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School of Commerce

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Operational Challenges in the Ethiopian Pharmaceutical Manufacturing Industry and Their Impact on Sector Development and Market Share Growth

By

Alemu Lobe (B.Pharm)

A Thesis Submitted to Addis Ababa University College of Business and EconomicsSchoolof Commerce in Partial Fulfillment of the Requirements for the Degree of Master of Arts in Marketing Management

Advisor: Temesgen Belayneh (PhD)

Addis Ababa, Ethiopia

June, 2024

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Declaration

I, Alemu Lobe, hereby declare that this research entitled "Operational Challenges in the Ethiopian Pharmaceutical Manufacturing Industry and Their Impact on Sector Development and Market Share Growth" is my own original work. All sources of materials used for this study have been identified and acknowledged as complete references. This research study has not been previously submitted in full or partially for any degree in any recognized educational institution. This research study is being submitted in partial fulfillment of the requirement for the Master of Arts in Marketing Management.

Declared by Name: **Alemu Lobe (alemulobe7@gmail.com)**

Signature: _____

Date: _____

Advisor:**Temesgen Belayneh (PhD)**

Signature: _____

Date: _____

ADDIS ABABA UNIVERSITY SCHOOL OF COMMERCE

Letter of Certification

This is to certify that Alemu Lobe conducted the research on the topic titled "Operational Challenges in the Ethiopian Pharmaceutical Manufacturing Industry and Their Impact on Sector Development and Market Share Growth." This work is original and is suitable for submission for the award of the Master of Arts in Marketing Management.

Approved by:

ExternalExaminer: _____ Signature: _____ Date: _____

InternalExaminer: _____ Signature: _____ Date: _____

Advisor:_____ Signature: _____ Date: _____

_____

Head of Department

Acknowledgment

First and foremost, I extend my deepest gratitude to God Almighty. All praise to our Creator for the blessings bestowed upon us! Without God's grace, none of this would have been possible; and now, I stand here in success! For all that has been achieved, may your name be exalted forever and ever!

I would also like to express my heartfelt thanks to my advisor, Dr. TemesgenBelayneh, for his valuable guidance from the inception of my proposal to the completion of this thesis.Additionally, I am deeply appreciative of all the participants from manufacturing firms and stakeholder institutions who provided crucial information and assistance during the data collection process.Finally yet importantly, my sincere thanks go to the Addis Ababa University School of Commerce, Department of Marketing Management Postgraduate Coordination Office for granting me the opportunity to pursue and complete my thesis work.

Dedication

To the cherished memory of my beloved mother, WolateShaheboAbbae, whose unwavering support and sacrifices paved the way for my success. Her dreams for me were boundless, and her encouragement was my constant companion. Though she left us too soon, her spirit and vision continue to inspire me every day. To my dad, Lobe WotiteBasore (a wonderful and model farmer of his community), whose advice and storytelling built my self-confidence and strength, to my beloved sister, Worknesh Lobe, who has always been supportive and by my side from my childhood to the present. You all made me the person I am today.

Abbreviations and Acronyms

CAPA: Corrective and preventive actions

cGMP: Current Good Manufacturing Practices

EFDA: Ethiopian Food and Drug Authority

EFMHACA: Ethiopian Food Medicine and Health Care Administration Authority

EiC: Ethiopian investment commission

EPSA: Ethiopian Pharmaceutical Supply Agency

EPSA: Ethiopian Pharmaceuticals Supply Agency

FBPIDI: Food, Beverage, and Pharmaceutical Development Institute

GIZ: German development agency

GMP: Good Manufacturing Practices

GTP: Growth Transformation Plan

HIV: Human Immunodeficiency Virus

HSTP: Health sector transformation plan

MOH: Ministry of Health

MOH: Ministry of Health

MoTI: Ministry of trade and industry

NSPA-Pharma: National Strategy & Plan of Action for the Dev't of Pharmaceutical manufacturing

OCPMIs:operational challenges of pharmaceutical manufacturing industries

OSCM: Operations and Supply Chain Management

PIDI: Pharmaceutical Industry Development Institute

PMPA: Pharmaceutical Manufacturing Plan for Africa

PQM+: Promoting the Quality of Medicines Plus

SAP: Systems Applications and Products in Data Processing

SDG: Sustainable Development Goal

UNIDO: United Nations Industrial Development Organization

USAID: United States Agency for International Development

USD: U.S. dollar

USP: United States Pharmacopeia

WHO: World Health Organization

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Abstract

This study examines the operational challenges in Ethiopia's pharmaceutical manufacturing sector and their impact on sector development and market share growth. The industry faces financial constraints, raw material disruptions, technological limitations, and supply chain inefficiencies, with low capacity utilization reported by most respondents. Critical issues include forex shortages, raw material supply problems, political instability, and customs regulations. While government policies are generally supportive, there is a call for stronger protection of local manufacturers. The study highlights the sector's potential to contribute to national health and economic development, emphasizing strategies such as financial support, policy reforms, supply chain optimization, human resource development, technological advancements, and strategic alliances. These efforts could enhance operational efficiency, competitiveness, and long-term growth. Future research should explore comparative studies, policy assessments, innovation, and foreign investment to deepen understanding and guide effective strategic planning in the industry.

Key words: *Operational Challenges, Ethiopian Pharmaceutical Manufacturing Industry, Market Share Growth.*

CHAPTER ONE–INTRODUCTION

1.1 Background of the Study

The manufacturing sector plays a critical role in the global economy, contributing significantly to innovation, productivity, trade, and employment. It represents approximately 16% of global GDP and 14% of total employment, driving economic growth, particularly in developing nations, and fostering advancements in living standards across the globe (McKinsey & Company, 2012; Halloran, 2013). However, the industry is grappling with significant challenges. Global disruptions such as natural disasters, geopolitical tensions, and supply chain uncertainties have increased lead times, raised costs, and compromised product quality (McDowell, 2023; Maxwell, 2009). Moreover, factors such as free trade agreements, environmental sustainability practices, and responsible sourcing continue to shape the global manufacturing landscape, offering both opportunities and challenges for businesses (Styles, 2017).

The current era marks the fourth industrial revolution (4IR), with technologies such as artificial intelligence, robotics, the Internet of Things (IoT), and 3D printing ushering in a new wave of growth and competitiveness (Koleva, 2018; Dharbal, 2023). These technological advancements offer new avenues for growth but require businesses to adapt, innovate, and make significant investments. The industry is also transitioning to Industry 5.0, emphasizing human-centric systems where collaboration between humans and machines is key (Adel, 2022). Despite its importance, manufacturing in developing countries faces several operational challenges that limit its potential, but strategic operational management can help overcome these barriers and unlock growth (Project et al., 2022; SolutionBuggy, 2022).

The pharmaceutical industry is essential to national health, economic stability, and social well-being. Despite operational hurdles, companies that successfully adapt by innovating production models and offering differentiated products can significantly influence public health and economic prosperity (Sarkis et al., 2021; Papalexi, Bamford, and Breen, 2020; Selam et al., 2022). A key observation from existing literature indicates that, traditionally, the pharmaceutical industry has often deprioritized strategic operations management due to competing business demands. However, recent challenges like the COVID-19 pandemic, inflation, and geopolitical tensions have made it critical for companies to revisit and refine their operational strategies (Maria Gomez Albrecht, Mark Green, 2023).

Ethiopia's pharmaceutical industry has a history spanning over 50 years, marked by significant growth and reform, but also by major challenges. EPHARM, the first pharmaceutical factory in Ethiopia, was established in 1964 in collaboration with a British firm. During the military regime (1974–1991), EPHARM was the sole producer of human medicines, and the National Veterinary Institute (NVI) was responsible for animal medicines and vaccines. Until 1993, EPHARM was the only producer of medicines, as socialist policies hindered private investment. From 1995 to 2004, the sector witnessed growth with new pharmaceutical factories emerging, yet this period was also marked by significant difficulties such as the lack of supportive policies and poor management, leading to bankruptcies (Gebre-Mariam, Tahir, and Gebre-Amanuel, 2016).

The growth of the pharmaceutical manufacturing sector in Ethiopia has been constrained by challenges such as limited production capacity, technology gaps, and insufficient investment in infrastructure and skills development. The government has introduced measures to tackle these barriers, focusing on healthcare improvement and industrial growth. Policy reforms and incentives have been implemented to attract private investment into the pharmaceutical sector (MoH and MoI, 2015; Gebre-Mariam, Tahir, and Gebre-Amanuel, 2016; Ethiopian Investment Board, 2017).

Despite Ethiopia’s population of about 123.4 million in 2022, which positions it as the second most populous nation in Africa, the country remains among the poorest with significant health challenges (World Bank, 2024). The pharmaceutical sector plays an essential role in addressing these challenges by providing the necessary medicines and medical supplies. However, it faces significant operational challenges such as the scarcity of raw materials, skilled labor, advanced technology, and quality assurance systems. These constraints impede the sector's growth and development (MoH, 2021; Papalexi, Bamford, and Breen, 2020; Festa et al., 2022; Calnan, 2023).

Despite government support, the Ethiopian pharmaceutical sector remains heavily reliant on imports, with local production covering only about 15% of the national demand. The industry is also plagued by outdated machinery, financial limitations, and difficulties in meeting international regulatory standards. While some growth has been observed, the sector’s low production capacity, poor technology adoption, and weak quality assurance mechanisms continue to limit its potential to satisfy domestic and international market demand (MoH, 2021; AUC-UNIDO, 2012). These operational inefficiencies directly affect medicine availability, affordability, and quality, thereby impacting both public health outcomes and the economy by limiting job creation, tax revenue, and foreign exchange earnings (MoH, 2015; EiB, 2017).

A critical gap exists in the literature regarding how pharmaceutical manufacturers can integrate operational challenges with marketing strategies to enhance their market position. While considerable research has explored operational difficulties, fewer studies have examined how these challenges can be leveraged as opportunities to improve marketing outcomes. Addressing operational challenges from a marketing perspective can offer insights into how enhancing operational efficiency can become a key element of competitive marketing strategies, improving product quality, brand reputation, and customer trust (Maria Gomez Albrecht, Mark Green, 2023; Grassl, 2000; Harvard Business School, 1995). This research aims to bridge this gap by evaluating operational challenges in the Ethiopian pharmaceutical sector from a marketing standpoint, offering strategies that could lead to greater operational efficiency and market share growth.

Through this investigation, the study seeks to identify and address the operational barriers faced by the pharmaceutical manufacturing industry in Ethiopia, highlighting the interlinkages between operational performance and marketing strategy. In doing so, it will offer recommendations for enhancing both the operational and marketing dimensions of the industry, thereby contributing to the growth of the sector, improved product availability, and ultimately better patient outcomes.

1.2 Statement of the Problem

The pharmaceutical sector is essential for the health, well-being, and economic growth of any nation. However, Ethiopian pharmaceutical manufacturers face various operational challenges that inhibit their growth, competitiveness, and sustainability. By integrating operational strategies with marketing techniques, these challenges could be transformed into competitive advantages. Key issues include quality management, regulatory compliance, innovation, market dynamics, human resources, infrastructure constraints, and environmental impacts. These challenges are particularly pronounced in developing nations like Ethiopia, where the pharmaceutical sector is underdeveloped and overly reliant on imports (Sarkis et al., 2021; Papalexi, Bamford, and Breen, 2020; Selam et al., 2022).

Despite the Ethiopian pharmaceutical industry's long history, its capacity to contribute meaningfully to the nation's economy remains limited, primarily due to low technological advancement, underdeveloped production capacity, and financial constraints. The sector contributes minimally to Ethiopia's GDP, and local industries are constrained by high operating costs and low-quality production standards (WHO, 2011). Given the country's significant burden of communicable and non-communicable diseases, as well as frequent epidemics, reliable access to quality pharmaceutical products is vital to meeting healthcare needs (Marew and Richmond, 2022). However, local

pharmaceutical production has not yet reached its full potential, with only 15% of essential medicines produced domestically, creating a dependence on imports and making the sector vulnerable to external shocks and supply disruptions (EFDA, 2017; Selam et al., 2022).

This study aims to assess the operational challenges facing the pharmaceutical manufacturing industry in Ethiopia, identifying their causes, effects, and potential solutions, while exploring their impact on the sector's development. By examining these challenges from a marketing perspective, the study will provide strategies for enhancing the industry's operational efficiency and its market position. Ultimately, this research will offer recommendations for improving the pharmaceutical manufacturing sector's contribution to the national health system and economy.

1.3 Research Questions

In alignment with the problem statement, this research aims to address key questions concerning the operational challenges within the Ethiopian pharmaceutical manufacturing industry, and their impact on both sector development and market share growth.

Core Research Question:

- What are the primary operational challenges faced by pharmaceutical manufacturing industries in Ethiopia, and how do these challenges influence the sector's development and market share growth?

Specific Research Questions:

1. What specific types of operational challenges do pharmaceutical manufacturing industries in Ethiopia encounter?
2. How do these operational challenges impact the economic, social, environmental, and technological development of the pharmaceutical sector in Ethiopia, as well as its market positioning and growth potential?
3. What are the best practices and strategic solutions for overcoming these operational challenges, and how can they contribute to enhancing the sector's development and increasing its market competitiveness?

1.4 Objectives of the Study

This study is designed to assess the operational challenges in the Ethiopian pharmaceutical manufacturing industry while exploring their impact on sector development, market share growth, and overall performance. The study will also focus on identifying strategies that integrate operational improvements with marketing approaches to enhance the sector's efficiency, competitiveness, and resilience.

1.4.1 General Objective of the Study

- To assess the operational challenges faced by pharmaceutical manufacturing industries in Ethiopia and analyze their impact on the sector's development, market competitiveness, and market share growth.

1.4.2 Specific Objectives of the Study

1. To identify the main operational challenges faced by pharmaceutical manufacturing industries in Ethiopia, including those related to production capacity, technology, quality assurance, and supply chain issues.
2. To evaluate the potential solutions and strategies to address these challenges, focusing on how operational improvements can be integrated with marketing strategies to enhance the sector's development and market positioning.
3. To provide actionable recommendations and suggestions for policymakers, industry stakeholders, and researchers on improving operational efficiency, enhancing competitiveness, and leveraging operational challenges as opportunities for market share growth and improved patient outcomes.

1.5 Significance of the Study

The significance of this study lies in its potential to address the critical operational challenges faced by Ethiopia's pharmaceutical manufacturing industry, with a particular focus on how these challenges impact both sector development and market share growth. The study will contribute to the literature by bridging the gap between operational challenges and marketing strategies, emphasizing how improvements in operations can also serve as strategic marketing tools that enhance product quality, brand reputation, and patient well-being.

By integrating operational challenges with marketing concepts, pharmaceutical manufacturers can navigate the complex and competitive landscape of the industry more effectively. This holistic approach positions operational challenges not just as barriers, but as opportunities for market differentiation and growth. Addressing these challenges from a marketing perspective will help companies improve their market share, enhance their competitiveness, and deliver high-quality medications, thereby contributing to improved public health outcomes.

The findings of this study can also inform the development of policies, standards, and best practices aimed at fostering a more competitive pharmaceutical manufacturing sector in Ethiopia. This, in turn, can support Ethiopia's ambition to become a leading producer and exporter of quality medicines in Africa, ensuring that the country meets both its domestic healthcare needs and its international market potential.

1.6 Scope of the Study

This study aims to explore the operational challenges and their impact on the performance of local pharmaceutical production and the sector's development in Ethiopia. It will involve the 13 pharmaceutical (11 human medicines, one veterinary products and one empty gelatin) manufacturing companies and selected stakeholders working for the sector's development. The study will exclude other similar industries such as medical device & supplies manufacturers due to time constraint. (See Annex ll for the list of surveyed companies).

1.7 Definition of Terms / Concepts

Operations: Refers to all the activities concerned with the transformation of materials, information or customers (open.edu).

Operations management (OM): is the administration of business practices to create the highest level of efficiency possible within an organization concerned with converting materials and labor into goods and services as efficiently as possible. (MCCLAY, 2022)(Hayes,2023).

Operational challenges: are the difficulties or problems that arise in the process of performing operations. Some examples of operational challenges are quality issues, capacity constraints, supply chain disruptions, environmental impacts, and human resource management (doi.org).

Industry 4.0: Refers to manufacturing digitalisation and automation of processes, introducing autonomous, computerised systems (Sarkis et al., 2021).

Pharma 4.0: Adaptation of digital strategies and tools of Industry 4.0 principles, and their application to pharmaceutical manufacturing and supply chain practices (Sarkis et al., 2021).

Pharma industry: is a pharmaceutical industry comprised of companies engaged in researching, developing, manufacturing & distributing drugs for human or veterinary use(Finn, 2016).

Pharmaceuticals (biopharmaceuticals, drugs, medicines): are defined as any substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or any substance (other than food) intended to affect the structure or function of the body(Pharmaceutical, Products and Food, 2018).

Active pharmaceutical ingredients (APIs): are the compounds that make drugs effective/ biologically active compounds in a drug formulation that imparts the desired therapeutic effect(Pharmaceutical, Products and Food, 2018).

Excipients: are the inert substances that give a medication its form, such as cornstarch (to make a tablet) or sterile water (to make a liquid), and serve as a delivery vehicle to transport the active ingredient to the site in the body where the drug is intended to exert its action(Pharmaceutical, Products and Food, 2018).

Generic (Generic Medicine): A pharmaceutical product (medicine) which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicine, and whose bioequivalence with the reference medicine has been demonstrated by appropriate bioavailability studies(Vogler and Zimmermann, 2016).

Good Manufacturing Practices (GMP): That part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization(Vogler and Zimmermann, 2016).

Manufacturing: includes all operations of receipt of materials, production, packaging, repackaging, labelling, relabeling, quality control, release, storage, and distribution of products and related controls(Vogler and Zimmermann, 2016).

Multi-faceted: having many different aspects, dimensions, or characteristics. It describes something that has multiple, varied, or complex features. Refer to the different sides, angles, or perspectives that make up the whole.

Sector: A sector is a segment of the economy representing a large grouping of companies with similar business activities, such as the manufacturing, extraction of natural resources agriculture, service provision and etc. (investopedia.com/terms/s/sector.asp)

Market share growth: Increase in the percentage of total sales within a particular market that is controlled by a specific company, product, or industry over time.

1.8 Organization of the Study

This thesis comprises five chapters. The first chapter serves as an introduction, covering the study's background, problem statement, research questions, study objectives, significance, and scope. The second chapter delves into a review of related literature, encompassing concepts, theories, empirical reviews, and a conceptual framework. The third chapter details the methodology employed for the assessment. In the fourth chapter, findings from data analysis, interpretations, results, and hypothesis testing are presented. Finally, chapter five is constituted of summary of the previous chapters' findings, and leading to a conclusion based on the results, recommendations, and future research directions.

CHAPTER TWO - LITERATURE REVIEW

2.1 Introduction

This literature review examines the operational challenges affecting pharmaceutical manufacturing in Ethiopia and their impact on the industry's development, market share growth, and competitive positioning. Pharmaceutical manufacturing is crucial for ensuring access to essential medicines, but various operational difficulties hinder growth, product quality, and performance.

2.2 The concept of Operational Management

Operations Management (OM), which evolved from production management, focuses on optimizing business practices to achieve efficiency by converting raw materials and labor into goods and services. It aims to balance costs and revenues while maximizing profitability. OM plays a critical role in strategic decision-making, aligning processes across departments such as marketing, finance, and supply chain management. Effective OM emphasizes the efficient use of resources, innovation, and adapting to market demands.

Key theories in OM include Business Process Reengineering (BPR), Six Sigma, Lean Manufacturing, and Reconfigurable Manufacturing Systems. These theories aim to improve business workflows, quality control, and waste reduction. By applying OM principles, organizations can enhance productivity, reduce costs, and meet consumer demands more effectively (Hayes, 2023; Bhartiya, 2020).

In the pharmaceutical sector, operational management directly influences market competitiveness. Challenges such as regulatory compliance, supply chain disruptions, and technological advancements are significant for maintaining a competitive edge. Addressing these operational obstacles also offers marketing opportunities to differentiate products and build brand reputation. By prioritizing quality control and compliance, pharmaceutical companies can gain customer trust, which is crucial in a market focused on consumer safety and reliability (Kotler& Armstrong, 2018; Lee & Ha, 2019).

Incorporating operational management with marketing strategies enables pharmaceutical companies to tackle industry challenges effectively, increase efficiency, and improve market positioning. Thus, operational improvements translate into enhanced consumer perceptions, stronger brand loyalty, and greater market share growth.

2.3 Operational challenges in Pharmaceutical Manufacturing

Operational challenges are the difficulties or problems that arise in the process of performing operations. Some examples of operational challenges are quality issues, capacity constraints, supply chain disruptions, environmental impacts, and human resource management.

The pharmaceutical manufacturing industry is a vital and strategic that contributes to the health, well-being, and economic development of a nation. However, the sector faces various operational challenges that affect its performance, competitiveness, and sustainability(Sarkis et al., 2021), (Papalexi, Bamford and Breen, 2020a), (Selam et al., 2022). These challenges, which include quality issues, regulatory compliance, innovation barriers, market dynamics, human resource constraints, infrastructure deficiencies, and environmental and social impacts, are especially pronounced in developing countries, where the pharmaceutical sector is still underdeveloped and dependent on imports.

According to (Navigator Business Solutions, 2022) the pharmaceutical industry faces operational challenges, including supply chain interruptions, data management, lack of agility and transparency, and workforce optimization. Technological advancements like cloud computing and SAP solutions for life sciences can help address these challenges by streamlining operations, improving data collection and analysis, and enhancing workforce efficiency. These technologies enable companies to gather and manage information effectively, collaborate with customers, and optimize their workforce, ultimately providing an edge over competitors.

The pharmaceutical industry encounters challenges in achieving operational efficiency with multiple automated production lines. Implementing automated management systems for KPIs like OEE is crucial for enhancing production performance. However, the low adoption of automated KPI systems results in unreliable data and industry losses. Full automation integration with company management is vital for high efficiency, especially in Industry 4.0. OEE, linking productivity, quality, and readiness, is key for financial performance. While top companies reach OEE rates of 85-90%, most struggle with rates below 60% due to KPI monitoring issues. Achieving full production integration is crucial for digital transformation and optimizing efficiency(Bieber,2013).

Pharmaceutical manufacturing faces challenges in quality maintenance, cost management, and innovation to meet healthcare demands. Automation and digitalization offer opportunities to enhance operations, improve patient outcomes, and streamline processes. Collaboration with research institutions and healthcare providers can drive innovation, while advancements like 3D printing and

personalized medicine hold promise for the industry's future. Automation and digitalization can help pharmaceutical manufacturers streamline their processes by reducing human error, increasing efficiency, and improving overall quality control. Through automation, repetitive tasks can be performed with precision and consistency, leading to enhanced productivity and reduced variability in manufacturing processes. Digitalization enables real-time monitoring and data analysis, facilitating proactive decision-making and problem-solving. Additionally, digital tools can optimize inventory management, supply chain logistics, and regulatory compliance, contributing to a more streamlined and agile manufacturing operation.

Balfour, 2022highlights six major challenges facing pharmaceutical and biopharmaceutical manufacturers as identified by representatives from contract manufacturing and development organizations. These challenges include supply and demand issues, the need to adapt to novel technologies such as mRNA vaccines and therapeutics, the emergence of cell and gene therapy, the increasing pressure for speed to market, and the skilled labor shortage. These challenges impact the manufacturing processes and require companies to adapt and innovate to meet the demands of the industry. According to (Joyeux, Simon, Dipen Shah, 2023), the pharmaceutical industry faces challenges due to the impending patent cliff, leading to financial pressure and loss of market exclusivity for top-selling drugs. However, there are opportunities for investment in the life sciences sector, with increased deal volume and partnerships.

The industry is changing its business models to focus on performance-centric models, digital solutions, and green technology, leading to more mergers and acquisitions. Pharmaceutical companies are investing in new therapies like cell and gene therapies to generate revenue and offset the financial impact of patent expirations. They are also prioritizing performance improvement through technologies like AI, cloud computing, real-world evidence, and advanced analytics to manage costs and enhance adaptability. Life sciences companies have shifted from diversified portfolios to a performance-centric model due to the pandemic, resulting in more spin-offs as companies concentrate on core sectors.

According to (SolutionBuggy, 2022) top challenges faced by manufacturing industries include demand forecasting, inventory management, production efficiency, return on investment, and technology adoption. It emphasizes on the importance of accurate demand forecasting, efficient inventory management systems, optimized production processes, and strategic investment planning as potential solutions. It also highlights the need for manufacturing companies to adapt to new technologies, such as Industry 4.0, to stay competitive in the market

According to (Sarkis et al., 2021), The pharmaceutical industry faces challenges in manufacturing and distribution due to complex supply chains, diverse products, economic viability, and standardization. Innovative solutions like Continuous Manufacturing and Pharma 4.0 are needed. Continuous Manufacturing offers benefits like smaller equipment, longer runs, higher yields, and faster production with real-time monitoring. Pharma 4.0 applies digital strategies to enhance communication and monitoring in factories. Opportunities for improvement include digital innovation for communication and monitoring of storage conditions, as well as optimizing supply chain design for efficient distribution of various product types using digital technologies.

Papalexi, Bamford and Breen, 2020explored operational inefficiencies in the pharmaceutical supply chain (PSC) in the UK and Greece, identifying common challenges such as quality, visibility, speed, and cost in medicine delivery. Major concerns include financial constraints, communication issues, waste management, and inventory complexity. The findings suggest targeted interventions to address these challenges and improve delivery processes, communication, and waste management in European healthcare organizations.

On their Indian health-care industry scenario analysis (Festa et al., 2022) have discussed the Indian pharmaceutical sector offers growth opportunities like low production costs, government support, clinical trials, export potential, and innovation. Recent changes at institutional and corporate levels have impacted the industry significantly, including intellectual property regulations, R&D investments, government initiatives, regulatory changes, and export dynamics. The threats and weaknesses facing Indian pharmaceutical companies include challenges in the patent regime, raw material dependence, pricing regulations, lack of R&D focus, competition, and external competition. Addressing these issues is vital for sustainable growth and expansion in the industry.

Steele et al., 2020, advocates for local pharmaceutical manufacturing in Africa, especially in response to the COVID-19 pandemic. It stresses the importance of African nations developing their pharmaceutical industry to ensure access to affordable, high-quality medicine. The article discusses how restrictions in higher-income countries impact African drug manufacturers' access to machinery, packaging, and active pharmaceutical ingredients (APIs). It underscores the significance of local pharmaceutical production in addressing local health crises and the challenges posed by the current pandemic, emphasizing the need for accessibility and continuity of medical supplies in Africa.

2.4 Challenges of Pharmaceutical Manufacturing Business in Ethiopia

This section reviews the operational challenges faced by the pharmaceutical manufacturing industry in Ethiopia and examines how these challenges impact sector development and market share growth. The pharmaceutical industry is crucial for ensuring the availability and accessibility of medicines, but local manufacturers face significant operational hurdles that limit their competitiveness and growth potential. Key challenges include supply chain inefficiencies, high import dependency, low production capacity, regulatory barriers, inadequate infrastructure, and a lack of innovation. These challenges not only impede the growth and sustainability of the sector but also hinder the ability of local manufacturers to meet market demand for affordable and high-quality medicines(Selam et al., 2022, FBPD, 2020, Gerba, 2018, WHO, 2011).

A significant operational challenge in the Ethiopian pharmaceutical sector is the supply chain. Issues such as forecasting inaccuracies, long lead times, and inadequate inventory management are prevalent, resulting in high supply chain costs and disruptions that impact the timely delivery of medicines. Moosivand, Ghatari, and Rasekh (2019) proposed a system dynamics methodology to address these challenges, recommending strategic policies to improve supply chain efficiency. The introduction of better supply chain management practices, coupled with improved procurement processes, could not only boost local production but also reduce dependency on costly imports, thereby lowering the cost of medicines and enhancing market share for local manufacturers.

Mohammed, Brahma, and Aderaw (2019) examined the impact of Total Quality Management (TQM) on the operational performance of Ethiopian pharmaceutical manufacturing plants. They found that customer focus, process management, product design, and people management had significant positive effects on the quality, cost, delivery, and flexibility of the products and services. However, top management support, suppliers' quality management, and continuous improvement did not show significant contributions to the performance measures(Aderaw, Mohammed, 2019).

The Ethiopian Food and Drug Administration EFDA, 2016, conducted a national pharmaceutical sector assessment using the World Health Organization (WHO) indicators. It revealed that the sector faced several challenges, such as low local production capacity, high dependence on imports, poor quality assurance and control, weak regulation and enforcement, inadequate human resources and infrastructure, and low access and affordability of essential medicines. The assessment also identified some opportunities and recommendations for improving the sector, Strengthening regulatory systems, ensuring consistent enforcement of standards, and fostering a culture of compliance could

help local manufacturers build trust with consumers and stakeholders, which would be an important marketing strategy for brand differentiation in the market(EFDA, 2017).

An assessment report by (FBPD and EFDA, 2020), discusses about capacity and challenges of local pharmaceutical industries in Ethiopia and identified lack of hard currency, price increase and blockade of transportation due to covid 19, shortage from suppliers, poor access to finance/loans and inadequate utilities being the top challenge faced by local pharmaceutical manufacturers. These challenges are hindering the producers' ability to yield medicines at full capacity. This report also indicated China, India, Europe, United Arab Emirates (UAE) and Egypt as main sources of APIs for the local manufacturers.

Based on a report by Manufacturing Africa, The pharmaceutical market in Ethiopia is growing, with potential for local manufacturing to meet the rising demand. Currently, the market is dominated by imports, with opportunities for local production of finished pharmaceutical products (FPPs) and excipients. The government has implemented measures to improve the sector, including a 10-year strategy and the development of a dedicated industrial park for pharmaceutical manufacturing. The country's well-established air logistics network could also position it to export pharmaceutical products to the larger sub-Saharan market(Maritz, 2022).

Marew and Richmond, 2022, discussed the trends and challenges in access to essential medicines in Ethiopia and the contributions of local pharmaceutical production and highlights the need for a more sustainable supply of essential medicines to reduce reliance on imports and increase access. According to their finding the main challenges faced by Ethiopia in ensuring access to essential medicines include limited local pharmaceutical production meeting only 15-20% of national demand, reliance on imports, and limited availability of essential medicines in public and private health facilities.

Additionally, circulation of counterfeit or substandard medicines poses a challenge to the health system. The strategic plan for improving local pharmaceutical production in Ethiopia has shown progress with the establishment of pharmaceutical industry parks, incentive schemes for local manufacturers, and policy reforms. However, challenges such as reliance on conventional production technologies, low capacity utilization, and lack of sustainable financing persist. The government is working to strengthen infrastructure and enact fundamental policy reforms to capitalize on opportunities such as the growing local/regional market and the country's strategic location.

The operational challenges faced by Ethiopia's pharmaceutical manufacturing industry significantly affect its development and market growth potential. However, by addressing these challenges strategically, there are opportunities for improvement. Strengthening regulatory frameworks, improving quality control, investing in new technologies, and developing local production capacities are key to enhancing the sector's performance and expanding its market share. Integrating operational management practices with targeted marketing strategies can enable pharmaceutical manufacturers to differentiate themselves in the market, ultimately improving their competitive position both locally and globally.

By overcoming operational hurdles, Ethiopian pharmaceutical manufacturers can improve production efficiency, market share, and product quality, contributing to the broader goal of ensuring affordable and high-quality medicines for the country and the region.

2.5 Marketing Concepts Application

The pharmaceutical industry operates in a highly competitive and regulated environment where operational excellence is not just a business goal but a regulatory mandate. The assessment of operational challenges in this sector is pivotal for maintaining a competitive edge and ensuring the delivery of high-quality medications to the market. The operational challenges concern within this industry is significant because they directly affect the production of safe and effective medications. Addressing these challenges is not only a matter of operational efficiency but also a moral imperative to ensure the well-being of patients worldwide(Maria Gomez Albrecht, Mark Green, 2023, Grassl, 2000, Harvard businesses school, 1995).

From a marketing perspective, these operational challenges present an opportunity for pharmaceutical manufacturers to differentiate themselves. By focusing on quality assurance, regulatory compliance, and innovative solutions, local manufacturers can build brand reputation and trust among consumers, healthcare providers, and other stakeholders(Grassl, 2000,openstax.org).

Technological advancements, supply chain and cost management can be leveraged to create value propositions that appeal to cost-conscious healthcare providers and patients. Furthermore, aligning with consumer demands for sustainability and social responsibility can be an effective marketing strategy. Environmental sustainability, in particular, is becoming increasingly important to consumers and could be a powerful selling point for Ethiopian pharmaceutical manufacturers in the global market (Maria Gomez Albrecht, Mark Green, 2023).

Quality control: Quality control is directly linked to the brand's image. Consistent delivery of safe and effective medications reinforces brand equity and can lead to increased market share. It also mitigates the risk of costly recalls and legal issues(Kotler and Armstrong, Gary, 2018, Lee, J., & Ha, 2019).

Regulatory compliance: Regulatory compliance is not only a legal obligation but also a strategic marketing tool. Adherence to stringent regulations can be leveraged as a key differentiator in the market, positioning a company as a trustworthy and reliable manufacturer. This can enhance brand reputation and foster customer loyalty(Yang, 2020, YSarkar, P., & Singh, 2019).

Technological advancements: Investing in technological advancements can lead to innovative products and processes that set a company apart from competitors. Embracing new technologies can improve operational efficiency and create new market opportunities(Tidd, J., & Bessant, 2018, Maria Gomez Albrecht, Mark Green, 2023).

Supply chain and cost management: Additionally, the industry faces increasing pressure for sustainable sourcing and dealing with supply chain disruptions(Harvard businesses school, 1995). Efficient supply chain management is crucial for meeting market demands and reducing costs. Effective cost management enables competitive pricing strategies without compromising quality. By controlling costs, pharmaceutical manufacturers can offer better value to customers, which is a compelling marketing proposition(Christopher, 2016,Papalexi, Bamford and Breen, 2020, Chopra, S., & Meindl, 2015, Charles T. Horngren, Srikant M.Datar, 2018, Weru, 2018, Kotler and Armstrong, Gary, 2018).

Environmental sustainability: Environmental sustainability is becoming increasingly important to consumers. Companies that commit to sustainable practices can improve their public image and appeal to a growing segment of environmentally conscious consumers(Kotler and Wong, 1995, Kotler and Armstrong, Gary, 2018, UNIDO, 2018).

In conclusion, operational challenges and marketing strategies are interconnected in the pharmaceutical manufacturing industry. By addressing the operational challenges pharmaceutical manufacturers can not only enhance operational efficiency and product quality but also strengthen their market position. Ultimately, these efforts contribute significantly to the well-being of patients worldwide, aligning business success with social responsibility. Enhancing operational efficiency contributes to the overall market presence and consumer perception of a pharmaceutical brand.

By integrating operational challenges with marketing strategies, pharmaceutical manufacturers can navigate the complex landscape of the industry and emerge as leaders in providing high-quality, effective medications to the global market. This approach underscores the importance of a holistic view of operations, where every challenge is an opportunity for market growth.

2.6 Appropriate Interventions Based on the Literatures Discussed

Based on the literature reviewed, several strategic interventions are essential to overcoming the operational challenges in Ethiopia's pharmaceutical manufacturing sector. These interventions not only focus on operational improvements but also integrate marketing strategies to enhance the sector's competitiveness and market share growth.

To enhance the pharmaceutical sector in Ethiopia, the government and local manufacturers must collaborate on evidence-based policy reforms that address challenges such as supply chain inefficiencies, regulatory hurdles, and market access. Implementing effective business management practices, such as lean manufacturing and continuous improvement strategies, will drive operational efficiency, lower production costs, and boost the competitiveness of local manufacturers. These operational changes should be integrated with marketing strategies that effectively communicate improvements in product quality and availability, fostering consumer trust and increasing market demand.

Additionally, strengthening the regulatory frameworks and enforcement mechanisms is crucial for ensuring the safety and quality of pharmaceutical products. By enhancing the capacity of the Ethiopian Food and Drug Administration (EFDA) and rigorously enforcing regulations against counterfeit medicines, the government can bolster the credibility of local pharmaceutical companies. Regulatory compliance and quality assurance can serve as vital selling points in marketing, enabling local manufacturers to leverage certifications like Good Manufacturing Practices (GMP) and WHO prequalification to build brand reputation and consumer confidence.

Governmental support, including tax exemptions, subsidies, and preferential procurement policies, can significantly empower local pharmaceutical manufacturers by reducing operational costs and making locally produced medicines more competitive against imports. Moreover, providing managerial support through training, resource access, and industry-specific consultancy can enhance companies' marketing capabilities, improve product positioning, and increase market share.

Improving procurement and importation processes is also essential for ensuring easier access to raw materials and production equipment at reasonable prices. Streamlining these processes will decrease dependency on imports and alleviate supply chain disruptions. Marketing strategies can emphasize the benefits of local production in reducing import reliance, enhancing supply chain security, and contributing to the country's economic self-sufficiency.

Developing human resource capacity is vital for driving innovation, product quality, and operational efficiency within the pharmaceutical industry. Partnerships between government and private sectors to enhance training and educational programs will ensure a skilled workforce in critical areas such as research and development, manufacturing, and quality assurance. A highly skilled workforce can facilitate technological adoption and innovation, providing a competitive advantage that can be highlighted in marketing campaigns.

Promoting research and development (R&D) collaborations among local pharmaceutical manufacturers, academic institutions, and research organizations is essential for fostering innovation and product diversification. By investing in R&D, local manufacturers can create new products tailored to local needs, enhancing their market competitiveness. From a marketing perspective, promoting innovation and the development of locally relevant medicines can help establish a strong brand identity and increase consumer loyalty.

Lastly, implementing modern operations management theories such as Business Process Reengineering (BPR), Six Sigma, lean manufacturing, and reconfigurable manufacturing systems can significantly improve efficiency, quality, and flexibility in pharmaceutical manufacturing processes. These approaches will minimize waste, optimize production cycles, and ensure consistent product quality. By aligning these operational improvements with customer-centric marketing strategies, manufacturers can effectively demonstrate their commitment to quality, cost-effectiveness, and consumer satisfaction, thereby gaining a competitive edge in the market.

2.7 Literature gaps

Despite recognizing the operational challenges facing Ethiopia's pharmaceutical manufacturing sector, there remains a significant gap in leveraging these challenges as strengths in marketing. There is a pressing need for research that integrates operational excellence with marketing strategies to enhance market positioning and improve patient care(Maria Gomez Albrecht, Mark Green, 2023, Grassl, 2000, Harvard businesses school, 1995).. Specifically, empirical evidence is lacking regarding the impact of the policy environment and investment climate on sector growth. Understanding how macroeconomic factors and policy frameworks influence both operational performance and market dynamics could enable local manufacturers to align their business strategies with national policy objectives.

Moreover, the potential for sustainable stakeholder collaboration is underexplored. Effective partnerships among government bodies, the private sector, and other stakeholders can drive innovation, facilitate policy reforms, and improve infrastructure, ultimately benefiting both operational efficiency and marketing outcomes. Additionally, more research is needed to bridge operational challenges with marketing initiatives that emphasize the quality, accessibility, and affordability of locally produced medicines. Establishing this connection is crucial for enhancing market share and improving patient care.

A comprehensive assessment of operational challenges is also necessary, involving data-driven evaluations of issues such as supply chain disruptions, workforce shortages, and data security risks. Understanding how these challenges impact operational outcomes and market performance can provide valuable insights. By examining these issues from economic, social, environmental, and technological perspectives, stakeholders can identify strategies to enhance operational efficiency while simultaneously using these insights as strategic marketing tools. For instance, adopting sustainable practices and innovations can serve as marketing differentiators, appealing to environmentally conscious consumers and partners.

2.8 Conceptual Framework

This section outlines the study's conceptual framework, detailing how operational challenges impact the pharmaceutical sector's development and potential interventions. A conceptual framework serves to organize ideas and literature into a cohesive structure, identifying key concepts, variables, relationships, and research gaps. Interventions such as good business management practices, evidence-based policy reforms, effective strategies, and sustainable stakeholder collaboration are proposed. Low-quality and limited availability of medicines worsen health outcomes, increasing morbidity, mortality rates, and disease burden. Reliance on imports due to low local production heightens risks like supply shortages, price fluctuations, and quality issues. This dependence has hindered medicine availability, accessibility, affordability, and quality, hampering sector competitiveness.

The low competitiveness and profitability of the local manufacturers also affect the economic outcomes of the country, as they reduce the employment opportunities, tax revenues, and foreign exchange earnings. Some of the common operational challenges are: Supply chain disruptions, such as delays, shortages, or losses of raw materials, intermediates, finished products, or equipment, due to natural disasters, political instability, trade barriers, or other factors(Business, 2022). Workforce shortage, such as the lack of qualified, skilled, or experienced personnel, especially in the areas of research and development, manufacturing, quality assurance, and distribution(Viseven.com, 2024). Data security risks, such as the unauthorized access, theft, or manipulation of sensitive or confidential data, such as clinical trial data, patient data, intellectual property, or trade secrets, due to cyber-attacks, human errors, or malicious insiders(Deloitte, 2023).

These operational challenges affect the sector's development by: Increasing the costs and reducing the profits of the pharmaceutical companies, as they have to invest more in contingency plans, inventory management, quality control, training, and security measures(Business, 2022)(Viseven.com, 2024). Reducing the innovation and competitiveness of the pharmaceutical companies, as they have to deal with more uncertainties, complexities, and regulations, which may hamper their ability to develop new products, enter new markets, or adopt new technologies(Business, 2022)(Deloitte, 2023)(Viseven.com, 2024). Compromising the quality and safety of the pharmaceutical products and services, as they may be exposed to contamination, degradation, or falsification, which may harm the health and well-being of the patients and consumers(Business, 2022)(Viseven.com, 2024).

This study proposes a **conceptual framework** to understand how operational challenges impact the pharmaceutical sector's development and how these challenges can be addressed through various interventions. The framework emphasizes the relationship between key variables, with a focus on improving operational efficiency and market share growth.

The conceptual framework follows the **Input-Process-Output (IPO) Model**, where the operational challenges (input) are addressed through interventions such as policy reforms, business management practices, and regulatory improvements (process), leading to improved sector development and market outcomes (output).

Independent Variables (X): These are the operational challenges that affect the pharmaceutical manufacturing sector, such as Low productivity, High production costs, Poor quality standards, Inadequate infrastructure, Weak regulatory framework, Lack of innovation and technology adoption, Limited access to finance, raw materials, skilled labor, and technology. Addressing these challenges through targeted interventions, including marketing strategies, will help local manufacturers gain competitive advantages and expand their market share.

Process (Intervening Variables): Solutions such as policy reforms, capacity building, technology adoption, and multi-stakeholder collaboration act as interventions to overcome the operational challenges. **Interventions and Solutions**: Improving Access to Finance, Strengthening, Regulatory Framework, Investing in Research & Development (R&D), Promoting Technology Transfer, Government-Private Sector Collaboration.

Dependent Variables (Y): The desired outcomes from addressing these challenges include improvements in operational efficiency, production capacity, and product quality, which ultimately lead to enhanced market competitiveness, market share, and sustainable growth.

By focusing on these interventions and aligning operational improvements with targeted marketing efforts, the Ethiopian pharmaceutical manufacturing sector can improve its competitiveness, meet growing demand, and contribute to the country's economic and healthcare development.

Input-Process-Output (IPO) Conceptual Framework Model

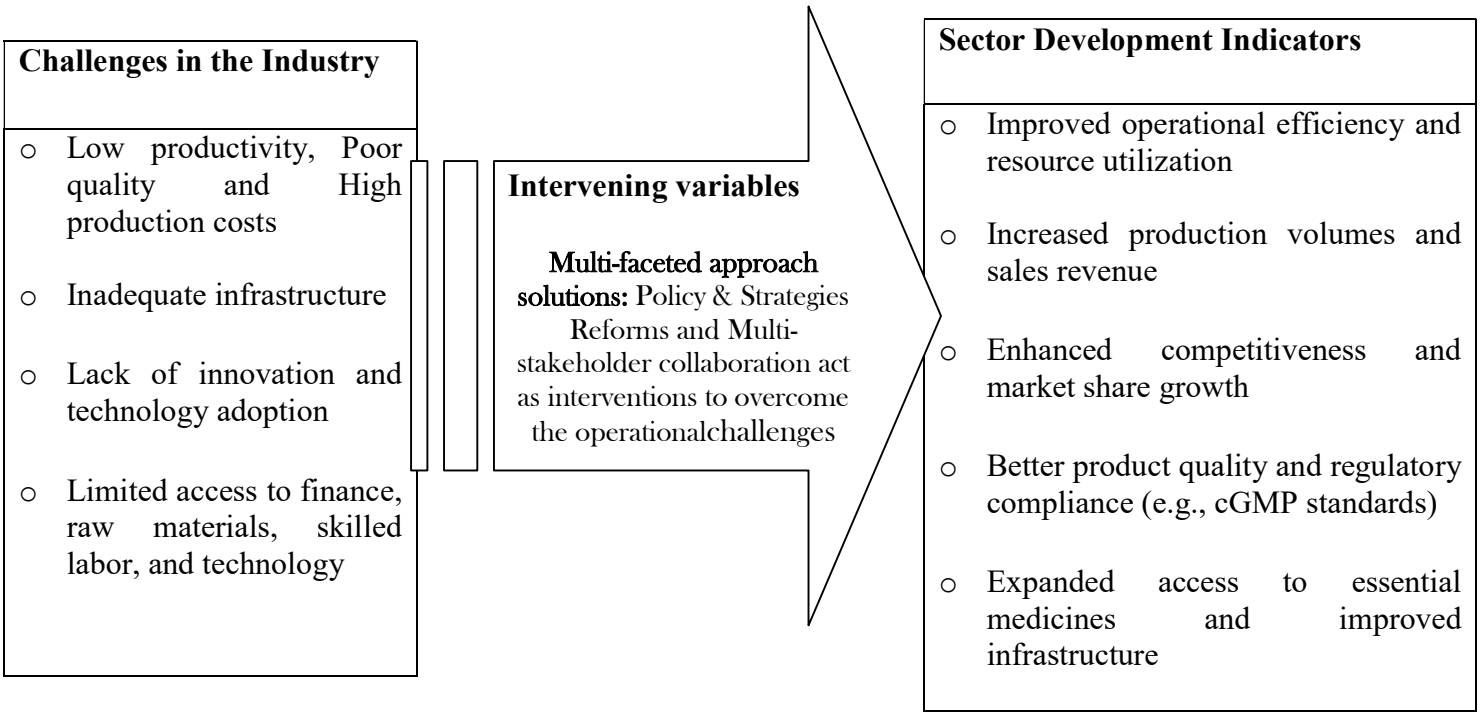

Figure 2.1 *Conceptual Framework*: Input-Process-Output (IPO) Model

Relationships:Operational challenges (Inputs) directly influence the **interventions/solutions (Process)**, which in turn contribute to the **sector's development outcomes (Outputs)**. Challenges and interventions could show continuous improvement, where addressing one challenge leads to enhanced capacity, allowing for further improvements in other areas.This conceptual model effectively connects the operational issues faced by the pharmaceutical sector to potential interventions, ultimately aiming for the desired sectorial growth and market share expansion.

2.10 Hypothesis [H] of the Study

Based on theoretical and practical evidences, the following hypotheses are proposed

H1: Pharmaceutical manufacturing industries in Ethiopia face significant operational challenges.

H2: Improving the operational efficiency by implementing appropriate strategies can help overcome the challenges and enhance the sector's development.

CHAPTER THREE- METHODOLOGY

Introduction

The pharmaceutical manufacturing industry in Ethiopia is vital for the nation's health, well-being, and economic prosperity. However, the sector faces persistent operational inefficiencies that hinder its growth and competitiveness, resulting in a heavy reliance on imported essential medicines. This study aims to conduct a comprehensive assessment of the operational challenges faced by the pharmaceutical manufacturing industry in Ethiopia to foster growth, improve market share, and enhance contributions to the healthcare system and economy. This chapter outlines the methodology used in this study, detailing the research approach, design, data sources, target population, sampling methods, data collection techniques, and data analysis procedures.

3.1 Description of the Study Area

The study focuses on identifying the operational challenges facing pharmaceutical manufacturing firms in Ethiopia and assessing their impact on sector development and market share growth. The research targeted 13 licensed and actively operating pharmaceutical manufacturing companies in Ethiopia (Ministry of Health, 2021), representing a cross-section of the industry involved in producing pharmaceutical products for domestic and regional markets.

3.2 Research Approach

A mixed-methods approach was employed, combining both quantitative and qualitative data collection and analysis techniques. This approach enables a comprehensive understanding of the operational challenges faced by the pharmaceutical manufacturing industry in Ethiopia by integrating numerical data with personal insights. The combination of these methods captures the complexity of the sector's challenges and their impact on business performance and market share.

3.3 Research Design

A descriptive research design was used to systematically assess the operational challenges in Ethiopia's pharmaceutical manufacturing industry. This design facilitated data collection through surveys, interviews, and observations to identify specific operational challenges, their root causes, and their consequences on sector development, market competitiveness, and growth.

3.4 Population and Sample

The study targeted all actively operating pharmaceutical manufacturing firms in Ethiopia. A census approach was used to include all firms engaged in pharmaceutical manufacturing, along with relevant stakeholder organizations supporting industry development. The primary focus was on the existing

pharmaceutical manufacturing companies producing medicinal products in Ethiopia. According to the Ministry of Industry, there are approximately 13 pharmaceutical companies in the country.

Given the relatively small number of pharmaceutical manufacturers, a census method was deemed appropriate. The target population comprised purposively selected respondents, including top managers, middle managers, and senior experts from the manufacturing firms, as well as representatives from stakeholder organizations such as government agencies, regulatory bodies, and industry associations. A total of 57 respondents were identified as the study population, based on the potential number of participants from each firm. The Surveyed covered all 13 pharmaceutical manufacturers, with the list of these firms summarized in Appendix II. The study population consisted of carefully selected professionals within Ethiopia's pharmaceutical industry. The distribution of potential respondents is detailed in Appendix III.

3.5 Data Sources and Types

Both primary and secondary data were utilized. Primary data were collected through self-administered questionnaires, surveys, and key informant interviews with industry professionals and stakeholders. Secondary data were obtained from existing reports, publications, and databases related to the pharmaceutical sector in Ethiopia, including resources from the Ethiopian Food and Drug Authority (EFDA) and the Ministry of Health (MoH).

3.6 Data Collection Procedures

Data were collected through a cross-sectional field survey involving pharmaceutical manufacturing firms and key stakeholders in the sector. The survey included closed-ended, multiple-choice, and rating scale questions to gather quantitative data. In addition, semi-structured open-ended interviews were conducted with key informants to explore operational challenges in greater depth.

3.7 Data Analysis

Quantitative data were analyzed using descriptive statistics to summarize key features such as mean, median, mode, standard deviation, range, and frequency distribution. Inferential statistics, including chi-square tests, were employed to explore relationships between categorical variables, while correlation analysis was used to assess the strength and direction of linear relationships between operational challenges (independent variables) and sector development (dependent variables). Statistical software (SPSS) was used to process survey responses, identify key trends, and present the data using tables, frequency distributions, and percentages for clarity.

The study, being descriptive in nature, relied on both quantitative and inferential analysis techniques. Descriptive analysis provided detailed information about operational challenges faced by pharmaceutical manufacturing firms in Ethiopia and the characteristics of relevant variables.

Qualitative data were analyzed using thematic analysis to uncover recurring themes and insights not captured by quantitative measures. This involved systematically reading each interview transcript line by line, attaching codes, developing categories, and conducting a detailed analysis. The steps included organizing the data, gaining an overall understanding, and analyzing the information gathered from participants.

A mixed-methods approach was used to integrate findings from both quantitative and qualitative analyses. This combination of numerical data and thematic insights allowed for a deeper understanding of the operational challenges faced by the pharmaceutical sector and their impact on its development and market share growth. By merging these methods, the study provided a comprehensive and meaningful interpretation of the findings.

3.8 Data reliability and Validity

The Cronbach's Alpha coefficient measures the internal consistency or reliability of a set of items (variables). It indicates how well these items correlate with each other.

Satisfaction Level on Government Policies and Pharmaceutical Business

Case Processing Summary

		N	%
Cases	Valid	49	100.0
	Excluded[a]	0	.0
	Total	49	100.0

Reliability Statistics

Cronbach's Alpha	N of Items
.709	7

The reliability test using Cronbach's Alpha resulted in a value of .709, indicating a moderate level of internal consistency among the items. This value still suggests that the items in this set of data are measuring the same underlying construct which is considered acceptable.

Reliability Statistics

Cronbach's Alpha	N of Items
.906	8

Pharmaceutical Industry Challenges, Strategies to Overcome and Leverage Government Support

Case Processing Summary

		N	%
Cases	Valid	49	100.0
	Excluded[a]	0	.0
	Total	49	100.0

[a.] Listwise deletion based on all variables in the procedure

The reliability test using Cronbach's Alpha yielded a Cronbach's Alpha value of .906, indicating a high level of internal consistency among the items. This suggests that the items in this set of data are measuring the same underlying construct reliably. Overall, both sets of data have acceptable levels of reliability based on the Cronbach's Alpha values.

3.9 Ethical Consideration

Confidentiality concerns were valued with anonymous summaries provided in reporting survey findings. Respondents' consent to participate was sought, and their privacy and rights were observed throughout the study.

CHAPTER FOUR - RESULTS AND DISCUSSION

Introduction

This chapter summarized the findings of the study, and interpreted the findings. The pharmaceutical manufacturing industry in Ethiopia encounters various operational challenges that significantly impede its development. These challenges range from financial constraints and disruptions in raw materials to technological limitations and supply chain inefficiencies. Understanding these issues is crucial for devising strategies to enhance the sector's growth and competitiveness.

To gain clear and definitive responses, a set of structured questions was designed, including multiple-choice questions, yes/no questions and additionally, a three-part Likert scale questions was employed: the first part measured satisfaction levels, the second assessed core variables computing agreement levels, and the third identified the critical significance of challenges in a ranked order, complemented by semi-structured interview questions posed to 8 key informants. The study employed a mixed-methods approach, combining both quantitative and qualitative data collection and analysis methods. The quantitative data was collected through a survey of 49 respondents from pharmaceutical manufacturing firms and stakeholder institutions.

This thesis aims to assess the operational challenges of pharmaceutical manufacturing in Ethiopia, their effects on the sector's development, and potential solutions. Through detailed demographic analysis, survey data, and thematic analysis the study provides valuable insights for policymakers, industry stakeholders, and researchers to improve operational efficiency and support the sustainable development of the Ethiopian pharmaceutical industry.

4.1: Socio-Demographic data of the participants' in the study

Variables	Measurements	N	Frequency	Percent %
Respondent's institution type	manufacturer	49	22	44.9
	Stakeholder		27	55.1
Gender	Male	49	33	67.3
	Female		16	32.7
Age	Less than 30 years	49	2	4.1
	31 - 45 years		35	71.4
	46 – 60 years		12	24.5
Educational Background	Phd	49	1	2.0
	Masters		18	36.7
	Bachelor		30	61.2
Job position title	CEO, GM, Plant Manager	49	12	24.5
	Director, LEO, Dep't Head, Line Manager		15	30.6
	Expert		22	44.9
Total years of work experience	Less Than 5 Years	49	2	4.1
	5-10 Years		8	16.3
	10-15		25	51.0
	15-20		4	8.2
	More Than 20 Years		10	20.4
Total Number of responses		49	49	100.0

Table 4.1 ***Socio-Demographic Data***

This table describes a detailed overview of the demographic characteristics of the respondents based on the variables included in the survey data analysis.

The demographic profile of the respondents indicates participation of a diverse group of professionals working in the pharmaceutical manufacturing sector in Ethiopia. The respondents are from 11 manufacturing firms and 9 stakeholder installations. The majority of respondents are male, aged between 31-45 years, hold a bachelor's degree, and have 10-15 years of work experience. The distribution of job positions shows a mix of senior management, middle management, and expert roles within the industry.

The survey data reveals that the majority of respondents are from stakeholder installations (55.1%) compared to manufacturers (44.9%). In terms of gender, 67.3% are male and 32.7% are female. The age distribution shows that 71.4% fall within the 31-45 age group, followed by 24.5% in the 46-60 age group. Educational background indicates that 61.2% hold a Bachelor's degree, 36.7% have a Master's degree, and only 2.0% have a PhD. Regarding job positions, 44.9% are categorized as experts, 30.6% hold directorial positions, and 24.5% are in CEO or top managerial roles. The majority of respondents (51.0%) have 10-15 years of work experience, with fewer individuals having less than 5 years (4.1%) or more than 20 years (20.4%) of experience.

4.2 General Overview of Operational Challenges and Strategiesto Overcome

The survey aimed to explore the operational constraints faced by local pharmaceutical manufacturers in Ethiopia, their strategies for overcoming these challenges, and their perspectives on the competitive landscape, with a focus on marketing management. The analysis is based on multiple-choice questions (MCQs) responses. The survey collected data to assess various aspects of their operations, including capacity utilization, strategies to overcome challenges, sources of raw materials, government policies, competition in the local market, and protection measures for local manufacturers.

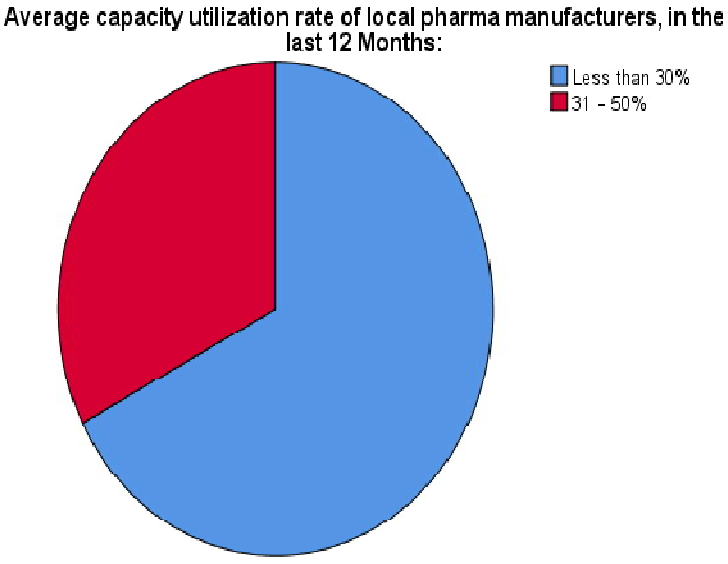

Figure 4.2.1 average capacity utilization rate of pharmaceutical manufacturers

Respondents were asked to report the average capacity utilization rate over the past year and to identify the major constraints that affect production capacity development. A substantial majority (67.3%) of respondents reported a capacity utilization rate of less than 30%. The remaining 32.7% of respondents reported a utilization rate between 31% and 50%, none of the respondents reported more than 50% capacity utilization rate.

The most significant operational constraint identified was "Access to Forex& weak raw material supply," highlighted by 100% of respondents. "Political instability & security threats" were also a notable challenge, reported by 65.3%. Additionally, "Customs procedures, tight regulations, high duties, and levies" were mentioned by 32.7% of respondents. "Market demand" was not identified as a major issue, with only 2% of respondents citing it as a challenge.

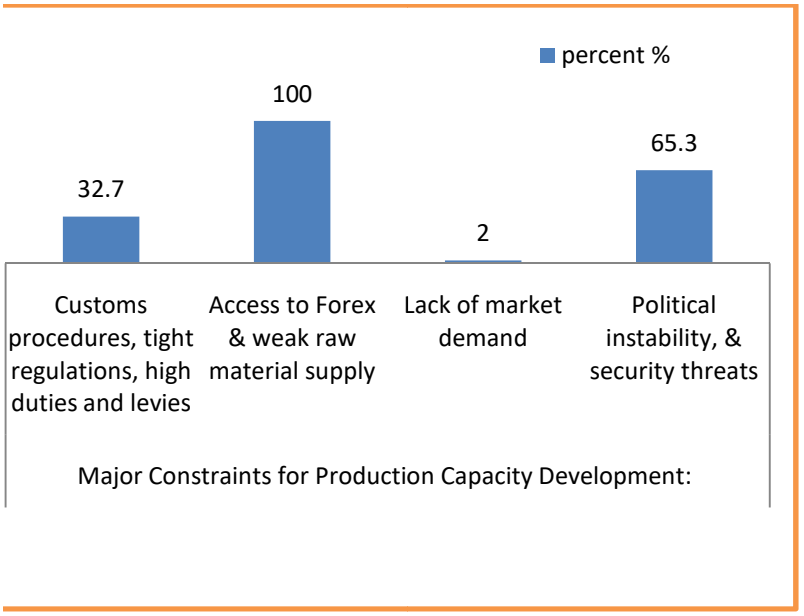

Figure 4.2.2 Major constraints

Regarding best practice/strategies to address these challenges, the survey respondents have primarily focused on lobbying for policy or regulatory reforms, seeking external funding or partnerships, and improving human resource management. Other notable strategies include a diversity of additional approaches being considered: investing in technology and innovation, expanding market share through diversification, and enhancing quality assurance while reducing production costs.

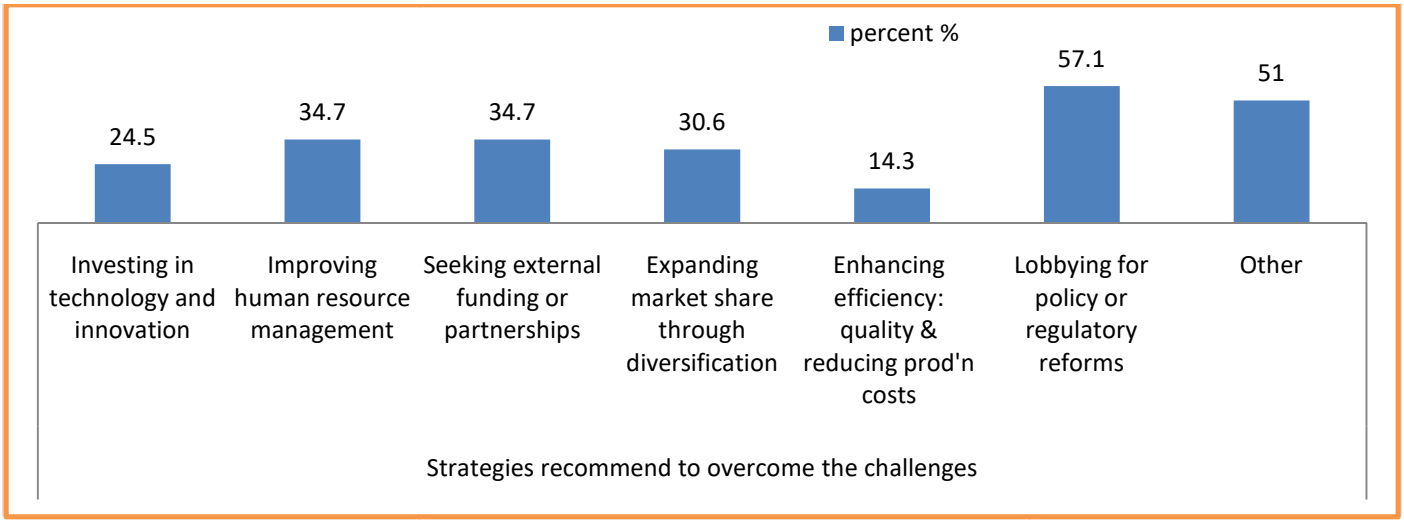

Figure 4.2.3 strategies to overcome challenges

Respondents generally view government policies and regulations as supportive (77.6%), although some (6.1%) find them restrictive or overly stringent, hindering industry growth. There's also concern about counterfeit products affecting competitiveness (16.3%. Regarding protection measures for local manufacturers, opinions vary a substantial majority (85.7%) advocating for stronger protective measures, while a small percentage (4.1%) believes such protections should not be applied. In terms of raw material

sources 100% of respondents indicate reliance on imports as sources of raw materials they use. So, this analysis result provides valuable insights into the challenges faced by local pharmaceutical manufacturers in Ethiopia and highlights areas for improvement to enhance competitiveness and growth in the industry.

4.3 The sector's current state, challenges and potential solutions

To assess the sector's current state, challenges and potential solutions true/false questions were presented to the respondents. The responses data analysis highlights significant issues and offers insights into the sector's current state, challenges, and potential solutions.All respondents from manufacturing firms replied they have faced operational challenges in the past year, and 100% respondents agreed that operational challenges have affected manufacturers' performance and sector growth. 100% respondents also reported inadequate access to inputs and infrastructure necessary for pharmaceutical production.

An overwhelming majority (91.8%) find pooled procurement of inputs useful for overcoming supply challenges, while 8.2% do not. A significant majority (95.9%) are not satisfied with the current state of pharmaceutical manufacturing in Ethiopia. Nearly all respondents (98%) believe the sector could contribute to the health and economic development of the nation. This reveals a consensus on the significant challenges facing the pharmaceutical manufacturing sector in Ethiopia.

4.4: Government Policies and Pharmaceutical Manufacturing Business

1. Government policies, incentives, supports and regulations towards the pharmaceutical sector
2. Proper Implementation of gov't policies, incentives, supports and regulations
3. Availability of infrastructure & skilled human resources
4. Environmental, social, political and security issues
5. How satisfied on the pharmaceutical manufacturing business in Ethiopia
6. How satisfied you are with respect to the firm's production capacity utilization
7. How satisfied you are with respect to the firm's profitability

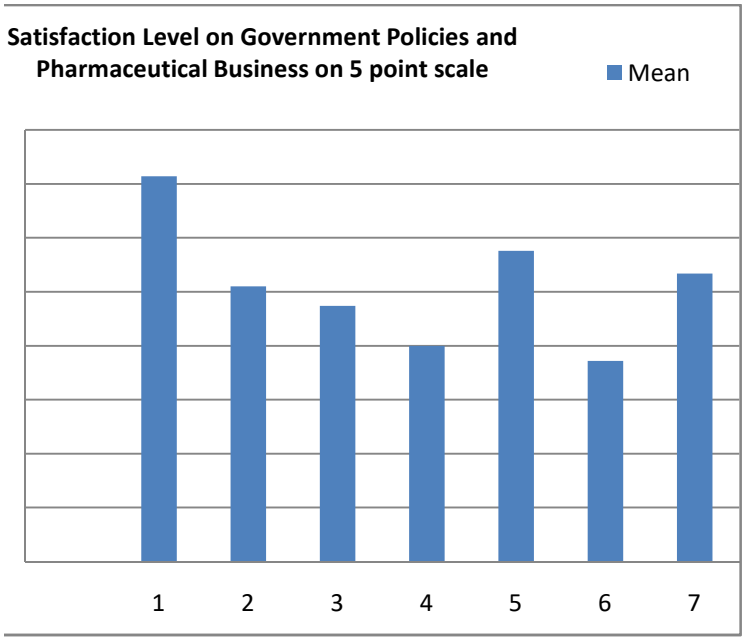

Figure 4.4: government policies Vs. Pharmaceutical business

The frequency analysis of key variables in the Ethiopian pharmaceutical manufacturing sector provides an in-depth view of respondents' satisfaction levels with government policies, infrastructure, environmental issues, and various operational factors. This section includes analysis on how government policies affect the growth and competitiveness of the sector, particularly regarding market share and business performance.

The descriptive statistics reveal that respondents generally rated government policies, incentives, support, and regulations positively, with a mean score of 3.57. However, satisfaction with the implementation of these policies was lower, scoring just 2.55 on average. The availability of infrastructure and skilled human resources was rated moderately (mean score of 2.37), while environmental, social, political, and security issues scored even lower (mean score of 2.00). Respondents expressed moderate satisfaction with the pharmaceutical manufacturing business (mean score of 2.88) and profitability (mean score of 2.67), but the satisfaction level with the firm's production capacity utilization was the lowest, at 1.86.

These findings reflect the ongoing challenges in the sector and emphasize the need for improved policy implementation, better infrastructure, and addressing broader environmental and security issues to enhance the competitiveness and market share growth of the pharmaceutical industry in Ethiopia.

Cross-tabulation of Implementation of Government Policies Vs. other variables

The cross-tabulation analysis examines the relationships between the proper implementation of government policies, infrastructure, skilled human resources, environmental and security issues, and satisfaction with production capacity utilization. Chi-Square tests indicate significant associations between these variables. The results are as follows:

- Government policies towards the pharmaceutical sector: $\chi^2(9) = 38.439$, $p < 0.001$
- Availability of infrastructure & skilled human resources: $\chi^2(6) = 16.449$, $p = 0.001$
- Environmental, social, political, and security issues: $\chi^2(4) = 14.791$, $p = 0.022$
- Satisfaction with firm's production capacity utilization: $\chi^2(6) = 37.524$, $p < 0.001$

The significant correlations between these factors emphasize that the proper implementation of government policies is crucial for improving infrastructure, addressing environmental challenges, and enhancing production capacity utilization. The implementation of these policies is directly linked to the overall effectiveness of the pharmaceutical manufacturing sector, impacting market share growth and sector development.

4.5 The Industry with Respect to the Main Variables

Pharmaceutical Industry Challenges and Strategies for Government Support

8. Improving operational efficiency & mitigating the challenges contribute to sector development
7. Improving access to finance, strengthening regulatory frameworks, investing in R&D, are best solution
6. Implementing Potential solutions and strategies for overcoming operational challenges
5. Multi-faceted approach required to address challenges.
4. These challenges are common for many pharmaceutical manufacturers worldwide.
3. The local manufacturers face several challenges
2. Ethiopian pharmaceutical industry is characterized by low productivity, high production costs, inadequate infrastructure, lack of technology adoption and etc.
1. Government support. Competitive incentive packages and committed to support the sector

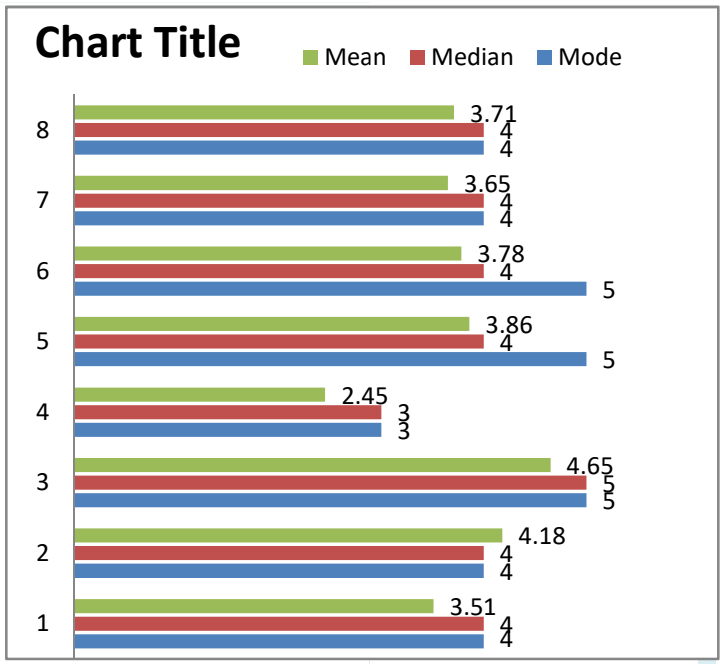

Figure 4.5 **Pharmaceutical Industry Challenges and Strategies to Overcome**

NB: This analysis describes the rate of level of agreement, which assessed respondents' agreement with various statements related to the pharmaceutical industry in Ethiopia. The survey used a 5-point Likert scale (1-5), where 1 represents "Strongly Disagree" and 5 represents "Strongly Agree".

The pharmaceutical industry faces numerous challenges that hinder its development, necessitating a comprehensive approach to overcome these obstacles. Key areas of focus include improving operational efficiency and addressing the specific challenges that local manufacturers encounter, which are often reflective of broader issues faced by pharmaceutical manufacturers worldwide. Enhancing access to finance is critical, along with strengthening regulatory frameworks and investing in research and development (R&D) to foster innovation. Implementing potential solutions and strategies is essential for navigating these operational challenges effectively. Furthermore, leveraging government support through competitive incentive packages and a strong commitment to sector growth will be vital in creating a conducive environment for the pharmaceutical industry to thrive. By adopting a multi-faceted approach, stakeholders can work collaboratively to enhance the industry's resilience and competitiveness.

Independent Variables: Pharmaceutical Industry Challenges

The industry faces multiple challenges, including low productivity, high production costs, poor quality, inadequate infrastructure, weak regulatory frameworks, and a lack of innovation and technology adoption. The mean rating for these challenges is 4.18, indicating strong agreement among respondents about their severity. The high mode (4) and standard deviation (0.950) further suggest a consistent acknowledgment of these issues across the respondents.

Intervening Variables: Multi-Faceted Approach, Strategies, and Solutions

A multi-faceted approach is essential for addressing the challenges faced by the pharmaceutical sector. This approach involves collaboration between the government, private sector, and various stakeholders, as well as policy reforms to create a conducive environment for industry growth. Additionally, capacity building is necessary to enhance skills and infrastructure, while technology adoption can significantly improve productivity and product quality. The mean rating for the necessity of this multi-faceted approach is 3.86 indicating general agreement on its importance. Similarly, the mean rating for the implementation of potential solutions and strategies is 3.78 reflecting optimism about their effectiveness.

Potential strategies and solutions include improving access to finance by simplifying financial mechanisms and creating incentives for investment, strengthening regulatory frameworks by establishing clear and enforceable regulations, investing in research and development to encourage innovation and local production capabilities, and promoting technology transfer to facilitate the adoption of advanced technologies. The mean rating for these strategies is 3.65, which indicates general agreement on their significance; however, the high standard deviation of 1.332 suggests varying opinions on the best methods for implementation.

Dependent Variables: Sector Development Indicators

Sector development is measured through several indicators, including human resource development to enhance workforce skills and knowledge, improved infrastructure to upgrade facilities to meet international standards, innovation and technology adoption to increase the use of modern technologies in manufacturing processes, and enhanced production capacity and quality for higher output and better product standards. Additionally, market demand and supply networks must be efficient, with regulatory compliance adhering to international standards such as cGMP and WHO

prequalification. Competitiveness and market share are also vital, aiming for increased competitiveness along with larger local and international market shares. The mean rating for "improving operational efficiency and mitigating challenges for sector development" is 3.71 reflecting consensus on its positive impact. These findings suggest that with appropriate strategies in place, significant growth and development are achievable, ultimately enhancing competitiveness and market share within the industry.

Crosstabs Analysis

The cross-tabulation analysis reveals relationships between challenges in the Ethiopian pharmaceutical industry, strategies to overcome them, and improvements in operational efficiency and resource utilization. Key findings indicate that challenges such as low productivity, high production costs, poor quality, and inadequate infrastructure strongly correlate with operational inefficiencies. A multi-faceted approach involving collaboration, policy reforms, capacity building, and technology adoption is positively correlated with improvements in operational efficiency. Furthermore, improved access to finance, stronger regulatory frameworks, and increased investment in research and development are crucial for overcoming the sector's challenges and enhancing operational efficiency.

These findings underscore the importance of a holistic and collaborative approach to tackling challenges in the pharmaceutical industry, particularly regarding improving operational efficiency, capacity utilization, and revenue growth. By addressing these challenges through targeted strategies and leveraging government support, the sector can achieve significant market share growth and long-term development.

In conclusion, the statistical analysis strongly supports the notion that addressing operational challenges through targeted, multi-faceted strategies can significantly improve operational efficiency and overall sector development. The findings highlight the critical role of government policies, regulatory frameworks, and collaboration among key stakeholders in driving the Ethiopian pharmaceutical industry toward sustainable growth and increased competitiveness in both local and international markets.

4.6: Challenges Facing Pharmaceutical Manufacturing Operations in Ethiopia

The pharmaceutical sector in Ethiopia faces several key challenges that hinder its growth and operational efficiency. The most critical issue is the difficulty in accessing foreign currency, which significantly impacts the importation of raw materials and essential equipment needed for production.

This financial constraint limits the growth potential of pharmaceutical companies. Another significant challenge is the lack of local capacity for equipment maintenance and calibration.

The absence of technical expertise undermines operational efficiency and the longevity of production equipment, highlighting the need for investment in technical infrastructure and capacity building.

Additionally, limited financial capacity and a lack of access to loans pose serious obstacles. High-interest rates and restricted financing prevent many companies from expanding or modernizing their facilities, leading to increased production costs and reduced competitiveness in the market.

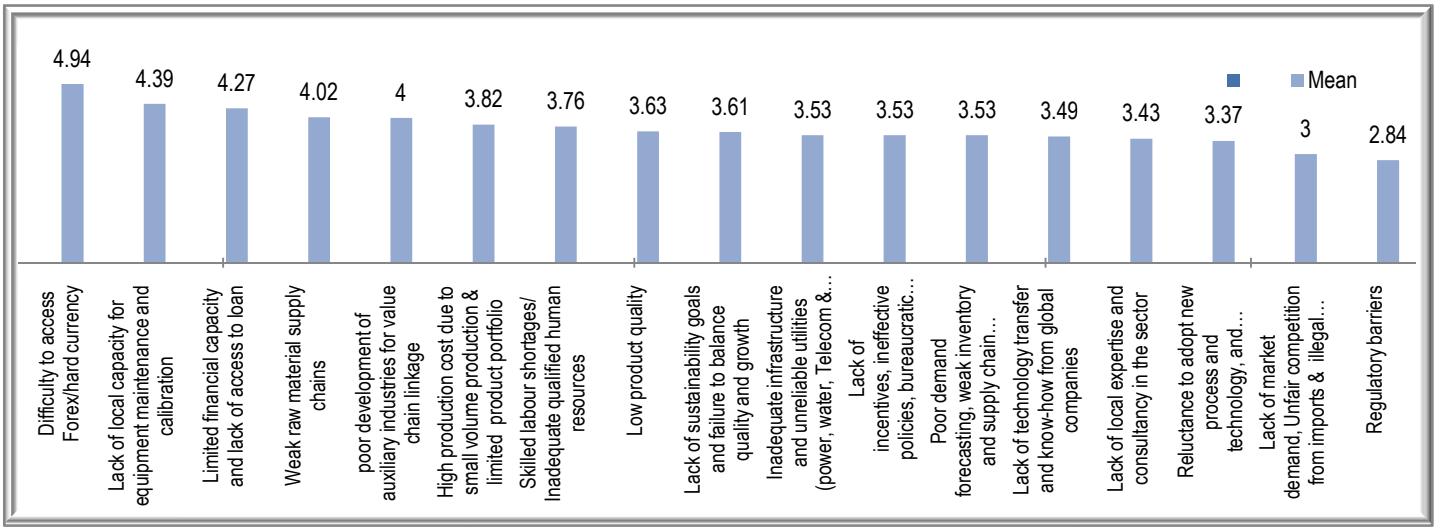

Fig 4.6: challenges facing pharmaceutical manufacturing in Ethiopia

The figure illustrates the critical operational challenges encountered by the pharmaceutical manufacturing industry in Ethiopia, based on the respondents' perceived level of critical significance. The ranking of these challenges highlights areas requiring urgent intervention to foster sector growth and improve market share.

Supply chain issues, characterized by inconsistent raw material supply and high costs, further disrupt production schedules and affect profitability. These disruptions are often exacerbated by foreign exchange constraints, creating bottlenecks in the supply chain. Regulatory challenges also exist but are viewed as less severe compared to other issues. Nevertheless, the lack of regional harmonization in product registration and high taxation on imported inputs complicate industry operations.

Addressing these challenges, particularly by improving access to foreign currency, enhancing financial resources, and ensuring reliable supply chains will be essential for enhancing the operational efficiency of Ethiopia's pharmaceutical sector and supporting its growth and competitiveness in the market.

4.7 Qualitative Data Analysis Report Using Thematic Analysis

The thematic analysis of interviews content with key informants provides valuable insights into the operational challenges in Ethiopia's pharmaceutical manufacturing industry. The analysis identifies critical themes and proposes strategies to overcome these obstacles, promoting sector development and market share growth.

Key Themes Identified:

1. Operational Challenges Facing Pharmaceutical Manufacturing Firms
2. Impact of Operational Challenges on Sector Development
3. Recommended Best Practices and Strategies

1. Operational Challenges

The pharmaceutical sector faces significant operational challenges, primarily due to financial constraints, particularly the scarcity of foreign exchange. This limitation complicates the import of raw materials, machinery, and equipment, resulting in high production costs and low output. Additionally, many firms rely on outdated technologies, which further reduce efficiency and capacity utilization. The absence of adequate maintenance systems and calibration centers exacerbates these technological gaps, hindering global competitiveness.

Human resource challenges also persist, with a notable shortage of skilled labor necessitating workforce development through targeted training programs. Regulatory issues, including inconsistent taxation on imports and difficulties in adhering to Good Manufacturing Practices (GMP), diminish the competitiveness of local companies. The lack of a streamlined product registration process complicates operations further. Supply chain and logistical constraints, such as extended lead times for importing essential materials, limited local raw material availability, and poor-quality packaging, increase production costs, while foreign exchange shortages restrict access to necessary materials.

2. Impact of Operational Challenges on Sector Development

The operational challenges within Ethiopia's pharmaceutical sector lead to significant economic and technological impacts, including underutilization of production facilities, with many firms operating at less than 30% capacity. This inefficiency results in lost economic opportunities, reduced national market share, and increased reliance on imports. Moreover, the lack of technological advancement stifles innovation and research and development, further limiting growth potential.

Environmentally, inefficient production processes result in suboptimal resource use, negatively impacting sustainability, while high production costs and limited local output drive up medicine prices, reducing access to affordable healthcare.

3. Best Practices and Strategies

To address these challenges, several strategies are recommended. The government should prioritize foreign exchange allocation to local industries and provide incentives like tax exemptions to encourage growth. Enhanced access to financing through low-interest loans or grants is also essential. Investing in modern production technologies and establishing maintenance centers will improve efficiency and equipment longevity. Continuous training programs in collaboration with educational institutions will help address the skilled labor shortage and ensure the workforce meets emerging technological needs.

Furthermore, streamlining regulatory processes and providing technical support for companies can enhance sector competitiveness, while regional harmonization of product registration can reduce market entry barriers. Improving logistical infrastructure, such as expedited customs clearance corridors, will decrease lead times for importing essential materials. Investing in local raw material production and enhancing packaging quality will also decrease reliance on imports. Finally, fostering collaborations with international organizations and academia can stimulate research and development, encouraging innovation and the establishment of biotech start-ups to diversify Ethiopia's pharmaceutical offerings and enhance global competitiveness.

4.8 Discussions

The survey findings reveal that a significant majority (67.3%) of pharmaceutical manufacturers in Ethiopia operate at less than 30% capacity, with no respondents reporting utilization rates above 50%. This aligns with earlier studies highlighting inadequate infrastructure, limited raw material access, and financial constraints as major barriers to optimal operation (WHO, 2019; Ethiopian Ministry of Health, 2017).

Access to foreign exchange (forex) and unreliable raw material supplies were identified as the most pressing challenges, with 100% of respondents acknowledging these issues. This finding mirrors previous research emphasizing the critical role of stable and affordable raw material supplies in pharmaceutical manufacturing (WHO, 2019; IFC, 2018). Both the survey results and thematic analysis underscore that Ethiopia's pharmaceutical manufacturing sector faces significant operational

challenges driven by external factors such as forex shortages and political instability, as well as internal factors like outdated technology and insufficient skilled labor. These issues have led to underutilized production capacity, stifling the sector's growth potential.

While government policies and regulations are generally perceived as supportive, some respondents described them as overly restrictive, particularly concerning import/export processes. Political instability and security risks were also highlighted by 65.3% of respondents as critical barriers, corroborating Eshetie's (2018) findings that such factors disrupt production and productivity.

A strong consensus (85.7%) emerged among respondents advocating for stronger protection measures for local manufacturers. This aligns with global trends in developing economies, where protectionist policies are often essential for nurturing local industries (UNCTAD, 2017). Respondents also emphasized the importance of lobbying for policy reforms, seeking external funding, and enhancing human resource management as effective strategies to address the identified challenges.

The results underscore the need for a multi-faceted approach that includes government policy reforms, increased investment in infrastructure, technology adoption, and capacity building. A comprehensive strategy involving financial support, regulatory improvements, and collaboration with international stakeholders is crucial for overcoming these barriers and fostering sector growth.

The findings reaffirm previous research on the importance of capacity building and strategic partnerships to enhance sector development (WHO, 2019; IFC, 2018). They further highlight the necessity of effective government policy implementation to support the pharmaceutical sector's growth. The integration of quantitative and qualitative findings provides a coherent picture of the challenges and opportunities in Ethiopia's pharmaceutical manufacturing industry, forming a solid foundation for targeted interventions aimed at improving sector performance and global competitiveness.

4.9 Hypothesis testing

The hypotheses posited were: H1, that pharmaceutical manufacturing industry in Ethiopia face significant operational challenges, and H2, that improving operational efficiency and competitiveness through potential solutions and strategies can help overcome these challenges and enhance the sector's development.

H1: Survey results showed strong agreement on the challenges faced, such as lack of access to finance, raw materials, skilled labor, technology, and regulatory issues, with mean scores of 4.65 and 4.18 for related statements. The Pearson Chi-Square test (25.469, $p < .000$) and Pearson's R (.673, $p < .000$) indicated significant positive correlations between these challenges and operational inefficiencies, strongly supporting H1.

H2: Survey responses indicated moderate agreement on the effectiveness of proposed solutions, with mean scores ranging from 3.65 to 3.86 for statements on improving access to finance, enhancing operational efficiency, and implementing policy reforms and technology adoption. Crosstab analyses showed significant positive correlations (Pearson Chi-Square: 60.047, $p < .000$; Pearson's R: .925, $p < .000$) for a multi-faceted approach, and similar results for other strategies, moderately supporting H2.

Overall, the findings robustly support H1, confirming significant operational challenges in the Ethiopian pharmaceutical manufacturing industry, and moderately support H2, suggesting that implementing potential solutions and strategies can help overcome these challenges and promote sector development. Further exploration and targeted strategies are needed for desired improvements. Addressing these challenges through strategic interventions can significantly improve operational efficiency and resource utilization, leading to increased sales and revenue. Collaborative efforts and targeted strategies are essential for sustainable sector development.

CHAPTER FIVE- SUMMARY, CONCLUSION AND RECOMMENDATION

5.1 SUMMARY

This study investigates the operational challenges faced by Ethiopia's pharmaceutical manufacturing industry, focusing on their implications for sector development and market share growth. Using a mixed-methods approach, the research identifies key barriers, including financial constraints, raw material disruptions, technological limitations, and supply chain inefficiencies.

The survey data reveal that 67.3% of respondents reported capacity utilization below 30%, with none exceeding 50%. Access to foreign exchange (forex) and raw material supply were identified as critical issues by all respondents, while political instability and security threats were cited by 65.3%. Customs and regulatory challenges affected 32.7% of participants. While 77.6% of respondents viewed government policies as generally supportive, 85.7% called for stronger protections for local manufacturers, particularly those relying on imported raw materials.

The study highlights significant dissatisfaction with the industry's current state, with 95.9% of respondents expressing concern. Nevertheless, 98% believed in the sector's potential to contribute to national health and economic development. Key challenges include low productivity, high production costs, poor product quality, inadequate infrastructure, weak regulatory frameworks, and limited innovation.

Key Insights and Impacts: Financial constraints, including forex shortages, limited access to loans, and high production costs, were major issues. Outdated technology and low capacity utilization hindered efficiency, while human resource gaps, such as skill shortages and insufficient training, further exacerbated challenges. Regulatory barriers, including high taxation and difficulties in complying with Good Manufacturing Practice (GMP) standards, and supply chain inefficiencies, such as logistics delays and substandard packaging materials, compounded operational difficulties.The consequences of these challenges were multi-faceted:

Economic: Low capacity utilization, high costs, and minimal market contribution led to reduced profitability and higher unemployment.

Social: Limited availability and affordability of medicines affected public health.

Technological: Barriers to research and development (R&D) and technology adoption stifled innovation.

Environmental: Inefficient production processes raised sustainability concerns.

Quantitative data indicated that access to forex and raw materials was universally problematic, while political instability and regulatory hurdles were significant secondary barriers. Most respondents (95.9%) expressed dissatisfaction with the sector's performance, emphasizing the need for infrastructure and skilled human resources, which scored poorly on evaluation metrics.

Qualitative data corroborated these findings, highlighting operational bottlenecks such as forex shortages, outdated technology, and inadequate maintenance systems. Interview insights pointed to underutilized capacity, high costs, and reliance on imports as major impediments to growth. Participants underscored the importance of financial access, technological modernization, and workforce development.

The integration of quantitative and qualitative data reveals a coherent picture of the industry's challenges and opportunities. Forex shortages, inadequate infrastructure, and outdated technology emerged as critical bottlenecks. A significant gap between policy formulation and implementation was evident, with inconsistent regulatory enforcement and delays in product registration posing additional burdens.

5.2 CONCLUSION

Ethiopia's pharmaceutical manufacturing sector faces significant challenges driven by external factors such as foreign exchange shortages and political instability, alongside internal issues like outdated technology and insufficient skilled labor. These obstacles have resulted in underutilized production capacity, high costs, and limited market share growth, significantly hindering the sector’s development and competitiveness.

The study highlights these operational challenges as key barriers to the industry's growth. Issues such as low capacity utilization, financial constraints, raw material supply disruptions, political instability, and stringent customs regulations are pervasive. Addressing these challenges requires a targeted, collaborative, and multi-faceted approach to enhance efficiency and competitiveness.

Findings from both quantitative and qualitative data converge on several key points:

1. The lack of foreign exchange and reliance on outdated technology are critical hurdles to growth and efficiency.Strengthening the supply chain, particularly by ensuring reliable forex access and stabilizing raw material supplies, is crucial for sustainable growth.

2. The government plays a vital role in providing financial support, regulatory clarity, and policy enforcement to promote sector development.

3. Investment in infrastructure, human capital development, and research and development is essential to improve the sector's competitiveness.

Although government policies are generally viewed as supportive, concerns persist regarding policy implementation, loose regulations, and the prevalence of counterfeit products. Respondents strongly advocate for enhanced protections for local manufacturers and stricter regulatory enforcement to ensure quality and fairness in the market.

The study underscores the interdependence of various factors affecting the industry, emphasizing the need for a comprehensive approach that integrates policy reforms, infrastructure development, technological upgrades, and international collaboration. By addressing these challenges, Ethiopia’s pharmaceutical sector can achieve higher resource utilization, improve productivity, and expand its market share both locally and regionally.

Despite these challenges, there is widespread belief in the potential for Ethiopia's pharmaceutical industry to contribute significantly to national health and economic development.

The integration of findings provides a coherent understanding of the sector’s challenges and opportunities. A multi-stakeholder approach involving collaboration among government, industry, and international partners is critical to fostering competitiveness and sustainability. By implementing these interventions, Ethiopia’s pharmaceutical manufacturing industry can overcome existing barriers and unlock its potential to contribute more effectively to public health and economic growth.

5.3 Recommendations:

The following recommendations are proposed to address the operational challenges faced by the Ethiopian pharmaceutical manufacturing industry and promote market share growth:

1. Financial and Investment Support: Provide government incentives to alleviate financial constraints, ensure regular foreign exchange allocations for local manufacturers, and facilitate access to affordable loans and tax incentives for investment in production facilities and technology.

2. Policy Reforms: Strengthen policy implementation and streamline customs procedures to improve access to raw materials and equipment. Enhance financing for local manufacturers, establish price controls to protect producers, and enforce policies against counterfeit products.

3. Supply Chain Optimization: Enhance supply chain efficiency by creating special customs corridors for faster processing of materials and investing in logistics to reduce delays and ensure quality packaging.

4. Human Resource Development: Implement ongoing training programs to bridge the skills gap and strengthen ties between academia and the pharmaceutical industry to enhance relevant expertise.

5. Technological Advancements: Increase investment in technology to modernize production processes, improve product quality, and establish maintenance systems for existing equipment.

6. Production Advancements: Improve quality monitoring systems to maintain high production standards, reduce costs, and modernize outdated equipment for more efficient practices.

7. Strategic Alliances: Encourage public-private partnerships and international collaborations for knowledge exchange, technology transfer, and support for biotech firms to drive market share growth.

8. Government Support: Strengthen regulatory frameworks for product quality and safety, provide financial incentives for domestic manufacturers, and improve policy execution with price control systems to protect local producers from market volatility.

By implementing these recommendations, Ethiopia's pharmaceutical manufacturing industry can overcome current challenges, improve operational efficiency, and increase market share, contributing significantly to national health and economic development goals.

5.4 Limitations of the Study

The limitations of this study are multifaceted. Firstly, due to limited resources, it did not cover all potential industry variables that could influence the pharmaceutical manufacturing sector. Additionally, the reliance on self-reported data may introduce response bias, which can affect the reliability of the findings. The generalizability of the results is also limited, as they may not apply to other countries or industries due to Ethiopia's unique context. Furthermore, the study's narrow focus on operational challenges may have overlooked significant factors such as market dynamics, global competitiveness, and consumer behavior. Access to reliable and comprehensive data on the pharmaceutical sector in Ethiopia was another constraint. Lastly, varying levels of awareness regarding operational excellence within the industry may further impact the applicability of the findings.

5.5 Future Research Directions

To build upon this study and further advance the understanding of the Ethiopian pharmaceutical manufacturing industry, future research should focus on the following areas:

1. **Longitudinal Studies**: Conduct longitudinal studies to assess the long-term impacts of implemented strategies and policies on sector growth and market share.
2. **Comparative Analysis**: Compare Ethiopia's pharmaceutical industry with other developing countries to identify best practices for overcoming operational challenges and increasing market share.
3. **Policy Impact Assessment**: Evaluate the effectiveness of government policies and incentives in real-time to determine their impact on industry development and competitiveness.

Focusing on these areas will provide deeper insights into the complexities and opportunities facing the Ethiopian pharmaceutical manufacturing industry, leading to more informed decision-making and strategic planning for sustainable growth and market share expansion.

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Appendix I: Survey Questionnaire and Key Informants Interview Questions

College of Business and Economics
School of Commerce

Research Project Questionnaire for Fulfillment of MA in Marketing Management

Dear Respondents,
Thank you for participating in this study

This questionnaire is intended for experts from pharmaceutical manufacturing firms and stakeholder institutions working for the development of the local pharmaceutical manufacturing industry in Ethiopia.

The study aims to gather data on the operational challenges faced by pharmaceutical manufacturing industries in Ethiopia, including their types, causes, effects, and solutions, and how these challenges impact the sector's development in economic, social, environmental, or technological aspects.

NB: Confidentiality will be maintained and Reporting will provide completely anonymous summaries of survey findings. Please respond to all questions.

I. General Information

I. **Institution Profile:** Institution Name: _____**Address:** Province_____, City_____, and contact: Mob. No: _____Tel. No.: _____, telegram_____

II. Respondent Profile: Provideus with some basic information about yourself**;** mark (✓) where applicable

1. Gender: Male ☐ Female ☐ Age: < 30 ☐ 31 - 45 46 ☐ 60 61+ ☐ ☐
2. Educational Background: a. Level: _____ _____ b. Field of study: _____ _____ ____
3. Job Position/ title: _____ Department: ……
4. Total years of work experience? ….....In pharmaceutical industry....., in your current position……

II. Multiple Choices Questions: Feel free to respond with your choices!

1. **Average Capacity Utilization Rate Of Local Pharma Manufacturers, In the Last 2 Years:**
   a) Less than 30%
   b) 31 – 50%
   c) 51 – 80%
   d) Over 80%

2. **Constraints for Production Capacity Development**: Choose constraints that apply:
   a) Customs procedures, tight regulations, high duties and levies
   b) Access to Forex& weak raw material supply
   c) Lack of market demand
   d) Political instability, & security threats
   e) Others (please specify): _____ _____

3. **Strategies you have implemented/recommend to overcome the challenges**: (Select those apply)
   a) Investing in technology and innovation
   b) Improving human resource management
   c) Seeking external funding or partnerships
   d) Expanding market share through diversification
   e) Enhancing quality assurance
   f) Lobbying for policy or regulatory reforms
   g) Reducing production costs by increasing efficiency
   h) Other (please specify)

4. **Raw Material Sources**: Select all that apply:
   a) In-house production
   b) Local suppliers
   c) Imported (countries thatraw materials imported from? __ __ ___ ___ ___)

5. Do you think Pooled procurement of inputs (APIs, excipients, chemicals, packaging & labeling) is useful for pharma manufacturers?; (tick where applicable ✓) A) Yes B) No

If yes, why?		✓	If no, why?		✓
a.	Minimise intermediaries		a.	Bad for free and competitive market	
b.	Increase the market size & bargaining power of buyers		b.	Corruption and superseding interests	
c.	Lower prices and reduced transaction costs in bulk processing		c.	Requires acceptance of agreed standards across all stakeholders	
d.	Ease access to foreign currency		d.	has no effect at all	
e.	Improve trust in local products, availability & security of supply		e.	Requires investment of time and resources to participate	
f.	Enhanced quality assurance & regulatory compliance		f.	no idea	
g.	Increased local production and innovation		g.	Others (please specify):	
h.	Others (please specify):				

6. **Government Policies and Regulations Applicable so far**: Choose one:
   a) Supportive
   b) Restrictive
   c) Too stringent & hindered industry growth
   d) Loose and counterfeit products are making competition hard to survive
   e) Neutral
7. **Describe the state of Competition of Local Manufacturers with each other**: Choose one:
   a) Very tough b) Strong c) Weak d) No competition at all
8. **Describe state of Competition with Global Manufacturers Marketing in Ethiopia.**
   a) Very tough b) strong c) weak d) no competition at all
9. **Protection of Local Manufacturers:**
   a) Not good: should not be applied
   b) Very good: should be applied
   c) Has any effect
   d) No idea

III. Short Answer/Yes or No Questions: Please reply Yes or No to the following

1. **Operational Challenges**:
   Do you think the operational challenges have affected the sector's performance and growth?
2. **Solutions and Resources:**
   a. Have you implemented or recommended any solutions to overcome the operational challenges?
   b. Do you think there is adequate access to inputs, & infrastructure for pharmaceutical production?
3. **Quality and Compliance:**
   Do you monitor and evaluate the quality and safety of local products regularly?
4. **Collaboration and Expansion:**
   Do you cooperate with local pharmaceutical manufacturers in Ethiopia?
5. **Government and Support**:
   a. Do you think the government must establish strong drug price control mechanisms?
   b. Do local pharmaceutical manufacturers receive any support or incentives from the government?
   c. Do local pharma manufacturers receive any support from other stakeholders for their business?
6. **Innovation and Satisfaction:**
   a. Do you participate in any innovation or research activities related to drug manufacturing?
   b. Do local pharma manufacturers measure customer satisfaction & get feedback for their products?
7. **Sector Perspective:**
   a. Are you satisfied with the current state of the pharma manufacturing in Ethiopia?
   b. Would you recommend the sector as a viable & attractive business opportunity in Ethiopia?
   c. Do you think the sector contributes to the health & economic development of the nation?

IV. Judgmental Liker Scale Questions:

Please rate your perceptions by indicating your position on the point scale.

S. No	Challenges and Opportunities in the EthiopianPharmaceutical Sector Please rate your level of satisfaction on the following statements on a scale of 1 to 5, "where 1 very dissatisfied to 5 very satisfied"(tick ✓where applicable)		very dissatisfied	dissatisfied	neutral	satisfied	very satisfied
			1	2	3	4	5
1.	Government policies, incentives, supports & regulations towards the pharma sector						
2.	Proper Implementation of these policies, incentives, supports and regulations						
3.	Market demand and competition						
4.	Available Infrastructure, skilled human resources and logistics						
5.	Environmental , social, political and security issues						
6.	On doing the pharmaceutical manufacturing business in Ethiopia						
7.	How do you rate your efficiency with respect to	o Production capacity					
		o Product quality & regulatory compliance					
		o Profitability					

	Strategies for Enhancing the Ethiopian pharmaceutical industry: Overcoming Challenges and Leveraging Government Support. Please show your level of agreement on point scale ranging "from 1 strongly disagree to 5 strongly agree" (tick ✓where applicable)	Strongly disagree	Disagree	No opinion	Agree	Strongly Agree
1.	Ethiopian government provides adequate support. competitive incentive packages and committed to support the sector					
2.	Ethiopian pharmaceutical industry is characterized by low productivity, high production costs, poor quality, inadequate infrastructure, weak regulatory framework, and lack of innovation and technology adoption					
3.	The local manufacturers face several challenges, such as lack of access to finance, raw materials, skilled labor, technology, regulatory issues, etc.					
4.	These challenges are common for many pharmaceutical manufacturers worldwide.					
5.	Addressing these challenges requires a multi-faceted approach that involves collaboration between the government, private sector, and other stakeholders.					
6.	Implementing potential solutions and strategies such as policy reforms, capacity building, technology adoption, and collaboration can help overcome these operational challenges and enhance the sector's development.					
7.	Improving access to finance, strengthening regulatory frameworks, investing in R&D, promoting technology transfer are best solution to the challenges.					
8.	Improving operational efficiency & mitigating the challenges increase capacity utilization make better use of resources and rise volume of production, sales & revenue contributing to sector development.					

	Critical Challenges Facing Pharmaceutical Manufacturers In Ethiopia Please rate the level of critical significance of the challenges on point scale ranging "from 1 Not important to 5 Extremely important" (tick ✓where applicable)	Not important	Slightly important	Important	Very important	Extremely important
1.	Limited financial capacity and lack of access to loan					
2.	Difficulty to access Forex/hard currency					
3.	Skilled labour shortages/ Inadequate qualified human resources					
4.	Low product quality					
5.	High production cost due to small volume production & limited product portfolio*					
6.	Regulatory barriers					
7.	Lack of market demand, Unfair competition from imports & illegal counterfeit products*					
8.	Weak raw material supply chains					
9.	Poor demand forecasting, weak inventory and supply chain management*					
10.	poor development of auxiliary industries for value chain linkage					
11.	Lack of sustainability goals and failure to balance quality and growth					
12.	Reluctance to adopt new process and technology, and operational inefficiency					
13.	Lack of technology transfer and know-how from global companies					
14.	Inadequate infrastructure and unreliable utilities (power, water, Telecom & etc.)					
15.	Lack of incentives, ineffective gov't policies, bureaucratic hurdles, environmental & security traits					
16.	Lack of local expertise and consultancy in the sector					
17.	Lack of local capacity for equipment maintenance and calibration					

V. **Descriptive Questions** for **key informants interview**

Challenges and Benefits in the Pharmaceutical Sector in Ethiopia:

1. Briefly describe the main challenges and benefits of operating pharmaceutical manufacturing business in Ethiopia.

2. How do these challenges impact the sector's development?

3. What are the best practices or strategies that you recommend to overcome these challenges?

Appendix II: List of Currently Active Medicines Manufacturers Surveyed

1.	Addis Pharmaceuticals Factory(APF): Established in 1997 Contact address: Adigrat city, Tigray, P.O.BOX: 25505 code 100, Tel number: +251344453007 Fax: +251114664987
2.	Africure Pharmaceuticals (Ethiopia) PLC Addis Ababa at Kilinto Pharmaceutical Industrial Park. t.mekonen@avacareglobal.com
3.	Cadila Pharmaceuticals (Ethiopia) PLC: Established in 2003 Contact address: Finfine special Zone, Gelan town, Oromia, P.O.box: 571; Code 1250, Tel: +251-114-45-02-57/58, Fax: +251-114-450-259
4.	East African Pharmaceuticals PLC: Established in 1996 Contact address: woreda 07, Bole sub city, Addis Ababa, Phone number:+25116461457/1762 FAX: +25116670346, Website:www.eastafrican.pharma.com, Email: g.m.eap.ca@gmail.com
5.	Ethiopian Pharmaceutical Manufacturing Company (EPHARM): Established in 1964 Contact address: Nifas silk Lafto Sub city: Addis Ababa, Phone number: +251113711000 FAX: +251113712088, Website: www.epharmsc.com , Email: info@epharmsc.com
6.	Human well Pharmaceutical Ethiopia: Established in 2015 Contact address: TuleffaHageremariam, North Shoa Zone, Amhara, Ethiopia Tel: +251118903393, E-mail: chengpeng@renfu.com.cn, website: http://en.humanwell.com.cn
7.	Julphar pharmaceutical PLC: Established in 2013 Contact address: Region: Woreda/kebele: 07, sub city: Bole, Addis Ababa P.O.box: 46326, Tel: 011-667-0331, Fax: 011-667-0353, E-mail: Julpharethiopia@gmail.com , Website: www.julpharethiopia.com
8.	KilitchEstro Biotech Pvt. Ltd: Established in 2015. Contact address: Lega Bari LegaBollo Addis Ababa to Dessie - Mekale Road, Ethiopia. Tel: +251- 911- 67-08-20-Mr Daniel Waktole, +251- 924- 91-04-84- MrBhavin Mehta. website: www.kilitchestro.com, E-mail: danielw@kilitchestro.com, bhavinmehta@kilitch.com
9.	Medsol Pharmaceuticals Manufacturing: Established in 1999 Contact address: Region: Woreda/Kebele 07, Bole sub city, Addis Ababa, Tel number: +251118296444, Email: medsolpharm@gmail.com
10	NationalVeterinaryInstitute (NVI): Established in 1964 Contact address: Phone: 251-114-33-84-11/16, Mobile : 0903-04-88-88, Fax: 251 -114-33-93-00, P.O. Box : 19, Bishoftu , Ethiopia, E-Mail:nvi-rt@ethionet.et , info@nvi.com.et
11	Pharmacure Pvt. Ltd. Co.: Established in 1998. Contact address: Kebele 16, sub city: Bole ,City: Addis Ababa, Ethiopia P.o.box: 5542, Fax: +251116604825, Tele: +251116604820/0911207636, E mail: pharmacure@ethionet.et,
12	Sansheng Pharmaceutical PLC: Established in 2018 Contact address: Dukem Eastern Industrial park, Oromia, Ethiopia.
13	Sino-Ethiop Associate Africa PLC (SEAA): Established in 2001 Contact address: Gelan, shegercitya, Oromia, P.O.Box:30609, Tel number :+25114450063 Fax: 0114450034, E-mail: Zafpharmaceuticals@gmail.com, shegaw@sino-ethiop.com, website: https://sinoethiop.com
NB: Two firms (the 2nd and 5th) didn't respond to the questionnaire provided on time	

Appendix III: List of relevant stakeholder institutions Participated in the surveyed

S.No	**Stakeholder organization**	**No#of Participants**	**Remark**
1.	Two representatives from each manufacturer	2x13=26	
2.	MoH	2	
3.	MoI	4	
4.	EFDA	6	
5.	EPSS	2	
6.	AHRI	6	
7.	EIC	2	
8.	EPMSMA	3	
9.	WHO	1	
10.	USP/QM	1	
11.	UNIDO	1	Could not be reached physically (didn't respond to the questionnaire provided via email)
12.	USAID	1	
13.	CAHI	1	
Total		56	
NB: 22 from manufacturers and 27 from stakeholder institutions of 56 proposed respondents were participated			

Table3. 4: Budget Schedule

	Activities		**Unit of Measure**	**Unit Rate**	**Quantity**	**Total Cost (in Birr)**
1	Stationery materials /services purchases	Pc(laptop)	Pcs	120, 000	01	120,000.00
		Flash drive	Pcs	1,000	01	1,000.00
		Wi-Fi router	pcs	10,000	01	10,000.00
		Subscription fee	year	8,000	01	8,000.00
		Bags	Pcs	2,300	06	13,800.00
		Papers	Pack/desta	500	04	2,000.00
		printer	pcs	5000	01	5000.00
		Pens, pencils, erasers	Pack	500x3	01(from each)	1,500.00
2	Fee for 05 data collectors		Per questionnaire	350 birr	134 x 350	46,900.00
3	Transportation for 06 persons		Days	1,800	15	27,000.00
4	Sub Total					234,300.00
5	Contingency (10%)					23,430.00
	Grand Total					257,730.00

Annexes IV: Survey Statistical Data

Table 4.1: demographic data frequency analysis

Variables	Measurements	N	Frequency	Percent %
Respondent's institution type	manufacturer	49	22	44.9
	Stakeholder		27	55.1
Gender	Male	49	33	67.3
	Female		16	32.7
Age	Less than 30 years	49	2	4.1
	31 - 45 years		35	71.4
	46 – 60 years		12	24.5
Educational Background	Phd	49	1	2.0
	Masters		18	36.7
	Bachelor		30	61.2
Job position title	CEO, GM, Plant Manager	49	12	24.5
	Director, LEO, Dep't Head, Line Manager		15	30.6
	Expert		22	44.9
Total years of work experience	Less Than 5 Years	49	2	4.1
	5-10 Years		8	16.3
	10-15		25	51.0
	15-20		4	8.2
	More Than 20 Years		10	20.4
Total Number of responses		49	49	100.0

Table 4.2 MCQ Frequency data		Cases	Responses		Percent
4.2 .1 Multiple Response MCQ Cases summary (Dichotomy group tabulated at selected value)		N	N	Percent	of Cases
Major Constraints for Production Capacity Development:	a)Customs procedures, tight regulations, high duties and levies	49	16	16.3%	32.7
	b)Access to Forex& weak raw material supply		49	50.0%	100.0
	c)Lack of market demand		1	1.0%	2.0
	d)Political instability, & security threats		32	32.7%	65.3
	Total		98	100.0%	200.0
Strategies you have implemented/recommend to overcome the challenges:	a)Investing in technology and innovation	49	12	9.9%	24.5
	b)Improving human resource management		17	14.0%	34.7
	c)Seeking external funding or partnerships		17	14.0%	34.7
	d)Expanding market share through diversification		15	12.4%	30.6
	e)Increasing efficiency: Enhancing quality assurance & Reducing production costs		7	5.8%	14.3
	f)Lobbying for policy or regulatory reforms		28	23.1%	57.1
	g)Other (please specify)		25	20.7%	51.0
	Total		121	100.0%	246.9
Raw Material Sources:	a) In-house production	49	10	10.8%	20.4
	b) Local suppliers		34	36.6%	69.4
	c)Imported		49	52.7%	100.0
	Total		93	100.0%	189.8

4.2.2 Single response MCQ Frequency data			Frequency	Percent
Average capacity utilization rate of local pharma manufacturers, in the last 12 Months	Less than 30%	49	33	67.3
	31 – 50%		16	32.7
	Total		49	100.0
Government Policies and Regulations Applicable so far	a) Supportive	49	38	77.6
	b) Restrictive		2	4.1
	c) Too stringent & hindered industry growth		1	2.0
	d) Too Loose		8	16.3
	Total		49	100.0
Describe the state of Competition of Local Manufacturers with each other	a) Very tough	49	4	8.2
	b) Strong		14	28.6
	c) Weak		22	44.9
	d) No competition at all		9	18.4
	Total		49	100.0
Describe state of Competition with Global Manufacturers Marketing in Ethiopia	a) Very tough	49	1	2.0
	b) strong		19	38.8
	c) weak		21	42.9
	d) no competition at all		8	16.3
	Total		49	100.0
Protection of Local Manufacturers	a) Not good: should not be applied	49	2	4.1
	b) Very good: should be applied		42	85.7
	c) Has no effect		2	4.1
	d) No idea		3	6.1
	Total		49	100.0

Table 4.3. Short Answer Questions Frequency

The sector's current state challenges and potential solutions	Yes /No	Count	Percent
1. Have you faced any operational challenges in the past year? *this is only for manufacturing firms respondents	Yes	22 / 22	100%
	No	0	0%
2. Do you think the operational challenges have affected manufacturers' performance and the sector growth?	Yes	49	100%
	No	0	0%
3. Have you implemented or recommended any solutions to overcome the operational challenges?	Yes	47	95.9%
	No	2	4.1%
4. Do you think there is adequate access to inputs, & infrastructure for pharmaceutical production?	Yes	0	0%
	No	49	100%
6. Do you monitor and evaluate the quality and safety of local products regularly?	Yes	37	75.5%
	No	12	24.5%
8. Do you cooperate with other pharmaceutical manufacturers in Ethiopia?	Yes	48	98%
	No	1	2%
10. Do you think the government must establish strong drug price control mechanisms?	Yes	33	67.3%
	No	16	32.7%
11. Do local pharmaceutical manufacturers receive any support or incentives from the government?	Yes	47	95.9%
	No	2	4.1%
12. Do local pharma manufacturers receive any support from other stakeholders for their business?	Yes	34	69.4%
	No	15	30.6%
13. Do you participate in any innovation or research activities related to drug manufacturing?	Yes	33	67.3%
	No	16	32.7%
14.Do local pharma manufacturers measure customer satisfaction & get feedback for their products?	Yes	37	75.5%
	No	12	24.5%
15. Are you satisfied with the current state of the pharma manufacturing in Ethiopia?	Yes	2	4.1%
	No	47	95.9%
17. Would you recommend the sector as a viable & attractive business opportunity in Ethiopia?	Yes	42	85.7%
	No	7	14.3%
18. Do you think the sector contributes to the health & economic development of the nation?	Yes	48	98%
	No	1	2%
19. Do you think Pooled procurement of inputs is useful for pharma manufacturers to overcome inputs supply challenges?	Yes	45	91.8%
	No	4	8.2%

Table 4.4 Government Policies vs. Pharmaceutical Business

Descriptive StatisticsFrequency table

	1.Government policies, incentives, supports and regulations towards the pharma sector	2. Proper Implementation of gov't policies, incentives, supports &regulations	3. Availability of infrastructure & skilled human resources	4. Environmental, social, political & security issues	5. How satisfied on the pharmal manufacturing business in Ethiopia	6. How satisfied you are with respect to the firm's production capacity utilization	7. How satisfied you are with respect to the firm's profitability
Mean	3.57	2.55	2.37	2.00	2.88	1.86	2.67
Mode	4	2	2	2	3	2	3
Std. Deviation	.791	.937	.487	.500	.484	.408	.689
Minimum	2	1	2	1	2	1	1
Maximum	5	4	3	3	4	3	3

Government Policies, Challenges and Pharmaceutical Business		Ratings	Frequency	Percent
1. Government policies, incentives, supports and regulations towards the pharmaceutical sector	Valid 49	dissatisfied	6	12.2
		neutral	12	24.5
		satisfied	28	57.1
		very satisfied	3	6.1
		Total	49	100.0
2. Proper Implementation of gov't policies, incentives, supports and regulations	Valid 49	dissatisfied	6	12.2
		neutral	19	38.8
		satisfied	15	30.6
		very satisfied	9	18.4
		Total	49	100.0
3. Availability of infrastructure & skilled human resources	Valid 49	dissatisfied	31	63.3
		neutral	18	36.7
		Total	49	100.0
4. Environmental, social, political and security issues	Valid 49	very dissatisfied	6	12.2
		dissatisfied	37	75.5
		neutral	6	12.2
		Total	49	100.0
5. How satisfied on the pharmaceutical manufacturing business in Ethiopia	Valid 49	dissatisfied	9	18.4
		neutral	37	75.5
		satisfied	3	6.1
		Total	49	100.0
6. How satisfied you are with respect to the firm's production capacity utilization	Valid 49	very dissatisfied	8	16.3
		dissatisfied	40	81.6
		neutral	1	2.0
		Total	49	100.0
7. How satisfied you are with respect to the firm's profitability	Valid 49	very dissatisfied	6	12.2
		dissatisfied	4	8.2
		neutral	39	79.6
		Total	49	100.0

Table 4.5 Industry With Respect to the Main Variables - Descriptive Statistics and Frequency Distribution

Rate level of agreement to the following statements on a point scale of 1 to 5	N	Minimum	Maximum	Mode	Median	Mean	Std. Dev'n
1. Government support. competitive incentive packages and committed to support the sector	49	2	5	4	4.00	3.51	.869
2. Ethiopian pharmaceutical *Industry characteristics, and common challenges*	49	2	5	4	4.00	4.18	.950
3. The local manufacturers face several challenges	49	4	5	5	5.00	4.65	.481
4. These challenges are common for many pharmaceutical manufacturers worldwide.	49	1	4	3	3.00	2.45	.792
5. Multi-faceted approach required to address challenges.	49	1	5	5	4.00	3.86	1.443
6. Implementing Potential solutions and strategies for overcoming operational challenges	49	1	5	5	4.00	3.78	1.403
7. Improving access to finance, strength regulatory frameworks, investing in R&D,..are best solution	49	1	5	4	4.00	3.65	1.332
8. Improving operational efficiency & mitigating the challenges contribute to sector development	49	2	5	4	4.00	3.71	1.061

1. Ethiopian government provides adequate support. competitive incentive packages & committed to support the sector

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Disagree	9	18.4	18.4	18.4
	No opinion	9	18.4	18.4	36.7
	Agree	28	57.1	57.1	93.9
	Strongly agree	3	6.1	6.1	100.0
	Total	49	100.0	100.0	

2. Ethiopian pharmaceutical industry is characterized by low productivity, high production costs, poor quality, inadequate infrastructure, weak regulatory framework, and lack of innovation and technology adoption

Valid	Disagree	6	12.2	12.2	12.2
	Agree	22	44.9	44.9	57.1
	Strongly agree	21	42.9	42.9	100.0
	Total	49	100.0	100.0	

3. The local manufacturers face challenges: lack of access to finance, raw materials, skilled labor, technology, regulatory issues, etc.

Valid	Agree	17	34.7	34.7	34.7
	Strongly agree	32	65.3	65.3	100.0
	Total	49	100.0	100.0	

4. These challenges are common for many pharmaceutical manufacturers worldwide

Valid	Strongly disagree	6	12.2	12.2	12.2
	Disagree	18	36.7	36.7	49.0
	No opinion	22	44.9	44.9	93.9
	Agree	3	6.1	6.1	100.0
	Total	49	100.0	100.0	

5. Addressing these challenges requires a multi-faceted approach (collaboration b/n the government, private sector, and other stakeholders

Valid	Strongly disagree	6	12.2	12.2	12.2
	Disagree	6	12.2	12.2	24.5
	Agree	14	28.6	28.6	53.1
	Strongly agree	23	46.9	46.9	100.0
	Total	49	100.0	100.0	

6. Implementing potential solutions and strategies such as policy reforms, capacity building, technology adoption, and collaboration can help overcome these operational challenges and enhance the sector's development

Valid	Strongly disagree	6	12.2	12.2	12.2
	Disagree	6	12.2	12.2	24.5
	Agree	18	36.7	36.7	61.2
	Strongly agree	19	38.8	38.8	100.0
	Total	49	100.0	100.0	

7. Improving access to finance, strengthening regulatory frameworks, investing in R&D, promoting technology transfer are best solution to the challenges

Valid	Strongly disagree	6	12.2	12.2	12.2
	Disagree	6	12.2	12.2	24.5
	Agree	24	49.0	49.0	73.5
	Strongly agree	13	26.5	26.5	100.0
	Total	49	100.0	100.0	

8. Improving operational efficiency & mitigating the challenges increase capacity utilization, make better use of resources and rise volume of sales & revenue

Valid	Disagree	12	24.5	24.5	24.5
	Agree	27	55.1	55.1	79.6
	Strongly agree	10	20.4	20.4	100.0
	Total	49	100.0	100.0	

Challenges Facing Pharmaceutical Manufacturing Operations in Ethiopia

Ranked by Critical Significance

Table 4.6 Descriptive Statistics

S.No	Challenges Facing Pharmaceutical Manufacturing Operations In Ethiopia	N	mode	Median	Mean
1.	Difficulty to access Forex/hard currency	49	5	5	4.94
2.	Lack of local capacity for equipment maintenance and calibration	49	5	4	4.39
3.	Limited financial capacity and lack of access to loan	49	5	4	4.27
4.	Weak raw material supply chains	49	4	4	4.02
5.	poor development of auxiliary industries for value chain linkage	49	4	4	4.00
6.	High production cost due to small volume production & limited product portfolio	49	4	4	3.82
7.	Skilled labour shortages/ Inadequate qualified human resources	49	4	4	3.76
8.	Low product quality	49	4	4	3.63
9.	Lack of sustainability goals and failure to balance quality and growth	49	4	4	3.61
10.	Inadequate infrastructure and unreliable utilities (power, water, Telecom & etc.)	49	3	3	3.53
11.	Lack of incentives, ineffective policies, bureaucratic hurdles, environmental & security traits	49	3	3	3.53
12.	Poor demand forecasting, weak inventory and supply chain management	49	4	4	3.53
13.	Lack of technology transfer and know-how from global companies	49	4	4	3.49
14.	Lack of local expertise and consultancy in the sector	49	4	4	3.43
15.	Reluctance to adopt new process and technology, and operational inefficiency	49	3	3	3.37
16.	Lack of market demand, Unfair competition from imports & illegal counterfeit products	49	4	3	3.00
17.	Regulatory barriers	49	2	3	2.84
	Valid N (listwise)	49			