INTEGRATED RISK MANAGEMENT IN THE SUPPLY CHAIN OF ESSENTIAL MEDICINES IN ZAMBIA

By

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Declaration

I declare that I am responsible for the work contained in this submitted dissertation, unless otherwise for the work that has been acknowledged and referenced as defined by the university's policy and guidelines.

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CERTIFICATE OF APPROVAL

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Abstract

Access to health care is a human right, which includes having timely access to affordable and quality essential medicines at the right place and in sufficient quantity. However, inefficient public sector supply chain management contributes to constant shortages of essential medicines at health facilities.

Literature review involved a desktop study of published research studies and reports on risk management, supply chain management of essential medicines and their integration to increase the efficiency of the latter.

The research was conducted on a sample population of offices under Ministry of Health Headquarters, Lusaka Provincial and District Offices, selected health facilities in Lusaka, Medical Stores Limited, Zambia Medicines Regulatory Authority and Cooperating Partners. Individuals involved in study were selected judgmentally by their functions under selection and quantification, regulation, procurement, storage, distribution, quality assurance and dispensing of essential medicines. Structured interviews and discussions were held with selected experts and self-administered questionnaires were distributed.

The highest prioritised risks were; inadequate and inconsistent fund disbursements, weak information management systems, weak quality management systems and insufficient resources (HR and infrastructure) among others. Analysis of the supply chain of essential medicines and the risks that were identified, assessed and ranked helped in designing and proposing the Organisation Risk Management Model.

The results for this research can be used to increase the efficiency of the public sector supply chain of essential medicines and other pharmaceuticals. The results of the study also showed that there is need to implement effective risk management systems by participating institutions and organisations to increase the efficiency of the entire supply chain in order to avoid and/or reduce shortages of essential medicines at health facilities.

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List of Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-Retroviral Therapy
ARV	Anti-Retroviral
CHAZ	Churches Health Association of Zambia
CPs	Cooperating Partners
EMA	European Medicines Agency
EML	Essential Medicines List
GRZ	Government Republic of Zambia
HIV	Human Immunodeficiency Virus
ICH	International Conference on Harmonisation
MoFNP	Ministry of Finance and National Planning
MoH	Ministry of Health
MSL	Medical Stores Limited
PIC/S	Pharmaceutical Inspection Corporation Scheme
SCM	Supply Chain Management
SCRM	Supply chain risk management
SNDP	Sixth National Development Plan
TB	Tuberculosis
UNDP	United Nations Development Programme
USAID	United States Agency for International Development
USFDA	United States Food and Drug Administration
WHO	World Health Organisation
ZAMRA	Zambia Medicines Regulatory Authority

1 CHAPTER ONE: INTRODUCTION

1.0 Background and Justification of research

Every human being has a right to good health care including medication. Mona et al, (2013) indicates that access to medicine is a basic Human Right and is one of the main objectives of any health care system. Therefore, every Zambian citizen has the right to have access to the right medicine, with the right quantity, quality and efficacy, which is safe, at the right place and time. Research and studies have shown that drug shortages or stock outs are a global problem in health care systems and are worsening with time and creating more difficulties for healthcare professionals and compromising patient safety (International Pharmaceutical Federation, 2013). In Africa, almost every country is facing medicines shortages for different reasons which are dependent on the country's supply chain management of medicines. In South Africa, the results of a telephonic survey conducted between September and October 2013 showed that 21% of the five facilities reported a stock out or drug shortage of Anti-Retroviral (ARV) and/or Tuberculosis (TB) medicines in the preceding three months, of which 52.7% were still facing shortages at time of survey (Stop Stockouts Project, 2013). Ghana has been experiencing drug stock outs and shortages which prompted the establishment of a national health commodity supply chain master plan (Ministry of Health Ghana, 2012). The problem is the same in Tanzania, shortages of essential medicines are a major issue in public health facilities despite increasing attention through numerous reforms and initiatives. A conducted survey in 2013 found that 41% of patients were unable to get the medicines they needed from a public health facility (Joseph et al., 2014). Secondly, supply chain challenges and its deficiencies of the Ugandan essential medicines supply chain was evidenced by stock outs and shortages at the health facilities whilst the National Medical Stores of Uganda planned to destroy expired medicines (Pross Nagitta et al., 2010).

Medicines shortages and stock outs are caused by diverse factors which are mainly dependent on the specific country's supply chain. Consequently, the in-country supply chain is managed differently from one country to the other. From the above, causes and solutions to the medicines shortages and stock outs are country-specific. However, the major causes of medicines shortages in developed countries, where manufacturing is

done within the country, are manufacturing related within the supply chain of essential medicines. In 2012, medicine shortages in the United States of America (USA) were attributed to the following; (i) manufacturing reasons-36%, (ii) supply/demand-8.3%, (iii) discontinuation of manufacturing a product – 7.8% (iv) lack of raw materials – 3.9% and (v) others combined at 44%. In Europe it was found that 52.4% of shortages occurred when there was either a single or a limited number of suppliers, 43.7% were related to raw materials and 43.7% were due to manufacturing quality problems (South African Pharmaceutical Journal, 2013). On the other hand, in Sub-Saharan Africa the medicine shortages and stock outs are largely caused by procurement and distribution management.

In the workshop conducted by World Health Organisation, (2006) it identified that the main challenges to access of essential medicines were poor information, communication and consumption data, inadequate storage facilities, temperature control systems and a lack of quality assurance procedures. Pross Nagitta et al, (2010) affirm that, the bottlenecks in the supply chain of essential medicines in the Ugandan are: the district hospitals faced lack of credible data, poor planning and forecasting and poor logistics. Norman N et al, (2007) asserted that the main reason for the observed shortage of drugs at the health centres in Malawi was insufficient deliveries from the Regional Medical Store. While on one hand the public sector may be procuring drugs to meet the country's needs, on the other hand, there may be a leakage of drugs from the public sector into the private sector. A difference between the information recorded on the stock cards at the health centres and that recorded in the patient records may have contributed to the overall poor drug supply situation. The above examples point out that in many developing countries as opposed to developed countries, the major causes of medicine shortages and stock outs are mainly due to procurement and distribution management.

Zambia is a Lower Middle Income (LMI) country which has been implementing the Vision 2030 aimed at transforming it into a prosperous middle-income nation by 2030 as indicated in the Ministry of Health, Zambia National Health Strategic Plan (Ministry of Health Zambia, 2011). Among the key issues of this vision is to improve accessibility of quality health to all citizens including achieving the set targets for the Millennium Development Goals; No. 4 – Reducing Child Mortality; No. 5 – Improving

Maternal Health; and No.6 – Combating HIVandAIDS, Malaria and other Diseases (United Nations Development Programme, 2013). However the health sector continues to face challenges, which include high disease burden characterised by high prevalence and impact of communicable diseases, particularly, malaria, Human Immunodeficiency Virus (HIV), Acquired Immune Deficiency Syndrome (AIDS), Sexually Transmitted Infections (STIs), TB, high maternal, neonatal and child morbidities and mortalities. Other contributing factors include inadequate medical staff, weak logistics management in the supply of drugs and medical supplies (Ministry of Health Zambia, 2011).

The Revised Sixth National Development Plan (Ministry of Finance and National Planning Zambia, 2014) reports that the availability of essential drugs averaged 82 percent per year as of 2011 compared to 71 percent in 2005. Meeting this increasing demand has not only been left to the government through the Ministry of Health (MoH) but shared with the participation and corporation of different co-operating partners (CPs) such as the United Nations Development Programme (UNDP) and Churches Health Association of Zambia (CHAZ), United Nations Children's Fund (UNICEF) and United States Agency for International Development (USAID) facilitated health projects. Therefore, in achieving this goal of having the essential medicines available, there has been a supply chain which starts with planning of what essential medicines should be procured, in what quality, quantity and at what time. This is followed by procurement of the planned and budgeted medicines, shipping/transporting, storage, distribution and dispensing. Yadav (2007) opined that for the MoH and UNDP-Global Fund procured medicines and for donated medicines to the government; they are stored and distributed by the Medical Stores Limited (MSL) whereas for those that are procured under Global Fund-CHAZ, CHAZ provides storage and distribution while John Snow, Inc. (JSI) provides storage and distribution for those that are procured under USAID.

The public sector supply chain of medicines and medical supplies contribute to over 60% of health care obtained in Zambia. Medical Stores Limited (MSL) is the national medical store and it manages the storage and distribution of drugs for the MoH. Each district is served once a month by MSL (some may require additional deliveries) in compliance with a pre-set schedule The distribution system follows a pull-logic wherein shipments are based on actual demand off take (or stock levels) at the districts

and not a centrally developed forecast for each district (Yadav, 2007). Therefore, the supply chain of medicines (including essential medicines) through MSL can be described using figure 1.1 Yadav (2007);

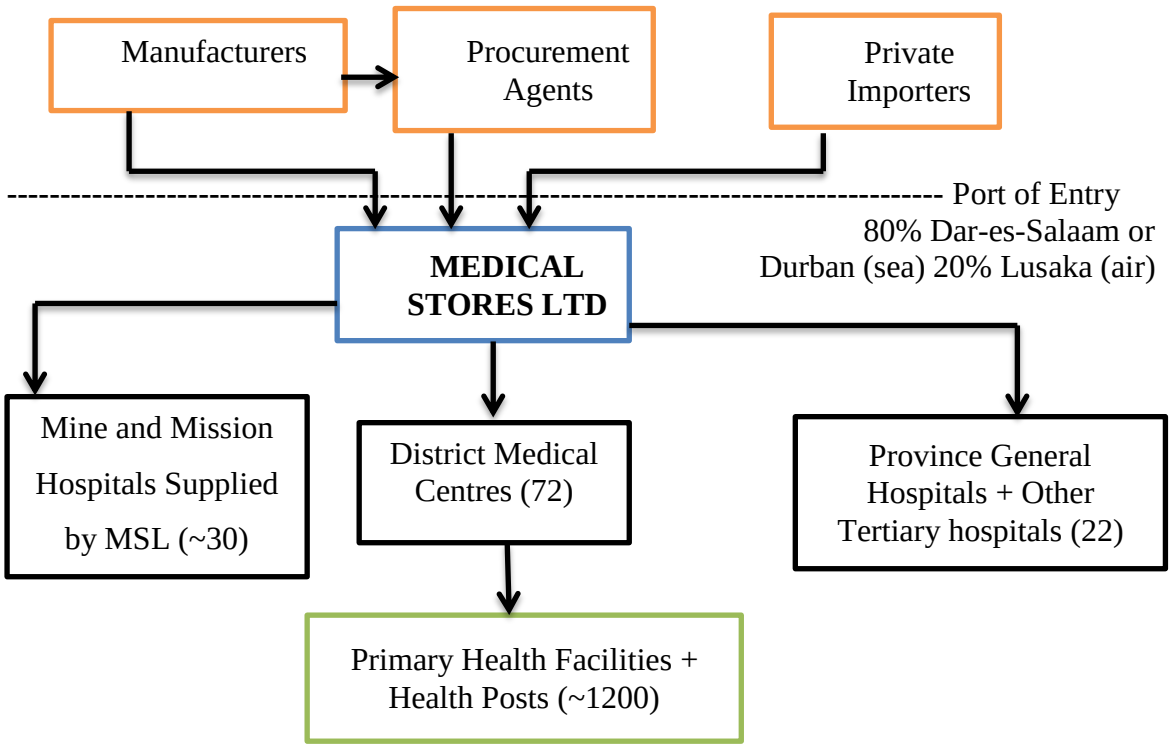

Figure 1.1 Public-Sector Distribution Chain of Medicines in Zambia
Source: Yadav (2007)

Generally most of the essential medicines in the Zambian supply chain are stored and distributed by MSL. However, there are also other local distributors who participate in the supply chain within Zambia. From the above information, it shows that there are a lot of efforts being put into the supply chain to ensure that every citizen has access to the right medicine, in the right quantities, quality and efficacy, which is safe, at the right place and time. This also has been aimed at making the essential medicines available at the affordable price.

1.1 Problem statement

Since 1992, the Zambian Government has been implementing health sector reforms, aimed at strengthening health service delivery in order to improve the health status of

Zambians. The country has remained under pressure to further reduce the disease burden (Ministry of Health Zambia, 2011).

Therefore, the Zambian Government with the assistance of CPs has spent and continues to spend increased amounts of money on ensuring that these health systems improve through availability of essential medicines. Most of the money spent in improving health systems is allocated to the procurement, storage and distribution of essential medicines throughout Zambia. Taryn (2006) indicates that drug supply is an essential component of health care systems, accounting for 10-30% of health care costs.

However, with increasing CPs being involved in procurement of essential medicines, the process has continued to create complexity in the supply chain. This has led to situations where dispensing health facilities are running out of essential medicines. This is an example of the current problems which start with several parties not communicating adequately during procurement to avoid procuring the same medicines. This is evidenced by published news articles in the Zambian media for cases of ARV medicines running out of stock in parts of Zambia as reported by Chishimba, (2014); Sakala, (2013) and Namaiko, (2015). This has potential to increase drug resistance in citizens on Anti-Retroviral Therapy (ART) as they need the medicines at specific times, place, quantity and quality. There are also prevailing situations where essential medicines in stock at dispensing health facilities expire before they can be used and/or even delivered with quality concerns on their efficacy. These mismanaged issues contribute to the costs of making these essential medicines available, as more funds continue to be spent on the entire supply chain.

The examples provided have consequences such as increasing cost and putting lives of citizen at risk. The major contributing factors would be attributed to lack of effective and efficient Risk Management within the supply chain. Efforts have been made by MoH and CPs to improve the supply chain management but, the results show that not much improvement has been achieved from the continuous reports of drug shortages and stock-outs. These efforts include the creation of the Programme Management Unit (PMU) under MoH-UNDP which also manages the procurement of medicines under Global Fund aided programmes.

The problem statement therefore is; despite the efforts by MoH and CPs to improve the efficiency and effectiveness of the supply chain of essential medicines through different interventions and programmes they have not addressed the risks that are inherent to the supply chain management which reduce the efficiency and effectiveness of these efforts by MoH and CPs.

1.2 Aim of research

The main objective of the study was to identify, analyse and prioritise the risks in public-sector supply chain of essential medicines in Lusaka District and to propose a system that may be used to control and monitor risks.

1.3 Research Objectives

This research was conducted with the following specific objectives:

i. Identify risks in the supply chain of essential medicines, from planning for procurement to dispensing at health facilities;

ii. Rank and prioritise the identified risks according to severity on the supply chain of essential medicines;

iii. Determine the impact and consequences of the risks on the supply chain with focus on timely availability and affordable essential medicines at health facilities; and

iv. Propose a model for identifying, analysing, prioritising, controlling and monitoring negative risks within the supply chain so as to improve the efficiency of the supply chain.

1.4 Research Questions

i. What supply chain problems do health facilities face in ensuring that they have adequately stocked essential medicines?

ii. What problems are faced by the provincial and district health offices to ensure that health facilities within the district are stocked with sufficient and quality essential medicines?

iii. What measures are put in place by essential medicines distributors to ensure that the medicines are stored appropriately, delivered at the right point and how is quality and security of medicines assured during storage and transportation to the health facilities?

iv. What measure and systems are put in place by procuring entities to ensure that they procure the essential medicines in right quantities and quality as required by the dispensing health facilities?

v. What measures and systems are put in place by the national medicines regulator to ensure that the quality, efficacy and safety of essential medicines along the supply chain?

1.5 Delimitation

The study only focused on the public sector supply chain of essential medicines in Lusaka District. It did not include the private sector supply chain and used the definition of WHO for essential medicines. However, there were some administrative challenges with getting authorisation from MoH to assist with the research in its offices along supply chain. This could be attributed to the sensitivity of the research subject as well as recent changes from MoH's policies and guidelines on conducting health research within its offices at the time of the study. Therefore, the study was conducted with participants contributing in their personal capacity and using their experiences to respond to the questionnaire surveys.

1.6 Summary

In this chapter, an introduction and background to the challenges in accessing medicines in various countries around the world, in Africa and particularly in Zambia were highlighted. These challenges in accessing the essential medicines have been understood to vary from one country to the other with same similarities in the division into developed, developing and underdeveloped countries as literature indicates. Therefore, Zambia shares similar challenges to other developing countries in which the in-country supply chain of essential medicines does not include manufacturing but however, starts with procurement through to dispensation at health facilities.

1.7 Dissertation outline

i. Chapter 2: Literature review

The chapter discusses the definitions, classifications and studies in risk management and related subjects within the medicines supply chains. It highlights risk management and how it is integrated into supply chain management. The relationship between supply

chain efficiency and integrated risk management with an output focused on timely availability of affordable essential medicines with right quality and quantity.

ii. Chapter 3: Research methodology

The chapter illuminates the research methodology that was adopted and applied in conducting the research. The chapter includes the research design, the sample population and the sampling tool, including techniques adopted for the data collection.

iii. Chapter 4: Data analysis

The chapter elaborates the obtained results using the methodology as outlined in this chapter. The results are analysed in relation to satisfying the research objectives and answering the established research questions.

iv. Chapter 5: Discussion of results

The chapter discusses the results of the data analysis as presented in this chapter. It indicates the classification and prioritising of the risks to highlight the importance of the risks with regard to further control. The discussion of results includes assessment of the supply chain and the impact of the analysed risks

v. Chapter 6: Proposed RM system for essential medicines

The chapter proposes a risk management system that may be adopted by implementing organisation and institutions within the public sector supply chain of essential medicines categories.

vi. Chapter 7: Conclusion and recommendations

This chapter presents the final conclusions from the study and recommendations. The conclusions that were made from the results of the study in line with the initial objectives and the recommendations of the direct and indirect benefits of the results in improving supply chain management of essential medicines.

2 CHAPTER TWO: LITERATURE REVIEW

2.0 Introduction

The previous chapter gave an introduction and background to the study, definition of some terms, the statement of problem and the justification of the study. In addition to the aforesaid, objectives of the study were also outlined. Literature concerning studies and publications in the fields of risk management and supply chain management of essential medicines were reviewed as described in this chapter. The studies and publications were cautiously selected from the available materials based on the relevance to; supply chain of essential medicines, causes of essential medicines shortages and stock outs, risk management in supply chain, quality assurance of essential medicines in supply chain and quality risk management. The review is presented in two parts; part one looking at definitions and part two presents a review of studies in supply chain of essential medicines.

The definitions assisted the researcher to appreciate and understand the concepts applicable in the field of general risk management and classifications of some risks obtaining in supply chain of essential medicines within Zambia. The review of published risk management studies in supply chain of essential medicines aided the researcher to comprehend the risk management techniques and their applications in different areas of supply chain management.

2.1 Definitions

2.1.1 Essential Medicines

The World Health Organisation (WHO) defines essential medicines as "those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford." Therefore, they are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

2.1.2 Risk

Risk is a measure of the probability and consequence of not achieving a defined project goal (Kerzner, 2009). Risk has two primary components for a given event and as shown in Figure 2.1:

- A probability of occurrence of that event
- Impact (or consequence) of the event occurring (amount at stake)

Risk = Probability (of a given event) x Severity (negative business impact)

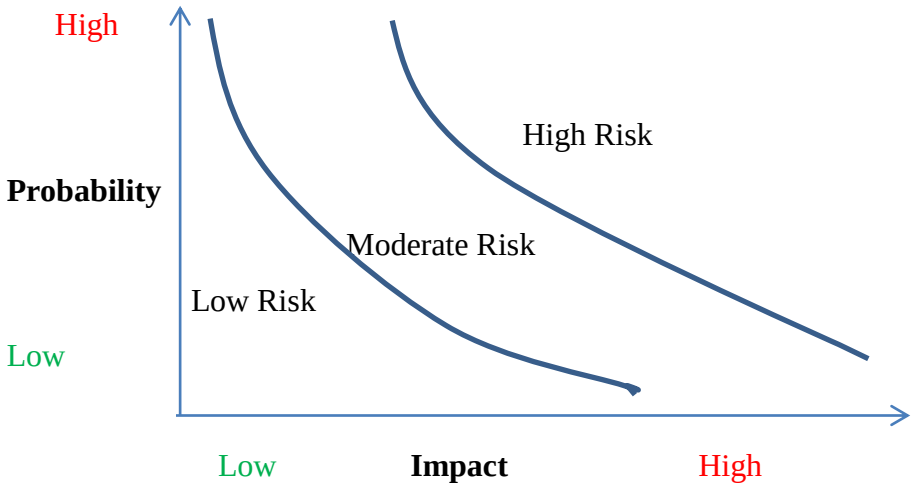

Figure 2.1: Overall risk is a function of its components
Source: Kerzner (2009)

2.1.3 Risk Management

Risk management is the act or practice of dealing with risk. It includes planning for risk, identifying risks, analysing risks, developing risk response strategies and monitoring and controlling risks to determine how they have changed (Kerzner, 2009).

This research sought to focus on risk management that is performed with some elements of quality management. International Conference on Harmonisation (ICH): Harmonized Tripartite Guideline Q9 defines it as "a systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product lifecycle". This means that under risk management there will be processes of risk identification, assessment, ranking and

prioritization, responses, control and monitoring. As the aforementioned processes are to be undertaken in the execution of the supply chain, there should be a regular communication as well among parties within the supply chain. Therefore, Muhammad and Rehana (2014) affirm the use of Figure 2.2 as a risk management tool in Quality Risk Management in pharmaceuticals. It summarises the essential phases and stages of generic risk management for organisations, institutions and project management teams.

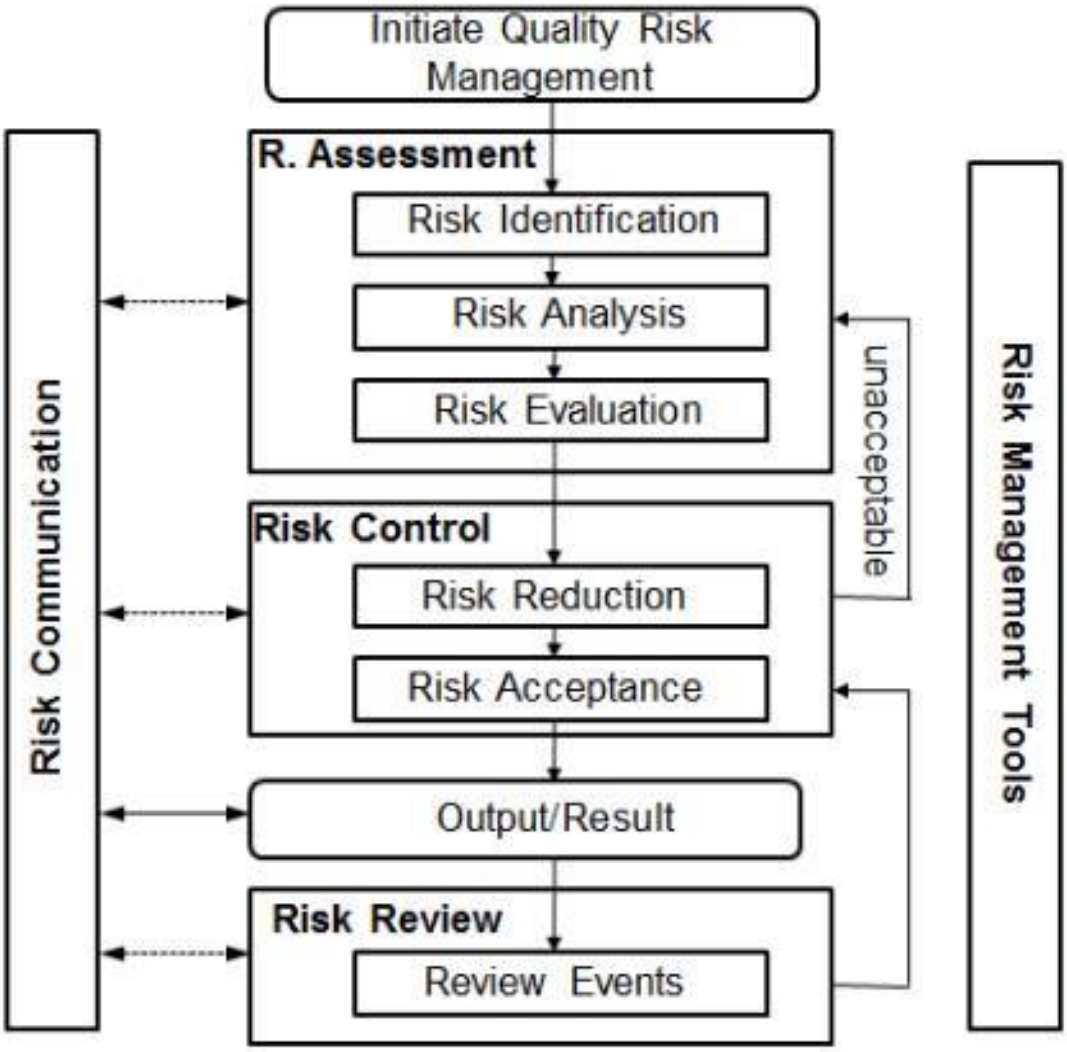

Figure 2.1: Risk Management Process
Source: Muhammad and Rehana (2014)

2.1.4 Risk identification

This is an organized use of information to identify hazards referring to the risk Vijayakumar et al., 2014). Project Management Institute, (2013) affirms the use of information in determining which risks might affect the project and then documenting

characteristics of those risks. According to Project Management Institute, (2013) risk identification can be performed using but not limited to the following techniques;

- **Delphi technique**

  This is a technique that is used in risk identification using the participation of experts within the subject under study. It uses several iterations in the process of building consensus among participants (Chia-Chien & Brian A., 2007). It involves a process of soliciting information on risk identification and finally agreeing on the results from experts while maintaining anonymity among them. It has an advantage of removing biasness from participants and is able to capture exhaustive technical input. However, it has a disadvantage of having a situation of not having available experts to participate and usually takes longer than the available time.

- **SWOT Analysis**

  The Strength, Weakness, Opportunity and Threats (SWOT) analysis is a technique used in formulation of strategy and company performance improvement processes (Dinu, 2012). The technique involves assessing the company or organisation's areas of strength and weakness, the opportunities presented and the threats that surround the effective management of the organisation. Risk identification then is applied following the factors that generate the challenges to the organisation in utilising its strength, improving on its weaknesses, inability to utilise the opportunities and failure to address the threats. The technique has a disadvantage of not being specific with the risk identification and thereby increases operational risks in utilising it.

- **Cause and Effect Diagramming**

  This technique is also called the "fish bone" technique and is used in various processes including risk identification. The technique depends on initially identifying the contributing factors towards achieving the objective and mapping the possible areas and points of failure (Bialek et al., 2009). This technique presents a direct way of identifying risks but its efficiency is dependent on the area being studied as some causes may not be fully isolated for effective analysis towards contributing to the effect.

- **Brainstorming**

  This technique involves a process of organising sessions of group discussion with different personnel who are in direct contact with the areas in which risk identification is being carried out (Dinu, 2012). The technique requires different sessions for each type of grouping of the organisation including technical areas, support areas and management group. It is effective in organisations where participants fully understand the operations of the organisation. However, it becomes ineffective for sessions in which certain participants can't provide the required input for accurate determination of the risks and thereby renders the process inefficient.

- **Interviewing and Questionnaire**

  This technique of risk identification requires having individualised or group interviews with the participants that are involved with the activities requiring risk identification. This is done with guiding questions through which the risks have to be identified by the participants (Dinu, 2012). A questionnaire is done similar to the interviews. In addition, it provides for a possibility of validating the risks being identified by respondents. At the same time, it provides for open ended responses that can account for the missing risks that may require addition.

Therefore, in this study, interviews and a questionnaire survey were identified to be dependable to be used as risk identification instruments. This was arrived at with regard to the study population which was presented with varying work levels and expertise as well as working in different environments. Special consideration was also given to the available time in selecting the instruments to use. Consequently, interviews and a questionnaire survey presented both reliability and validity towards the research as well as avoiding biasness by the respondents.

2.1.5 Risk analysis and evaluation

Risk analysis is the estimation of the risk associated with the identified hazards. It is the qualitative or quantitative process of linking the likelihood of occurrence and severity of harms. In some risk management tools, the ability to detect the harm also

factors in the estimation of risk and risk evaluation compares the identified and analysed risk against given risk criteria (U.S. Department of Health and Human Services Food and Drug Administration, 2006). Viornery and Le Goff, (2010) also affirm that the evaluation of the risk to quality of the medicine is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient. Therefore, risk analysis and evaluation is undertaken with focus on three major components as O'Mahony, (2011) indicates that evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient. These components are priority, severity and detectability. Vijayakumar et al, (2014) summarises the three components in risk equation 2.1;

RISK = PRIORITY * DETECTABILITY * SEVERITY …… **(2.1)**

Where,

Severity - Criticality of the product.

Priority - Complexity of the site (multi-product).

Detectability - Audit history.

However, Muhammad and Rehana, (2014) assert that risk assessment consists of identification of hazards and the analysis and evaluation of risk associated with exposure to those hazards. The steps include risk identification, risk analysis and risk evaluation. The factors used to evaluate the risk are severity, likelihood and detection.

Severity: The severity of the negative impact that will accompany an adverse event. This is expressed on scale deemed appropriate.

Likelihood/Probability: The likelihood of an adverse event occurring is measured on a relative scale such as across a time period or number of operations (Probable to improbable).

Detection: The likelihood that a negative condition will be detected before the negative impact occurs.

2.1.6 Risk response and control

Risk control includes decision making to reduce and/or accept risks. The purpose of risk control is to reduce the risk to an acceptable level. The amount of effort used for risk control should be proportional to the significance of the risk (Muhammad & Rehana, 2014). Watson et al., (2013) as well as U.S. Department of Health and Human Services Food and Drug Administration, (2006) define it as the process of determining the appropriate set of responses for each of the risk events identified and prioritized, using the risk evaluation approach to an acceptable level because the amount of effort used for risk control should be proportional to the significance of the risk. Watson et al., (2013) indicate that the following can be used to control negative risks which are usually selected based on the features of the risk events;

Hedging

To hedge against supply chain risks, strategically placed resources are provided within the supply chain to make the supply chain less susceptible to the impact of risk events; this minimizes the disruption of operations. One example of hedging is to place buffer stock at specific levels in the supply chain to respond rapidly to changes in demand.

Reducing

Reducing risks to the supply chain refers to approaches that limit the consequences of risk events by focusing on the underlying causes of the risk.

Avoiding

Avoiding risk refers to approaches that reduce the likelihood of risk events occurring by changing the dynamics of the supply chain.

Accepting

Risk acceptance is a deliberate decision to take no action on the identified risk. Instead,

efforts of the risk management team focus more on developing a contingency plan to minimize disruption to the supply chain if the risk event occurs.

2.1.7 Risk review, monitoring and communication

This a continuous process that happens throughout the entire risk management process as Watson et al., (2013) affirm that risk monitoring process includes identifying, analysing, planning, and tracking new risks; constantly reviewing existing risks; monitoring trigger conditions for contingency plans; and monitoring residual risks. The amount or frequency of monitoring must be sufficient to guarantee that the risk is under control and the personnel conducting the monitoring of risks and their control measures should be trained in monitoring procedures.

It also includes reviewing the execution of risk responses while evaluating their effectiveness, Vijayakumar et al., (2014) agree to indicate that risk communication is the sharing of information about risk and risk management between the decision makers and others. The output/result of the quality risk management process should be appropriately communicated and documented. The information included might relate to the existence, nature, form, probability, severity, acceptability, control, treatment, detectability or other aspects of risks to quality.

The entire process must be done comprehensively with all stakeholders of the supply chain. World Health Organisation, (2013) supports that the key stakeholders to be involved include those engaged in both the data collection process for the risk assessment and the decision-making for risk control. The communication should include key risks within an organisation and should be listed in a register document for the purposes of inspection. This risk register (or equivalent title document) should list and track all key risks as perceived by the organisation and should summarise how these have been mitigated. There should be a clear reference to risk assessments and a list of risk assessments conducted should be included in or linked to the register.

2.1.8 Supply Chain

Supply chain conceptually covers the entire physical process from ordering and obtaining the raw materials through all process steps until the finished product reaches the end consumer (Chartered Institute of Purchasing and Supply, 2014). Mona et al., (2013) also assert that supply chain is a set of players, processes, information, and resources which transfers raw materials, and components to finished products or services and delivers them to the customers. Therefore, in supply chain of health

products including essential medicines the supply chain is entirely done with an objective of ensuring the essential medicines and other health products are delivered to the patient. Figure 2.3 summarises the conceptual supply chain, defined above, as a customer focused process;

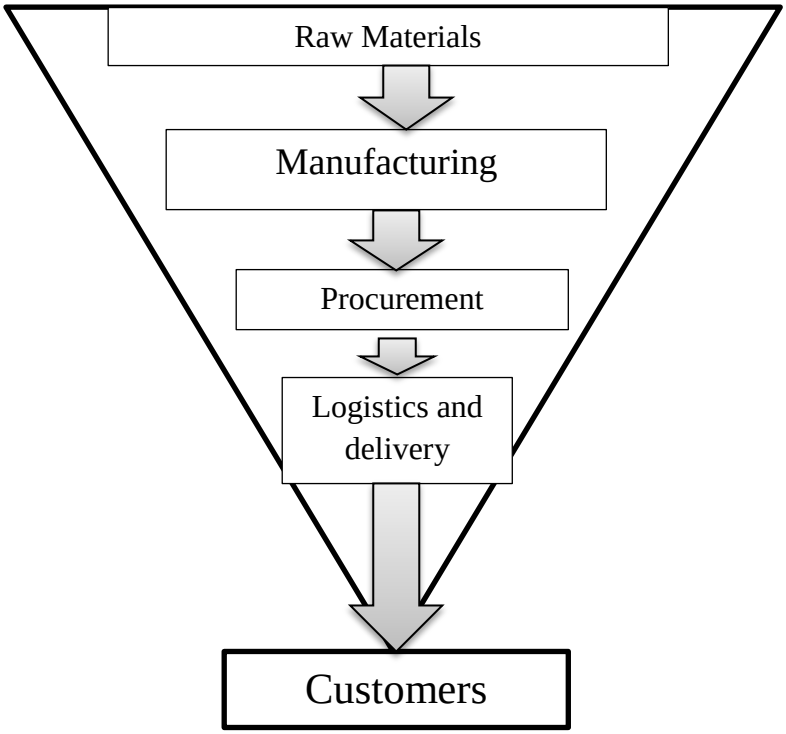

Figure 2.2 Supply chain
Source: Researcher (2015)

Therefore, for the supply chain to function there is a need for coordination among participating partners and organisation as stressed by Shanmugan and Sajal (2012) that supply chain relationships are generally long term and require considerable strategic coordination within the organization and between the supply chain partners.

2.1.9 Supply Chain Management

This is the continuous planning, developing, controlling, informing and monitoring of actions within and between supply chain links so that an integrated supply process results which meets overall strategic goals (Chartered Institute of Purchasing and Supply, 2014). Therefore, supply chain management can be described using the cycle as indicated in the USAID Guidelines for managing the HIV/AIDS supply chain (John Snow, 2005) as shown below;

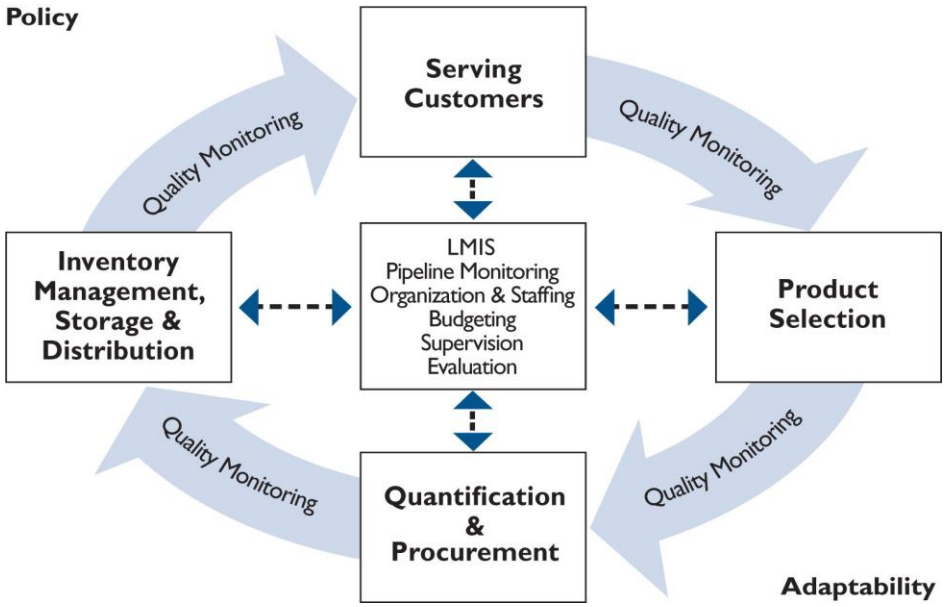

Figure 2.3: Logistics Cycle
Source: Watson et al., (2013)

Emphasis in supply chain management is made on having several processes and interested parties being involved at different stages and phases. Naude and Badenhorst-Weiss (2011) also indicate that supply chain management includes the purchasing of materials, transforming them into intermediate goods and final products, and delivering a product or service to the final customers and includes all those activities involved in the flow of materials through the supply chain.

2.2 Risk Management in Medicines

Pharmaceuticals risk management is not applied independently but together with quality management (World Health Organisation, 2013). Risk management has recently been introduced into quality management of pharmaceuticals after several experiences that quality management cannot be effectively managed without addressing risk management. Therefore, international standards and guidelines bodies such as USFDA, EMA, PIC/S, WHO and other institutions are promoting risk based quality management systems in pharmaceuticals which includes essential medicines. Muhammad and Rehana, (2014) confirm that despite involving several stakeholders, managing the risk and quality of pharmaceuticals is considered very important in the protection of the patient.

2.3 Supply Chain Management of Medicines

The medicine supply chain is a complex system with public and private organisations such as private distributors, governmental warehouses and NGOs with several tiers as described by Anna, (2013). The complex of such a system applies equally in Zambia. In line with Anna, Yadav (2007) also agrees that to ensure people have access to essential medicines and to preserve the quality of the medicine, a functioning medicine supply chain is necessary, which includes procurement, appropriate warehousing and efficient transportation.

Dalberg and MIT-Zaragoza (2008) emphasise that achieving good health outcomes requires supply chains that provide consistent availability of affordable, high-quality products in a location that is geographically accessible to the target population. However, due to some challenges the consistent availability of affordable medicines is not guaranteed as John Frimpong et al., (2013) also affirm that in most sub-Saharan Africa, the medical supply systems are often unreliable and therefore do not guarantee regular supply of these essential medicines. Therefore, supply and availability of health commodities including affordable essential drugs, vaccines and contraceptives depend on effective and efficient logistics systems to move essential commodities down the supply chain to the service delivery point and, ultimately, to the end user (patient). Figure 2.5 summarises the pharmaceutical supply chain with it components and various parties that are involved in different specific functions with a final objective of delivering the product to the patient.

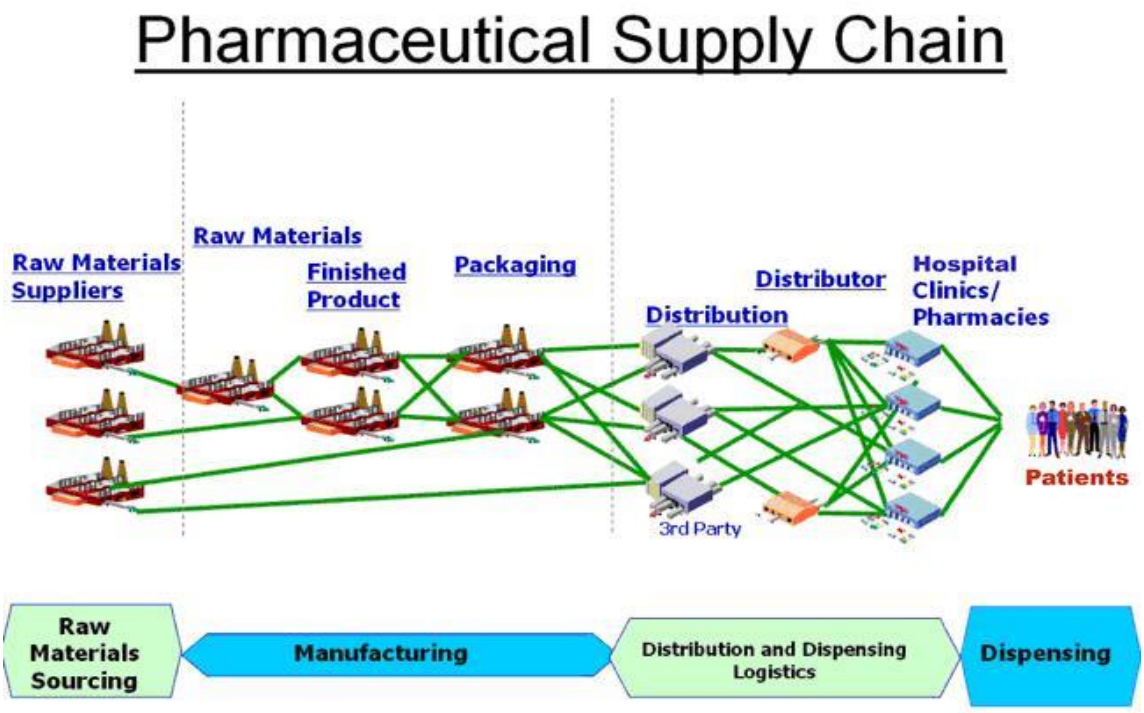

Figure 2.4 Pharmaceutical supply chain
Source: Prashant et al., (2011)

2.3.1 In – country supply chain management

In contrast to Figure 2.5 shows that supply chain is the same except that in Zambia manufacturing is not part it. This is because most of the essential medicines are not manufactured within the country but imported. According to Prashant et al., (2011) and Yadav (2007) the public sector supply chain of medicines in Zambia (in-country) involves selection and quantification, registration, procurement, storage, distribution and dispensing as shown in Figure 2.6 Yadav (2007). It shows the mentioned categories and the involvement of each institution including CPs. The CPs support the entire supply chain with different and specific programs according to Ministry of Health Zambia, (2011).

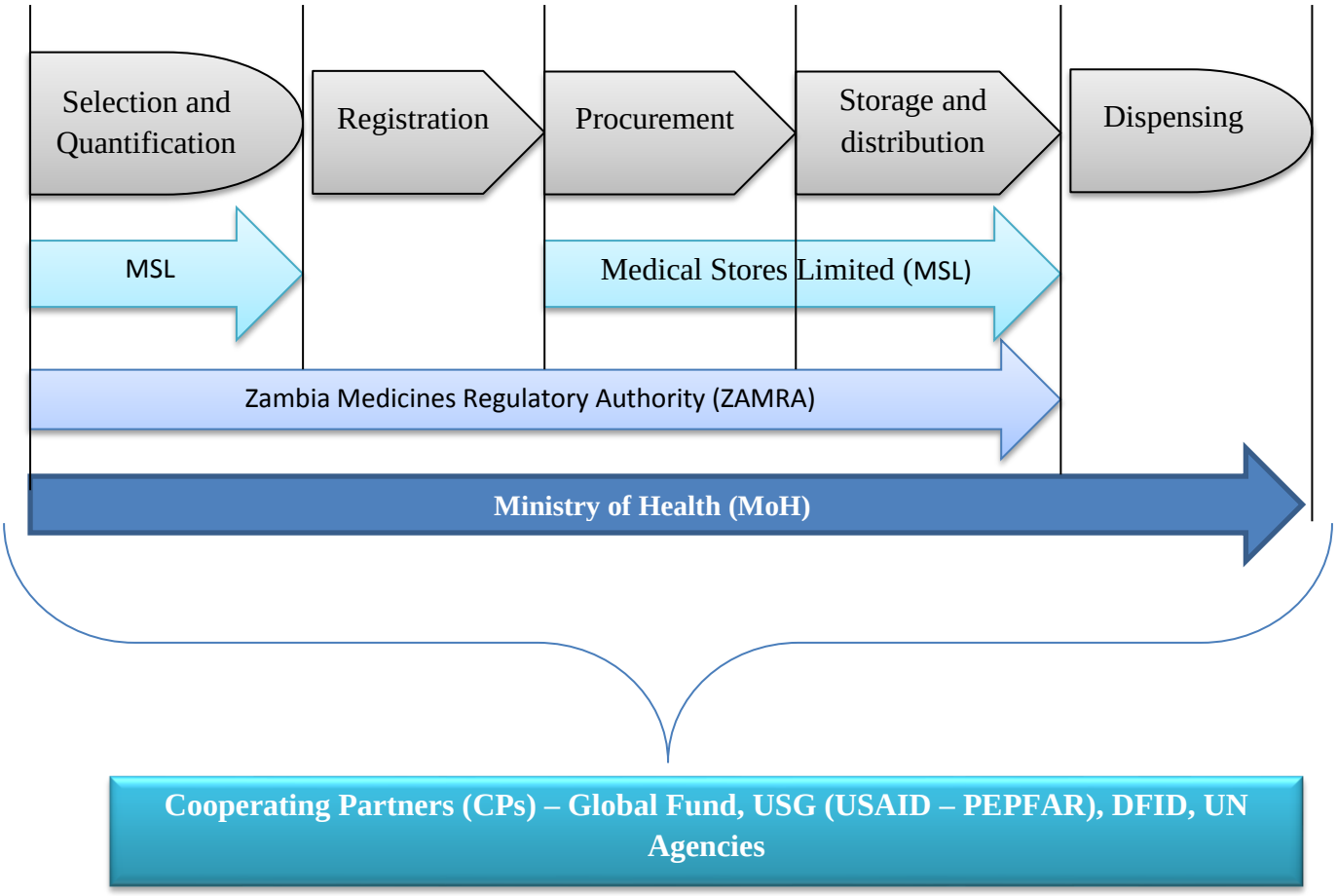

Figure 2.5 Zambia public sector supply chain of medicines
Source: Researcher (2015)

(i) **Selection and Quantification**

Selection and quantification is based on resource availability to select the medicines for procurement for a defined period. Budget and cost benefit analysis is used to guide drug selection using the national Essential Medicines List (EML) and done by a committee comprising of staff from MoH, ZAMRA and MSL (Prashant et al., 2011). Selection takes into account efficacy, safety, costs, product storage requirements and shelf life (Kamuzora, 2011).

(ii) **Registration**

Registration of medicines is done by the national regulatory authority, ZAMRA, on behalf of MoH. Its responsibilities include product registration, licensing of pharmaceutical establishments, and post-marketing surveillance (Prashant et al., 2011).

(iii) **Procurement**

The procurement of medicines is done by the government through the MoH and with assistance and participation from ZAMRA, MSL and CPs. The Ministry of Health receives funds for health financing from both the Ministry of Finance and the bilateral and multilateral cooperating partners. Some cooperating partners channel their funds directly to MoH and others channel it through the Ministry of Finance. The ministry makes the funds available to MoH for drug purchasing based on a quarterly/monthly disbursal schedule (Prashant et al., 2011).

(iv) **Storage and Distribution**

Medical Stores Limited (MSL) is the national medical supplier and it manages the storage and distribution of drugs for MoH. MSL provides and manages warehousing and storage of medicines on behalf of MoH and then distributes them on a schedule to district medical offices and some health facilities depending on the received orders periodically as planned (Prashant et al., 2011). Regulation and quality assurance of medicines under storage both at MSL and at health facilities is done by ZAMRA (Zambia Medicines Regulatory Authority, 2014).

(v) **Dispensing (Delivery)**

Dispensing of pharmaceuticals is carried out at most health facilities free of charge (Prashant et al., 2011).

2.3.2 Efficiency of supply chain management of medicines

Efficiency can be defined as the ratio of output to the input i.e. (Output/Input). Mike et al., (2011) define an effective supply chain as being characterized by the timely, reliable movement of health commodities and data up and down the supply chain: from the service delivery point (such as health posts, clinics, and hospitals where health commodities are dispensed) to the district, regional, and national levels and back. Therefore efficiency and effective supply chain management leads to high performance of the supply chain. Prashant et al., (2011) agree that a well-designed medicines supply system ensures that procurement, warehousing and transportation are seamlessly linked to form a network that can deliver the requested medicines to health facilities and pharmacies in good time, in the correct quantities and at the

lowest possible cost. This is in agreement with the WHO's definition and policy on essential medicines globally.

Increasing performance of any system depends on the inputs factors. Omar and Valerie, (2009) summarise the four categories that encompasses critical success factors (CSF)s of well performing supply chain management system which are as follows;

i. **Performance characteristics**

This class gathers various forms of performances which include: customer performance, supplier performance, financial performance, market performance, delivery performance, performance of service providers, alliance performance, and organizational performance. The goal is generally to improve these performances.

ii. **Relational and contextual characteristics**

These characteristics represent the various relationships, which can exist between the actors of the supply chain, and characterize the context, in which evolves the company. These characteristics describe the behaviour, the vision, the type of relationships and interactions between a company and its partners (suppliers or / and customers).

iii. **Technical and technological characteristics**

This class is based on the use of information technologies. It combines the techniques and the technological choices made by a company such as information sharing support technology, inter-firm system integration mode and e-business technologies.

iv. **Characteristics of supply chain practices**

This class collects characteristics dealing with supply chain practices. These practices have been defined as a set of activities undertaken in an organization to promote effective management of the supply chain such as the practices of information sharing, production and planning.

However, Mohamed and Abubakar, (2014) further detail the CSFs as collaborative partnership, information technology, top management support and human resource. These are further explained as below;

i. Collaborative Partnership

The goal of collaboration in supply chain is to have a common, transparent and visible demand pattern that comes in a wide range of forms. Successful collaborative partnership in supply chain offers many positive outcomes such as minimizing costs, improved service efficiency and effectiveness, improved revenue and allows for a greater operational flexibility.

ii. Information Technology

Information has always been central to the efficient management of logistics and now enabled by technology, it is providing the driving force for competitive logistics strategy. Information and Communication Technology (ICT) has a positive relationship with what will improve supply chain performance, support supply chain efficiency, and enable greater supply chain integration.

iii. Top Management Support

Management support is critical in Supply Chain Management (SCM). Top management support comes in the form of allocating resources, reward and time, supporting strategic purchasing, developing strategic supplier relationship and striving for information technology adoption.

iv. Human Resource

Even though organizational support is important, supply chain managers who have the right skills will have a better chance of being successful. One of the components of human resource management (HRM) is training, as equipping the best employees with proper training will benefit the supply chain processes. Managerial support and employee commitment will lessen the supply chain implementation barriers and enhance supply chain performance.

In addition, Mungu, (2013) explains further that an efficient and effective SCM addresses the following challenges;

- Distribution network configuration: Includes number, location and network missions of suppliers, production facilities, distribution centres, warehouses, cross-docks and customers.
- Distribution strategy: Questions of operating control (centralized, decentralized or shared); delivery scheme and transportation.
- Trade-Offs in logistical activities: The above activities must be well coordinated in order to achieve the lowest total logistics cost. Trade-offs may increase the total cost if only one of the activities is optimized.
- Information: Integration of processes through the supply chain to share valuable information, including demand signals, forecasts, inventory, transportation, potential collaboration, inventory management, quantity and location of inventory, including raw materials, work-in-process and finished goods.
- Cash-Flow: Arranging the payment terms and methodologies for exchanging funds across entities within the supply chain.

In concluding the aforementioned factors which are in agreement with those proposed by Yadav, (2007) indicate that an efficient public sector supply chain management is dependent on the individual performances of each participating organisation, institution and the entire supply chain system of medicines. Frimpong et al., (2013) also agree that effective and efficient health logistics management in the health supply system depend on four essential factors. Firstly, financial resource for the procurement of health commodities is very important. Secondly, effective supervision from top-down the supply chain and the entire health care delivery system is vital to ensuring efficiency in the health commodity supply system. Thirdly; constant monitoring and evaluation within the supply chain by health logistics managers. Lastly, distribution of health commodities evenly within the supply system also brings about effectiveness and efficiency in health logistics system. Thus, financial resource, supervision, monitoring and evaluation and ensuring that health commodities are distributed evenly are crucial in getting effective and efficient logistics management in health sector.

In conclusion, an efficient supply chain management will ensure that affordable medicines are made available at the right place, in time and in good quality. The

outcome efficiency is guaranteed by the performance of individual organisations within the supply chain. For in-country supply chain of medicines, the organisations and institutions fall under the categories of selection and quantification (forecasting), registration (regulation), procurement, storage (warehousing), distribution and dispensing of medicines (Prashant et al., 2011). Therefore, efficient and effective management of the above mentioned categories guarantees an efficient SCM of medicines within the country.

2.4 Integration of Risk Management into Supply Chain Management of Medicines

Supply chain risk management (SCRM) is a crucial and indivisible part of supply chain managements that sets out to achieve its objectives and attempts to minimize supply chain vulnerability and uncertainties through mitigation plans (Mona et al., 2013). Risk management has been traditionally handled by specific corporate bodies, mostly insurance companies. However, Andreas and Ulf, (2004) assert that, following the Albuquerque accident, Ericson has made risk management part of organisation management in its supply chain. Ericson's integration of risk management in its supply chain operations ensured that negative impacts from risks are reduced and mitigated efficiently after occurrence. This has led to improved performance management and an efficient supply chain management system.

Medicines like other products are not immune to supply chain risks. According to Nagitta et al., (2010) a number of risks exist in the supply chain of essential medicines however, they are not managed efficiently and effectively as the risk management process is not fully integrated. Effective risk management has a lot of benefits as proposed by Watson et al., (2013). Some of the benefits include;

- Increasing the likelihood of achieving the supply chain objectives
- Reducing costs and improve the overall efficiency of the supply chain operations
- Improving the governance and leadership of the supply chain
- Improving customer and stakeholder confidence and trust in the supply chain
- Focusing the supply chain manager on proactively managing risk, not only reacting to unforeseen events
- Bringing stakeholders together and improves coordination

However, due to the inability to integrate risk management into the supply chain management of essential medicines, the challenges as identified by Anna (2013) as well as Joseph et al. (2014) are not effectively and efficiently managed thereby affecting the performance of the supply chain management of essential medicines. This is also evidenced by Mike et al. (2011) and Kamuzora (2011) who indicate that risks are identified and their mitigation is not effective as developing countries continue to face recurring challenges in availability of essential medicines. The only studies that have been done by Watson et al. (2013) on the proposed integration of risk management as generic tool have not addressed the risk management for essential medicines. Essential medicines deserve different kind of attention as defined by World Health Organisation, (2015).

Therefore, the knowledge gap and the lack of research suggest that further research needs be done on integrating risk management into supply chain management of essential medicines. As evidenced above, effective risk management provides benefits into supply chain management of health products (Watson et al., 2013). This clearly confirms the fact that integration of risk management into supply chain management of essential medicines would reproduce similar benefits with minor differences owing to the specific requirements surrounding management of essential medicines.

2.5 Summary

This chapter outlined both conceptual and theoretical framework literature review from which the study was designed through establishing a gap in research and knowledge in the integration and application of risk management into supply chain management of essential medicines in Zambia. Global, regional and national published literature on risk management and supply chain management of essential medicines was reviewed.

A criterion for selection of literature to review was based on relevance to general risk management, supply chain management and their integration as management tools to improve organisational, institutional and project teams' performance. The reviewed literature established the existing gap in research and knowledge regarding integration of risk management into supply chain management to improve performance management of the latter.

The next chapter illuminates the research methodology that was adopted and applied in conducting the research. The chapter includes the research design, the sample population and the sampling tool, including techniques adopted for the data collection.

3 CHAPTER THREE: RESEARCH METHODOLOGY

3.0 Introduction

The previous chapter outlined both conceptual and theoretical framework literature review from which the study was designed through establishing a gap in research and knowledge in the integration and application of risk management into supply chain management of essential medicines in Zambia. Global, regional and national published literature on risk management and supply chain management of essential medicines was reviewed.

This chapter presents the research methodology that was adopted in conducting the research. The chapter includes the research design, the sample population and the sampling tool including techniques adopted for the data collection. The methodology is further explained in relation to the selection and application in order to maintain reliability and validity of the data to be collected and analysed.

3.1 Research design

Based on the literature reviewed from the previous chapter, it is evident enough that not so much research has been undertaken in integrating risk management into supply chain management of essential medicines. Therefore, a descriptive methodology was adopted for this research using a case study approach. Despite being descriptive, a mixed method approach was used by adopting both qualitative and quantitative methods as advised by Jan and Bartjan, (2010). Medecins Sans Frantiers (2002) agrees that the research has to establish the existence of a phenomenon in the study area and determine the contributing factors.

3.1.1 Qualitative research

This is a study approach that involves conducting research descriptively without quantifying the observations (Medecins Sans Frantiers, 2002). The methods used under this type of research include; interviews, brain storming, discussions and questionnaires. The main difference with quantitative researche is that qualitative research does not involve mathematical procedures in interpreting and explaining the research results (Michael et al., 2000). This method of research is used mainly to

study the way organisations, institutions and individuals behave and interact (Medecins Sans Frantiers, 2002).

3.1.1.1 Validity and reliability

Validity in research is concerned with the accuracy and truthfulness of scientific findings that should demonstrate what actually exist and a valid instrument or measure should actually measure what it is supposed to measure (Brink, 1993). Internal validity is the term used to refer to the extent to which research findings are a true reflection or representation of reality rather than being the effects of extraneous variables. External validity addresses the degree or extent to which such representations or reflections of reality are legitimately applicable across groups. However, Tony and Martin (2000) define it by indicating that an account is valid or true if it represents accurately those features of the phenomena that it is intended to describe, explain or theorise. It is normally established through consideration of three main aspects: content validity, criterion-related validity and construct validity.

Tony and Martin (2000) define reliability as the degree of consistency with which instances are assigned to the same category by different observers or by the same observer on different occasions. Brink (1993) also agrees that the ability of a research method to yield consistently the same results over repeated testing periods. This clearly indicates that any chosen research method is supposed to have a degree of reliability. Brink (1993) further states that many qualitative researchers avoid using validity and reliability and use terms such as credibility, trust worthiness, truth, value, applicability, consistency and conformability, when referring to criteria for evaluating the scientific merit of qualitative research.

3.1.2 Case study

Like many other research methodologies, it is always expected that the selection of a research method will be dependent on the reviewed literature and the theory that comes of it (Pamela and Susan, 2008). Therefore, the research method will be adopted with the expectation that it will be able to address the research problem identified in the literature review. According to Pamela and Susan (2008), a case study design should be considered when:

a) the focus of the study is to answer “how” and “why” questions;
b) you cannot manipulate the behaviour of those involved in the study;
c) you want to cover contextual conditions because you believe they are relevant to the phenomenon under study; or
d) the boundaries are not clear between the phenomenon and context.

And then once it has been determined that the research question is best answered using a qualitative case study and its boundaries have been determined, then there must be consideration on what type of case study will be conducted. The selection of a specific type of case study design is usually guided by the overall study purpose which can be explanatory, exploratory or descriptive (Pamela & Susan, 2008).

3.1.2.1 Single vs multiple case study research

Michael et al. (2000) indicate that single case study research is applicable when the case is:

- critical or unique or where the researcher is able to access a previously remote phenomenon;
- critical for testing a well formulated theory;
- an exploratory study or pilot study; shown to be representative of a large population

Pamela and Susan (2008) assert that the ability to look at sub-units that are situated within a larger case is powerful when you consider that data can be analysed within the subunits separately (within case analysis), between the different subunits (between case analysis), or across all of the subunits (cross-case analysis). The ability to engage in such rich analysis only serves to better illuminate the case.

Pamela and Susan (2008) state that; if a study contains more than a single case then a multiple-case study is required. Multiple case studies provide a purposive sample and the potential for generalizability of findings and also provide a more rigorous and complete approach than single case study research due to the triangulation of evidence (Michael et al., 2000). A multiple or collective case study will allow the researcher to analyse within each setting and across settings. Pamela and Susan (2008) continue that this type of a research design has its advantages and disadvantages. Overall, the evidence created from this type of study is considered

robust and reliable, but it can also be extremely time consuming and expensive to conduct.

3.1.2.2 Reliability and validity

Michael et al., (2000) affirm that case study research can achieve integrity or rigour of validity through five approaches: construct validity; confirm-ability; internal validity/credibility; external validity/transferability and finally, reliability/ dependability which are explained as below:

Construct validity: First, construct validity ensures adequate operational measures for the concepts under investigation. Case study research can achieve construct validity by developing its constructs through a literature review, use of multiple sources of evidence, establishing a chain of evidence, and having key external informants review draft case study reports (Michael et al., 2000).

Confirm-ability: Confirm-ability is defined as ability of others to satisfy themselves that the research was carried out in the way it is described by the researcher. The basic technique for ensuring confirm-ability is developing a record of data collected (such as recorded cassette tapes, transcriptions, interview notes, secondary sources) to allow other researchers to observe a chain of evidence. This audit trail would allow an external observer to trace the logical progression of reasoning from the evidence presented to the conclusions drawn (Michael et al., 2000).

Internal validity/credibility: Internal validity/credibility in quantitative research is defined as the identification of causal relationships whereby certain variables may influence other variables in the research study. In case study research, internal validity/credibility can be established by the use of case analysis, cross case analysis, pattern matching, assurance of internal coherence of findings, expert peer review, and the development of diagrams, illustration and data matrices to demonstrate the internal consistency of the information collected (Michael et al., 2000).

External validity/transferability: External validity/transferability is defined as the scope to which the research findings can be replicated beyond the proximate research case studies or generalizability (Michael et al., 2000).

Reliability/dependability: Finally, the test of reliability/dependability deals with the ability of other researchers to carry out the same study and achieve similar results. Therefore, to achieve reliability/dependability in case study research demands the enactment of case study procedures so as to identify documentation trail (Michael et al., 2000).

The essence of case study methodology is triangulation, the combination on different levels of techniques, methods, strategies, or theories. Therefore, a case study approach was adopted in this research. In order to achieve the study objectives and ensure that an effective implementation of risk management process is achieved, the required factors and characteristics were considered in using the methodology to ensure that reliability and validity is guaranteed.

3.2 Data collection

From the literature reviewed in previous chapter, the data collection was chosen in relation to the type of data and with respect to the sample population of the study. The adopted data collection technique included both qualitative and quantitative approaches. The techniques used in the data collection included using ten interviews and discussions as well as fifty self-administered questionnaires.

3.2.1 Sample population

The sample population for the research was taken from the organisations, institutions and individuals involved in the in-country supply chain as established in previous chapter. To achieve the objectives of the research and maintain representation of the entire supply chain, the sample population was drawn from MoH, Lusaka Provincial Medical Office, Lusaka District Medical Office, MSL, ZAMRA and CPs. The mentioned sample population is shown in Figure 2.6 summarised and elaborated in Figure 3.1.

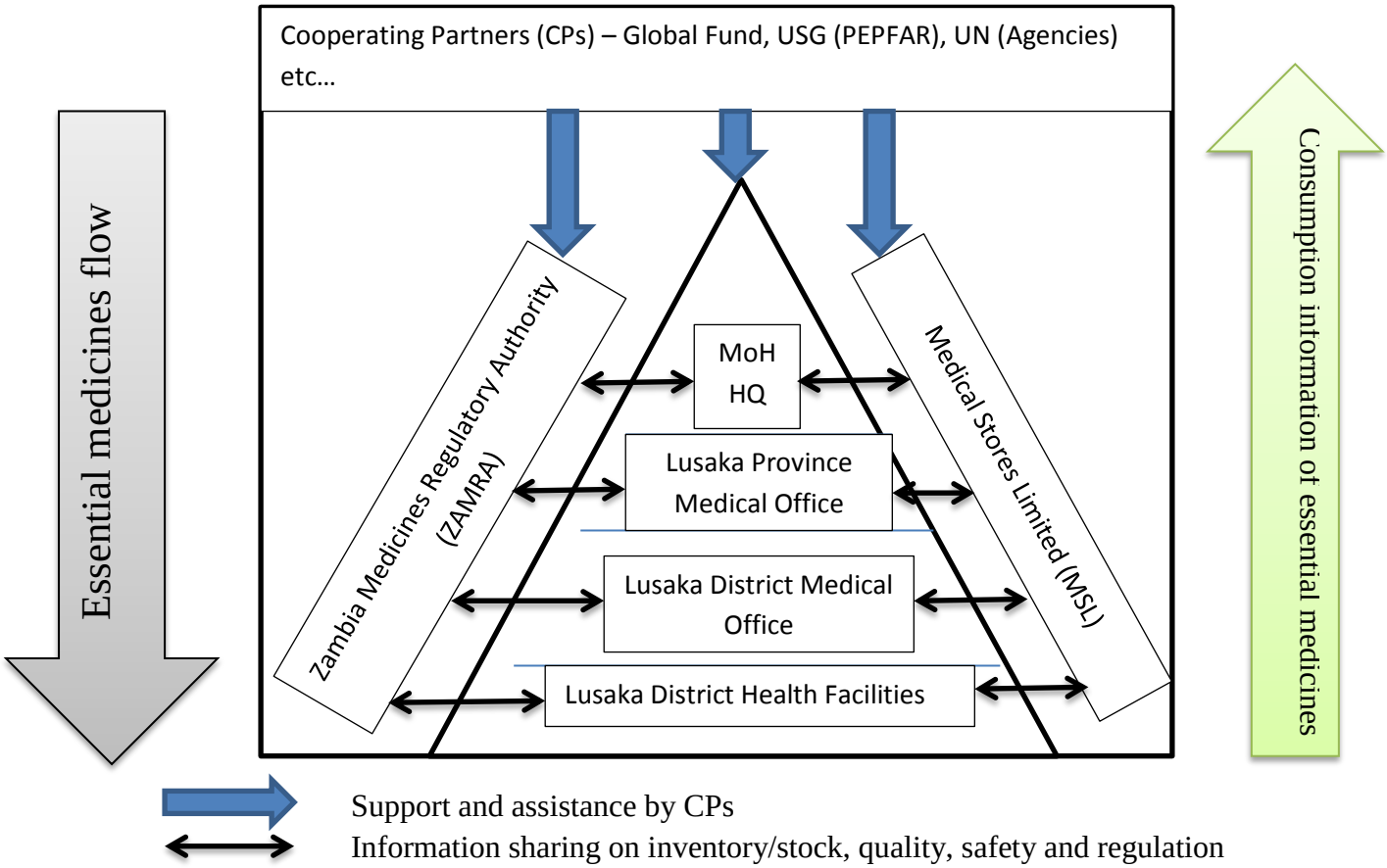

Figure 3.1: Sample population
Source: Researcher (2015)

The sample population as shown in Figure 3.1 can further be explained on the involvement of the institutions and organisations in the public sector supply chain management of essential medicines;

(i) Ministry of Health (MoH) Headquarters

MoH coordinates and facilitates the national selection, quantification and forecasting of essential medicines. The ministry also procures essential medicines, provides governance, policy guidance and oversight to the ZAMRA on essential medicines regulation, MSL on storage and distribution of essential medicines to the district medical offices and health facilities and finally to the provincial, district medical offices and health facilities on storage and dispensing essential medicines to patients.

Lusaka Province Medical Office :

The PMO provides governance, policy guidance and oversight to the district medical offices and health facilities on the storage and dispensing essential medicines to patients. It also coordinates and consolidates the selection and quantification of essential medicines as required by the districts within the province.

Lusaka District Medical Office

The DMO provides governance, policy guidance and oversight to the district health facilities on the storage and dispensing essential medicines to patients. It also coordinates and consolidates the selection and quantification of essential medicines as required by the health facilities within the district.

Lusaka district health facilities

Implement the policy guideline on the storage and dispensing essential medicines to patients. They also coordinate and consolidate the selection and quantification of essential medicines as required by the health facility.

Zambia Medicines Regulatory Authority (ZAMRA)

ZAMRA provides policy guidance and implementation on medicine regulation to ensure safety, quality and efficacy of essential medicines along the public sector supply chain on behalf of government through MoH. Regulation of essential medicines is performed during selection and quantification, registration, procurement, storage and distribution of essential medicines.

Medical Stores Limited (MSL)

MSL implements the storage and distribution of medicines and health supplies including essential medicines in the public sector supply chain. It also gives guidance and input from the consumption data of the distribution into the procurement, selection and quantification of essential medicines for the national level.

Cooperating Partners (CPs)

The CPs provide financial and technical assistance and support to the supply chain management of essential medicines. The support and technical assistance is provided

directly and indirectly to the government through the ministries of finance and health. Then they also support the regulation and quality assurance functions through ZAMRA and MSL.

The above can be summarised using the Table 3.1. In the table it represents direct functions of each institution and organisation in the public sector supply chain of essential medicines. The provincial, district offices and health facilities are taken under MoH.

Table 3.1: Functions under public sector supply chain

SN	Category of Supply chain	Primary responsibility (institutions)
1	Selection and quantification	MoH, ZAMRA, MSL, CPs
2	Registration	ZAMRA
3	Procurement	MoH, MSL, CPs
4	Storage	MSL
5	Distribution	MSL
6	Dispensing	MoH
7	Quality assurance	MoH, ZAMRA, MSL

3.2.1.1 Qualitative and quantitative data collection

Robert and Ladislav (2005) asset that qualitative research does not aim at securing confidence intervals of studied variables around exact values in a population. Instead, qualitative research typically tries to sample broadly enough and to interview deeply enough that all the important aspects and variations of the studied phenomenon are captured in the sample. Therefore, the qualitative data collection was done by desktop study of published literature review on the risks experienced in supply chain management of essential medicines in developing countries and then consolidating them using the interviews and discussions and then finally qualifying the risks using self-administered questionnaires.

Then interviews and discussions were held with selected expert professionals within the supply chain categories of selection and quantification, registration, procurement, storage, distribution and dispensing of essential medicines. Experts were purposively (judgementally) and conveniently selected because of the uniqueness and limited number of available individuals with the requests for

consideration as an expert under the study. For the purposes of this research only, an expert is considered to be a professional who has worked in an area of the related category of the above mentioned categories for minimum of ten (10) years. Convenience sampling was used for some categories with enough individuals to choose from, which include selection and quantification, procurement and dispensing.

Ten experts participated in the research through interviews and discussions which were held using one-on-one approach. Table 3.2 gives the full description of the individuals who participated and their areas of expertise.

Table 3.2: Participants in interviews and discussions

Category	**Number of participants**	**Number of Pharmacists**	**Other profession**
Selection and quantification	5	4	1
Regulation (Registration)	5	4	1
Procurement	5	4	1
Storage and distribution	5	5	0
Dispensing	8	8	0

Table 3.2 shows a large involvement of pharmacists (average of 88%) as observed from all the categories of the public sector supply chain management.

For the second stage, the identified risks from the reviewed literature and interview/discussions were then drafted into questionnaires for validating the identification of risks. Therefore, 50 self-administered questionnaires were distributed to assist with the risk identification and analysis qualitatively and quantitatively. Five questionnaires were pilot tested and corrected with the necessary changes. All questionnaires were hand delivered and collected to reduce non responsiveness from the participants. Participants were purposively selected with a view of obtaining responses/feedback that can be used with confidence. This is in agreement with majority of authors who have proposed that purposive (judgemental)

sampling is widely used in qualitative and case study research methodologies (Robert & Ladislav, 2005).

Each questionnaire was designed with three (3) major sections being; risk identification, qualitative risk analysis (probability) and quantitative risk analysis (impact, severity) of the identified risks. Therefore, each participant was required to complete all the three sections that were applicable to the selected category (ies). For the purposes of analysis and avoiding invalid or unreliable responses, applicants were instructed on how to complete the questionnaire. Instructions required that participants complete the questionnaires for the categories that they ticked to have been involved/working for their experiences.

3.3 Ethical consideration

Ethics was taken into consideration in conducting the research. This was done by seeking permission from organisations and individuals while ensuring and guaranteeing that confidentiality and anonymity is preserved. Participants were met in person and detailed explanations were given to highlight the objectives of the research and what type of data was needed from participants as input to answer the research questions. Despite some challenges in getting approval from the Ministry of Health HQ which prompted the writing of letter as attached in Annex 1, individuals were approached and those who consented to participating in the study were administered with the questionnaire.

3.4 Summary of research design and methodology

The previous chapter outlined the reviewed literature and establishing the gap in knowledge and research that this study sought to achieve. Therefore, the research design was done based on the literature review which included identifying the research problem, establishing the research objectives and questions. Finally a research methodology was adopted after analysing which methods would ensure that the method results addresses the established research objectives and questions. Figure 3.2 gives a summary of the entire research design and adopted methodology.

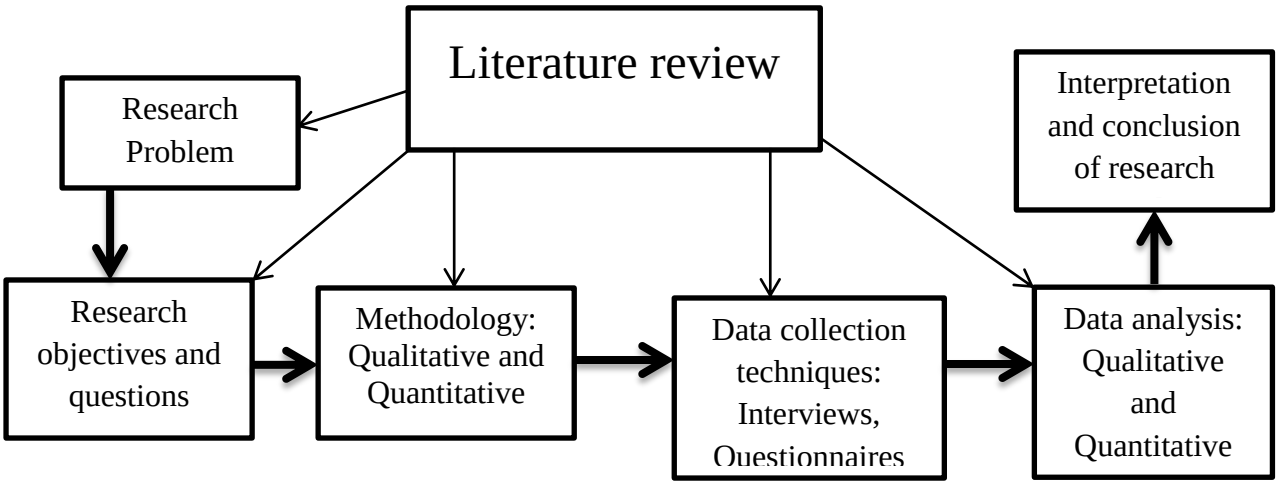

Figure 3.2: Summary of research design and methodology

3.5 Summary

This chapter presents the research methodology that was adopted and applied in conducting the research. The chapter included the research design, the sample population and the sampling tools and techniques adopted for the data collection. The adoption of the methodology was further explained in relation to the selection and application in order to maintain reliability and validity of the data that was collected and analysed.

Additionally, it detailed the integration of mixed method approach for the research methodology in ensuring that the results achieve the research objectives and answer the research questions. A procedure has been explained on the process that was adopted in carrying out the data collection and explanations on the reasons for the application and adoption of the methodologies that were used in the research.

The next chapter elaborates the obtained results using the methodology as outlined in this chapter. The results are analysed in relation to satisfying the research objectives and answering the established research questions.

4 CHAPTER FOUR: DATA ANALYSIS

4.0 Introduction

The previous chapter discussed the research design and methodology that was used in conducting the research. It outlined the data collection techniques that were applied and measures that were used to ensure reliability and validity of the methodology in achieving the research objectives.

This chapter discusses the data that was collected using the procedures as described in previous chapter. The data will be presented and analysed with focus on the relation of the results towards achieving the research objectives.

4.1 Data presentation and analysis

The research was carried out with four specific objectives, among them was to identify risks in the public sector supply chain of essential medicines. This was done in three phases involving firstly a review of literature on essential medicines in Zambia, then secondly interviews and discussions with selected professional experts and finally using the self-administered questionnaires. Analysis of data obtained in the research was done using Microsoft Excel package version 2010.

After a review of the available literature on SCRM of essential medicines, the data was used in conducting the interviews and discussions with selected professional experience. Interviews and discussions were held using the one-on-one approach based on the guiding questions as attached on Annex 2. Using the categories as proposed in the methodology, the design of the guiding questions for interviews and discussions was focused mainly on risk identification, qualitative and quantitative analysis of the identified risks basing on the individual expert's experience in the related category (ies).

Therefore, using the literature review, six (6) categories of the supply chain were identified and used as below;

- Selection and quantification
- Registration (Regulation)
- Procurement

- Storage and distribution
- Quality Assurance
- Financial

4.1.1 Qualitative and Quantitative Analysis of risks

As it was established in literature review, that risk identification can be done through different ways depending on the research design and methodology. It this study, the identified and analysed risks, from each participant during the interviews and discussions, were consolidated together in order to come up with a more comprehensive list of identified risks. This was done as some identified risks were the same despite being expressed differently with the language and context.

The identified risks from the interviews and literature review were then subjected to confirmation of existence in the supply chain of essential medicines by participants working in the related categories as defined through a self-administered questionnaire. After confirmation of existence (or non-existence), the participants further analysed the identified risks qualitatively and quantitatively with regard to their hands on experience with the routine duties within the supply chain. The responses from the questionnaires were then analysed and treated using Microsoft Excel package version 2010. 50 questionnaires were distributed and collected by the researcher in person to increase responsiveness. 42 questionnaires were received however, 7 were excluded from analysis for having being incomplete and/or not having usable feedback data to the research. This meant that 35 questionnaires were usable in the data analysis representing 70 % response which is sufficient to be representative of the selected sample population for the research. The questionnaire is attached in Annexe 3.

The frequency for levels used in the qualitative and quantitative analysis of the identified risks in the questionnaire is presented in each section. The given scores reported in the analysis were arrived at by finding an average of the participants' individual scores within each category.

Qualitatively (Probability or Likelihood);

Very High (Very certain) – Happens (often) more than once in each process,

High (Certain) – Happens once in each process

Medium (Almost certain) – Happens once in three times of the process

Low (Unlikely) – Rarely happens (once in more than five times of the process)

Very Low (very unlikely) – Does not happen

Quantitatively (Impact or Severity);

Very High (Catastostophic) – Affects the supply chain by more than three months,

High (Significant) – Affects the supply chain by one to three months

Medium (Moderate) – Affects the supply chain by one to four weeks

Low (Mild) – Affects the supply chain by one to seven days

Very Low (Insignificant) - Affects the supply chain by less than twenty four (24) hours

4.1.1.1 Participants in questionnaire survey

All participants for this research were taken from within Lusaka district. Table 4.1 shows the representation of the involved professions.

Table 4.1: Profession representation – questionnaire survey

Category	Number of participants	Number of Pharmacists	Other profession
Selection and quantification	27	25	2
Regulation (Registration)	12	7	5
Procurement	20	13	7
Storage and distribution	17	12	5
Dispensing	25	25	0

Table 4.1 shows a large involvement of total pharmacists (average of 77 %) as expected in all the categories of the public sector supply chain.

Information in Table 4.1 can be represented as Figure 4.1:

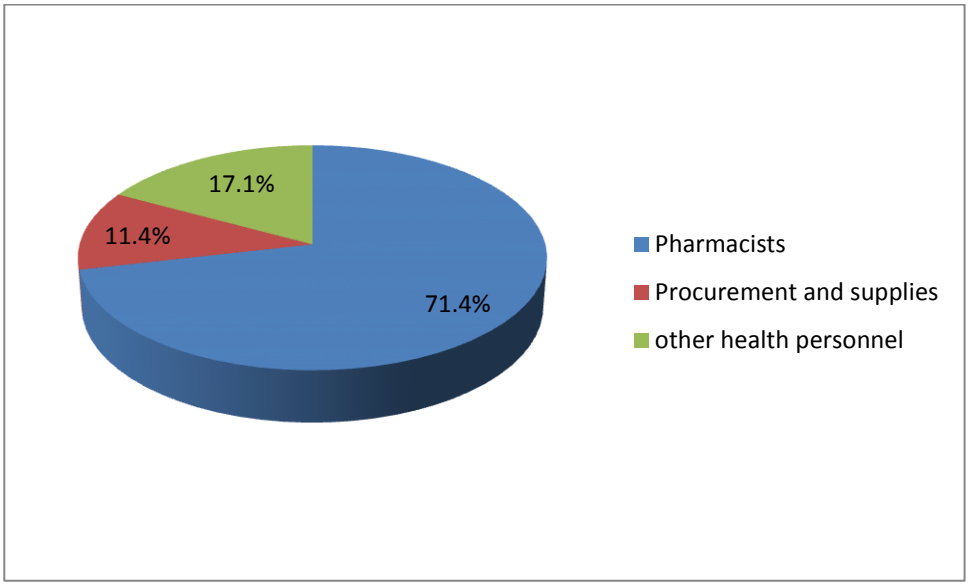

Figure 4.1: Profession representation of participants

With the above data indicating and showing the professions of participants in the categories as established in Table 4.1. Further, the variation experiences of the participants are shown in Figure4.2 with regards to data input as part of reliability and credibility of their responses/feedback that were used in the data analysis. Figure 4.2 shows the representation and classification of experiences of the participants by profession.

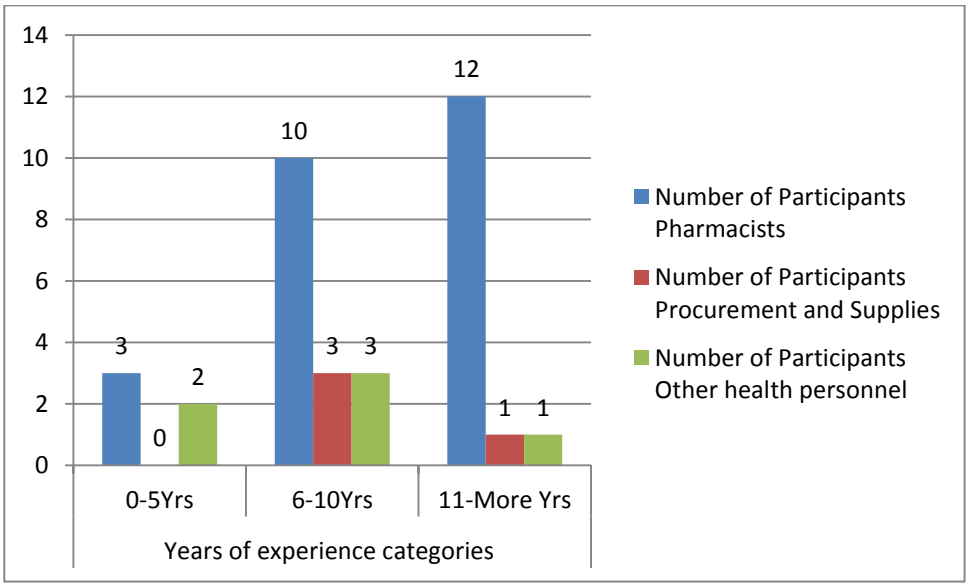

Figure 4.2: Representation of experiences of participants

From Figure 4.2 it can be seen that majority of the total participants had working experiences of between 5 and 10 years accounting for approximately 46% and followed by those with more than 10 years working experience representing 40%. This was considered to be a good contribution to the reliability and validity of the questionnaire responses/feedback in the research. However, the contribution of those who are new in the profession (Less than five years) was vital as their responses were used to account for changes with professional practice due to technological advancements and also with knowledge advancements by research and developments.

4.1.1.2 Selection and quantification

Medicine selection and quantification is a very important process that is undertaken using a bottom-up approach. The process has evolved while essentially maintaining its objective of coming up with a national plan containing the required essential medicines and the quantity. In the current bottom – up system, the process for selection and quantification of essential medicines is initiated at the health facility level then followed by the district and provincial medical offices before finally taking it to the national stage. This process is based on consumption data collected from the health facility through the district and provincial medicals offices, MSL and then finally to the national level were a committee is convened involving representatives of MoH, MSL, ZAMRA and CPs. The selection and quantification process is done comprehensively using the consumption data and the national EML.

The following risks were identified during the interview and discussion sessions with the selected experts:

- Weak information management system
- Weak coordination and transparency among stake holders
- Lack of available updated EML
- Inadequate capacity (specific training)
- Insufficient finances

Table 4.2 shows the identified risks and the probability scores after analysing data from the questionnaires. The Average Probability Score (APS) and Average Impact

Score (AIS) were taken to be the most agreed score by the participants (Most common) or the mathematical average of the most agreed risk scores in case(s) of more than one common score with the percentage agreement score value calculated using Equation 4.1:

$$\textbf{Percentage Agreement Score (\%AS)} = \left(\frac{\textbf{Numb.of agreed participants}}{\textbf{Total numb of participants(TNP)}}\right) * 100$$

Equation 4.1

Table 4.2: Qualitative risk analysis - Selection and Quantification

SN	Risk description	% Yes-Risk Agreed	APS	% A S
1	Lack of guidelines/policies	8	1	78
2	Lack of procedures/SOPs	23	2	56
3	Lack of understanding the process	60	3	52
4	Insufficient guidelines and procedures	6	1	78
5	Insufficient financial resources	77	5	74
6	Lack of cooperation/coordination	23	1	89
7	Stakeholder conflicts	14	2	78
8	Lack of participation	8	1	96
9	Lack of technical skills/training	54	4	67
10	Logistical and organizational	63	4	78
11	Lack of consumption information	54	3	93

Table 4.1 showed that of the total participants, 27 had been involved with selection and quantification of essential medicines. The 27 participants provided a qualitative analysis as shown on Table 4.2 and then went on to identify the probability of occurrence of each risk based on their individual experiences.

The above identified risks were then analysed quantitatively assess the impact (severity) they have on the efficiency of the public sector supply chain of essential medicines. Table 4.3 shows the quantitative analysis of the identified risks with regard to the impact they have on the efficiency of the supply chain of essential

medicines. Then the risks were given a Priority Score (P. Score) calculated as in Equation 4.2

$$P.\ Score = (AIS + APS)/2 \qquad \textbf{Equation 4.2}$$

Table 4.3 Quantitative Analysis - Selection and Quantification

SN	Risk description	AIS	% A S	APS	P. Score
1	Lack of participation	2	78	1	1.5
2	Insufficient guidelines and procedures	2	64	1	1.5
3	Lack of guidelines/policies	3	60	1	2
4	Lack of cooperation/coordination	3	71	1	2
5	Lack of procedures/SOPs	3	67	2	2.5
6	Stakeholder conflicts	3	64	2	2.5
7	Lack of understanding the process	4	77	3	3.5
8	Lack of technical skills/training	4	70	4	4
9	Logistical and organizational	4	86	4	4
10	Lack of consumption information	5	95	3	4
11	Insufficient financial resources	5	88	5	5

Quantitative analysis of the identified risks was done by the participants with regards to their individual experiences. The priority score for each risk was calculated using Equation 4.2. The risks having a minimum score of 3 were considered to be the important risks as they had both high probability of occurring and having an impact on the supply chain. Therefore, the risks considered to be important from this category in order of priority were:

- Insufficient financial resources
- Lack of technical skills/training
- Logistical and organizational
- Lack of consumption information
- Lack of understanding the process

4.1.1.3 Registration (Regulation)

The Medicines and Allied Substances Act No. 03 of 2013 provides for the continuous existence of Zambia Medicines Regulatory Authority (ZAMRA) from the previous Pharmaceutical Regulatory Authority established by Act No. 14 of 2004. ZAMRA has been given mandate by the Act of Parliament to protect the public health through ensuring (regulating) quality, efficacy and safety of available essential medicines. Part of the regulating of essential medicines involves issuing market authorisation to applicants after evaluating quality, efficacy and safety of the medicine. The conclusion of the process results in having the essential medicine registered by ZAMRA.

The following risks were identified by the participants of the interviews and discussions. They were identified based on the participants' experience and consolidated in order to avoid repetition of the same risk being described differently:

- Long process
- Inadequate capacity (required expertise and sufficient HR)
- Insufficient finances

Table 4.4 shows the risks that were identified under registration of essential medicines. The risks were obtained from the interviews and discussions and inclusion of the risks from the literature review to identify those that apply in the category in Zambia. The responses from the participants in the questionnaire survey are tabulated in Table 4.4.

Table 4.4: Qualitative Analysis – Registration

SN	Risk description	% Yes-Risk Agreed	APS	% A S
1	Lack of guidelines	10	1	95
2	Available guidelines not clear/adequate	8	1	70
3	Complicated registration process	12	2	67
4	Long registration process	75	5	54
5	High registration fees	9	1	80
6	Insufficient human resources	96	5	88

The identified risks in Table 4.4 were then analysed quantitatively to assess the impact (severity) they have on the efficiency of supply chain of essential medicines. Table 4.5 shows the quantitative analysis of the identified risks with regard to the impact they have on the efficiency of the supply chain by the participants of the questionnaire survey.

Table 4.5: Quantitative Analysis – Registration

SN	Risk description	AIS	% A S	APS	P. Score
1	Available guidelines not clear/adequate	2	60	1	1.5
2	Complicated registration process	1	74	2	1.5
3	Lack of guidelines	3	53	1	2
4	High registration fees	3	63	1	2
5	Insufficient human resources	3	86	5	4
6	Long registration process	4	76	5	4.5

From Table 4.5, the priority score shows that only two risks were regarded as more important according to the priority score. The following were the risks in order of their ranking as per priority score:

- Long registration process
- Insufficient human resources

4.1.1.4 Procurement

The procurement of medicines for public sector is done by the government through MoH and with assistance, support and participation of ZAMRA, MSL and CPs. The Ministry of Health receives funds for health financing from both the Ministry of Finance and the bilateral and multilateral CPs. Some CPs channel their funds directly to MoH and others channel it through the Ministry of Finance and National Planning (MoFNP). The MoFNP makes the funds available to MoH for drug purchasing based on a quarterly/monthly disbursal schedule. Some CPs provide assistance and support through procuring essential medicines directly and distributed to the public sector supply chain through MSL. Other CPs provide financial

assistance and support directly to the government and then periodically disburse the funds for procurement through the MoFNP and MoH.

From the interviews and discussions with the participants, a number of risks were identified based on the participants' experience with the procurement process. The identified risks are:

- Inadequate technical input (pharmaceutical skills)
- Long lead times
- Inconsistent fund disbursement
- Insufficient finances

Table 4.6 shows the risks that were identified under registration of essential medicines from the literature review and discussions. The risks were exposed to the participants through the questionnaire survey for agreement that indeed they are the risks obtaining and analyse them both qualitatively and quantitatively. Table 4.6 shows the level of agreement as risks and a qualitative analysis result of the identified risks by the participants of the questionnaire survey.

Table 4.6: Qualitative Analysis – Procurement

SN	Risk description	% Yes-Risk Agreed	APS	% A S
1	Lack of procedures/SOPs	12	1	75
2	Lack of technical skills/training	34	2	80
3	Poor quality of medicines	9	1	94
4	Inadequate procurement plan	21	1	78
5	Non-conformances to specifications by bidders/suppliers	11	2	68
6	Insufficient finances	87	4	93
7	Complex/complicated process	14	1	75
8	Lack of guidelines	12	1	78
9	Lack of coordination by stakeholders	68	3.5	75
10	Procurement lead times	70	3	73

The above identified risks in Table 4.6 were then analysed quantitatively as to how much (severity) impact they have on the efficiency of public sector supply chain of essential medicines through procurement. Table 4.7 shows the quantitative analysis of the identified risks with regard to the impact they have on the efficiency of the supply chain as responded by the participants of the questionnaire survey.

Table 4.7: Quantitative Analysis – Procurement

SN	Risk description	AIS	% A S	APS	P. Score
1	Lack of procedures/SOPs	2	65	1	1.5
2	Complex/complicated process	2	56	1	1.5
3	Poor quality of medicines	3	75	1	2
4	Lack of guidelines	3	75	1	2
5	Lack of technical skills/training	3	58	2	2.5
6	Inadequate procurement plan	4	78	1	2.5
7	Non-conformances to specifications by bidders/suppliers	3	74	2	2.5
8	Procurement lead times	4	63	3	3.5
9	Lack of coordination by stakeholders	4	73	3.5	3.75
10	Insufficient finances	5	69	4	4.5

Table 4.7 shows the quantitative (impact) analysis of the identified risks. A priority score was calculated for each quantified risk and compared the scores among the risks. The risks with a priority score of 3 or more was considered to be important. Therefore, the following risks in order of priority were considered to be important:

- Insufficient finances
- Lack of coordination by stakeholders
- Procurement lead times

4.1.1.5 Storage and distribution

Storage and distribution of essential medicines is carried out by MSL on behalf of MoH on national level and health facilities provide storage before dispensing. Therefore, in analysing the results of the study it was thought that they can be combined as the organisations and institutions involved in both categories were the

same. MSL is a government owned company with shares by MoH and MoFNP. MSL provides warehousing to the directly and indirectly procured essential medicines through MoH and CPs. It provides the required warehousing infrastructure while assuring quality, efficacy and safety of the medicines. Essential medicines are distributed periodically to district medical offices, MSL regional hubs and some health facilities. The distribution of medicines is carried out using a pull system by the facilities in communication with MSL. Therefore, there is an expected data exchange in consumption and inventory between the health facility and MSL. Despite having the regional hubs, management of all logistics and warehousing is still centrally done by MSL. The regional hubs assist in local (regional) storage and distribution of the medicines.

The discussions and interviews revealed the following listed risks based on the participants' individual experiences and were consolidated to ensure that all risks were considered and not repeated:

- Inadequate communication between MSL and health facilities
- Inadequate coordination and cooperation among stakeholders
- Insufficient storage spaces
- Inadequate human resources
- Lack of security

Some risks were not taken into consideration for the phase of the questionnaire survey simply because literature review had already described them as some risks that could not be obtained with the improvement of supply chain management of pharmaceuticals. Therefore, a comprehensive list of the identified risks was established by adding to the ones identified by interviews and discussions, those that were based on published literature. Table 4.8 shows the identified risks and their qualitative analysis as responded by the participants of the questionnaire survey. The analysis involved the likelihood of risk occurring in the storage and distribution.

Table 4.8: Qualitative Analysis - Storage and Distribution

SN	Risk description	% Yes-Risk Agreed	APS	% A S
1	Lack of guidelines/procedures SOPs	11	2	65
2	Insufficient vehicles	64	4	76
3	Lack of communication	11	1	86
4	Inadequate communication	68	4	71
5	Inadequate distribution management systems	12	1	69
6	Insufficient storage infrastructure	59	5	67
7	Inadequate inventory management system	34	2	53
8	Lack of inventory management Systems	12	1	89
9	Inadequate distribution management systems	20	2	73
10	Long procurement and delivery lead times	75	4	77
11	Insufficient finances	86	5	96
12	Inadequate human resources	64	3	86
13	Inadequate distribution plans/schedules	12	1	94

Using the same self-administered questionnaires, the participants further analysed the identified and qualified risks quantitatively by scoring the impact of each risk on the efficiency of the supply chain using the provided guide on scoring. Table 4.9 illustrates the result of the analysis and the priority score for each risk using Equation 4.2.

Table 4.9: Quantitative Analysis - Storage and Distribution

SN	Risk description	AIS	% A S	APS	P. Score
1	Lack of guidelines/procedures SOPs	2	65	2	2
2	Inadequate inventory management system	2	83	2	2
3	Inadequate distribution plans/ schedules	3	65	1	2
4	Inadequate distribution management systems	3	86	1	2
5	Lack of inventory management Systems	4	78	1	2.5
6	Inadequate distribution management systems	3	63	2	2.5
7	Lack of communication	4	52	1	2.5
8	Inadequate communication	3	76	4	3.5
9	Insufficient vehicles	3	68	4	3.5
10	Inadequate human resources	3	85	3	3
11	Insufficient storage infrastructure	3	73	5	4
12	Long procurement and delivery lead times	4	86	4	4
13	Insufficient finances	4	83	5	4.5

Following up on the analysis, it can be expressed that some risks are more important than the other in terms of priority for addressing. Priority scores show that those risks with a score of 3 or more, present a bigger threat to the supply chain efficiency. Therefore, the following are most important the extracted risks for the combined categories in order of their priority scores:

- Insufficient finances
- Long procurement and delivery lead times
- Insufficient storage infrastructure
- Insufficient vehicles
- Inadequate communication
- Inadequate human resources

4.1.1.6 Quality Assurance

WHO (2015) defines quality assurance as a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. With regard to pharmaceuticals, quality assurance can be divided into major areas:

development, quality control, production, distribution, and inspections. Therefore, for the Zambian public sector supply chain of essential medicines means that assuring quality of the medicines starting with implementing quality assurance systems from procurement until dispensing. Thus, it's a cross-cutting process with all parties involved. Hence, quality assurance is implemented by MoH and stakeholders in the selection and quantification, procurement, registration, storage, distribution and dispensing of essential medicines. This is mainly done by implementing quality management procedures in all categories and carrying out quality control checks of the essential medicines along the supply chain to ensure quality, safety and efficacy. ZAMRA through the National Drug Quality Control Laboratory conducts the quality control checks within country while CPs have their procured medicines tested by their selected laboratories.

The following risks were identified in the interviews and discussions with participants, based on their professional individuals' experiences:

- Lack of infrastructure
- Inadequate infrastructure
- Insufficient skilled personnel
- Inadequate infrastructure

The above identified risks were then added on and consolidated with the risks identified from the literature review. The risks were qualified by the participants by their likelihood (probability) of occurrence in the supply chain. Table 4.10 shows the results of the analysis.

Table 4.10: Qualitative Analysis - Quality Assurance

SN	Risk description	% Yes-Risk Agreed	APS	% A S
1	Inadequate quality management systems	67	5	86
2	Lack of skills/training	66	3	68
3	Insufficient testing facilities	93	5	95
4	High fees for testing	73	4	72
5	Inadequate human resources	65	3	73
6	Insufficient finances	75	5	78

Within the same questionnaires, the participants were further required to respond on the quantitative analysis of the qualified risks. This was based on the impact (severity) of the identified risks on the supply chain basing on their individual experiences. Table 4.11 shows the results of the quantitative analysis together with the calculated priority scores for each risk:

Table 4.11: Quantitative Analysis - Quality Assurance

SN	Risk description	AIS	% A S	APS	P. Score
1	High fees for testing	1	85	4	2.5
2	Lack of skills/training	2	69	3	2.5
3	Inadequate quality management systems	2	67	5	3.5
4	Inadequate human resources	4	79	3	3.5
5	Insufficient finances	4	81	5	4.5
6	Insufficient testing facilities	3	73	5	4

The quantitative analysis showed that most of the risks presented in quality assurance did not have a direct impact on the supply chain but are frequently been observed. It was then established that the following risks in priority order were more important according to the priority scores for each risk as calculated above:

- Insufficient finances
- Insufficient testing facilities
- Inadequate human resources
- Inadequate quality management systems

4.1.1.7 Financial

Financing of the public sector supply chain of essential medicines are handled by Ministry of Health and Ministry of Finance and National Planning. However, direct financing of the activities in the categories of the supply chain is handled by MoH. Funds are disbursed by MoFNP and CPs, to MoH for implementing the activities for each category through different programmes.

The participants in the interviews and discussions presented the following risks as related to financing and budgeting of the supply chain of essential medicines:

- Lack of alternative sources of funds by GRZ
- Lack of cooperation by stakeholders
- Disbursement of funds delay

The above risks together with those identified from the literature review were presented for further qualification by their likelihood to occur. Table 4.12 below shows the results of the qualitative analysis of the identified risks by the participants through the self-administered questionnaires:

Table 4.12: Qualitative Analysis - Financing

SN	Risk description	% Yes-Risk Agreed	APS	% A S
1	Insufficient budgetary allocation	24	2	79
2	Inadequate financial disbursements	89	5	65
3	Delayed and irregular disbursements	91	5	86
4	Financial mismanagement	23	1	58

Based on the above analysis, the identified and qualitatively analysed risks were then quantified by the participants with regards to the individual risk's impact on the efficiency of the supply chain. Table 4.13 shows the results of the financial quantitative analysis and also indicates the calculated priority scores for each risk.

Table 4.13: Quantitative Analysis - Financial

SN	Risk description	AIS	% A S	APS	P. Score
1	Insufficient budgetary allocation	3	63	2	2.5
2	Financial mismanagement	4	59	1	2.5
3	Delayed and irregular disbursements	3	91	5	4
4	Inadequate financial disbursements	3	86	5	4

Table 4.13 shows that some of the risks are more important than others. As earlier adopted, the risks with a risk score of more than 3./0 were considered to be important and are as follows:

- Inadequate financial disbursements
- Delayed and irregular disbursements

4.2 Conclusion

This chapter outlined the analysis of the data that was collected through the interviews and discussions with selected experts. The results of the analysis include those of the self-administered questionnaires. Risk identification was done through interviews/discussions and from the reviewed published literature. The results of the data analysis from the questionnaires include the qualitative (probability) and quantitative (impact) analysis of the identified risks on the efficiency of the supply chain based on the participants' individual experience. The risks with a priority score of 3.0 and more were regarded as important.

The next chapter discusses the results of the data analysis as presented in this chapter. It indicates the classification and prioritising of the risks to highlight the importance of the risks with regard to further control. The discussion of results includes assessment of the supply chain and the impact of the analysed risks.

5 CHAPTER FIVE: DISCUSSION OF RESULTS

5.0 Introduction

The previous chapter discussed the presentation of the results from the qualitative and quantitative analysis of the identified risks. The qualitative and quantitative analysis led to the calculation of the priority risk score of each individual risk to illuminate its importance as regards other risks. The priority score was used to determine the important risks that each category presented from the data analysis of the identified risks.

This chapter details the discussion of the results as obtained from the previous chapter. The focus of the discussion is on the priority scores and impact of each important risk as classified in previous chapter. It will further discuss the risks obtaining in the Zambian supply chain of essential medicines in public sector in relation with the earlier discussed literature review. The discussion will also outline the effects of the risks on the availability of essential medicines at health facilities.

5.1 Discussion of results

The results from the data analysis presented different information on the risks obtaining as shown from the data collection. The risks are summarised and grouped together as shown in Table 5.2. Further, the identified and priority scored risks were subjected to further calculation to obtain the Percentage Risk Score in order to rank the risks. The risk ranking was based on the region of the percentage risk score of each individual risk on the risk map as shown in Table 5.1.

Table 5.1: Risk Mapping

Risk likelihood, R(L), From 1-Low to 5-Very High						
	5					VH
	4				H	
	3			M		
	2		L			
	1	VL				
		1	2	3	4	5
	Risk impact, R(I), From 1-Insignificant to 5-Catastrophic					

VL = Very Low (1)

L = Low (2-4)

M = Medium (5-9)

H = High (10-16)

VH= Very High (17-25)

Table 5.2: Percentage Risk Score

	Important Risks - Description	Priority Score	PRS (%)
1. Selection and Quantification	**1.1** Insufficient financial resources	5	**100**
	1.2 Lack of technical skills/training	4	**80**
	1.3 Logistical and organisational	4	**80**
	1.4 Lack of consumption information	4	**80**
	1.5 Lack of understanding the process	3.5	**70**
2. Registration	**2.1** Long registration process	4.5	**90**
	2.2 Inadequate human resources	4	**80**
3. Procurement	**3.1** Insufficient finances	4.5	**90**
	3.2 Lack of coordination by stakeholders	3.75	**75**
	3.3 Procurement lead times	3.5	**70**
4. Storage and Distribution	**4.1** Insufficient finances	4.5	**90**
	4.2 Long procurement and delivery lead times	4	**80**
	4.3 Insufficient storage infrastructure	4	**80**
	4.4 Insufficient vehicles	3.5	**70**
	4.5 Inadequate communication	3.5	**70**
	4.6 Inadequate human resources	3	**60**
5. Quality Assurance	**5.1** Insufficient finances	4.5	**90**
	5.2 Insufficient testing facilities	4	**80**
	5.3 Inadequate human resources	3.5	**70**
	5.4 Inadequate quality management systems	3.5	**70**
6. Finance	**6.1** Inadequate financial disbursements	4	**80**
	6.2 Delayed and irregular disbursements	4	**80**

Percentage Risk Score (%RS) = Priority Score * 20 **Equation 5.1**

5.1.1 Finance

It can be deduced from Table 5.2 that the most import risks in all the categories are associated with insufficient financing of the activities. The risks related to finance were calculated to having the highest percentage risks scores of 90 % and 100 % in four of the six categories. This is a reflection of the stress the MoH is exposed to while trying to ensure availability of healthcare services to the public. This is because of the fact that MoH has to finance most of the activities that are undertaken by different institutions in the categories of the public sector supply chain of essential medicines. The level of importance by percentage score also outlines the significance of having sufficient finances for the activities in the supply chain. During the discussion and interviews, financing was observed to have been a prominent risk in almost every category which has been verified through the questionnaire survey. It further qualifies financing as the risk driver for the entire risk management process of the supply chain of essential medicines in public sector. At top level, this risk area is within the control of the law and policy makers in ensuring that guidance and oversight governance of financial management is undertaken effectively by the implementing authorities and professional personnel.

5.1.2 Selection and Quantification

Despite not having sufficient finances, certain important risks can be controlled and effectively managed if detected early and planned for within the activity action plans. Lack of technical skills/training, consumption data and understating the process under selection and quantification are some areas that effective risk management can reduce or avoid the impact of the risks on the supply chain. From the discussions and interviews, it was understood that effective implementation of continuous in-service training of personnel on selection and quantification of medicines is necessary due to the frequent transfers of trained and untrained personnel from one area of implementation to the other within and across categories of the supply chain. Therefore continuous training of personnel would be an effective mitigation measure to ensure adequate skills are available and updated, understanding of the process is made easier and would also guarantee provision of accurate and sufficient consumption data. Inaccurate consumption data of essential medicines at health facilities has major impact on the efficiency of the supply chain as procurement aided

by selection and quantification of essential medicines depend on consumption data from health facilities.

5.1.3 Registration

The most important risks that require priority mitigation in the risk management process under the category of registration were the lengthy registration process of essential medicines and inadequate human resources (HR). The two most important risks of the category are inter-related in nature because one risk can be largely reduced and avoided by mitigation of another. The risk of having a long registration process is due to a number of factors but discussions and interviews revealed that the process is lengthened by the insufficient human resources and expertise to handle the required work by ZAMRA. This is because ZAMRA personnel are also required to process the registration of other pharmaceutical and allied substances as stipulated by the Act of Parliament. Therefore, early detection and control of these most important risks of the category would increase the efficiency of the supply chain and as a result ensure timely procurement and availability of essential medicines at health facilities.

5.1.4 Procurement

As observed from Table 5.2, the most important risks from the category were lack of coordination and cooperation by stakeholders and long procurement lead times. The risks however, had some interdependence on financing risk. This was because completion of the entire procurement process effectively required availability of sufficient funds for the activities and programmes to be successfully done. Coordination and cooperation among stakeholders relates to the integrity, ability to communicate and share information, frequent and necessary open consultations in the entire procurement process.

Information sharing and frequent communication is very important in every process that involves more than one party in implementing policies and procedures. Hence, the procurement process is not an exception from information sharing and communication practices. Inadequate information sharing and communication led to parallel procurement of similar medicines by MoH and CPs some years ago but this has been rectified through the implementation of the National Drug Budget Line under MoH. Nevertheless, in some instances lack of coordination and cooperation has

led to some unnecessary multiple donations on medicines not on the priority list by health facilities. Therefore, implementing risk management process under this category would ensure that there is early detection of risks thereby allowing to plan for mitigation and control. Effective risk management process would also reduce the cost of the entire procurement process that requires emergency procurement when unforeseen risks occur and may affect the availability of essential medicines at health facilities.

5.1.5 Storage and Distribution

The programmes and activities under this category are implemented by MSL as discussed and highlighted in the previous chapter. MSL depends on funding by GRZ through grants and support from CPs. Hence, all operations and management of activities are implemented using the GRZ grant and CPs assistance. However, as earlier discussed under financial related risks, the funding of the operations are insufficient resulting in a number of risks occurring which are mitigated using emergency solutions that ultimately become costly. Failure to effectively implement risk management process in the activity plans results in costly mitigation of risks upon occurrence.

The important risks as shown in Table 5.2 are partly dependent on the finances but however, they can be avoided and/or controlled to reduce the impact and consequently also reduce the percentage risk score. The length of procurement lead times had an effect on how the storage and distribution was carried out. This is because MSL plans its storage and distribution in line with the procurement plan as provided by MoH. Hence, changes in procurement process implied a corresponding effect of the storage and distribution plan. In addition, essential medicines are transported to various corners of the country by road. Therefore, distribution is hugely affected by limited number of vehicles used in transporting the medicines.

Storage at national and regional level is provided by MSL while health facilities provide their own storage infrastructure. This involves providing own inventory systems, storage spaces and related management systems for ensuring quality, safety and efficacy of essential medicines are preserved before been dispensed. Insufficient storage infrastructure is experienced by many health facilities in Zambia. The lack of

sufficient storage space removes the ability of health facilities to be adequately stocked with required medicines. This leads to frequent ordering of medicines from MSL than necessary. MSL is already constrained with number of available vehicles and some health facilities are in hard to reach areas thereby leading to shortages of essential medicines. Therefore, effective implementation of risk management process in the activities would reduce or avoid the risk impact.

5.1.6 Quality Assurance

The most important risks under this category included, insufficient finances, insufficient testing facilities, inadequate human resources and quality management systems. Testing medicines for quality control purposes along the supply chain is a responsibility by MoH but delegated by the Act of Parliament to ZAMRA through regular inspections and testing using the National Drug Quality Control Laboratory. However, quality control checks are not done at every point due to cost limitations. Therefore, ZAMRA ensures that the quality, safety and efficacy of essential medicines is done through inspections and testing. Being the only public drug testing laboratory and only located in Lusaka, means that medicines in other areas of the country have to be taken to the laboratory for analysis and decision making, which may take long.

Human resource is vital for an effective quality management system. This is because a well-documented quality management system is only effective when it is implemented by trained and qualified personnel working in affected areas under the quality management system. The results of data collection show that policies, guidelines and procedures, collectively known as Standard Operating Procedures (SOPs) are available but their implementation requires trained and qualified personnel.

5.2 Conclusion

This chapter discussed the results of the analysis for data that was collected. Contributing factors behind the risks were discussed and it was found that financial related risks are the most important risks in all categories of the supply chains. A

summary of the comparison of the important risks in relation to the total identified risks is highlighted in Figure 5.1.

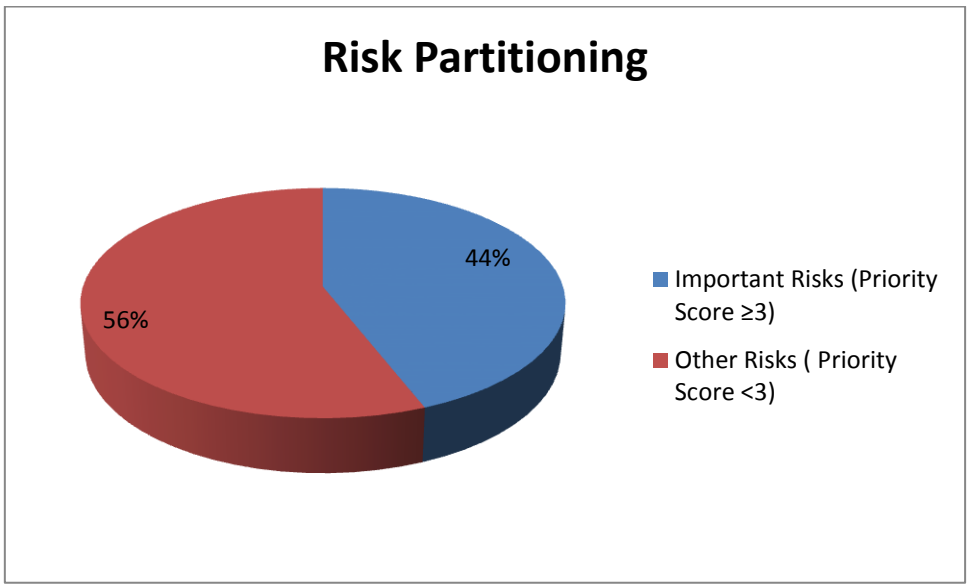

Figure 5.1: Risk partitioning

Figure 5.1 shows that 44% of the identified risks are import thereby highlighting the importance of implementing risk management process to reduce or avoid the risks from occurring as well as improving the efficiency of the supply chain of essential medicines in public sector.

The next chapter proposes a risk management system that may be adopted by implementing organisations and institutions within the public sector supply chain of essential medicines.

6 CHAPTER SIX: PROPOSED RM SYSTEM FOR ESSENTIAL MEDICINES

6.0 Introduction

The previous chapter discussed the results of the study. It outlined the risks obtaining in each category of supply chain and how some of them interrelate and interdepend on each other for occurrence and mitigation. This chapter proposes a model of risk management system that may be adopted by institutions and organisations within the supply chain.

6.1 Proposed Risk Management System

The identified risks through literature review and discussions/interviews with experts and which were validated by the questionnaire survey, established that general principles of risk management can be applied in supply chain of essential medicines for the public sector. The data analysis and discussion of results also proved that a lot of risks' impact on efficiency of supply chain could be reduced or avoided with an effectively implemented risk management process. Therefore, a risk management system was adopted, adapted and proposed for implementation by individual organisations and institutions within the supply chain of essential medicines for public sector as shown in Figure 6.1. The risk management processes are described in detail in relation to Figure 6.1.

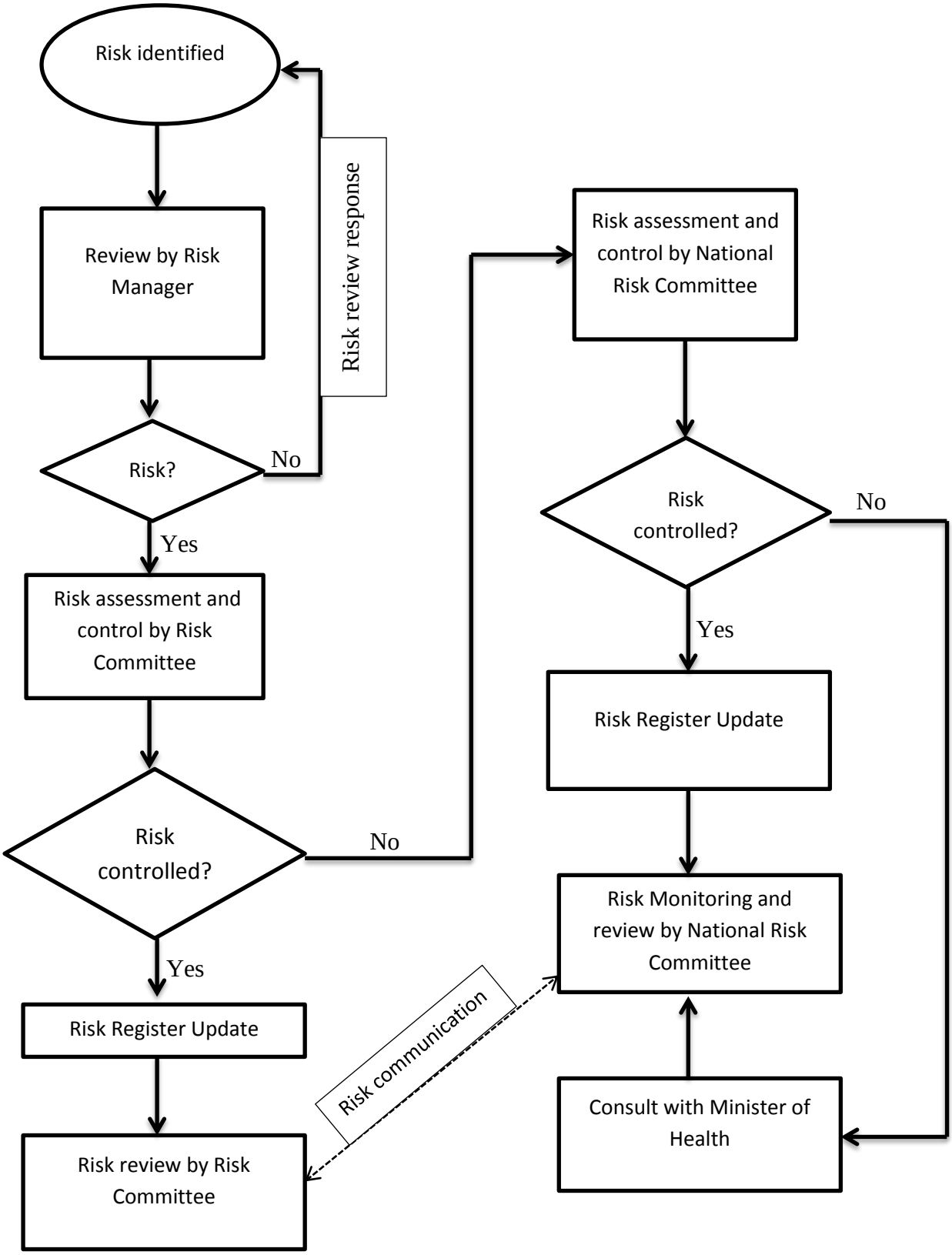

Figure 6.1: Organisational Risk Management Model

6.1.1 Risk identification

From Figure 6.1, risk identification could be done by individuals within and outside the organisation. These individuals can be members of the risk committee or any other member of staff implementing the objectives of the organisation to contribute to the efficiency of the supply chain of essential medicines. Risk identification should be done using a documented form that can be used for recording keeping in events of going back to the particular risk. This form should contain minimum information on the description of the risk, an indication of likelihood for occurrence, the specific impact it can present on the supply chain related activities and with possible preventive and contingency actions. Then the form should be submitted to the risk manager upon filing in the required information.

6.1.2 Risk Manager and Committee

The risk manager would have the responsibility of providing leadership in implementing the risk management process of the organisation. The risk manager would have the responsibilities of reviewing the identified risks and decide whether a further review by risk committee is necessary. He would provide feedback to the risk identifier and keeps the risk identification forms as records. The committee would then continuously review all the risks that would be regarded as such by the risk manager. Further, the committee would propose the mitigation measures and plans that would be necessary to the relevant functions of the organisation for action. Once a risk has been processed, it's recorded in the risk register and further evaluated during the regular monitoring and review of the effectiveness of the control measures. Being a public sector supply chain, risks that may not be mitigated or controlled by the organisation could be processed at national level through the national risk committee.

6.1.3 National Risk Committee

The national risk committee would be composed of representatives of all stakeholders within the categories of the public sector supply chain of essential medicines. This committee would be responsible for reviewing risk management performance of individual organisations that contribute to the efficiency of the supply chain. They would then review risks that may not be controlled at organisational level and requires multiple or combined efforts by different organisations. This committee would

provide governance and policy implementation regarding risk management process in supply chain of essential medicines for public sector. Then consequently they would be reporting and providing guidance to the Minister of Health through the Permanent Secretary.

6.1.4 Risk review and communication

The first step of risk review would be done by the organisation risk manager. The step would involve assessing the identified risk by reviewing the risk details and verifying that the risk has not been addressed already in the risk plan. The risk manager would then inform the risk identifier of the results of review and also submit the risk to the risk committee when the identified risk needs to be assessed and controlled. Once measures for control have been conducted, the risk committee shall monitor and evaluate the effectiveness of the control measures. The risks that would not be effectively controlled by the organisation would be passed on to the national risk committee for further assessment and control. Then the national risk committee would regularly monitor and evaluate the effectiveness of the control measures in mitigating the risks. Those risks that would not be controlled by the national risk committee would be communicated and mitigated through the office of the Minister of Health.

Risk communication would be done at all points through the processes. This would be done firstly by the organisation risk manager communicating with various risk identifiers, the risk committee and risk mitigation implementing offices. The organisation risk committee would also be responsible for communicating the risks and results of mitigating measures to the national risk committee so that the risk plan could continuously be updated. Then finally the national risk committee would communicate with various participating organisational risk committees on the risk plan and its updated progress and inform the office of the Minister of Health on the implementation of the risk management system for the public sector supply chain of essential medicines.

6.2 Conclusion

The proposed risk management model can be adopted and adapted by the organisations that are within the supply chain of essential medicines within the categories as established in this study. Due to variations on how each organisation function regarding management, the model could not be validated as there was no firm basis for validation among the organisations and institutes involved in the activities and programmes along the supply chain. The next chapter provides the conclusions and recommendations from the study.

7 CHAPTER SEVEN: CONCLUSION AND RECOMMENDATION

7.0 Introduction

The previous chapters discussed the analysis of the data that was collected in the research study, discussion of results of the analysis and a proposed risk management model. This chapter presents the final conclusions from the study and recommendations.

The main objective of the research study was to identify, analyse and prioritise by ranking the risks in public-sector supply chain of essential medicines in Lusaka District and also to propose a system that may be used to control and monitor risks. The specific objectives of the research were as follows;

a) identify risks in the supply chain of essential medicines that are obtaining from planning for procurement to dispensing at health facilities;
b) rank and prioritise the identified risks according to severity on the supply chain of essential medicines;
c) determine the impact and consequences of the risks on the supply chain with focus on timely availability and affordable essential medicines at health facilities; and
d) propose a model for identifying, analysing, prioritising, controlling and monitoring negative risks within the supply chain so as to improve the efficiency of the supply chain.

The main objective of the study was achieved through the specific objectives which included identification of risks as done through literature review and through ten (10) interviews and discussions. The identified risks were then validated and analysed both qualitatively and quantitatively through the returned and usable thirty-five (35) self-administered questionnaires. The results were then used to prioritise the risks and determine risks that have considerable impact on the public sector supply chain of essential medicines in Lusaka. A risk management model was proposed which can be adapted and adopted by different organisations within the supply chain.

7.1 Conclusions

Risk management is always initiated by risk identification as highlighted and discussed under literature review. This is followed by risk analysis (assessment) which contains qualitative (likelihood/probability) and quantitative (severity/impact) of the identified risk. The analysed risks are prioritized and consequently ranked in order of priority for mitigation and control. A continuous process for effective mitigation measures and controls is done through risk monitoring and review.

This study was conducted using categories of the supply chain of essential medicines for public sector as identified from the literature review. These categories were as follows:

- Selection and quantification
- Registration (Regulation)
- Procurement
- Storage and distribution
- Quality Assurance
- Financial

7.1.1 Risk identification

Risk identification for the study was done through the interviews and discussions with selected experts. In addition, other risks which were identified from the literature review were consolidated with those identified under interviews and discussions. The following risks were identified using the aforementioned processes:

Selection and quantification

- Weak information management system
- Weak coordination and transparency among stake holders
- Lack of available updated EML
- Inadequate capacity (specific training)
- Insufficient finances

Registration

- Lengthy process

- Inadequate capacity (required expertise and sufficient HR)
- Insufficient finances

Procurement

- Inadequate technical input (pharmaceutical skills)
- Long lead times
- Inconsistent fund disbursement
- Insufficient finances

Storage and distribution

- Inadequate communication between MSL and health facilities
- Inadequate coordination and cooperation among stakeholders
- Insufficient storage spaces
- Inadequate human resources
- Lack of security

Quality Assurance

- Lack of infrastructure
- Inadequate infrastructure
- Insufficient skilled personnel
- Inadequate infrastructure

Financial

- Lack of alternative sources of funds by GRZ
- Lack of cooperation by stakeholders
- Disbursement of funds delay

7.1.2 Risk Analysis (Assessment)

The risks were validated by participants of the questionnaire survey and analysed. The analysis of risks by participants was done based on their individual experience in the supply chain categories. The detailed analysis involved scoring the risks' probability and impact on the supply chain. Finally a priority score was calculated for each risk.

Based on the score, a priority score of 3.0 was considered to be high enough for a risk to be classified as an important risk. Therefore, all risks that obtained a priority score of 3.0 and above were considered important risks for each category. The following are the important risks for each category:

Selection and Quantification

- Insufficient financial resources
- Lack of technical skills/training
- Logistical and organisational
- Lack of consumption information
- Lack of understanding the process

Registration

- Long registration process
- Inadequate human resources

Procurement

- Insufficient finances
- Lack of coordination by stakeholders
- Procurement lead times

Storage and Distribution

- Insufficient finances
- Long procurement and delivery lead times
- Insufficient storage infrastructure
- Insufficient vehicles
- Inadequate communication
- Inadequate human resources

Quality Assurance

- Insufficient finances
- Insufficient testing facilities
- Inadequate human resources

- Inadequate quality management systems

Finance

- Inadequate financial disbursements
- Delayed and irregular disbursements

7.2 Recommendation

The results of the study have outlined the importance of implementing an effective risk management system that would reduce the impact of financial related risks on the efficiency of the supply chain of essential medicines. It is recommended that an effective risk management system should be firmly implemented in all organisations that are directly involved in the supply chain. Adopting and adapting the proposed risk management model by organisations can certainly improve and assist the implementation of the risk management system. The risk management system can be well integrated in the institutional quality assurance programmes of essential medicines.

The research study only covered the qualitative methods of through a case study approach to establish the current risks obtaining in the management of supply chain of essential medicines for the public sector. Further research should be done quantitatively to determine the correlation between an effective risk management system and enhanced performance of an organisation to improve efficiency and effectiveness of the supply chain of essential medicines for public sector.

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ANNEX 1: Introductory Letter to Ministry of Health

THE UNIVERSITY OF ZAMBIA
SCHOOL OF ENGINEERING
OFFICE OF THE DEAN

Great East Road | P.O. Box 32379 | Lusaka 10101 | Tel: +260-211-293792 | 290929 | 290962
Fax: +260 – 211 293792 | 290962 | Email: dean-eng@unza.zm | info-eng@unza.zm | Website: www.unza.zm

31 March, 2015

Senior Research Associate
Zambia Ministry of Health
Disease Surveillance Control and Research Unit
Global Health Corps Fellow,
LUSAKA.

Dear Sir,

RE: MARIO MUSONDA

This is to confirm that the bearer of this letter **Mario Musonda,** Computer No. 513809369 is a Master of Engineering (MEng) student at the University of Zambia, in the School of Engineering, Department of Civil and Environmental Engineering.

He is currently researching on "**The integrated risk management in the supply chain of essential medicines in Zambia**". It is for this reason that we write to you so that you may kindly assist with any information and data to enable him successfully carryout and complete his research.

The School commits itself to have the information used strictly for educational research purposes only and be kept confidential within the School itself.

Yours faithfully,

UNIVERSITY OF ZAMBIA
SCHOOL OF ENGINEERING
31 MAR 2015
DEAN'S OFFICE

Prof. Mundia Muya
DEAN - SCHOOL OF ENGINEERING

Excellence in Teaching, Research and Community Service

ANNEX 2: Guiding questions for interviews and discussions

THE UNIVERSITY OF ZAMBIA

INTERVIEW/DISCUSSION POINTS FOR

INTEGRATED RISK MANAGEMENT IN THE SUPPLY CHAIN OF ESSENTIAL MEDICINES IN ZAMBIA

1. GENERAL INFORMATION

1.1 What type of essential medicines have you been involved in?

1.2 Which categories of the supply chain of essential medicines have been involved in?

DISCUSSION POINTS

- What are your views on the following processes of essential medicines?
- Do you agree or disagree that the process is adequate enough to contribute to the efficiency of the supply chain management of essential medicines in Zambia?
- What are the main challenges that are encountered during the processes?
- Can the challenges faced during the processes affect the efficiency of the supply chain of essential medicines and how often do they occur?
- When these challenges are encountered during the process, how much is the impact of these challenges on the efficiency of the supply chain of essential medicines?

1. Selection and quantification
2. Registration
3. Procurement
4. Storage
5. Distribution
6. Quality Assurance and Quality Control
7. Budget/Finances

ANNEX 3: Questionnaire used in research

THE UNIVERSITY OF ZAMBIA

QUESTIONNAIRE SURVEY FOR

INTEGRATED RISK MANAGEMENT IN THE SUPPLY CHAIN OF ESSENTIAL MEDICINES IN ZAMBIA

DISTRICT: …….

OCCUPATION OF RESPONDENT: ……..

PROFESSION OF RESPONDENT: ……

YEARS OF EXPERIENCE IN PHARMACEUTICAL MANAGEMENT/SUPPLY MANAGEMENT: ……

1. SECTION ONE: GENERAL INFORMATION

1.1 What type of essential medicines have you been involved in? (*Please tick the relevant box(s), √*)

- Anti-Retroviral (ARVs) □
- Malaria □
- Tuberculosis (TB) □
- Others (Specify): ……

1.2 Which categories of the supply chain of essential medicines have been involved in? (Please tick the relevant box(s), √)

- Regulatory □
- Selection and quantification □
- Procurement □
- Storage and distribution □
- Dispensing □
- Quality assurance and quality control □
- Other (Specify):
  ……..

2. SECTION TWO: RISK IDENTIFICATION

2.1 Selection and quantification

Challenges encountered during the process of selection and quantification of essential medicines are more to do with:

	Agree	**Disagree**	**Don't know**
• Lack of guidelines/policies	□	□	□
• Lack of procedures/SOPs	□	□	□
• Lack of understanding the process	□	□	□
• Insufficient guidelines and procedures	□	□	□
• Lack of financial resources	□	□	□

• Lack of cooperation/coordination	□	□	□
• Stakeholder conflicts	□	□	□
• Lack of participation	□	□	□
• Lack of technical skills/training	□	□	□
• Logistical and organizational	□	□	□
• Lack of consumption information	□	□	□

2.2 Registration

The problems encountered during registration of essential medicines are more to do with:

	Agree	**Disagree**	**Don't know**
• Lack of guidelines	□	□	□
• Available guidelines not clear/adequate	□	□	□
• Complicated registration process	□	□	□
• Long registration process	□	□	□
• High registration fees	□	□	□
• Insufficient human resources	□	□	□

2.3 Procurement

The problems encountered during procurement of essential medicines are more to do with:

	Agree	**Disagree**	**Don't know**
• Lack of procedures/SOPs	□	□	□
• Lack of technical skills/training	□	□	□
• Poor quality of medicines	□	□	□
• Inadequate procurement plan	□	□	□
• Non-conformances to specifications			
• by bidders/suppliers	□	□	□
• Insufficient finances	□	□	□
• Complex/complicated process	□	□	□
• Lack of guidelines	□	□	□
• Lack of coordination by stakeholders	□	□	□
• Procurement lead times	□	□	□

2.4 Storage

The problems encountered during storage of essential medicines are more to do with:

	Agree	Disagree	Don't know
• Insufficient human resources	□	□	□
• Lack of guidelines/procedures SOPs	□	□	□
• Insufficient storage infrastructure	□	□	□
• Inadequate inventory management system	□	□	□
• Lack of inventory management Systems	□	□	□

2.5 Distribution

The problems encountered during distribution of essential medicines are more to do with:

	Agree	Disagree	Don't know
• Lack of guidelines/procedures SOPs	□	□	□
• Insufficient vehicles	□	□	□
• Lack of communication	□	□	□
• Inadequate communication	□	□	□
• Inadequate distribution management systems	□	□	□
• Long procurement and delivery lead times	□	□	□
• Insufficient finances	□	□	□
• Insufficient human resources	□	□	□
• Inadequate distribution plans/schedules	□	□	□

2.6 Quality assurance and Quality control

The problems encountered under quality assurance and quality control of essential medicines are more to do with:

	Agree	Disagree	Don't know
• Inadequate quality management systems	□	□	□
• Lack of skills/training	□	□	□
• Insufficient testing facilities	□	□	□
• High fees for testing	□	□	□
• Insufficient human resources	□	□	□
• Insufficient finances	□	□	□

2.7 Budget/Finances

The problems encountered under finances of essential medicines are more to do with:

	Agree	Disagree	Don't know
• Insufficient budgetary allocation	□	□	□
• Inadequate financial disbursements	□	□	□
• Delayed and irregular disbursements	□	□	□
• Financial mismanagement	□	□	□

3. SECTION THREE: RISK PROBABILITY ASSESSMENT

Very High – Happens (often) more than once in each process,

High – Happens once in each process

Medium – Happens once in three times of the process

Low – Rarely happens (once in more than five times of the process)

Very Low – Does not happen

3.1 Selection and quantification

What is the probability of occurrence of the risks associated with the following?

	Very High (5)	High (4)	Medium (3)	Low (2)	Very Low (1)
• Lack of guidelines/policies	□	□	□	□	□
• Lack of procedures/SOPs	□	□	□	□	□
• Lack of understanding the process	□	□	□	□	□
• Insufficient guidelines and procedures	□	□	□	□	□
• Insufficient financial resources	□	□	□	□	□
• Lack of cooperation/coordination	□	□	□	□	□
• Stakeholder conflicts	□	□	□	□	□
• Lack of participation	□	□	□	□	□
• Lack of technical skills/training	□	□	□	□	□
• Logistical and organizational	□	□	□	□	□
• Lack of consumption information	□	□	□	□	□

3.2 Registration

What is the probability of occurrence of the risks associated with the following?

	Very High (5)	High (4)	Medium (3)	Low (2)	Very Low (1)
• Lack of guidelines	□	□	□	□	□
• Available guidelines not clear/adequate	□	□	□	□	□
• Complicated registration process	□	□	□	□	□
• Long registration process	□	□	□	□	□
• High registration fees	□	□	□	□	□
• Insufficient human resources	□	□	□	□	□

3.3 Procurement

What is the probability of occurrence of the risks associated with the following?

	Very High (5)	High (4)	Medium (3)	Low (2)	Very Low (1)
• Lack of procedures/SOPs	□	□	□	□	□
• Lack of technical skills/training	□	□	□	□	□
• Poor quality of medicines	□	□	□	□	□
• Inadequate procurement plan	□	□	□	□	□
• Non-conformances to specifications by bidders/suppliers	□	□	□	□	□
• Insufficient finances	□	□	□	□	□
• Complex/complicated process	□	□	□	□	□
• Lack of guidelines	□	□	□	□	□
• Lack of coordination by stakeholders	□	□	□	□	□
• Procurement lead times	□	□	□	□	□

3.4 Storage

What is the probability of occurrence of the risks associated with the following?

	Very High (5)	High (4)	Medium (3)	Low (2)	Very Low (1)

• Insufficient human resources	□	□	□	□	□
• Lack of guidelines and procedures SOPs	□	□	□	□	□
• Insufficient storage infrastructure	□	□	□	□	□
• Inadequate inventory management system	□	□	□	□	□
• Lack of inventory management Systems	□	□	□	□	□

3.5 Distribution

What is the probability of occurrence of the risks associated with the following?

	Very High (5)	**High (4)**	**Medium (3)**	**Low (2)**	**Very Low (1)**
• Lack of guidelines and procedures SOPs	□	□	□	□	□
• Insufficient vehicles	□	□	□	□	□
• Lack of communication	□	□	□	□	□
• Inadequate communication	□	□	□	□	□
• Inadequate distribution management systems	□	□	□	□	□
• Long procurement and delivery lead times	□	□	□	□	□
• Insufficient finances	□	□	□	□	□
• Insufficient human resources	□	□	□	□	□
• Inadequate distribution plan/schedule	□	□	□	□	□

3.6 Quality assurance and Quality control

What is the probability of occurrence of the risks associated with the following?

	Very High (5)	**High (4)**	**Medium (3)**	**Low (2)**	**Very Low (1)**
• Inadequate quality management systems	□	□	□	□	□
• Lack of skills/training	□	□	□	□	□
• Insufficient testing facilities	□	□	□	□	□
• High fees for testing	□	□	□	□	□

• Insufficient human resources	□	□	□	□	□
• Insufficient finances	□	□	□	□	□

3.7 Budget/Finances

What is the probability of occurrence of the risks associated with the following?

	Very High (5)	**High (4)**	**Medium (3)**	**Low (2)**	**Very Low (1)**
• Insufficient budgetary allocation	□	□	□	□	□
• Inadequate financial disbursements	□	□	□	□	□
• Delayed and irregular disbursements	□	□	□	□	□
• Financial mismanagement	□	□	□	□	□

4. SECTION FOUR: RISK IMPACT ASSESSMENT

Very High – Affects the supply chain by more than three months,

High – Affects the supply chain by one to three months

Medium – Affects the supply chain by one to four weeks

Low – Affects the supply chain by one to seven days

Very Low - Affects the supply chain by less than twenty four (24) hours

4.1 Selection and quantification

What is the impact of the risks associated with the following on the supply chain?

	Very High (5)	**High (4)**	**Medium (3)**	**Low (2)**	**Very Low (1)**
• Lack of guidelines/policies	□	□	□	□	□
• Lack of procedures/SOPs	□	□	□	□	□
• Lack of understanding the process	□	□	□	□	□
• Insufficient guidelines and procedures	□	□	□	□	□

• Insufficient financial resources	□	□	□	□	□
• Lack of cooperation/coordination	□	□	□	□	□
• Stakeholder conflicts	□	□	□	□	□
• Lack of participation	□	□	□	□	□
• Lack of technical skills/training	□	□	□	□	□
• Logistical and organizational	□	□	□	□	□
• Lack of consumption information	□	□	□	□	□

4.2 Registration

What is the impact of the risks associated with the following on the supply chain?

	Very High (5)	**High (4)**	**Medium (3)**	**Low (2)**	**Very Low (1)**
• Lack of guidelines	□	□	□	□	□
• Available guidelines not clear/adequate	□	□	□	□	□
• Complicated registration process	□	□	□	□	□
• Long registration process	□	□	□	□	□
• High registration fees	□	□	□	□	□
• Insufficient human resources	□	□	□	□	□

4.3 Procurement

What is the impact of the risks associated with the following on the supply chain?

	Very High (5)	**High (4)**	**Medium (3)**	**Low (2)**	**Very Low (1)**
• Lack of procedures/SOPs	□	□	□	□	□
• Lack of technical skills/training	□	□	□	□	□
• Poor quality of medicines	□	□	□	□	□
• Inadequate procurement plan	□	□	□	□	□
• Non-conformances to specifications by bidders/suppliers	□	□	□	□	□
• Insufficient finances	□	□	□	□	□
• Complex/complicated process	□	□	□	□	□
• Lack of guidelines	□	□	□	□	□
• Lack of coordination by stakeholders	□	□	□	□	□

• Procurement lead times	□	□	□	□	□

4.4 Storage

What is the impact of the risks associated with the following on the supply chain?

	Very High (5)	**High (4)**	**Medium (3)**	**Low (2)**	**Very Low (1)**
• Insufficient human resources	□	□	□	□	□
• Lack of guidelines and procedures SOPs	□	□	□	□	□
• Insufficient storage infrastructure	□	□	□	□	□
• Inadequate inventory management system	□	□	□	□	□
• Lack of inventory management Systems	□	□	□	□	□

4.5 Distribution

What is the impact of the risks associated with the following on the supply chain?

	Very High (5)	**High (4)**	**Medium (3)**	**Low (2)**	**Very Low (1)**
• Lack of guidelines and procedures SOPs	□	□	□	□	□
• Insufficient vehicles	□	□	□	□	□
• Lack of communication	□	□	□	□	□
• Inadequate communication	□	□	□	□	□
• Inadequate distribution management systems	□	□	□	□	□
• Long procurement and					
• delivery lead times	□	□	□	□	□
• Insufficient finances	□	□	□	□	□
• Insufficient human resources	□	□	□	□	□
• Inadequate distribution plan/schedule	□	□	□	□	□

4.6 Quality assurance and Quality control

What is the impact of the risks associated with the following on the supply chain?

	Very High (5)	High (4)	Medium (3)	Low (2)	Very Low (1)
• Inadequate quality management systems	□	□	□	□	□
• Lack of skills/training	□	□	□	□	□
• Insufficient testing facilities	□	□	□	□	□
• High fees for testing	□	□	□	□	□
• Insufficient human resources	□	□	□	□	□
• Insufficient finances	□	□	□	□	□

4.7 Budget/Finances

What is the impact of the risks associated with the following on the supply chain?

	Very High (5)	High (4)	Medium (3)	Low (2)	Very Low (1)
• Insufficient budgetary allocation	□	□	□	□	□
• Inadequate financial disbursements	□	□	□	□	□
• Delayed and irregular disbursements	□	□	□	□	□
• Financial mismanagement	□	□	□	□	□