the growth of industries. Coordination of efforts amongst various stakeholders and implementation of the support package are necessary to address a variety of issues, and overcoming different obstacles is an ongoing process (United Nations Industrial Development Organisations, 2024).

Trade, investment, and intellectual property rights policies impact how industrial and health policies complement and interact with one another. Priorities in a nation's access to medicine needs could be targeted by direct and indirect government support, such as investment incentives, to local pharmaceutical manufacturing. Government procurement, trade facilitation, and tariff and fiscal concessions can all help to guarantee the sustainability and competitiveness of regional pharmaceutical production (UNECA, 2020).

The unsustainable concentration of global supply chains in pharmaceuticals, vaccines, and other health items has been evident over the last eighteen months. Government support, in the form of grants, investment financing, and market interventions like advance purchase commitments, is another important trend that has been highlighted. Although these interventions have primarily taken place in developed nations, they offer LMICs potential paths forward. When taken as a whole, these trends show that government assistance and blended finance are two significant factors influencing the improvement of financing options for LMIC producers (WHO, 2021).

The pharmaceutical industry is multifaceted, with a wide range of participants, industries, policy domains, and procedures. All things considered, trade agreements, industrial policy, and national and regional pharmaceutical policies all have an impact on the pharmaceutical industry. Pharmaceutical products are produced on the supply side, which encompasses various aspects such as product development and research, authorization of products and market participants, pricing, quality control, pharmacovigilance, marketing, and promotion. Additionally, the supply side involves various stakeholders, including the private sector, NMRAs, quality control laboratories, and research institutions. The pharmaceutical market's demand side, or consumer consumption, is impacted by a number of factors, including supply

chain management, distributors, wholesalers, and procurement agencies and agreements (UNIDO, 2019).

According to the report of Rahman R and Salam M.A, Drug security and the healthcare system will depend on localizing pharmaceutical item and medication production, thus the government, pharmaceutical companies, and other pertinent stakeholders should support this (Rahman and Salam, 2021).

6. CONCLUSION and RECOMMENDATION

6.1 Summary of Findings

The pharmaceutical industry was found at infant stage currently even though the government views it as a crucial strategic commodity and has given it the attention it deserves by enacting a number of supportive laws and incentives. Numerous difficulties have played a part in this. The government lacks a clear directive to fully implement the strategic plan and policies in place, adequate foreign exchange, and a dedicated organization to closely monitor and support the sector's development.

The production of pharmaceuticals in the country has also been severely impacted by the challenges of having sufficient access to hard currency. Other issues related to the manufacturers' low-capacity utilization include limited access to financing, insufficient utilities, and a reliance on imports for API, high-tech equipment. The country's ability to manufacture pharmaceuticals locally will require investment, commitment, advocacy, and concerted efforts by public and commercial partners. Without an enabling climate, the pharmaceutical business cannot thrive.

In technical terms, strengthening domestic pharmaceutical systems entails fortifying the foundational elements of health systems, such as legislation, governance, policy, regulatory frameworks, innovation, R and D, production, and commerce, as well as funding, information, and human resources.

Research from nations that have successfully established domestic manufacturing industries demonstrates that long-term planning and policy coherence are essential for success. A cohesive, complementary, and mutually reinforcing set of policies is needed to guarantee long-term sustainability.

6.2 Conclusion

This study assessed the difficulties with local pharmaceutical manufacturers operating in country. Through a qualitative research method, the study provided detailed information on main challenges faced by local pharmaceutical manufacturers operating in country, root cause of the obstacles, the support obtained from different stakeholders and how they the handle or overcome the challenges.

From the finding of the study, different main difficulties like related to strategic planning and implementation, efficiency in production, international financial issue such as shortage of foreign currency, regulation, supply chain management, human resource management, and infrastructure were identified and found inline with Diagnostic Report 2020 for the Pharmaceutical Industry in Kenya emphasizes and a report of Alruthia et al., 2018, Alrasheedy, 2020 and Yechalework Aynalem (2019). The findings of this study aligned with resource dependency theory, which stated that organizations are constantly influenced by the availability, control, and flow of critical resources such as raw materials, capital, and information.

Participants in the study from the local manufacturer and stakeholders do not agree on the extent or expectations of help provided by the responsible entity. However, to strengthen the domestic pharmaceutical producer, many forms of support were given, particularly by regulatory bodies, national banks, EICs, AHRIs, and EPSS. This finding was found in line with a report of a survey conducted by the Center for Health, Human Rights, and Development (CEHURD) (2013).

From the finding of the study, regarding the identifying of the root cause of the main challenges and way of tackling the problems is found inline with the study done by Ekeigwe, A. A. (2019).

6.3 Recommendations

The following recommendations are based on the findings presented in this thesis and are intended to help the domestic pharmaceutical maker overcome its current challenges.

- Since Ethiopian domestic industries rely heavily on imported inputs, it is possible to produce the components locally. Domestic pharmaceutical manufacturer might begin by manufacturing additives and packing materials. In addition, pharmaceutical manufacturers primarily rely on suppliers for vital raw materials such active pharmaceutical ingredients (APIs), excipients, packaging materials, and specialized gear. To address this dependence, pharmaceutical businesses might employ supplier diversification (ensuring alternative sources), vertical integration (purchasing suppliers or controlling parts of the supply chain), and long-term partnerships or contracts to reduce the risks of supply chain interruptions. Establishing strategic alliances with suppliers can also help secure access to essential technology and materials.

- In order to overcome technological obstacles and reap the rewards of economies of scale through mass production and exportation to neighboring nations, established local pharmaceutical industries must take note of the positive experiences that new entrants have had with joint ventures and actively seek out partnerships and integration with multinational and experienced companies. Additionally, this will qualify them for all of the extensive government incentives offered to exporters.
- In order for domestic pharmaceutical producers to sell their products internationally, they must work to overcome obstacles and comply with international laws.
- Allocating enough skilled labor to the pharmaceutical company in accordance with relevant studies and evaluations in order to successfully overcome industrial barriers.
- In order to guarantee that staff members obtain up-to-date, worldwide technological expertise, it should be imperative that their training and continuing education demands are met. In addition, by taking part in industry associations or groups and engaging in dialogue with them, pharmaceutical businesses need to actively manage their relationships with regulators. Additionally, businesses can ensure that their internal resources, such as regulatory expertise and compliance teams, are robust enough to adapt to new regulations.
- Pharmaceutical institutions require a diversified effort to solve the problems of water and HVAC systems. In the case of pharmaceutical manufacturers, this means incorporating new control and monitoring technologies to optimize their systems and ensure reliability; investing in energy-saving equipment that delivers consistent performance; adhering to rigorous maintenance procedures validation protocols;; understanding where sustainability fits into your plant recycling water or poop-to-power.; These steps not only assure compliance with the laws in force but also enhance productivity and product quality as a whole.
- A clear directive should be in place to indicate ways of communication, feedback system and accountability with a responsibility of each responsible organization. In doing so, it will facilitate the implementation of the developed policies and strategic plan regarding the pharmaceutical industry.
- It seems that there is a special need for alignment between industrial and investment policies, procurement policies, intellectual property policies, health insurance policies, science, technology, and innovation policies, and medical regulations.

- Since public health is the main concern, policies from all ministries should be consistent and work toward the same objectives in order to support local pharmaceutical production and meet public health demands.
- Generally speaking, government authorities at different levels and those at the same level share responsibilities for pharmaceutical manufacture. The problem might be improved by the creation of a single governmental body that would oversee all other governmental bodies. Representatives from relevant governmental agencies, such as the Ministries of Trade, Industry, Land, Health, and Customs, should be on this authority. It ought to offer standardized data and protocols and promote proactive cooperation between ministries and government organizations involved in the creation of regulations for the pharmaceutical industry.
- To shield the industry from external effects and preserve foreign exchange, the government should provide incentives for investment in API manufacturing. Putting money into the fundamental production of active ingredients will reduce reliance on imports and generate job opportunities.
- To ensure that, the expansion of the expanding medicinal industries developing nations and help them become competitive, governments must provide short to medium term support.
- The national bank of the country needs to revise the available directives in order to give more emphasis for the pharmaceutical industries.
- To ensure the integrity of the pharmaceutical manufacturer and preserve public health, regulatory authorities must collaborate more effectively, strengthen their regulatory capability, and enact stricter enforcement measures.

6.4 Future researcher

The present study aims to shed light on the difficulties encountered by Ethiopian local pharmaceutical manufacturers while also advancing existing research inquiries.

- Future research should concentrate on evaluating and detailing the implementation of various policies, as doing so will increase the capacity of local manufacturers and provide deeper insights into how stakeholder efforts together improve operational efficiency in meeting international standards and producing medicines.

- Research in different settings is needed to confirm that the findings of this study can be generalised.
- Moreover, the primary focus of the study was from point view all stakeholders and drug industry key personnel however some stakeholders were excluded due to different conditions. As such, future studies should include all relevant stakeholders.

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Annex 1: KEY INTERVIEW CHECKLIST

ADDIS ABABA UNIVERSITY

College of Business and Economics

Dear respondent, first of all I would like to thank you for giving your precious time to participate in this interview. My name is Solomon Getachew and I am a postgraduate MBA student in the Addis Ababa university distance programme for the year of 2021. The Purpose of this interview is to gather relevant information which will inform the challenges of Local pharmaceutical manufacturer operating in Ethiopia. The information you provide will help me to better understand the situation of local pharmaceutical manufacturer and will be used as an input for completing my MBA Thesis of management stream in Addis Ababa University.

This is to ensure you that this interview will not precede without your consent. Kindly be aware that all responses will be kept confidential. And your identity will remain anonymous. Please be aware that your responses will be recorded for data accuracy purpose however will be presented coded and will not contain your actual name. At any time of the interview please be informed that you have the full right to withdraw from the process and end the interview at any time. If you have questions, please let me know before I proceed?

Are you willing to participate in this interview? Yes _____ No _____

If you say yes, the interview begins.

Instrument One: Key Informant Interview

This interview to be held with key personnel of the local pharmaceutical manufacturer.

Part I. Background information of participant

1. Gender –
2. Educational status
   A. Bachelor Degree B. M. Pharm/MSc C. PhD
3. Profession –
4. Name of organization and Department -
5. Years of total work experience –
6. Current position -
7. Year of experience in this position –

Part II. Points for discussion

1. How do you describe the overall situation of pharmaceutical industry in Ethiopia?
2. What are the main challenges faced your pharmaceutical company to manufacture the product? Could you more describe additional challenges?
3. How often these obstacles happened?
4. What do you think the root cause of the challenges?
5. How is the company trying to solve the problem?
6. Could you tell me more about the current support you get from the government? Bank, EIC, AHRI, EFDA, EPSS?
7. How do you describe the company's satisfaction regarding the support you got from the stakeholders?
8. What mechanism or strategy do you recommend to tackle the challenges?
9. From your point of view, are there any relevant aspects or questions that you feel should be addressed, but weren´t mentioned thus far?

Annex 2 - Key Informant Interview with Stakeholders

I want to thank you for your time that you allow me to talk with you. My name is Solomon Getachew and I am the principal investigator for the research entitled "**Explore the Challenges of Local Pharmaceutical Manufacturer in Ethiopia: A Qualitative Study**". The objective of the study is to explore the challenges of local pharmaceutical manufacturer in Ethiopia**.** I would like to talk with you about your view and the actual support provided by your organization and the challenges faced during the support if any. The interview will take about 30 -45 minutes. I will take note of your comments, but it might be difficult to capture all of your comments. Hence, in order not to miss any of your comments, I need your permission to use a tape recorder. Your participation in the study is completely voluntary and you can refuse to answer any question at any time, for any reason, if you so decide. The information you will provide me will be kept confidential and I ensure you that the information in the report will not identify you as the respondent. Hence, I kindly request you to provide me honest and actual information.

Are you willing to participate in this interview? Yes _____ No _____

If you say yes, the interview begins.

Instrument: Key Informant Interview

This interview to be held with key personnel of the stakeholders.

Part I. Background information of participant

1. Gender –
2. Educational background

   A. Bachelor Degree B. M. Pharm/MSc C. PhD

3. Profession –

4. Name of organization –

5. Years of total work experience –

6. Current position -

7. Year of experience in this position –

Part II. Points for discussion

1. How do you describe the overall situation of pharmaceutical industry in Ethiopia?
2. What kind of support provided by your organization to the local pharmaceutical manufacturers?

3. In your opinion, what conducive conditions are available for pharmaceutical industries in Ethiopia?

4. What do you think the main challenges faced by the pharmaceutical company to manufacture the product? Could you more describe additional challenges?
5. What do you think the root cause of the challenges?
6. What mechanism or strategy do you recommend to tackle the challenges?

7. From your point of view, are there any relevant aspects or questions that you feel should be addressed, but weren´t mentioned thus far?

Annex:3 FGD CHECKLIST

ADDIS ABABA UNIVERSITY

College of Business and Economics

Dear Respondent, first of all I would like to thank you for taking your valuable time to participate in this interview. My name is Solomon Getachew and I am a 2021 graduate MBA student at Addis Ababa University distance program. The information you provided will help me better understand the situation of the local pharmaceutical manufacturer and will be used as a resource to complete my MBA thesis of management at Addis Ababa University. I would like to assure you that this interview will not be conducted without your consent. I would like to inform you that all responses will be kept confidential and your identity will not be disclosed in the survey. I confirm that you have every right to withdraw from the process at any time during the interview and to stop the interview at any time. If you have questions, please let me know before I continue.

Are you willing to participate in this interview? Yes _____ No _____

If you say yes, the interview begins.

Part I. Background information of participant

1. Gender –
2. Educational status

   A. Bachelor Degree B. M. Pharm/MSc C. PhD

3. Profession –

4. Name of organization and Department -

5. Years of total work experience –

6. Current position -

7. Year of experience in this position –

Part II. Points for discussion

1. How would you describe the current state of Ethiopia's pharmaceutical industry? (From the point of view of the past: various peer countries and developed countries)
2. What are the main problems the local pharmaceutical company faced in developing the product? Can you describe any additional challenges? Prob: internal and external factors
3. What do you think is the root cause of the main problems?
4. What kind of mechanisms/strategies your pharmaceutical manufacturer implements to solve the challenges?
5. Can you tell me more about the support you received from government offices and other stakeholders? For example, from the bank, from the Ethiopian Investment Commission, from the Minister of Industry, from the Ethiopian Food and Drug Control Authority, from the Ethiopian Pharmaceutical Supply Agency?
6. What do you recommend/think could be done to address the challenges you described?
7. From your point of view, are there any relevant aspects or questions that you feel should be addressed, but weren´t mentioned thus far?

Annex 4: Key informant interview guide for qualitative study, Amharic version

ጥልቅ የቃለ ምልልሶች ዝርዝር ከአምራቾች

የንግድ እና ኢኮኖሚክስ ኮሌጅ, አዲስ አበባ ዩኒቨርሲት

ውድ ምላሽ ሰጪ፣ በመጀመሪያ በዚህ ቃለ መጠይቅ ላይ ለመሳተፍ ውድ ጊዜዎን ስለሰጡኝ ላመሰግን እወዳለሁ። ስሜ ሰለሞን ጌታቸው እባላለሁ በ2021 በአዲስ አበባ ዩኒቨርሲቲ የርቀት ፕሮግራም የድህረ ምረቃ የ MBA ተማሪ ነኝ የዚህ ቃለ ምልልስ አላማ በኢትዮጵያ ውስጥ የሚገኙቱን የሀገር ውስጥ ፋርማሲዩቲካል አምራች ፈተናዎችን የሚያሳውቅ ጠቃሚ መረጃዎችን መሰብሰብ ነው። ያቀረብቱን መረጃ የሀገር በቀል ፋርማሲዩቲካል አምራቹን ሁኔታ በደንብ እንድረዳ ይረዳኛል እንዲሁም በአዲስ አበባ ዩኒቨርሲቲ የ MBA ቱሲስ ኦፍ ማኔጅመንት ለማጠናቀቅ እንደ ግብአት ይጠቅማል።

ይህ ቃለ መጠይቅ ያለፈቃድዎ እንደማይደረግ ለማረጋገጥ እወዳለሁ። ሁሉም ምላሾች በሚስጥር እንደሚጠበቁና ማንነትዎ በጥናቱ እንደማይገለፅ ለማሳወቅ እወዳለሁ። በቃለ መጠይቁ በማንኛውም ጊዜ ከሂደቱ የመውጣት እና በማንኛውም ጊዜ ቃለ መጠይቁን ማቆም እንደሚችሉ ሙሉ መብት እንዳለዎት አረጋግጣለሁ። ጥያቄዎች ካሉዎት፣ ከመቀጠሌ በፊት እባክዎን ያሳውቁኝ?

በዚህ ቃለ መጠይቅ ላይ ለመሳተፍ ፈቃደኛ ነህ? አዎ ---------- አይደለሁም ----------

ክፍል I. የተሳታፊ ዳራ መረጃ

1. ፆታ -

2. የትምህርት ደረጃ A. ባችለር ዲግሪ/ቢፋርም B.M. Pharm/MSc C. ፒኤችዲ

3. ሙያ -

4. የሚሰሩበት የድርጅቱ ስም -

5. አጠቃላይ የሥራ ልምድ ዓመታት -

6. አሁኑ ያሉበት የስራ ሀላፊነት -

7. አሁኑ ባሉበት የስራ ሀላፊነት ያሎት የሥራ ልምድ በዓመት -

ክፍል II. የመወያያ ነጥቦች

1. የኢትዮጵያን የመድኃኒት ኢንዱስትሪ አጠቃላይ ሁኔታ እንዴት ይገልጹታል?

2. የመድኃኒት ኩባንያዎ ምርቱን ለማምረት ያጋጠሙት ዋና ዋና ችግሮች ምንድን ናቸው? ተጨማሪ ተግዳሮቶችን የበለጠ መግለጽ ይችላሉ?

3. እነዚህ መሰናክሎች ስንት ጊዜ ተከሰቱ?

4. የችግሮቹ ዋና መንስኤ ምን ይመስልዛል?

5. ኩባንያው ችግሩን ለመፍታት እየሞከረ ያለው እንዴት ነው?

6. ከመንግስት መ/ቤቶች ስላገኙት ድጋፍ የበለጠ ሊነግሩኝ ይችላሉ? ለምሳሌ ከባንክ፣ ከኢትዮጵያ ኢንቬስትመንት ኮሚሽን፣ ከኢንደስትሪ ሚንስተር፣ ከኢትዮጵያ ምግብና መድሀኒት ቁጥጥር ባለስልጣን ፣ ከኢትዮጵያ ፋርማሲዩቲካል ሰፕላይ ኤጀንሲ?

7. ከባለድርሻ አካላት ያገኙትን ድጋፍ በተመለከተ የኩባንያውን እርካታ እንዴት ይገልጹታል?

8. ምን ቢደረግ የገለፃቸውን ተግዳሮቶችን ለመቅረፍ ይቻላል ብለው ይመክራሉ/ያስባሉ?

9. በዚህ ውይይት ያልተነሳ ነገር ግን በእርስዎ እይታ መቅረት የሌለበት ብለው የሚያስቡት ነገር ካለ እባክዎት ይጨምሩ?

Annex 5: ቁልፍ መረጃ ሰጪ ቃለ መጠይቅ ከተለያዩ ባለድርሻ አካላት ጋር

ውድ ምላሽ ሰጪ፣ በመጀመሪያ በዚህ ቃለ መጠይቅ ላይ ለመሳተፍ ውድ ጊዜዎን ስለሰጡኝ ላመሰግን እወዳለሁ። ስሜ ሰለሞን ጌታቸው እባላለሁ በ2021 በአዲስ አበባ ዩኒቨርሲቲ የርቀት ፕሮግራም የድህረ ምረቃ የ MBA ተማሪ ነኝ የዚህ ቃለ ምልልስ አላማ በኢትዮጵያ ውስጥ የሚገኙቱን የሀገር ውስጥ ፋርማሲዩቲካል አምራች ፈተናዎችን የሚያሳውቅ ጠቃሚ መረጃዎችን መሰብሰብ ነው። ያቀረብቱን መረጃ የሀገር በቀል ፋርማሲዩቲካል አምራቹን ሁኔታ በደንብ እንድረዳ ይረዳኛል እንዲሁም በአዲስ አበባ ዩኒቨርሲቲ የ MBA ቴሲስ ኦፍ ማኔጅመንት ለማጠናቀቅ እንደ ግብአት ይጠቅማል።

ይህ ቃለ መጠይቅ ያለፈቃድዎ እንደማይደረግ ለማረጋገጥ እወዳለሁ። ሁሉም ምላሾች በሚስጥር እንደሚጠበቁና ማንነትዎ በጥናቱ እንደማይገለፅ ለማሳወቅ እወዳለሁ። በቃለ መጠይቁ በማንኛውም ጊዜ ከሂደቱ የመውጣት እና በማንኛውም ጊዜ ቃለ መጠይቁን ማቆም እንደሚችሉ ሙሉ መብት እንዳለዎት አረጋግጣለሁ። ጥያቄዎች ካሉዎት፣ ከመቀጠሌ በፊት እባክዎን ያሳውቁኝ?

በዚህ ቃለ መጠይቅ ላይ ለመሳተፍ ፈቃደኛ ነህ? አዎ ---------- አይደለሁም ----------

ክፍል I. የተሳታፊው ዳራ መረጃ

1. ጾታ -

2. የትምህርት ዳራ A. ባችለር ዲግሪ B.M. Pharm/MSc C. ፒኤችዲ

3. ሙያ -

4. የድርጅቱ ስም -

5. አጠቃላይ የሥራ ልምድ ዓመታት -

6. አሁኑ ያሉበት የስራ ሀላፊነት -

7. አሁኑ ባሉበት የስራ ሀላፊነት ያሎት የሥራ ልምድ በዓመት -

ክፍል II. የመወያያ ነጥቦች

1. የኢትዮጵያን የመድኃኒት ኢንዱስትሪ አጠቃላይ ሁኔታ እንዴት ይገልጹታል?

2. መ/ቤትዎ ወይም ድርጅትዎ ለሀገር ውስጥ ፋርማሲዩቲካል አምራቾች ምን አይነት ድጋፍ ይሰጣል?

3. በእርስዎ አስተያየት በኢትዮጵያ ውስጥ ለፋርማሲዩቲካል አምራቾች (ኢንዱስትሪዎች) ምን ምቹ ሁኔታዎች አለ ብለው ያስባሉ?

4. የመድኃኒት አምራች ኩባንያ ምርቱን ለማምረት የሚያጋጥማቸው ዋና ዋና ችግሮች ምን ይመስልዎታል? ተጨማሪ ተግዳሮቶችን መግለጽ ይችላሉ?

5. የችግሮቹ ዋና መንስኤ ምን ይመስልሃል?

6. ተግዳሮቶችን ለመቅረፍ የትኛውን ዘዴ ወይም ስልት ይመክራሉ?

7. በዚህ ውይይት ያልተነሳ ነገር ግን በእርስዎ እይታ መቅረት የሌለበት ብለው የሚያስቡት ነገር ካለ እባክዎት ይጨምሩ?

Annex 6: **ቁልፍ መረጃ ሰጪ የቡድን ውይይት ከአምራቾችጋር**

ውድ ምላሽ ሰጪ፣ በመጀመሪያ በዚህ ቃለ መጠይቅ ላይ ለመሳተፍ ውድ ጊዜዎን ስለሰጡኝ ላመሰግን እወዳለሁ። ስሜ ሰለሞን ጌታቸው እባላለሁ በ2021 በአዲስ አበባ ዩኒቨርሲቲ የርቀት ፕሮግራም የድህረ ምረቃ የ MBA ተማሪ ነኝ የዚህ ቃለ ምልልስ አላማ በኢትዮጵያ ውስጥ የሚገኙቱን የሀገር ውስጥ ፋርማሲዩቲካል አምራች ፈተናዎችን የሚያሳውቅ ጠቃሚ መረጃዎችን መሰብሰብ ነው። ያቀረብቱን መረጃ የሀገር በቀል ፋርማሲዩቲካል አምራቹን ሁኔታ በደንብ እንድረዳ ይረዳኛል እንዲሁም በአዲስ አበባ ዩኒቨርሲቲ የ MBA ቴሲስ ኦፍ ማኔጅመንት ለማጠናቀቅ እንደ ግብአት ይጠቅማል።

ይህ ቃለ መጠይቅ ያለፈቃድዎ እንደማይደረግ ለማረጋገጥ እወዳለሁ። ሁሉም ምላሾች በሚስጥር እንደሚጠበቁና ማንነትዎ በጥናቱ እንደማይገለፅ ለማሳወቅ እወዳለሁ። በቃለ መጠይቁ በማንኛውም ጊዜ ከሂደቱ የመውጣት እና በማንኛውም ጊዜ ቃለ መጠይቁን ማቆም እንደሚችሉ ሙሉ መብት እንዳለዎት አረጋግጣለሁ። ጥያቄዎች ካሉዎት፣ ከመቀጠሌ በፊት እባክዎን ያሳውቁኝ?

በዚህ ቃለ መጠይቅ ላይ ለመሳተፍ ፈቃደኛ ነህ? አዎ ---------- አይደለሁም ----------

ክፍል I. የተሳታፊ ዳራ መረጃ

1. ፆታ -

2. የትምህርት ደረጃ A. ባችለር ዲግሪ/ቢፋርም B. M. Pharm/MSc C. ፒኤችዲ

3. ሙያ -

4. የሚሰሩበት የድርጅቱ ስም -

5. አጠቃላይ የሥራ ልምድ ዓመታት -

6. አሁኑ ያሉበት የስራ ሀላፊነት -

7. አሁኑ ባሉበት የስራ ሀላፊነት ያሎት የሥራ ልምድ በዓመት -

ክፍል II. የመወያያ ነጥቦች

1. በአሁኑ ወቅት የኢትዮጵያን የመድኃኒት ኢንዱስትሪ አጠቃላይ ሁኔታ እንዴት ይገልጹታል? (ከበፊት ከነበረው አንፃር ፡ ከተለያዩ አቻ ሀገራት እና ከበለፀጉ አገራት አንፃር)

2. የመድኃኒት ኩባንያዎ ምርቱን ለማምረት ያጋጠሙት ዋና ዋና ችግሮች ምንድን ናቸው? ተጨማሪ ተግዳሮቶችን ካሉ ቢገልፁ መግለጽ ይችላሉ? ፕሮቭ፡ ውስጣዊ እና ውጫዊ ምክንያቶች

3. የችግሮቹ ስርወ መንስኤ ምን ይመስልሃል?

4. የተጠቀስቱን ተግዳሮቶችን ለመፍታት የመድኃኒት አምራችዎ ምን ዓይነት የመፍትሄ እርምጃዎችን ይጠቀማል?

5. ከተለያዩ የመንግስት መ/ቤቶችና ሌሎች ባለድርሻ አካላት ስላገኙት ድጋፍ ሊነግሩኝ ይችላሉ? ለምሳሌ ከባንክ፣ ከኢትዮጵያ ኢንቬስትመንት ኮሚሽን፣ ከኢንደስትሪ ሚንስተር፣ ከኢትዮጵያ ምግብና መድሀኒት ቁጥጥር ባለስልጣን ፣ ከኢትዮጵያ ፋርማሲዩቲካል ሰፕላይ ኤጀንሲ?

6. ምን ቢደረግ የገለፃቸውን ተግዳሮቶችን ለመቅረፍ ይቻላል ብለው ይመክራሉ/ያስባሉ?

7. ሌላ ተጨማሪ የሚያነሳቸው ሀሳቦች ካሉ/