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# Pharmaceutical Supply Chain and Distribution Network

Implications on Access to Medicine and Quality Health Care

Critical Analysis of The Public Pharmaceutical Sector in Tanzania



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at

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## STATEMENT OF AUTHENTICATION

I, Nesia Satoki Mahenge do declare that this thesis is my original work written solely by me and it has not been presented to any other institutions for any award.

I further certify that all statements and information contained herein are accurate, correct and true to the best of my knowledge and belief. Efforts were made to indicate clearly the contributions of others with due reference to literature

This thesis was done under the close supervision of *Professor Jan Van Dalen* and Process Innovation's ideas support from *Professor Jacques W. Brook* at the Maastricht School of Management, The Netherlands.

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D .

## **In Loving Memory of My Lovely Parents:**

Professor Satoki .T. Mahenge, Dad & Dr. Mrs. Gloria Mahenge, Mom

It is with honor to dedicate this Thesis to You! You always wanted the best for me.

(C) (GS.I

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"So do not fear, for I am with you; do not be dismayed, for I am your God. I will strengthen you and help you; I will uphold you with my righteous right hand".

Isaiah 41:10.

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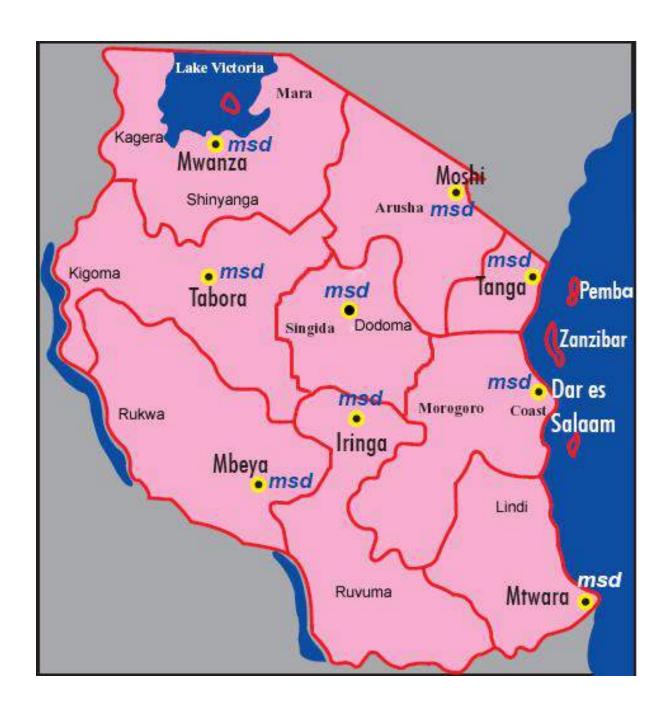
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## MAP OF TANZANIA AND ZONAL MEDICAL STORES DEPARTMENTS



## **ABSTRACT**

**Problem:** Despite the efforts made by the Government of Tanzania since 1994 to reform the health sector, Tanzania is still facing a number of challenges: increasing morbidity and mortality rate due to HIV/AIDS and Malaria, increasing demand for health care due to population increase at a 2.032% growth rate and varying disease patterns, difficulties in forecasting demand fluctuations of medicines, shortfall in annual health sector budget allocations and increasing costs of essential health care medicines. These challenges hinder the achievement of quality health and weaken the nation.

**Objective:** The aim of this research is to critically analyze the current challenges facing the pharmaceutical supply chain and distribution network, evaluate implications on access to medicine and quality health care and identify areas for application of process innovation to improve the performance and match demand and supply of pharmaceuticals. The case study focuses on public pharmaceutical sector in Tanzania.

**Design/Methodology/Approach:** This is an explanatory research design based on embedded multiple case studies. The unit of analysis is pharmaceutical supply chain and its participating organizations. The case study was based on "how" and "what" type of questions with a mixture of qualitative and quantitative data. Multiple sources of evidence "triangulation" were use to collect primary and secondary data. Worldwide pharmaceutical supply chain cases from the USA, India, China, Ghana and Zambia were selected for analysis to guide analytic generalization and recommendations. Cross-case and within case analysis techniques along with the conceptual framework and literature review were used to analyze the cases and case study protocol and data were developed.

**Key Findings:** The study found critical challenges; significant delays of more than 3 months of government funding to MSD, medicines are expensive; more than 20 million US dollar expenditures per year on medicines, a staggering debt of approximately 24 million US dollar to government, lack of stock control, poor demand and stock information flow, errors in demand forecasting as a result causing delays in delivery, stock-out, medicine shortages at health facilities and demand-supply mismatching. Changing disease patterns is also contributing to unavailability of medicines.

**Conclusion:** The poor performance of pharmaceutical supply chain and distribution network has negative implications on access to medicines and quality health care.

**Recommendations:** Process innovation model was proposed for analyzing the pharmaceutical supply chain performance. It was recommended a need for integration of activities in the supply chain along with collaboration and coordination at each stage.

#### **KEYWORDS:**

Pharmaceutical Supply Chain, Distribution Network, Health Care Quality, Access to Medicine, Challenges, Multiple Case Studies, Process Innovation Model, Performance

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#### LIST OF ABBREVIATIONS

**CIA** Central Intelligence Agency

**CMS** Central Medical Stores

**DH's** District Hospitals

**FY** Financial Year

**HF's** Health Facilities

MDG's Millennium Development Goals

MNH Muhimbili National Hospital

**MOF** Ministry of Finance

MOHSW Ministry of Health and Social Welfare

**MSD** Medical Stores Department

**NDP** National Drug Policy

**NEDL** National Essential Drug List

**OB** Objective

**OECD** Organization for Economic Co-operation and Development

**PBM** Pharmacy Benefit Managers

**PMO-RALG** Prime Minister's Office-Regional Administration and Local

Government

**PSU** Pharmaceutical Supply Unit

**RQ** Research Question

**RPP** Resources, Process, Priorities

**SCM** Supply Chain Management

**TFDA** Tanzania Food and Drugs Authority

UN United Nations

**USA** United States of America

**USAID** United States Agency for International Development

**WHO** World Health Organization

WTO World Trade Organization

## **CHAPTER ONE**

## **INTRODUCTION**

#### 1.1 RESEARCH TITLE

Critical Analysis of the Pharmaceutical Supply Chain and Distribution Network and its Implications on Access to Medicine and Quality Health Care: **The Case Study of Public Pharmaceutical Sector in Tanzania**. This study specifically focuses on the sole supplier and distributor of pharmaceuticals in the country. In this case, the Medical Stores Department (MSD) plays a crucial role as a sole public supplier and distributor of pharmaceuticals and medicines supplies in Tanzania for the public sector and also a primary supplier to faith based and other non-government, non-commercial groups providing health services in the country. The study also highlights and analyzes the players in the supply chain; it excludes the role of local and international manufacturers.

#### 1.2 BACKGROUND OVERVIEW

## 1.2.1 <u>Motivation and Choice of Selected Topic</u>

Achieving the desired health outcomes can succeed if there will be an adequate medicine supply to the right people which will be used in the right way. To ensure safe, affordable and effective medicine selection, the adequate supply and distribution network of medicines requires proper purchasing arrangements which will take into account the asymmetric information between suppliers and other participants in the supply chain.

The researcher has been working in the public health sector in Tanzania for three years and experienced challenges facing the health facilities to provide quality health care for achieving the desired health outcomes. The researcher became interested in conducting this research in order to analyze the current situation of the performance of pharmaceutical supply system and distribution network and identify implications on quality health care and accessibility of essential medicines in Tanzania.

## 1.2.2 Country Background

The United Republic of Tanzania is a union between Tanganyika (Tanzania Mainland) and Zanzibar; the country has a total area of *947,300 square kilometers* and a total population of 41.9 million with a growth rate estimate of 2.032%. Tanzania's population is at 30<sup>th</sup> largest in the world and it has a total number of 26 regions (CIA World Fact

book: July, 2010 estimates). About 80 % of the population lives in rural areas and depends primarily on agriculture for their basic needs. GDP is growing by an annual average of 6.7 % and the agriculture sector, which contributes about 45 % of GDP, is growing by 6 %. Per capita income is estimated at US\$270 per year (Mtei, G. et al. 2007).

## 1.2.3 National Health Sector Background

Based on the information provided by the Ministry of Health and Social Welfare (MOHSW), its main mission is to "facilitate the provision of basic health services that are of good quality, accessible, affordable, equitable, gender sensitive and sustainable" <sup>1</sup>. Since 1994 the Government of Tanzania has been striving to bring about in-depth reforms of the health sector, seeking improvement of quality and accessibility of services throughout the country. According to MOHSW, the Health system is mainly comprised of referral system whereby the Government is the main provider of health services. Furthermore the provision of health services is divided into three parts; national, regional and district. The Government referral system assumes the pyramid (figure 1.1) pattern starting from village level, where there are village health posts to national level where there are national and specialized hospitals.

**OWNERSHIP** TREATMENT ABROAD **Ministry of Health** SPECIALISED/ CONSULTANT HOSPITAL NATIONAL HOSPITAL **Ministry of Health** Regional REGIONAL HOSPITAL DISTRICT HOSPITAL District **HEALTH CENTRES** District DISPENSARIES District COMMUNITY HEALTH CENTRES (Community / Household)

Figure 1.1: <u>Tanzania Referral System Arrangements</u>
Referral System

Source: Adapted from Ministry of Health Tanzania: <a href="http://www.moh.go.tz">http://www.moh.go.tz</a>

<sup>&</sup>lt;sup>1</sup> MOHSW, (2010): Mission Statement. Available at http://www.moh.go.tz/index.php, Accessed on 29th April, 2010

The Ministry of Health and Social Welfare MOHSW,( 2007) manage and controls the national hospitals, consultant referral hospitals, special hospitals at national and regional level; the provision of health services is vested in the Regional Administrative Secretary with technical guidance from the Regional Health Management team (figure 1.1). At district level, management and administration of health services has been devolved to districts through their respective Council Authorities, Health Service Boards, Facility Committees, and Health Management Teams. About 87% of all health facilities are dispensaries; health centers account to 9% and hospitals account to 4% (MOHSW, 2007) <sup>2</sup>. Approximately 6,000 health facilities are geographically distributed where 70% of the population is within 5 km of a facility and 90% is within 10 km (MOHSW, 2003) <sup>3</sup>. Administratively, the health system is largely decentralized. The MOHSW has direct responsibility for referral and regional hospitals, and regulatory power over all health facilities. The district facilities are independently run by the Prime Minister's Office Regional Administration and Local Government (PMO-RALG).

#### 1.2.4 Pharmaceutical Sector Overview

## 1.2.4.1 Pharmaceutical Sector Background

Based on the report written by MOHSW, (2008): "In Depth Assessment of Medicine Supply in Tanzania", it was indicated that in Tanzania, provision of medicines and medical supplies is through both private (44%) and public (56%) system<sup>4</sup>. In 1991 the government approved the National Drug Policy (NDP) and National Essential Drug List (NEDL) for Tanzania to be used in medicine quantification, procurement and supply to attain better quality of health services to patients. Although various developments have taken place since 2004 to review and update both the National Drug Policy (NDP) and Pharmaceutical Master Plan, the outcome remains that the sector is still without policy and overall plan (Euro Health Group 2007)<sup>5</sup>. The pharmaceutical master plan is coordinated by the Pharmaceutical Support Unit (PSU) as it was indicated in the report by MOHSW, (2008).

<sup>&</sup>lt;sup>2</sup> MOHSW, (May 2007), Assessment of Health Financing System in Tanzania

<sup>&</sup>lt;sup>3</sup> MOHSW, (April 2003), Second Health Sector Strategic Plan (HSSP), July2003-June 2008

<sup>&</sup>lt;sup>4</sup>MOHSW, (2008), In Depth Assessment of Medicine Supply System in Tanzania

<sup>&</sup>lt;sup>5</sup>Euro Health Group, (August 2007), Tanzania Drug Tracking Study

Some of the key roles of the PSU mentioned are to: ensure that adequate funds to procure drugs and medical supplies are provided to Medical Stores Department (MSD), assist health facilities with capacity to quantify drugs requirements, establish effective strategies for improving rational drugs use, ensure the quality of medicines through Tanzania Food and Drugs Authority (TFDA), establish effective drug management and monitoring systems at health facility level and reduce drug waste and pilferage and ensure an appropriate allocation of resources to health facilities for drugs that takes into account equity, patient load, morbidity and drug needs.

## 1.2.4.2 Financing of Drugs Supply

In Tanzania financing of drugs supply is centralized and managed from the MOHSW department of drugs and supplies (PSU). However, this is only as far as the disbursements for medicines outside the vertical programmes are concerned. The Euro Health Group in its study; Tanzania Drug Tracking Study, (2007) indicated that the vertical programmes represent an increasing part of total resource allocation for medicines in Tanzania and constitute approximately 47% of total cost for medicines by year 2005/06. At each start of the Financial Year (FY) the Ministry of Finance (MOF) disburses first part of approved budget for medicines to the MOHSW on a quarterly basis. The first quarter is delayed every year because of late approval of yearly Government budget of Tanzania. In the same report the Euro Health Group indicated that the medicines budget is the highest priority with the MOF, see figure 1.2. To ensure the budget is actually used on medicines, the budget is centralized at the MOHSW level. In order for funds to be released from the MOF at the start of the FY, the MOHSW has to deliver a cash-flow and procurement plan.

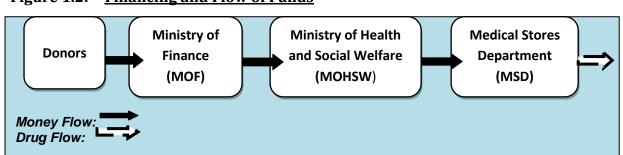


Figure 1.2: Financing and Flow of Funds

 $Source: Adapted \ from \ Euro \ Health \ Group: Tanzania \ Drug \ Tracking, Study$ 

When the money from MOF for medicines and supplies is received at the account of the MOHSW, the procedure is to transfer the money to the MSD, who are responsible for all activities related to the procurement and supply of medicines and supplies to the hospitals and primary health (Euro Health Group: Tanzania Drug Tracking Study, 2007).

## 1.2.4.3 Supply Chain and Distribution Network

The previous study done by Euro Health Group: Tanzania Drug Tracking Study, (2007) indicated that the essential medicines and all levels of medical supplies in Tanzania are mainly procured, stored and distributed by the centralized procurement system at the national level, the Medical Stores Department (MSD).

MSD is a non for profit autonomous single agency owned by the government and an independent department within the Ministry of Health and Social Welfare. In addition to that, MSD is the sole supplier of essential medicines for the public sector and primary supplier to faith based and other non government, non commercial groups providing health services in the country (MSD Source: <a href="http://www.msd.or.tz/pages/aboutus.html">http://www.msd.or.tz/pages/aboutus.html</a>).

There are four different supply chains of medicines in Tanzania and MSD administers three chains: essential drugs distributed in bulk by MSD, vertical Programme (VP) items distributed by MSD, essential drugs distributed by private wholesalers and kit's and indents packs distributed by MSD. As indicated by the Euro Health Group, MSD procures essential medicines in bulk from local and international wholesalers and medicines are stored centrally at MSD. Wholesalers provide emergency supplies when there is an interruption in the flow of normal purchasing operations at MSD. On the other hand the Tanzania Food and Drugs Authority (TFDA) regulates medicines supply and conducts inspections of private and public drugs outlets including hospitals, private pharmacies, wholesalers and nonprescription medicine shops in Tanzania (Source: TFDA Website) <sup>6</sup>. Drugs are taken from MSD central pool to service the packing of indent in which family health facilities are packed individually. Indent as explained on the MSD website is a system whereby a Health centre or a dispensary in the rural area orders drugs and medical supplies according to their requirement up to the budget limit.(Source: MSD Website)<sup>7</sup>

<sup>&</sup>lt;sup>6</sup>TFDA Regulations: <a href="http://www.tfda.or.tz/register.htm">http://www.tfda.or.tz/register.htm</a>. Accessed on 30th April, 2010

<sup>&</sup>lt;sup>7</sup> MSD Indent Program: http://www.msd.or.tz/pages/indent.html. Accessed on 27th April, 2010

Then drugs are taken from the same MSD central pool and sold to hospitals in the districts and regions through the MSD's zonal stores which are nine (9) <sup>8</sup> in total. As indicated in the Drug Tracking Study (2007), vertical program items are procured by MSD through supervision of program or procured externally by units like UNICEF or Crown Agents. All vertical program items pass through MSD warehouse and use the same distribution network (trucks) as for essential drugs. MSD operates its own transportation system for drug distribution. Vertical program items are items that are procured by MSD under special integrated arrangement that aims at reducing cost and increase efficiency. This program includes family planning, immunization, AIDS, TB/Leprosy, micro nutrients and national eye program (Source: MSD Website) <sup>9</sup>.

According to the report, major wholesalers/importers and almost all manufacturers are located in Dar Es Salaam and are accountable for wholesale drugs distribution to private and public clients including retailers i.e. pharmacies and nonprescription medicine shops "duka la dawa baridi". They mainly import their products from Egypt, Kenya, China, India and Europe. Wholesalers use their own transport system for drug distribution; they use private carriers which includes rail, freight or bus. For local customers they normally receive the delivery free of charge and other customers who are located far from the distribution centre have to travel or pay transportation cost from the distributor to their location.

<sup>&</sup>lt;sup>8</sup> MSD head office is located in Dar Es Salaam, nine (9) zonal stores are located in different regions in the country: Mwanza, Mbeya, Iringa, Tabora, Mtwara, Tanga, Moshi and Dar Es Salaam

<sup>&</sup>lt;sup>9</sup> MSD Definition of Vertical Program. <a href="http://www.msd.or.tz/pages/vertical.html">http://www.msd.or.tz/pages/vertical.html</a> (Accessed on 27th June, 2010)

#### 1.3 PROBLEM DEFINITION WORLDWIDE

According Dr. Margaret Chan, the world has changed, and not at all for the better in the roughly one billion people who live on the margins of survival. The gaps in health outcomes are greater today than at any time in recent history. A person in a wealthy country can expect to live more than twice as long as someone from a poor country. A woman in sub-Saharan Africa faces a risk of dying during pregnancy and childbirth that is more than 100 times greater than a woman living in Europe. These are largely preventable deaths, in which lack of access to essential medicines plays a major role (Dr. Margaret Chan, WHO Director General: Technical Symposium on Access to Medicine, 16<sup>th</sup> July, 2010).

Improving access to medicines has been a priority for WHO since the Organization began its work in 1948. "Half of the world's population in 1975 was without access to life—saving essential medicines". "While the proportion has decreased to about one third of world's population, the absolute number has remained constant at approximately 2 billion people have no regular access to essential medicines" (WHO, 2000). "While the problem of access to medicines is nothing new, the context today is strikingly different than in the past. A quest for greater fairness, in income levels, opportunities, access to medicines and health services, has become a strategy for coping with unique pressures of a globalizing world" (Dr. Margaret Chan: WHO, 16th July, 2010). Expanding access to existing interventions, including essential medicines, for infectious diseases, maternal and child health and non communicable disease would save more than 10.5 million lives a year by 2015 (WHO, 2004).

According to the survey conducted by WHO, "44 low-income countries show that 44% of public sector and 66% of private sector outlets had the listed generic medicines in stock and lack of medicines in the public sector forces patients to go without or purchase medicine from private sector outlets where generic medicines cost on average 630% more than their international reference price" (WHO, May 2010). Many developing countries are faced by problems of irregular and insufficient supply of drugs, this cause the patients to purchase medicines from the private pharmacy or to pay unofficial charges in health facilities to avoid rationing. The WHO indicated that lack of reliable and sustainable pharmaceutical supply systems is one of the major reasons for the chronic shortage of essential medicines in many countries, resulting in unnecessary suffering and death (WHO, 2003).

<sup>&</sup>lt;sup>10</sup> Explained in the report of UN Millennium Project, Prescription for Healthy Development: Increasing Access to Medicine, Report of Task Force on HIV/Aids, Malaria, TB and Access to Essential Medicines, (2005), at 4.

#### 1.3.1 PROBLEM DEFINITION IN TANZANIA

Tanzania is currently facing number of challenges which hinder the sustainability of quality health outcomes; it is faced by increasing morbidity and mortality rate due to HIV/AIDS and Malaria (MOHSW, July 2010). According to USAID, Malaria is regarded as the number one killer of children less than 5 years and HIV/AIDS is the leading disease which kills most of adults. USAID indicated that annual malaria deaths in Tanzania are estimated to be "60,000, with 80% of these deaths among children under the age of five". Approximately "14 to 18 million" clinical malaria cases are reported annually by public health services (USAID, April, 2010). There is a high demand of health care due to increasing population and varying disease patterns. Difficulties in forecasting medicines demand fluctuations, shortfall in annual health sector budget allocations and increasing cost of essential health care medicines weakens health of the nation (MOHSW, July 2010).

Most curative and many preventive health services depend on medicines and patients tend to perceive availability of medicines in a health facility as an indicator of quality of health hence the shortage of medicines continue to weaken the service quality and jeopardize the performance of the health system as a whole (World Bank, 2003). Hence there is a high need to have an efficient supply system of pharmaceuticals in Tanzania to ensure enough availability and accessibility of medicines to improve health care and save lives of people. This study critically analyzes the performance of pharmaceutical supply chain and distribution network and identifies implications on access to medicine and quality health care. Table 1.1 depicts characteristics of pharmaceutical supply chain.

Table 1.1: Public Pharmaceutical Supply Chain Characteristics in Tanzania

Pharmaceutical Supply Chain	Characteristics
Structure	Centralized procurement system
Essential Medicines	<ul> <li>Procured, Stored and Distributed by MSD</li> </ul>
Importer/National Wholesaler	<ul> <li>Only one integrated wholesaler (MSD) with 9 regional zones, sole supplier and distributor to Government, Faith based and Parastatal</li> </ul>
Hospitals	<ul> <li>Government: 89</li> <li>Private: 36</li> <li>Faith Based: 90, Parastatal: 8</li> </ul>
Health Centers	<ul> <li>Government: 379</li> <li>Private: 49</li> <li>Faith Based: 125, Parastatal: 12</li> </ul>
Dispensaries	<ul> <li>Government: 3348</li> <li>Private: 801</li> <li>Faith Based: 658, Parastatal: 123</li> </ul>

Source: Compilation from Annual Health Statistical Abstract Tanzania Mainland (2008)

#### 1.4 RESEARCH OBJECTIVES

#### 1.4.1 Main Objective

**OBO.** To critically analyze the current challenges facing the pharmaceutical supply chain and distribution networks, evaluate implications on medicine accessibility and quality health care and identify areas for application of innovation to improve performance and match the demand and supply of pharmaceuticals.

## 1.4.2 **Specific objectives of the study**

- **OB1.** To identify factors that enables the performance of the pharmaceutical supply chain and distribution network.
- **OB2.** To identify the aggravating factors of pharmaceuticals supply and demand mismatch and propose strategies for improvement.
- **OB3.** To identify the current challenges facing the performance of pharmaceutical supply chain and distribution network and propose innovative solutions for improvement.
- **OB4.** To evaluate the implications of pharmaceutical supply chain challenges to health care quality and medicines accessibility and identify implication indicators.
- **OB5.** To identify areas in which innovation can be applied to improve the performance of the pharmaceutical supply chain and distribution networks.

## 1.5 RESEARCH QUESTIONS

## 1.5.1 Major Research Question

**RQ0**. How can the matching of demand and supply of medicines, quality of health care and efficient accessibility of medicines be achieved through the performance of pharmaceutical supply chain, distribution network and application of innovation?

#### 1.5.2 Minor Research Questions

- **RQ1.** What are the enablers of pharmaceutical supply chain and distribution network?
- **RQ2.** What are the aggravating factors of pharmaceuticals demand and supply mismatching and can those factors be improved?
- **RQ3.** What are the challenges facing the pharmaceutical supply chain and distribution network in Tanzania and can those challenges be improve?
- **RQ4.** How does the challenges of pharmaceutical supply chain impact the quality of health care and medicines accessibility and what are the indicators?
- **RQ5.** How can innovation be applied to improve the performance of pharmaceutical supply chain and distribution network?

#### 1.6 CONCEPTUAL FRAMEWORK

Based on the summary of problem statement and objectives of this thesis, the researcher adopted the conceptual framework designed by Daniella et al, (2008), the authors of Technical partner paper 13: "Private Sector Role in Health Supply Chains". This model at this time takes into consideration all important variables for the improvement of pharmaceutical supply chain and it depicts interrelationship between the variables. It links features and characteristics of pharmaceutical supply chain and distribution networks to provide clear understanding of the system and it gives focus and direction to build towards achieving high performance efficiency of the supply chain. The variables influencing the pharmaceutical supply chain are identified and analysis is based on this framework. These variables represent areas where management effort may be directed in order to improve performance of the supply chain for efficient accessibility of medicine and improvement of health care quality. In addition to that, the dimensions and indicators of the variables to be used are discussed in details in chapter 3 and key drivers for each variable of the conceptual model are also discussed.

## 1.7 RESEARCH ASSUMPTIONS

This research considered some assumptions which guided the discussion and conclusion about the topic. The assumptions made include;

- a) Despite the bureaucracy, the government organizations will collaborate with the researcher and reliable data will be collected from them.
- b) All the respondents will answer the questionnaires honestly and truthfully.
- c) There is a positive relationship between the performance of pharmaceutical supply chain, distribution network and accessibility of medicines and health care quality.
- d) Improvement in performance of the pharmaceutical supply chain and distribution network will lead to the improvement in accessibility of medicines hence improving the quality of health care.
- e) Application of innovation in pharmaceutical supply chain and distribution network will help to improve the efficiency of the supply chain performance.
- f) All factors and indicators other than the ones used in this thesis are assumed not to favor alternative explanations or outcomes.

#### 1.8 METHODOLOGY AND RESEARCH DESIGN

#### 1.8.1 Research Design

This is an explanatory research based on embedded multiple case study design as it consists more than one unit of analysis. A "how" and "what" type of questions were used as suggested by Yin (1994) to formulate the research questions. Moreover this case study is based on a mixture of both qualitative and quantitative research. The quantitative approach is derived from qualitative data to confirm and support the qualitative part. The multiple cases were adapted to achieve the literal replication requirement of case studies as suggested by Yin (1994). The public pharmaceutical sector consists of different organizations involved in the supply chain. These organizations; MSD, MOHSW, TFDA, MNH, Private pharmacies, Private hospitals, dispensaries and patients are treated as individual cases and data will be collected from each organization. These organizations were selected because they play critical roles in the supply chain and are critical basis to address research problems in this study.

In addition to this case study, the researcher also identified worldwide cases to be used for analytic generalization and as a benchmarking for recommendations in *chapter 6*. These cases are from developed (USA) and developing countries (India, China, Ghana and Zambia). The characteristics, challenges and initiatives taken by each country to improve their pharmaceutical supply chain are analyzed in *chapter 3* by the researcher. Similarities and differences are identified and compared with this case study in *chapter 5* and further recommendations in chapter 6 are executed basing on the findings from this case study and worldwide cases.

#### 1.8.2 Data Source and Collection Methods

Multiple sources of evidence were used to collect both primary and secondary data. The data were checked properly to ensure reliability, accuracy, consistency and transparency. Several tools were used to collect the data; questionnaires were sent via emails to MSD, MOHSW, TFDA, MNH, Private pharmacies, Private hospitals, dispensaries and patients for primary data collection. Documentation review and archival records were used as secondary sources of information for data collection from articles, reports, related case studies, journals and other thesis on related topic and websites like Ministry of Finance in Tanzania, MOHSW, MSD, TFDA, World Bank, OECD, WHO, CIA World Fact book etc. Database was created to store the data.

## 1.8.3 Unit of Analysis

As suggested by Yin (1994), "cases are not sampling units and should not be chosen for this reason". He suggested aiming towards the analytic generalization in doing case studies. For this case, the unit of analysis is the supply chain and in the supply chain the participating organizations are analyzed. The criteria were based on the selection of the organizations that are the main key players in the supply chain and distribution network and have impact on the supply chain of the pharmaceuticals, access to medicine and quality of health care. The patients and organizations are individual cases which together formulate multiple-cases. MSD is the sole supplier of pharmaceuticals to the public and faith based organizations and other private organizations, MOHSW provide funds to MSD for procurement of pharmaceuticals for public health facilities, TFDA is the authority regulating importation and circulation of medicines in Tanzania, MNH is the public national hospital, Private pharmacies, Private hospitals and dispensaries are impacted by the functions of pharmaceutical supply chain and distribution network.

In addition to that; data were also collected from five individuals who are end users in the supply chain (patients). The data was collected at Dar Es Salaam, the financial/capital city of Tanzania. The biasness of personal perception was minimized by the researcher through triangulation techniques during data collection of this study hence increasing the validity of the data.

#### 1.8.4 Data Analysis Techniques:

"Developing a case description, relying on theoretical propositions and thinking about rival explanations" are three general analytical strategies suggested by Yin (2003) for analyzing case studies with the ultimate goal of treating the evidence fairly to produce compelling analytic conclusions and to rule out alternative interpretations. The researcher adopted the first strategy which requires developing a case description to organize the case study analysis. Utilizing the embedded multiple cases design; the researcher adopted the within-case and cross case analysis techniques to analyze the cases. "Within-case" analysis technique is used to analyze individual cases of the organizations and patients and "cross-case technique" combines individual cases and analyze together. This cross-case technique is also used in analyzing the worldwide cases with this case study.

## 1.9 THE QUALITY, VALIDITY AND RELIABILITY OF THE RESEARCH DESIGN:

The case study design was based on the four tests of the validity and quality of the research; external validity, reliability, construct validity and internal validity as suggested by Yin (1994). These validity and quality tests are discussed in details in Chapter 4 of research design and methodology.

#### 1.10 SCOPE AND LIMITATIONS

## 1.10.1 <u>Scope of the Research</u>

This study focuses on key players in the pharmaceutical supply chain and distribution network. The center of analysis is MSD; the public supplier and distributor of pharmaceuticals in Tanzania and other players are analyzed briefly. The study analysis is limited to headquarter organizations located in Dar Es Salaam. As much as the analysis will not cover the whole country, these headquarter organizations contain all the information and will be able to represent other subdivisions in other regions. All pharmaceuticals in the country are distributed from the MSD headquarters to other individual organizations in other regions. The study also covers the worldwide cases from USA, India, China, Ghana and Zambia. The researcher identified these five cases to be used as a benchmarking for recommendations and analytic generalization.

#### 1.10.2 <u>Limitations</u>

However, there are limitations on this research:

- a) Incomplete availability of data from the rural areas and other health sectors
- b) Research mainly focuses on MSD and it further analyzes other players in the supply chain based in the main city, Dar Es Salaam. It excludes the private suppliers, local and international manufacturers and other regions.

#### 1.11 BENEFICIARIES AND SIGNIFICANCE OF THE RESEARCH

Factual results from this study will be used to facilitate a coordinated forecasting, reorganizing procurement priorities and ways for sustaining an un-interrupted supply chain and distribution network to improve the accessibility of medicines in the country. The beneficiaries of this thesis are expected to be; the pharmaceutical companies in the country, Ministry of Health, Government and Food and Drugs Authority who have major influence on pharmaceutical supply chain and distribution in the country, readers who

are interested in the management of pharmaceutical supply chain, innovation, distribution network, medicine accessibility and health care quality, researchers who are conducting research on similar subject, the end-user (health facilities, pharmacies and patients) and community in general, policy makers, private investors and international donors; they will benefit from the improvement of the medicine accessibility and health care quality.

#### 1.12 STRUCTURE OF THE THESIS

This thesis in six different chapters; *Chapter 1* provides the introduction and overview of supply chain and distribution network of pharmaceuticals. It also deals with the problem definition and how the research is conducted.

## Chapter 2

Reviews different literatures and offers opportunities to analyze existing knowledge and validate models to be implemented in the analysis of the problems. It also presents different fundamental concepts about challenges and management of pharmaceutical supply chain and distribution network. This chapter also explains how innovation can be applied in pharmaceutical supply chain to improve performance.

## **Chapter 3**

It reviews the worldwide cases from USA, India, China, Ghana and Zambia by identifying characteristics of the supply chain, challenges and initiatives. It also discusses in details the local case study and presents the structure of the pharmaceutical supply chain in Tanzania

## Chapter 4

It illustrates the multiple case study design and methodology used in this study. It also describes the data collection methods, analysis techniques and quality verification

## Chapter 5

Presents within-case and cross case analysis of the multiple case study results and answers the research questions. Key findings and discussions from the analysis are identified.

#### Chapter 6

Highlight conclusions, practical implications and recommendations for further research.

## **CHAPTER TWO**

#### LITERATURE REVIEW

#### 2.1 INTRODUCTION

This chapter focuses on review of different literature written by other research colleagues. As indicated in Chapter 1, this chapter covers different issues in details about; the study assumptions used in this literature review, scope of the literature review, concept definitions, pharmaceutical supply chain and distribution network, implications on access to medicine and quality health care and innovation in pharmaceutical supply chain management.

#### 2.2 STUDY ASSUMPTIONS USED TO REVIEW THE LITERATURE

The following are the assumptions that guide the discussion in this chapter;

- Achieving the desired health outcomes can succeed if there will be an adequate medicines supply to the right people and will be used in the right way.
- Efficient accessibility at all times in health facilities is a key factor in providing quality health care
- To satisfy customers (patients), products needs to be delivered on time according to schedule and the supply chain should not be broken since one part in a chain impacts the other and vice versa
- The longer the lead time the less responsive the supply chain system will be to changes in demand
- Application of innovation in pharmaceutical supply chain management should help to improve the efficiency.

#### 2.3 SCOPE OF THE LITERATURE REVIEW

The topic under discussion is a collection of various subjects and concepts. Based on these concepts, the researcher limited the scope to; challenges and enablers of pharmaceutical supply chain, implications of pharmaceutical supply chain on access to medicine and quality health care and application of innovation.

#### 2.4 DEFINITION OF CONCEPTS

The author of this thesis uses the following terms interchangeably throughout; "medicines", "drugs", "pharmaceutical products" and "pharmaceuticals". The focus of this thesis is limited to essential medicines.

## 2.4.1 Pharmaceutical Supply Chain

The pharmaceutical supply chain represents the conduit through which essential pharmaceuticals are delivered to the ultimate end-users at the right quality at the right place at the right time (Enyinda &Tolliver, 2009).

## **Health Supply Chain**

A health supply chain is the "network of entities that plan, source, fund, and distribute products and manage associated information and finances from manufacturers through intermediate warehouses and resellers to dispensing and health service delivery points" (WHO, 2006).

## Pharmaceutical Supplier

The World Health Organization (WHO) defines a pharmaceutical supplier "as a person or company providing pharmaceutical products on request. Suppliers include distributors, manufacturers or traders" (WHO, 2006).

#### 2.4.2 Distribution Network

According to the WHO report; distribution is considered as a significant activity in the integrated supply-chain management of pharmaceutical products (WHO, 2006). The report indicated that several people and companies are generally responsible for the handling, storage and distribution of such products and in some cases, however, a person or entity is only involved in and responsible for certain elements of the distribution process.

#### <u>Distribution</u>

"The division and movement of pharmaceutical products from the premises of the manufacturer of such products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments" (WHO, 2006).

#### 2.4.3 Pharmaceutical Product and Essential Medicine

#### **2.4.3.1** Pharmaceutical Product

Several authors in the literature defined a pharmaceutical product in different ways. However, WHO defined the pharmaceutical product as; "any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form, which is subject to control by pharmaceutical legislation in both the exporting state and the importing state" (WHO, 2006).

#### **2.4.3.2** Essential Medicines

One of the most cost-effective aspects in contemporary health care is the Essential medicines. WHO indicated that these medicines have a remarkable potential health impacts. They described as those medicines that satisfy the priority of health care needs of population and are in–tended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and at a price the individual and community can afford (WHO: <a href="http://www.who.int/medicines/services/essmedicines def/en/">http://www.who.int/medicines/services/essmedicines def/en/</a>).

#### 2.4.4 Access to Medicine

Access to medicines is defined as "having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population" (Definition by the United Nations Development Group)<sup>11</sup>". MOHSW used the framework provided by the WHO to identify the pillars for medicines access. The Pillars include evidence based selection and rational use, adequate resources (human and financial), affordable prices and adequate and reliable Supply Systems (MOHSW, 2008).

## 2.4.5 Rational Use of Medicines

Rational use of medicines as defined by the WHO is the appropriate medicines received by patients according to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time and at the lowest cost to them and their community (WHO, 2002).

<sup>&</sup>lt;sup>11</sup>MDG Gap Task Force, Goal 8: Delivering on the Global Partnership for Achieving the Millennium Development Goals: MDG Gap Task Force Report 2008 (New York: United Nations, 2008) at 35

#### 2.4.6 Irrational Use of Medicines

There are several factors that contributed to the incorrect use of medicines. One of the factors mentioned by the WHO, (2002) is unaffordable medicines. Patients tend to look for alternatives cheaper medicines that they can afford to pay for. This might cause the patients to end up purchasing from the grey market. Grey markets for pharmaceuticals are the markets which sell their products outside the normal distribution channel and it is normally unofficial, unauthorized and/or unintended by the manufacturers. Another factor for irrational use of medicines is the unreliable drug supply system. This consists of drug shortages, unreliable suppliers and the expired drugs that are supplied by the suppliers. One of the impacts of the irrational use of medicines is the reduction in the quality of medicines therapy which leads to the increased morbidity (sickness and diseases) and mortality (WHO, 2002).

## 2.4.7 Delivery and Distribution flexibility

Delivery flexibility is described as "ability to change delivery dates" (Beamon, 1999). However, the author of International Journal of Integrated Supply Chain Management; Pujawan, (2004) explained more about the definition of the delivery flexibility. He indicated that; "it is the ability of the supply chain to deliver different types of products to the customers with a wide range of volume at an acceptable cost and time".

#### 2.4.8 Quality Health Care

Though there are various factors which determine the health, the researcher focuses on health care as one of factors which determine the health condition. Health Care is defined as "combined functioning of public health and personal medical services" (OECD Health Working Paper, 2006). Kelley, E and Hurst, J. (2006) continued to define the concept of health care and pointed out that a health care system is contributed by certain performance attributes. Among those attributes there is quality of care, access to care and cost of care. Health Care System "is a set of activities and actors whose principal goal is to improve health through the provision of public and personal medical services" (Arah, 2005) and Quality of Care is the level to which health services for people and populations increase the chances of desired health outcomes and are reliable with current professional comprehension (IOM, 1990; OECD, 2004).

## 2.4.9 Supply Chain Flexibility

According to Upton, (1994); flexibility is defined as the ability to change or react to environment uncertainty with little penalty in time, effort, cost or performance. Supply flexibility can be described as the ability to reconstruct the supply chain, modifying the supply of product in line with customer demand (Duclos et al. 2003). Duclose continues to define the flexibility of the supply chain as "ability of purchasing function to respond in a timely and cost effective manner to changing requirements of purchased components in terms of volume mix and delivery date". There are other factors which determine flexibility of supply chain i.e. uncertainty and supply chain integration. In this thesis, the author limited the concept to a general concept of supply chain flexibility as explained by Duclose. In other words, Duclose etal (2003) explained the supply flexibility as "ability to meet the changing needs of customers, changing supply of product, including mix, volume, product variations and new products".

#### 2.5 KEY PLAYERS AND PHARMACEUTICAL SUPPLY CHAIN AND THE ENABLERS

This part discusses different literatures about enablers of the pharmaceutical supply chain and it will highlight the key players involved in the supply chain.

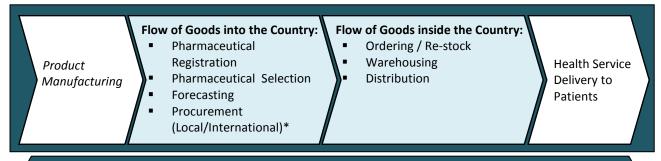
## 2.5.1 Key Players in the Supply Chain

The authors of the report Private Sector Role in Health Supply Chains indicated four stages of the health supply chains and different key players. These key players are important in making the supply chain to work. The authors mentioned different players; "donors/funders, government (policymakers), procurement agents, program managers, regulators, suppliers, distributors and dispensing staff from the public, private and faith based sector", these players are involved in different activities at different stages within the supply chain. The activities mentioned by authors are; "product registration, forecasting, procurement, importation, warehousing and distribution" (Dalberg Global Development Advisors and MIT – Zaragoza, 2008).

The researcher takes into considerations the players and different activities pointed out to indicate the flow of pharmaceutical products in the supply chain as shown in figure 2.1. This thesis focuses on the flows of goods into and inside the country and the services delivered to patients by MSD. As it was indicated in the previous chapters, the focus will

not be on product manufacturing but rather on the pharmaceuticals and how it flows within the supply chain from the MSD as a central focus to end users.

Figure 2.1: Pharmaceutical Supply Chain Activities and Enablers.



#### **SUPPLY CHAIN ENABLERS**

- Financing and Money flows
- Demand and Stock Information flows\*
- Regulations and Enforcement

Source: Adapted from Dalberg Global Development Advisors and MIT-Zaragoza, (2008)

\* Added by the Researcher, (2010)

## 2.5.2 Pharmaceutical Supply Chain Enablers Literature

The flow of pharmaceuticals into and inside the country involves different activities which involves different key players in the supply chain. For any flow of goods to be successful, companies need to have enablers to enable them to implement the activities in a successful way (see figure 2.1).

"The supply chain enablers are critical thread that runs through all activities and stages of the supply chain. Better information ensures better use of resources, which are often in short supply". (Dalberg Global Development Advisors and MIT – Zaragoza, 2008)

## 2.5.2.1 <u>Timing of Resource Allocation: Financial and Money Flows</u>

In order to ensure uninterrupted flows of pharmaceutical products and sustainable supply chain system for consistently delivery of pharmaceuticals, companies need to have timely financial flows between different levels in the supply chain. Effective financial flows are also crucial for the supply chain and for the health system as a whole to function properly. (Dalberg Advisors and MIT-Zaragoza, 2008)

#### 2.5.2.2 Demand and Stock Information Flows

Demand and stock information are very important throughout the supply chain for decision making. The upstream decisions about quantities to be procured will effectively be made through the flowing up of information in the supply chain. Appropriate levels of stock at delivery units need to be established in order to decide the proper restock rates at different stages of the supply chain. Maintaining desired stock levels will limit the probability of both stock-outs and excess inventory, which often lead to product expiry. (Dalberg Advisors and MIT-Zaragoza, 2008)

## 2.5.2.3 <u>Regulation and Enforcement</u>

Regulation is a vital enabler of pharmaceutical supply chain. It includes the pharmaceutical registration, thorough inspection of drugs at the port of entry, oversight of distribution as well as inspection of pharmacies and drug shops. Without adequate regulation at each step in the supply chain, product integrity can be compromised, leading to unnecessary deaths and the development of drug resistance (Dalberg Advisors and MIT-Zaragoza, 2008)

## 2.6 CHALLENGES FACING THE PHARMACEUTICAL SUPPLY CHAIN

As pointed out in the WHO Publication, "EMRO, 2006", health systems are undergoing rapid change and the requirements for conforming to the new challenges of changing demographics, disease patterns, emerging and re-emerging diseases coupled with rising costs of health care delivery have forced comprehensive review of health systems and their functioning. "As the countries examine their health systems in greater depth to adjust to new demands, the number and complexities of problems identified increases. Some health systems fail to provide the essential services and some are creaking under the strain of inefficient provision of services" (WHO Publication, 2008)

Number of issues including governance in health services, financing of health care, access and quality of health services, along with the impacts of reforms in other areas of the economies significantly affect the ability of health systems to deliver. As global competition increases, organizations are subject to changing competitive pressures, which create key challenges for both individual enterprises and for the supply system that form part of. (Lee H.L, 2002). In addition to that, Christopher, (1998) pointed out that the challenges have been related to the three themes of responsiveness, reliability

and relationships. Customers increasingly expect supply to meet their demands rapidly and accurately (Christopher, 1998, p.31-32). Supply chain management has been defined by Lambert, et al. (1998) as "the integration of key business processes from end user customers through original suppliers that provides products, services, and information that adds value for customers and other stakeholders".

# 2.6.1 Mismatching Supply-Demand of Pharmaceuticals

Gattorna, J. (1998) explained the relationship between demand and supply of a product. He stated there is an interdependent relationship between supply and demand. There are several factors which cause mismatching of demand and supply of pharmaceuticals. Among those factors/drivers, Gattorna mentioned stock-outs, excess inventory and longer lead-time. Figure 2.2 depicts the aggravating and mitigating factors.

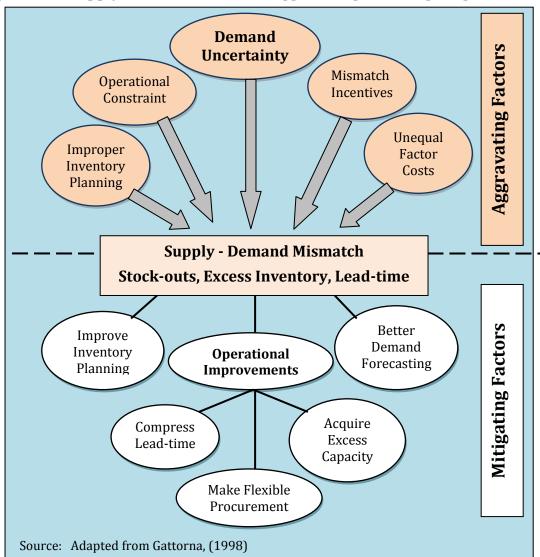


Figure 2.2: Supply-Demand Mismatch: Aggravating and Mitigating Factors

In order to manage and create future demand and achieve desired customer satisfaction level, companies need to understand customer demand. The main idea from Gattorna is the integration of supply and demand chains to overcome uncertainties and gain greatest value. He recommended that companies should have a better inventory planning techniques to reduce stock-out and excess inventory which will lead them to manage the matching of supply and demand. *He* also recommended that companies need to cut down their lead times in transportation and procurement (Gattorna J. 1998).

# 2.6.2 Irregular and Insufficient Supply of Drugs Challenges

It can be seen in "Purchasing Pharmaceutical article (2004)" that drugs are critical input to the proper functioning of the health services. The article pointed out that two decades ago, health sectors in many developing countries were facing number of problems, an important one being irregular and insufficient supply of medicines, which forced patients to buy drugs in the private markets or to pay unofficial charges in health facilities to avoid rationing. The insufficient supply of drugs resulted into mismatching between demands and supply due to shortages of drugs. Mahender Singh (2005) indicated different causes of the drug shortages; demand forecasting is one of the causes of drug shortages. *He* mentioned that poor forecasting are the central to the inefficient operation of any supply chain and unpredictable demand cause the organizations to fail the matching of demand and supply.

# 2.6.3 Lack of Access to Essential Medicines Challenges

According to WHO, despite the progress in increasing the number of people with access to essential medicine over the past decades, a substantial share of the world's population still lacks access to reliable supplies of basic medicines (WHO, 2000). While this is estimated to be the case for more than one third worldwide, it is the case for more than half of the population in the poorest parts of Africa and Asia. However there are many factors which influence whether poor people can obtain affordable essential drugs of good quality. It was stated that "increased access to drugs depends on effective resource allocation and an efficient purchasing system, that is on rational selection and use of medicines, adequate and sustainable financing, affordable prices and reliable health supply system" (World Bank: HPN, 2004).

Moreover, Stephen P. Marks in his article "Access to Essential Medicines as a Component of the Right to Health" stated that as a component of the right to health, the right to essential medicines depends not only on production, distribution and pricing of medicines but also on functioning of health systems so that medicines are part of a national system quality treatment and care as well as on infrastructure so that they can be delivered to all areas where they are needed. He continued to argue that trends in access to medicines, particularly in poor countries, provide evidence for policies in global health to increase access at all stages of the process from setting research priorities for development of new drugs to manufacturing, pricing, marketing and distribution.

# 2.6.4 Uncoordinated Supply Chain Challenges

Despite the fact that to-date several partners are involved in the medicine supply chains of countries, include Multilateral and Bilateral donors, non-governmental organizations, faith based organizations and private sector as it was stated in the report MOHSW, (2008), most of the partners have varied and diverse interest in health programs which results into uncoordinated multiple vertical supply chain arrangements, wastage of resources and inefficiency in supply chain management. As pointed out by Waller. D.L. (2003), he said that even though the supply chain may be complex i.e. belonging to separate organizations, many kilometers apart or may be involving different countries; the supply chain has to be considered as an integrated network. For effective management, "the supply chain has to be considered as an integrated network since a problem in one part can impact the other and vice versa" (Waller, D.L. 2003).

To understand the importance of coordination among different key players in the supply chain, John L. Gattorna (1998) indicated four different forms of integration and its important; Information, Decision, Financial and Operational.

<u>"Information Integration</u>: this enables the organization across the supply chain to share useful information. <u>Decision Integration</u>: this supports the planning and control functions of management across multiple firms within the supply chain. <u>Financial Integration</u>: this changes the terms and conditions of payment across supply chain. <u>Operational Integration</u>: this encompasses the sharing of physical and human assets between participants within a supply chain".

In addition to the integrated supply chain concept; Michael Porter, (1996), addressed the important issue about the strategic alignment through the concept of activity systems and types of fit. The main idea from this concept is that companies need to understand not only how activities are performed and configured but how activities in the supply chain relate to one another. There is a need to have a perfect strategic fit for a sustainable supply chain in order to integrate decisions and actions across many independent activities in the supply chain. "Improvement in one activity will pay dividends in others" (Porter, 1996).

# 2.6.5 Lead Time and Late Delivery Challenges

Waller, D.L, (2003), mentioned that in order to satisfy customers, products needs to be delivered according to schedule and to be sure the supply chain is not broken.

Any delays in any activity in the supply chain will of-course add to the total length of lead-time hence cause the products to be delivered late.

All along the supply chain are planning factors that need to be considered to avoid missing the client delivery date. According to Christopher .M. (1998); the longer the lead time the less responsive to changes in demand the system will be. Lead time can be defined "as the length of time involved for each step/procedure in the supply chain". The longer lead time is one of the major causes of drug stock out and it has a negative implication on cost and quality of pharmaceuticals. This indicates that the supply chain is slow to respond to changes in demand. This longer lead time results into higher cost (inventory carrying costs) in the in the supply chain and lowers the quality of pharmaceutical products.

Longer lead time causes the expiry duration of the products to be reduced before it reaches the end users and the end user will either receive expired drugs or drugs with short expiry duration. Whilst improving forecast accuracy will always be a desirable goal, it may be that the answer to the problem lies not in investing ever greater sums of money and energy in improving forecasting techniques, but rather in reducing the lead time gap. The bullwhip effect as explained by Lee, Padmanabhan and Whang (1997) is a result of delays of information caused by the supply chain arrangement. They also indicated that the strictness of the bullwhip effect related positively to lead times. Raff and Salmon (1997) assumed that the lead time reduction might reduce the financing costs while Fisher (1997) mentioned the need for reducing the lead time to enable quick

responses to unpredictable demand for minimizing stock-outs and obsolete inventory. Simchi Levi (2008) added that lead time reduction can significantly reduce the bullwhip effect throughout the supply chain. This can be achieved through the use of Electronic Data Interchange for reduction of information lead-time.

# 2.6.6 Distribution Network and Transportation Challenges

In addition to the lead time, meeting the distribution demands of the customer is a key requirement for the successful planning and operations of a distribution (Cooper .J. 1990). Transportation is another key factor in the supply chain and distribution network since even if products are produced according to schedule, are of acceptable quality and at right price, if the correct transportation is not available it will result in late delivery" (Waller .D.L. 2003). In addition to that, in delivery of products from the warehouse to the retail centre, there are essentially two extremes of delivery. One is that trucks might serve only a single store delivering a variety of different products so that only one truck park and unload. The alternative would be one truck serving many stores with the same product. In this latter case, there is a lot of dead time as the truck has to negotiate traffic at the number of deliver y sites; the greater is the amount of non-added value due to delays.

## 2.7 IMPLICATIONS ON ACCESS TO MEDICINE AND QUALITY HEALTH CARE LITERATURE

This part discusses in details the negative implications of the poor performance of pharmaceutical supply chain on access to medicine and quality health care. The researcher uses the World Health Organization's (WHO) concepts and framework for medicine accessibility. In addition to that, the researcher depicts some impacts of essential medicines to people and the populations in general as mentioned by the WHO.

"Serious illness is a major reason why poor populations remain trapped in poverty. Either they cannot afford health care or else its cost is so high that they are pushed into debt and dependency. The knock-out effects are many and enduring; parents cannot afford to send their children to school, working days are lost and economic productivity declines. In countries hit hardest by diseases such as Malaria and HIV/AIDS, development has ceased altogether" (WHO, 2000: http://apps.who.int/medicinedocs/es/d/Js0975e/).

#### 2.7.1 IMPLICATIONS ON ACCESS TO MEDICINE

## 2.7.1.1 <u>Decrease in Health System Effectiveness</u>

One of the highest priorities of the WHO is to help the countries by saving the life of their people through the improvement of health by bridging the vast gap among the "potential that essential medicines have to offer and the reality that for millions of people (particular disadvantaged and poor people) medicines are unavailable, unaffordable, unsafe or improperly used" (WHO, 2000). "Essential drugs are one of the tools for fighting ill health. By increasing access to essential medicines, their safety and their rational use, we could make the most of pharmaceutical potential to improve health status and secure development gains" (WHO, 2000). In other words it can be seen that the availability of essential medicines is the crucial factor for the well functioning of the health services and the availability also draws the patients to the health facilities to get preventive services. In addition to that the WHO pointed out that, efficient procurement of drugs and transparency increases the confidence of the Government, Ministry of Finance and Donors in the health system of the country. It also increases the encouragement to provide financial and other resources for the development of the health system.

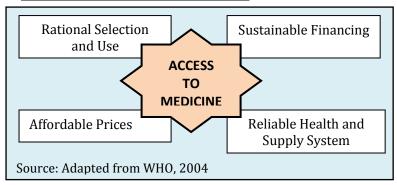
"Expanding access to existing interventions including essential medicines for infectious diseases, maternal and child health and non communicable disease would save more than 10.5 million lives a year by 2015" (WHO, 2000).

The pharmaceutical supply chains are essential for providing consistent availability of affordable, high-quality diagnostic and treatment products in locations that are geographically accessible to the target population (Dalberg Advisors and MIT-Zaragoza, 2008)

Pharmaceuticals are a vital input to the well functioning of the health services and pharmaceutical supply chains underline the whole health system. There is interdependence between the supply chain and supply-demand of pharmaceuticals. The supply chain provides crucial information about the supply and demand of essential medicines. This information could be used by policymakers and planners to effectively manage the financial flows and efficiently allocate the resources into the supply chain. However there are other factors which together with the supply system contribute to the accessibility of medicines.

The WHO, (2004) indicated the framework of medicine accessibility; this framework explains the importance of different factors to be taken into considerations when improving access to medicines. Any poor performance of the chain can "cripple the health system and undermine positive health outcomes" (WHO, 2000). Figure 2.3 highlights the factors for improving access to essential medicines.

Figure 2.3: Access to Medicine Framework



# 2.7.2 IMPLICATIONS ON QUALITY HEALTH CARE

"Patients tend to perceive availability of drugs in a facility as an indicator of quality of health hence the shortage of drugs continue to weaken the service quality and jeopardize the performance of the health system as a whole" (World Bank, 2003)

# 2.7.2.1 <u>Decrease in Quality of Health Care</u>

Poor performance of the supply chain and inconsistent availability of essential medicines weakens the quality of health care. Different factors can contribute to the poor performance of the supply chain. For example; longer lead time may cause delays of the medicines availability at health facilities, this delay may result into stock-out of medicines hence cause shortages. Due to shortages of medicines, ill people will not be able to receive the services in full and might cause the disease to prolong. The fact that there is an increase of disease patterns, rapidly changing economic environment as well as the existing disease challenges (Malaria, Tuberculosis and HIV/AIDS); lack of access to essential medicines will contribute to increase the death rate of ill people. The shortages of essential medicine can have a huge impact on quality of patient care, since they hinders the treatment alternatives available to patients and people who prescribe the medicines. "Millions of people continue to suffer and die with diseases which are preventable and/or treatable". (The WHO Website, "Essential Medicines and Pharmaceutical Policies" Available at: <a href="http://www.emro.who.int/emp/">http://www.emro.who.int/emp/</a>)

#### 2.8 INNOVATION APPLICATION IN PHARMACEUTICAL SUPPLY CHAIN

"Innovation refers to the successful application of new techniques or ways of organizational working that improve the effectiveness of an individual and organization", Archibugi et al. (1994). Innovation is divided into three degrees as described by Budworth (1996); "incremental, radical and fundamental". He indicated that incremental type of innovation is most likely to exist in less developed and poor countries. This section focuses on the "incremental type of innovation" to discover ways in which the pharmaceutical supply chain can be improved and ensure efficient accessibility and distribution of medicines to improve the health care quality.

#### 2.8.1 Incremental Innovation

This is the type of innovation that aims at improving the process or system that already exist. Since this study focuses on "the critical analysis of the pharmaceutical supply chain and distribution network", the discussion focuses much on the process innovation to identify ways in which the pharmaceutical supply chain can be improved trough the improvement of processes.

# 2.8.1.1 <u>Assessing Organization's Capabilities</u>

It is important to understand how the pharmaceutical companies can implement the innovation successfully. Christensen, C.M. and Kaufman, S.P., (2009) presented a framework; Resources, Process, Priorities (RPP Framework), for assessing the organization capabilities. They indicated that "an organization's capabilities become its disabilities when disruption is afoot". Pharmaceutical companies need to analyze accordingly what type of capabilities and disabilities exist in their organization in order to understand what they need to improve for the success of innovation process. The following section explains the RPP framework variables;

## **Resources**

According to Christensen, C.M. and Kaufman, S.P., (2009), resources are the most tangible sets of factors in the framework. The resources include people, equipments, technology, product, information, financial resources, and relationships with customers and other stakeholders involved in the pharmaceutical supply chain.

#### **Process**

This includes a pattern of coordination, interaction, communication and decision making through which they accomplish a certain task. According to Christensen, C.M. and Kaufman, S.P., (2009; process include methods, through which budgeting, resource allocation, distribution, procurement and delivery of pharmaceuticals are achieved. Most of the time the cause of innovation's failure is the usage of wrong process to manage performance and development of pharmaceutical supply chain. Indeed, as explained by Christensen, C.M. and Kaufman, S.P., (2009), some managers tend to "use the established process to execute new and different tasks because it is simple to use one-size fits all process for doing things".

#### **Priorities**

There is a high need for players in the pharmaceutical supply chain specifically the government, pharmaceutical companies, health facilities and donors to increase the training capacity to its employees at every level in order to make prioritization decisions that are consistent with the company goals. According to Christensen, C.M. and Kaufman, S.P., (2009), the priorities should focus those activities which help the pharmaceutical supply chain to improve performance and reduce cost in a manner that is sustainable.

# 2.8.2 Innovating Pharmaceutical Supply Chain

## 2.8.2.1 <u>Process Innovation</u>

The OECD, (2005) defines the process innovation as the "implementation of new or significantly improved process or delivery methods which include significant changes in techniques, equipment and/or software". According to OECD, the process innovation can be intended to decrease unit costs of delivery OECD, (2005). In addition to that, Davenport, T.H., (1993) emphasized the benefit of process innovation in pharmaceutical companies by saying that process innovation intends to achieve radical business improvement. He further said that pharmaceutical companies need to learn how to continuously improve their processes after the implementation of process innovation. In addition to that, Davenport, T.H., (1993) pointed out that process innovation should target changes in the pharmaceutical supply chain that can be quantified and those changes must focus on improving the efficiency of the pharmaceutical supply chain. The direction of focus should be on "reducing the lead time, reducing the distribution cost,

improving the delivery efficiency ordering process". Information Technology should be used as an enabler of the process innovation to bring changes in processes.

# 2.8.2.2 <u>Information Management Process</u>

Davenport, T.H., (1993) indicated that organizations should establish an information management process in order to provide basis upon which processes can improve. He further added that in order to achieve enormous long-term success, organizations need to manage its internal knowledge through management of information. It includes management of information like customers, demand forecasting and analysis, internal capabilities, processes and distribution. Players across the pharmaceutical supply chain can benefit through information sharing both internally and externally. Through information sharing, the players can engage in tracking and tracing of purchase orders, expired drugs, counterfeited drugs and they can manage inventory efficiently. Figure 2.4 highlights the information process procedures.

Figure 2.4 <u>Information Management Process in an Organization</u>

7	Identification of information needs and requirements	Information collection	Information categorization/	Information packaging/	Information dissemination/ distribution	Information analysis/use	$\rangle \mid$
Source: Adapted from Davenport, T.H., (1993)							

# 2.8.2.3 Balancing Supply and Demand

It was suggested that "companies should anticipate demand effectively since it takes time to respond to demand side changes and furthermore, the "integrated supply chain" should be the pivotal strategy component for company to succeed", Boston Consulting Group: Special Report, Creating the Optimal Supply Chain<sup>12</sup>. In addition to that, it was recommended that "careful coordination" of the supply chain and high level of *collaboration* are among the primary criteria for success. The report continued to indicate that collaboration and coordination ranges from "communication to technology and electronic data interchange" as well as the management of tracking ordering, inventory transportation and flow of funds among the players in the supply chain. Pharmaceutical companies will be able to "collaborate, coordinate and obtain relevant information" through technology and integrated supply chain.

<sup>&</sup>lt;sup>12</sup> Boston Consulting Group, Special Report. Available at: <a href="http://www.bcg.com/documents/file14863.pdf">http://www.bcg.com/documents/file14863.pdf</a> (Accessed on 9th June, 2010)

#### 2.9 GAPS AND INTERESTING THINGS DISCOVERED IN THE LITERATURE

# 2.9.1 Interesting things discovered by author in the Literature Review

All important literature has been considered by the researcher and it was reviewed carefully to complete the study. However, the researcher identified interesting things while reviewing the literature;

• Not only the poor performance of the pharmaceutical supply chain but also increase in disease patterns both emerging and re-emerging diseases were seen to be other factors contributing to the drug stock-out in the health facilities. This could be an interesting future research topic to identify how these disease patterns impact the performance of the pharmaceutical supply chain.

# 2.9.2 Gaps discovered by author in the Literature Review

From the literature reviewed; many researches on supply chain of pharmaceuticals have been conducted by different researchers and emphasized much on the challenges and management of supply chain. Despite the essence of having an effective pharmaceutical supply chain, there is a high need to show a clear link between performance of pharmaceutical supply chain, distribution network and implication on access to medicine and quality health care. The researcher also sees another need to identify how challenges on pharmaceutical supply chain performance impacts either negatively or positively the health quality and accessibility of medicines.

Furthermore the researcher has seen the significance of process innovation in improvement of performance. However; the researcher sees a crucial need to apply innovation in pharmaceutical supply chain in order to improve efficiency hence improving the performance to achieve the desired health outcomes.

Based on the discovered research gaps, the researcher decided to conduct this research on this topic to address the gaps and identify solutions for the addressed challenges by the adopted methodology in chapter 4 of this thesis.

# 2.10 Summary of the Chapter

The chapter started by introducing and identifying study assumptions and concept definitions to be used in reviewing the literature. The researcher limited the scope of the literature by focusing within the variables of the research topic. The literature focused on the pharmaceutical supply chain enablers and challenges. Here the discussions based on factors which enable the supply chain to perform effectively as well as factors which undermine the performance of the supply chain. The researcher continued to indicate the implications of performance of the pharmaceutical supply chain on medicine accessibility and health care quality.

In addition to that, the researcher described the application of innovation in pharmaceutical supply chain and identified ways on how the process innovation can used to improve processes and efficiency of the pharmaceutical supply chain and distribution network. The researcher believed that the health care quality and medicine accessibility could improve if there is an efficient improvement of pharmaceutical supply chain performance through application of process innovation along with other initiatives.

The chapter ended by highlighting the interesting things discovered while reviewing the literature, it was seen that increased disease patterns and rapidly environmental economic changes are also part of the reasons why there is drug stock out problems; this could be an interesting future research topic. The researcher also indicated research gaps and reasons for choosing this thesis topic.

## CHAPTER THREE

#### WORLDWIDE AND LOCAL CASE STUDIES OF PHARMACEUTICAL SUPPLY CHAIN

#### 3.1 **WORLDWIDE CASE STUDIES**

This part provides a summary of worldwide cases of the pharmaceutical supply chain. It starts by giving the summary characteristics of each supply chain from the selected countries and it also provides a summary of initiatives done to improve their supply chain performance.

The main aim of this part is to briefly analyze if developed and developing countries are facing any challenges with their pharmaceutical supply chains and what type of initiatives have been made so far to improve their challenges. The USA was selected to represent the developed countries, China and India represents Emerging markets and Ghana and Zambia represents the West and South African as part of the developing countries.

#### USA: 3.1.1 USA PHARMACEUTICAL SUPPLY CHAIN STRUCTURE

Manufacturer 3% 30% 65% 2% Wholesalers Pharmacy Independent Mail order Non-retail providers Clinics, Hospitals, Chains and Food pharmacies pharmacies Federal facilities, HMOs Stores with 14% 15% 43% **Patients** 28% Source: Adapted from Prashant Yadav, Kaisser Permanente, US Government Accountability Office:

Figure 3.1: USA Pharmaceutical Supply Chain Structure:

Cited in Dalberg Advisors and MIT-Zaragoza, (2008)

#### 3.1.1.1 USA PHARMA SUPPLY CHAIN CHARACTERISTICS AND INITIATIVES

#### A: SUPPLY CHAIN CHARACTERISTICS (2005, 2008)

- Relatively few large multinationals pharmaceutical manufacturers (*The Health Strategies*, 2005)
- Highly automated and virtually supply chain, electronically claims transactions
- Wholesale distributors sell drugs to pharmacies at wholesale acquisition cost plus some negotiated percentage. (The Health Strategies, 2005). Few drugs are distributed directly to consumers.
- Fast growth of mail-order pharmacy sales. (*The Health Strategies, 2005*)
- Complex supply chain; involves multiple organizations that play differing but sometimes overlapping roles in drug distribution and contracting. (*The Health Strategies, 2005*)
- Around 57,490 pharmacies, more than 100 full-line private wholesalers in 2007. (*Yadav*)
- Average distance travelled by patient to pharmacy is 2.36miles. (*Yadav et al.*)
- Frequency of delivery to each pharmacy is around 1-2 per day (*Yadav et al.*)
- Key players: manufacturers, wholesalers, pharmacy benefit managers, pharmacies
- Manufacturers manage actual distribution of pharmaceuticals from manufacturing facilities to wholesalers and sometimes directly to retail pharmacy chains, mail-order and specialty pharmacies, hospital chains.

# **B:** CHALLENGES FACING PHARMACEUTICAL SUPPLY CHAIN

- Consolidated wholesale distribution industry with declining number of wholesale distributors
- Price variability across different types of consumers due to complexity of the supply chain
- Supply chain not well understood by patients and policymakers due to complexity.

#### **C: INITIATIVES**

- Presence of pharmacy benefit managers (PBM) who offers wide range of prescription drug management tools; offers services like drug utilization review, disease management, consultative services, claims processing, record keeping, develop networks of pharmacy provides and mail order fulfillment services.
- Manufacturers play roles in stimulating demand by engaging in the promotion and marketing of products to health care providers and direct to consumer advertising
- Use of electronic bar coding technology on drug packaging for drug tracking
- Safety of pharmaceutical supply chain is ensured through the use of informational labeling for prescribers and consumers to understand
- Provision of specialized services by wholesale distributors; specialty drug distribution, drug repackaging, electronic order services and drug buy-back program

Source: Compilation by the Researcher from Prashant Yadav, Kaisser Permanente, US Government Accountability Office; Cited in Dalberg Advisors and MIT-Zaragoza, (2008)

The Health Strategies Consultancy, (March 2005): Kaiser Family Foundation: Follow the Pill, Understanding the U.S Commercial Pharmaceutical Supply Chain

The US pharmaceutical supply chain is complex in terms of the activities involved. Unlike the Tanzania supply chain, US does not have a main distributor, the manufacturer is the one who takes charge of distributing the medicines to the wholesalers and direct to retail pharmacies. One of the unique things about the US supply chain is the use of the Pharmacy Benefit Managers. Pharmacy Benefit Managers (PBM) performs pharmaceutical management functions and do not take the physical possession of the drugs except when they offer the mail-order and specialty-pharmacy services by buying the drugs from the manufacturers or wholesalers and then distributing them directly to patients.

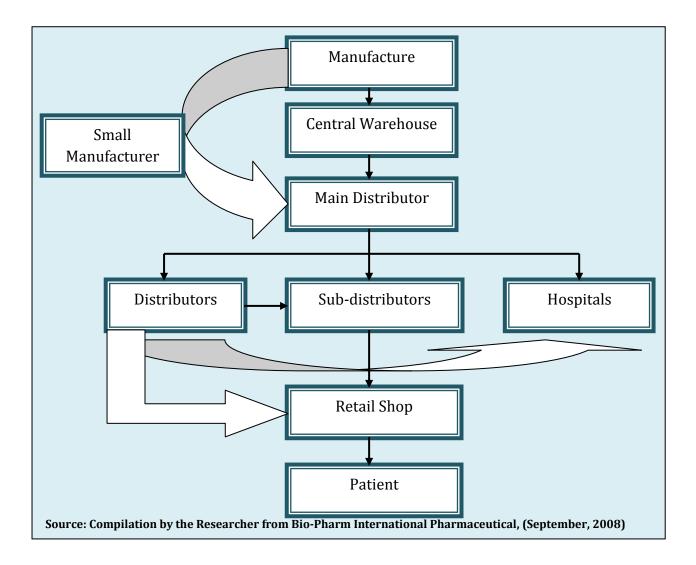
Another unique thing is the use of mail-order services to deliver drugs to patients and other retail users through the use of mail, fax, phone or internet at a central location. "The mail-order facilities are owned and operated by the PBMs and large number of retail pharmacy chains owns the mail-order pharmacy" California Health Care Foundation: Navigating the Pharmacy Benefits Marketplace, (2003). The National Health Policy Forum: The ABCs of PBMs, (1999) indicated that the driving forces for the rapid growth of mail-order services are; the increase in an aging population and the upswing in pharmaceutical treatments for common chronic ailments such as diabetes and depression.

It was indicated that most of pharmacies in the US purchase their drugs supply from wholesaler distributors and sometimes mail-order pharmacies obtain directly from the manufacturers. The pharmacies then distribute drugs to physicians or directly to consumers. Other large organizations and retail chain pharmacies as well as the specialty pharmacies they possess the operational infrastructures (distribution facilities, warehousing facilities and inventory control system) which allow them to bypass the wholesalers and deal directly with the manufacturers.

The wholesalers facilitate the drug buy-back program in collaboration with the manufacturers. The drug buy-back program allows pharmacies to minimize financial risk of keeping the unwanted stock and products which have a short-term expiration dates and also sell it back to manufacturers. This is very important as it reduce the risk of having the expired drugs in the market and drug shortages.

# INDIA: 3.1.2 INDIA PHARMACEUTICAL SUPPLY CHAIN STRUCTURE

Figure 3.2: <u>India Pharmaceutical Supply Chain Structure:</u>



#### 3.1.2.1 INDIA SUPPLY CHAIN CHARACTERISTICS AND INITIATIVES

## A: SUPPLY CHAIN CHARACTERISTICS (by 2008)

- Highly fragmented nature of distribution network, 70% of population lives in rural areas
- Limited advancement in regulatory reforms
- Presence of strong resistance from lobbies of traders involved in the supply chain
- Long channel of distribution
- Parallel supply chain network
- Around 65,000 distributors and 550,000 pharmacies serving 1,130 billion population
- Presence of 2 procurement agents by year 2006

#### **B: CHALLENGES FACING PHARMACEUTICAL SUPPLY CHAIN**

- Poor health care infrastructure
- More than 3/5 (60%) of Indians do not have access to modern medicines
- High distribution cost, rural areas are highly geographically dispersed
- Pharmaceutical companies do not have direct access to retailer's data of sales

#### **C: INITIATIVES**

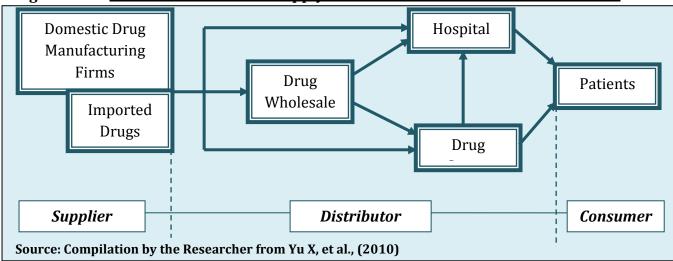
- Organized retail pharmacies through franchising to increase accessibility of medicines
- Increased IT adoption and use of customized software (SAP and SAS) in pharmaceutical supply chain for implementation of integrated solutions to keep inventory at optimum levels, improve distribution
- Multilayered distribution channel and lobbying at all levels to prevent bypassing the multiple distribution layers in order to reach customers directly
- Use of RFID technology for tracking drugs along the entire supply chain and also for preventing counterfeit drugs to enter the market.

#### Source: Compilation by the Researcher from Bio-Pharm International Pharmaceutical, (September, 2008)

Despite the fact that there are large numbers of distributors and pharmacies; India is also facing similar challenges of poor accessibility of medicines and distribution network. It also shows that large numbers of people who live in rural areas have lack of access to medicines; the population is highly unattended. However, several initiatives were implemented to overcome the challenges and some of the initiatives are mentioned in the summary box. The interesting thing about India is that despite the fact that India is leading in technology and the drastically increment of IT adoption yet the use of Radio Frequency Identification is very slow. India also uses the Clearing and Forwarding Agents (CFA) to store pharmaceuticals and forward the stock keeping unit to distributors on request.

#### CHINA 3.1.3 CHINA PHARMACEUTICAL SUPPLY CHAIN STRUCTURE

Figure 3.3: China Pharmaceutical Supply Chain Structure



#### 3.1.3.1 CHINA PHARMA SUPPLY CHAIN CHARACTERISTICS AND INITIATIVES

#### A: SUPPLY CHAIN CHARACTERISTICS (by 2010)

- Weak and large-scale distribution system
- Complex and competitive drug distribution system; all players take on a role as distributor
- Decentralization of public health services and increased autonomy of health facilities
- Imbalance of retail market sales within the supply chain
- Around 298,408 health facilities including 19,852 public hospitals serving 1.3 billion population
- Manufacturing sell their drugs to wholesalers, drug stores and direct to hospitals
- Presence of 13,000 wholesalers, 341,000 retailers, 554,000 rural drug supply outlets

# **B:** CHALLENGES FACING PHARMACEUTICAL SUPPLY CHAIN

- Unaffordable access to medicines; highly costly
- Ineffective supervision, lack of drug regulations transparency
- Lack of integration and poor IT systems
- Fragmentation and too many small players in the supply chain

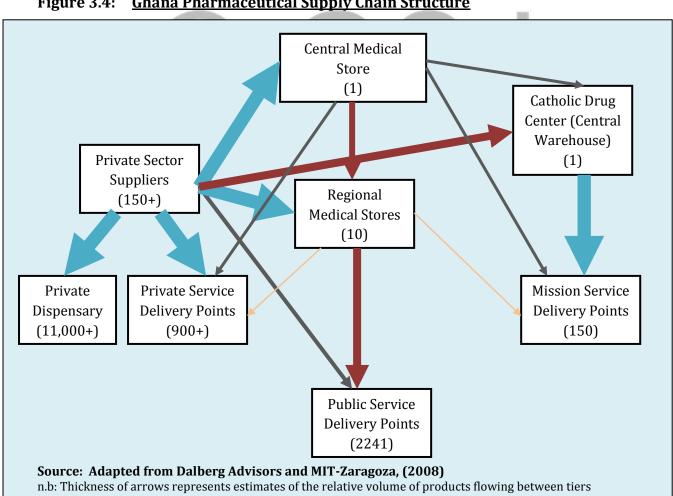
#### **C: INITIATIVES**

- Reformed supply chain from centrally controlled supply system to market-oriented system to improve availability of pharmaceuticals
- Use of commercial promotion activities and sales person to sell medicines direct to consumers
- Government to spend \$124.26 billion to provide accessible and affordable health care to the country
- Upgrading drug appraisal and approval standards to enhance focus on safety and encouraging innovation
- Introduced new health care reform plan in April 2009 to simplify the complex, fragmented and multilayered supply chain

Source: Compilation by the Researcher from Yu X, et al., (2010)

One of the interesting things in China is the transformation of the supply chain from centrally controlled to market-oriented supply system to cope with the changing economic system as it can be seen in *Section 3.1.3.1*. Previously the supply chain in China was centrally controlled and the pharmaceuticals were distributed by a state owned monopoly company as stated by Yu X, et al. (2010). This system is similar to Tanzania supply chain system; the "China state owned company distributed the pharmaceuticals to several regional wholesalers who then distributed the pharmaceuticals to local wholesalers. Hospital facilities used to purchase drugs only from different wholesales" Yu X, et al. (2010). Yu X indicated that this old supply chain in China had some advantages, there were greater regulation on pharmaceuticals quality and price but the regulated chain lacked competitive mechanisms which could result in bureaucratic behaviors, inefficiencies and imbalances in the supply of pharmaceuticals.

#### 3.1.4 GHANA PHARMACEUTICAL SUPPLY CHAIN STRUCTURE **GHANA**



**Ghana Pharmaceutical Supply Chain Structure** Figure 3.4:

## 3.1.4.1 GHANA PHARMA SUPPLY CHAIN CHARACTERISTICS AND INITIATIVES

## A: SUPPLY CHAIN CHARACTERISTICS (by 2007)

- Distribution is a tiered pull system, it is Inefficient and highly costly distribution system
- Central Medical Stores manage the physical supply of pharmaceuticals
- Involvement of donor agencies (PEPFAR, USAID, UNFPA and UNICEF) in the procurement process
- Low service level at Central Medical Store and presence of large number of intermediaries
- Regional medical stores purchase pharmaceuticals from private sector suppliers
- 35 local manufacturers registered by food and drug board and account for approximately 30% of total pharmaceuticals demand
- 2241 public health facilities served by 10 regional and central medical stores
- 28.8% of people in the northern part have access to medicines

#### **B:** CHALLENGES FACING PHARMACEUTICAL SUPPLY CHAIN

- Major supply chain disruptions due to delays by donors and/or supranational procurement agents
- Delays in the release of funds and delivered goods from donors and/or supranational procurement agents and Funding delays within the government
- Lack or little information about the cause of delays or projected release date of the funding and delivery of goods
- Local manufacturers facing challenges like limited access to affordable capital, long and variable lead time from suppliers mostly from China and India
- Holding large inventory to avoid stocking out
- Failure of some regions to implement the scheduled delivery service due to lack of funding, appropriate trucks, proper procedures and poor service level at central medical stores

#### **C: INITIATIVES**

- Use of basket funding to strengthen the health service delivery
- The Supplies, Stores and Drug Management established a framework contract agreement with local suppliers to minimize the lead time and operate within the agreed contract.
- Renovation of the central medical stores and the physical infrastructure was upgraded. The facility is within 4km of the port and 30km of the airport
- Approved policy for the implementation of scheduled delivery service from every regional medical stores to service delivery points
- Use of newly designed Requisition, Issue and Receipt voucher to simplify ordering, receiving and invoicing of products and minimize the complexity and replace the use of store issue voucher, stores receipt advise and certificate of non-availability.

Source: Compilation by the Researcher from Dalberg Advisors and MIT-Zaragoza, (2008)

In Ghana there is a high involvement of private sector in the provision of health services as compared to the public which handles about 40% of total health services. The main challenge that was seen in the Ghana supply chain is the longer lead time of delivery of goods and allocation of financial resources. The procurement process is complex; there is an involvement of donors and other supranational procurement agents which cause the delays to prolong.

Despite many efforts made by the government to implement policies to improve the accessibility and availability of pharmaceuticals, there is a failure and delays in actual implementation due to lack of funding and proper procedures.

Interestingly, in Ghana there are illicit cross border flows of pharmaceuticals and consolidation of the distribution services by the foreign firms due to complex and the varieties point of product entry.

# ZAMBIA 3.1.5 ZAMBIA PHARMACEUTICAL SUPPLY CHAIN STRUCTURE

Medical Store Limited (1)**CHAZ Central** Warehouse **Private Sector** Suppliers District (50)**Medical Stores** (72)Private Private Service **CHAZ Service Delivery Points Delivery Points** Dispensary (59 Pharmacies) (125)**Public Service Delivery Points** (2000)Source: Adapted from Dalberg Advisors and MIT-Zaragoza, (2008) n.b: Thickness of arrows represents estimates of the relative volume of products flowing between tiers

Figure 3.5: Zambia Pharmaceutical Supply Chain Structure

#### 3.1.5.1 ZAMBIA PHARMA SUPPLY CHAIN CHARACTERISTICS AND INITIATIVES

#### A: SUPPLY CHAIN CHARACTERISTICS (2008)

- Large number of institutions involved in the procurement of pharmaceuticals
- Heavy reliance on external donors for financial resources in the procurement of pharmaceuticals
- The national medical stores (Medical Stores Limited) manage the storage and distribution of pharmaceuticals for the ministry of health.
- 14 trucks (ten tons) are used for the distribution of pharmaceuticals
- Essential drugs lines are usually in stock; approximately over 50% are in stock
- Poor visibility of the supply chain after delivery of pharmaceuticals to the districts
- Use of pull-logic to distribute drugs and the shipment based on actual demand while medicine kits use push-logic

#### **B:** CHALLENGES FACING PHARMACEUTICAL SUPPLY CHAIN

- Flooding of some drugs and shortages of drugs as the external donors do not purchase other drugs in the assumption that it will be purchased by others
- Higher frequency of drug stock out at medical stores limited due to budgetary constraints
- Highly variability lead time of the distribution chain both procurement lead-time of Ministry of Health and delivery lead-time of a supplier
- Expired drugs do not return back to medical stores limited
- Little traceability to ensure the expired drugs are destroyed out
- Weak tracking system

#### C: INITIATIVES

- Use of emergency procurement in smaller quantities by both Ministry of Health and external donors during the period of drug shortages
- Districts and provisional hospitals are allowed to use some of their budget for emergency purchases during the time when medical store limited runs out of stock
- Utilization of framework contracts with few local suppliers to reduce the lead time of procurement through the international open-tender process
- Government contracted the management of medical stores limited to Crown Agents to improve the efficiency of the medical stores
- Improved physical infrastructures for storage and distribution through the recommendation of capital investment by Crown Agents
- Periodic visits to the districts done by customer service teams of medical stores limited
- All districts required to place the order by hand-delivered or fax before the preset of each month
- Medical Stores Limited sends a stock-status report to all districts every month
- Use of panic over-ordering when there is unavailability of drugs at the medical stores limited

Source: Compilation by the Researcher from Dalberg Advisors and MIT-Zaragoza, (2008)

One of the biggest challenges in Zambia is the heavy reliance on external donors for financial support for the procurement of pharmaceuticals. The heavy reliance creates complexity in the management of pharmaceutical procurement. The poor management contributed to the flooding of some drugs and shortages.

In comparison to Ghana and Tanzania, Zambia has more regional/district medical stores located in different parts of the country. Despite the large number of the district medical stores, Zambia still has a challenge of drug stock-out which is caused by the budgetary constraints.

However, the Government of Zambia took several initiatives to overcome the challenges. The Government contracted the management of the medical stores to the Crown Agents to improve the efficiency of the medical stores.

In addition to that, Zambia uses the emergency procurement in small quantities when they face delays from the suppliers of pharmaceuticals. These small quantities are used to prevent the shortages and stock-out.

Other good initiatives are the physical periodic visits done by medical stores staff to district stores and the use of stock-status report by medical stores. These initiatives ensure the flow of relevant information to be used during the ordering and stock control it can also be used to predict any future changes.

## 3.1.6 Summary of the Five Cases

The discussed five cases of pharmaceutical supply chain from developed (USA) and developing countries (China, India, Ghana and Zambia), highlighted the characteristics, challenges and initiatives taken by each country. Some of the challenges are similar to some countries in the discussion and other challenges are unique. There are number of interesting initiatives taken by different countries and among these initiatives, some of them can be applied to other countries for the improvement of the performance of the pharmaceutical supply chain and distribution network.

These five cases are analyzed in chapter 5 along with the Tanzania case study by cross-case analysis technique in this thesis to identify the similarities and differences of the challenges and initiatives and furthermore the findings are used as a benchmark for recommendations to Tanzania.

# 3.2 LOCAL CASE STUDY

#### 3.2.1 INTRODUCTION

This chapter discusses in details the pharmaceutical sector profile and specifically the center focus of the discussion will base on the functions and challenges facing the public pharmaceutical supplier and distributor in the country as it was indicated briefly in chapter one.

## 3.2.2 COUNTRY PROFILE

As indicated in chapter one, Tanzania has a total Area of 947,300 square kilometers, of which 883,000 square kilometers are land; 881,000 square kilometers in the mainland and 2,000 square kilometers in Zanzibar. Projections for 2009 indicated the Tanzania's total population of "41.9 millions", of which "44.4% (18.6 million)" are children under 15 years (MOHSW, 2008). According to the CIA Fact book the Tanzania's population is at 30th position in comparison to the world. CIA Fact book also indicated that the estimates of the population in Tanzania explicitly take into account the effects of excess mortality due to AIDS and this can result in lower life expectancy, higher infant mortality, higher death rates, lower population growth rates and changes in distribution of population by age and sex than would otherwise be expected (CIA Fact book, July 2010 estimates). Table 3.1 summarizes the country in terms of population growth rate, birth and death rate and disease situation.

 Table 3.1
 Country Population, Disease, Birth and Death Rate

Indicators	Rate	World Comparison	Estimate Year
Population growth rate	2.032 %	52	2010
Birth rate	33.44 births/1,000 population	40	2010
Death rate	12.31 deaths/1,000 population	28	2010
*Malaria deaths (annual)	60,000		2010
80% of deaths are children			
under 5 years.			
HIV/AIDS deaths	96,000	7	2007
HIV/AIDS – Adult	6.2 %	12	2007
prevalence rate			

Source: Compilation by the Researcher from CIA World Fact book:

https://www.cia.gov/library/publications/the-world-factbook/geos/tz.html. (Accessed on 24th July, 2010)

http://www.pmi.gov/countries/profiles/tanzania\_profile.pdf. (Accessed on 21st May, 2010)

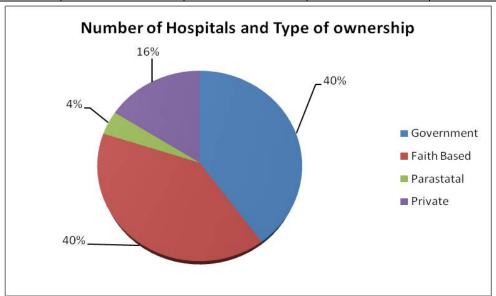
<sup>\*</sup>Source: Compilation by the Researcher from USAID, (April, 2010):

#### 3.2.3 HEALTH FACILITIES IN TANZANIA

The health facilities in Tanzania consist of both public and private hospitals, health centers and dispensaries. The following tables summarize the total number of health facilities and type of ownership in Tanzania.

 Table 3.2
 Hospitals and Type of Ownership

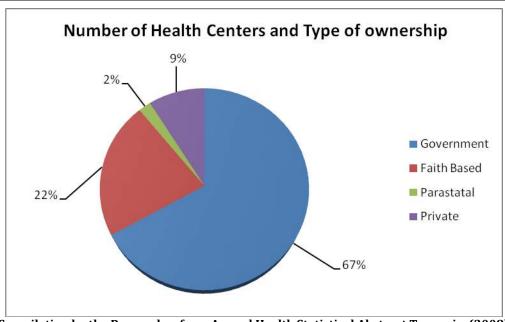
Government	Faith Based	Parastatal	Private	Total
89	90	8	36	223
40%	40%	4%	16%	



Source: Compilation by the Researcher from Annual Health Statistical Abstract Tanzania, (2008)

Table 3.3 Health Centers and Type of Ownership

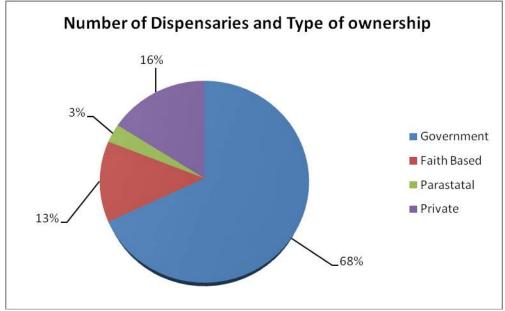
Government	Faith Based	Parastatal	Private	Total
379	125	12	49	565
67%	22%	2%	9%	



Source: Compilation by the Researcher from Annual Health Statistical Abstract Tanzania, (2008)

 Table 3.4
 Dispensaries and Type of Ownership

Government	Faith Based	Parastatal	Private	Total
3,348	658	133	801	4940
68%	13%	3%	16%	



Source: Compilation by the Researcher from Annual Health Statistical Abstract Tanzania, (2008)

#### 3.2.4 OVERVIEW OF PHARMACEUTICAL SECTOR IN TANZANIA

The Government of Tanzania privatized its two pharmaceutical industries in 1997 (Annual Health Statistical Abstract Tanzania, 2008). The main objective for the privatization was to allow private management of the pharmaceutical industries and reduce government expenditures. Currently there are ten local manufacturers of pharmaceuticals in the country. One of the challenges facing the government is the procurement of medicines. Currently 80% of the medicines are imported and 20% are procured locally (MSD Stakeholders Meeting in Tanzania, July, 2010). All imported and locally procured medicines are done through the MSD centralized procurement system. In addition to that, Tanzania also depends on drug donations from donors. Drugs regulation and legislation are conducted through the Food and Drugs Authority, (TFDA).

# 3.2.4.1 <u>Regulations and Legislation of Pharmaceuticals by TFDA</u>

TFDA regulates the medicines supply and conducts inspections of the private and public drugs outlets including hospitals, private pharmacies, wholesalers and nonprescription medicine shops in Tanzania. TFDA objectives of import regulations are to ensure that the pharmaceuticals entering the country are meeting the quality standards. TFDA believes that regulation is one step toward achieving the goal of making available the

medicines that are of good quality, effective and safe to the majority of Tanzanians. It was indicated in one of the recent meeting (July, 2010) conducted by stakeholders who are involved in the pharmaceutical supply chain that; there are eleven approved ports of entry for the importation of pharmaceuticals in Tanzania. These ports of entry are one of the sources of counterfeited drugs. *TFDA* reported the challenges facing the organization; "presence of unauthorized ports of entry, lack of adequate resources to control unauthorized importation due to the presence of several ports of entry and lack of some required information in importation documents".

# 3.2.4.2 Challenges facing the Sustainability of Health Care Quality in Tanzania

Tanzania still faces number of challenges in ensuring sustainability of health care quality and efficient accessibility of medicines. Those challenges are; increasing morbidity and mortality due to HIV/Aids and Malaria, increasing demand for health care due to increasing population and varying disease patterns and difficulties in forecasting demand fluctuations, shortfall in annual health sector budget allocations and increasing costs of essential health care inputs (MSD Stakeholders Meeting in Tanzania, July, 2010).

# 3.2.5 PUBLIC PHARMACEUTICAL SECTOR IN TANZANIA

As it was pointed out in chapter one, Euro Health Group: Tanzania Drug Tracking Study, (2007) indicated that the essential medicines and all levels of medical supplies in Tanzania are mainly procured, stored and distributed by the centralized procurement system at the national level, the Medical Stores Department (MSD).

# 3.2.5.1 <u>Overview of Medical Stores Department (MSD)</u>

Based on the information provided by MSD, the medical stores department was created by an act of Parliament of Tanzania in 1993 to serve the nation's health care needs. MSD is a non for profit semi autonomous single agency owned by the government and an independent department within the Ministry of Health and Social Welfare. It operates its activities on a commercial basis and is responsible for its own self sustaining financially. In addition to that, MSD is the main supplier of essential medicines for the public sector and primary supplier to faith based and other non government, non commercial groups providing health services in the country. The main objective of the MSD organization is to maintain, develop and manage efficient and cross-effective the procurement system, distribution and storage of pharmaceuticals in the country.

# 3.2.5.2 <u>Pharmaceutical Supply in Tanzania</u>

As it was indicated earlier in this discussion, MSD is responsible for the procurement, storage and distribution of all medicines and other medical supplies throughout the nation. It was indicated in one of the recent presentation of July, 2010 from MSD that until 1984, health facilities ordered their requirements from the former central medical stores (CMS) then from 1984 to 2000; the CMS/MSD used the push system to deliver medicines to the dispensaries and health centers using kits. Hospitals were also ordered their requirements to the CMS/MSD. In 2000 the MOHSW introduced a new system, Indent System (IS). This is a system in which "health facilities and dispensaries in the rural areas orders the medicines according to their requirements up to the budget limit". MSD use *pull system* to supply medicines with the new system which serves orders from distant customers and finally deliver to health facilities and dispensaries. Figure 3.6 depicts the structure of drug supply and distribution network in Tanzania.

352 Registered **Private Pharmacy** 197 Registered Private Wholesalers 6000 Duka la Dawa baridi Essential **Patient Essential MSD** Drugs Hospital Essential MSD pool MSD Local **Essential Drugs Primary Health** of Essential **Procurement** Manufacturer **Facilities** Drugs **Indent Packing MSD Procurement** International **Program Control** Supplier **District** External **Vertical Program Items** Procurement Vertical Program

Figure 3.6 Pharmaceutical Supply Chain and Distribution Network in Tanzania

Source: Adapted from Euro Health Group: Tanzania Drug Tracking Study (2007)

# 3.2.5.3 <u>Lead Time of Pharmaceutical Supply Chain</u>

It takes approximately 6-12months for MSD to receive medicines from the international supplier. This lead time causes difficulties to MSD to respond on a timely manner to the fluctuating demand as explained in the Drug tracking report, (2007). The summary of the lead time is illustrated on figure 3.7. After receiving the drugs from international supplier and/or local supplier, MSD distribute the medicines to zonal stores, again it takes minimum of two weeks to one month to deliver the orders then from MSD zonal they distribute to health facilities.

**Health Facilities:** 1/<sub>2</sub> - 1m **Local Supplier Private Private** 1/<sub>2</sub> - 1m 0m Wholesaler **Pharmacy Private** <sup>1/</sup><sub>2</sub> - 3m Government 0m **MSD** International **MSD Zonal Faith Based** € <sub>0m</sub> <sup>1/</sup><sub>2</sub> - 1m 6 - 12m Headquarter **Supplier Stores Parastatal** Source: Compilation by the Researcher from Euro Health Group: Tanzania Drug Tracking Study (2007)

Figure 3.7: Pharmaceutical Supply Chain Lead Time for MSD and Private Wholesalers

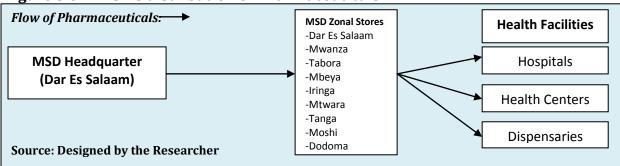
#### 3.2.5.4 <u>Donation of Medicines in Tanzania</u>

"Access to medicines has a high priority in health system of all countries. Nevertheless millions of people worldwide have either limited or no access to medicines" (Pecoul et.al, 1999). In one of the study conducted by Mariacher, G.G., (2008); "Drug Donation in Tanzania", it was indicated that Tanzania is a country with "low access to essential drugs that receives substantial drug donations as in-kind gifts" in order to bridge the supply gap. The findings of that report indicated that Tanzania has a 30% supply gap of essential medicines. However the TFDA indicated experienced challenges faced by the country from the donation of the medicines. Most of the donations contained medicines that are unserviceable. This includes; "medicines delivered from donations have too short shelf-life of less than six months and medicines delivered from donations were very close to expiry dates or thus expired".

# 3.2.5.5 <u>Distribution and Transportation of Pharmaceuticals in Tanzania</u>

As indicated in the Drug Tracking Study report (2007), approximately 80% of the vehicles used by MSD to supply and distribute medicines are more than 10 years old and are no longer in good quality. Most of pharmacies are in major urban areas while approximately 75% of population lives in rural and peri-urban communities. The distribution of pharmaceuticals is also done by MSD. It has a total number of nine zonal medical stores which are situated in nine different regions within Tanzania. MSD delivers the medicines to the zonal stores then zonal stores distribute medicines to health facilities in different regions as required as it can be seen in figure 3.8

Figure 3.8 MSD's distribution of Pharmaceuticals



Through the indent system, it takes around twelve weeks cycle for medicines to be delivered to health facilities since the placement of order. MSD is also using the integrated logistic system (same basic system and procedures) to process orders and distribute medicines. Table 3.5 on the following section indicates a summary of distance covered from MSD Headquarter in Dar Es Salaam to MSD zonal stores and the regions.

Table 3.5 <u>Distance covered by MSD to distribute medicines in Tanzania</u>

From MSD Head Quarter	To MSD Zonal Stores	Road Travel Distance (in Km)	Average Distance (in Km)
Dar Es Salaam	Tabora	855.52 - 929.91	743.93
Dar Es Salaam	Mwanza	980.56 - 1065.82	852.66
Dar Es Salaam	Mbeya	786.14 - 854.50	683.60
Dar Es Salaam	Iringa	470.99 - 511.95	409.56
Dar Es Salaam	Mtwara	457.76 - 497.56	398.05
Dar Es Salaam	Tanga	222.86 - 242.24	193.79
Dar Es Salaam	Moshi	506.24 - 550.26	440.21
Dar Es Salaam	Dodoma	455.77 – 495.40	396.32
Dar Es Salaam	Dar Es Salaam	Less than 10	Less than 10

*Note: This table continues on the following section.* 

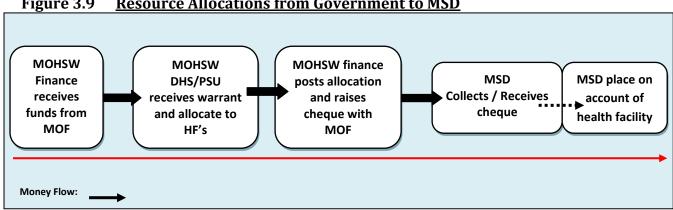
From MSD Zonal Stores	To Regions	Road Travel Distance (in Km)	Average Distance (in Km)
Tabora	Kigoma	404.65 - 439.84	351.87
Mwanza	Kagera	251.17 - 273.01	218.41
	Shinyanga	162.05 - 176.14	140.91
	Mara	247.71 – 269.25	215.40
Mbeya	Rukwa	265.40 - 288.48	230.78
Dar Es salaam	Pemba	932.27 - 1013.34	810.67
	Zanzibar	81.24 - 88.30	70.64
Iringa	Ruvuma	373.00 - 405.44	324.35
Mtwara	Lindi	79.32 - 86.21	68.97
Moshi	Arusha	103.21 - 112.19	89.75
	Manyara	196.62 - 213.71	170.97
Dodoma Singida		926.92 – 1007.52	806.02

Source: Compilation by the Researcher from

http://distancecalculator.globefeed.com/Tanzania Distance Calculator.asp

#### 3.2.5.6 **Timing of Resources Allocation**

Resource allocation for essential medicines is a key factor for the distribution and delivery system to operate efficiently. As indicated in the drug tracking study report MOHSW, (2007), the money allocated for medicines are disbursed from the MOHSW to MSD for procurement. There are delays in government budget and as a result it increases the lead time for the supply of medicines in the country. Figure 3.9 on the following section illustrates the allocation of resources. In Tanzania, the total amount of money allocated by Ministry of Health for the essential medicines in year 2005/06 was USD 29.2 million (Tanzanian Shillings 33.7 billion) and the total amount of money spent were USD 27.7 billion (Tanzanian Shillings 29.7 billion) equivalent to 88% as stated in the drug tracking study (Euro Health Group: Tanzania Drug Tracking Study, 2007)



**Resource Allocations from Government to MSD** Figure 3.9

Source: Compilation by the Researcher from Euro Health Group: Tanzania Drug Tracking Study (2007)

There was an under spending of 12% of the allocated budget. In the report .Drug Tracking Study, (2007), it was pointed out that the "reasons for the under spending could be directed to the "out of stock (28 days duration)" medicine from the main provider, MSD. The public sector health facilities and other hospitals which purchase drugs and supplies from MSD are forced to procure from alternative suppliers, this is time-consuming and burdensome. The stock availability problems at MSD zonal stores and public sector drug financing policy made it difficult for a public sector hospital to procure supplies from any other source than MSD.

# 3.2.5.7 Initiatives made by Government and MSD

Based on the presentation by the MSD (July, 2010) at stakeholders meeting in Tanzania, it was pointed that MSD is continually striving to improve the performance of services. As one of the initiatives, MSD has started using the framework contracts which enable them to have flexibility in efficiency, delivery and value for money. In addition to that, MSD has a valid contract with suppliers of medicines. As one of the strategic direction, MSD is implementing its medium term strategic planning for 2007 - 2013 which aim at improving the existing operations and product/service development.

## 3.2.6 Summary of the Chapter

This chapter has provided an in-depth review of the pharmaceutical sector in Tanzania. It mainly focused on the public pharmaceutical sector. The chapter also described briefly the regulation situation of medicines and also highlighted the challenges facing the sustainability of health care quality in Tanzania. The MSD being a single autonomous organization owned by the Ministry of Health and Social Welfare; procures, supply and distributes medicines in Tanzania.

Furthermore the chapter described the pharmaceutical supply situation in the country by focusing on the transportation and distribution. The chapter ended by describing timing of resources allocation including the donations of medicines received by the country.

In chapter 5 of this study, the current situation of the pharmaceutical supply chain is analyzed in details and the findings are discussed in the same chapter after the analysis.

# **CHAPTER FOUR**

# CONCEPTUAL FRAMEWORK, CASE STUDY DESIGN AND METHODOLOGY

#### 4.1 INTRODUCTION

This chapter discusses in details what was briefly pointed out in Chapter 1 about the conceptual framework and the case study design. From the conceptual framework, a model is developed to guide the researcher to show a logical sense of the relationships of variables that have been identified as relevant for the research problem. Problem statement, research objectives and methodology are also covered in this chapter.

## 4.2 PROBLEM STATEMENT

As it was pointed out in chapter 1, the desired health outcomes can be achieved if there is an adequate medicine supply to the right people and will be used in the right way. Medicines are critical health care products in the primary health care system and are cardinal in the reduction of morbidity and mortality. The accessibility, availability and use of medicines to minimize mortality and morbidity cannot be debated.

Many developing countries are faced by problems of irregular and insufficient supply of medicines, high incidence of diseases and spend substantial amounts of the health budget on medicines and medical supplies. Tanzania's indicators on health are still below acceptable levels when compared to other developing countries (WHO Country Cooperation Strategy: 2010-2015; 2009). The causes of unfavorable conditions include, but not limited to: inadequate budget for the health sector, increased demand for health care services due to population growth and changes in disease pattern, morbidity and mortality due to HIV/AIDS and Malaria. Difficulties in forecasting demand fluctuations, shortfall in annual health sector budget allocations and increased cost of essential health care medicines weakens health of the nation.

There is a need for health facilities to maintain adequate stock of medicines and develop an efficient health care system to guarantee equitable access to health services and efficient availability of essential medicines to the country.

## 4.3 RESEARCH OBJECTIVES

# 4.3.1 Main Objectives

The main objectives of this study are to critically analyze the pharmaceutical supply chain and distribution network and evaluate the implication on access to medicines and quality health care. To provide innovative solutions that will be implemented to improve the supply chain and distribution network that will lead to the efficient accessibility of medicines and improvement of the health care quality. The research will mainly address the following; a) enabling factors of the pharmaceutical supply chain performance, b) aggravating factors of pharmaceutical supply and demand mismatching and strategies for improvement, c) challenges facing the pharmaceutical supply chain and distribution network in Tanzania and innovative solutions for improvement, d) the implication of performance of the pharmaceutical supply chain and distribution network on accessibility of medicines and quality of health care in Tanzania, e) the application of innovation in the pharmaceutical supply chain and distribution network.

#### 4.4 RESEARCH LIMITATIONS

However, there are limitations on this research:

- a) The central focus of the study is MSD and other players in Dar Es Salaam city; it excludes the private suppliers, local and international manufacturers.
- b) According to Yin (1994), the case study is not a sample unit and the findings of this study are only based on analytic generalization and not statistical generalization.
- c) All factors and indicators other than the ones used in this study are assumed to be constant and not to have influence on study results.
- d) Incomplete availability of data from the rural areas and other health sectors limit the focus at Dar Es Salaam city only.

#### 4.5 CONCEPTUAL FRAMEWORK

The conceptual framework as explained by Miles and Huberman, is a written or visual presentation that "explains either graphically, or in narrative form, the main things to be studied – the key factors, concepts or variables -and the presumed relationship among them" (Miles and Huberman, 1994. p.18).

The researcher adopted the conceptual framework designed by Daniella etal., (2008), the authors of the technical partner paper 13:"Private Sector Role in Health Supply Chains" which was highlighted in Chapter 1 of this thesis. This model indicates how good pharmaceutical supply chain performance contributes to good health quality outcomes.

Figure 4.1: Conceptual Framework: How Good Pharmaceutical Supply Chain Performance
Contribute to Good Health Outcomes

#### **Achieving Health Quality Outcomes** Geographic Access **Availability** Affordability Quality "Able to provide the "Able to provide safe, "Able to provide "Able to provide product at a location consistent availability products at prices authentic, efficacious within a reasonable of the right type and that patients/the and unexpired distance to the quantity of product" system is able to bear product" patient" and sustain" **Key Drivers: Key Drivers: Key Drivers: Key Drivers:** Matching of supply Disincentives for Location and Market and demand counterfeiting number\* of competition product dispensing Lead time Quality products Free dispensing point enters supply Financing gaps, vs. user fees chain delays and leakage Modes of product Expired drugs\* transport\* Stock control\* Short expiry Distance covered\* Transport capacity drugs\*

#### **Sustainability of Quality Health Outcome**

Pharmaceutical Supply Chains must be:

- \*Flexible (Adaptable), Cost-effective and have Financial Integrity
- \*Flexible (Adaptable) to changes in product portfolio, good management and use of funds

Source: Adapted from Dalberg Advisors and MIT-Zaragoza, (2008)

\* Added by the Researcher

# 4.5.1 The Conceptual Framework Variables Interrelationships

In order to achieve the quality health outcomes, the pharmaceutical supply chain must provide consistent availability of affordable, high quality medicines that are geographically accessible to patients and other target group in the society. Figure 4.1 illustrates the four variables of pharmaceutical supply chain as suggested by Dalberg Advisors and MIT-Zaragoza, 2008 and figure 4.2 depicts the interrelationship between the variables of the pharmaceutical supply chain performance. Though these variables are interrelated, the focus of this study excludes the affordability variable as is not the main concern of the research.

: Positive Impact Geographic : Negative Impact Access Hard to ensure quality the further you extend the reach Hard to ensure availability the Fixed cost of outlet further you extend the reach Access to capital to city to procure in enables bulk is lower than investment to fixed cost of patient extend reach travelling separately Better financial flows enable better Reduced acquisition cost and planning and smooth flow of products markups results in lower prices **Affordability Financial Availability** Integrity Better availability leads to Increased and more stable increased sales and better cash product demand velocity If products are available in formal Better planning **Higher quality products** are more costly enables using better outlets patients will Reduced suppliers, no need not go to grey acquisition cost and for emergency market for poor markups results in procurement that quality products lower prices skimp on quality Highest quality products are usually only available via international suppliers with long lead-times making it Quality difficult to ensure Source: Adapted from Dalberg Advisors and MIT-Zaragoza, (2008)

Figure 4.2: The Pharmaceutical Supply Chain Performance Variables and Interrelationships

#### 4.5.1.1 Geographic Access

Following the definition of Access to Essential Medicine in section 2.4.4, geographic access is the ability of medicines to be accessible by the end users in supply chain with respect to number and location of medicines dispensing point and location of end users. The geographic access also depends on modes of transport used or distribution system. A good distribution system as explained by "the WHO" ensures the timely availability of essential medicines at all levels of the health system. Timely distribution of medicines means that they must be distributed and dispensed within their expiry date <sup>13</sup>.

#### 4.5.1.2 <u>Availability</u>

The availability is concerned with the physical presence of essential medicines at health facilities. Different factors determine the availability of medicines as indicated in the conceptual framework. Stock-out/inadequate supply of medicines at health facilities contributes to the un-matching of demand and supply. This cause shortages and unavailability of medicines at health facilities. Moreover; longer lead time and poor distribution system cause delays of the medicines availability. Indeed, another key factor for availability of medicines is the financial resources. Any delays or gaps in financing, budget approvals and funds disbursement has a negative implication on the timely availability of medicines.

#### 4.5.1.3 Affordability

With reference to the conceptual framework, the affordability concerns with prices of medicines. This is not the main focus of the study and it is excluded in this discussion.

#### 4.5.1.4 **Quality**

The quality of medicines which are distributed to the health facilities contributes to the quality of health outcomes. Quality products must enter the supply chain and must not be expired or counterfeited to provide positive impact on the quality of health outcomes.

#### 4.5.1.5 <u>Financial integrity</u>

In order to sustain the quality of health outcomes, the supply chain must have a financial integrity. The strong financial management and enough financial resource enable the supply chain to operate smoothly and achieve the desired health outcomes.

<sup>&</sup>lt;sup>13</sup>WHO Definition, Chapter 7 Access to Essential Medicines. Available at: <a href="http://apps.who.int/medicinedocs/en/d/Is6160e/9.html">http://apps.who.int/medicinedocs/en/d/Is6160e/9.html</a>. (Accessed on 27th May, 2010)

#### 4.5.1.6 <u>Sustainability of Quality Health Outcomes</u>

The sustainability of quality health outcomes depends on the performance variables and drivers as explained in the conceptual framework and in addition to that it also depends on cost efficiency and the flexibility of the pharmaceutical supply chain. Sustainable health quality outcomes can be achieved if the pharmaceutical supply chain will be robust. In order to maximize the health impacts and maintain the functioning of the supply chain, the sound financial management is required. Moreover, the flexibility of the supply chain is very important for incorporating innovations and product changeovers. It can be seen from figure 4.2 that any improvement made in one aspect can support and make stronger another aspect (arrows with black color). However there is a possibility that improving another variable can have an opportunity cost on the other aspect (arrows with red color). For example, as it was indicated by Dalberg Advisors and MIT-Zaragoza, (2008); "extending the geographical coverage to remote populations often requires leveraging distribution networks or retail platforms that have less supply chain visibility and oversight making product integrity and quality harder to ensure".

According to the framework in figure 4.1 and the aspects interrelationship illustrations in figure 4.2, the researcher will proceed by indicating the dimensions/measurements of the aspects of pharmaceutical supply chain performance that are going to be used as a guideline for the analysis of the data collected. These indicators are also used to analyze the research variables which will be explained in section 4.5.2.

#### 4.5.2 DEPENDENT AND INDEPENDENT VARIABLES FOR ANALYSIS

#### 4.5.2.1 <u>Pharmaceutical Supply Chain Performance Variables</u>

Based on the conceptual framework on figure 4.1, the performance of pharmaceutical supply chain including distribution network are analyzed using variables to identify whether performance of pharmaceutical supply chain is good or poor (Summary in Table 4.1). The variables are used to answer the research questions and the factors to be analyzed are: stock control, demand management, supplier performance, distribution network and delivery flexibility and supply chain flexibility.

The distribution network is analyzed by the geographic access indicators. Mode of transports number of zonal stores contributes to the accessibility and availability of medicines. All these factors are analyzed when responding to the research questions.

Table 4.1: Supply Chain Performance: Dependent and Independent Variables

Dependent Variables	Dependent Variables	Independent Variables	Research Questions
Pharmaceutical Supply Chain Performance	Supply Chain Flexibility	<ul> <li>Supply capacity and lead time</li> <li>Resource Allocation lead time</li> <li>Multiple modes of transport</li> <li>Number of Zonal stores</li> </ul>	RQ1, RQ3, RQ5
	Stock control	<ul> <li>Stock out/shortage</li> <li>Stock holding</li> <li>Lead time</li> <li>Recording system</li> </ul>	RQ1, RQ2, RQ3
	Demand-Supply Management	<ul> <li>Stock out</li> <li>Forecast error/uncertainty</li> <li>Excess inventory</li> <li>Lead time</li> <li>Tracking / Recording system</li> </ul>	RQ1, RQ2, RQ3, RQ5
	Supplier Performance	<ul> <li>Procurement Lead time</li> <li>Delivery lead time</li> <li>Conformity of ordered drugs vs. delivered drugs</li> <li>Stock out</li> <li>Short expiry drugs</li> <li>Expired drugs</li> <li>Counterfeit drugs</li> </ul>	RQ1, RQ3, RQ5
	Distribution Network & Delivery Flexibility	<ul> <li>Multiple modes of transport</li> <li>Delivery lead time</li> <li>Number of Zonal stores</li> <li>Distance covered</li> </ul>	RQ3, RQ5

Source: Compilation by the Researcher

Note: There are other applicable indicators but the author chose these indicators to fit within the scope of the thesis topic

#### Stock control

This means the management and control of the amount of stock in order to meet the demand and minimizing the stock out or shortage.

#### Lead-time

Is defined as the duration of time it takes to deliver products from a supplier to an end user. The focus of this study will be on delivery, procurement and resource allocation lead-time

#### Stock-out

This indicates the absence of drugs in the stock due to either delay in the supply chain other factors like expired drugs.

#### **Stock-holding**

This represents the buffer stock that the supplier or end user will hold the stock to prevent any changeovers in the supply chain which might result into non availability or delays.

# Counterfeit drugs

These are drugs that are deliberately and fraudulently mislabeled with respect to identity and/or source. There is a high chance of having counterfeited drugs for situations where there is unmet demand. Indeed, this has an implication on health; in extreme cases it can cause death (WHO: Factsheet No. 275, January, 2010)

#### 4.5.2.2 Accessibility and Availability of Medicines Variables

Accessibility of medicines as it was indicated in the conceptual framework means the geographic access and physical availability. Table 4.2 depicts the independent and dependent variables to be used for analyzing the research questions.

 Table 4.2:
 Medicines Accessibility and Availability Variables

Dependent Variable	Independent Variables	Research Questions
Geographic Accessibility of Medicines	<ul> <li>Number of zonal stores</li> <li>Distance covered from headquarter to zonal stores</li> <li>Distance covered from zonal stores to the end users</li> <li>Multiple modes of transport</li> </ul>	RQ3, RQ4
Physical Availability of Medicines	<ul> <li>Resource Allocation lead time</li> <li>Lead-time (procurement)</li> <li>Distribution transport</li> <li>Tracking system of demand and inventory</li> <li>Matching demand/supply</li> </ul>	RQ3, RQ4, RQ5

Source: Compilation by the Researcher

Note: There are other applicable indicators but the author chose these indicators to fit within the scope of the thesis topic

#### 4.5.2.3 <u>Dependent Variable: Quality Health Care</u>

The researcher selected the quality variables which best fits the discussion topic. The quality of pharmaceuticals is analyzed using the variables mentioned in table 4.3 and these variables are also used to answer the research questions.

**Table 4.3: Ouality Health Care Variables and Indicators** 

Dependent Variable	Independent Variables	Research Questions
Quality	<ul><li>Lead time</li><li>Stock out</li><li>Expired drugs</li><li>Counterfeit drugs</li></ul>	RQ3, RQ4

Source: Compilation by the Researcher

Note: There are other applicable indicators but the author chose these indicators to fit within the scope of the thesis topic

#### 4.6 RESEARCH METHODOLOGY

#### 4.6.1 Research Type.

Based on concepts of case studies described by Yin (1994); this is an "explanatory research" based on multiple cases. Indeed; the case study based on a mixture of both qualitative and quantitative approach. The main objective of this study is to analyze critically the pharmaceutical supply chain and distribution network and also analyze implications on medicine accessibility and quality health care. The central focus of the analysis is on MSD as a sole supplier and distributor of pharmaceuticals furthermore the analysis is extended to other players in the supply chain. It includes the Ministry of Health which provides funds to MSD for procurement of medicines, the Public National Hospital (MNH) which procures medicines through MSD, private hospitals, pharmacies, dispensary and patients are also part of the analysis.

The main aim to include other players is to analyze how they are affected by the functioning of pharmaceutical supply chain in Tanzania. These other organizations are considered to be embedded elements within the supply chain. Since it involves more than one unit of analysis, it is considered to be the embedded multiple cases as described by Yin, (1994). The following section describes in details how the multiple cases are conducted for this study.

# 4.6.1.1 <u>Multiple Cases</u>

Heriott and Firestone (1983)<sup>14</sup>; describe the importance of having multiple case studies against single case study, they indicated that "the evidence from multiple cases is often considered more compelling and overall study is therefore regarded as being more robust". The researcher selected the multiple cases to provide enough evidence and maximize the overall robustness of the study. The multiple cases follow the literal replication logic which predicts similar results as explained by Yin (1994, p.46). Furthermore, Yin (1994) used the three steps to conduct the case study methodology. These methodology steps are used to describe the case study design. The section below highlights the methodology steps to be used;

- a) Design the Case Study
- b) Conduct the Case Study
- c) Analyze the Case Study

#### 4.6.2 Case Study Designing

According to Yin (1994, p.20); the case study designing must contain five components; "study's questions, study propositions, unit of analysis, the logic linking the data to propositions and the criteria for interpreting the findings". Though Yin (ibid) suggested using the study propositions and logic linking data to propositions; our analysis focuses on linking the data to objectives along with the guide of conceptual framework described in figure 4.1 and literature review. The following section describes the components to be used in this study.

#### 4.6.2.1 <u>Case Study Questions</u>

The nature of the study questions for this case study based on "how" and "what" type of questions. Furthermore Yin (1994, p. 20) emphasized the use of "how" and "why" type of questions to be used on case study. The researcher of this study analyzed how the performance of the pharmaceutical supply chain and distribution network has an impact on the accessibility of medicines and quality health care and how the application of innovation can improve the performance of the supply chain.

<sup>14</sup>Cited on Yin (1994, p.45)

Therefore, the following section addresses the research questions for analysis

#### **Major Research Question:**

**RQ0.** How can the matching of demand and supply of medicines, quality of health care and efficient accessibility of medicines be achieved through the performance of pharmaceutical supply chain, distribution network and application of innovation?

#### **Minor Research Questions:**

- **RQ1.** What are the enablers of pharmaceutical supply chain and distribution network?
- **RQ2.** What are the aggravating factors of pharmaceuticals demand and supply mismatching and can those factors be improved?
- **RQ3.** What are the challenges facing the pharmaceutical supply chain and distribution network in Tanzania and can those challenges be improved?
- **RQ4.** How does the performance of pharmaceutical supply chain impact the quality of health care and medicines accessibility and what are the indicators?
- **RQ5.** How can innovation be applied to improve the performance of pharmaceutical supply chain and distribution network?

### 4.6.2.2 Unit of Analysis

The unit of analysis as described by Yin (1994, p.21) is the major entity that is being analyzed in the study; it is the case study that is being studied. This study involves the multiple cases of different organizations in the supply chain as individual cases. Furthermore, it focuses on the three major issues that are crucial for the understanding of the case study being analyzed.

Based on Yin (1994, p.41); this study involves more than one unit of analysis and it considered to be embedded multiple case. The embedded multiple cases call for a conduct of survey at each individual case of different organizations in the supply chain. The survey data are part of the findings and the conclusions are part of the summary report. The embedded units of analysis within the supply chain are analyzed in this study, the units includes MSD, MOHSW, MNH (national public hospital), TFDA, Dispensaries, Patients, Private pharmacies and hospitals. The analysis includes outcomes from individual organizations and patients within the supply chain.

#### 4.6.2.3 <u>Linking the Data to Objectives</u>

In order to respond to research questions, data are linked to the study objectives and conceptual framework. Concepts and ideas from the literature are also linked to the analysis of data. Each individual case is analyzed against each research question and objective. Furthermore; each individual case report are used to formulate a single report and analyzed together.

## 4.6.2.4 The Criteria for Interpreting the Findings

The findings of this study are interpreted based on within-case and cross-case techniques. The findings as suggested by Yin, (1994, p.26) are interpreted basing on the following criteria; Collecting data of all events (research questions, objectives and actual data), Storing the data in the empirical pattern, Matching of the empirical pattern (actual data) and the research questions/objectives, Analysis of the actual data basing on the research objectives/questions, If the analyzed data meet the objectives, then a solid conclusion can be drawn from the results.

# 4.6.3 Conducting the Case Study

#### 4.6.3.1 Prepare for Data Collection

A case study does not involve a statistical generalization rather it involves the analytic generalization to support the external validity. According to Yin (1994, p.31), "cases are not sampling units and should not be chosen for this reason", *he* further emphasized that a researcher "should try to aim toward analytic generalization in doing case studies and should avoid thinking in such confusing terms" as "the sample cases" or the "small sample size of cases as if a single case study were like a single respondent in a survey".

#### Generalization

Since generalization is important for the case study, the researcher uses the analytic generalization together with the analogical reasoning. The analogical reasoning presents the similarities of the cases that have been researched and the case study being researched. Recalling the main objective of this study, the following section provides multiple sources of evidence (triangulation) for multiples cases that are used for generalization;

- i) Embedded unit of analysis is more than one. It consists of the public supplier of pharmaceuticals as a central focus and other players in the pharmaceutical supply system as mentioned earlier in section 4.6.2.2.
- ii) Embedded analysis follows the literal replication logic which predicts similar results to be obtained from the cases.
- iii) Case studies from developed (USA) and developing countries (China, India, Zambia and Ghana) were selected to be used for analogical reasoning. These cases provide the benchmarking for comparison with this case study.

# Replication Methodology to Multiple Cases on Data Collection

Specific measures/indicators were identified for this study as indicated in *section 4.5.2* of the research variables. These measures are the guidelines for the case study design and data collection process. Each unit of analysis is treated as individual case within the multiple cases. Different tools were used to collect data from each individual case and a summary report will be drawn from each individual case and multiple case results. The report from each individual case will point out the reasons for the results.

## 4.6.3.2 Methodology

## i) <u>Data Collection and Triangulation</u>

Based on the generalization idea, multiple sources of evidence (triangulation) were collected to construct the validity and use it for generalization. Primary and secondary sources of data were collected and the data gathered was qualitative with a portion of quantitative data. The data were collected between; 5<sup>th</sup> May – 20<sup>th</sup> July, 2010.

#### ii) <u>Data Collection Tools</u>

The tools included the company reports, documentation review, archival records and questionnaires. *Table 4.4* provides a summary of the source, type of data collected and summary details. The researcher also collected data about the pharmaceutical supply chain cases from USA, India, China, Ghana and Zambia as benchmarking for recommendations.

 Table 4.4
 Tools used to collect Sources of Evidence

Type of Data	Source of Evidence	Summary Details	
Primary	Questionnaires	Questionnaires were sent to the following;	
		<ul><li>Medical Stores Department (MSD)</li></ul>	
		<ul><li>Ministry of Health</li></ul>	
		<ul><li>Muhimbili National Hospital (MNH)</li></ul>	
		<ul><li>Tanzania Food and Drugs Authority (TFDA)</li></ul>	
		<ul><li>Dispensaries</li></ul>	
		<ul><li>Private Hospitals</li></ul>	
		<ul><li>Private Pharmacies</li></ul>	
		<ul><li>Patients</li></ul>	
Secondary	Documentation	<ul> <li>MSD's Presentation Reports (July, 2010)</li> </ul>	
		<ul><li>Ministry of Health website</li></ul>	
		<ul> <li>MSD Website</li> </ul>	
		<ul><li>MNH website</li></ul>	
		■ TFDA website	
		<ul><li>Other online resources</li></ul>	
Secondary	Archival Records	<ul> <li>WHO Reports</li> </ul>	
		<ul> <li>OECD Reports</li> </ul>	
		<ul><li>Literatures</li></ul>	
		<ul> <li>USA Pharmaceutical Supply Chain Reports</li> </ul>	
		<ul> <li>Ghana Pharmaceutical Supply Chain Report</li> </ul>	
		<ul> <li>Zambia Pharmaceutical Supply Chain Report</li> </ul>	
		<ul> <li>India Pharmaceutical Supply Chain Report</li> </ul>	
		<ul> <li>China Pharmaceutical Supply Chain Report</li> </ul>	

Source: Compilation by the Researcher

### a) Company Reports

Recent (July, 2010) company reports were collected which contained presentations from different stakeholders who are part of the supply chain. These stakeholders represented different organizations being researched and contains multiple evidence of information. The information gathered is very relevant and valid for this report.

### b) <u>Documentation Review and Archival Records</u>

Along with the literature review, the researcher reviewed documents containing previous research and case studies on topics about the pharmaceutical supply chain, distribution network, health care quality, availability and accessibility of medicines. Documents were mainly obtained from the online sources including the websites of Ministry of Health and Social Welfare in Tanzania, WHO, The OECD, MSD, Ministry of Finance Tanzania, TFDA, MNH, Management Science for Health and other reports of developed and developing countries' cases.

#### c) Questionnaires

Since this study involves a multiple case study methodology and more than one unit of analysis, seven different structured questionnaires with a mixture of closed and openended questions were designed and sent to seven different individual organizations involved in the supply chain and one questionnaire sent to five patients. As it was indicated earlier in the discussion, the questions based on the performance of MSD in the supply chain of pharmaceuticals; "it excludes the private supplier, local and international manufacturer in the supply chain".

## The following are the criteria used to develop the questions for questionnaire:

- Questionnaire based on issues to be addressed for this study
  - Pharmaceutical Supply chain performance
  - Distribution and Transportation
  - o Procurement and Stock management
  - o Resource Allocation
  - Medicine accessibility and availability
  - o Information flow
  - o Regulation and Quality assurance
  - Health care quality
- Questionnaire based on type of organization with respect to the issues to be addressed

#### iii) Target Cases and Selection Criteria

The target cases were selected based on the study objectives, study questions and how the results of the research are to be used in this study. Since this study simply review and critically analyzes the current situation of the pharmaceutical supply chain and distribution network, the representatives from each organization were selected based on their experience. The researcher contacted each organization by email and obtained key representative who responded positively and provided relevant and reliable data for this study. The questionnaires data were collected between; 25th June – 20th July, 2010.

The selection criteria of the target organizations were also based on the concentration of the health services and functioning of the MSD. All the target cases were based at Dar es Salaam; the main city and commercial capital of Tanzania. Dar es Salaam was purposely selected due to time constraints of this study, geographical distance and unavailability of

data in rural areas. Though MSD has other zonal stores in different regions in Tanzania including Dar es Salaam, all other key players in the pharmaceutical supply chain operates their activities in Dar es Salaam hence allowed easy collection of data. Table 4.5 provides a summary of the target group and respondent titles from each organization.

Table 4.5 Type of Questionnaires and Target Group

Questionnaire Type	Target Organization Case/Group	No	Respondent Title	No. Of Years*
Questionnaire No. 1	Medical Stores Department	1	Headquarter Procurement Officer	5
Questionnaire No. 2	Ministry of Health and Social Welfare	1	Chief Pharmacist	7
Questionnaire No. 3	Muhimbili National Hospital (Public National Hospital)	1	Pharmaceutical Technicians	20
Questionnaire No. 4	Tanzania Foods and Drugs Authority	1	Quality Assurance Manager	6
Questionnaire No. 5	Private Hospitals	3	Medical Doctors	9,
Questionnaire No. 6	Dispensaries	3	Medical Officers In Charge	9,5,4
Questionnaire No. 7	Private Pharmacies	3	Procurement Specialist	8, 6, 5,
Questionnaire No. 8	Patients	5	Patients	
Total Number of Questionnaires		18		

Source: Compilation by the Researcher

### iv) <u>Data Treatment and Analysis Techniques</u>

#### **Data Treatment**

The researcher recognizes the importance of data collected and procedures followed for this study. As it was indicated earlier, the data were collected between  $25^{th}$  June –  $20^{th}$  July, 2010 and the researcher documented the data and handled it in database in a comprehensive and systematic way. The excel database was prepared in formats that can be referenced to assist in sorting, categorizing and storing for retrieval and data analysis.

<sup>\*</sup>Number of years of working experience for respondent.

#### **Analysis Techniques**

There are three general analytical strategies suggested by Yin (2002) for setting priorities before analyzing the data: "relying on theoretical propositions, rival explanations or developing a case description". The researcher adopted the case description strategy to describe how analysis was conducted. Since this study involves qualitative data with a portion of quantitative, our data analysis followed three steps as discussed by Miles and Huberman (1994). The first step focuses on data reduction; data collected from each unit of analysis were entered in different sheets within the same excel database and later on open coding were performed with the guidance of research questions and conceptual framework to assign categories according to research variables and condense the information.

Within-case analysis was conducted at each individual case along with the guidance of research questions, literature review and conceptual framework. The researcher also used different interpretations to find a relationship between the research variables and the outcome results with reference to the case study questions and objectives. As suggested by Jones, et al. (2007), the researcher of this study tried to be a positivist and remained open to new insights and approaches while analyzing the data. The data were categorized, tabulated and recombined to present the original case study objectives and the researcher conducted a cross-check of reality and differences. Since this study is a qualitative research with a portion of quantitative, the collected quantitative data are used to confirm and support the qualitative data that are crucial to understand the fundamental relationships.

The second step involved the displaying of data by cross-case analysis. Here the researcher compared and combined the categories of individual cases to identify the similarities and differences. Later one these cases are compared with case studies of pharmaceutical supply chain performance from USA, India, China, Ghana and Zambia to also identifies the similarities and differences. The outcome of the comparison between the local case and worldwide case are used as a benchmark for recommendations in chapter six. The last step involved the conclusion as a final analytical part. The analysis of research question five (RQ5) is based on findings that are obtained from analysis of research questions one to four (RQ1-RQ4) and this analysis is done in form of recommendations on how to improve the challenges/performance of pharmaceutical supply chain and distribution network through application of innovation.

#### 4.6.4 Data Validity and Quality of Case Study Design

The case study design was based on the four logical tests of the validity and quality of research design in order to prove (according to U.S. General Accounting Office, 1990) its credibility, confirmability, trustworthiness and data dependability. According to Yin (1994, p.33), the four logical tests include; Construct Validity: During Data Collection, Internal Validity: During Data Analysis, External Validity and Reliability: During Data Collection. Table 4.6 summarizes the case study tactics for four logical tests.

# 4.6.4.1 <u>Construct Validity: During Data Collection</u>

The researcher used multiple sources of evidence (triangulation) and established chain of evidence during data collection to increase construct validity. Moreover the researcher provided definitions of different concepts used in this research along with the conceptual framework and different measures were identified to ensure construct validity.

#### 4.6.4.2 <u>Internal Validity: During Data Analysis</u>

There are other variables and indicators which have influence on quality of health care and pharmaceutical supply chain performance but we adopted within-case and crosscase analysis techniques to achieve the internal validity of the research by controlling any extraneous variables constant across cases.

# 4.6.4.3 <u>External Validity: During Research Design</u>

The researcher applied the analytic generalization along with the literal replication logic. The cross-case analysis technique along with literature review was used to ensure the external validity. Particular set of results from this study are applicable for generalization with the support from identified worldwide cases in this study.

#### 4.6.4.4 Reliability: During Data Collection

The researcher created a database and data were saved systematically and stored in an electronic media (CD) for reference to ensure reliability of this research. Both primary and secondary data were collected and case protocol was used to increase the reliability.

Table 4.6 Case Study Tactics for Logical Tests of Validity

Logical Test	Case Study Tactics	Phase of Research for a tactic
Construct Validity	Multiple Sources and chain of evidence	Data Collection
Internal Validity	Within-case and Cross-case technique	Data Analysis
External Validity	Literal Replication Logic	Research Design
Reliability	Case Study Database and Case Protocol	Data Collection

Source: Adapted from COSMO Corporation, Cited in Yin (1994, p.33)

#### 4.7 CHAPTER SUMMARY

In this chapter the conceptual framework, case study designing and research methodology have been discussed. The chapter started with the general introduction about the issues to be discussed and recall the problem statement and research objectives from chapter one.

The researcher adopted the conceptual framework discussed in section 4.5 which depicted different variables for good performance of the pharmaceutical supply chain that leads to good health quality outcomes. Furthermore the researcher provided the diagram which showed the interrelationship between the variables of the conceptual framework and conceptual framework variables have been used as the guideline for the research variables. From the research variables in section 4.5.2, several factors and indicators have been highlighted to guide the researched during the data collection process in chapter 4 and data analysis process in chapter 5.

Furthermore in this chapter, the research methodology and type of research have been discussed in section 4.6. The multiple cases were discussed as the type of case study to be adapted in this research and the research type is explanatory based on the qualitative data and a portion of quantitative data.

Three steps were adapted from Yin (1994) to guide the designing of the case study. Moreover, this chapter presented the case study propositions to be used along with the case study questions. The case study questions based on "how" and "why" type of questions. In addition to that, five criteria were mentioned to guide the interpretation of the findings in chapter 5. The chapter also discussed about the multiple sources of data (triangulation) and multiple evidence as fundamental requirement of the case study. The analytic generalization and literal replication were also discussed as part of the generalization requirement of the multiple cases study.

The chapter also discussed different techniques to be used during the analysis process in chapter 5. Within-case and cross-case analyses were discussed as part of the analysis techniques for this study.

The chapter concluded by discussing the four logical tests of the validity of data and quality of research design; both construct, internal, external validity and reliability were part of the discussion.

## **CHAPTER FIVE**

## DATA ANALYSIS, FINDINGS AND CASE DISCUSSIONS

#### 5.1 INTRODUCTION

This chapter presents the analysis of data collected in details as explained briefly in chapter 4. The analysis is divided into two parts with respect to the multiple case design and embedded unit of analysis as discussed in section 4.6. The chapter starts with individual case analysis by using within-case technique and later on individual cases are grouped together for a second analysis; here the researcher adopted the cross-case analysis technique to identify the similarities and differences and depicts patterns which match with the research questions. In addition to cross-case analysis, the cases from the U.S.A, India, China, Ghana and Zambia are analyzed against the local case study to identify the similarities and differences. We are analyzing the data in section 5.2 and draw insights from them using the conceptual framework described in figure 4.1 and 4.2 and based the analysis on the literature review and research questions.

#### 5.2 DATA ANALYSIS

# 5.2.1 Analysis Part 1: <u>Within-Case Analysis</u>

With reference to the unit of analysis; this part analyzes each individual case based on research questions with the guidance of conceptual framework and literature review whereby each research question is analyzed at a time. As mentioned earlier, 18 questionnaires were sent to; MSD (1), MNH (1), MOHSW (1), TFDA (1), Private Hospitals (3), Private Pharmacies (3), Dispensaries (3) and Patients (5). All questionnaires were received within 26 days and response rate was 100%. Questions from each questionnaire were grouped according to our objectives. The following sections analyze the cases.

#### 5.2.1.1 <u>Analysis of Research Question: RQ1</u>

#### **RQ1:** Enablers of Pharmaceutical Supply Chain and Distribution Network.

With respect to the literature review in section 2.5.2, the independent variables to be analyzed in this part are; timing of resource allocation, demand and stock information flows and regulation.

#### Variable 1: Timing of Resource Allocation

There are two units of analysis (cases; MOHSW and MSD) analyzed under this variable.

#### Case 1: Ministry of Health and Social Welfare (MOHSW) at Dar Es Salaam

One of the biggest challenges indicated by MOHSW is the delays of budget approval from government; it takes more than 3 months for funds to be disbursed from the Ministry of Finance to MSD via MOHSW.

#### Case 2: Medical Stores Department (MSD) Headquarter

For each financial year presented in the questionnaire (2006/2007 – 2008/2009), MSD spent more than 20 million US Dollar on pharmaceutical expenditure. Insufficient government funding and unscheduled delivery of funds from the government are major challenges facing MSD with regards to resource allocation. MSD reported to have a "staggering debt of more than 36 billion Tanzanian Shillings (approximately 24 million US Dollar) to the MOHSW.

#### Variable 2: Demand and Stock Information Flows

Five units of analysis are analyzed under this variable: MSD, MNH, Dispensaries (D1, D2, and D3), Private hospitals (PVHSP1, PVHSP2, PVHSP3) and Private pharmacies (PVPH1, PVPH2, PVPH3).

## Case 1: Medical Stores Department (MSD) Headquarter

MSD has a budget planning and funds allocation for computerization of inventories using electronically information sharing system. Orders from customers are received either by electronic mail system, fax or post. MSD indicated to prefer fax mostly as "it gives room for the sales officer to notify the customer on the availability of certain medicines and customers are advised accordingly on the substitutes hence decreasing waiting time when customers comes to pick the supplies". MSD is facing challenges of poor forecasting due to unreliable data and poor quantification.

#### Case 2: Muhimbili National Hospital (MNH) at Dar Es Salaam

MNH does not produce monthly report of medicines consumption and stock requirement. In addition to that, quantities delivered by MSD are not in compliance with quantities ordered by MNH

#### Case 3: Dispensaries (D1, D2, D3) at Dar Es Salaam

Two dispensaries produce monthly report of medicines consumption and stock requirement and one indicated not to produce the monthly report and all dispensaries indicated that deliveries from MSD are not in compliance with their orders.

#### Case 4: Private Hospitals (PVHSP1, PVHSP2, PVHSP3) at Dar Es Salaam

All private hospitals indicated they produce monthly report of medicines consumption and stock requirement and in addition to that, they have a challenge of receiving deliveries from MSD which are not in compliance with their ordered quantities.

#### Case 5: Private Pharmacies (PVPH1, PVPH2, PVPH3) at Dar Es Salaam

Monthly reports of medicines consumption are produced by all pharmacies.

#### Variable 3: Regulation and Enforcement

One case (TFDA) is analyzed under this variable.

## Case 1: Tanzania Food and Drugs Authority (TFDA) at Dar Es Salaam

TFDA regulate the pharmaceuticals by conducting thorough inspection of medicines, pharmaceutical registration and quality assessment including storage condition, quality of service and expiry duration of medicines.

### 5.2.1.2 <u>Analysis of Research Question: RQ2</u>

#### RQ2: Aggravating Factors of Pharmaceuticals' demand and supply mismatching

The analysis based on three variables; stock-out/shortage, excess inventory and lead-time with reference to our literature review in section 2.6.1, 2.6.2, 2.6.5 and figure 2.2. Five individual cases are analyzed; MSD, MNH, private hospitals (PVHSP1, PVHSP2, PVHSP3), private pharmacies (PVPH1, PVPH2, PVPH3) and dispensaries (D1, D2, D3).

#### Variable 1 and 2: Stock-out/Shortage of Medicines and Excess Inventory

#### Case 1: Medical Stores Department (MSD) Headquarter

MSD is experiencing medicines stock-out and under-stocking problems; many vital drugs have either expired or been out of stock. These problems are caused by poor demand forecasting and poor quantification due to unreliable data. The respondent also

indicated that the issue of quantification on the part of customers has been a very big problem to MSD. It has been engineered by the financial constraints from customers and poor consumption data. Errors in demand forecasting at MSD is one of the major causes of drug stock out. According to MSD, the "increase or decrease of future demand of pharmaceuticals will vary depending on the regulations, changes in prescribing habits, customer frequency and drugs that will no longer be used in the future". The respondent indicated that MSD will "manage to meet expected future demand increase only if all the debts are paid".

#### Case 2: Muhimbili National Hospital (MNH) at Dar Es Salaam

MNH is experiencing drug stock out and major reasons for the stock out are delays in delivery from MSD. MNH also indicated to receive quantities from MSD which are not in compliance with their orders. MSD is also experiencing two weeks period of drug shortage within a period of three months. To prevent the shortage, MNH is maintaining large inventory and does frequency ordering. In addition to that MNH is allowed to purchase medicines from other approved supplier only if MSD is out of stock or certain types of medicines are not available at MSD.

# Case 3: Dispensaries (D1, D2, D3) at Dar Es Salaam

Stock-out is a major problem to all three dispensaries. The major causes of drug stock-out are delays in delivery from MSD (100%), errors in demand forecasting (100%) and deliveries from MSD were not in compliance with dispensary orders (67%). Figure 5.1 depicts the causes of stock out at dispensaries.

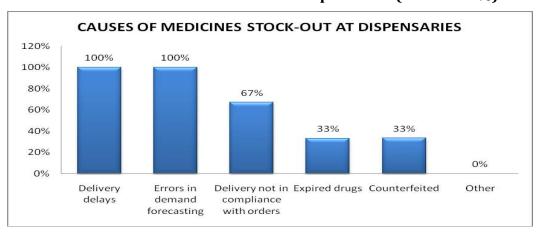


Figure 5.1: Causes of Medicine Stock-out at Dispensaries (out of 100%)

Two dispensaries indicated to have more than one month of drug shortage at 67% response rate while one dispensary at 33% response rate indicated to have one month drug shortage within a period of three months. To prevent the shortage, dispensaries

are maintaining large amount of inventory (67%) and do frequency ordering (67%). Figure 5.2 depicts the causes of medicines stock out at dispensaries. From the figure, expired and counterfeited drugs were not seen as major causes of stock-out.

MEDICINES SHORTAGE DAYS AT **PREVENTING MEDICINES** DISPENSARIES SHORTAGES AT DISPENSARIES 67% 67% 67% 70% 70% 60% 60% 50% 50% 33% 40% 40% 30% 30% 20% 20% 10% 10% 0% 0% 0% 0% 0% 0% 0% 3 days 1 week 2 weeks 1 More Maintain Frequency Run out Other month than 1 large ordering of stock

inventory

Figure 5.2: Medicines Shortage at Dispensaries (out of 100%)

## Case 4: Private Hospitals (PVHSP1, PVHSP2, PVHSP3) at Dar Es Salaam

month

Expired drugs is a major cause of medicines stock-out at 100% response rate from the private hospitals followed by delivery delays, errors in demand forecasting and counterfeited drugs which all together scored 67% of the response; see figure 5.3.

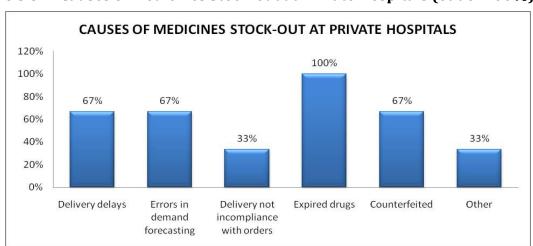


Figure 5.3: Causes of Medicines Stock-out at Private Hospitals (out of 100%)

33% of the responses indicated lack of funds as other reasons of drug stock out as illustrated on figure 5.3. Deliveries not incompliance with orders was not a major cause of stock-out. 67% indicated to have one week of medicines shortage while 33% indicated to have two weeks of medicines shortage within a period of three months. To

prevent their shortage, private hospitals are maintaining large inventory (67%) and do frequency ordering (67%) as it can be seen on figure 5.4.

PREVENTING MEDICINES SHORTAGE MEDICINES SHORTAGE DAYS AT AT PRIVATE HOSPITALS **PRIVATE HOSPITALS** 67% 67% 67% 70% 70% 60% 60% 50% 50% 40% 33% 40% 30% 30% 20% 20% 10% 10% 0% 0% 0% 0% 0% 0% 0% 3 days 1 week 2 weeks 1 Maintain Frequency Run out Other More ordering of stock month than 1 large inventory month

Figure 5.4: Medicines Shortage at Private Hospitals (out of 100%)

Case 5: Private Pharmacies (PVPH1, PVPH2, PVPH3) at Dar Es Salaam

Private pharmacies indicated to have three major causes of medicines stock out; delivery delays, errors in demand forecasting and expired drugs at the response rate of 67%. Figure 5.5 depicts the results of the analysis. Deliveries not in compliance with orders and counterfeited at response rate of 33% were not seen as major causes.

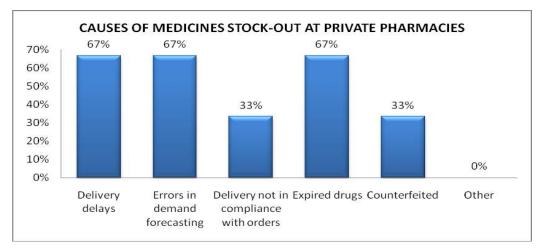


Figure 5.5: Causes of Medicines Stock-out at Private Pharmacies

Moreover; 67% of private pharmacies in our study are experiencing medicines shortage of two weeks and 33% experience one week shortage within a period of three months. To prevent their shortage, 100% indicated to do frequency ordering while 33% maintain large inventory as it can be seen on figure 5.6

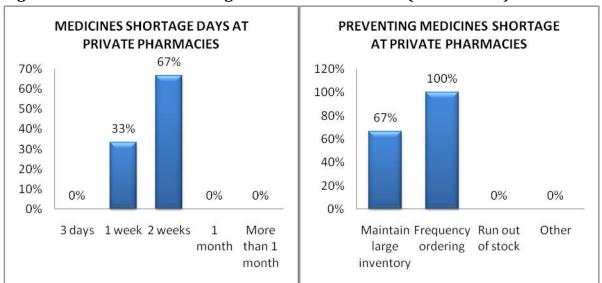


Figure 5.6: Medicines Shortage at Private Pharmacies (out of 100%)

#### Variable 3: Lead-time

Analysis of lead time based on two type; resource allocation lead-time and procurement lead-time. Two cases are analyzed; MOHSW for resource allocation lead-time and MSD for procurement lead-time.

# Case 1: Ministry of Health and Social Welfare (MOHSW) at Dar Es Salaam

With reference to the analysis in section 5.2.1.1 at Case 1(MOHSW); it takes more than 3 months for funds to be disbursed from the Ministry of Finance to MSD via MOHSW.

#### Case 2: Medical Stores Department (MSD) Headquarter

Over 70% of pharmaceuticals are procured internationally from Europe and the process involves international competitive bidding. MSD indicated that it takes more than 1 month to clear goods either from airport, seaport or at border point. Orders from hospitals are sent at anytime to MSD while other health centers sent their orders on quarterly basis. However; the respondent quoted that "the first steps of procurement are a bit complicated involving many stakeholders like ministries, TFDA, Government chemist and Clearing agents; but when the consignment lands at MSD offices, it's distribution to the final destination is quick and fast".

#### 5.2.1.3 <u>Analysis of Research Question: RQ3</u>

#### **RQ3:** Challenges facing the pharmaceutical supply chain and distribution network.

The analysis is divided into five challenge parts with reference to the conceptual framework in figure 4.1 at section 4.5 and the indicators in table 4.1, 4.2 and 4.3 at

section 4.5.2; geographic access challenges, physical availability challenges, distribution network challenges, pharmaceuticals quality challenges, general supply chain and distribution challenges.

# **Challenge 1: Geographic Access Challenges**

The analysis based on three variables; number of zonal stores, distance covered and mode of transport and one case (MSD) is analyzed under this part.

#### Variable 1: Number of Zonal Stores

MSD headquarter offices are situated at Dar es Salaam and currently it has nine zonal stores in different regions of the country. It covers Tabora, Mwanza, Mbeya, Iringa, Mtwara, Tanga, Moshi, Dodoma, and Dar es Salaam.

#### Variable 2: Distance Covered

MSD distributes medicines from Dar es Salaam zonal store to other MSD regional zonal stores; MSD regional zonal stores after receiving the consignment they also distribute to other regions within the allocated geographical area. The road distance covered by MSD is summarized in table 3.5 at section 3.2.5.5 in this study. The analysis also shows that; the average road distance from Dar es Salaam to regional zonal stores range from 194 – 853 kilometers and from regional stores to other regions within the allocated geographical area ranges from 69 – 806 kilometers.

## Variable 3: Mode of Transport

Mode of transport is not seen as a problem at MSD. They are using big truck vehicles to distribute medicines to different zonal stores.

#### **Challenge 2: Physical Availability of Medicines**

#### Case 1: Patients (P1, P2, P3, P4, P5)

All five patients indicated to experience problems with medicines availability. They mentioned that it is not easily available especially at public hospitals. Figure 5.7 indicates patient's source of medicines. 100% indicated to obtain their medicines from private pharmacies while 80% from private hospitals. Local stores and public pharmacies were not seen as major source of their medicines.

0%

0%

Other

PATIENT'S SOURCE OF MEDICINES

120%
100%
80%
60%
40%
20%
20%

Public

Pharmacy

Figure 5.7: Patient's Source of Medicines (out of 100%)

# Case 2: Medical Stores Department (MSD) Headquarter

Private

Pharmacy

It can be seen on figure 5.8 that under-stocking, expired drugs, counterfeited, uncontrolled stock are major challenges at 100% response rate. Other challenges were indicated to be poor quantification and unreliable data from customers.

0%

Public

Hospital

Private

Hospital



Figure 5.8: Stock Control Challenges at MSD(out of 100%)

**Local Stores** 

#### Other Cases: MOHSW, MNH, Dispensaries, Private Hospitals and Pharmacies.

With reference to the conceptual framework at figure 4.1, the variables to be analyzed under this challenge includes procurement and resource allocation lead-time, mode of transport, stock –out/shortage, financing gap, demand and stock information. All these variables were analyzed to our six cases in section 5.2.1.1 and 5.2.1.2.

- **Variable 1:** Procurement lead-time Analyzed at variable 3 of section 5.2.1.2
- **Variable 2:** Resource allocation lead-time Analyzed at variable 1 of section 5.2.1.1
- **Variable 3:** Mode of transport Analyzed at variable 3 of section 5.2.1.3
- **Variable 4:** Stock-out/shortage Analyzed at variable 1 and 2 of section 5.2.1.2
- **Variable 5:** Financing gap Analyzed at variable 1 of section 5.2.1.1
- **Variable 6:** Demand and stock information flow Analyzed at variable 2 of section 5.2.1.1

# **Challenge 3: Distribution Network challenges**

One case (MSD) is analyzed under this challenge and our variables to be analyzed include; mode of transport, distance covered and number of zonal stores. We have already analyzed these variables under MSD case at challenge 1 of section 5.2.1.3. However, MSD respondent indicated that "due to increase in delays of distribution of medicines, MSD has embarked for the pilot delivery of medicines to the health centers. This exercise has proved to be cumbersome, tedious and costly; so much money needs to be injected for the exercise to operate successfully".

## **Challenge 4: Pharmaceuticals quality challenges**

The variables to be analyzed under this challenge include; counterfeit drugs and expiry of medicines (short expiry and expired medicines). Six cases are analyzed under this challenge; MOHSW, MSD, MNH, Dispensaries, Private hospitals and Private pharmacies.

#### Variable 1: Counterfeit drugs

Among all cases in the analysis, only MSD indicated to have this challenge of receiving counterfeited drugs from other suppliers during the procurement process.

#### Variable 2: Expiry of Medicines

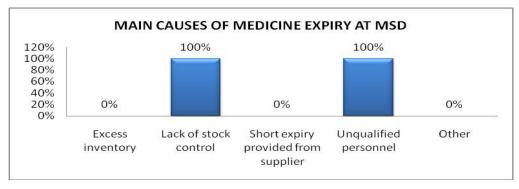
### Case 1: Ministry of Health and Social Welfare (MOHSW) at Dar Es Salaam

MOHSW is facing challenges of receiving drug donations with short expiry duration. Donations are mainly received by Government to support certain health programs like HIV/AIDS care and treatment.

### Case 2: Medical Stores Department (MSD) at Dar Es Salaam

MSD is experiencing challenges of medicine expiry. The main causes of the expiry are lack of stock control and unqualified personnel, see figure 5.9.

Figure 5.9 Main causes of Medicine Expiry at MSD. (out of 100%)



## Case 3: Muhimbili National Hospital (MNH) at Dar Es Salaam

The case analysis shows that expired and short expiry medicines are received by MNH from MSD deliveries.

#### Case 4: Dispensaries (D1, D2, D3) at Dar Es Salaam

Dispensaries are receiving medicines with short expire from MSD. This was seen as a major cause for their medicine expiry at 100% response rate. However, there are other causes of expiry as it can be seen from figure 5.10 like lack of stock control (67% response rate) and unqualified personnel (at 33% response rate).

CAUSES OF MEDICINE EXPIRY AT DISPENSARIES 120% 100% 100% 80% 67% 60% 33% 40% 20% 0% 0% 0% Other Excess supply Lack of stock Short expiry Unqualified control drugs from MSD personnel

Figure 5.10: Causes of Medicines Expiry at Dispensaries. (out of 100%)

Case 5: Private Hospitals (PVHSP1, PVHSP2, PVHSP3) at Dar Es Salaam

Private hospitals are experiencing medicine expiry challenges which are mainly caused by lack of stock control (100% response rate) and short expiry of medicines received from MSD (100% response rate). Unqualified personnel were seen to be a minor cause of medicine expiry. Figure 5.11 illustrate the causes of expiry.

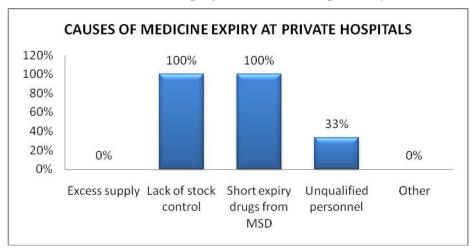


Figure 5.11: Causes of Medicine Expiry at Private Hospitals. (out of 100%)

## Case 6: Private Pharmacies (PVPH1, PVPH2, PVPH3) at Dar Es Salaam

At private pharmacies, medicine expiry is mainly caused by lack of stock control and short expiry of medicines received from MSD (all causes were indicated at 100% response rate). However; unqualified personnel were seen to be a minor cause (at 33% response rate). In addition to that; disease pattern is not uniform and this was seen to be other cause of medicine expiry (at 33% response rate), see figure 5.12.

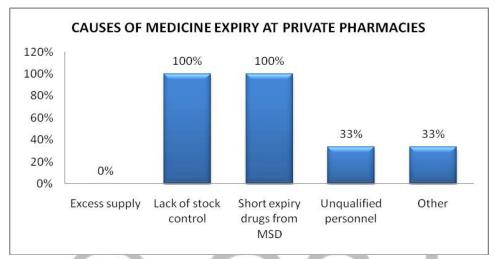


Figure 5.12: Causes of Medicine Expiry at Private Pharmacies. (out of 100%)

# **Challenge 5: General Supply Chain and Distribution Network**

Figure 5.13 reveals that MSD is experiencing major challenges with regards to supply chain and distribution network of pharmaceuticals. Insufficient government funds, unscheduled funds disbursement from government, non-availability of medicines at MSD were major challenges at both 100% response rates.

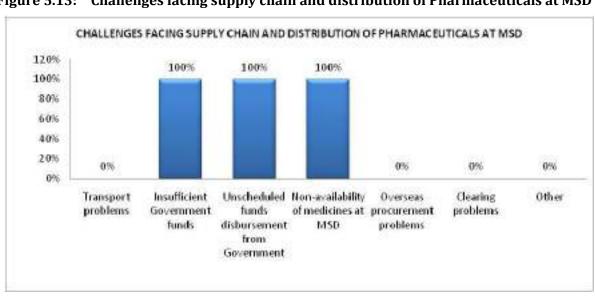


Figure 5.13: Challenges facing supply chain and distribution of Pharmaceuticals at MSD

#### 5.2.1.4 Analysis of Research Question: RQ4

# RQ4: Pharmaceutical Supply Chain performance impacts on Quality of Health Care and Medicine Accessibility

With reference to table 4.2 and 4.3 at section 4.5.2, our variables to be analyzed under this question include; geographic access, physical availability and quality of pharmaceuticals. All these variables have already been analyzed at section 5.2.1.3 under challenge 1, 2 and 3. However; the researcher analyzes together other specific variables indicated by the respondent; under supply/shortage of medicines, delivery delays, counterfeited, complex accessibility and expired medicines. Five cases are analyzed; MOHSW, MNH, Dispensaries, Private hospitals and patients.

## Case 1: Ministry of Health and Social Welfare (MOHSW) at Dar Es Salaam

MOHSW indicated that under supply or medicines shortage are the major factors contributing to poor health care quality and unavailability of medicines.

## Case 2: Muhimbili National Hospital (MNH) at Dar Es Salaam

MNH indicated that under supply or shortage of medicines, delivery delays and complex accessibility contribute to the poor health care quality and inaccessibility of medicines.

### Case 3: Dispensaries (D1, D2, D3) at Dar Es Salaam

Medicines shortage/undersupply, complex accessibility and counterfeited medicines are major factors contributing to poor health care quality and inaccessibility of medicines at 100% response rate from the dispensaries. It can also be seen at figure 5.14 that expired medicines and delivery delays (both 67% response rate) were also contributing to poor quality of health care.

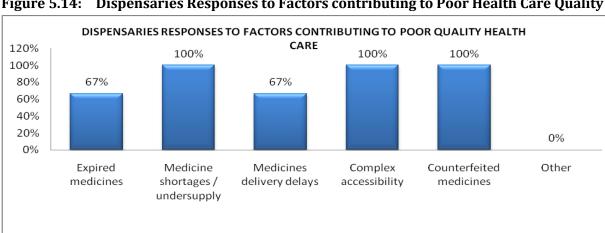


Figure 5.14: Dispensaries Responses to Factors contributing to Poor Health Care Quality

## Case 4: Private Hospitals (PVHSP1, PVHSP2, PVHSP3) at Dar Es Salaam

Medicine shortages/undersupply, complex accessibility and counterfeited medicines are major factors contributing to poor health quality from private hospitals responses at 100% rate. Expired medicine with 67% response rate is also part of factors contributing to poor health quality as indicated in figure 5.15.

PRIVATE HOSPITALS RESPONSES TO FACTORS CONTRIBUTING TO POOR QUALITY **HEALTH CARE** 120% 100% 100% 100% 100% 67% 80% 60% 33% 40% 20% 0% 0% Counterfeited Other Expired Medicine Medicine Complex medicines medicines shortages / delivery delays accessibility undersupply

Figure 5.15: Private Hospitals Responses to Factors contributing to Poor Health Quality

Case 5: Patients (P1, P2, P3, P4, P5) from Dar Es Salaam

Expired and counterfeited medicines are major factors contributing to poor health care quality and unavailability of medicines at 100% response rate followed by medicines shortage/undersupply and complex accessibility at 80% response rate from patients while delivery delays is not seen as major factor (40% response rate). However; patients indicated that other factors like shortage of qualified health personnel and lack of necessary equipment are also contributing to poor health care quality as it can be seen on figure 5.16.

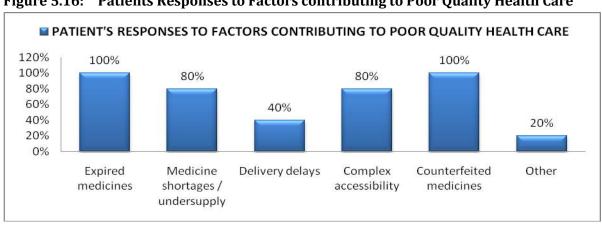


Figure 5.16: Patients Responses to Factors contributing to Poor Quality Health Care

## 5.2.1.5 Analysis of Research Question: RQ5

# RQ5: Application of innovation to improve performance of pharmaceutical supply chain and distribution network.

As it was indicated earlier in the analysis techniques at section 4.6.3.2 of methodology in chapter 4, the analysis of research question five (RQ5) is based on findings that are obtained from analysis of research questions one to four (RQ1-RQ4) and this analysis is done in form of recommendations on how to improve the challenges/performance of pharmaceutical supply chain and distribution network through application of innovation.

# 5.2.2 Analysis Part 2: Cross-Case Analysis

As explained earlier in analysis techniques at section 4.6.3.2 of methodology, the cross-case analysis attempts to identify the similarities and differences among local case study based on research questions as well as cross-case analysis with worldwide cases. Analysis of worldwide cases based on the data in chapter 3.

# i) Cross-case Analysis of Local Case Study

5.2.2.1 <u>Analysis of Research Question: RQ1</u>

## **RQ1:** Enablers of Pharmaceutical Supply Chain and Distribution Network.

Table 5.1 Local Case similarities of RQ1

Cases	Variable 1: Timing of Resource Allocation
MOHSW	-More than 3 months to disburse funds to MSD
	-Delays of budget approval from Ministry of finance
MSD	- Monthly fund request to MOHSW
	-Delays of funds allocation from MOHSW
	Variable 2: Demand and Stock Information flow
MSD	- Poor information flow caused to have unreliable data from customers which led to have poor forecasting of demand
MNH, PVHSP's, Dispensaries	- Deliveries from MSD are not in compliance with orders due to poor information flow

The only difference which was seen among these cases is the production of consumption report whereby all private hospitals and pharmacies indicated to produce monthly consumption reports.

#### 5.2.2.2 <u>Analysis of Research Question: RQ2</u>

RQ2: Aggravating Factors of Pharmaceuticals' demand and supply mismatching Table 5.2 Local Case Similarities of RQ2

Cases	Aggravating Factors	
MSD, MNH,	- Errors in demand forecasting	
PVHSP',	- Medicine stock-out/shortages	
PVPH,	- Delivery delays	
Dispensaries	- Short expiry and expired medicines	
	- Maintaining excess inventory to prevent medicine shortages	

The difference was on the lead-time between MSD and MOHSW. It takes more than 3 months for MSD to receive funds from MOHSW while at the same time MOHSW indicated delays of resource allocation from the Ministry of finance.

## 5.2.2.3 Analysis of Research Question: RQ3

RQ3: Challenges facing the pharmaceutical supply chain and distribution network.

Table 5.3 Local Case Similarities of RQ3

Cases	Challenges
MSD, MNH,	Challenges: Physical Availability and Quality of Medicines
PVHSP',	-Expired medicines
PVPH,	-Short expiry medicines
Dispensaries	-Under-stocking
	-Stock-out
	-Uncontrolled stock/lack of stock control

The differences arise on the side of MSD. Non-availability of medicines, unscheduled funds from the government and insufficient funds were seen to be major challenges facing MSD.

## 5.2.2.4 <u>Analysis of Research Question: RQ4</u>

# **RQ4:** Pharmaceutical Supply Chain performance impacts on Quality of Health Care and Medicine Accessibility

Table 5.4 Local Case Similarities of RQ4

Cases	Factors impacting Health Care Quality and Medicine Accessibility
MOHSW,	- Undersupply/shortage of medicines
MSD, MNH,	- Complex accessibility
PVHSP',	- Expired medicines
PVPH,	- Counterfeited medicines
Dispensaries,	-Delivery delays
Patients	

Other: The shortages of qualified personnel and lack of working equipments also have impact on quality health care and medicine accessibility pointed by patients.

# ii) Cross-case Analysis between Worldwide Cases and Local Case Study

With reference to section 3.1 at chapters 3 of worldwide cases, our cross-case analysis based on the data from each case and the comparison is done against these data. The country cases to be analyzed in this section include; USA, India, China, Ghana, Zambia and Tanzania (our local case study). Things to be analyzed include the characteristics of supply chain of each country, challenges and initiatives from each worldwide case.

Table 5.5 Similarities between Worldwide cases and Local Case Study

Countries	Characteristic : Complexity of the Pharmaceutical Supply Chain
USA	Complex supply chain, involves multiple organizations that play differing but sometimes overlapping roles in distributions and contracting like presence of pharmacy benefit managers.
INDIA	Complex, presence of strong resistance from lobbies of traders in pharmaceutical supply chain
CHINA	Complex, large number of small players in the supply chain
GHANA	Complex, large number of players, involvement of donor agents in the supply chain (PEPFAR, USAID, UNFPA, UNICEF)
ZAMBIA	Complex, large number of institutions involved in procurement of pharmaceuticals
TANZANIA	Complex, large number of players in the supply chain; regulatory bodies, government, donors.
	Challenge 1: Distribution System
USA	Consolidated wholesale distribution industry with declining number of wholesale distributors
	<b>Initiatives:</b> - Manufacturers manage actual distribution of pharmaceuticals and play roles in stimulating demand by engaging in the promotion and marketing of pharmaceuticals to health care providers and direct to consumers
	- Frequency of delivery is done 1to 2times per day
INDIA	Highly fragmented nature of distribution network with high cost of distribution
	<b>Initiatives:</b> -Multi-layered distribution channel and lobbying at all levels to prevent bypassing the multiple distribution layers in order to reach customers directly
	-Increase IT adoption and use of customized software for implementation of integrated solutions to improve distribution

CHINA	Weak, large scale and complex distribution system
	Initiative: Introduced new health care reform plan in April 2009 to simplify the complexity of the distribution system
GHANA	Inefficient tiered distribution system, high distribution cost
	Initiatives: -Use of basket funding to strengthen health service delivery
	-Approved policy for implementation of scheduled delivery service from every regional medical stores to service delivery points
	-Upgraded physical infrastructure
ZAMBIA	Highly variability lead-time of distribution system
	Initiative: - Government contracted the management of the medical stores limited to private company to improve efficiency
	- Improved physical infrastructure for distribution improvement
TANZANIA	High distribution delays from MSD
	Initiative: How can it be improved?? (To be discussed at findings and recommendations part in this thesis)

Countries	Challenge 2: Medicine Accessibility and Availability
USA	Initiative: Use of mail order system; internet, mail, phone to increase accessibility
INDIA	-More than 60% of Indians do not have access to modern medicines
	-Large number of people who lives in rural areas lack access to medicines
	Initiative: Organized retail pharmacies through franchising to increase accessibility of medicines
CHINA	-Unaffordable access to medicines and highly costly
	Initiatives: - Government to spend \$124.26 billion to provide accessible and affordable health care to the country
	- Reformed supply chain from centrally controlled to market-oriented supply system to improve availability of medicines
GHANA	- Average 28.8% of people living in the northern part have access to medicine from public health facilities
	-High delays in deliveries of medicines
	Initiatives:- Contracting with local suppliers to minimize delivery lead-time and operate within agreed contract to improve availability and accessibility

	- Renovated and upgraded central medical stores and physical infrastructure to increase easy accessibility.
ZAMBIA	-High frequency of medicines stock-out due to budgetary constraints
	Initiatives:- Use of panic-ordering when there is unavailability of medicines at medical stores limited
	-Use of emergency procurement in smaller quantities by both Ministry of Health and external donors during the period of medicine shortages
TANZANIA	- Unavailability of medicines at MSD and health facilities; complex accessibility
	Initiative: How can it be improved?? (To be discussed at findings and recommendations part in this thesis)

**Table 5.6** Worldwide cases and Initiatives Differences

Countries	1. Demand and Stock Information Initiatives
USA	-Use of electronically claims transactions, mail order, internet, phone to obtain information and deliver medicines to patients
	- Use of electronic bar coding technology for packaging and tracking of medicines
INDIA	-Use of RFID technology for tracking medicines along the supply chain and preventing counterfeited medicines
	-Increased IT adoption and use of customized software for integrated solutions to keep inventory at optimum levels
CHINA	-Lack of integration and poor IT systems
GHANA	-Use of newly designed requisition, issue and receipt voucher to simplify ordering, receiving and invoicing of medicines and to minimize complexity
ZAMBIA	- Medical stores limited sends a stock-status report to all districts every month
	-All districts are required to place orders to medical stores by hand-delivery or fax before the preset of each month
	-Periodic visits to districts done by medical stores customer service team to obtain information
TANZANIA	-Currently: Use of fax, post or electronic mail system to receive orders.

#### 5.3 CASE STUDY FINDINGS AND DISCUSSIONS

According to Jones (2007), the results of the analysis have to be linked to the objectives in order to answer the research questions. This section presents the results of the analysis and discussions are based on the literature review in chapter 2 and conceptual framework in chapter 4. The case study objectives discussed in chapter 1, section 1.4 are addressed

## 5.3.1 Key findings of Case Study Objective 1

## OB1. To identify enablers of the pharmaceutical supply chain

The researcher was able to identify three important enablers of the pharmaceutical supply chain as suggested by Dalberg Advisors and MIT-Zaragoza, (2008); timing of resource allocations, demand and stock information flow and regulation and enforcement as discussed in chapter 2, section 2.5.2 of literature review. Despite the identified enablers, two key findings were observed in the study; timing of resource allocation and demand and stock information flow were critical problems to Government, MSD and health facilities.

# Key finding 1: Staggering debt, Insufficient and Untimely resource allocation

The findings show that insufficient Government funding, delays of budget approval and unscheduled delivery of funds from MOF to MSD via MOHSW are major causes of delays in resource allocation. It takes more than three months for funds to be disbursed from Government to MSD for procurement of pharmaceuticals. MSD spent more than 20 million US Dollar on procurement of pharmaceuticals. By recalling figure 3.9 from section 3.2.5.6 of this study (below figure 5.17), analysis indicates that MOHSW receives and performs funds requests monthly from MSD.

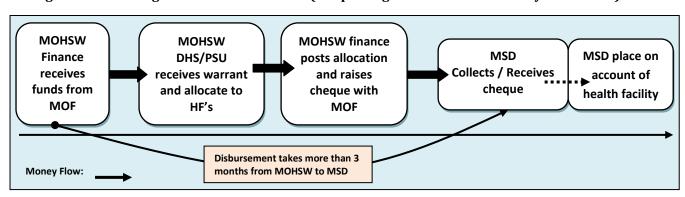


Figure 5.17: Timing of Resource Allocation (Adopted figure 3.9 and modified by the Author)

Source: Compilation by the Researcher from: Euro Health Group: Tanzania Drug Tracking Study (2007)

As a result of insufficient funding, MSD is having a staggering debt of approximately 24 million US Dollar to the Government. This amount of debt is a critical challenge to MSD to ensure efficient and timely availability of pharmaceuticals to health facilities and to meet future demands.

A worrying situation observed at MSD analysis is that; the future increase of pharmaceutical demands can be met by MSD only if all the staggering debts are paid to the Government. This problem of financial constraint is also common to Zambia from our cross-case analysis; there is high frequency of medicine stock-out due to budgetary constraints. According to Dalberg Advisors and MIT-Zaragoza, (2008); effective financial flows are crucial for the supply chain and for health system as a whole to function properly. Emphasizing on resource allocation, companies need to have timely financial flows between different levels in the supply chain, coordination and integration in order to ensure uninterrupted flows of pharmaceuticals and sustainable supply chain system for consistently timely delivery.

## **Key finding 2: Poor Demand and Stock Information Flow**

There is poor demand forecasting of pharmaceuticals is due to unreliable data received by MSD from health facilities, poor information flow between the players in the system and poor quantification. As a result of poor information flow, MSD is delivering medicines which are not in compliance with orders from health facilities. This indicates that there is poor coordination between MSD and health facilities and information asymmetry. The poor quantification has an implication on the availability of stocks at health facilities; it can result into either under or over supply of medicines. Integration and information flow in the pharmaceutical supply chain are very important for effective decision making. It is also suggested by Dalberg Advisors and MIT-Zaragoza, (2008) that the decisions about quantities to be procured can effectively be made through collaboration and the flowing up of information in the supply chain.

#### 5.3.2 Key findings of Case Study Objective 2

## OB2. To identify the aggravating factors of pharmaceuticals supply and demand mismatching

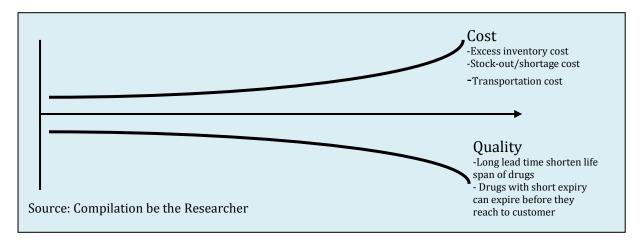
The researcher was able to identify three aggravating factors of demand and supply mismatching in the analysis; *stock-out, excess inventory and lead-time*. According to Gattorna, J. (1998), there is an interdependent relationship between supply and demand and companies need to understand customers demand in order to manage and achieve customer satisfaction level. However, from the analysis one major finding was observed that there is mismatching between demand and supply of pharmaceuticals. This mismatching is mainly caused by longer lead-time.

#### Key finding: Mismatching between demand and supply of pharmaceuticals

It was found out that longer lead-time, stock-out/shortage and errors in demand forecasting were major problems to all health facilities in our local case study which led to mismatching of demand and supply. The shortages of medicine range from a minimum period of one week to more than one month. Errors in demand forecasting were mainly caused by poor quantification and unreliable data from health facilities. On the side of MSD it was also observed that the main causes of longer lead-time which were delays in resource allocation from Government to MSD, procurement delays from international supplier and involvement of many stakeholders in the supply chain. Referring back to the literature review in Chapter 2, many authors have discussed the implication of longer lead-time; Waller, D.L, (2003), mentioned that in order to satisfy customers, products needs to be delivered according to schedule and to be sure the supply chain is not broken. Any delays in any activity in the supply chain will of-course add to the total length of lead-time hence cause the products to be delivered late. Michael M, (1998) also indicated that the longer the lead time the less responsive to changes in demand the system will be. From the findings it indicated that the supply chain is slow to respond to changes in demand also longer lead-time has a negative implication on the quality of pharmaceuticals and cost. This implication was seen at health facilities where they maintained large inventory to prevent the shortages. In principle, maintaining larger inventory has consequences on the quality of pharmaceuticals; it can result into expiry of medicine and delivery of expired medicines. In addition to that the longer lead-time from MSD side shortens the life span of pharmaceuticals. Gattorna J. (1998) recommended that companies should have a better

inventory planning techniques to reduce stock-out and excess inventory which will lead them to manage the matching of supply and demand. *He* also recommended that companies need to cut down their lead times in procurement. Figure 5.18 illustrate the implications of lead-time on quality of pharmaceuticals and cost.

Figure 5.18: Lead Time Implications on Cost and Quality of Medicines



#### 5.3.3 Key findings of Case Study Objective 3

# OB3. To identify challenges facing the performance of pharmaceutical supply chain and distribution network

Referring back to the conceptual framework at figure 4.1 and 4.2 in Chapter 4, Dalberg Advisors and MIT-Zaragoza, (2008) indicated that in order to achieve desired health outcomes, the pharmaceutical supply chain should be flexible to provide pharmaceuticals at a location which is within reasonable distance to patients, provide consistent availability of right type and quantity of medicines and should be able to provide safe, efficacious and unexpired medicines. With reference to this; the researcher found key challenges facing the performance of the supply chain and distribution network. These findings are divided into two parts; Pharmaceutical Supply Chain Challenges and Distribution Network Challenges.

#### **Pharmaceutical Supply Chain Challenges**

Key finding 1: Financing gap (discussed at section 5.3.1)

Key finding 2: Lack of stock-control (discussed at section 5.3.2)

Key finding 3: Poor demand and stock information flow (discussed at section 5.3.1)

Key finding 4: Longer lead-time (discussed at section 5.3.2)

Key finding 5: Errors in demand forecasting (discussed at section 5.3.2)

Key finding 6: Unavailability and Poor quality of medicines

#### **Distribution Network Challenges**

Key finding 7: Distribution Network challenges

The key findings 6 and 7 are discussed below.

#### **Key finding 6:** Unavailability and Poor Quality of Medicines Challenges

#### **Unavailability of Medicines**

It was observed that there are number of factors which contribute to unavailability of medicines. Despite other factors previously mentioned like stock-out and undersupply; other factors like expired medicines, short expiry medicines and counterfeited medicines were mentioned to be major causes of unavailability at health facilities and MSD. It was found out that the unavailability of medicines at MSD were mainly due to lack of financial resources. From the findings; there is mismatching of demand and supply of medicines due to undersupply and stock out, longer lead-time, lack of stock control and financing gaps. These pose critical challenges to Government and health facilities to achieve the desired health quality outcomes. It also indicates the inflexibility and inability of the supply chain to respond to changing needs from health facilities as a result it causes delivery delays. It was also observed that changing disease patterns and lack of qualified personnel were also contributing to stock-out of medicines at health facilities.

#### **Poor Quality of Medicines**

The researcher observed poor quality challenges due to presence of expired medicines. The causes of expired medicines were lack of stock control and the drug donations received by Government. It was also reported that some donated medicines arrive with short expiry and this poses a challenge to Government and health facilities. The researcher also found challenges with regards to counterfeited medicines due to increased number of ports of entry as reported by TFDA. Referring to the conceptual framework in Chapter 4 figure 4.2; if medicines are available to health facilities, patients will not go to grey market for poor quality medicines. Dalberg Advisors and MIT-Zaragoza, (2008) indicated key drivers for availability; matching of demand and supply, lead-time, stock control, transport capacity and financing gap.

#### **Key finding 7: Distribution Network Challenges**

It was found out that the inaccessibility of medicines is mainly caused by the distribution network covered by MSD. There are nine MSD regional zonal stores which receive medicines from MSD headquarter and later distribute to health facilities. Though access to medicines were defined by UN (2008) as having medicines continuously available and affordable at health facilities that are within one hour's walk from the homes of the population; the researcher identified interesting observations from the analysis with regards to distance covered by MSD to distribute medicine and number of zonal stores. With regards to distance; it ranges from a minimum of 194 – 853 kilometers from MSD headquarter to MSD regional zonal stores and then a minimum of 69 – 806 kilometers from regional zonal stores to the allocated regions. With reference to Tanzanian country size of 947,300 km² and a population of 41.9 millions, it is difficult for this number of MSD zonal stores to ensure accessibility of medicines to the whole country within the defined context of accessibility by UN (2008) and it indicates inflexibility of the distribution system.

The distribution challenges are also facing other countries. From the worldwide crosscase analysis, it was observed that USA is also having distribution problems with declining number of distributors; India has highly fragmented nature of distribution network while China has a weak, large and complex distribution system. Ghana and Zambia are also facing similar challenges of inefficient distribution system. The problem of inaccessibility of medicines was also seen in other parts of the world; it was estimated by WHO (2000) that more than half of the population in the poorest parts of Africa and Asia still lack access to medicines. This can also be seen from the worldwide cross-case analysis. In India, more than 60% do not have access to modern medicines, in China there is unaffordable access to medicines and it is highly costly while in Ghana average 28.8% of people living in northern part have access from public health facilities. Referring back to the conceptual framework, the longer the distance covered the hard it is to ensure the quality and availability of medicines.

#### 5.3.4 Key findings of Case Study Objective 4

# OB4. To evaluate the implication of pharmaceutical supply chain to health care quality and medicines accessibility and identify indicators for implication.

With respect to the findings in section 5.3.2 and 5.3.3, the researcher was able to identify indicators for implications on health care quality and medicine accessibility in the analysis. Expired medicines, counterfeited medicines, complex accessibility and undersupply/shortages were seen to be major indicators for negative implication on health care quality and accessibility. Inaccessibility of medicines has major negative implication on health care quality.

#### **Key finding 1:** Inaccessibility and Unavailability of Medicines

From the analysis, it was found that the supply chain is facing large number of challenges which impact the performance of pharmaceutical supply chain hence resulting into poor performance. According to WHO (2000), any poor performance of the supply chain can cripple the health system and undermine positive health outcomes. With reference to the conceptual framework at figure 4.1 in chapter 4, two among the four key factors for achieving the desired health outcomes are the accessibility and availability of medicines to health facilities. Referring back to the literature review in section 2.7.1.1; essential medicines are one of the tools for fighting ill diseases as explained by the WHO (2000). The accessibility of medicines depends on the functioning of the supply chain. Dalberg Advisors and MIT-Zaragoza, (2008) added that the pharmaceutical supply chains are essential for providing consistent availability of affordable, high-quality diagnostic and treatment products in locations that are geographically accessible to the target population.

#### Key finding 2: Poor Health Care Quality

The researcher found interesting observations that undersupply/shortage, complex accessibility, expired and counterfeited medicines were given highest score as major factors contributing to poor health quality. In addition to that; delivery delays were also seen as part of the factors. According to World Bank, (2003) patients tend to perceive availability of drugs in a facility as an indicator of quality of health hence the shortage of drugs continue to weaken the service quality and jeopardize the performance of the health system as a whole. Inconsistent availability of essential medicines due to longer lead-time weakens the quality of health care. The shortages of essential medicine can

have a huge impact on quality of patient care, since they hinders the treatment alternatives available to patients and people who prescribing the medicines.

#### 5.3.5 Key findings of Case Study Objective 5

# OB5. To identify areas in which innovation can be applied to improve the performance of the pharmaceutical supply chain and distribution network

With reference to the previous analysis techniques in Chapter 4 section 4.6.3.2 of the methodology, the analysis of research question 5 is based on the findings of the objectives in previous section 5.3.1-5.3.4. The researcher found number of interesting observations which need application of innovation for improvement of performance efficiency. The following is the major finding which need application of innovation;

#### Key Finding: The Need for Innovation in Pharmaceutical Supply Chain

As discussed in the previous sections in this thesis, the pharmaceutical supply chain plays a crucial role in delivering the health services specifically the delivery of medicines and other medical supplies. Despite its crucial role, we found in our analysis that the pharmaceutical supply chain is faced with number of critical challenges; poor demand and stock information flow, longer lead-time, mismatching of demand and supply of pharmaceuticals, insufficient and untimely resource allocation, poor distribution system and poor quality of pharmaceuticals; these weaken the delivery of health services hence impacting the health of people. Pharmaceutical companies together with other stakeholders have taken number of initiatives to overcome those challenges. However along with the initiatives, there is a high need to have sustainable solutions to these challenges which will ensure high efficiency of pharmaceutical supply chain and distribution network. Indeed there is a high need to change the existing organizational models in order to allow effective supply chain that focuses on management of information, relationships and knowledge by focusing on process innovation as suggested by Christensen, C.M. and Kaufman, S.P., (2009). Referring back to the literature; the OECD, (2005) defines the process innovation as the implementation of new or significantly improved process or delivery methods which include significant changes in techniques, equipment and/or software.

The need for innovation in organizations is stressed by many authors. Davenport, T.H., (1993) pointed out that process innovation should target changes that can be quantified and those changes must focus on improving the efficiency of the companies. The

direction of focus should be on "reducing the lead time delivery, resource allocation and procurement, reducing the distribution cost, improving the delivery efficiency, ordering and information process". Information Technology should be used as an enabler of the process innovation to bring changes in processes. Successful implementation of ideas and initiatives requires organizations to have "right procedures, knowledge, information, process and strategy" to facilitate them to achieve efficiencies in the pharmaceutical supply chain.

#### 5.3.6 Similar Key findings from Worldwide Cases and Local Case Study

#### **Complex Pharmaceutical Supply Chain**

The supply chain was seen to be complex across all worldwide cases and local case study; involvement of multiple organizations (USA); presence of strong resistance from lobbies of traders (India); large number of small players (China); large number of players and involvement of donor agents like PEPFAR, USAID, UNFPA, UNICEF (Ghana); large number of institutions (Zambia); large number of players i.e. regulatory bodies, government and donors (Tanzania).

#### Consolidated and Fragmented Distribution System

The distribution system was seen to be a challenge across all worldwide cases and local case study; consolidated and declining number of distributors (USA); fragmented with high cost of distribution (India); weak and large scale (China); inefficient tiered system with high cost of distribution (Ghana); high variability distribution lead-time(Zambia); high distribution delays, long distance covered, few distribution centers (Tanzania).

#### Lack of Access and Unavailability of Medicines

Similar challenges were seen from India (more than 60% do not have access and large number of people in rural areas); China (highly costly and unaffordable access); Ghana (high delays in deliveries and average 28.8% in northern part have access to public health care); Zambia (high frequency of medicines stock out); Tanzania (complex accessibility, unavailability of medicines at MSD and health facilities)

#### **CHAPTER SIX**

#### CONCLUSION, RECOMMENDATIONS AND FURTHER RESEARCH

#### 6.1 INTRODUCTION

This chapter briefly highlights the summary of the study and key findings from the analysis. It also presents the conclusions based on the conceptual framework in figure 4.1 and 4.2 at Chapter 4 and it answers the main research question. Concrete recommendations for donors, government, MSD, health facilities and other stakeholders are further drawn based on the major findings. The chapter also indicates generalization and practical implication of this research.

#### 6.2 SUMMARY OF THE STUDY AND KEY FINDINGS

#### 6.2.1 Summary of the Case Study

The main objective of this study was to critically analyze the performance of pharmaceutical supply chain and distribution network, evaluate the implications on access to medicine and quality health care and propose innovative solution for improvement of performance efficiency. The study attempted to identify enablers of the pharmaceutical supply chain, aggravating factors of demand-supply mismatching, challenges and implications on access to medicine and quality health care. It also addressed areas which need application of innovation for improvement of performance.

The researcher adopted the multiple case studies methodology and identified the participant organizations in the pharmaceutical supply chain as units of analysis. Qualitative data with a portion of quantitative were collected from multiple sources of information; both primary and secondary data were used to analyze the case studies. The data were collected using questionnaires which were sent to units of analysis, company reports from sources like MSD, MOHSW, TFDA, MNH; several case studies, archival records from sources like WHO, OECD, CIA, World Bank, USAID. Furthermore five worldwide similar cases from USA, India, China, Ghana and Zambia were identified and compiled by the researcher to assist in the recommendations and generalizations of this research. The data were stored in excel database and extensively analyzed in chapter 5 using within-case and cross-case analysis techniques. The key findings and discussions were addressed in chapter 5. The following section 6.2.2 highlights the summary of the key findings.

#### 6.2.2 Summary of the Key Findings

#### 6.2.2.1 Enablers of Pharmaceutical Supply Chain

The researcher found that insufficient and untimely resources allocations from Government to MSD were major core source of problems in the pharmaceutical supply chain. MSD spent more than 20 million US Dollar on procurement of pharmaceuticals. It takes more than 3 months for budget approval and funds to be disbursed from Government due to insufficient funding. As a result MSD is having a staggering debt of approximately 24 million US Dollar to the Government. Meeting future pharmaceuticals demand increase is a critical challenge to MSD; it was indicated that this can be met only if all the staggering debt are paid to the Government. The problem of insufficient funding is also similar to Zambia.

#### 6.2.2.2 Aggravating Factors of Pharmaceuticals Demand-Supply Mismatching

The researcher found that errors in demand forecasting, longer lea-time and stock-out/shortage are the major causes of pharmaceuticals demand-supply mismatching. The shortages at health facilities range from 1 week to more than 1 month period. Errors in demand forecasting at MSD are mainly caused by unreliable data from health facilities, poor quantification and poor information flow. Poor information flow is caused by poor coordination and integration in the supply chain. The stock-out at both MSD and health facilities are mainly caused by lack of stock control, short expiry medicines and expired medicines. The longer lead-time at MSD was mainly caused by delays in resource allocation from Government and procurement delays from international supplier while at health facilities the longer lead-time were mainly caused by delivery delays from MSD.

#### 6.2.2.3 Challenges facing the Pharmaceutical Supply Chain and Distribution Network

The researcher found that Government, health facilities and MSD are faced by number of challenges in the pharmaceutical supply chain. The major challenges that were seen include; financing gaps, lack of stock control, poor demand and stock information flow, longer lead-time, errors in demand forecasting, poor distribution network, poor quality and unavailability of medicines. Changing disease patterns and unqualified personnel were also contributing to stock-out. The financing gaps were seen as a major critical challenge to the Government and MSD and it is a core source of other challenges. Distribution challenges were also common to USA, India, China, Ghana and Zambia.

#### 6.2.2.4 Implications of Access to Medicines and Quality Health Care

The researcher found that the challenges facing the pharmaceutical supply chain and distribution network have major implications on access to medicines and quality health care. Evidence from the study indicated that inaccessibility and unavailability of medicines at MSD and health facilities are major problems caused by poor distribution system, delivery delays, financing gaps, procurement and resource allocation lead-time. Furthermore; the quality of health care is impacted by delivery delays, undersupply/shortage of medicines, complex accessibility, expired and counterfeited medicines at health facilities. Access to medicines problems were also seen in India, China, Ghana and Zambia.

#### 6.2.2.5 Innovation in Pharmaceutical Supply Chain and Distribution Network

Evidence from the findings and challenges indicate the high need for innovation to improve the performance and efficiency of pharmaceutical supply chain and distribution network. The identified challenges which need application of process innovation include; poor demand and stock information flow, longer lead-time, mismatching of demand and supply of pharmaceuticals, insufficient and untimely resource allocation, poor distribution system and poor quality of pharmaceuticals.

#### 6.2.2.6 Worldwide Cases (USA, India, China, Ghana and Zambia) and Local Case Study

The researcher found that there are challenges which are similar to both worldwide cases and local case study. Complexity of pharmaceutical supply chain was seen across all countries; USA, India, China, Ghana, Zambia and Tanzania. The complexity is caused by presence of large number of players/participants in the pharmaceutical supply chain. Consolidated and Fragmented Distribution System associated with high cost was also a challenge to both countries. However, lack of access and unavailability of medicines were not seen as challenges to USA but to other countries. The study also found that public health facilities and people who are living in rural areas are faced by challenges of inaccessibility and unavailability of medicines.

#### 6.3 CONCLUSIONS

While pharmaceuticals are vital input to the well functioning of the health services; pharmaceutical supply chain and distribution network underline the whole health system in delivering the health services to the nation. According to WHO, health systems are undergoing rapid change and the requirements for conforming to the new challenges of changing demographics, disease patterns; emerging and re-emerging diseases coupled with rising costs of health care delivery have forced comprehensive review of health systems and their functioning (WHO, 2006). Tanzania is currently faced by challenges of increasing demand for health care due to increasing population, varying disease patterns and increasing morbidity caused by HIV/AIDS and Malaria. Therefore the researcher decided to carry out this research to analyze critically the current performance situation of the pharmaceutical supply chain and distribution, evaluate implications on accessibility of medicines and quality health care and identify areas for application of innovation. The following are the conclusions drawn from the findings of this research. These conclusions are drawn from each research question based on the literature review in chapter 2, conceptual framework in chapter 4 and the findings of this study in chapter 5.

#### **RQ1 Conclusion:** Enablers of Pharmaceutical supply Chain

Although the pharmaceutical supply chain enablers are critical thread that runs through all activities and stages of the supply chain as suggested by Dalberg Advisors and MIT-Zaragoza (2008); these enablers are not effectively managed by MSD, Government and health facilities and there is lack of coordination in the supply chain. The huge financing gap from Government, staggering debt at MSD and untimely resource allocation from the Government hinders the performance of supply chain to function properly. It negatively implicates the timely availability of medicines to health facilities and affects the sustainability of quality health outcomes. It also cause inflexibility to the system to adjust to changes and affects the ability to meet future increase of pharmaceutical demands. The asymmetry and huge gap of demand and stock information flow between health facilities and MSD led to delays in deliveries, errors in demand forecasting and stock-out of medicines. There is a high need to have an integrated pharmaceutical supply chain with careful coordination and high level of collaborations that will facilitate information sharing among players in the supply chain.

#### **RQ2 Conclusion:** Aggravating Factors of Demand and Supply Mismatching

Matching of demand and supply is a key driver for pharmaceutical supply chain to ensure consistent availability of medicines at health facilities and MSD. Longer lead-time of procurement, resource allocation and delivery are major aggravating factors of demand and supply mismatching and is the major cause of medicines stock-out at MSD and health facilities due to delivery delays. Long lead-time of procurement and delivery has negative implications on quality of medicines and cost. It shortens the life span of medicines i.e. medicines with short expiry can expire before they reach to health facilities. Health facilities are maintaining large/excess inventory to prevent the stockout; as result it increases the obsolete inventory cost. It is important to have reliable data for proper demand forecasting planning and flexible procurement.

# RQ3 Conclusion: Challenges facing the Pharmaceutical Supply Chain and Distribution Network

#### Pharmaceutical Supply Chain Challenges

Financing gap, staggering debt and untimely resource allocation are the core causes of other challenges facing the pharmaceutical supply chain. According to Dalberg Advisors and MIT-Zaragoza (2008); strong financial management and enough financial resources enable the supply chain to operate smoothly and achieve the desired health outcomes. According to Duclose et al. (2003), these challenges also indicate the inability of MSD to respond in a timely and cost effective manner in terms of changing needs from health facilities and delivery date. MSD as the Government institution with semi-autonomous governance is the backbone for supplying pharmaceuticals and medical supplies to Tanzania's public health sector. The question of whether it will continue to be a sole supplier in the future depends with liquidity and current state of which MSD is operating. However, evidence from the findings indicates that it is extremely difficult for another supplier to come and operate with the current financial operating challenges. In order to achieve and sustain the desired quality health outcomes, there is a high need to have a strong financial management and enough financial resources and a flexible supply chain that will respond in a timely and cost effective manner to any changes.

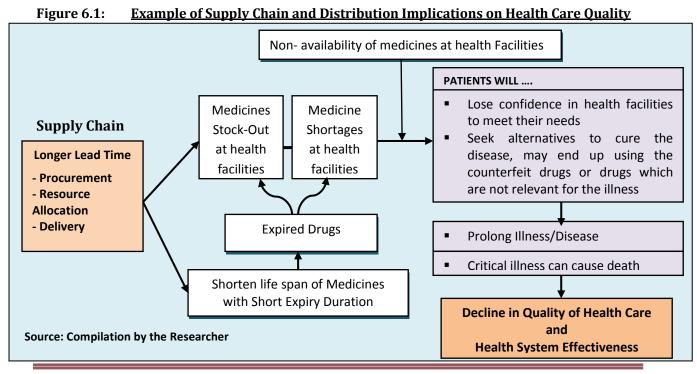
#### <u>Distribution Network Challenges</u>

With reference to Tanzanian country size of 947,300 square kilometers and a population of 41.9 million people; MSD is having a workload of distributing medicines in all regions

of Tanzania. The locations and current number of MSD regional zonal stores (9) are not enough to cover all areas in the country. This contributes highly to inaccessibility of medicines and increases delivery delays to health facilities. Moreover; the fact that MSD headquarter delivers medicines first to MSD regional zonal stores then regional zonal stores delivers to health facilities; it cause complex accessibility and unnecessary delays to health facilities. It is important to have delivery flexibility that will ensure efficient accessibility and availability of medicines at health facilities.

#### **RQ4 Conclusion:** Implications on Access to Medicines and Quality Health Care

The challenges in pharmaceutical supply chain and distribution network weaken the performance hence contributing highly to the poor performance. The poor performance of pharmaceutical supply chain and distribution network has a negative implication on access to medicine and quality health care; it decreases the effectiveness of health system and quality health care. According to WHO (2000); any poor performance in the supply chain can cripple the health system and undermine the positive health outcomes. An example of implication is the undersupply/shortage of medicines at health facilities which can be caused by longer lead-time. Due to shortages of medicines at health facilities, ill people will not be able to receive the services in full and might cause the disease to prolong. The lack of access and unavailability of medicines can increase the death rate of ill people for the critical disease. An illustration of the implication on quality health care can be seen on figure 6.1



# RQ5 Conclusion: Innovation in Pharmaceutical Supply Chain and Distribution Network

With respect to the crucial roles played by pharmaceutical supply chain and distribution network to deliver health services; there is a high need to improve its efficiency and performance through application of process innovation in order to improve accessibility and increase availability of medicines at health facilities hence saving lives of people. The desired quality health outcomes can be achieved if the supply chain will be robust and flexible. Dalberg Advisors and MIT-Zaragoza (2008) suggested that any improvement made in one aspect of the pharmaceutical supply chain can support and make stronger another aspect. Furthermore Christensen, C.M. and Kaufman, S.P., (2009) emphasized the need for organizations to assess the capabilities and disabilities in to improve performance and efficiency. Through process innovation; Government, MSD, health facilities and other stakeholders participating in the supply chain will be able to improve the processes, manage information process and balance demand and supply of pharmaceuticals.

#### Worldwide Cases Conclusion: USA, India, China, Ghana and Zambia

The distribution challenges and complexity of pharmaceutical supply chain are common across all cases and these challenges contribute highly to inaccessibility and unavailability of medicines. In developing; rural areas and public health facilities are affected by lack of access and unavailability of medicines. The complexity which is caused by presence of large number of players in the system contributes to poor coordination and integration. Even though there is complexity i.e. belongs to separate organizations, many kilometers apart or involves different countries; the supply chain has to be integrated for effective management since a problem in one part of the supply chain impact the other part (Waller, D.L., 2003)

#### 6.3.1 Addressing the Central Research Question and Final Conclusion

The main objective of this research was to critically analyze the current challenges facing the pharmaceutical supply chain and distribution networks, evaluate implications on medicine accessibility and quality health care and identify areas for application of innovation to improve performance and match the demand and supply of pharmaceuticals. This was formulated in the central research question: *How can the matching of demand and supply of medicines, quality of health care and efficient accessibility of medicines be achieved through the performance of pharmaceutical supply chain, distribution network and application of innovation?* 

To achieve successfully the matching of demand and supply, efficient accessibility of medicines and quality health care the current performance of pharmaceutical supply chain and distribution network need to be integrated and improved through the implementation of a model for matching demand and supply, pharmaceutical supply chain performance framework and proposed process innovation model such as presented in this research.

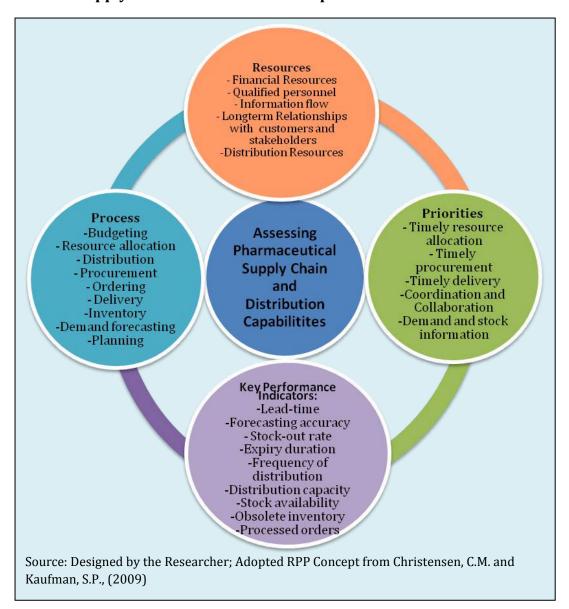
#### **Concluding Remarks:**

With respect to the conceptual framework presented in chapter 4 and the local case study findings along with conclusions at each research question; the researcher is concluding that:

The performance of pharmaceutical supply chain and distribution network is positively related to accessibility of medicines and quality health care. Any poor performance in the pharmaceutical supply chain and distribution network has negative implications on accessibility of medicines and quality health care. The poor performance has major impacts on availability of medicines.

Following this conclusion, the researcher is proposing a model (figure 6.2) based on the RPP framework concept from Christensen, C.M. and Kaufman, S.P., (2009) to be used along with the conceptual framework and demand-supply matching model for implementing the process innovation to improve the performance and efficiency of the pharmaceutical supply chain and distribution network.

Figure 6.2: A Proposed Process Innovation Model for Assessing Pharmaceutical Supply Chain and Distribution Capabilities



#### 6.3.2 Generalization of the Case Study and Findings

With respect to generalization; the researcher followed the analogical reasoning and literal replication approach to increase the external validity of the findings and conclusions based on the embedded unit of analysis and worldwide cases. The worldwide cases from developed, emerging and developing countries were selected intentionally for analytic generalization purpose. The unit of analysis in this research is the pharmaceutical supply chain and its participants and the worldwide cases are USA, India, China, Ghana and Zambia.

The reason for selecting multiple case design approach was projected to construct the literal replication by identifying the similarities and differences between the units of analysis within the local case studies and worldwide cases. The findings identified number of similarities between the pharmaceutical supply chain and distribution system of local case study and the five worldwide cases and the findings have been supported firmly by the empirical data, literature review and a conceptual framework. Moreover, several other countries are striving to improve the availability and accessibility of medicines to improve health outcomes and save lives of people.

The presented conceptual framework and a proposed process innovation model in this research provide better opportunities to understand the importance of achieving and sustaining desired quality health outcomes by improving the performance of pharmaceutical supply chain and distribution network through process innovation and increasing accessibility and availability of medicines to save lives of people. Hence the findings and conclusions of this study can be generalized to all parts of the world.

#### 6.4 RECOMMENDATIONS

#### 6.4.1 Practical Managerial Implications and Academic Contributions

#### 6.4.1.1 <u>Practical Managerial Implications</u>

The research findings and conclusions have provided new insights for practical managerial implications for a) donors, b) private investors, c) Government d) policy makers and regulators, e) pharmaceutical suppliers and companies, f) health facilities and g) patients.

- The most significant area of managerial implications this research has contributed to; is the implications of challenges facing the pharmaceutical supply chain and distribution network on access to medicine and quality health care.
- From the perspective of challenges; this research illustrated the consequences of long lead-time and financing gaps ad it presented a conceptual framework useful for increasing access and availability of medicines, attaining and sustaining the desired quality health outcomes through the efficient performance of the pharmaceutical supply chain and distribution network.

- The study also presented key performance indicators and two models; 1) for matching demand and supply and 2) for process innovation implementation to assess pharmaceutical supply chain and distribution network capabilities. These indicators and models will assist in effective management, monitoring and evaluation of pharmaceutical supply chain and distribution network and ensure efficient accessibility of medicines and the sustaining of desired health outcomes
- This study has also emphasize the need of having an integrated supply chain and importance of information sharing, coordination, integration and high level of collaboration among players in the pharmaceutical supply chain. It also illustrated the need for flexible pharmaceutical supply chain and delivery distribution

#### 6.4.1.2 <u>Academic Implications</u>

This research makes significant contributions to researchers and other academicians across all areas of pharmaceutical supply chain management, distribution management, process innovation, health management and organization performance management. These contributions are;

- The presented conceptual framework that explains different variables that have influence on the performance of the pharmaceutical supply chain and distribution network; interrelationship of these variables and how they can be used to improve the performance.
- The proposed process innovation model for management and evaluation of pharmaceutical supply chain and distribution network performance can be used as a research model for further research

#### 6.4.2 General Recommendations

The participant should aim at increasing integration and coordination of activities within the pharmaceutical supply chain by focusing on information, decision, financial and operational integration.

Figure 6.3: Recommendation Framework 1: Key Players in Supply Chain

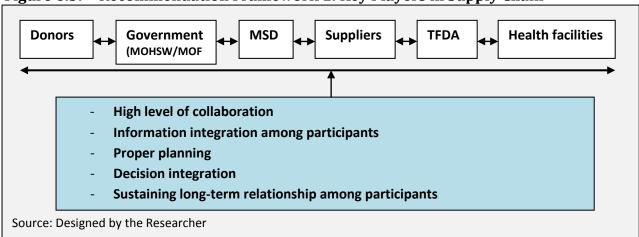
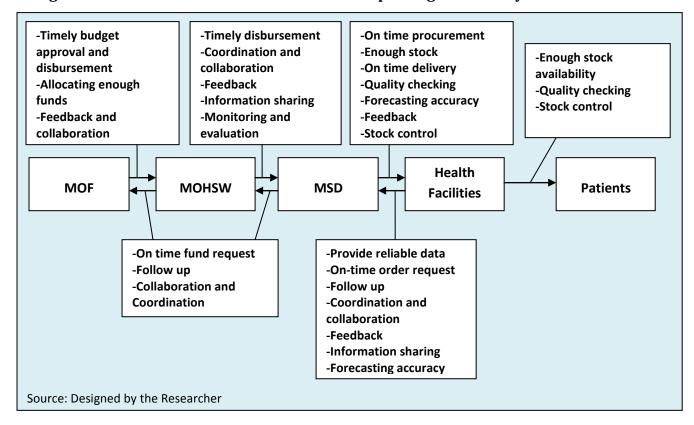


Figure 6.4: Recommendation Framework 2: Improving Availability of Medicines



**Table 6.1: Specific Recommendations** 

	6.4.3 Specific Recommendations						
	Addressed Issue	Recommendations	Strategies	Responsible Organization			
CES	1. Untimely Resource Allocation	-Government should ensure timely approval and allocation of resources as highest priority and should focus on reducing the lead time -Develop/assess the disbursement plan	<ul> <li>Review the financial plan and policy</li> <li>Allocate short-time interval for disbursement</li> <li>Emphasize on on-time fund request from MSD</li> <li>Identify reasons for delays</li> <li>Review allocation processes</li> </ul>	-MOF -MOHSW			
F INANCIAL RESOURCES	2. Insufficient Financial Resources	-Government should ensure enough funds are allocated for health facilities and this should be the highest and first priority in budgeting	<ul> <li>Allocate funds according to budget</li> <li>Review budget and expenditure statements</li> <li>Reduce unnecessary expenditures</li> <li>Increase budget allocation amount (like China initiative)</li> <li>Establish/ Strengthen the use of basket funding (like Ghana)</li> </ul>	-MOF -MOHSW			
	3. Staggering debt	-Government should ensure on time payment of funds to MSD -Debt settling should be the highest priority	<ul> <li>Develop budget management plan</li> <li>Track monthly expenditures</li> <li>Evaluate expenditure statements</li> <li>Reduce debt by installment</li> </ul>	-MOF -MOHSW -MSD			
SUPPLY CHAIN STRUCTURE	1. Complex structure	-Collaboration and coordination among players -Integration of activities -Develop/review the health care reform plan	<ul> <li>Communication and feedback</li> <li>Frequency flow of information</li> </ul>	All players: -MOF -MOHSW -MSD -Health facilities -Donors -Suppliers			

HAIN	3.	Sole supplier  Inflexible  Poor performance	-Reduce MSD workload -Reform the supply chain from centrally controlled to market oriented system (like China)  -Integrate the supply chain activities -Implement process innovation -Ensure sound financial management  -Develop supply chain balanced scorecard to assess and measure the		Invite private investors Allow supplier competition Improve the standards requirement of local suppliers Establish a framework contract agreement with local suppliers (like Ghana) Coordinate and collaborate Analyze and strengthen the capabilities Analyze and improve the disabilities Review and improve activity processes Identify uncertainties  Identify key performance indicators Identify critical success factors	-MOF -MOHSW -MSD  All players: -MOF -MOHSW -MSD -Health facilities -Donors -Suppliers All players: -MOF
SUPPLY CHAIN RFORMANCE			performance -Analyze the process, priorities and resources	•	Stick to KPI's Apply process innovation	-MOHSW -MSD -Health facilities -Donors -Suppliers
	1.	Few MSD zonal stores	-Increase number of zonal stores and network coverage	•	Increase zonal stores at each region Increase capacity of zonal stores	-MOF -MOHSW -MSD
DISTRIBUTION	2.	Long distance covered by MSD	-Minimize the distance covered by allowing direct delivery from MSD headquarters to health facilities	•	Contract the distribution to private carrier companies Develop policy for private carrier	-MOF -MOHSW -MSD
DIST	3.	Delivery delays	-Minimize/eliminate intermediaries in the distribution network -Implement process innovation to improve delivery process	•	Allow direct deliver to health facilities Contract the distribution to private carrier companies Improve distribution infrastructures Develop delivery plan	-MOF -MOHSW -MSD

GEMENT	1. Demand- Supply Mismatching	-Improve operations through process innovation should be continuous -Ensure enough financial resources for procurement -Strengthen collaboration and coordination -Ensure enough availability of stock -Emphasize feedback type of communication -Develop electronic claims transaction system (like USA)	<ul> <li>Forecasting accuracy</li> <li>Demand planning</li> <li>Inventory planning</li> <li>Flexible procurement</li> <li>Reduce procurement, financial and delivery lead time</li> <li>Track ordering</li> <li>Information sharing</li> <li>Proper quantification</li> <li>Implement automated stock management</li> <li>Establish follow up approach</li> </ul>	-MSD -Health facilities -MOF -MOHSW
INVENTORY MANAGEMENT	2. Stock-out and undersupply	-MSD periodic visit to zonal stores and health facilities -Use panic-over ordering when there is unavailability of medicines at MSD (like Zambia)	<ul> <li>Identify appropriate stock levels</li> <li>Identify appropriate re-order levels</li> <li>Provide reliable data</li> <li>Simplify ordering and invoicing processes</li> <li>Produce monthly consumption reports</li> </ul>	-MSD -Health facilities -MOHSW
INI	3. Quality - Short expiry - Expired - Counterfeit	-Donors to deliver medicines with long expiry which take into account the transportation lead time -TFDA to regulate and control the amount of expired and counterfeited medicines -Use medicine tracking technology to trace medicines along the supply chain (like India)	<ul> <li>Develop policy for buying back expired medicines from health facilities (like USA)</li> <li>Establish/strengthen effective policy for destroying counterfeited and expired medicines</li> <li>Monitor and evaluate quality at MSD and health facilities</li> <li>Reduce obsolete inventory</li> </ul>	-MSD -Health facilities -MOF -MOHSW -TFDA -Donors
INFORMATION SHARING	1. Poor Information flow	-Emphasize coordination and collaboration  -Increase the use of IT -Establish proper documentation report	<ul> <li>Increase communication frequency</li> <li>Provide feedback</li> <li>Establish follow up approach</li> <li>Produce monthly consumption reports</li> </ul>	All players: -MOF -MOHSW -MSD -Health facilities -Donors -Suppliers

#### 6.5 LIMITATIONS AND RECOMMENDATIONS FOR FURTHER RESEARCH

Developed and developing countries are striving to continue improving the health services to save lives of people. Following the current symposium speech from the WHO Director General; Dr. Margaret Chan; "the world has changed, and not at all for the better in the roughly 1 billion people who live on the margins of survival. The gaps in health outcomes are greater today than at any time in recent history. These are largely preventable deaths, in which lack of access to essential medicines plays a major role (WHO: Dr. Margaret Chan, 16<sup>th</sup> July, 2010). Therefore further research pharmaceutical supply chain and distribution network is needed to continue analyzing other implications on access to medicines and identify other strategies for improvement. The following are significant recommendations for further research;

- a) Assessing the performance of MSD zonal store: This research was limited to a case study of pharmaceutical supply chain and participating organizations located in Dar Es Salaam, the main city of Tanzania. The central focus was at MSD headquarter. Further research need to be extended to the zonal stores and assess the performance implications on accessibility of medicines and quality health care.
- b) Availability of Medicines and Impact of changing disease patterns: from the findings it was observed that changing disease patterns is contributing to medicines stock at health facilities. There is a need to conduct further research to analyze how and to what extent the changing disease patterns affect the availability of medicines at health facilities.
- c) Accessibility of Medicines in Rural areas: from the findings the researcher observed that health facilities located in Dar Es Salaam are facing challenges of inaccessibility of medicines. These health facilities are within the same city with the MSD headquarter but still they facing major challenges. The question is; what about the rural areas? Further research can be conducted and focus on rural areas to identify several pharmaceutical supply chain challenges and implications on access to medicines and quality health care
- **d) Involvement of private supplier in pharmaceutical supply chain and its impact:** there is a need to conduct a research to identify the advantages and disadvantages of involving private supplier in pharmaceutical supply chain as a

means to increase availability and accessibility of medicines to improve quality health care.

- e) Effectiveness of Collaboration and Coordination in pharmaceutical supply chain and distribution network: the researcher observed the need for collaboration and coordination in pharmaceutical supply chain and distribution network. Further research can be conducted to identify the effectiveness and benefits of coordination and collaboration.
- f) Further research on other countries to identify the current challenges and initiative and further discover ways of mapping their initiatives: in this study the researcher observed significant number of initiatives taken by worldwide countries from USA, India, China, Ghana and Zambia and these initiatives are very useful for other countries to try to adopt. Further research can be extended to other parts of the world like Europe, Asia, and Africa etc.
- **g)** Impact of insufficient human and financial resources on pharmaceutical supply chain and quality health care and Identification of other factors impacting the accessibility and availability of medicines
- **h)** Assessing the benefits of implementing process innovation in pharmaceutical supply chain and distribution network and testing the suggested process innovation model and further research on implementation of innovation on health care quality and pharmaceutical supply chain
- i) Extending this case study research by testing other methodologies and use of theoretical replication to test the contrasting results as suggested by Yin (1994).
- j) Testing the presented conceptual framework and recommendation measures and identify and Identify other performance measures and indicators of pharmaceutical supply chain and distribution network

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### **Appendix 1: Case Study Protocol**

Section	Contents	Purpose
Introduction	<ul> <li>Protocol Layout</li> </ul>	<ul> <li>To provide brief layout, objective and summary of the case study procedures, instruments used and analysis</li> </ul>
General	Case Study Overview	<ul> <li>To analyze the current challenges of pharmaceutical supply chain and distribution network focusing on public pharmaceutical sector and evaluate implications on access to medicines and quality health care</li> <li>To Identify areas for application of process innovation to improve the performance</li> </ul>
	<ul><li>Case Study Design</li></ul>	<ul> <li>Explanatory research based on Multiple Cases and Embedded Unit of analysis is pharmaceutical supply chain and its key players. It involved worldwide cases for recommendations and analytic generalization</li> </ul>
	<ul> <li>Case Research Methods and Triangulation</li> </ul>	Detail Review of literature, Collection of Secondary data from archival records, Documentation review of company reports, articles and Collection of Primary data from the unit of analysis by questionnaires
Procedures	Initial Approach to Organiza	tions:
	-Selection of Cases	<ul> <li>Identified participating organizations in the pharmaceutical supply chain excluded local and international manufacturers. Cases were based on the main city of Tanzania. It was difficult to conduct the research in rural areas.</li> </ul>
	-Number of Cases	8 cases were selected: government (1), supplier (1)public national hospital (1), private hospitals (3), private pharmacies (3), dispensaries (3), regulatory body (1), patients (5)
	-Establishing contact	<ul> <li>The contact was done on phone and via email; this was the most effective way of communicating</li> <li>Information from selected cases was collected between 5<sup>th</sup> May – 20<sup>th</sup> July, 2010</li> </ul>
	<ul><li>Case Study Questions</li></ul>	<ul> <li>The questions to organizations based on current situation of; supply chain performance, distribution and transportation, procurement and stock control, resource allocation, information flow, quality of medicines, access to medicine, regulation and quality assurance</li> </ul>
Research Instruments	<ul><li>Qualitative/Quantitativ e data</li></ul>	<ul> <li>Questionnaires with both open and close ended questions to each player with similar questions</li> </ul>
Data Analysis	<ul> <li>Data Treatment</li> </ul>	<ul> <li>Developed excel database for storage</li> <li>Data were entered in tabular form using open coding based on research questions and variables</li> </ul>
	Analysis Techniques:	
	<ul> <li>Within Case Analysis of explanatory data</li> </ul>	<ul> <li>Developed case description from each player as individual case</li> <li>Developed individual analysis and report for each variable of the research question</li> </ul>
	<ul> <li>Cross-case Analysis of explanatory data</li> </ul>	<ul> <li>Conducted cross-case analysis among individual cases and developed a brief report</li> <li>Conducted cross-case analysis between local case study and worldwide cases</li> </ul>

Validity and Quality of	<ul> <li>Construct Validity (during data collection)</li> </ul>	Multiple sources (triangulation) and chain of evidence were used during data collection
Research	<ul> <li>Internal Validity (during data analysis)</li> </ul>	<ul> <li>Identified indicators guided the analysis and controlled any extraneous variables constant across cases</li> <li>Within-case and Cross-case techniques were used to detect the cause and effect of research variables</li> </ul>
	<ul> <li>External Validity (during research design)</li> </ul>	<ul> <li>Analytic generalization and literal replication logic were used and Worldwide cases were used to increase the external validity</li> </ul>
	<ul> <li>Reliability (during data collection)</li> </ul>	<ul> <li>Excel database were created to store the data. The database was saved in an electronic media</li> <li>Developed case protocol</li> </ul>
Timeline	<ul><li>Attached</li></ul>	
Questionnaire	<ul><li>Attached</li></ul>	

## TIME LINE OF THE THESIS:

Period:	January ·	<ul><li>August</li></ul>	2010
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THESIS TIMETABLE	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept
Developing 1 page proposal	✓								
Submission 1 page proposal		✓							
Allocation of Supervisor		<b>✓</b>							
Preparing 10 pages proposal		✓	✓						
Submission 10 pages proposal				✓					
Presentation 10 pages proposal				✓					
Reviewing Literature / Writing up				✓	✓				
Drafting Methodology and Data Collection					✓	✓	✓		
Data Analysis and Writing up						✓	✓	✓	
Conclusion and Recommendation							✓	✓	
Reviewing the whole thesis							✓	✓	
Thesis submission								✓	
Thesis power point preparation								✓	
Thesis Defense								$\checkmark$	

#### **APPENDIX 2**

#### **RESEARCH QUESTIONNAIRES**

## CRITICAL ANALYSIS OF THE SUPPLY CHAIN AND DISTRIBUTION NETWORK OF PHARMACEUTICALS: IMPLICATION ON ACCESS TO MEDICINE AND QUALITY HEALTH CARE

Dear Participant,

Thank you for taking your time to read this questionnaire.

This research is conducted by Nesia Satoki Mahenge, a Tanzanian student pursuing her Master's of Business Administration in Corporate Strategy and Economic Policy at the Maastricht School of Management in The Netherlands. The research is a partial fulfillment of the requirements for the degree of Masters Studies.

This research questionnaire aims at analyzing the current situation of the pharmaceutical supply chain and distribution network and it will assess the implication on efficient access to medicine and quality of health care. It also seeks to identify the current challenges facing the supply chain of pharmaceuticals in Tanzania.

The results of this research will be useful for the improvement of the medicine accessibility and health care quality in Tanzania. It will also provide recommendations on the strategies for sustaining un-interrupted supply chain and distribution network for essential medicines.

Your questionnaire answers will be strictly confidential and data collected will be used for academic purpose only. It will take approximately 15-20 minutes to complete the questionnaire.

For any questions about this questionnaire, please contact me on:

**Telephone:** +316 14 852767

Email: mahenge.mba26@msm.nl

Please send back the questionnaire to the person who submitted to you or please email back to me using the above address.

Thank you very much for your participation and support.

Notabenye

Nesia Satoki Mahenge MBA Student Maastricht School of Management

### **PART I: GENERAL INFORMATION**

Date	e:							
Orga	nization Nam	ie:						
Num	iber of Years i	n the Organizatio	on:					
	Department:							
2 ор.								
<u>Pleas</u>	se Tick All the Bo	exes That Are Applica	able and Provide extr	<u>a information where n</u>	<u>1ecessary.</u>			
DD∩	CUREMENT:							
_	_	MSD receive and ne	erform the order fron	n customers?				
-	a) Daily	. Mob receive and pe	order ir on	reastomers.				
	b) Week	-						
	☐ c) Month							
	d) Quart							
	f) Annua							
		ding to the needs						
		Please specify						
2		stimated expenditur	e of pharmaceuticals	purchases made at each	ch financial			
Γ	year? Period	A	В	С	Select			
	Terrou				(A/B/C)			
	2006/2007	0 – 10 Million USD	10 – 20 Million USD	More than 20 Million U				
	2007/2008	0 – 10 Million USD	10 – 20 Million USD	More than 20 Million U				
Ĺ	2008/2009	0 – 10 Million USD	10 – 20 Million USD	More than 20 Million U	SD			
3	. What is the av	verage lead time in r			C-1+ (A /D /C)			
		A	В	C	Select (A/B/C)			
	From Airport		More than 1	More than 1				
	Б. С	week	week	month	_			
	From Seapor	Less than 1 week	More than 1 week	More than 1 month				
	At border	Less than 1	More than 1	More than 1				
	point	week	week	month				
4	. How can you	describe the process	s of procurement of p	harmaceuticals and m	edicine			
	supply? Pleas	e provide the length	of days for each;					
	a) Intern	ational Competitive	Bidding					
	<del></del>	nal Competitive Bido	ling					
		iated tender						
	d) Select							
	=	shopping						
_		·Please specify						
5		does MSD use to pro						
		rement is done on b	•					
		rement is done acco	=	. 1 1 -	2			
	=		raing to MSD previou	is trends and experien	ice?			
	a) Other	Please Specify						

6.	How do you deal with the shortages or under supply of the drugs?
L	
7.	Apart from Tanzania, where else do you procure pharmaceuticals and medical supplies?
TRAN	SPORTATION AND DISTRIBUTION:
8.	Which transport does MSD use for the distribution of pharmaceuticals?
	a) Pick up van (big vehicle)
	b) Motorbike
	c) Pick up (small vehicle)
	d) OtherPlease specify
9.	J 1
	supplies?
	a) Geographic distance
	b) Climate condition (temperature, humidity)
	<ul> <li>c) Poor storage facilities</li> <li>d) Transport problems (poor road conditions, outdated vehicles, poor vehicle</li> </ul>
	condition)
	e) OtherPlease specify
PHAR	MACEUTICAL SUPPY CHAIN:
10	. Describe the medicine supply chain situation at MSD;
10	a) Complex i.e. Involves a lot of procedures
	b) Complex supply chain i.e. Involves large number of key players
	c) Simple with few procedures
	d) Simple with few procedures  I d) Simple supply chain with few number of key players
	e) OtherPlease specify

11. Who a	re the key players in the supply chain and distribution network of
pharm	aceuticals?
┌ a)	Local Manufacturers
b)	International Manufacturers
c)	Public wholesalers
d)	Private wholesalers
e)	Importer (MSD)
f)	Public Hospitals
g)	Private Hospital
☐ h)	Public Pharmacy
□ i)	Private pharmacy
□ j)	OtherPlease Specify
12. Will M	SD continue to operate as a sole supplier of pharmaceuticals and medicine
suppli	es in the future?
= 1	Yes
□ b)	No
13. If the	demand is increasing, can MSD manage to meet the expected future increase?
□ a)	Yes
□ b)	No
14. What a	are the main challenges facing the supply chain and distribution of
pharm	aceuticals by MSD?
	Transport problems
□ b)	Insufficient Government funding
-	Unscheduled delivery of funds from the Government
d)	Non availability of drugs at MSD
e)	Overseas procurement problems
f)	Clearing problems (Customs problems)
	OtherPlease specify
	MSD have any resource problems?
	Shortage of human resources
	Shortage of insufficient financial resources
c)	Shortage of technology facilities (Computers etc)
	OtherPlease Specify
STOCK CONT	ROL:
16. What a	are the main causes of stock out?
	Delays in delivery
=	Errors in demand forecasting
=	Quantities delivered not in compliance with the quantity ordered
	Stealing
	OtherPlease specify
17. What a	are the main causes of drug expiry?
□ a)	Excess Supply
□ b)	Lack of stock control
□ c)	Short expiry provided by MSD
	Unqualified personnel
□ e)	OtherPlease specify

18. How can you estimate future demand of pharmaceuticals?
a) Increasing
b) Decreasing
$\square$ c) Constant
d) Unpredictable
e) OtherPlease specify
19. What challenges does MSD face in stock control?
a) Under-stocking
b) Over-stocking
$\square$ c) Expired drugs
d) Counterfeit
e) Controlled stock
f) OtherPlease specify
20. Does MSD have a procurement policy for pharmaceuticals and medicine supplies?
a) Yes
☐ b) No
21. Does MSD have a procurement plan?
a) Yes
☐ b) No
If yes, please respond question number 22
22. Does the procurement plan includes the budget planning and funds allocation for?
a) Medicines
b) Storage and Warehousing
c) Remuneration and Warehousing staff
d) Personnel Development for supply chain management e) Computerization of inventory
e) Computerization of inventory f) OtherPlease specify
OUESTIONNAIRE NO.2: MINISTRY OF HEALTH AND SOCIAL

## <u>PART II: TO BE FILLED IN BY MINISTRY OF HEALTH AND SOCIAL WELFARE (MOHSW)</u> RESOURCE ALLOCATIONS:

1. What is the total cost of the medicines procured in public sector?

	Period	A	В	С	Select (A/B/C)				
					$(H \cup H \cup H)$				
	2006/2007	0 – 10 Million USD	10 – 20 Million USD	More than 20 Million USD					
	2007/2008	0 – 10 Million USD	10 – 20 Million USD	More than 20 Million USD					
	2008/2009	0 – 10 Million USD	10 – 20 Million USD	More than 20 Million USD					
2	2. How does the MOHSW receive and perform funds request from Medical Stores								

007/2008	0 – 10 Million USD	10 – 20 Million USD	More than 20 Million USD	
008/2009	0 – 10 Million USD	10 - 20 Million USD	More than 20 Million USD	
How does the MOHSW receive and perform funds request from Medical Stores				
Department (	MSD)?			
i) Daily				
j) Week	ly			
k) Month	ıly			
l) Quart	erly			
m) Semi-	annual			
n) Annua	al			
o) Accor	ding to the needs			
p) Other	Please specify			

3.	Are public hospitals allowed to purchase drugs from other approved suppliers than
	MSD?  ☐ a) Yes
	$\Box$ b) No
TIMIN	IG OF RESOURCE ALLOCATIONS:
4	Handan dan it tale for more to be dishard from Comment to MCD air MOHCIAI2
4.	How long does it take for money to be disbursed from Government to MSD via MOHSW?  a) Less than 1 week
	b) More than 1 week
	c) More than 2 weeks
	d) More than 1 month
	e) More than 2 months
	☐ f) More than 3 months ☐ g) OtherPlease specify
	g) OtherFlease specify
5.	What are the challenges facing MOHSW to allocate financial resources to MSD for drugs
	procurement?
	a) Delays of budget approval from Government
	<ul><li>b) Insufficient financial resources</li><li>c) Unclear budget forecast</li></ul>
	d) OtherPlease specify
SOUR	CE OF FUNDS:
6.	
	<ul><li>□ a) Government (Tanzania)</li><li>□ b) Donors</li></ul>
	c) OtherPlease specify
_	
7.	Is there any financial source outside the government budget?  a) Yes
	□ b) No
8.	Does MOHSW receive any drug donations from donors?
	☐ c) Yes ☐ d) No
	If yes, please respond question number 9
	n yee, preuse response question names y
Q	How much drugs are supplied by donors? (% estimate of total drugs)
9.	a) $0 - 10\%$
	☐ b) 10 - 20%
	□ c) 20 – 30%
	d) 30 – 40%
	<ul><li>☐ e) 40 – 50%</li><li>☐ f) More than 50%</li></ul>
	g) OtherPlease specify
10	What are the challenges facing MOHSW when receiving the drug donations?
	<ul><li>a) Donations of inappropriate drugs</li><li>b) Oversupply of donations</li></ul>
	c) Short expiry of donated drugs
	d) OtherPlease specify

### **QUALITY OF HEALTH CARE:**

11.	Which of the following factors contribute to the poor quality of health care?  a) Counterfeited/expired drugs  b) Drug shortages/undersupply  c) Drugs delivery delays  d) Complex accessibility of drugs  e) OtherPlease Specify
	Do you think the poor performance of pharmaceutical supply chain has a negative implication on access to medicine and quality health care?  a) Yes  b) No
	QUESTIONNAIRE NO.3: MUHIMBILI NATIONAL HOSPITAL
]	PART II: TO BE FILLED IN BY MUHIMBILI NATIONAL HOSPITAL (MNH)
	Fick All the Boxes That Are Applicable and Provide extra information where necessary.
	REMENT:
1.	How quick can you get the drugs from MSD?
	a) Within 24 hours b) Within 1 week
	☐ c) Within 1 week
	d) More than 1 month
2.	How do you procure medicines if MSD is out of stock?
[	a) Private pharmacies
L	b) Public pharmacies
L	c) Wait for MSD
L	d) OtherPlease specify
SUPPLI	ER PERFORMANCE
<b>3.</b> 1	Do you use any indicators to assess the quality of pharmaceuticals and medicine supplies
	delivered to you?
[	a) Yes
L	→ b) No
4. ]	If yes on 3 above; which indicators do you use for assessment?
l I	a) Damage/Expiry date/Losses b) Products conforms to order
[	c) Delivery time
[	d) Quality of service
[	e) Storage condition
[	f) OtherPlease specify
STOCK	CONTROL:
<b>5.</b> 1	Does MNH allowed to purchase drugs from other approved supplier than MSD?
Γ	a) Yes
[	b) No

0
?
on?

	you think the poor performance of pharmaceutical supply chain has a negative plication on access to medicine and quality health care?
	c) Yes
	d) No
	QUESTIONNAIRE NO. 4: TANZANIA FOOD AND DRUGS
PART II:	TO BE FILLED IN BY TANZANIA FOOD AND DRUGS AUTHORITY (TFDA)
Please Tic	k All the Boxes That Are Applicable and Provide extra information where necessary.
<b>REGULA</b>	ΓΙΟΝS:
1. Ho	w does the TFDA control the quality of drugs?
	a) As per scheduled plan
	] b) Irregular
	c) OtherPlease specify
	you use any indicators to assess the quality of pharmaceuticals and medicine supplies
de	elivered to you?
	la) Yes
	b) No
3. If y	ves on 2 above; which indicators do you use for assessment? [a] Damage/Expiry date/Losses
	b) Products conforms to order
	c) Delivery time
	d) Quality of service
	le) Storage condition
	f) OtherPlease specify
4. Ho	w does TFDA store and retrieve information in practice about the quality inspection
ar	nd pharmaceutical registration?
	a) Software and databases
	b) Manually
	c) Computerized information
	d) OtherPlease specify
5. Do	es TFDA have the following guidelines?
	a) Good Distribution Practices b) Good Manufacturing Practices
	c) OtherPlease specify
 6 Do	es TFDA provide transparency on the accessible and assessment process of the
	oplication for pharmaceutical and medical supplies registration?
	a) Yes
	]b) No
QUEST	TIONNAIRE NO.5 - 7: PRIVATE HOSPITALS, DISPENSARIES AND PRIVATE PHARMACIES
1. <u>Do</u>	you produce monthly reports of the consumption of drugs?
	a) Yes
_ L	b) No
	you use any indicators to assess the quality of pharmaceuticals and medicine supplies
de.	livered to you?
	c) Yes
	]d) No

3.	If yes on 4 above; which indicators do you use for assessment?
	a) Damage/Expiry date/Losses
	b) Products conforms to order
	c) Delivery time
	d) Quality of service
	e) Storage condition
	f) OtherPlease specify
4.	Which transport does MSD use for the distribution of pharmaceuticals?
	a) Pick up van (big vehicle)
	☐ b) Motorbike
	c) Pick up (small vehicle)
	d) OtherPlease specify
5.	What are the main causes of stock out?
	a) Delays in delivery
	b) Errors in demand forecasting
	c) Counterfeited/expired drugs
	d) Quantities delivered not in compliance with the quantity ordered
	e) OtherPlease specify
STOCE	K CONTROL:
6	What are the main causes of drug expiry?
0.	a) Excess Supply
	b) Lack of stock control
	☐ c) Short expiry provided by MSD
	d) Unqualified personnel
	e) OtherPlease specify
7.	How many times do you experience shortages of drugs in a 3 months period?
	a) 3 Days
	b) One week
	c) 2 weeks
	d) 1 month
	e) More than 1 month
8.	How do you prevent the drug shortages or undersupply?
	a) Maintain large inventory
	b) Frequency ordering
	c) Run out of stock
	d) OtherPlease specify
PROC	UREMENT:
9.	How do you procure medicines if MSD is out of stock?
	a) Private pharmacies
	b) Public pharmacies
	c) Wait for MSD
	d) OtherPlease specify

10	. Have you ever received any of the following from MSD?
	a) Short-expiry drugs
	b) Expired drugs
	c) Ineffective drugs
	d) Counterfeited drugs
	e) OtherPlease specify
QUALI	TY OF HEALTH CARE:
11.	. Which of the following factors contribute to the poor quality of health care?
	k) Counterfeited/expired drugs
	l) Drug shortages/undersupply
	☐ m) Drugs delivery delays ☐ n) Complex accessibility of drugs
	o) OtherPlease Specify
12.	. Do you think the poor performance of pharmaceutical supply chain has a negative
	implication on access to medicine and quality health care?
	e) Yes
	f) No
	QUESTIONNAIRE NO.7: PATIENT
	PART II: TO BE FILLED IN BY A PATIENT
Please	Tick All the Boxes That Are Applicable and Provide extra information where necessary.
rouse	Trenth the Bones That is emphasize and Fronting end a high matter where necessary.
1.	What is the source of your medicines?
1.	p) Private pharmacy
	q) Local stores
	r) Public pharmacy
	s) Public Hospitals / Dispensary
	t) Private Hospitals / Dispensary
	u) Owned drugs v) OtherPlease Specify
2.	How can you describe the price of medicines?
	a) Affordable
	b) Highly costly
	□ c) Less costly
	d) Normal price
3.	How can you describe the availability of medicines when you go to public hospitals?
	a) Easily available
	b) Not easily available
4.	Which of the following factors contribute to the poor quality of health care?
	a) Counterfeited/expired drugs
	b) Drug shortages/undersupply
	c) Drugs delivery delays
	d) Complex accessibility of drugs
_	e) OtherPlease Specify
5.	Do you think the poor performance of pharmaceutical supply chain has a negative
	implication on access to medicine and quality health care?
	g) Yes
	h) No

#### **BIOGRAPHY**

#### **EDUCATION**

2009 – 2010: Masters of Business Administration in Corporate Strategy and Economic Policy at Maastricht School of Management, Netherlands

2001 – 2004: Bachelor of Commerce and Management at University of Dar Es Salaam Tanzania

#### **PROFESSIONAL EXPERIENCE**

2007 – 2009: Project Manager at University of Health and Allied Sciences, Tanzania

2005 – 2007: Marketing Executive at Toyota Tanzania Limited, Tanzania

2004 – 2005: Disbursement Auditor at Tanzania Commission for Aids, Tanzania

2003: Credit Analyst at National Bank of Commerce, Tanzania

#### **VOLUNTEER EXPERIENCE**

March 2010 – Present: Project Supporter at SIFE Maastricht, Netherlands

2008 – Present: Project Manager at MAO, Tanzania

2004 – Present: Inter-Action Leader at British Council of Tanzania, Tanzania

#### **BACK HOME ACTION PLAN**

Action Plan	Procedures	Time Frame	
1. Summarizing the study findings and recommendations	Prepare a report and PowerPoint presentation	20 <sup>th</sup> – 22 <sup>nd</sup> September, 2010	
2. Disseminating the findings and recommendations to study cases	a)Call for different meetings with representatives of each organization and presenting the findings to:  i. MSD  ii. MOHSW  iii. MOF  iv. Health facilities  b) Call for a single general meeting with all representatives for discussions	23 <sup>rd</sup> – 30 <sup>th</sup> September, 2010  4 <sup>th</sup> – 6 <sup>th</sup> October, 2010	
3. Follow up			
4. Conducting similar research to rural areas	- Follow the same study procedures	2011	