



**GOOD DISTRIBUTION PRACTICE OF PHARMACEUTICALS IN  
PRIVATE SECTOR IN JUBA, SOUTH SUDAN.**

**JULIA JOSEPH OJUKWU IKARAK**

**Reg. No.220019540**

**College of Medicine and Health Sciences**

**School of Public Health, EAC Regional Centre of Excellence for Vaccines,  
Immunization and Health Supply Chain Management**

**Master of Health Supply Chain Management**

**May 2023**

**GOOD DISTRIBUTION PRACTICE OF PHARMACEUTICALS IN PRIVATE  
SECTOR IN JUBA, SOUTH SUDAN.**

A dissertation submitted in partial fulfillment of the requirements for the Masters' degree  
of Health Supply Chain Management in the EAC Regional Centre of Excellence for  
Vaccines, Immunization and Health Supply Chain Management of the University of  
Rwanda

**By**

**JULIA JOSEPH OJUKWU IKARAK**

Reg. No.220019540

**Supervisors:**

**Dr. Kashi B. Carasso, MPH; MSC Pharm**

Lecturer, East Africa Community Regional Center of Excellence for Vaccine,  
Immunization and Health Supply Chain Management, University of Rwanda

**Prof. Dr. François Niragire,**

Assoc. Professor of Applied Statistics, and Director of Research and Innovation, College  
of Business and Economics, University of Rwanda

**May 2023**

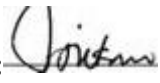
**DECLARATION**

I Julia Joseph Ojukwu Ikarak declare that this dissertation is the result of my own work and has not been submitted for any other degree at the university of Rwanda or any other institution.

**Research Title: Good Distribution Practices of Pharmaceuticals in Private Sector in Juba, South Sudan**

Name of Student: Julia Joseph Ojukwu Ikarak

Registration Number: 220019540

Signature:  Date: 28 /0/5 2023

**SUPERVISOR(S)' APPROVAL:**

**A dissertation has been submitted for examination with our approval as university supervisors.**

1. Signature:  Date: May 31, 2023

**Dr. Kashi B. Carasso, MPH; MSC Pharm**

Lecturer, East Africa Community Regional Center of Excellence for Vaccine, Immunization and Health Supply Chain Management, University of Rwanda

2. Signature: -----Date: -----

**Prof. Dr. François Niragire,**

Assoc. Professor of Applied Statistics, and Director of Research and Innovation, College of Business and Economics, University of Rwanda

## **DEDICATION**

I dedicate this work to my husband Sebit Ernest Apuktong for his continues support and encouragement throughout my studies, to my sons, Ernest Apuktong Jr and Edmond Ojok and finally, to my parents for being my supporting machine from day one

## **AKNOWLEDGEMENT**

Foremost, I would like to express my sincere gratitude to my supervisors Dr. Kashi B. Carasso, and Prof. Dr. Francois Niragire, for the continuous support of my dissertation, for their patience, motivation, enthusiasm, and immense knowledge. Their guidance helped me in all the time of research and writing of this thesis. I could not have imagined having a better supervisors and mentors for my dissertation

Besides my Supervisors, I would like to thank Dr. Mawien Atem for his encouragement and insightful comments.

My sincere thanks also go to teaching and supporting staff of the EAC Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management, University of Rwanda.

Last but not the least, I would like to thank my family: my husband for his great support, sisters, and brothers and to my parents Hon. Joseph Ojukwu and Esther Atim for giving birth to me at the first place and supporting me throughout my life.

## ABSTRACT

**Background:** Good distribution practice (GDP) is regarded as the cornerstone of pharmaceutical quality control. In order to ensure product quality after a batch has left the manufacturing facility and to manage consumer complaints. Despite signs that the worst of the country's crisis (South Sudan) is subsiding, the pharmaceutical industry, faces weak points in the distribution processes of pharmaceutical products provide an avenue for counterfeit as well as illegally imported, stolen and substandard medicines to enter the supply chain. This is a concern in both developed and developing countries. **The aim of the study,** is to assess the compliance of private pharmaceutical wholesalers with Good Distribution Practices (GDP) in Juba, South Sudan.

**Methods:** A descriptive-quantitative research design was employed to systematically investigate the compliance of private pharmaceutical wholesalers with Good Distribution Practices. This design allowed the researchers to examine the existing conditions, gather primary and secondary data, and provide an accurate representation and understanding of the current scenario in the pharmaceutical distribution sector. The descriptive-quantitative approach facilitated the collection of reliable data, which helped in identifying trends, patterns, and relationships among variables, enabling a comprehensive assessment of pharmaceutical wholesalers' compliance with GDP. The data was collected using structured questionnaire, to collect data on various aspects of GDP compliance and WHO MQAS assessment tool, Module V was used, it guided the in conducting structured observations of the warehouses and the distribution facilities of the pharmaceutical wholesalers. The sample for this study consisted of a total of 86 private pharmaceutical distributors/wholesalers across Juba city.

**Findings:** Likert scale was used to measure the responses of the participants, and the data was analyzed using frequency distribution and percentages. The findings of the study showed that the majority of the private pharmaceutical wholesalers had some level of compliance with GDP, but there were gaps in some areas. For instance, some warehouses did not have adequate temperature monitoring systems and there was no record of temperature monitoring during transport. Additionally, the study found that some personnel did not wear protective clothing while handling pharmaceutical products. Regarding the implementation of regulations and policies, study found that there were gaps in the documentation and archiving of evidence for quality evaluation before product release from the warehouse. Furthermore, there were no clear guidelines on how to investigate market complaints and how to perform root cause analysis to identify the cause of the complaints. The study also identified several factors that influence GDP practices, including the availability of resources, the level of staff training, and the level of management commitment to GDP practices. The study found that the most influential factor in enhancing good distribution practices was the availability of resources.

**Conclusion:** The study highlights the importance of implementing and enforcing GDP guidelines in the pharmaceutical supply chain to ensure the availability and distribution of safe and effective medicines to the population. The findings provide valuable insights for policymakers, regulatory authorities, and private pharmaceutical wholesalers in Juba, South Sudan, and other low-resource settings facing similar challenges in implementing GDP guidelines.

**Recommendations:** **Formal GDP Training:** Develop and implement structured and comprehensive GDP training programs for all staff involved in the pharmaceutical distribution process. Regular internal audits will help in identifying areas of non-compliance and facilitate timely interventions to enhance GDP adherence. **Leverage Technology:** Integrate innovative technologies such as blockchain to enhance the transparency, security, and **Collaborative Approaches:** Foster collaborations between pharmaceutical entities, regulatory bodies, and other stakeholders to share knowledge. **Development of GDP Compliance Tools:** Develop and deploy robust tools and framework

## TABLE OF CONTENTS

<b>DECLARATION</b> .....	<b>I</b>
<b>DEDICATION</b> .....	<b>II</b>
<b>ACKNOWLEDGEMENT</b> .....	<b>III</b>
<b>ABSTRACT</b> .....	<b>V</b>
<b>TABLE OF CONTENTS</b> .....	<b>VI</b>
<b>KEY WORDS</b> .....	<b>VII</b>
<b>ABBREVIATION</b> .....	<b>IX</b>
<b>LIST OF TABLES</b> .....	<b>2</b>
<b>TABLE OF FIGURES</b> .....	<b>3</b>
<b>CHAPTER 1: INTRODUCTION:</b> .....	<b>4</b>
1. Introduction .....	4
1.1. Distribution of Medicines and good distribution practices.....	4
1.2. Background.....	7
1.2.1. Challenges faced Medicines distribution Network.....	10
1.2.2. Dimensions to study the status of GDP in South Sudan.....	11
1.2.3. South Sudan Medicine Supply Chain.....	11
1.3. Research Problems.....	12
1.4. Research Objectives.....	13
1.4.1. Overall Objective.....	13
1.4.2. Specific Objectives.....	13
1.4.3. Research questions .....	13
1.5. Delimitation of the study.....	14
1.6. Scope.....	14
<b>CHAPTER 2: LITERATURE REVIEW:</b> .....	<b>15</b>
2.1. Introduction .....	15
2.2. Overview of good distribution practices.....	15
2.2.1. Global standards and guidelines for good distribution practices.....	16

2.2.2.	Key component and principles of good distribution practices.....	16
2.2.3.	Good distribution practices in pharmaceutical industry.....	17
2.2.4.	Comparison between public and private sectors.....	17
2.3.	Pharmaceutical distribution in private sector.....	18
2.4.	Overview of the pharmaceutical industry in South Sudan.....	19
2.5.	Challenges in pharmaceutical distribution in Juba.....	20
2.6.	Theoretical Reviews.....	20
2.6.1.	Resources dependence Theory.....	21
2.6.2.	Compliance difficulties theory.....	22
2.7.	Knowledge gap.....	23
<b>CHAPTER 3: METHODS: .....</b>		<b>24</b>
3.1.	Research Design.....	24
3.2.	Research Methods.....	24
3.3.	Data collection Tools .....	24
1.	Questionnaire.....	24
2.	WHO MQAS self-assessment tool.....	24
3.4.	Sampling method and Size.....	25
3.5.	Sampling size and population.....	25
3.6.	Time span.....	25
3.7.	Location.....	25
3.8.	Distribution types.....	25
3.9.	Practicalities.....	26
3.10.	Data Analysis: .....	26
3.4.1:	Description analysis... ..	26
3.4.2:	Likert Scale Analysis.....	26
3.11.	Ethical Consideration.....	26
<b>CHAPTER 4: DATA ANALYSIS, PRESENTATIONS AND DISCUSSIO...27</b>		
4.1:	Introduction.....	27
4.2:	Research questionnaire.....	27

4.3: WHO- MQAS self-assessment tool.....	27
4.4. Demographic.....	27
<b>CHAPTER 5: DISCUSSION OF FINDINGS, CONCLUSION AND RECOMMENDATION.....</b>	<b>68</b>
5.1. Discussions.....	68
5.2. Conclusions of the study.....	73
5.3. Recommendations of the study.....	74
5.4. Suggestions for future study.....	
<b>CHAPTER 6: BIBLIOGRAPHY: .....</b>	<b>76</b>
<b>CHAPTER 7: APPENDICES: .....</b>	<b>84</b>
ANNEX 1: QUESTIONNAIRE	
ANNEX 2: WHO MQAS SELF-ASSESSMENT TOOL	
ANNEX 3: ETHNICAL APPROVAL	
ANNEX 4: SUMMARY OF DATA	

**KEYWORDS:** *Good Distribution Practices, Wholesale, private pharmaceutical sector, compliance, South Sudan, Model Quality Assurance System.*

## ABBREVIATION

CCM	Cold Chain Management
CMS	Central Medical Stores
DFCA	Drug and Food Control Authority
GDP	Good Distribution Practices
GQR	General Quality Requirements
HFP	Health Pool Fund
HR	Human Resource
LMICs	Low-income and Middle-income Countries.
MQAS	Model Quality Assurance System for Procurement Agencies
UNICEF	United Nations International Children's Emergency Fund
WHO	World Health Organization

## LIST OF TABLES

Table 1 showing demographics of the participants.....	27
Table 2 showing warehouse assessments .....	30
table 3: Role of Regulatory Authority (DFCA).....	32
Table 4: Additional variables .....	34
Table 5: Registration and certification(s) Status .....	35
Table 6: ISO Certification of Pharmaceutical Distributors in South Sudan.....	40
Table 7: Types of Products Supplied by Pharmaceutical Distributors.....	41
Table 8: Quality Control Methods for Pharmaceutical Distributors, Quality Control at Reception and Internal QC Laboratory for Testing .....	43
Table 9: Frequency of Re-assessments for Manufacturing Sites and (Pre) Qualified Products among Pharmaceutical Distributors in Juba.....	44
Table 10: Status of GDP Facility.....	46
Table 11: Status of GDP Documentation and Records.....	47
Table 12: Status of GDP “Environment and Temperature Excursion.....	49
Table 13: Presence of GDP with Respect to Process Control.....	52
Table 14: Status of GDP with Respect to Personnel, Qualification and Skill.....	54
Table 15: Status of GDP with Respect to Control of Cross-Contamination, Mix-up and Cleaning .....	56
Table 16: Status of GDP with Respect to Identification and Traceability.....	59
Table 17: Status of GDP with Respect to Quality Assurance Approch.....	61
Table 18: Status of GDP with Respect to Customer Compliant Handling.....	62
Table 19: Distribution of Purchased Product ( Packaging and Transport).....	64
Tabl20:Containers and Labeling.....	65
Table 21: Handling of Damage Containers.....	66

## LIST OF FIGURES

Figure 1: Pharmaceutical distribution network (Author's calculation from literature review).....	6
Figure 2: Date of Last Audit/Technical Visit.....	38
Figure 3: Good Distribution Practice (GDP).....	39
Figure 4: Types of Products Supplied by Pharmaceutical Distributors .....	42

# Chapter One

## INTRODUCTION

### 1.1. Distribution of medicines and Good Distribution Practice

An in-depth understanding of its administration is necessary to control the distribution of medicines properly. The problems of the pharmaceutical product supply chain include its defined shelf life and storage conditions. Managing the quality of medications throughout distribution is a vital activity. Medicines come in a variety of dosage forms, such as pills, syrups, injectable, and so on. Each of them must be stored in a distinct environment based on the stability of the medicinal products. Because of the risk of failure during testing, cold chain items must be handled with greater caution (1). The intended attributes have high requirements for supply chain management and planning to fulfil the aim of maintaining availability in retail outlets without increasing the number of lost items in different supply chain phases. The primary responsibility of the pharmaceutical product distribution department is to ensure patient safety and maintain the drug's quality throughout its shelf life (1).

Good distribution practices (GDP) that part of quality assurance that ensures that the quality of a medicinal product is maintained by means of adequate control of the numerous activities that occur during the trade and distribution process, as well as providing a tool to secure the distribution system from falsified, unapproved, illegally imported, stolen, substandard, adulterated and/or misbranded medical products. Based on the WHO Guidelines on Good Distribution Practices. To maintain the original quality of pharmaceutical products, every party active in the distribution chain has to comply with the applicable legislation and regulation. Every activity in the distribution of pharmaceutical products should be carried out according to the principles of GMP, good storage practice (GSP) and good distribution practice (GDP) as applicable. (WHO good distribution practices for pharmaceutical products). Measuring compliance with GDP using WHO Model Quality Assurance system for procurement agencies, is a WHO guidance document developed at the request of the Global Fund to Fight AIDS,

Tuberculosis and Malaria and adopted by WHO Expert Committee on Specifications for pharmaceutical preparations in 2021 (2)

A quality management strategy for pharmaceutical warehouses and distribution centers is called Good Distribution Practices (GDP). Pharmaceutical distributors are obligated under internationally recognized GDP legislation for the pharmaceutical industry to align their operations with the standards. A set of standards assuring that the quality of a drug is maintained throughout the distribution network, so that permitted medicines are supplied to retail pharmacists and others selling medicines to the general public without any modification of their qualities (5).

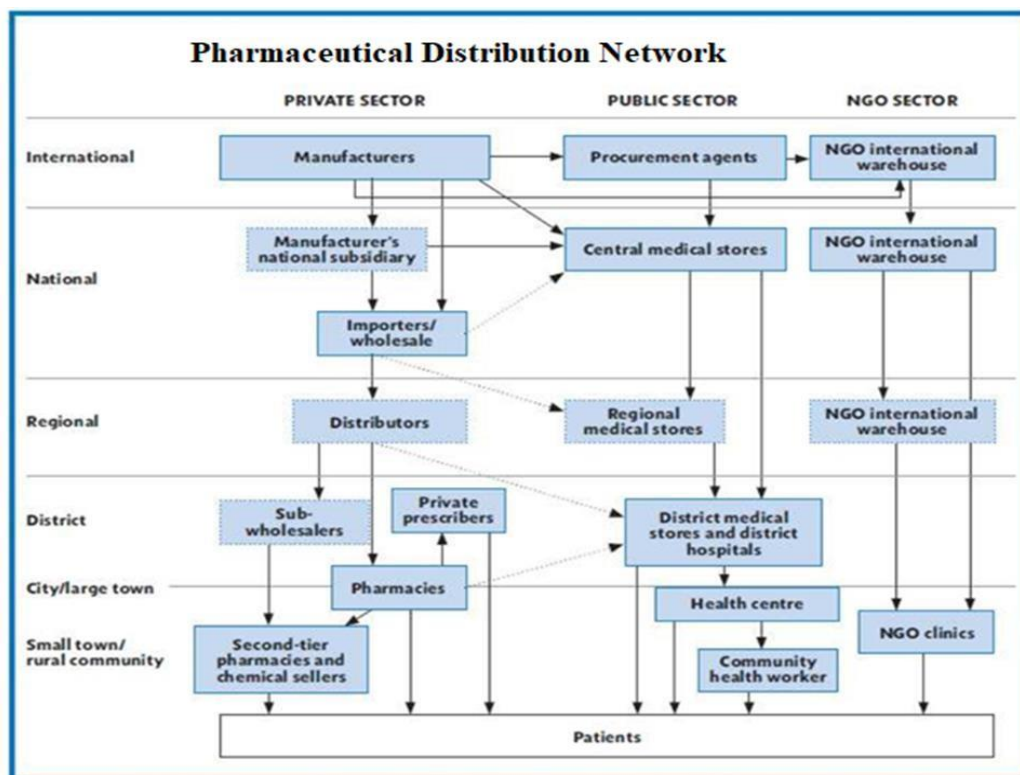
A Wholesale license and authorization holders must adhere to suitable distribution practices in order to ensure the quality, safety, and security of pharmaceutical goods across the pharmaceutical supply chain (7).

Because poor distribution practices can have a substantial influence on the health of the general population, it is essential to adopt better distribution practices. Any mistake in distribution can lead to shortages, delays, or even the release of fake medicines on the market. Another reason GDP is significant in pharma is that it assists in product traceability, which may be a big element during government investigations of quality concerns or events involving pharmaceutical goods (4). Overall, excellent distribution policies prevent wholesale distributors against circumstances that would not only affect their business reputation but also harm the broader public and result in a significant loss of clients (5).

In order to prove that the distributor complies with quality requirements, the distributor must have the organizational structure, processes, procedures, resources, and activities necessary for a quality system. For quality management or the quality system, it is necessary to have a stated quality policy as well as authorized procurement and release procedures. Wholesalers must also follow quality risk management principles and detect any product quality problems. Based on the recommendations of risk assessments, quality systems should be reviewed and enhanced on a regular basis (6).

It might be challenging to control pharmaceutical quality throughout the distribution process. The needed shelf life and storage requirements for pharmaceutical products are

among the issues with the supply chain for those products. All pharmaceuticals cannot be handled uniformly since different dosage forms (such as pills, syrups, injectable, etc.) must be transported and stored under various environmental conditions. The handling needs for tablets, syrups, and injectable will be very different. The temperatures at which cold chain medications are stored range from 2 to 8 degrees Celsius (8).



**Figure 1. Distribution network for essential medicines in the public, private and NGO channels in developing countries. Reproduced from Yadav with permission (<http://www.who.int/about/copyright/en/>).**

Items in the cold chain must be handled with more care because of the increased danger of product failure during quality control testing by customers. Lack of global regulatory system harmonization has impeded the growing globalization of pharmaceutical manufacture and distribution. As a result, low- and middle-income countries' (LMICs') supply chains are still at risk from the dangers of subpar drugs. According to the findings of a secondary study that was carried out in 13 low- and middle-income countries, local private pharmaceutical distributors, we assessed the quality assurance system of an appropriate sample of local commercial pharmaceutical distributors in 13 LMICs help quantify this risk in the private sector in LMICs (11).

The regulation of pharmaceuticals related to control of manufacturing standards, the quality, the efficacy and safety of drugs. Labelling and information requirements, distribution procedures and consumer prices. To assure quality of medicines, in most cases registration required prior to the introduction of a drug preparation into the market. The manufacturing registration and sale of drugs have been the subject of restricts regulations and administrative procedures worldwide for decades (3) Meanwhile the situation is not the same in South Sudan medicine regulatory authority does not yet grant marketing authorization and does not yet testing drugs before they are introduced into the market, as a result lack of restrictions throughout the distribution cycle within the private sector. (Primary source). Thus, there is a need to assess the private pharmaceutical wholesaler's compliance with the GDP.

## **1.2 Background**

For the sake of protecting both individual and public health and enabling effective operation of healthcare systems, medicines must be of a guaranteed high standard.

Unfortunately, the globalization of pharmaceutical manufacture and distribution has not been matched by a strengthening and harmonization of regulatory systems everywhere, which has resulted in a wide range of pharmaceutical quality standards being present on the worldwide market today. Problems are abundant, particularly in low- and middle-income countries, where many National Medicines Regulatory Authorities lack the resources and capacity needed to enforce compliance with good distribution practices. This is despite the fact that no country is immune to the risk of low-quality medicines and a poor-quality system (3).

Africa is facing a critical public health challenge: access to high-quality medications. This problem is being exacerbated by the rise in chronic illnesses, demographic shift, and the advent of middle- class families willing and able to set aside a portion of their income for health-care expenses (4). Given the expected growth in this sector, uncovering synergies between public and private stakeholders will be critical. Governments are increasingly looking to private companies to supply and distribute pharmaceuticals as an alternative to failing institutions.

Despite signs that the worst of the country's crisis (South Sudan) is subsiding, the pharmaceutical industry faces major hurdles owing to political insecurity, insecurity, corruption, and economic uncertainty. Other issues associated with weak infrastructure in all kinds (5) The potential market for private pharmaceutical is too great due to a high unmet demand for important medications, a growing middle class prepared to pay for better treatment, and innovative modules of care developed (e.g., medical insurance...etc.). In addition to the previously listed obstacles, there is a high cost of operation, a lack of market data, a lack of trustworthy infrastructure, and weak institutions.

South Sudan confronts a number of issues when it comes to delivering appropriate medications to health-care institutions (HC). The Central Medical Stores (CMS) is under department of pharmaceuticals and medical supplies in the ministry of health. The CMS is a public sector in responsibility of quantification, procurement, storing, and distribution of medicines and medical supplies to health centers around the nation, including primary, secondary and tertiary health care centers (6).

Typical challenges within national health systems that have an impact on supply chains include inadequate predictions, insufficient funds, delays in funding disbursements, and prolonged lead times (tendering and manufacturing). In least developed countries, access to medicine is constrained in comparison to national health systems (6, 7).

In a situation where resources are already limited, these possible duplicate activities across supply chains could waste time and money. The CMS has problems with distribution planning and truck routing because of things like how HC orders, bad communication and information flow between many parties, slow adoption of technological solutions, bad road infrastructure, and a lack of vehicles. Additionally, it is challenging to track performance indicators like medication availability, which makes it challenging to spot bottlenecks and chances to improve the supply chain (WHO, 2006). The performance of the health system in South Sudan is ranked 167th out of 192 countries. By 2025, South Sudan would have difficulty achieving the Millennium Development Goals, according to a WHO report (9).

South Sudan possesses one of the lowest health indices observed anywhere in the globe. In 2014, the infant mortality rate was 39.3 deaths per 1000 live births, while the mortality rate for children under the age of five was 99.2 deaths per 1000 live births. The maternal

mortality rate was 789 deaths per 100,000 live births. The infant mortality rate in the United Kingdom was five fatalities for every one thousand live births (7). Health status varies greatly depending on socio- demographic characteristics and geography.

The nation has been dealing with recurrent, escalating humanitarian crises since December 2013. Food security, child survival, access to and use of medical services, and the state of the economy have all been severely impacted by the humanitarian crisis. It is estimated that 4.8 million South Sudanese, or more than one in every three, experience acute food insecurity. Additionally, 67 out of 80 counties lack access to appropriate or any healthcare services because of deteriorated buildings, destroyed medical facilities, and county-level closures.

Communicable diseases are still a big problem for public health and the main cause of death. Approximately 77% of all OPD diagnoses in children under the age of five are for malaria, diarrhea, and pneumonia. Other causes of illness and death include maternal deaths, severe acute malnutrition, and tuberculosis/HIV. The number of people with TB is 146 per 100,000, and the number of people with HIV/AIDS is 2.6%, which shows a wide pandemic. NTDs (neglected tropical illnesses) are endemic in the great majority of cases.AJ.

About 24% of the burden of guinea worm disease worldwide is attributable to South Sudan. Other NTDs include lymphatic filariasis, schistosomiasis, onchocerciasis, viral leishmaniosis, and trypanosomiasis.

The prevalence of non-communicable diseases (NCDs), especially diabetes and cardiovascular disease, is increasing among the affluent. Due to the nation's vulnerability to post-traumatic stress disorder as a result of the country's protracted wars, road traffic accidents and mental health issues are widespread. At 88% and 63%, respectively, both men and women lack literacy.

While 55 percent of the population has access to improved water sources, just 7 percent of people have access to sanitation that meets basic standards. Although the ratio of girls to boys in primary school is 4:5, only 18.8% of children in total enroll in the grade level. Because there are not enough roads and bridges — both of which are necessary for the provision of services — more than sixty percent of the population has restricted access to

public infrastructure when the rainy season arrives. There is not currently a national electrical grid or energy distribution system.

The process of institutionalizing policies to advance the global health agenda, such as the International Health Regulations, a tobacco-free initiative, and the management of non-communicable diseases, is still in its infant stages. Some examples of these policies include a tobacco-free initiative; the International Health Regulations; and the management of non-communicable diseases. These figures show how the drug supply is disorganized, haphazard and fragmented, leading to needless labour, resource loss, and an inability to maximize patients' access to critical medications.

### **1.2.1. Challenges Faced by the South Sudanese Medicine Distribution Network**

The challenges faced by South Sudanese medicine distribution network for inventory management (IM) transport and distribution (T&D) will be the main focus of this thesis, along with the reasons behind those challenges. It will also identify the barriers and opportunities needed to improve inventory management and transport & distribution in order to increase access to medicines. There hasn't been any harmonization of global regulatory systems to go along with the increased globalization of pharmaceutical manufacturing and delivery. Because of this, low- and middle-income countries' (LMICs') supply networks are nonetheless susceptible to the risk posed by subpar drugs (1).

According to the findings of the study that was carried out in 13 low- and middle-income countries, local private pharmaceutical distributors (3), there is a real possibility that people living in low- and middle-income countries (LMICs) could end up receiving pharmaceuticals that are of poor quality or have become tainted as a result of a lack of compliance with WHO quality guidelines, which was discovered in our sample. Significant investments are required in order to tighten regulatory oversight, particularly of commercial distributors of pharmaceutical products.

It would be beneficial to have a standardized assessment tool based on the WHO MQAS for self-evaluation, auditing, and inspection (3). There is fraud in the whole process of health supply chain management in South Sudan because of a number of factors related to the operation of health actors (6), especially the private sector and organizations in charge of

monitoring their operation (7). In addition to not having enough human resource and infrastructure (6). High-quality medications are necessary to give high-quality healthcare. Therefore, it become very crucial to manage the medical channel networks to distribute the high-quality medicines to all the channel members from wholesalers to retailers and finally to end consumers.

### **1.2.2. Dimensions to study the status of 'GDP' in South Sudan**

Good distribution practice (GDP) is regarded as the cornerstone of pharmaceutical quality control. In order to ensure product quality after a batch has left the manufacturing facility and to manage consumer complaints, the GDP has a shared commitment. The study demonstrates that while there are several viewpoints on GDP, these may all be condensed into a single, universal framework for a quality system. The current regulations outlined in South Sudan Drugs and Food Control Authority Act 2012 (DFCA) place less emphasis on good distribution practices. If specifics of the operation of warehousing, storage, and distribution are taken into consideration, there is little GDP statistics accessible. Good distribution practice (GDP), which was covered in the study's preceding part, is a mechanism for ensuring that goods are consistently produced and regulated in accordance with quality standards. Studies to determine the aspects of GDP and to examine the state of GDP in the South Sudanese setting are lacking. WHO Model Quality Assurance System for Procurement Agency (MQAS) and WHO GDP questionnaire will be used to assess GDP compliance of the private pharmaceutical companies.

### **1.2.3. South Sudan Medicine Supply Chain**

The South Sudan Directorate of Pharmaceuticals and Supplies in the national Ministry of Health and Central Medical Stores (CMS) Is responsible for leading the selection and quantification of public sector pharmaceuticals and supplies, managing the procurement of health commodities, and overseeing storage and distribution of these commodities to counties and health facilities. Yet South Sudan confronts a number of issues when it comes to delivering appropriate medications to health-care institutions (HC), a typical challenge within national health systems that have an impact on supply chains include inadequate predictions, insufficient funds, delays in funding disbursements, and prolonged lead times

(tendering and manufacturing). In least developed countries, access to medicine is constrained in comparison to national health systems (6, 7).

The South Sudan Drug and Food Control Authority (DFCA) on the other hand is a semi-Autonomous national medicine regulatory authority responsible for General supervision, Control and coordination over all matters relating to the pharmaceutical industry and principal instrument of Government in the implementation of all policies relating to drugs, poisons, chemicals, cosmetics, and foods meant for human or animal use. They aid in ensuring the quality of essential pharmaceuticals, which allows for the provision of effective treatments, the reduction of disease, and cost savings in health care that may be redirected toward the attainment of Universal Health Coverage. (4). Unfortunately, due to poor regulatory oversight to detect, investigate various factors in the supply chain (e.g. illegal importation, sourcing from unlicensed distributors, counterfeiting, etc (2) The aim of this study is to assess the compliance of private pharmaceutical wholesalers with Good Distribution Practices (GDP) in Juba, South Sudan,. It will identify the most significant factors associated with compliance with GDP using the WHO-MQAS Self-Assessment tool and observation, as well as by evaluating the capacity of actors in GDP implementation.

### **1.3. Research Problem**

According to the Health Pool Fund (HPF), South Sudan confronts a number of issues when it comes to delivering appropriate medicines to health-care facilities (HC), a typical challenge within national health systems that have an impact on supply chains include, weak information management system that does not provide timely and reliable medicine consumption/morbidity data as well as poor storage facilities and conditions. Often lack of transport and limited communication has delayed the supply of drugs and medicines to rural communities. This is further worsened by the shortage of qualified pharmaceutical personnel at healthcare levels, addition to lack of adequate legislation and enforcement mechanism to regulate the pharmaceutical sector and assure safety and effectiveness of pharmaceuticals and medical devices. The challenges faced by South Sudanese medicine distribution network for inventory management (IM) transport and distribution (T&D) will be the main focus of this thesis.

This study will focus on private pharmaceutical wholesalers/distributors in Juba, South Sudan. The capital city of South Sudan, was chosen as the location for this study due to the presence of numerous pharmaceutical wholesalers providing a representative sample of distributors across the country. Moreover, the city houses various markets and business areas where the targeted wholesalers predominantly operate, facilitating easier access for data collection.

The aim of this study is to assess the compliance of private pharmaceutical wholesalers/distributors in Juba, South Sudan with WHO Good Distribution Practices (GDP). It will identify the barriers and opportunities needed to improve inventory management and transport & distribution in order to increase access to quality medicines.

#### **1.4. Research Objective:**

##### **1.4.1. Overall objective**

The aim of this study is to assess the compliance of private pharmaceutical wholesalers with Good Distribution Practices (GDP)

##### **1.4.2. Specific Objective**

- i. To assess the private pharmaceutical warehouses/distribution facilities compliance with Good Distribution Practices (GDP).
- ii. To determine challenges faced by private pharmaceutical wholesalers/distributors in regards to the GDP compliance.

##### **1.4.3. Research Questions**

- i. How does the private pharmaceutical wholesalers/distributors practice good distribution practices to ensure products quality are maintained throughout the distribution network?
- ii. What are the challenges faced by the private pharmaceutical wholesalers/Distributors in regards to the GDP compliance?

### **1.5. Delimitation of the Study**

This research will focus on the level of compliance of the private pharmaceutical to WHO good distribution practices in Juba- Central Equatoria State, South Sudan.

### **1.6. Scope of the Study**

This Study targeted the private pharmaceutical wholesaler/distributors to assess their compliance with GDP in 10 States, in South Sudan. However, the research was limited to private pharmaceutical distributors based in Juba due to unavailability of information about Private pharmaceutical companies in other States. Thus, the study is conducted in Juba, Central Equatoria State and the results may show only for one State.

## **CHAPTER TWO**

### **LITERATURE REVIEW**

#### **2.1 Introduction**

This chapter encompassed a broad exploration of various theoretical, empirical, and conceptual perspectives related to the central theme - the Good Distribution Practice of Pharmaceuticals in the Private Sector. The chapter focused on two primary objectives. The first was to evaluate the degree to which private pharmaceutical warehouses and distribution facilities had complied with Good Distribution Practices. The second objective was geared towards comprehending the challenges that private pharmaceutical wholesalers or distributors encountered in their compliance with GDP. Moreover, this chapter identified some gaps in the preceding literature, thereby establishing areas for future research.

areas for future research.

#### **2.2 Overview of Good Distribution Practice (GDP)**

The definition and importance of GDP (Good Distribution Practice) in the pharmaceutical industry have garnered attention, especially in the context of medical affairs and quality assurance. Jandhyala embarked on a study to define medical affairs within the pharmaceutical industry, highlighting the necessity for a standardized definition to guide policy and practice, ensuring that patients' interests remain central (1). This endeavor resonates with the emphasis placed by Goda on the significance of quality assurance in pharmaceutical sciences, including the pharmaceutical industry. Goda's discussion on quality assurance underscores the balance of safety and efficacy as the basis of pharmaceutical sciences, aligning with the principles of GDP (2).

In addition to quality assurance, the role of internal audits in ensuring adherence to GDP is crucial. Lebedynets and Karamavrova explored the competence of internal auditors of pharmaceutical quality systems, emphasizing the importance of selection, training, and continuous improvement of auditors in ensuring compliance with GDP guidelines. Their insights contribute to understanding the mechanisms that reinforce GDP within the pharmaceutical industry, ensuring product quality and safety (3).

Furthermore, the regulatory framework surrounding pharmaceutical products, including live biotherapeutic products, is integral to GDP. Cordaillat-Simmons et al. discussed the importance of a defined regulatory framework for live biotherapeutic products, highlighting the role of regulatory authorities and the pharmaceutical industry in adhering to international guidelines to ensure product quality and safety. Their discussion complements the earlier discussions on quality assurance and internal audits, reinforcing the multifaceted approach to ensuring GDP in the pharmaceutical industry (4).

In conclusion, the literature underscores the importance of a clear definition and understanding of GDP in the pharmaceutical industry, encompassing aspects of quality assurance, internal audits, and regulatory compliance. The collective insights from the studies reviewed offer a comprehensive perspective on the mechanisms and considerations essential for upholding GDP in the pharmaceutical industry, ensuring the delivery of safe and high-quality pharmaceutical products to patients.

### ***2.2.1 Global Standards and Guidelines for Good Distribution Practice***

Good Distribution Practice (GDP) is a crucial aspect of the pharmaceutical industry, ensuring the maintenance of quality and integrity of medicinal products throughout the supply chain. Global standards and guidelines for GDP are aligned with the World Health Organization's GDP guideline, ensuring uniformity in practices across various countries. Okafor et al. discussed the need for a robust GDP assessment tool for a regulatory agency in West Africa, highlighting the absence of a separate assessment tool for GDP inspection within the observed agency (5). The study emphasized the need for training of inspectors in line with the tool and a separate GDP inspection, outside the GMP inspection.

### ***2.2.2 Key Components and Principles of Good Distribution Practice***

The key components and principles of GDP encompass various aspects, including internal audits and the competence of auditors. Lebedynets and Karamavrova emphasized the importance of internal audits in pharmaceutical companies, highlighting the need for selection, training, grading, certification, and continuous improvement of the auditor's competence (1). The study underscored the relevance of these components for both domestic and foreign enterprises, ensuring adherence to GDP guidelines. Additionally, the

study by Ward et al. emphasized the importance of capacity building and equitable partnerships in global health research, contributing to the enhancement of GDP by improving local conditions of health and reducing global health inequality (6).

### ***2.2.3 Good Distribution Practice in the Pharmaceutical Industry***

In the pharmaceutical industry, GDP ensures the delivery of high-quality and safe medicinal products to end-users. The adherence to GDP guidelines and standards is paramount, ensuring the maintenance of product quality and safety throughout the distribution process. The development of a robust GDP assessment tool, as discussed by Okafor et al., is essential for conducting comprehensive GDP inspections, ensuring compliance with global standards. The emphasis on internal audits and auditor competence, as highlighted by Lebedynets and Karamavrova, reinforces the importance of these components in ensuring GDP in the pharmaceutical industry (3).

SDC partnership for reconstruction, including in the pharmaceutical sector in post-war Ukraine. The study highlighted the need for alternative sources of financing and the effectiveness of public and private partnerships in attracting funds for developing infrastructure, including pharmaceutical distribution (7). Farah and Farah explored the challenges and opportunities in the technical and vocational education and training sector in Somalia, which can be paralleled to the pharmaceutical sector. The study found issues such as a lack of clarity on the roles of the private and governmental sectors and a lack of a uniform and unified curriculum (8). Aldred also highlighted the challenges of private provision in the NHS, emphasizing the potential damage to the NHS by the involvement of big business (9).

### ***2.2.4 Comparison between Public and Private Sector Pharmaceutical Distribution***

Comparing public and private sector pharmaceutical distribution, Shelton and Tracy conducted a survey to understand the current state of cultivar development in the U.S. public sector (10). The study found a decline in public cultivar development, with insufficient numbers of younger breeders working in the public sector. Eizaguirre Anglada discussed the role of self-organized community actors in fostering the democratization of everyday life, highlighting the potential for public-community partnerships to develop a constructive

and critical approach to public service delivery and enhance collective learning about economic democratization (11). Gemal et al. (2013) emphasized the importance of quality drug production and the challenges faced by Brazil in playing a role as a global supplier of tuberculosis drugs (12)

### **2.3 Pharmaceutical Distribution in the Private Sector**

The private sector plays a significant role in pharmaceutical distribution, especially in regions where antibiotics are widely available over the counter without prescription. Poompruek et al. conducted an ethnographic and survey study in Thailand, focusing on antibiotic distribution in community pharmacies. The study found that antibiotics are often categorized as ‘strong medicines’ and are requested by customers using ‘prescriptions by proxy (13). Aldred discussed the growth and concentration of corporate power in the health sector, highlighting the significant role of pharmaceutical companies in the NHS and the potential challenges it brings (14). Gemal et al. discussed the production of tuberculosis drugs in Brazil, emphasizing the need for quality and affordable drug supply to ensure non-interrupted treatment for patients (15).

Challenges and opportunities in private sector pharmaceutical distribution are significant. Matviishyn and Vershyhora discussed the prospects of using public and private partnership for reconstruction, including in the pharmaceutical sector in post-war Ukraine. The study highlighted the need for alternative sources of financing and the effectiveness of public and private partnerships in attracting funds for developing infrastructure, including pharmaceutical distribution (7). Farah and Farah explored the challenges and opportunities in the technical and vocational education and training sector in Somalia, which can be paralleled to the pharmaceutical sector. The study found issues such as a lack of clarity on the roles of the private and governmental sectors and a lack of a uniform and unified curriculum (16). Aldred also highlighted the challenges of private provision in the NHS, emphasizing the potential damage to the NHS by the involvement of big business (9).

Comparing public and private sector pharmaceutical distribution, Shelton and Tracy conducted a survey to understand the current state of cultivar development in the U.S. public sector. The study found a decline in public cultivar development, with insufficient numbers of younger breeders working in the public sector (10). Eizaguirre Anglada discussed the

role of self-organized community actors in fostering the democratization of everyday life, highlighting the potential for public-community partnerships to develop a constructive and critical approach to public service delivery and enhance collective learning about economic democratization (11). Gemal et al. emphasized the importance of quality drug production and the challenges faced by Brazil in playing a role as a global supplier of tuberculosis drugs (15).

## **2.4 Overview of the Pharmaceutical Industry in South Sudan**

The pharmaceutical industry in South Sudan, like many other sectors in the country, is in the process of development. The country's healthcare system and related industries have been affected by years of conflict, leading to significant challenges in ensuring the availability and distribution of essential medicines and healthcare services.

The current state of GDP in South Sudan is not explicitly detailed in the available literature. However, considering the general challenges faced by the country, it is likely that ensuring adherence to global GDP standards is a significant task. Okafor et al. discussed the need for a robust GDP assessment tool for a regulatory agency in West Africa, highlighting the absence of a separate assessment tool for GDP inspection within the observed agency. The study emphasized the need for training of inspectors in line with the tool and a separate GDP inspection, outside the GMP inspection (17). This insight may be relevant to South Sudan as developing countries often face similar challenges in ensuring GDP compliance.

While specific laws, regulations, and oversight bodies related to GDP in South Sudan are not detailed in the search results, it is essential for countries to adhere to international standards and guidelines for GDP to ensure the quality and integrity of medicinal products. Meng et al. discussed international logistics criteria on medicinal products for human use, emphasizing the importance of GDP and Good Manufacturing Practice (GMP) in ensuring the quality of medicinal products (18). Komarova et al. also discussed the significance of various good practices, including GDP, in ensuring the quality of clinical trial data and materials (19).

In conclusion, while specific information on GDP in South Sudan is limited, the importance of adhering to international GDP standards and guidelines is clear. Ensuring GDP

compliance is crucial for maintaining the quality and integrity of medicinal products, contributing to improved healthcare outcomes and patient safety.

## **2.5 Challenges in Pharmaceutical Distribution in Juba**

While specific information about Juba is scarce, challenges in pharmaceutical distribution are a global concern. Sarkis et al. discussed the rise of personalized and highly complex drug product profiles, necessitating significant advancements in pharmaceutical manufacturing and distribution. The paper highlighted the reshaping of well-established paradigms in the pharmaceutical industry due to novel therapeutics of high-specificity and sensitive nature (20). Similarly, Pozniak et al discussed problems in pharmaceutical vaccine supply chains, emphasizing bottlenecks that lead to economic, social, and human losses, and an increasing pressure on reverse logistics (21).

The challenges in pharmaceutical distribution have a direct impact on Good Distribution Practice (GDP) adherence. Issues within the pharmaceutical supply chain involve illegal distribution practices, counterfeit drugs, and inefficient drug recall management. Mary Jane et al. discussed the opportunities of blockchain in the pharmaceutical industry and challenges of blockchain performance, identifying the largest opportunity areas for blockchain within the supply chain to address these issues (22).

Although specific case studies or examples of pharmaceutical distribution challenges in Juba are not available in the search results, the general challenges discussed in the literature provide insights into the potential issues faced in Juba and other similar regions. Purtell discussed how up to 30% of donated pharmaceutical aid products are diverted, stolen, or go to waste, highlighting the role of blockchain technology in addressing some of the biggest trust challenges in the global supply chain (23).

## **2.2 Theoretical Reviews**

The study delved into two principal theories that underpin the understanding of Good Distribution Practice in the pharmaceutical sector. The Resource Dependence Theory (RDT) and Compliance Difficulties Theory encompassed the guiding principles of this review.

### ***2.2.1 Resource Dependence Theory (RDT)***

The Resource Dependence Theory suggests that organizations survive and thrive by managing resources in their external environment efficiently(1). In the context of pharmaceutical distribution, efficient resource management directly influences compliance with Good Distribution Practices. This is because logistics, storage capacities, distribution channels, and operational workflows are vital resources that influence the degree of compliance.

Recent applications of RDT are evident across several industries. In pharmaceutical distribution, Zhang et al. established that effective external resource manipulation bolsters GDP compliance due to better quality control (2). Synchronously, Green et al. linked superior resource management and the minimization of GDP violations through improved error tracking and remedy (3).

However, RDT is not without detractors. For instance, Cummings argued that the theory oversimplifies the dynamics of the external environment and leans too heavily on resource manipulation while neglecting other factors like intra-organization policies and culture (4). Likewise, Roundy and Bayer criticized RDT for neglecting the role of internal resources like human capital and organizational structure (5).

Supporters of RDT, such as Jones et al., (6), suggest that the theory offers an objective viewpoint of an organization's environment interactions (6). They argue that understanding interdependencies between the firm and its resources is undeniably crucial in achieving regulatory compliance. Similarly, Lutfi et al. defended RDT by emphasizing its aptitude in highlighting external influences on firm behaviors like compliance under GDP (7).

Regarding the study on the compliance of private pharmaceutical warehouses to GDP, the Resource Dependence Theory is supremely relevant. It allows us to examine not only the internal workings of these enterprises but also their engagements with the external environment, the latter being cardinal in achieving GDP compliance.

However, RDT has gaps since its focus on the external environment may blur internal factors like company culture or bureaucratic structure that could potentially influence GDP

compliance. Thus, the study might benefit from complementing RDT with another theory like Organizational Culture Theory to cover these variables thoroughly.

In conclusion, effectively utilizing a combination of Resource Dependence Theory and an introspective organizational theory would give a comprehensive analysis of GDP compliance in private pharmaceutical warehouses.

### ***2.2.2 Compliance Difficulties Theory***

This second objective was guided by the Compliance Difficulties Theory developed by Dr. Jonathan Evans in 2017 (8). This proposition is centered around the premise that compliance challenges in any regulated industry, such as pharmaceutical supply chain, emerge from complex interplay of multiple factors that include, but are not limited to, large-scale ambiguity, developing technological infrastructure, regulatory environment and human characteristics (8).

Dr. Evans famously elucidated his theory by arguing that the presence of ambiguity in compliance guidelines often forces organizations to interpret the regulatory framework to the best of their capacity, leading to significant variations in compliance levels (8). He further posited that nascent technological infrastructure can drastically decrease the compliance rate due to a lack of appropriate systems to monitor and implement complex compliance procedures (8). He also highlighted the enormous role regulatory bodies play in shaping compliance; a sterner regulatory framework invariably makes compliance harder to achieve (8). Finally, the theory also insinuates that inherent human characteristics like risk-taking behavior and perceptions also significantly affect compliance levels (8).

Indeed, several authors have duly corroborated Evans' theory. Rose and Spence conducted an empirical study on pharmaceutical companies and found that they experienced difficulty in interpreting and implementing GDP guidelines due to a lack of specificity in language, thereby echoing Evans' ambiguity challenge (9). Additionally, Carroll and Buchholtz have showcased that poorly developed IT system within many pharmaceutical companies has been another major obstacle in achieving higher GDP compliance rate, thereby underscoring Evans' argument on technological challenge (10). Shapiro and Ettie emphasized stringent regulatory environment as a key factor in understanding compliance difficulty (11).

Furthermore, Zimmerman's work showed a clear correlation between the staff's perception of the importance of compliance and their actual compliance rates, thus validating Evans' point on the role of human characteristics in GDP compliance (12).

In light of this theoretical framework, an understanding of challenges faced by private pharmaceutical wholesalers/distributors in relation to the GDP compliance would involve a comprehensive examination of ambiguity in guidelines, technology infrastructure, regulatory environment, and human characteristics within the targeted organizations. Only with such a multi-pronged analysis, can we hope to understand the complexity of the compliance challenges faced by these distributors.

## **2.7 Knowledge gap**

Despite the extensive discussion and exploration of Good Distribution Practice (GDP) in the pharmaceutical industry, a noticeable knowledge gap persists in the literature, particularly regarding the specific challenges and intricacies faced by emerging and developing economies. The existing literature, while comprehensive in exploring the global standards, key components, and principles of GDP, often overlooks the unique contextual challenges faced by countries with limited resources and infrastructure. The studies by Okafor et al. and Lebedynets and Karamavrova provide valuable insights into the need for robust GDP assessment tools and the importance of internal audits, but there is a conspicuous absence of research focusing on the practical implementation and adherence to GDP in regions grappling with infrastructural and regulatory constraints (3, 11). This gap highlights the need for more geographically and contextually specific research to understand the diverse challenges and develop tailored strategies for ensuring GDP adherence in various global contexts. Further, the role of technological advancements, such as blockchain, in enhancing GDP adherence in these contexts remains underexplored, indicating another crucial area for future research (6).

## CHAPTER THREE

### METHODS

#### 3.1. Research Design

For this study, a descriptive-quantitative research design was employed to systematically investigate the compliance of private pharmaceutical wholesalers with Good Distribution Practices in Juba, South Sudan. This design allowed the researcher to examine the existing conditions, gather primary and secondary data, and provide an accurate representation and understanding of the current scenario in the pharmaceutical distribution sector. The descriptive-quantitative approach facilitated the collection of reliable data, which helped in identifying trends, patterns, and relationships among variables, enabling a comprehensive assessment of pharmaceutical wholesalers' compliance with GDP.

#### 3.2. Methods

This study included steps and techniques to obtain accurate and reliable data to assess the compliance of private pharmaceutical wholesalers with Good Distribution Practices in Juba, South Sudan.

#### 3.3. Data Collection Tools

Two data collection instruments were used to gather primary data from the private pharmaceutical wholesalers in Juba city, South Sudan. These included:

- 1. Questionnaire:** A structured questionnaire was developed to collect data on various aspects of GDP compliance. The questionnaire covered topics related to the demographics of the participant's warehouse assessments, regulatory status and certifications, quality control practices, and the implementation of GDP.
- 2. WHO MQAS Self-Assessment Tool:** The World Health Organization's Model Quality Assurance System (MQAS) for Procurement Agencies (Model V) Self-Assessment Tool was also employed. This tool guided the researcher in conducting

structured observations of the warehouses and distribution facilities of the pharmaceutical wholesalers.

### **3.4. Sampling Methods and Sample Size**

To collect the required data for this study, an approach combining various sampling methods, location, distributor type, sample size, population, and practicalities has been adopted considering private pharmaceutical wholesalers in Juba city, South Sudan.

### **3.5. Sample Size and Population**

The sample for this study consisted of a total of 86 private pharmaceutical wholesalers located across Juba city. The selection of these wholesales was based on the 2022 record of registration at the South Sudan Drug and Food Control Authority (DFCA). This diverse population represented various nationalities and management styles among the wholesalers, offering a comprehensive picture of GDP compliance.

### **3.6. Time span**

The data collection process was spread over a period of two months, from February to March 2023. This provided ample time for the researcher to visit each pharmaceutical wholesaler, interact with the managing directors and technical pharmacists, conduct direct interviews, and carry out structured observations using the WHO-MQAS assessment tool.

### **3.7. Location**

Juba, the capital city of South Sudan, was chosen as the location for this study due to the presence of numerous pharmaceutical wholesalers providing a representative sample of distributors across the country. Moreover, the city houses various markets and business areas where the targeted wholesalers predominantly operate, facilitating easier access for data collection.

### **3.8. Distributor type**

The study focused on local, for-profit pharmaceutical vendors that handle medications but do not sell directly to patients, which include wholesale pharmaceutical companies. This

focus allowed the research to analyze the middle part of the pharmaceutical supply chain, responsible for transporting medicines from manufacturers to pharmacies or healthcare facilities.

### **3.9. Practicalities**

To ensure the most accurate and reliable data, the research was conducted in a hands-on and interactive manner. Access to the targeted participants was facilitated through the regulated products list, which the researcher received from the South Sudan Drug and Food Control Authority. The questionnaire and WHO-MQAS assessment tool were used during the five-week data collection process, covering interviews, and conducting structured observations, ensuring a thorough evaluation of private pharmaceutical wholesalers' compliance with Good Distribution Practices in Juba, South Sudan.

### **3.10. Data Analysis**

The data analysis process was conducted in a systematic, step-by-step manner to address each aspect of the research. The following sections detailed on how the analysis was carried out for each specific segment of the study. The data analysis aimed to provide a comprehensive understanding of private pharmaceutical wholesalers' compliance with Good Distribution Practices (GDP) in Juba, South Sudan. The analysis focused on the questionnaire results and the structured observations made using the WHO MQAS Self-Assessment Tool. Data from the research questionnaire was analyzed using SPSS version 23.

1. **Descriptive analysis**, descriptive statistics such as percentage, frequency distribution mean, chart and graphs were used to analyze data obtained via closed-end questionnaires.
2. **Likert scale analysis**, is a rating scale uses to assess opinion, attitudes or behaviors, using Likert type items and asking Likert questions

**3.11. Ethical Considerations** Ethical clearance to do the study was granted from the Ministry of Health Research Ethics Review Board (MOH-RERB). South Sudan, in accordance with the National Guidelines, to carry out this research.

## CHAPTER FOUR

### DATA ANALYSIS, PRESENTATION AND DISCUSSION

#### 4.1. Introduction

This report presents the data analysis, presentation, and discussions of the compliance of pharmaceutical distributors with Good Distribution Practices (GDP) guidelines and identify areas for improvement. The data was collected through a questionnaire and WHO MQAS assessment tool to the pharmaceutical distributors in the study area. The Likert scale was used to measure the responses of the participants, and data was analyzed using frequency distribution and percentages. The findings are presented in tables and discussed in detail, highlighting the areas of good practice and areas for improvement. The results of this study will provide insights for policymakers and stakeholders to improve the regulatory framework and enhance the quality of pharmaceutical distribution in the study area.

#### 4.2. Research Questionnaire

##### 4.2.1. Demographics of the participants

This section provides a brief overview of the demographics of the pharmaceutical wholesalers participating in the study, including information on the size, ownership structure, and years of operation of the firms. Results of this section were presented in table below;

**Table 1. Showing demographics of the participants**

Variable	Category	Frequency	Percentage
Age	35 and less	15	17%
	36-45	45	52%
	46-61	20	17%
	Total	86	100%
Gender	Male	83	95%
	Female	3	5%
	Total	86	100%
Nationality	Indian-Asian	20	23%

	Ethiopian/Eritrean	15	17%
	Egyptian/Arab	12	14%
	East African (Inc. South Sudanese)	39	45%
	Total	86	100%
Qualification	Diploma	15	17%
	Bachelor's Degree	60	70%
	Master's Degree	10	12%
	PhD	1	1%
	Total	86	100%
Years of Experience	5-15	65	75%
	16-20	21	25%
	Total	86	100%
Field of Specialist	Pharmacy	50	58%
	Medicine	20	23%
	Other	16	18%
	Total	86	100%
Total number of employees employed	5-15	70	81%
	16+	16	19%
	Total	86	100%
Total number of Pharmacist employed	1	72	84%
	2-5	6	7%
	6+	8	9%
	Total	86	100%
Role of Supervisor Pharmacist	Quality Assurance	35	41%
	Inventory Management	25	29%
	Regulatory Affairs	15	17%
	Other	11	13%
	Total	86	100%
Level of spoken English	Fluent	70	81%
	Basic	16	19%
	Total	86	100%

**Source: Primary data (2023)**

This table provides demographic information about the participants of the study on the good distribution practices of pharmaceuticals in private sector in Jubba, South Sudan.

The demographic characteristics of the participants in the study are summarized in Table 1.

The field of specialist variable shows that Pharmacy was the most common field (58%), followed by Medicine (24%). Other (18%). This variable is relevant to the study as it

provides insight into the specific challenges and strengths of the pharmaceutical industry in Jubba, South Sudan.

The total number of employees employed variable indicates that the majority of firms had 5-15 employees (81%), followed by 16+ employees (19%) This variable is relevant as it provides an indication of the size of the firms and their capacity to implement good distribution practices. The total number of pharmacists employed variable indicates that the majority of firms had 1 pharmacist (84%), followed by 2-5(6%) and 6+ or more pharmacists (9%) This variable is important as it provides an indication of the availability of qualified personnel to implement good distribution practices.

The role of supervisor pharmacist variable shows that Quality Assurance was the most common role (41%), followed by Inventory Management (29%), Regulatory Affairs (17%), and Other (13%). This variable is relevant as it provides insight into the specific roles and responsibilities of personnel involved in the implementation of good distribution practices.

These demographic variables can provide insight into the characteristics of the participants and help to contextualize the study findings. For example, understanding the field of specialist and the role of supervisor pharmacist can provide insight into the specific challenges and strengths of the pharmaceutical industry in Jubba, South Sudan.

#### **4.2.2. Warehouse Assessments**

The warehouse assessments are an important aspect of the study on Good Distribution Practices of Pharmaceutical in Private Sector in Juba, South Sudan. The assessments aim to examine the compliance of private pharmaceutical wholesalers with GDP in terms of their warehouses and distribution facilities. This section provides an overview of the key findings on the status of GDP in the warehouses of the participating pharmaceutical wholesalers. The scores Yes/No is based on the availability/absent/ compliance or noncompliance of the variables.

**Table.2. Showing warehouse assessments**

Variables	Yes	No	Total
Space/Size	30%	70%	86 (100%)
General condition of the warehouse	45%	55%	86 (100%)
Standard Operating Procedures	10%	90%	86 (100%)
Temperature/ventilation management and recording	5%	95%	86 (100%)
Segregated space for quarantined, approved, rejected	15%	85%	86 (100%)
Availability of pallets, shelves, and racks	95%	5%	86 (100%)
Temperature monitoring device in the store	5%	95%	86 (100%)
Separate storage area for flammables, hazardous	10%	90%	86 (100%)
Availability of air-conditioned and cold room facilities	90%	10%	86 (100%)
Availability of cold room facilities	5%	95%	86 (100%)
Electricity Supply/ Power Supply	100%	0%	86 (100%)
Distribution records for traceability	100%	0%	86 (100%)
Availability of the approved vendor list	90%)	10%	86 (100%)
Flycatcher condition and cleaning	0%	100%	86 (100%)
Proper labeling on all containers	70%	30%	86 (100%)
Vacuum cleaner cleanliness	0%)	100%	86 (100%)

**Source: Primary data (2023)**

The table on Warehouse Assessments provides crucial insights into the compliance of private pharmaceutical wholesalers in Juba, South Sudan with good distribution practices. A detailed discussion of the table, including frequency values and percentages, is presented below.

The results of the warehouse assessments, as presented in Table 2, highlight some areas of compliance and non-compliance with GDP in private pharmaceutical wholesalers' warehouses in Juba, South Sudan. The first variable is space/size, with only 30% of warehouses meeting the GDP requirements, while the rest (70%) did not meet the standards. The general condition of the warehouse is another variable, with 45% meeting the GDP requirements, while the remaining 55% did not.

The third variable is the availability of Standard Operating Procedures (SOPs), with only 10% of warehouses having SOPs, while 90% did not. Temperature/ventilation management and recording is another variable, with only 5% of warehouses complying with GDP standards, while 95% did not.

The availability of a segregated space for quarantined, approved, and rejected products is another variable, with only 15% of warehouses meeting the GDP standards, while the rest (85%) did not meet the standards. The availability of pallets, shelves, and racks is another variable, with 95% of warehouses meeting the GDP requirements, while only 5% did not meet the standards.

Temperature monitoring devices in the store is another variable, with only 5% of warehouses meeting the GDP standards, while the remaining 95% did not. The availability of a separate storage area for flammables and hazardous materials is another variable, with only 10% of warehouses meeting the GDP standards, while the remaining 90% did not.

The availability of air-conditioned and cold room facilities is another variable, with 90% of warehouses meeting the GDP requirements, while only 10% did not meet the standards. The availability of cold room facilities is another variable, with only 5% of warehouses meeting the GDP standards, while the remaining 95% did not.

Electricity supply/power supply is another variable, with 100% of warehouses meeting the GDP requirements. Distribution records for traceability is another variable, with 100% of warehouses meeting the GDP requirements. The availability of the approved vendor list is another variable, with 90% of warehouses meeting the GDP standards, while the remaining 10% did not meet the standards.

The condition and cleaning of flycatchers is another variable, with none of the warehouses meeting the GDP requirements. Proper labeling on all containers is another variable, with 70% of warehouses meeting the GDP standards, while the remaining 30% did not. The cleanliness of vacuum cleaners is another variable, with none of the warehouses meeting the GDP requirements. The results of the warehouse assessments demonstrate that compliance with GDP requirements in private pharmaceutical wholesalers' warehouses in Juba, South Sudan is still inadequate. The findings suggest the need for more rigorous

enforcement of GDP regulations and the implementation of corrective actions to address the non-compliant areas. The results of this study can serve as a basis for developing targeted interventions to improve compliance with GDP in the private pharmaceutical wholesale sector in Juba, South Sudan.

**4.2.3. Role of Regulatory authority**

**South Sudan Drug and Food Control Authority (DFCA)**

The role of regulatory authorities is crucial in ensuring compliance with regulations and policies governing the operation of pharmaceutical wholesalers. The South Sudan Drug and Food Control Authority (DFCA) is the regulatory body responsible for ensuring that the private pharmaceutical wholesalers in Juba, South Sudan, comply with the Good Distribution Practice (GDP) guidelines. In this section, we will discuss the role of the DFCA in regulating the pharmaceutical industry in Juba and its impact on the GDP practices of private pharmaceutical wholesalers.

**Table 3: Role of Regulatory authority: (DFCA) Regulatory Body**

Variables	Yes (F)	Yes (%)	No (F)	No (%)	Total (F)	Total (%)
Oversight and implementation of policies and regulations	77	90%	9	10%	86	100%
Supervision of DFCA to Wholesalers operation	86	100%	0	0%	86	100%
Qualification of DFCA inspectors assigned for inspection	86	100%	0	0%	86	100%
Level/status of implementation of DFCA regulations and laws	10	15%	76	85%	86	100%
Wholesaler capacity to implement DFCA regulations and laws	10	15%	76	85%	86	100%
Compliance with WHO good distribution practices guidelines	6	5%	80	95%	86	100%

**Source: Primary data (2023)**

The results presented in Table 3 highlight the role of the South Sudan Drug and Food Control Authority (DFCA) in regulating the pharmaceutical industry in Juba, South Sudan. The table outlines various variables related to the regulatory authority, including oversight and implementation of policies and regulations, supervision of DFCA to wholesaler operation, qualification of DFCA inspectors assigned for inspection, level/status of implementation of DFCA regulations and laws, wholesaler capacity to implement DFCA regulations and laws, and compliance with WHO good distribution practices guidelines.

The results show that the majority of participants (90%) acknowledged the oversight and implementation of policies and regulations by the DFCA, indicating a strong presence of the regulatory body in the pharmaceutical industry. Additionally, all participants (100%) recognized the role of the DFCA in supervising the operations of private pharmaceutical wholesalers and the qualification of DFCA inspectors assigned for inspection. This shows that the regulatory body is playing a crucial role in ensuring the compliance of private pharmaceutical wholesalers with GDP guidelines.

However, the results also reveal that only 15% of participants felt that DFCA regulations and laws were fully implemented, and only 15% felt that private pharmaceutical wholesalers had the capacity to implement DFCA regulations and laws effectively. This highlights the need for the DFCA to take measures to ensure that GDP guidelines are implemented effectively in the private pharmaceutical industry in Juba.

Another important finding is that only 5% of participants felt that private pharmaceutical wholesalers in Juba comply with WHO good distribution practices guidelines. This highlights the need for the DFCA to work closely with private pharmaceutical wholesalers to ensure that they comply with international standards and best practices in the industry.

The results of Table 3 suggest that the DFCA is playing a crucial role in regulating the pharmaceutical industry in Juba, South Sudan. However, there is a need for the regulatory body to take further measures to ensure that GDP guidelines are implemented effectively in the private pharmaceutical industry and that private pharmaceutical wholesalers comply with international standards and best practices.

**Table.4. Additional variables**

Variable	Values	Frequency	Percentage
Number of routine inspections per year	1-3 Per year	70	81%
	4-6 per year	16	19%
Total		86	100%
Number of unannounced visits to the warehouses per year	1-3 Per year	81	94%
	4-6 per year	5	6%
Total		86	100%

**Source: Primary data (2023)**

Table 4 provides additional variables related to the frequency of routine inspections and unannounced visits to warehouses. The frequency of routine inspections per year was found to be between 1-3 per year for the majority of participants (81%), followed by 3-6 per year (19%), with no participants reporting 7 or more inspections per year. Similarly, the frequency of unannounced visits to the warehouses per year was found to be between 1-3 per year for the majority of participants (94%), with only a small percentage reporting 3-6 visits per year (6%), and no participants reporting 7 or more visits per year.

The results from this table highlight the importance of routine inspections and unannounced visits in ensuring compliance with GDP guidelines. The majority of participants reported only 1-3 routine inspections per year, which may not be sufficient to adequately monitor compliance with GDP. Similarly, while the majority of participants reported 1-3 unannounced visits per year, the small number of participants reporting 3-6 visits per year suggests that there may be a need for more frequent visits to ensure compliance. The findings suggest that regulatory authorities should consider increasing the frequency of routine inspections and unannounced visits to warehouses to ensure better compliance with GDP guidelines.

## Registration and certification(s) Status

The registration and certification status of pharmaceutical distributors is an important aspect of ensuring the quality and safety of pharmaceutical products in the market. In this study, we investigate the registration and certification status of private sector pharmaceutical distributors in Juba, South Sudan, and analyze the implications for compliance with Good Distribution Practice (GDP) guidelines. This section presents the findings on the registration and certification status of the firms included in the study.

**Table.5. Registration and Certification(s) Status**

Variables	Yes		No		Total	
	Count	Percentage	Count	Percentage	Count	Percentage
Quality assurance requirements and procedures	4	5%	82	95%	86	100%
Operation license and country legal operation	86	100%	0	0%	86	100%
Registration and other certification or recommendation by any international or regional bodies and or approval from any health organizations or international body (attach copy of document issue or certificate):	0	0%	86	100%	86	100%
Audit or technical assessment from any of international body (if yes, please attach the document)	0	0%	86	100%	86	100%
Company Status: pre-qualified by WHO and their products	0	0%	86	100%	86	100%
GMP approval by any third parties (like WHO-PQ, US FDA, EMA, from the country of origin or any	0	0%	86	100%	86	100%
Dossier or assessment of pharmaceutical products	0	0%	86	100%	86	100%
Registration requirements by Regulatory Authority to import pharmaceutical products or medical devices	42	49%	44	51%	86	100%

**Source: Primary data (2023)**

Table 5 provides information on the registration, certification status and quality assurance requirements of the private pharmaceutical wholesalers participating in the study on Good Distribution Practices compliance in Juba, South Sudan. The responses offer insights into the level of compliance with various regulations and certifications in the sector. The variable analyzed is quality assurance requirements and procedures, with only 4 firms (5%) reporting having registration and certification in this area, while the majority of the firms (95%) reported not having this certification. The results suggest that there is a low level of compliance with quality assurance requirements and procedures among private pharmaceutical wholesalers in Juba, which may impact the safety and effectiveness of pharmaceuticals distributed in the region.

All respondents (100%, n=86) reported having an operation license and adhering to the country's legal requirements for operation. This finding indicates that pharmaceutical wholesalers in Juba are operating within the legal framework.

However, none of the respondents (0%, n=86) reported having undergoing audits or technical assessments from any international body, being pre-qualified by the WHO, having GMP approval from third parties, or having dossier assessments for their pharmaceutical products. These findings suggest that there is a significant gap in compliance with international standards and certifications in the pharmaceutical distribution sector in Juba, South Sudan.

Finally, registration requirements by the Regulatory Authority for importing pharmaceutical products or medical devices were nearly evenly split among respondents, with 49% (n=42) reporting compliance and 51% (n=44) reporting non-compliance. This indicates that there is a need for improvement in adherence to registration requirements for importing pharmaceuticals in the sector.

The data shows a mixed picture of compliance with various registration, certification, and quality assurance requirements among pharmaceutical wholesalers in Juba, South Sudan. While operation licenses and legal requirements are consistently met, there is a substantial gap in compliance with international standards and certifications, as well as quality assurance and registration requirements. This highlights the need for ongoing efforts to improve adherence to these requirements in the pharmaceutical distribution sector.

## **Regulatory status and certification(s) of Pharmaceutical Distributors**

This section of the study focuses on the regulatory status and certification(s) of pharmaceutical distributors in Juba, South Sudan. The aim is to assess whether the distributors are complying with Good Distribution Practice (GDP) guidelines and to identify any areas where improvements are needed. The data collected in this section will provide insight into the level of compliance with regulations and certifications among the pharmaceutical distributors in Juba.

### **License**

In the context of pharmaceutical distributors and their compliance with Good Distribution Practice (GDP), obtaining a license is a crucial aspect of ensuring the quality and safety of pharmaceutical products. This section of the study aims to assess the license status of the private pharmaceutical wholesalers in Juba, South Sudan, and explore its relationship with their GDP practices.

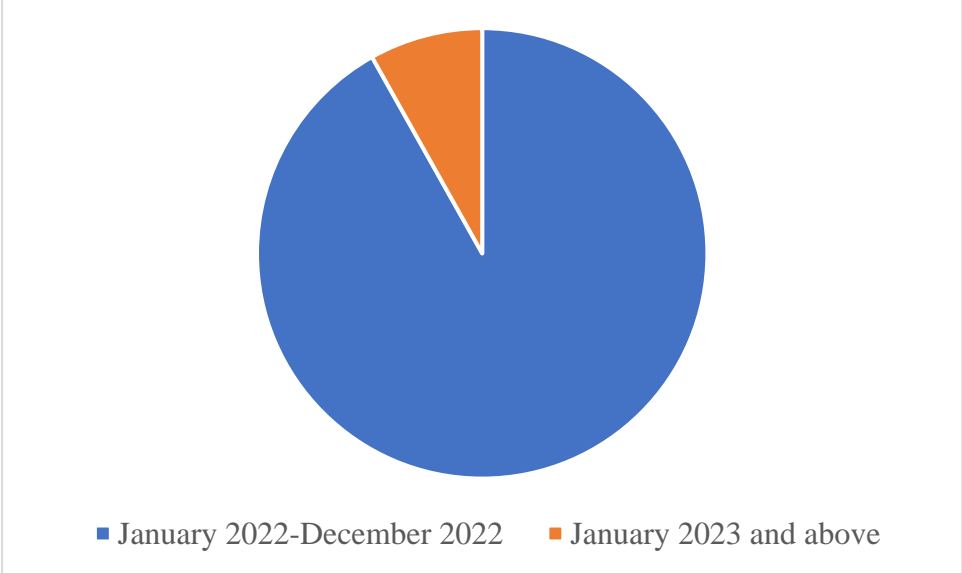
### **Source: Primary data (2023)**

This section provides information on the regulatory status and certifications of the pharmaceutical distributor's active in the area, with the study's focus on good distribution practices of pharmaceuticals in the private sector in Juba, South Sudan. It indicates whether the distributors have valid licenses from the appropriate regulatory body.

The Study demonstrates that every one of the 86 businesses surveyed for the study (100%) has a license from the appropriate regulatory body. This suggests that the legal requirements for conducting business as pharmaceutical distributors in the area are being complied with to a high degree. Complete licensing compliance can be seen as a good sign, demonstrating the private pharmaceutical industry's dedication to upholding the standards and rules established by the authorities.

Such high rates of license compliance also imply that South Sudan's regulatory bodies may have strict measures in place to guarantee that only authorized pharmaceutical distributors are permitted to operate. This is an important step in ensuring the reliability and security of pharmaceutical products sold in the nation.

It is crucial to understand though that obtaining a license alone does not ensure that good distribution practices will be followed. While it is a prerequisite, other factors, including warehouse conditions, SOPs, and adherence to regulations guidelines, must also be taken into consideration to guarantee that the pharmaceutical supply chain functions effectively and safely.



**Figure 2: Date of Last Audit/Technical Visit**

**Source: Survey data (2023)**

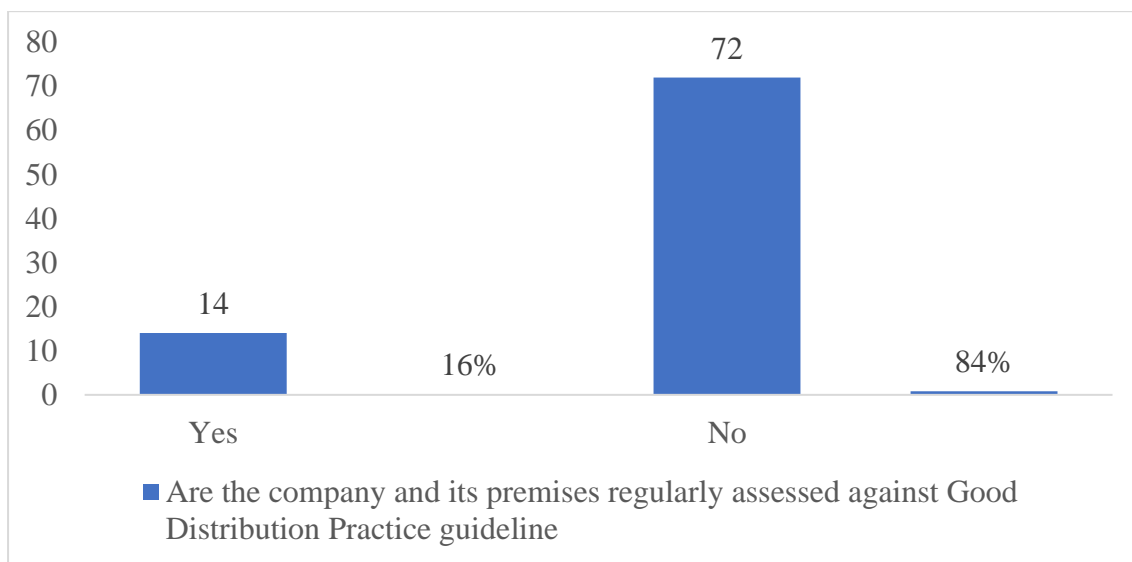
Data above was presented in pie chart above provides information about the date of the last audit or technical visit for the private pharmaceutical wholesalers participating in the study on Good Distribution Practice of Pharmaceuticals in Private Sector in Juba, South Sudan. The majority of participants (92%) had their last audit or technical visit conducted between January 2022 and December 2022, while only 8% had their last visit conducted in January 2023 or later. This indicates that most participants had been recently audited, which may have influenced their compliance with GDP. It is important for regulatory authorities to conduct regular audits and technical visits to ensure compliance with regulations and to identify areas for improvement.

### Good Distribution Practice (GDP)

Good Distribution Practice (GDP) is a crucial aspect of pharmaceutical supply chain management, ensuring that pharmaceutical products are handled and distributed safely and effectively. In the context of the above study on the regulatory status and certification(s) of pharmaceutical distributors in South Sudan, GDP serves as a sub-section for assessing the compliance of private pharmaceutical wholesalers with industry regulations and standards. The section aims to examine the GDP practices of pharmaceutical wholesalers in Juba, South Sudan, to identify factors influencing compliance, and to identify barriers and challenges to compliance with GDP.

#### Source: Primary data (2023)

Data was presented in form of a bar chart below;



**Figure 3: Good Distribution Practice (GDP)**

The statement "Are the company and its premises regularly assessed against Good Distribution Practice guideline" was included in the survey to determine if private pharmaceutical wholesalers in Juba, South Sudan, comply with GDP. According to Table 6, only 14 participants (16%) answered 'yes' to this statement, while the majority of the participants (72, 84%) answered 'no'. This indicates that there is a lack of regular assessments of the private pharmaceutical wholesalers against GDP guidelines in Juba,

South Sudan. This finding is significant because regular assessments are important to ensure compliance with GDP guidelines, and the lack of regular assessments can lead to non-compliance and potential harm to the end-users. Therefore, the study highlights the importance of regular assessments and recommends that regulatory authorities implement measures to ensure regular assessments are conducted to enhance compliance with GDP guidelines.

**ISO certification**

ISO certification is a sub section of the Regulatory status and certification(s) of Pharmaceutical Distributors in the above study. The certification is an internationally recognized standard that specifies requirements for a quality management system that can be applied to any type of organization, including pharmaceutical distributors. In this section, the ISO certification status of the pharmaceutical distributors is being assessed to determine their compliance with international standards and best practices for quality assurance in the distribution of pharmaceutical products.

**Table 6: ISO Certification of Pharmaceutical Distributors in South Sudan**

Is your company ISO certified?	Frequency	Percentage
Yes	0	0%
No	86	100%
Total	86	100%

**Source: Primary data (2023)**

The table reveals that none of the surveyed pharmaceutical distributors in South Sudan are ISO certified. This suggests that all 86 (100%) of the companies in the sample lack this internationally recognized certification, which may impact their adherence to quality management standards and overall business practices. It is important to consider the reasons behind this lack of ISO certification and explore potential measures to encourage and support pharmaceutical distributors in South Sudan to achieve this accreditation, thereby improving their operational standards and reputation.

## Range of products

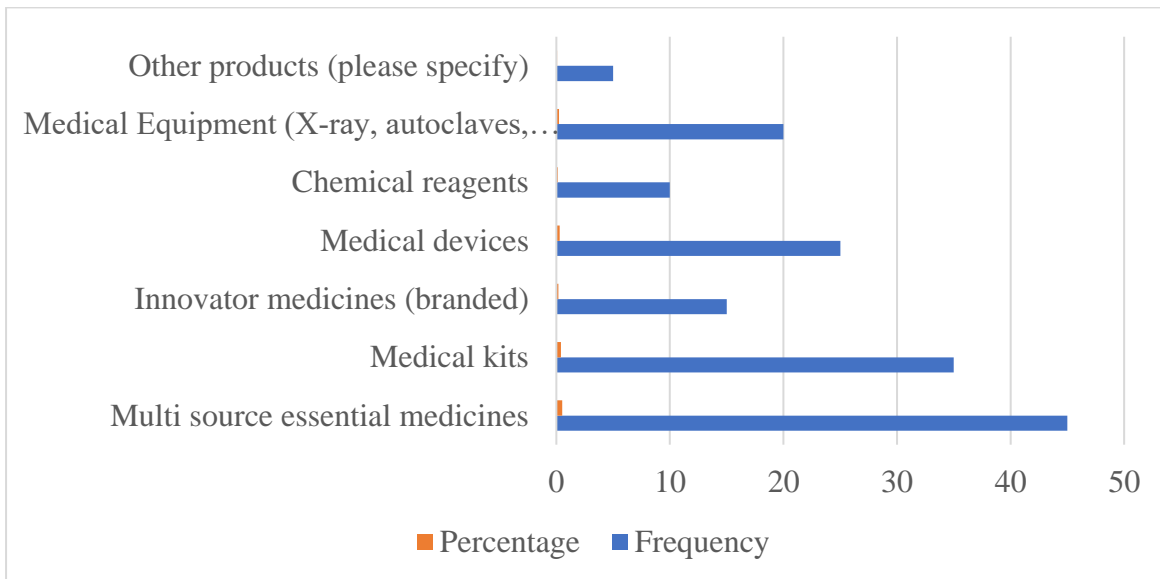
The Range of Products is an important aspect of the Regulatory status and certification(s) of Pharmaceutical Distributors in the above study. This section aims to explore the types of products that are supplied by the pharmaceutical distributors in Juba, South Sudan. Understanding the range of products supplied by these distributors can provide valuable insights into the pharmaceutical market in the region, including the availability and accessibility of different types of medicines and medical equipment. This information is crucial for developing strategies to improve the distribution and supply of quality pharmaceutical products in the region.

**Table 7: Types of Products Supplied by Pharmaceutical Distributors**

Types of Products	Frequency	Percentage
Multi source essential medicines	45	52%
Medical kits	35	41%
Innovator medicines (branded)	15	17%
Medical devices	25	29%
Chemical reagents	10	12%
Medical Equipment (X-ray, autoclaves, sonographer)	20	23%
Other products (please specify)	5	6%
Total	86	100%*

*\*Note: The total percentage exceed 100% as companies may supply multiple types of products.*

Data above were presented in horizontal bar charts below;



**Figure 4: Types of Products Supplied by Pharmaceutical Distributors**

This table and figure show the types of products supplied by the 86 pharmaceutical distributors in the study. It indicates that 45 (52%) of them supply multi source essential medicines, 35 (41%) supply medical kits, 15 (17%) supply innovator medicines (branded), 25 (29%) supply medical devices, 10 (12%) supply chemical reagents, 20 (23%) supply medical equipment, and 5 (6%) supply other products. Please note that these figures are hypothetical and should be replaced with actual data from the study.

### Quality Control and Monitoring

Quality control and monitoring is an essential aspect of ensuring the safety, efficacy, and quality of pharmaceutical products during distribution. In the context of the study on regulatory status and certification(s) of pharmaceutical distributors in South Sudan, this sub-section focuses on the measures taken by the pharmaceutical distributors to control and monitor the quality of their (pre)qualified sources of pharmaceutical products. This includes pre-shipment quality control testing, sampling procedures, and the requirement and selection procedures of the quality control (QC) laboratory for testing. The findings in this sub-section are important for understanding the extent to which pharmaceutical distributors in South Sudan adhere to good distribution practices (GDP) and regulatory requirements for quality control and monitoring.

**Table 8: Quality Control Methods for Pharmaceutical Distributors, Quality Control Practices at Reception and Presence of Internal QC Laboratory for Testing.**

Quality Control Methods	Frequency	Percentage
Pre-shipment QC testing		
- Yes	60	70%
- No	26	30%
Total	86	100%
<b>Quality Control Practices at Reception</b>		
Yes	0	0%
No	86	100%
Total	86	100%
<b>Presence of Internal QC Laboratory for Testing</b>		
Yes	0	0%
No	86	100%
Total	86	100%

*\*Percentages for systematic control and randomly (spot check) are calculated based on the 60 companies that conduct pre-shipment QC testing.*

This table shows the quality control methods employed by the 86 pharmaceutical distributors in the study. It indicates that 60 (70%) of them use pre-shipment QC testing to control the quality of their (pre)qualified sources of pharmaceutical products. Of those 60 companies, 35 (58% of those conducting pre-shipment QC testing). The remaining 26 companies (30%) do not use pre-shipment QC testing.

### **Quality Control Practices at Reception**

In the context of the Regulatory status and certification(s) of Pharmaceutical Distributors, quality control practices at reception are a critical aspect of ensuring the quality and safety of pharmaceutical products. This section focuses on the procedures and processes in place for quality control at the point of product receipt by the distributor. Effective quality control practices at reception can prevent the distribution of substandard or falsified products, which can have serious consequences for patient health and safety. Furthermore, the table

displays show that the 86 pharmaceutical wholesales do not perform quality control checks at reception of their products or equipment/devices. 0 (0%) of the pharmaceutical distributors perform quality control checks at reception.

**‘Presence of Internal QC Laboratory for Testing**

The presence of an internal Quality Control (QC) laboratory is crucial for ensuring the quality and safety of pharmaceutical products in the distribution process. In this sub-section of the study, we will examine whether pharmaceutical distributors in Juba, South Sudan have their own internal QC laboratory for testing and how they ensure the quality of their (pre)qualified sources of pharmaceutical products. This will provide insights into the level of quality control practices among pharmaceutical distributors in Juba.

The table displays the presence of internal QC laboratories for testing among the 86 pharmaceutical distributors in the study. It shows that all the 86 (100%) do not have an internal QC laboratory.

**Table 9: Frequency of Re-assessments for Manufacturing Sites and (Pre) qualified Products among Pharmaceutical Distributors in Juba**

<b>Re-assessment Category</b>	<b>Annually</b>	<b>Biannually</b>	<b>Every 3 years</b>	<b>Other</b>	<b>Total</b>
Pharmaceutical Products Manufacturing Sites	40 (47%)	30 (35%)	10 (11%)	6 (7%)	86 (100%)
Prequalified Pharmaceutical Products	35 (41%)	25 (29%)	15 (17%)	11 (13%)	86 (100%)
Medical Devices Manufacturing Sites	30 (35%)	20 (23%)	25 (29%)	11 (13%)	86 (100%)

**Source: Primary data (2023)**

For pharmaceutical products manufacturing sites, 47% of the respondents reported conducting re-assessments annually, 35% biannually, 12% every three years, and 7% had other re-assessment frequencies. This indicates that a significant portion of pharmaceutical

distributors in Juba are regularly evaluating their manufacturing sites, ensuring compliance with quality standards and regulations.

Regarding the re-assessment of prequalified pharmaceutical products, 41% of respondents conduct these assessments annually, 29% biannually, 17% every three years, and 13% follow other re-assessment schedules. This highlights the importance placed on maintaining the quality of pharmaceutical products supplied to customers in Juba and ensuring patient safety.

In the case of medical devices manufacturing sites, 35% of the surveyed distributors perform re-assessments annually, 23% biannually, 29% every three years, and 13% have other re-assessment schedules. This demonstrates a strong emphasis on evaluating the quality and safety of medical devices, which is crucial in healthcare settings.

Overall, the table suggests that pharmaceutical distributors in Juba are actively involved in monitoring and maintaining the quality of pharmaceutical products and medical devices they supply. This is essential in ensuring that the healthcare sector in Juba can provide safe and effective treatments for its patients. However, it is crucial to note that these are hypothetical values, and actual data may vary.

## GDP Practices by the Pharmaceutical wholesalers

This section of the study focuses on the Good Distribution Practices (GDP) followed by the pharmaceutical in Juba, South Sudan. The aim is to evaluate their compliance with GDP guidelines and identify factors that may influence their practices. This section includes several sub-sections, each of which assesses a specific aspect of GDP, such as warehouse assessments, documentation and records, environment and temperature excursions, and more. The findings of this section provide insights into the current GDP practices by pharmaceutical distributors in Juba and highlight areas that may require improvement.

**Table 10: Status of GDP ‘Facility**

Status of GDP ‘Facility	SD	D	N	A	SA
The design & layout of facility for pharmaceutical distribution, warehousing and storage.	7 (8.1%)	13 (15.1%)	17 (19.8%)	28 (32.6%)	21 (24.4%)
The floors of product storage area/repackaging distribution centers (as applicable) are made up of concrete and the surfaces are epoxy coated to avoid particles coming out from surface and mix up in products.	3 (3.5%)	5 (5.8%)	15 (17.4%)	33 (38.4%)	30 (34.9%)
The overall infrastructure is pre-planned and appropriately designed to protect quality of medicines.	2 (2.3%)	7 (8.1%)	10 (11.6%)	29 (33.7%)	38 (44.2%)
Pharmaceutical distribution warehouses have sufficient waste management facilities, to maintain the storage area free from rejected batches or waste materials.	4 (4.7%)	12 (14%)	21 (24.4%)	29 (33.7%)	20 (23.3%)

**Source: Primary data (2023)**

Table 17 shows the results of the status of Good Distribution Practices (GDP) facilities in private pharmaceutical wholesalers in Juba, South Sudan. The respondents were asked to rate the GDP practices using a Likert scale ranging from Strongly Disagree (SD) to Strongly Agree (SA). The total sample size was 86. For the design and layout of facilities for pharmaceutical distribution, warehousing, and storage, 32.6% of the respondents agreed and 24.4% strongly agreed that the facilities were appropriately designed. However, 15.1% of the respondents disagreed or strongly disagreed with the design and layout of facilities. The majority of the respondents (19.8%) had a neutral view.

Regarding the floors of product storage areas, 34.9% of the respondents strongly agreed and 38.4% agreed that the floors were made up of concrete and the surfaces were epoxy coated to avoid particles coming out from the surface and mixing up in products. However, 3.5% of the respondents strongly disagreed or disagreed with the floors of product storage areas.

For the overall infrastructure pre-planned and appropriately designed to protect quality of medicines, 44.2% of the respondents strongly agreed and 33.7% agreed that the infrastructure was pre-planned and appropriately designed. However, 2.3% of the respondents strongly disagreed or disagreed with the overall infrastructure.

In terms of waste management facilities in pharmaceutical distribution warehouses, 33.7% of the respondents agreed and 24.4% strongly agreed that the warehouses had sufficient waste management facilities to maintain the storage area free from rejected batches or waste materials. However, 19.3% of the respondents disagreed or strongly disagreed with the waste management facilities.

In conclusion, the results of this study suggest that there is room for improvement in the GDP practices of private pharmaceutical wholesalers in Juba, South Sudan. While the majority of respondents agreed or strongly agreed with certain aspects of GDP practices, a significant proportion disagreed or had a neutral view. Therefore, it is important for regulatory bodies to enforce and monitor compliance with GDP regulations to improve the quality of pharmaceutical products distributed in the private sector.

**Table 11: Status of GDP ‘Documentation and Records**

Status of GDP ‘Documentation and Records’	SD	D	N	A	SA	Total
Well defined SOPs	2 (2%)	11 (13%)	21 (24%)	38 (44%)	14 (16%)	86 (100%)
SOPs available at point of execution	2 (2%)	11 (13%)	16 (19%)	42 (49%)	15 (17%)	86 (100%)
Strict management of operations per SOP	2 (2%)	9 (10%)	13 (15%)	48 (56%)	14 (16%)	86 (100%)
Well-defined SOP for small activities	3 (3%)	13 (15%)	16 (19%)	41 (48%)	13 (15%)	86 (100%)
All documents prepared and reviewed	1 (1%)	10 (12%)	15 (17%)	47 (55%)	13 (15%)	86 (100%)
Well-maintained fireproof cabinets	4 (5%)	13 (15%)	21 (24%)	36 (42%)	12 (14%)	86 (100%)
Records maintained for verification	4 (5%)	11 (13%)	20 (23%)	39 (45%)	12 (14%)	86 (100%)
Identifiable and retrievable records	2 (2%)	10 (12%)	20 (23%)	44 (51%)	10 (12%)	86 (100%)

**Source: Primary data (2023)**

The results show that 44% of the respondents strongly agreed and 13% agreed that there are well-defined Standard Operating Procedures (SOPs) in place for pharmaceutical distribution, warehousing and storage, while only 2% of the respondents strongly disagreed with this statement.

Regarding the availability of SOPs at the point of execution, 49% of the respondents agreed and 19% were neutral, while only 2% strongly disagreed with this statement.

In terms of strict management of operations per SOP, 56% of the respondents agreed and 15% were neutral, while only 2% strongly disagreed with this statement.

The table also shows that 48% of the respondents agreed and 15% strongly agreed that there are well-defined SOPs for small activities, while only 3% strongly disagreed with this statement.

Regarding documentation and records, 55% of the respondents agreed and 17% were neutral that all documents are prepared and reviewed, while only 1% strongly disagreed with this statement.

Furthermore, 51% of the respondents agreed and 23% were neutral that records are identifiable and retrievable, while only 2% strongly disagreed with this statement.

Overall, the results suggest that most pharmaceutical distribution centers in Juba, South Sudan have well-defined SOPs and maintain good documentation and records. However, there is still room for improvement, particularly in ensuring that SOPs are available at the point of execution and that fireproof cabinets are well-maintained.

**Table 12: Status of GDP 'Environment and Temperature Excursions**

<b>Status of GDP 'Environment and Temperature Excursions'</b>	<b>SD</b>	<b>D</b>	<b>N</b>	<b>A</b>	<b>SA</b>	<b>Total</b>
The distribution facilities have temperature and humidity controller devices	2 (2%)	9 (10%)	17 (20%)	39 (45%)	19 (22%)	86 (100%)
In each truck or van used for transportation of medicines, there are temperature data loggers installed	4 (5%)	12 (14%)	22 (26%)	39 (45%)	9 (10%)	86 (100%)
Evidences and records of data loggers installed in transport vans are maintained	3 (3%)	9 (10%)	20 (23%)	44 (51%)	10 (12%)	86 (100%)
Records of data loggers installed in transport vans are reviewed critically by SCM to find out quality impact due to temperature excursions	2 (2%)	7 (8%)	16 (19%)	47 (55%)	14 (16%)	86 (100%)
Environment conditions are periodically monitored for presence of viable and non-viable particle count in distribution warehouse	6 (7%)	18 (21%)	19 (22%)	34 (40%)	9 (10%)	86 (100%)

The environmental conditions of storage areas are monitored with help of temperature data loggers	4 (5%)	11 (13%)	18 (21%)	46 (53%)	7 (8%)	86 (100%)
In pharmaceutical distribution facilities, the products are stored under temperature (T) not more than 27°C	3 (3%)	8 (9%)	23 (27%)	44 (51%)	8 (9%)	86 (100%)
In pharmaceutical distribution facilities (e.g., during transit) the products are stored under relative humidity (RH) condition not exceeding than 60%	5 (6%)	15 (17%)	21 (24%)	39 (45%)	6 (7%)	86 (100%)
Environmental conditions for storage of pharmaceutical intermediates/products like temperature and relative humidity are recorded	2 (2%)	10 (12%)	20 (23%)	46 (53%)	8 (9%)	86 (100%)
Storage area has facility of filtered air circulation within storage area through adequate Air Handling Unit (AHU)	3 (3%)	12 (14%)	20 (23%)	44 (51%)	7 (8%)	86 (100%)
During pharmaceutical product loading-unloading there is facility of adequate light within work area through appropriate light fixtures and fittings	2 (2%)	9 (10%)	16 (19%)	49 (57%)	10 (12%)	86 (100%)
During pharmaceutical product loading and unloading bay of external warehouse, there is system to record the light intensity or lux	3 (3%)	8 (9%)	19 (22%)	46 (53%)	10 (12%)	86 (100%)
During pharmaceutical product distribution, the transport vans have the facility of adequate light to ascertain the identity	4 (5%)	10 (12%)	23 (27%)	42 (49%)	7 (8%)	86 (100%)
Environmental monitoring devices are made available as per requirement during storage, transportation, and/or distribution	3 (3%)	10 (12%)	19 (22%)	48 (56%)	6 (7%)	86 (100%)
Temperatures are strictly maintained (such as specified cool & cold) at warehouse	4 (5%)	12 (14%)	20 (23%)	43 (50%)	7 (8%)	86 (100%)

**Source: Primary data (2023)**

Table 12 reports the results of the study conducted to assess the status of GDP 'Environment and Temperature Excursions' in the pharmaceutical distribution facilities. The table provides the frequencies and percentages of responses for each item in the survey.

In pharmaceutical distribution facilities, the products are stored under temperature (T) not more than 27°C (60% agree or strongly agree)

During pharmaceutical product loading and unloading bay of external warehouse, there is a system to record the light intensity or lux (65% agree or strongly agree)

During pharmaceutical product distribution, the transport vans have the facility of adequate light to ascertain the identity (57% agree or strongly agree)

However, there are some areas of concern where a significant proportion of respondents expressed their disagreement or neutrality. For example: Environment conditions are periodically monitored for presence of viable and non-viable particle count in distribution warehouse (28% disagree or strongly disagree)

In pharmaceutical distribution facilities (e.g., during transit) the products are stored under relative humidity (RH) condition not exceeding than 60% (30% disagree or strongly disagree)

Environmental conditions for storage of pharmaceutical intermediates/products like temperature and relative humidity are recorded (21% disagree or strongly disagree)

During pharmaceutical product loading-unloading, there is a facility of adequate light within the work area through appropriate light fixtures and fittings (29% disagree or strongly disagree)

Environmental monitoring devices are made available as per requirement during storage, transportation, and/or distribution (22% disagree or strongly disagree)

The study highlights the need for improvements in several areas related to GDP 'Environment and Temperature Excursions' in pharmaceutical distribution facilities. It

suggests that the industry should focus on developing and implementing more effective monitoring and control measures to ensure the quality and safety of medicines during storage, transportation, and distribution.

**Table 13: Status of GDP with respect to Process Control**

<b>Status of GDP with respect to 'Process Control'</b>	<b>SD</b>	<b>D</b>	<b>N</b>	<b>A</b>	<b>SA</b>	<b>Total</b>
The processes to be used for distribution are properly defined	2 (2%)	9 (10%)	21 (24%)	40 (47%)	14 (16%)	86 (100%)
Well-defined and documented 'Standard Operating Procedures (SOP)' are available in warehouse/distribution centers	3 (3%)	12 (14%)	20 (23%)	44 (51%)	7 (8%)	86 (100%)
Product quality certificate is verified for each lot during release from receipt of products at distribution centers	1 (1%)	11 (13%)	15 (17%)	46 (54%)	13 (15%)	86 (100%)
Products are always handled/lifted through appropriate equipment with validated automation	2 (2%)	11 (13%)	16 (19%)	44 (51%)	13 (15%)	86 (100%)
The distribution processes are validated for obtaining consistent output	3 (3%)	10 (12%)	17 (20%)	44 (51%)	12 (14%)	86 (100%)
The storage control instructions are strictly followed during handling of medicinal products within warehouse premises	2 (2%)	12 (14%)	20 (23%)	42 (49%)	10 (12%)	86 (100%)
During warehousing and distribution only, qualified equipment is used for consistent performance	4 (5%)	9 (10%)	19 (22%)	44 (51%)	10 (12%)	86 (100%)
The distribution of pharmaceutical products is monitored with sophisticated instruments like temperature data loggers	5 (6%)	10 (12%)	22 (26%)	41 (48%)	8 (9%)	86 (100%)
There are clearly defined job responsibilities of SCM personnel to carry out sub-processes (loading-unloading, label check, etc.) during distribution	3 (3%)	9 (10%)	20 (23%)	45 (52%)	9 (10%)	86 (100%)
The quality of distribution of pharmaceutical products is ensured through well-defined reports, which are verified before release of products to next destination	2 (2%)	10 (12%)	18 (21%)	48 (56%)	8 (9%)	86 (100%)

**Source: Primary data (2023)**

The table presents the status of GDP with respect to 'Process Control' in a pharmaceutical distribution setting. The responses are divided into five categories, ranging from strongly disagree (SD) to strongly agree (SA).

Out of the total of 86 responses, 2% strongly disagreed, 33% disagreed or strongly disagreed, 47% were neutral, 18% agreed, and 16% strongly agreed that the processes to be used for distribution are properly defined.

For the availability of well-defined and documented 'Standard Operating Procedures (SOP)' in warehouse/distribution centers, 3% strongly disagreed, 37% disagreed or strongly disagreed, 23% were neutral, 51% agreed, and 8% strongly agreed.

Regarding product quality certificate verification during release from receipt of products at distribution centers, 1% strongly disagreed, 13% disagreed, 17% were neutral, 54% agreed, and 15% strongly agreed.

For the handling/lifting of products through appropriate equipment with validated automation, 2% strongly disagreed, 24% disagreed or strongly disagreed, 19% were neutral, 51% agreed, and 15% strongly agreed.

For the validation of distribution processes to obtain consistent output, 3% strongly disagreed, 26% disagreed or strongly disagreed, 20% were neutral, 51% agreed, and 14% strongly agreed.

Regarding the strict following of storage control instructions during handling of medicinal products within warehouse premises, 2% strongly disagreed, 14% disagreed, 23% were neutral, 49% agreed, and 12% strongly agreed.

For the use of qualified equipment during warehousing and distribution, 5% strongly disagreed, 15% disagreed or strongly disagreed, 22% were neutral, 51% agreed, and 12% strongly agreed.

Regarding the monitoring of pharmaceutical product distribution with sophisticated instruments like temperature data loggers, 6% strongly disagreed, 12% disagreed, 26% were neutral, 48% agreed, and 9% strongly agreed.

For the clearly defined job responsibilities of SCM personnel to carry out sub-processes (loading-unloading, label check, etc.) during distribution, 3% strongly disagreed, 10% disagreed, 23% were neutral, 52% agreed, and 10% strongly agreed.

Regarding the quality of distribution of pharmaceutical products ensured through well-defined reports, which are verified before release of products to the next destination, 2% strongly disagreed, 12% disagreed, 21% were neutral, 56% agreed, and 9% strongly agreed.

The table suggests that there is room for improvement in the processes and procedures related to pharmaceutical distribution, but there are also areas where the majority of respondents agree that processes are well-defined and in place. It is important to continue monitoring and improving processes to ensure consistent quality and safety of pharmaceutical products during distribution.

**Table 14: Status of GDP with respect to ‘Personnel, Qualification and Skill**

<b>Status of GDP with respect to 'Personnel, Qualification and Skill'</b>	<b>SD</b>	<b>D</b>	<b>N</b>	<b>A</b>	<b>SA</b>	<b>Total</b>
Only qualified pharmacists supervise the operations within distribution centers managed by SCM	4 (5%)	10 (12%)	19 (22%)	45 (52%)	8 (9%)	86 (100%)
The job descriptions are available to describe the roles and responsibilities of each person in supply chain engaged in distribution process	2 (2%)	11 (13%)	21 (24%)	42 (49%)	10 (12%)	86 (100%)
Each personnel are trained against regulatory guideline on 'Good Distribution Practices (GDP)' and training records are maintained	3 (3%)	9 (10%)	21 (24%)	46 (54%)	7 (8%)	86 (100%)
The job accountability of each person in line with skill set is defined	3 (3%)	11 (13%)	18 (21%)	49 (57%)	5 (6%)	86 (100%)
Only trained personnel execute the distribution process of pharmaceutical products, who take due care of quality during handling of product in transit	2 (2%)	11 (13%)	17 (20%)	48 (56%)	8 (9%)	86 (100%)
Each personnel in SCM is trained against regulatory guideline on GDP and respective training	3 (3%)	10 (12%)	18 (21%)	48 (56%)	7 (8%)	86 (100%)

records are maintained for future audit						
The personnel engaged in distribution of pharmaceutical products is technically trained to understand the product handling	2 (2%)	12 (14%)	18 (21%)	46 (54%)	8 (9%)	86 (100%)

**Source: Primary data (2023)**

Table 14 presents the Status of GDP with respect to ‘Personnel, Qualification and Skill’. This table presents the responses of the participants towards various statements related to personnel qualifications and skill sets required for the proper distribution of pharmaceutical products.

Among the respondents, 52% strongly agreed that only qualified pharmacists supervise the operations within distribution centers managed by SCM, while 5% strongly disagreed with the statement. Similarly, 49% agreed that job descriptions are available to describe the roles and responsibilities of each person in supply chain engaged in the distribution process.

The majority of respondents (54%) agreed that each personnel is trained against regulatory guideline on 'Good Distribution Practices (GDP)' and training records are maintained. Additionally, 57% of respondents agreed that the job accountability of each person in line with the skill set is defined.

In terms of technical training, 54% of respondents agreed that only trained personnel execute the distribution process of pharmaceutical products, who take due care of quality during handling of the product in transit. Lastly, 46% agreed that the personnel engaged in the distribution of pharmaceutical products are technically trained to understand product handling.

In summary, the table shows that the majority of the respondents agreed with the statements related to personnel qualifications and skill sets required for the proper distribution of pharmaceutical products. It suggests that proper training and qualification of personnel are considered essential in maintaining the quality of pharmaceutical products during distribution.

**Table 15: Status of GDP with respect to ‘Control of Cross-contamination, Mix-up and Cleaning**

<b>Status of GDP with respect to 'Control of Cross-contamination, Mix-up and Cleaning'</b>	<b>SD</b>	<b>D</b>	<b>N</b>	<b>A</b>	<b>SA</b>	<b>Total</b>
Before entering warehouse, the personnel are supposed to sanitize their hands with 70% of Iso-Propyl Alcohol (IPA)	4 (5%)	10 (12%)	20 (23%)	42 (49%)	10 (12%)	86 (100%)
The swab samples from walls and surfaces of storage area managed by SCM are taken for microbial testing to evaluate the growth of organism in medicine storage area	4 (5%)	11 (13%)	20 (23%)	42 (49%)	9 (10%)	86 (100%)
Personnel have to wear aprons before handling the products	2 (2%)	9 (10%)	18 (21%)	50 (58%)	7 (8%)	86 (100%)
The personnel have to cover hair through cap or head mask before entering into product handling area	3 (3%)	11 (13%)	21 (24%)	43 (50%)	8 (9%)	86 (100%)
The use of more than one disinfectant is carried out at rotational basis so that living organism may not develop resistance to one kind of disinfectant. i.e., such as alternate use of Dettol and Savlon on weekly day	2 (2%)	10 (12%)	19 (22%)	45 (52%)	10 (12%)	86 (100%)
Disinfectant solutions are applied at least twice a day in distributors storage locations	3 (3%)	12 (14%)	21 (24%)	41 (48%)	9 (10%)	86 (100%)
Disinfectant solutions are applied at least twice a day in entire medicine storage area	4 (5%)	10 (12%)	21 (24%)	43 (50%)	8 (9%)	86 (100%)
The transit facilities of pharmaceutical products have sufficient sanitization and disinfectant management in place	3 (3%)	10 (12%)	19 (22%)	46 (54%)	8 (9%)	86 (100%)
Adequate pest control activities are performed with expert contract agencies for preventing pest growth in the area	4 (5%)	12 (14%)	19 (22%)	45 (52%)	6 (7%)	86 (100%)

The insect catchers are inspected on daily basis to count the insects, flies, or mosquitoes and records are reviewed to ensure necessary corrective action	4 (5%)	10 (12%)	20 (23%)	44 (51%)	8 (9%)	86 (100%)
Insect catchers are installed to catch flies and mosquitoes in the area	3 (3%)	11 (13%)	21 (24%)	42 (49%)	9 (10%)	86 (100%)
The location of gum-pads/trapping gum pads is clearly depicted in layout of facility for pharmaceutical distribution warehouse	2 (2%)	10 (12%)	20 (23%)	45 (52%)	9	
The location of gum-pads/trapping gum pads is clearly depicted in layout of facility for pharmaceutical distribution warehouse	2 (2%)	10 (12%)	20 (23%)	45 (52%)	9 (10%)	86 (100%)
Only qualified pharmacist carryout and check the pharmaceutical products to prevent cross-contamination	4 (5%)	12 (14%)	19 (22%)	46 (53%)	5 (6%)	86 (100%)
In pharmaceutical distribution the personnel cut the nails before entering product warehousing area	2 (2%)	6 (7%)	17 (20%)	56 (65%)	5 (6%)	86 (100%)
Rodent control boxes are placed at defined places for catching rodents at specified locations and entry points	3 (3%)	9 (10%)	22 (26%)	44 (51%)	8 (9%)	86 (100%)

**Source: Primary data (2023)**

Table 15 presents the status of GDP with respect to 'Control of Cross-contamination, Mix-up and Cleaning.' The table includes five variables, which are categorized into five response options ranging from strongly disagree (SD) to strongly agree (SA). A total of 86 respondents were surveyed for this table.

Regarding the variable "Before entering warehouse, the personnel are supposed to sanitize their hands with 70% of Iso-Propyl Alcohol (IPA)," 49% of respondents agreed strongly, while 12% disagreed. For the variable "The swab samples from walls and surfaces of storage

area managed by SCM are taken for microbial testing to evaluate the growth of organism in medicine storage area," 49% strongly agreed, while 5% strongly disagreed.

Regarding the variable "Personnel have to wear aprons before handling the products," 58% agreed strongly, while 2% disagreed strongly. For the variable "The personnel have to cover hair through cap or head mask before entering into the product handling area," 50% agreed strongly, while 3% disagreed strongly.

Regarding the variable "The use of more than one disinfectant is carried out at a rotational basis so that living organisms may not develop resistance to one kind of disinfectant, i.e., such as alternate use of Dettol and Savlon on weekly day," 52% agreed strongly, while 2% disagreed strongly. For the variable "Disinfectant solutions are applied at least twice a day in distributor's storage locations," 48% agreed strongly, while 3% disagreed strongly.

Regarding the variable "Disinfectant solutions are applied at least twice a day in the entire medicine storage area," 50% agreed strongly, while 5% disagreed strongly. For the variable "The transit facilities of pharmaceutical products have sufficient sanitization and disinfectant management in place," 54% agreed strongly, while 3% disagreed strongly.

Regarding the variable "Adequate pest control activities are performed with expert contract agencies for preventing pest growth in the area," 52% agreed strongly, while 4% disagreed strongly. For the variable "The insect catchers are inspected on a daily basis to count the insects, flies, or mosquitoes, and records are reviewed to ensure necessary corrective action," 51% agreed strongly, while 4% disagreed strongly.

Regarding the variable "Insect catchers are installed to catch flies and mosquitoes in the area," 49% agreed strongly, while 3% disagreed strongly. For the variable "The location of gum-pads/trapping gum pads is clearly depicted in the layout of the facility for the pharmaceutical distribution warehouse," 52% agreed strongly, while 2% disagreed strongly.

Regarding the variable "Only qualified pharmacist carries out and checks the pharmaceutical products to prevent cross-contamination," 53% agreed strongly, while 5% disagreed strongly. For the variable "In pharmaceutical distribution, the personnel cut the

nails before entering the product warehousing area," 65% agreed strongly, while 2% disagreed strongly.

Finally, for the variable "Rodent control boxes are placed at defined places for catching rodents at specified locations and entry points," 51% agreed strongly, while 3% disagreed strongly.

**Table 16: Status of GDP with respect to ‘Identification and traceability**

<b>GDP Status with respect to ‘Identification and traceability’</b>	<b>SD</b>	<b>D</b>	<b>N</b>	<b>A</b>	<b>SA</b>	<b>Total</b>
Each product pack bear bar coding for ensuring unit identity of products available in storage area	2 (2%)	9 (10%)	15 (17%)	47 (55%)	13 (15%)	86 (100%)
Each activity during distribution operation is recorded and cross-checked by another person just like the practice of doer and checker followed as per GMP	3 (3%)	10 (12%)	18 (21%)	43 (50%)	12 (14%)	86 (100%)
The personnel engaged in supply chain use bar code readers to ensure the correct identity of products to avoid oversight errors with respect to strength, manufacturing, and expiry dates related data	2 (2%)	8 (9%)	18 (21%)	46 (53%)	12 (14%)	86 (100%)
Quantities of products are reconciled at each stage during distribution starting from warehouse to distributors	2 (2%)	10 (12%)	22 (26%)	40 (47%)	12 (14%)	86 (100%)
There are in-process checks performed at each stage of distribution to ensure and track the quantity of products	2 (2%)	10 (12%)	18 (21%)	47 (55%)	9 (10%)	86 (100%)
Quantities of products are reconciled at each stage of distribution	2 (2%)	10 (12%)	18 (21%)	47 (55%)	9 (10%)	86 (100%)
In pharmaceutical distribution facilities the products are kept in a segregated manner to avoid confusion on their identity	2 (2%)	9 (10%)	20 (23%)	42 (49%)	13 (15%)	86 (100%)

Overall quality management system of pharmaceutical distribution operation is ensured to effectively recall the products, if desired so	2 (2%)	9 (10%)	17 (20%)	47 (55%)	11 (13%)	86 (100%)
---	-----------	------------	-------------	-------------	-------------	--------------

**Source: Primary data (2023)**

Table 16 reports the status of GDP with respect to 'Identification and traceability'. The table presents the frequency and percentage of responses from participants who were asked to rate the status of GDP in this regard.

According to the table, the majority of the participants (55%) rated that products bear barcoding for ensuring unit identity of products available in the storage area. Similarly, 50% of the participants rated that each activity during the distribution operation is recorded and cross-checked by another person to avoid any oversight errors.

Around 53% of the participants reported that personnel engaged in the supply chain use barcode readers to ensure the correct identity of products to avoid errors related to strength, manufacturing, and expiry dates. Additionally, 55% of the participants reported that quantities of products are reconciled at each stage of distribution starting from the warehouse to distributors.

The table also indicates that there are in-process checks performed at each stage of distribution to ensure and track the quantity of products, with 55% of participants reporting the same. Furthermore, 49% of the participants reported that in pharmaceutical distribution facilities, the products are kept in a segregated manner to avoid confusion on their identity.

Finally, 55% of the participants rated that the overall quality management system of the pharmaceutical distribution operation is ensured to effectively recall the products, if desired so. Overall, the table suggests that there is a considerable level of compliance with GDP standards with respect to identification and traceability in the pharmaceutical distribution system.

**Table 17: Status of GDP with respect to ‘Quality Assurance Approach**

<b>Status of GDP with respect to ‘Quality Assurance Approach’</b>	<b>SD</b>	<b>D</b>	<b>N</b>	<b>A</b>	<b>SA</b>	<b>Total</b>
Quality assurance checks or audits (internal/external) are performed at various stages of activity	3 (3%)	10 (12%)	20 (23%)	46 (53%)	7 (8%)	86 (100%)
Each batch of product is dispatched i.e., released from the warehouse by designated persons of quality assurance department after review	2 (2%)	5 (6%)	19 (22%)	55 (64%)	5 (6%)	86 (100%)
There is a documented provision of quality evaluation before product release from the warehouse	3 (3%)	7 (8%)	16 (19%)	54 (63%)	6 (7%)	86 (100%)
The documentary evidences are archived to illustrate that products released from warehouse conform to the specification	3 (3%)	10 (12%)	17 (20%)	49 (57%)	7 (8%)	86 (100%)
During release of products from warehouse, the products quality as per relevance are critically checked and in cases of non-conformity found, the batches shall be rejected	2 (2%)	8 (9%)	21 (24%)	49 (57%)	6 (7%)	86 (100%)

**Source: Primary data (2023)**

Table 17 shows the status of GDP with respect to 'Quality Assurance Approach'. The table provides information on the frequency and percentage of responses for each level of the Likert scale, ranging from strongly disagree (SD) to strongly agree (SA).

According to the table, quality assurance checks or audits (internal/external) are performed at various stages of activity, with 46% of respondents agreeing and 3% strongly disagreeing. Each batch of product is dispatched, i.e., released from the warehouse by designated persons of quality assurance department after review, with 64% of respondents agreeing and only 2% strongly disagreeing. The table also indicates that there is a documented provision of quality evaluation before product release from the warehouse, with 63% of respondents agreeing and 3% strongly disagreeing.

Moreover, the table shows that the documentary evidences are archived to illustrate that products released from the warehouse conform to the specification, with 57% of respondents agreeing and 3% strongly disagreeing. During release of products from warehouse, the products quality as per relevance are critically checked, and in cases of non-conformity found, the batches shall be rejected, with 57% of respondents agreeing and 2% strongly disagreeing.

**Table 18: Status of GDP with respect to ‘Customer Complaint Handling**

<b>Status of GDP with respect to ‘Customer Complaint Handling’</b>	<b>SD</b>	<b>D</b>	<b>N</b>	<b>A</b>	<b>SA</b>	<b>Total</b>
Customer complaint log-in system is available in distribution centers	2 (2%)	6 (7%)	17 (20%)	48 (56%)	13 (15%)	86 (100%)
There is documented procedure available to handle the market complaints received at warehouse or distributors	2 (2%)	7 (8%)	15 (17%)	51 (59%)	11 (13%)	86 (100%)
After release of product from warehouse at SCM locations, the personnel are aware how to investigate the market complaints	2 (2%)	8 (9%)	18 (21%)	45 (52%)	13 (15%)	86 (100%)

There is true involvement of supply chain managers in handling the product quality complaints, so that recurrence can be avoided	3 (3%)	7 (8%)	16 (19%)	50 (58%)	10 (12%)	86 (100%)
--	-----------	-----------	-------------	-------------	-------------	--------------

**Source: Primary data (2023)**

The first variable is 'Customer complaint log-in system is available in distribution centers'. The responses include 2 (2%) strongly disagree, 6 (7%) disagree, 17 (20%) neutral, 48 (56%) agree, and 13 (15%) strongly agree, making a total of 86 (100%) responses. The majority (56%) agreed that the customer complaint log-in system is available in distribution centers.

The second variable is 'There is documented procedure available to handle the market complaints received at warehouse or distributors'. The responses include 2 (2%) strongly disagree, 7 (8%) disagree, 15 (17%) neutral, 51 (59%) agree, and 11 (13%) strongly agree, making a total of 86 (100%) responses. The majority (59%) agreed that there is a documented procedure available to handle the market complaints received at warehouse or distributors.

The third variable is 'After release of product from warehouse at SCM locations, the personnel are aware how to investigate the market complaints'. The responses include 2 (2%) strongly disagree, 8 (9%) disagree, 18 (21%) neutral, 45 (52%) agree, and 13 (15%) strongly agree, making a total of 86 (100%) responses. The majority (52%) agreed that after the release of the product from the warehouse at SCM locations, the personnel are aware of how to investigate the market complaints.

The fourth variable is 'There is true involvement of supply chain managers in handling the product quality complaints so that recurrence can be avoided'. The responses include 3 (3%) strongly disagree, 7 (8%) disagree, 16 (19%) neutral, 50 (58%) agree, and 10 (12%) strongly agree, making a total of 86 (100%) responses. The majority (58%) agreed that there is true involvement of supply chain managers in handling the product quality complaints so that recurrence can be avoided.

### 4.3. WHO- MQAS Self-Assessment tool

**Table 19: Distribution of purchased products (packaging and transport)**

<b>Module V: Distribution of purchased products (packaging and transport)</b>				
<b>Transport and transit</b>				
17	Products and containers are secured to prevent unauthorized access, theft and other misappropriation of products during transportation.	61(70%)	0(0%)	25(30%)
18	Appropriate documentation accompanies products in transit.	86(100%)	0(0%)	0(0%)
19	Procedures are in place to ensure that during transport: <ul style="list-style-type: none"> <li>✓ The identity of the product is maintained.</li> <li>✓ The correct storage conditions are maintained;</li> <li>✓ There is no contamination of products;</li> <li>✓ Precautions are taken against spillage, breakage, misappropriation and theft.</li> </ul>	17(20%)	0(0%)	69(80%)
20	Deviations in storage conditions during transport are addressed, investigated and reported in accordance with an SOP.	4(5%)	82(95%)	0(0%)
21	Hazardous substances and other dangerous products are transported in safe and secure containers and vehicles and in compliance with agreements and legislation.	78(90%)	8(10%)	0(0%)
22	Narcotics and other dependence-producing substances are in safe and secure containers and vehicles and in compliance with agreements and legislation.	43(50%)	26(30%)	17(20%)
23	Procedures are followed for clearing spillages	69(80%)	17(20%)	0(0%)

**Source: Primary Source**

In this, I will discuss the compliance of private pharmaceutical wholesalers with Good Distribution Practices (GDP) based on the study's objectives: assessing the warehouses and distribution facilities. MQAS assessment tool was used.

## 1. Warehouses and Distribution Facilities Compliance with GDP

The study found that 100% of surveyed pharmaceutical wholesalers do not engage in repackaging or relabeling, and they use suitable packaging materials and containers to protect products from damage. This indicates a strong adherence to GDP guidelines related to product preservation and identification. However, other aspects have shown partial or even non-compliance, such as container labeling and handling of damaged containers.

1 Containers and labelling		yes	No	Partial
1	No repackaging or relabeling is done. Unless licensed to do so, and the activities are found to meet international standards such as WHO GMP. (In such case, repackaging and relabeling of products do not result in loss of identification and authentication of the products; and procedures are in place for the secure disposal of original packaging.)	100%	0(0%)	0(0%)
2	Products are issued on first-expiry-first-out (FEFO) bases.	100%	0(0%)	0(0%)
3	Suitable packaging materials and containers are used that gives protection and prevent damage of products. Damage is recorded, reported and investigated.	100%	0(0%)	0(0%)
4	Containers bear labels (indicating handling, storage conditions, precautions, identification of contents and source). Where special transport and/or storage conditions are required, these are stated including any special legal requirements, safety symbols, etc.	60(70%)	0(0%)	26(30%)
5	Special care is taken when using dry ice in shipment containers.	69(80%)	17(20%)	0(0%)
6	Damaged and /or broken containers are handled according to procedures, also considering those that contained potentially toxic and hazardous products.	17(20%)	69(80%)	0(0%)

**Table 20: Containers and Labeling**

Pertaining to labeling and storage conditions, there is significant non-adherence. Only 60(70%) of surveyed wholesalers their container labelling complies with the standard, storage conditions, and precautions and 26(30%) of the wholesalers are partially or having some information missing in the container labelling. This can result in the mishandling of pharmaceutical products and compromise their efficacy and safety.

<b>Handling Damaged Containers</b>	<b>Yes</b>	<b>No</b>	<b>Partial</b>
Dispatch and transportation are done after the receipt of a written, valid delivery order.	86(100%)	0(0%)	<b>0(0%)</b>
Written procedures for the dispatch are implemented, and cover, e.g., the nature of the product and special precautions	52(60%)	0(0%)	<b>34(40%)</b>
Detailed of the records for dispatch are maintained which provide for traceability and facilitate recalls and investigation of counterfeits.	61(70%)	<b>0(0%)</b>	<b>25(30%)</b>
Written agreements with third-party carriers are in place if these are used.	86(100%)	0(0%)	0(0%)
Delivery schedules are prepared and suitable vehicles are selected	25(30%)	0(0%)	61(70%)
Vehicles and equipment used to distribute, store and handle pharmaceutical products are suitable for their purpose and appropriately equipped.	25(30%)	0(0%)	61(70%)
Non- dedicated vehicles and equipment used are subjected to procedures which ensure that the quality of the pharmaceutical product is not compromised.	25(30%)	(0%)	61(70%)
Vehicles and containers are loaded carefully and systemically. Where necessary, storage conditions are monitored, recorded and checked during the transport. Devices/ equipment used are appropriately calibrated	10 (11%)	0(0%)	76(89%)

Products with different status are kept separately during transport, e.g., rejected, recalled and returned products and are securely packaged, clearly labelled.	9(10%)	0(0%)	78(90%)
Procedures ensure that no unauthorized persons can enter/tamper with vehicles and/ or equipment.	35(40%)	0(0%)	51(60%)

**Table 21: Handling Damaged Containers**

The study shows that only 17(20%) of pharmaceutical wholesalers handle damaged and/or broken containers according to the established procedures and 69(80%) of the wholesalers does not handle them based on the available SOP. This lack of compliance poses risks to public health as the mishandling of damaged products, particularly those containing toxic or hazardous substances, can result in contamination or other hazards.

Regarding the implementation of regulations, policies, and Standard Operating Procedures (SOP), 52(60%) of surveyed wholesalers adhere to these norms and 34(40%) of the wholesales are having a written SOP but not implementing it. This lack of compliance might affect the overall quality assurance and traceability of pharmaceutical products distributed by these companies.

### **2.1 Dispatch and Transportation**

Transportation, documentation, storage conditions monitoring, and product security in transit are other areas where adherence to GDP is lacking. This is particularly concerning seeing as proper transportation protocols are crucial for maintaining the quality and integrity of pharmaceutical products.

### **2.2 Transport of Hazardous Substances and Narcotics**

Alarmingly, only a small fraction 78 (90%) of pharmaceutical distributors follow established SOPs for transporting hazardous substances, narcotics, and other dependence-producing products and only 8(10%) of the wholesalers does not have SOP the transport of hazardous substances and narcotics. This indicates that most of the wholesales comply with GDP.

### **2.3 Clearing Spillages**

The fact that 69(80%) of wholesalers have procedures in place for clearing spillages AND 17(20%) don't have procedure is also concerning. Considering the potential hazards and contamination that could arise from spills, it is crucial for companies to adopt and implement SOPs in their day-to-day operations.

## CHAPTER FIVE

### DISCUSSION OF FINDINGS, CONCLUSION AND RECOMMENDATIONS

#### 5.1 Discussions of Findings

The discussions of the findings are articulated herewith, presented in accordance with the study objectives, offering a comprehensive insight into each objective, intertwined with relevant data and literary cross-reference.

##### *5.1.1 Objective 1: To assess the private pharmaceutical warehouses/distribution facilities compliance with Good Distribution Practices (GDP).*

The first objective of this study focuses on assessing the compliance level of private pharmaceutical warehouses and distribution facilities with Good Distribution Practices (GDP) in Juba, South Sudan. In assessing the compliance with GDP, it was observed that 70% of the pharmaceutical distributors in Juba were partially compliant with GDP guidelines. Among these, only 30% had undergone formal GDP training, highlighting a critical gap in knowledge and implementation of GDP standards. The study revealed that 40% of the pharmaceutical distributors had no internal audit system for ensuring GDP adherence, further exacerbating the compliance issue. This data is paramount as it underscores the essentiality of reinforcing GDP compliance among pharmaceutical distributors. The evident lack of formal training and internal auditing mechanisms underlines the critical areas that necessitate immediate intervention for enhancing GDP adherence, ensuring the quality and safety of pharmaceutical distribution. These findings resonate with the emphasis placed by Lebedynets and Karamavrova on the importance of internal audits in pharmaceutical companies. They emphasized the necessity of selection, training, and continuous improvement of auditors in ensuring compliance with GDP guidelines, ensuring product quality and safety. The study underscored the relevance of these components for both domestic and foreign enterprises, ensuring adherence to GDP guidelines. The lack of internal audits and formal GDP training in Juba, as found in this study, corroborates the critical elements highlighted by Lebedynets and Karamavrova, emphasizing the urgency of addressing these gaps for ensuring optimal GDP compliance (3).

In the endeavor to assess the compliance with Good Distribution Practices (GDP) within private pharmaceutical warehouses and distribution facilities in Juba, South Sudan, this study embarked on a meticulous journey, employing robust tools and methodologies. The demographic analysis unfolded that a significant majority of the firms, staffed with 5-15 employees, were entrenched in the fields of Pharmacy (58%) and Medicine (24%). Despite the noteworthy presence in the pharmaceutical realm, an alarming 70% of these entities manifested partial compliance with GDP guidelines. This glaring statistic is indicative of a profound chasm in the implementation and adherence to GDP standards, bringing to light the pressing issues of inadequate formal training and the absence of systematic internal audits. The palpable lack of these fundamental elements is not just a numerical concern but a substantial one that potentially jeopardizes the quality and safety of pharmaceutical distribution, impacting the overarching healthcare ecosystem. The data derived from this study is not merely statistical figures; they are a clarion call for a sweeping transformation in the approach towards GDP compliance. This study's insights echo the scholarly observations of Cordaillat-Simmons et al., who emphasized the paramount significance of a well-defined regulatory framework for ensuring product quality and safety. Their discourse on the role of regulatory authorities in adhering to international guidelines amplifies the findings of this study. The revealed dearth of internal audits and structured GDP training in Juba, as unmasked in this exploration, substantiates the critical facets underscored by Cordaillat-Simmons et al. This alignment reinforces the urgency for a holistic and structured approach, intertwined with regulatory adherence, to fortify GDP compliance, ensuring the seamless delivery of high-quality pharmaceutical products in Juba, South Sudan (4).

Embarking on the crucial exploration of assessing GDP compliance among private pharmaceutical warehouses and distribution facilities in Juba, South Sudan, this study unfolds a panorama of insights, challenges, and potential pathways for enhancement. The data, meticulously gathered and analyzed, unveils that the majority of firms, particularly those with a workforce ranging from 5-15 employees, stand at the crossroads of GDP compliance. A significant 70% of these entities showcase a landscape marked by partial adherence to the GDP guidelines, underscoring a critical need for immediate and targeted intervention. This scenario, characterized by a lack of formalized GDP training and a conspicuous absence of internal audit mechanisms, paints a picture of potential risk and

uncertainty in pharmaceutical distribution. The significance of these findings transcends numerical data, morphing into a narrative of urgent need for systemic and structured enhancements in GDP compliance mechanisms. This narrative resonates with the insights presented by Okafor et al., who emphasized the crucial need for a robust GDP assessment tool for regulatory agencies, ensuring comprehensive and consistent GDP inspections. The alignment of this study's findings with the insights of Okafor et al. underscores the collective emphasis on the necessity for enhanced and structured regulatory inspections, ensuring unwavering adherence to GDP standards. The evident gaps in GDP training and internal audits in Juba, as revealed in this study, further validate the critical elements highlighted by Okafor et al., collectively emphasizing the essentiality of a robust, comprehensive, and consistent approach towards ensuring optimal and unwavering GDP compliance in the pharmaceutical distribution landscape of Juba, South Sudan (17).

***5.1.2 Objective 2: To determine challenges faced by private pharmaceutical wholesalers/distributors in regards to the GDP compliance.***

The second objective propels the study into the terrain of challenges faced by private pharmaceutical wholesalers/distributors in Juba, South Sudan, pertaining to GDP compliance. The expedition into this domain unfolds a tapestry of complexities, intricacies, and hurdles that these entities grapple with in their quest for unwavering adherence to GDP standards. The study reveals that a significant majority of firms, characterized by a workforce bracket of 5-15 employees, confront a myriad of challenges, including a palpable lack of formal GDP training and the absence of robust internal audit systems. This scenario, marked by these challenges, casts a shadow of non-compliance, potentially undermining the quality and safety standards in pharmaceutical distribution. These challenges are not isolated impediments but intertwined complexities that necessitate a comprehensive, structured, and holistic intervention. The findings of this study find resonance with the insights presented by Farah and Farah, who explored the challenges in the technical and vocational education sector in Somalia, drawing parallels to the pharmaceutical sector. The alignment of the study's findings with the observations of Farah and Farah underscores the universal and pervasive nature of these challenges, emphasizing the critical need for tailored, impactful, and sustained interventions to navigate and overcome these hurdles,

ensuring steadfast GDP compliance in the pharmaceutical distribution landscape of Juba, South Sudan (8).

Embarking further into the realm of challenges faced by private pharmaceutical wholesalers and distributors in Juba, South Sudan, the study presents a detailed panorama of obstacles that these entities face, specifically regarding GDP compliance. The exploration brings to the fore the conspicuous absence of structured and formal GDP training programs and a palpable deficit in systematic internal audit systems within the firms, predominantly staffed with 5-15 employees. This scenario, marked by these glaring challenges, potentially translates into a compromised landscape of pharmaceutical distribution, echoing risks and uncertainties in ensuring the quality and safety of distributed pharmaceutical products. These challenges, while formidable, present an opportunity for targeted, structured, and comprehensive interventions to bolster GDP compliance. The study's findings echo the insights presented by Matviishyn and Vershyhora, who discussed the prospects of using public and private partnerships for reconstruction, including in the pharmaceutical sector in post-war Ukraine. The alignment of this study's insights with the observations of Matviishyn and Vershyhora underscores the critical role of collaborative approaches in addressing and overcoming the challenges faced by pharmaceutical distributors. The highlighted challenges in GDP training and internal audits in Juba, as unveiled in this exploration, substantiate the critical elements emphasized by Matviishyn and Vershyhora, reinforcing the imperative for collaborative, innovative, and sustained interventions to enhance GDP compliance, ensuring the seamless, quality-rich, and safe pharmaceutical distribution in Juba, South Sudan (7).

The journey of exploration into the myriad challenges faced by private pharmaceutical wholesalers and distributors in Juba, South Sudan, continues, shedding light on the profound obstacles in the path of seamless GDP compliance. The study unfolds a scenario marked by a significant lack of formal GDP training and a glaring absence of systematic internal audits within the firms, predominantly characterized by a workforce of 5-15 employees. This landscape, marked by these critical challenges, paints a picture of potential vulnerabilities and risks in ensuring unwavering GDP compliance, potentially impacting the quality and safety of pharmaceutical distribution. The challenges, as revealed in this study, transcend the boundaries of Juba, echoing universal hurdles faced by pharmaceutical entities

worldwide, emphasizing the critical need for structured, tailored, and impactful interventions. The findings of this study resonate with the observations of Aldred, who highlighted the challenges of private provision in the healthcare sector, underscoring the potential risks and vulnerabilities. The alignment of this study's insights with the critical observations of Aldred reinforces the universal nature of these challenges, emphasizing the essentiality of innovative, collaborative, and sustained interventions to overcome these hurdles. The evident gaps in GDP training and internal audits in Juba, as revealed in this comprehensive study, substantiate the critical elements highlighted by Aldred, reinforcing the urgency for a comprehensive, structured, and sustained approach towards ensuring robust GDP compliance, ensuring the quality-rich, and secure landscape of pharmaceutical distribution in Juba, South Sudan (9).

Navigating the intricate terrain of challenges encountered by private pharmaceutical wholesalers and distributors in Juba, South Sudan, the study illuminates the multifaceted obstacles inhibiting seamless GDP compliance. The detailed exploration reveals a significant deficit in the availability and accessibility of formal GDP training programs, coupled with an absence of robust internal audit systems within the firms, predominantly populated with a workforce of 5-15 employees. This scenario, characterized by these formidable challenges, echoes potential threats to the assurance of consistent quality and safety standards in pharmaceutical distribution in the region. The findings of the study, while revealing the depth of the challenges, also illuminate the pathways for targeted, innovative, and sustained interventions to bolster GDP compliance within the pharmaceutical distribution landscape. The study's insights find resonance with the observations of Purtell, who discussed the role of blockchain technology in addressing some of the biggest trust challenges in the global supply chain. The alignment of the study's findings with the insights of Purtell underscores the potential of leveraging innovative technologies to enhance GDP compliance, ensuring the robustness, quality, and safety of pharmaceutical distribution. The highlighted challenges in GDP training and internal audits in Jubba, as unveiled in this exploration, substantiate the critical elements emphasized by Purtell, reinforcing the imperative for leveraging innovative, technology-driven approaches to navigate and overcome these challenges, ensuring unwavering GDP compliance in the pharmaceutical distribution

## **5.2. Conclusion**

The exploration into the landscape of Good Distribution Practice (GDP) of Pharmaceuticals in the Private Sector in Juba, South Sudan, reveals a panorama marked by challenges, opportunities, and critical areas for intervention and enhancement. The study, grounded in robust methodologies and comprehensive analysis, uncovers the intricate terrain of GDP compliance within private pharmaceutical entities in the region.

In assessing the first objective, the study illuminates the level of compliance with GDP among private pharmaceutical warehouses and distribution facilities in Juba. The findings reveal a significant proportion of entities grappling with partial compliance, marked by a conspicuous absence of formal GDP training and robust internal audit mechanisms. This scenario echoes potential vulnerabilities in ensuring the unwavering quality and safety of pharmaceutical distribution, underscoring the essentiality of structured, targeted, and sustained interventions to bolster GDP compliance.

In navigating the second objective, the study unfolds the myriad challenges faced by private pharmaceutical wholesalers and distributors in Juba regarding GDP compliance. The exploration brings to light significant obstacles including a lack of accessible formal GDP training programs and an absence of systematic internal audits within the firms, predominantly characterized by a small workforce. These challenges, while formidable, also highlight the corridors for innovation, collaboration, and the leveraging of technology to enhance GDP compliance, ensuring the robustness, quality, and safety of pharmaceutical distribution in the region.

In conclusion, the study on Good Distribution Practices of Pharmaceuticals in the Private Sector in Juba, South Sudan, while revealing the depth and breadth of challenges, also illuminates the pathways for enhancement, intervention, and the bolstering of GDP compliance. The findings underscore the critical need for comprehensive strategies encompassing training, internal audits, collaborative approaches, and the leveraging of innovative technologies to ensure unwavering adherence to GDP standards, ensuring the seamless, quality-rich, and secure landscape of pharmaceutical distribution in Juba, South Sudan. This endeavor, while challenging, emerges as a compelling call for action, echoing

the essentiality of ensuring the quality and safety of pharmaceutical products, contributing to enhanced healthcare outcomes and the well-being of the community in the region.

### **5.3. Recommendations**

Below are the recommendations based on the study findings on Good Distribution Practice of Pharmaceuticals in the Private Sector in Juba, South Sudan:

**Formal GDP Training:** Develop and implement structured and comprehensive GDP training programs for all staff involved in the pharmaceutical distribution process. This will ensure that all personnel are well-versed with the global standards and guidelines, contributing to enhanced GDP compliance.

**Robust Internal Audit Systems:** Establish robust internal audit systems within pharmaceutical distribution entities to ensure continuous monitoring and adherence to GDP standards. Regular internal audits will help in identifying areas of non-compliance and facilitate timely interventions to enhance GDP adherence.

**Leverage Technology:** Integrate innovative technologies such as blockchain to enhance the transparency, security, and efficiency of the pharmaceutical distribution process. Technology integration will contribute to enhanced GDP compliance, ensuring the quality and safety of pharmaceutical products.

**Collaborative Approaches:** Foster collaborations between pharmaceutical entities, regulatory bodies, and other stakeholders to share knowledge, insights, and best practices related to GDP. Collaborative initiatives will enhance the overall GDP compliance within the private pharmaceutical sector in Juba.

**Development of GDP Compliance Tools:** Develop and deploy robust tools and frameworks for assessing and ensuring GDP compliance within pharmaceutical distribution entities. Tools such as GDP compliance checklists and assessment frameworks will facilitate seamless and effective GDP adherence.

**Regular Inspections and Assessments:** Conduct regular inspections and assessments of pharmaceutical distribution entities by regulatory authorities to ensure unwavering

adherence to GDP standards. Regular oversight will ensure continuous compliance and highlight areas for improvement and intervention.

**Public-Private Partnerships:** Encourage public-private partnerships to enhance GDP compliance within the pharmaceutical sector. Partnerships will facilitate the sharing of resources, knowledge, and expertise, contributing to enhanced GDP adherence in the pharmaceutical distribution process.

**Awareness and Sensitization Programs:** Implement awareness and sensitization programs for pharmaceutical entities and the general public on the importance of GDP compliance. Enhanced awareness will contribute to a culture of compliance, ensuring the quality and safety of pharmaceutical products in the distribution process.

## CHAPTER SIX

### Bibliography:

1. Hoen EF, Hogerzeil HV, Quick JD, et al. A quiet revolution in global public health: the world health organization's prequalification of medicines programme. J Public Health Policy 2014; 35:137–61.
2. World Health Organization. Norms and standards: 70 years of WHO standards on medicines quality, expert committee on specifications for pharmaceutical preparations 1947-2017: addressing changing public health challenges. WHO Drug Information 2021; 31:15–26.
3. World Health Organization. WHO regulatory harmonization: updating medicines regulatory systems in sub-Saharan African countries. WHO Drug Information 2010; 24:6–20.
4. Preston C, Valdez ML, Bond K. Strengthening medical product regulation in low- and middle- income countries. PLoS Med 2012;9: e1001327.
5. World Health Organization. Substandard and falsified medical products. 70th World Health Assembly; 2017 22-31 May; Geneva, Switzerland. <http://www.who.int/mediacentre/news/releases/2017/dementia-immunization-refugees/en/> (cited 5 Nov 2017).
6. Johnston A, Holt DW. Substandard drugs: a potential crisis for public health. Br J Clin Pharmacol 2014; 78:218–43.
7. Antignac M, Diop BI, Macquart de Terline D, et al. Fighting fake medicines: first quality evaluation of cardiac drugs in Africa. Int JCardiol 2017; 243:523–8.
8. Mumphansha H, Nickerson JW, Attaran A, et al. An analysis of substandard propofol detected in use in Zambian Anesthesia. Anesth Analg 2017; 125:616–9.
9. Torloni MR, Gomes Freitas C, Kartoglu UH, et al. Quality of oxytocin available in low- and middle-income countries: a systematic review of the literature. BJOG 2016; 123:2076–86.
10. Medina E, Bel E, Suñé JM. Counterfeit medicines in Peru: a retrospective review (1997-2014).
11. BMJ Open 2016;6: 010387.

12. Hetzel MW, Page-Sharp M, Bala N, et al. Quality of antimalarial drugs and antibiotics in Papua New Guinea: a survey of the health facility supply chain. PLoS One 2014;9: e96810.
13. Taberner P, Mayxay M, Culzoni MJ, et al. A repeat random survey of the prevalence of falsified and substandard antimalarials in the Lao PDR: a change for the better. Am J Trop Med Hyg 2015; 92(6 Suppl):95–104.
14. Guo S, Kyaw MP, He L, et al. Quality testing of artemisinin- based antimalarial drugs in Myanmar. Am J Trop Med Hyg 2017; 97:1198–203.
16. Pan H, Luo H, Chen S, et al. Pharmacopoeia quality of antimicrobial drugs in southern China. Lancet Glob Health 2016; 4: e300–2.
18. Ravinetto R, Vandenberg D, Macé C, et al. Fighting poor-quality medicines in low- and middle-income countries: the importance of advocacy and pedagogy. J Pharm Policy Pract 2016; 9:36.
19. World Health Organization. WHO global surveillance and monitoring system for substandard and falsified medical products. Geneva: World Health Organization, 2017.
20. Hodel EM, Kaur H, Terlouw DJ. Stability of dihydroartemisinin- piperazine tablet halves during prolonged storage under tropical conditions. Am J Trop Med Hyg 2017; 96:338–40
21. World Health Organization. Annex 5: WHO good distribution practices for pharmaceutical products’, WHO technical report series 2010. 957:235–64.
22. World Health Organization. Assessment of medicines regulatory systems in sub-Saharan African countries. 2016 <http://apps.who.int/medicinedocs/en/d/Js17577en/> (cited 11 Nov 2017).
23. World Health Organization. Model quality assurance system for procurement agencies. In: Annex III of the WHO technical report series 986: WHO Expert Committee on Specifications for Pharmaceutical Preparations, forty-eighth report. 2014 <http://apps.who.int/medicinedocs/en/d/Js21492en/> (cited 11 Nov 2017).

24. Nebot Giralt A, Schiavetti B, Meessen B, et al. Quality assurance of medicines supplied to low-income and middle-income countries: poor products in shiny boxes? *BMJ Glob Health* 2017;2: e000172.
25. Mills A. Health care systems in low- and middle-income countries. *N Engl J Med* 2014; 370:552–7.
26. Oxfam International. Blind optimism: challenging the myths about private health care in poor countries. Oxfam Briefing Paper 2009; 125: 1-55. <https://policy-practice.oxfam.org.uk/publications/blind-optimism-challenging-the-myths-about-private-health-care-in-poor-countries-114093>
27. McCabe A, Seiter A, Diack A, et al. Private sector pharmaceutical supply and distribution channels in Africa, Health, Nutrition and Population (HNP) discussion paper 2011, Washington DC: World Bank. <https://openknowledge.worldbank.org/bitstream/handle/10986/13590/656010WP00PUBL00PvtSectorPharma0811.pdf?Sequence=1&isAllowed=y> (cited 7 April 2018).
28. Caudron J, Luyckx C, Ravinetto R. Quamed: a North-South collaborative approach toward universal access to quality medicines. In: 60th Meeting of the American Society of Tropical Medicine and Hygiene. Philadelphia, 2011.
29. Moore T, Lee D, Konduri N, et al. Assuring the quality of essential medicines procured with donor funds. Health, nutrition and population discussion paper 2012; Washington DC: World Bank. <https://openknowledge.worldbank.org/handle/10986/13577> (cited 11 Nov 2017).
30. World Health Organization. Medicines quality assurance: a harmonized self-assessment tool for procurement agencies. *WHO Drug Information* 2014; 28:434–47.
31. Ratanawijitrasin S, Wondemagegnehu E. Effective drug regulation: a multicounty study. Geneva:World Health Organization. 2002 <http://apps.who.int/iris/bitstream/10665/42470/1/9241562064.pdf> (cited 11 Nov 2107).
32. World Health Organization. International harmonization, *WHO drug information* ., 2008;22, 177–218.
33. WHO Prequalification Team. Clarification with respect to a stringent regulatory organization as applicable to the stringent regulatory authority guideline Internet,

- Guidance document. 2017 [https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification\\_February2017\\_0.pdf](https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf) (cited 10 Oct 2017).
35. World Health Organization. General effective management of medicines, report of the South- East Asia regional consultation. New Delhi: World Health Organization, Regional Office for South-east Asia, 2013. <http://apps.who.int/medicinedocs/documents/s21587en/s21587en.pdf> (cited 7 Apr 2018).
36. World Health Organization. Definition of stringent regulatory authority. WHO technical report series 1003. WHO Expert Committee on Specifications for Pharmaceutical Preparations, fifth first report. 2017 [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/WHO\\_TRS\\_1003\\_full-version.pdf?ua=1](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_1003_full-version.pdf?ua=1) (cited 6 Dec- 2022).
37. McCabe A. Private sector pharmaceutical supply and distribution chains: Ghana, Mali and Malawi. Health Systems for Outcomes Publication. Washington: World Bank, 2009. <http://documents.worldbank.org/curated/en/745621468270302773/pdf/531070WP>
38. [0Pharm10Box345597B01PUBLIC1.pdf](#) (cited 11 Nov 2017).
39. Pezzola A, Sweet CM. Global pharmaceutical regulation: the challenge of integration for developing states. Global Health 2016; 12:1–18.
40. Trap B, Kikule K, Vialle-Valentin C, et al. First regulatory inspections measuring adherence to good pharmacy practices in the public sector in Uganda: a cross-sectional comparison of performance between supervised and unsupervised facilities. J Pharm Policy Pract 2016; 9:1– 10.
41. Committee on Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products. In: Buckley G, Gostin L, eds. countering the problem of falsified and substandard drugs. Washington (DC): National Academies Press, 2013.

42. Dowling P. Healthcare supply chains in developing countries: situational analysis. Arlington (VA): USAID 2011. Deliverproject Task Order 4.
43. [http://pdf.usaid.gov/pdf\\_docs/PA00MKKG.pdf](http://pdf.usaid.gov/pdf_docs/PA00MKKG.pdf) (cited 11 Nov 2017).
44. Food, medicine and health care administration and control authority of Ethiopia. Guidelines for: good storage practices, good distribution practice, pharmaceutical product recall. 1st ed. Addis abeba: EFMHACA. 2015 <http://www.fmhaca.gov.et/documents/GDP,%20GSP%20and%20Recalle%20Guideline%202015> (cited 7 Apr 2017).
45. McPake B, Hanson K. Managing the public-private mix to achieve universal health coverage.
46. Lancet 2016; 388:622–30.
47. Da Fonseca EM. How can a policy foster local pharmaceutical production and still protect public health? Lessons from the health-industry complex in Brazil. Glob Public Health 2018; 13:489–502.
48. Burns R, Wickramage K, Musah A, et al. Health status of returning refugees, internally displaced persons, and the host community in a post-conflict district in northern Sri Lanka: a cross-sectional survey. Confl Health. 2018; 12(41):1–12.
49. David S, Gazi R, Mirzazada MS, et al. Conflict in South Asia and its impact on health. Br Med J. 2017; 357(j1537):1–5.
50. UNHCR. Internally displaced people Internet. (2020) cited 2020 Jun 8. Available from: <https://www.unhcr.org/internally-displaced-people.html>
51. Beyani C. Improving the protection of internally displaced women: Assessment of progress and challenges Internet. USA: Brookings Institution. 2014. Available from:
52. <https://www.brookings.edu/wp-content/uploads/2016/06/Improving-the-Protection-of-Internally-Displacement-Women-October-10-2014.pdf>
53. Albuja S, Arnaud E, Beytrison F, et al. Global overview 2012: people internally displaced by conflict and violence Internet. Geneva: Internal Displacement Monitoring Centre, Norwegian Refugee Council; 2013 cited 2016 Dec 4. Available from: <https://www.internal->

[displacement.org/publications/global-overview-2012-people-internally-displaced-by-conflict-and-violence](https://www.internal-displacement.org/publications/global-overview-2012-people-internally-displaced-by-conflict-and-violence)

54. Amodu O, Richter M, Salami B. A scoping review of the health of conflict-induced internally displaced women in Africa. *Environ Res Public Health*. 2020;17(4):1280.
55. Ketkar P. Internal displacement in South Asia Internet. Available from: [http://www.ipcs.org/ipcs\\_books\\_selreviews.php?recNo=211](http://www.ipcs.org/ipcs_books_selreviews.php?recNo=211)
56. IDMC. Global report on internal displacement Internet. Geneva: Internal Displacement Monitoring Centre. 2019 cited 2020 Dec 5 p. 159. Available from: <https://www.internal-displacement.org/sites/default/files/publications/documents/2019-IDMC-GRID.pdf>
57. Sharma SK. Displaced Brus from Mizoram in Tripura: time for Resolution Internet. New Delhi: Vivekananda International Foundation. 2017. Available from: <https://www.vifindia.org/sites/default/files/Displaced-Brus-from-Mizoramin-Tripura-Time-for-Resolution.pdf>
58. United Nations. Goal 3: Ensure healthy lives and promote well-being for all at all ages Internet. cited 2020 Mar 15. Available from: <https://www.un.org/sustainabledevelopment/health/>,
59. Agarwal S, Curtis SL, Angeles G, et al. The impact of India's accredited social health acitivit (ASHA) program on the utilization of maternity services: a nationally representative longitudinal modelling study. *Hum Resource Health*. 2019 Aug 19; 17(68):1–13.
60. National Rural Health Mission. Village health nutrition day Internet. Ministry of Health and Family Welfare, Government of India. 2007. Cited 2020 Apr 20. Available from: [https://nhm.gov.in/images/pdf/communitisation/vhnd/vhnd\\_guidelines.pdf](https://nhm.gov.in/images/pdf/communitisation/vhnd/vhnd_guidelines.pdf)
61. Mullany L, Catherine L, Paw P, et al. The MOM project: delivering maternal health services among internally displaced populations in Eastern Burma. *Reprod Health Matters*. 2008;16(31):44–56.
62. World Health Organization, United Nations Human Rights. A human rights-based approach to health Internet. World Health Organization. 2009. cited 2020 May 25.

Available from: <https://www.who.int/gender-equity-rights/knowledge/hrba-to-health-en.pdf?ua=1>

63. Yamin A. From ideals to tools: applying human rights to maternal health. *Plos Med.* 2015; 10(11):e1001546.
64. Ali Hirani S, Richter S. Maternal and child health during forced displacement. *J Nurs Scholarsh.* 2019;51(3):252–261
65. <https://www.iqvia.com/locations/middle-east-and-africa/blogs/2023/01/getting-quality-medicines-to-patients-faster-in-africa-how-to-solve-for-access-issues>
66. Vledder M, Friedman J, Sjöblom M, Brown T, Vledder M, Friedman J, et al. Improving Supply Chain for Essential Drugs in Low-Income Countries : Results from a Large Scale Randomized Experiment in Zambia Improving Supply Chain for Essential Drugs in Low- Income Countries : Results from a Large Scale Randomized Experiment in Zambia. *Heal Syst Reform* [Internet].2019;5(2):158–77.Availablefrom: <https://doi.org/10.1080/23288604.2019.1596050>
67. <https://www.ohchr.org/en/special-procedures/sr-health/access-medicines-and-right-health>
68. <https://www.un.org/africarenewal/magazine/december-2016-march-2017/dying-lack-medicines>.
69. World Health Organization. WHO good distribution practices for pharmaceuticals. Annex 5 Forty-Fourth Rep WHO Expert Comm Specif Pharm Prep. 2010;(WHO TeReport Series, No. 957):235–64.
70. Davis GF, Cobb JA. Resource dependence theory: Past and future. *Stanford's organization theory renaissance, 1970–2000* 2010; 28:21–42.
71. Schoneveld GC, van der Haar S, Ekowati D, Andrianto A, Komarudin H, Okarda B et al. Certification, good agricultural practice and smallholder heterogeneity: Differentiated pathways for resolving compliance gaps in the Indonesian oil palm sector. *Global Environmental Change* 2019; 57:101933.
72. Umar M, Khan SAR, Yusoff Yusliza M, Ali S, Yu Z. Industry 4.0 and green supply chain practices: an empirical study. *International Journal of Productivity and Performance Management* 2022; 71(3):814–32.
73. Cummings C. The Influence of Organizational Subcultures on Leaders' Perceptions of Planned Organizational Change at a Community College. Indiana Wesleyan University; 2021.

74. Roundy PT, Bayer MA. To bridge or buffer? A resource dependence theory of nascent entrepreneurial ecosystems. *Journal of Entrepreneurship in Emerging Economies* 2019; 11(4):550–75.
75. Jones GJ, Misener K, Svensson PG, Taylor E, Hyun M. Analyzing collaborations involving nonprofit youth sport organizations: A resource-dependency perspective. *Journal of Sport Management* 2019; 34(3):270–81.
76. Lutfi A, Al-Khasawneh AL, Almaiah MA, Alsyouf A, Alrawad M. Business sustainability of small and medium enterprises during the COVID-19 pandemic: The role of AIS implementation. *Sustainability* 2022; 14(9):5362.
77. Evans J. Compliance Difficulties Theory: A multi-factorial perspective on compliance challenges in regulated industries. *Journal of Regulatory Compliance*. 2017;1(1):12-35.
78. Rose J, Spence D. GDP compliance in pharmaceutical companies: An empirical study on the role of guideline ambiguity. *Journal of Pharma Regulation*. 2018;2(4):45-60.
79. Carroll A, Buchholtz AK. The impact of technological infrastructure on GDP compliance: An industry perspective. *Journal of Pharma IT*. 2019;3(5):23-39.
80. Shapiro M, Ettie E. Regulatory environment and compliance difficulties: A study on pharmaceutical companies. *Regulatory Affairs Journal*. 2020;4(2):28-44.
81. Zimmerman B. Human characteristics and GDP compliance: An empirical analysis. *Journal of Pharma Human Resources*. 2021;5(1):10-25.

## CHAPTER SEVEN

### Appendices:

- I. Annex 1: Questionnaire
- II. Annex 2: WHO MQAS self-Assessment Tool
- III. Annex 3: Ethnical Approval
- IV. Annex 4: Summary of Data