ADDIS ABABA UNIVERSITY

SCHOOL OF COMMERCE

DEPARTMENT OF LOGISTICS AND SUPPLY CHAIN MANAGEMENT

CHALLENGES OF GLOBAL PHARMACEUTICALS SUPPLY CHAIN MANAGEMENT: THE CASE OF ZAF PHARMACEUTICALS PLC

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF ARTS IN LOGISTICS AND SUPPLY CHAIN MANAGEMENT

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This is to certify that the thesis prepared by Mr. Bayew Liknaw, entitled "Challenges of global Pharmaceuticals supply chain management: The case of Zaf Pharmaceuticals PLC", a thesis submitted to Addis Ababa University, school of commerce, department of logistics and supply chain management in partial fulfillment of the requirements for the Degree of Master of Arts in Logistics and Supply chain Management, complies with the regulation of the university and meets the accepted standards with respect to originality and quality.

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DECLARATION

I hereby declare that the work which is being presented in this thesis entitled Challenges Of Global Pharmaceuticals Supply Chain Management: The Case of Zaf Pharmaceuticals PLC is original work of my own, has not been presented for a degree of any other university and that all sources of material used for the thesis have been duly acknowledged.

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This is to certify that the above declaration made by the candidate is correct to the best of my knowledge.

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Thesis Advisor

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List of Acronyms& Abbreviations

COM……Council of Ministers

ESLSE……Ethiopian Shipping and Logistics Service Enterprise

FMHACA ……Ethiopian Food Medicine and Health Care Administration and Control Authority

FOREX……..…Foreign Exchange

HPRE……..House of peoples representatives of Ethiopia

NBE……National Bank of Ethiopia

MA…….Market Authorization of medicines to be distributed.

MOH……Ministry of Health

PFSA……Pharmaceuticals Fund and Supply Agency

RA……. Regulatory Affairs

PSC …….Pharmaceutical Supply Chain

SCM …….Supply Chain management

WHO……World Health Organizatio*n*

Abstract

Global supply chain management integrates supply and demand management within and across companies belonging to different countries. The planning of activities involving sourcing, outsourcing and supplying are subject to environmental conditions that compose the global market. However, the global dimension has introduced complexity in the supply chain. The management of global supply chains poses more challenges than the management of domestic supply chains. The case of global Pharmaceuticals supply chain management is one of the most difficult supply chain management operations as it is conducted in a highly government-regulated environment to protect human lives from adverse effects of medicines. The identified challenges faced during global SCM practice of Zaf Pharmaceuticals PLC collecting data from concerned departments' respondents. The data for study was collected from 57employees of Zaf Pharmaceuticals PLC and its global suppliers' representative offices based on purposive sampling technique through self-administered questionnaires. In addition, 5 managers were interviewed. The data collected through self-administered questionnaires was analyzed using descriptive statistics like percentage, mean and standard deviation. The qualitative data collected through interview was used during discussion of stated points. The result of the analysis indicated that shortage of foreign exchange and fluctuation of exchange rates, supply uncertainty, regulatory standard to get market authorization to distribute pharmaceuticals, longer and variable lead-times, supplier selection complexity and to some extent lingual and cultural differences and economical and political instability are found to be major challenges in global supply chain management practice of Zaf pharmaceuticals PLC respectively.

Based on the findings of the study it was recommended that working on supplier selection criteria, conducting periodic audit of suppliers, sourcing from high quality profile pharmaceuticals suppliers, reduction of suppliers' base and shifting to domestic sourcing to minimize foreign exchange scarcity challenges are found to be important.

Key words: Pharmaceuticals, global supply chain management, challenges, and suppliers

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CHAPTER ONE

INTRODUCTION

This section encompasses background of the study and study organization, statement of the problem, objective of the study, research question, limitation and scope of the study, among others.

1.1 Background of the study

Supply Chain Management encompasses the planning and management of all activities involved in sourcing and procurement, conversion, demand creation and fulfillment, and all Logistics Management activities. It also includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third party service providers and customers. In essence Supply Chain Management integrates supply and demand management within and across companies (Gibson, Mintzer, & Cook, 2005, p.22).

Simchi, Levi and Kaminiski (2008) defined SCM as the set of approaches utilized to efficiently integrate suppliers, manufacturers, warehouses, and stores so that merchandise is produced and distributed at the right quantities, to the right locations and at the right time in order to minimize system wide costs while satisfying service level requirements. In conjunction with the Global Supply Chain forum, Lambert, Stock, and Ellram, (1998) stated, “Supply Chain Management is the integration of key business processes from end user through original suppliers that provides products, services, and information that add value for customers and other stakeholders” as quoted in the work of Tracey, Lim and Vonderembse (2005).

In today's world, SCM is a key strategic factor for increasing organizational effectiveness and for better realization of organizational goals. So SCM can achieve the organizational goal through enhancing competitiveness, better customer care and by increasing profitability. The era of both globalization of markets and outsourcing has begun, and many companies select supply chain and logistics to manage their operations (Gunasekaran, Patel, and Tirtiroglu, 2001). Christopher, Mera, Khan, and Yurt (2011) stress on the need of supply chain design for global operations and

they argue that the choice of supply chain strategy impacts competitive performance (pp 67-81). The internationalization or globalization of supply chains has increased foreign competition in the countries' local markets. For this reason, companies must make quick and wise decisions at strategic and operational levels regarding the procurement of goods and services globally in order to minimize the extent of procurement risks or problems (Msimangira, 2003).

The pharmaceutical industry supply chain according to Whewell (2010), covers drug research, development, manufacture; distribution and application through a range of healthcare services, together with all the ancillary businesses that help these different stages function effectively. Pharmaceutical supply chain should provide medicines in the right quantity, with the acceptable quality, to the right place and customers, at the right time and with optimum cost to be consistent with health system's objectives and also it should make benefits for its stockholders (Kaufmann, Thiel, and Becker, 2005). There are occasions where international trade can have direct health and safety impacts on poor individuals; impacts that can be beneficial or detrimental. Perhaps most importantly, improving the health outcomes of poor people usually involves imports of medical products. It is simply not possible for a small, developing country like Ethiopia to produce the entire range of even some of the more basic medical supplies, no less more advanced medical equipment and pharmaceuticals (Reinert, 2005).

Firms internationalize the upstream side of their supply chain to have access to lower priced goods, higher quality goods, and worldwide technology and to benefit from delivery and reliability improvements (Monczka & Trent, 1991, pp 2-8). Firms also internationalize their downstream operations so that they are able to sell their products in new geographical markets (Kuemmerle, 2005, pp. 42-49). However, the international dimension has introduced complexity in the supply chain. In fact, the management of global supply chains poses more challenges (i.e., new and more suppliers, variable exchange rates and the change of local policies) than the management of domestic supply chains (Dornier, Ernst, Fender,& Kouvelis, 1998).

These challenges comprise, for instance, an increase on transportation costs, lead times and inventories. Moreover, infrastructural deficiencies in developing countries (e.g., transportation and telecommunications, inadequate worker skills, supplier availability, supplier quality, etc.)

create challenges that are normally not experienced in developed countries. Furthermore, global supply chains carry specific risks such as variability and uncertainty in currency exchange rates, economic and political instability, and changes in the regulatory environment. All the above mentioned challenges can lead to difficulties in getting the benefits associated with internationalization. Taking into account that supply chains are becoming more and more global, the study of challenges and strategies to overcome them is of great importance for the management world.

The pharmaceutical sector of Ethiopia is regulated by Food, medicine and Health care Administration and control Authority (FMHACA) based on proclamation No.661/2009 (FNG, 2009) established under council of ministers Regulation No.189/2010 (FNG, 2010). Ethiopian pharmaceuticals market is increasing from time to time. Most of the pharmaceuticals (75%) are sourced from global suppliers. However 25% of the Pharmaceuticals are manufactured in Ethiopia (PFSA, 2016). In addition, International Federation of Pharmaceutical Manufacturers & Associations states that Ethiopia had imported $309.77 Million worthy pharmaceuticals and exported pharmaceuticals having value of $2.02 Million (IFPMA, 2017).Currently there are more than 135 registered pharmaceutical importers in Ethiopia (EFMHACA, 2017). These importers distribute different kinds of pharmaceuticals sourcing from different global suppliers located in different countries.

Even though most of pharmaceutical products are sourced and imported by Pharmaceuticals Fund and supply agency (PFSA) from global suppliers via invitation to redundant international competitive bids, in terms of global supply chain management, private pharmaceutical companies are found to be good examples for establishing effective buyer-supplier relationship for mutual benefit and cooperation. To the knowledge of the, researcher, there are no researches conducted to assess challenges of global pharmaceuticals supply chain management in Zaf Pharmaceuticals PLC. This paper explored the challenges of global pharmaceuticals supply chain management taking Zaf Pharmaceuticals PLC, which is involved in sourcing different pharmaceutical products from more than 26 diversified global suppliers facing multifaceted challenges in managing its upstream global supply chain.

1.2 Back ground of study organization

Zaf Pharmaceuticals PLC is privately owned company which was established in 1991 with an objective of importation and distribution of Pharmaceuticals (Human and Veterinary), medical supplies, devices, infant formula and medical equipment throughout Ethiopia. Its office is located in the center of the capital city Addis Ababa Bole area which is convenient for the distribution of our products (ZAF, 2017). It has three standard warehouses constructed as per the FMHACA's standards and one of them is fitted with cold chain facilities to ensure that the products are kept as per their respective recommended storage conditions.

The main business activity of the company include but not limited to import and distribution of Safe, quality and efficacious medicines (Human and Veterinary), medical supplies and Medical equipment's, supplements and Infant formulas. At present the company has a market authorization to import and distribute more than 300 different medicines and medical supplies/ equipment from different Multinational and generic companies Zaf pharmaceuticals PLC., distributes its imported products mainly through wholesalers and retailers. In addition, it supplies different governmental and non- governmental health facilities participating in their bids (ZAF, 2017).

When we look into geographic distribution of its Suppliers, Denk Pharma and Bayer Healthcare are from Germany , Sandoz GmbH from Austria, Laboratorio Edol and Laboratorio Basi from Portugal, Liptis from Switzerland, Pradox from England, Carlo Erba from France, Ertunc Ozcan from Turkey, Pharma international from Jordan, Comfort rubber gloves from Malaysia, Alipinion medical systems from South Korea, Nihon Kohden from Japan, Eva Pharma from Egypt, True Dent Manufacturing export Co. from Pakistan, Orient International Holding, Tonghua Dongbao, Kunming pharmaceutical Ltd., Huanggang Huangzhou, Xianghui textiles, Aland Nutraceutical Co. Ltd, Changzhou, Nantong Medical apparatus, Edan Instruments Inc. Orient Gene tech china, and Changzhou from China, Medopharma, Ramsons international and Mais India from India and General Pharmaceuticals Ltd is from Bangladesh (ZAF, 2017).

The researcher considered Zaf pharmaceuticals PLC as an ideal case study firm to study challenges of global pharmaceuticals supply chain management practice as it deals with different

suppliers scattered in different countries. Moreover it is facing different challenges like supply delay and interruption in managing its global supply chain operations recently.

1.3 Statement of the problem

In the context of supply chain management, the term globalization implies that supply chains are not local anymore but they have expanded into international locations (Dornier et al., 1998). Firms globalize the upstream side of their supply chain to have access to lower priced goods, higher quality goods, and worldwide technology and to benefit from delivery and reliability improvements (Monczka and Trent, 1991). Firms also internationalize their downstream operations so that they are able to sell their products in new geographical markets (Kuemmerle, 2005).

The international dimension has introduced complexity in the supply chain. In fact, the management of global supply chains poses more challenges (i.e., new and more suppliers, variable exchange rates and the change of local policies) than the management of domestic supply chains (Dornier et al., 1998). These challenges comprise, for instance, an increase on transportation costs, lead times and inventories. Moreover, infrastructural deficiencies in developing countries (e.g., transportation and telecommunications, inadequate worker skills, supplier availability, supplier quality, etc.) create challenges that are normally not experienced in developed countries. Furthermore, global supply chains carry specific risks such as variability and uncertainty in currency exchange rates, economic and political instability, and changes in the regulatory environment. All the above mentioned challenges can lead to difficulties in getting the benefits associated with globalization.

According to Mentzer, Stank & Myers (2007a), the complexities of cross-border operations are exponentially greater than in a single country, and the ability to compete in the global environment often depends on understanding the subtleties that emerge only in cross-border trade - that is, in GSCM. The operation in a GSCM is based on the development of capabilities to integrate different companies, from different countries, languages and cultures and different economic and technological level. Modern supply chains are very complex, with many parallel physical, financial and information flows occurring in order to ensure that products are delivered in the right quantities, to the right place in a cost-effective manner. It has also been suggested that the drive towards more efficient supply chains during recent years has resulted in the supply

chains becoming more vulnerable to disruption and prone to challenges (Christopher & Lee, 2004, pp 388-96).

The pharmaceutical industry supply chain covers drug research, development, manufacture; distribution and application through a range of healthcare services, together with all the ancillary businesses that help these different stages function effectively (Amegashie & Nikoi, 2014). It is also globally heavily regulated and used by everyone in life. Changes in one area impact upon the others and environmental factors such as pricing, regulatory change or actions by competitors, impact the whole supply chain in ways that are not easily understood or properly managed (Whewell, 2010). The IBM Global Business Services report (2010) argues that pharmaceutical supply chains are ill-placed to cope with all the issues that face it these days. These supply chains are under enormous financial and competition strains. The biggest threat to the pharmaceutical industry, however, comes from issues it has with its customers concerning quality issues. Currently the policy used to face such challenges is adding more tests throughout the supply chain.

According to Ministry of Health of Ethiopia report, the annual pharmaceutical market in Ethiopia is estimated to be worth $ 400 to $ 500 million and growing at an impressive rate of 25% per annum. A 2012 estimate by Frost and Sullivan suggests the Ethiopian pharmaceutical market could witness growth rates of "slightly over 14%" to reach an approximate value of just under $ 1 billion by 2018 (MOH, 2015). This report states that there are approximately 200 importers of pharmaceutical products and medical consumables in Ethiopia. More than 75% of the pharmaceuticals are sourced from global suppliers however 25% of the Pharmaceuticals are manufactured in Ethiopia (PFSA, 2016).

Taking into account that pharmaceutical supply chains are becoming more and more global, the study of challenges and strategies to overcome them is of great importance for those who manage these operations. This research study identified key challenges of global Pharmaceuticals supply chain management in Zaf Pharmaceuticals PLC, which is currently facing frequent supply disruption and order delays.

1.4 Research Questions

1. What are the challenges of global pharmaceuticals supply chain management for Zaf Pharmaceuticals PLC?
2. Which challenges have more negative impact on the supply chain management of Zaf Pharmaceuticals PLC?
3. Which are major Ethiopian regulatory challenges which affect global pharmaceuticals SCM Practice of Zaf Pharmaceuticals PLC?

1.5 Objectives of the Study

1.5.1 General Objective

The general objective of this research was to assess the Challenges of global pharmaceutical supply chain management on organizational performance with particular reference to ZAF Pharmaceuticals PLC.

1.5.2 Specific Objectives

The specific objectives are:

1. To assess major global pharmaceutical supply chain management challenges in ZAF Pharmaceuticals PLC, Ethiopia.
2. To prioritize identified challenges on organizational performance of ZAF Pharmaceuticals PLC of Ethiopia during its global sourcing.
3. To identify major challenges related to Ethiopian regulatory challenges which affect global pharmaceuticals supply chain management of Zaf Pharmaceuticals PLC.

1.6 Significance of the Study

Being developing country, most of the pharmaceutical products (75%) (MOH, 2015) are imported from global suppliers which are Authorized to market their products through their licensed domestic distributors. According to Msimangria (2014), most developing countries like Tanzania benefit in engaging in global supply chain by purchasing goods and services globally or internationally in order to meet the customer requirements at low costs. However, global supply chain end component in developing countries like Tanzania faces many problems, at a company level, as well as at government level, due to the regulations.

Globalization in the pharmaceuticals sector is entering a new phase. Many new drugs are marketed globally, and these revenues encourage further investment in research and development. The industry is undergoing substantial transition, with increased competition and downward pressure on prices. Moreover, there have also been widespread concerns that R&D (Kiriyama, 2011). International Federation of Pharmaceutical Manufacturers & Associations **(**IFPMA) facts and findings of 2017 stated that Ethiopia had imported $309.77 Million worthy pharmaceuticals and exported pharmaceuticals having value of $2.02 Million (IFPMA, 2017). This shows that pharmaceuticals imported from global supplier have huge value which needs critical attention in managing end to end supply chain practices to reduce associated costs.
This study assessed the challenges of global pharmaceuticals supply Chain management during importation of Pharmaceutical products to Ethiopia, articulating experience of Zaf Pharmaceuticals PLC which has a 26 years' experience of sourcing from global suppliers. It tried to identify key challenges in pharmaceuticals supply chain management of upstream suppliers which affect the availability and cost of products in the downstream of the supply chain members taking the case organization.

Although, the study was carried out for academic purpose and targets to assess global supply chain practices in a single pharmaceutical company, the findings will contribute to deepen the knowledge of global pharmaceuticals supply chain in general and the study area in particular. The study result can provide valuable information for Pharmaceuticals supply chain managers, procurement managers and officers, and other concerned departments to understand the challenges of global supply chain management in pharmaceuticals in zaf Pharmaceuticals PLC. Supply chain members, service providers, regulatory bodies and policy makers may use the

findings to intervene in designing mitigating Strategies to minimize such challenges. This research will contribute in adding knowledge to the previous research findings and serve as a clue for further investigators.

1.7 Scope of the Study

In this study, the researcher tried to assess the challenges of global pharmaceuticals supply chain management. Despite the availability of a number of issues related to supply chain management, this research delimited itself only on the practice of pharmaceuticals supply chain management of Ethiopia to find out the challenges of global Pharmaceuticals supply chain management in the case of Zaf Pharmaceuticals PLC.

The scope of the study was limited to the global supply chain management practice of Zaf pharmaceuticals PLC. Which is working with more than 26 global suppliers located in different countries targeting to its sourcing and logistics management practice fulfilling regulatory requirements of FMHACA. The data for analysis was collected cross-sectionally from May 5-May 12,208 from concerned departments of the company.

1.8 Limitation of the study

The study focused only on the assessment of challenges of global pharmaceuticals supply chain management in the process of importing pharmaceuticals from global suppliers particularly taking the practice of Zaf Pharmaceuticals as the case study. The data was collected only from Zaf pharmaceuticals PLC procurement, Distribution, regulatory affairs business development and marketing departments and foreign suppliers' representative offices. In addition, interview was made with concerned department managers and with the General manger of the company. As the study is conducted in one of the companies involved in global pharmaceuticals supply chain management practice, detail analysis of data from other importers is needed for further generalization. The research result cannot be representative.

1.9 Key Concepts and Definitions of Terms

Globalization is defined as the worldwide involvement of technological, economic, political and cultural exchanges and in the context of supply chain is viewed as a network of contemporaneous events which requires a systematic strategy of supply chain management. Globalization increases interconnectedness among global organizations (Capineri, Christina & Leinbach, 2004) resulting in multi fold benefits to firms involved.

Global supply chain: an international network of manufacturers, wholesalers, distributors, and retailers who turn raw material into finished goods and services and are responsible for the successful delivery of goods/services to end customers. Careful examination of the recent literature related to the global supply chain suggests that a large-scale integrative research regarding challenges in the global supply chain, design of the global supply chain, collaboration in the global supply chain, and performance of the global supply chain is scarce (Manuj & Metnzer, 2008, pp133-155). There is even less literature focusing on how firms react to challenges in the global supply chain and how these challenges influence decisions on planning and implementing supply chain design strategies, and how these strategies influence supply chain performance.

The pharmaceutical industry can be defined as a complex of processes, operations and organizations involved in the discovery, development and manufacture of drugs and medications. The World Health Organization (WHO) defines a drug or pharmaceutical preparation as: any substance or mixture of substances manufactured, sold, offered for sale or represented for use in the diagnosis, treatment, mitigation or prevention of disease, abnormal physical state or the symptoms thereof in man or animal; [and for use in] restoring, correcting or modifying organic functions in man or animal.

pharmaceutical supply chain: the means of delivering medicines to patients by coordinating and collaborating the processes, operations and organizations involved in the product development, manufacturing, marketing and logistics of medicines (Horton, 2010; N. Shah, 2004). Specifically, the pharmaceutical supply chain originates from raw material suppliers, to manufacturing sites, to wholesale distributors, to pharmacies/hospitals, and ultimately to patients (Health Strategies Consultancy LLC, 2005). According to Shah (2004) and Pedroso and Nakano

(2009, p. 378), a typical PSC includes, but is not limited to, the following parties: manufacturers, intermediaries, healthcare providers, and customers.

Supply chain management: the management of upstream and downstream relationships with buyers and sellers in order to create value in the final market at less cost to the supply chain as a whole (Christopher, 1998). However, this definition does not highlight the ultimate objectives of SCM. Chopra and Meindl (2007) state that the ultimate objectives of every supply chain are to satisfy customer needs and to generate profits. Similarly, Christopher (2011) views the main aim of SCM as delivering superior customer value at the lowest possible cost to the supply chain as a whole.

1.10 Organization of the thesis

This study organized into five chapters. Chapter one deals with background of the study, statement of the problem, objectives, and research questions, scope of the study, significance of the study, delimitations and limitation of the study and Definition of key terms. Chapter two is mainly concerned with review of related literatures. It comprises theoretical, empirical literatures and conceptual underpinning. Chapter three focuses on research methodology which comprises rationale for the selection of research area, study design and sampling techniques, data collection methods and analysis. Chapter four deals with data analysis, results and discussion and Chapter five focuses on summary of findings, conclusion and recommendations.

CHAPTER II

LITERATURE REVIEW

2.1 Theoretical literature review

2.1.1 The supply chain management concept

There are many different definitions of the term "supply chain." Typically a supply chain can be defined as a network of organizations that are involved, through upstream and downstream linkages, in the different processes and activities that produce value in the form of products and services in the hands of the ultimate customer or consumer (Lysons & Farrington, 2006). The processes involved in a supply chain may include activities such as sourcing raw materials and parts, producing or assembling the products, storing the products, order processing and tracking, through to the distribution and delivery of the product to the final customer (Sanders, 2012). Chopra and Miendel (2007) defined supply chain management as the management of a network of retailers, distributors, transporters, storage facilities and suppliers that participate in the sale, delivery and production of a particular product.

In the current global competitive market, the management evolution is oriented for network operation, value and supply chain. This scenario, along with the constant advances in communication technologies and transportation, motivates the continuing evolution of supply chain management and different techniques for managerial efficiency (Simchi-Levi, *et al*., 2008). Supply Chain Management (SCM) has been an important approach of operations management area, and it is at the core of success of most leading companies (Sanders, 2012). All these concepts are understood through strategic management theories in order to seek collaborative advantage in a global environment. Nowadays companies source globally, sell globally, or compete with some companies that also do that. Thus, Global Supply Chain Management (GSCM) represents a major focus for many businesses and business schools today (Mentzer, *et al.*, 2007a).

2.1.2 Supply Chain Management and Global Operation

Global supply chain management integrates supply and demand management within and across companies (suppliers, intermediaries, third party service providers or customers) belonging to different countries and presenting distinction in their economic and technological level. The planning of activities involving sourcing, outsourcing and supplying are subject to environmental conditions that compose the global market (Sanders, 2012; Mentzer, *et al*., 2007a).

The characteristics and challenges of the integrated market have been creating new rules for the achievement and maintenance of competitive advantage. Many companies serve multiple global markets, with products sourced and produced across many continents. Even the smallest rural farms are affected by the global influx of foreign goods and trade regulations (Sanders, 2012). Thun (2010) states that the supply chain integration necessary to compete in the global market is defined as the improvement of cooperative relationships with customers and suppliers. The challenge is to develop the buyer-supplier cooperation in an environmental uncertainty with multidimensional constructs consisted of dynamism and complexity such as: (1) the dynamism regarding an internationally purchased item which measures the frequency, extent, and unpredictability of changes; (2) the complexity of that purchased item which measures technical complexity; (3) the cultural distance between the buyer's country and the supplier's country which measures informational and communication complexity; and (4) geographic complexity between the two countries which measures the complexity of the flow of goods or logistical complexity (Kaufmann &Carter, 2006).

Being global provides opportunities to tap into huge and growing markets, capitalize on new economic trends, and utilize natural resources available in other geographic areas (Sanders, 2012). The larger the portfolio of markets in which the supply chain operates, the greater the opportunities and, simultaneously, the greater the complexities and risks resulting from turbulent environmental conditions (Myers, Borghesi, & Russo, 2007). Trading on a global market scale is considerably more complicated than on a domestic one. There are time costs due to longer transit time and there are also operational costs involved in conducting business in a different part of the world. These include differences in labor productivity and access to labor skills, access to transportation and infrastructural support, as well as availability of technology. Besides, there are significant risks that include political instability, as well as currency fluctuation (Sanders, 2012).

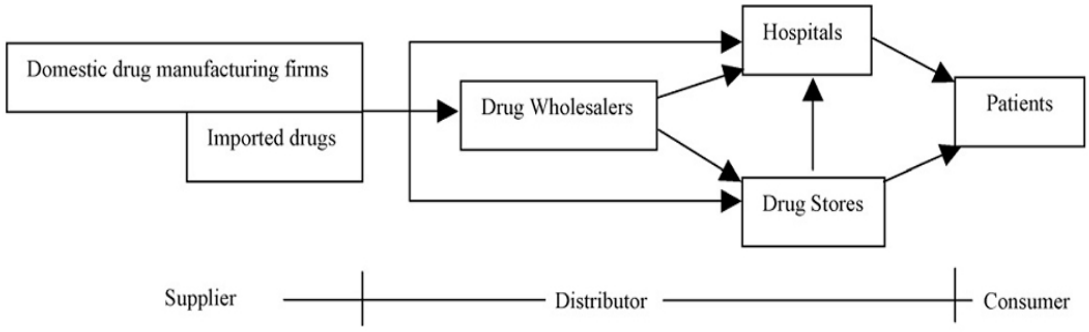
2.1.3 Pharmaceutical Supply Chain (PSC)

Porter (1990) characterizes the industrial structure of pharmaceuticals with high entry barriers (the need for huge fixed research and development costs and economies of scale in selling to physicians), slow development of substitutes, low price sensitivity of buyers, limited clout of suppliers providing mostly commodities, moderate rivalries which focuses on R&D rather than price, with patent protection slowing competitive imitation. This has supported the high profitability of the industry. In this conventional environment, the major source of competitive advantage has been differentiation by product innovation rather than cost leadership. Gassmann, Gerrit, &Maximilian (2007), stated that this structure is undergoing substantial changes. Contrary to the Porter (1990), the development of substitutes is becoming faster. This intensifies rivalries, including competition over prices, and can have a negative impact on company profits. Past experiences in this sector show that second entrants can overtake the market share of the "first-in-class" with improved features and intensive marketing effort; i.e. the first-mover advantage for the pioneer product is considerable but not insurmountable as stated in the work of Berndt, Linda, David, & Glen (1996).

Hadfield, Nichols, &Ernest (1999) defined pharmaceutical supply chain as the integration of all activities associated with the flow of and transformation of raw materials through to the end-user, as well as associated information flows, through improved supply chain relationships to achieve a sustainable competitive advantage. It is the integration of all activities involved in medicines selection, quantification, procurement, warehousing, distribution and use (MSH, 2012) and is the means of delivering medicines to patients by coordinating and collaborating the processes, operations and organizations involved in the product development, manufacturing, marketing and logistics of medicines (Shah, 2004).

Specifically, the pharmaceutical supply chain originates from raw material suppliers, to manufacturing sites, to wholesale distributors, to pharmacies/hospitals, and ultimately to patients (Health Strategies Consultancy LLC, 2005). According to Shah (2004) and Pedroso and Nakano (2009), a typical PSC includes, but is not limited to, the following parties: manufacturers, intermediaries, healthcare providers, and customers.

Figure 1. Pharmaceutical supply chain components



Adapted from Mehralian et al., 2012.

2.2 Current Pharmaceuticals supply chain structure in Ethiopia

Ethiopia is one of the sub-Saharan African countries where the pharmaceutical sector is being guided by a national medicine policy. The rapid growth and development of pharmaceutical sector after the downfall of the Dergue regime in Ethiopia has led to the majority of pharmaceuticals and medical supplies being provided by both the public and private sectors. (Sutton & Kellow, 2010).

Currently, there are 32 manufacturing plants (small and large scale) involved in the manufacturing of pharmaceuticals and related products of which only 12 are manufacturers of generic finished pharmaceutical dosage forms. The remaining ones are involved in the small scale manufacturing of medical devices, supplies, laboratory reagents, cosmetics, and disinfectants. Currently there are 133 importers, 272 wholesalers, 377 pharmacies, 1699 drug shops and 1392 rural drug venders currently existing in Ethiopia (Sultan *et al*., 2016).

The pharmaceutical market is intensely regulated in many countries because of the unique nature of demand and supply for drugs. According to the characteristic of the competition in drug market, governments are expected to create balance in both clinical and economic interests. The pharmaceutical sector has an important role in the medical and health system. The "Ethiopian Food, Medicines and Healthcare Administration and Control Authority" is mandated to execute the regulatory activities as per the council of ministers regulation 189/2010. The legal framework for pharmaceutical regulation of Ethiopia was founded to fulfill all the medicines regulatory

functions potentially enabling to combat illegal, substandard and falsified medicines and illegal establishments.

According to FMHACA's import, export and wholesale of pharmaceuticals and medical supplies control Directive No. 10/2012, any company which is engaged in this business shall get certificate of competence for both professional and facility criteria set by the Authority.

2.3 Overview of upstream pharmaceuticals supply chain management process in Ethiopia

2.3.1 Supplier selection and product Market Authorization

To begin with, most manufacturing companies perform their initial internationalization through exporting modes (Bradley, 1995). Exporting is a low resource commitment entry mode and when the firm later on has gained knowledge and experience it may shift to a high resource commitment entry mode, such as foreign investment (Kwon & Konopa, 1993). Exports for manufactured goods can further be divided into direct and indirect export, of which indirect export can be performed through selling to intermediaries such as export agents, whereas direct export is when companies are selling directly to the foreign buyers (Brassington & Pettit, 2000).

Exporting is one of the methods that organizations can use to enter foreign markets. In this entry method, products produced in one country are marketed in another country through marketing and distribution channels. Most manufacturing firms begin their global expansion as exporters and only later switch to another mode for servicing a foreign market. Exporting is the easiest and most common means for entering a new foreign market and it is also a low risk strategy.

Within the exporting category, a company may have its own export department, or division, and engage in direct exporting. It and its customers will negotiate agreements of purchase and sale. Where expert discussion is required, company personnel may travel round the world visiting various markets. Often the people visiting these markets are nationals of the country, or speak the language fluently. Most exporting organizations will have some form of foreign representation which may have to be supported by direct negotiations between members of the buying and selling organizations.

An alternative within this category is where an export merchant buys products in the country of origin and sells abroad at his own risk. A similar situation exists where a foreign customer has a

buying office, or is represented in the country of origin. Either way, the resultant contract is equivalent to a domestic transaction and does not give rise to the same problems as in inter-country transactions. It can expose the foreign buyer to the laws of the supplier country. Another alternative is the use of a foreign-based intermediary who can be either an agent or a distributor, giving rise to (often exclusive) distributor and agency agreements. A large proportion of sales to companies, other than affiliated companies, is handled through such intermediaries (Marilyn, Stone & McCall, 2004).

Companies who want to engage in importing pharmaceuticals have to fulfill all criteria required by the medicine regulatory Authority (FMHACA). An agency agreement should be made between the manufacturer of the product for registration and the agent responsible for the import, distribution, and sale of the product in Ethiopia The agent representing the manufacturer for importation should hold a license issued by the Ministry of Trade and a certificate of competence issued by the Authority at the time of importation of the product (FMHACA, 2014).

Registration of pharmaceuticals is a time taking process and every product has to get market authorization before being imported to the country. Good manufacturing practice (GMP) certificate of the pharmaceuticals manufacturing plant which is issued by FMHACA, Product dossier evaluation approval and Quality control tests for individual product have to be fulfilled to issue market Authorization for the product to be imported. The market Authorization certificate is valid for 4 years subject to consignment quality control test and suspension in case of quality defect report. Only these suppliers are allowed to export their products to Ethiopia through their authorized distributors/importers (FMHACA, 2014).

2.3.2 Placing Purchase order and Foreign exchange permit

Authorized distributors (importers) prepare purchase order based on the proforma invoices for suppliers for their suppliers with respect to registered pharmaceuticals and request approval from FMHACA. This approved purchase order along with the proforma invoice will be submitted to commercial banks for foreign currency permit request.

According to National Bank of Ethiopia’s directive to transfer NBE's foreign exchange functions to commercial banks directive No.FXD/07/1998, Importer is defined as a legal entity or a physical person having a valid trade licenses for foreign trade, investment or industry from

appropriate government body to engage in importation of goods and services from abroad. In this directive, pharmaceuticals are categorized under restricted goods which approval need certificate from Ministry Of Health (Mandate given to FMHACA by law) to issue FOREX permit (NBE, 2004). According to Directive No. FXD/ 46/ 2017), the amended directive of "transparency in foreign currency allocation of NBE)", pharmaceutical are categorized in fourth priority during foreign exchange allocation priorities. Common mode of payments applied for international suppliers are Letter of Credit and Cash against Payment (CAD) which will be valid for 90 days from operating date. Suppliers are expected to deliver orders within this period.

Suppliers start production and deliver the consignment within the LC period. Pharmaceuticals products must be produced as per the specified content and label during registration process. Any deviation is not tolerable by FMHACA and results detention of consignment at customs inspection area.

2.3.3 Production and transportation

Logistics services which include activities required for the transportation, storage and handling of production inputs and finished products from producer to consumer (or intermediary producer), play a critical role in international trade. Consumers of logistics services are typically suppliers of products themselves. Consequently, the efficient supply of logistics services helps to facilitate international trade in a whole range of other products. The more timely, reliable and efficient the logistics supply chain, the more efficiently and reliably goods can be delivered from the point of production to the point of consumption. In particular, increased international trade in unfinished products, i.e. the movement of intermediate goods within production processes, requires logistics services of ever higher quality with regard to the reliability, safety, security and frequency of deliveries (Kassahun, 2014).

There are essentially few factors that characterize the Ethiopian logistics and in particular maritime transport services environment in Ethiopia. First of all Ethiopia is a landlocked country. Ethiopian Shipping Lines and Logistics Enterprise (ESLSE) is a parastatal company owned by the state. It enjoys a monopoly in maritime transport and logistics services of the country. Ethiopian Shipping and Logistics Services Enterprise (ESLSE) is the sole sea freight transport service provider in Ethiopia although there is no express reservation by law reserving this service to ESLSE. It is a state-owned company that has de facto monopoly on transport of import goods.

Before ESLSE was established upon the amalgamation of three enterprises including Ethiopian Shipping Lines, the National Bank of Ethiopia has already issued, in 2008, a directive requiring importers to use Ethiopian Shipping Lines as a requirement for Letters of Credit (L/C). In cases where ESLSE vessels do not call on ports from which goods are shipped and ESLSE does not have a slot charter relationship with carriers calling on these ports, it provides waivers to importers to use other carriers. Since almost all commercial imports in Ethiopia require L/C to obtain foreign currency, ESLSE enjoyed an effective monopoly on most imports into Ethiopia excluding non-commercial imports (Kassahun, 2014).

2.4 Challenges of Global sourcing and Supply chain management

Global sourcing is defined as the worldwide integration of procurement, engineering, operations, logistics, and even marketing within the upstream portion of a firm's supply chain (Trent & Monczka, 2003). It is different from the concept of international purchasing. The enterprises which successfully implement global sourcing strategy achieve material cost-savings, and some other improvements in areas such as quality, supplier technology contribution, and supplier responsiveness.

According to Porter's generic strategies, the competitive strategies can be divided into low-cost strategy and product-differentiation strategy. Both of these are highly related to global sourcing strategy. There is no doubt that the search for lower costs has been the greatest driver of global sourcing. Other factors include a search for higher quality, greater material availability, and access to product and process technology (Monczka, Trent, & Petersen, 2008). The object of said activities is to accomplish the goals of manufacture or sale, which includes the choice of suppliers, confirming the quality and quantity, negotiating the price, and so on.

Factors that can affect the implementation of global sourcing are political, legal, and cultural differences between various countries. Moreover, enterprises have to face problems like transportation, technological and capacity weaknesses in production, and lack of management systems. Other features are languages barriers, customs, and trade regulations (Kendall, 1999). Consequently, in order to avoid unexpectedly losing global sourcing processes, the companies possessing potential capabilities must foresee and assess plenty of implied factors and risks, regardless of whether it’s direct or indirect, before they adopt a global sourcing strategy.

2.4.1 Different standards and regulations

Companies entering a foreign market face a plethora of challenges. Not only does each country have unique regulatory, marketing and reimbursement environments, but foreign government policies and practices can pose impediments to market expansion. The most commonly cited problems include regulatory review processes that are non-transparent; lack of effective protection and enforcement for intellectual property rights, which result in widespread sales of counterfeit medicines; burdensome reimbursement and pricing policies; and high tariffs. The following list elaborates on some, but not all, of the main issues facing U.S. companies in the pharmaceutical sector (Office of the U.S. Trade Representative, 2016).

Differences in regulatory approval requirements can lead to duplicative testing and clinical trial requirements, delays in product approval and higher costs to manufacturers. Many regulatory agencies lack adequate training and resources to review submissions in a timely and consistent manner, creating enormous backlogs, approval uncertainty and market access delays. There may also be concerns related to the security and maintenance of confidential business information (CBI), such as clinical data that must be submitted for approval (US department of commerce, 2016).

The main regulations impacting global sourcing are tariffs and quotas (Sowinski, 1999). Non-tariff restrictions including complicated documentation requirements for border-crossing processes, and many kinds of international trade bills are also difficult challenges which the buyers from abroad have to face (Cho & Kang, 2001).Governments make use of tariffs and quotas for two purposes: first, to earn revenue; second, to make foreign goods more costly in order to protect national products.

2.4.2 Complicated logistics in global sourcing

In global sourcing, international management of logistics is definitely a necessary and crucial procedure. Logistics in global sourcing refers to plenty of additional problems such as transportation delays, border-crossing procedures and longer inventory management (Bradley, Thomas, Gooley, & Cooke, 1998).

Moreover, lack of holistic logistics knowledge in low-cost developing countries would trouble the procurement executives when implementing global sourcing. Nowadays, logistics management has dramatically improved in the developed countries. On the other hand, less-developed country suppliers are short of experience with the most advanced approaches and are usually unfamiliar with high-standard requirements, such as sequence deliveries combined with Just-In-Time; electronic data interchange communications and vendor-managed inventory solutions (Cho & Kang, 2001). These capabilities of supply chain management are important in determining how much benefits a company can derive from global sourcing.

In addition, low-grade infrastructure of logistics in developing countries influences the efficiency of global sourcing. Besides, some unqualified vehicles and drivers also cause problems of logistics.

2.4.3 Cultural and lingual difference in global sourcing

Cultural issues in global sourcing are manageable, but it still should be recognized as a concern that must be dealt with (Cook, 2006). Perfect global sourcing management requires that mutual respect must be shown to the people, language, and culture of the countries where a company operates. It is meaningful to take the time to learn basic information about the special culture and possibly learn some basic language skills, at least how to say “Hello,” “Thank you” and so on. The capability to successfully cooperate on a personal level with foreign businesses will go a long way in developing a win-win working relationship, which is helpful to maximize the possibility for reaching successful global sourcing processes.

However, language barriers always threaten cultural communication and even technology transfer in global sourcing. Although many suppliers from developing countries have technical staff and sales people with English skill, difficulties still arise when they need to interact with Western experts to discuss professional technical issues. Main personnel of suppliers in developing countries do not always have sufficient command of English or of other Western languages to engage in lengthy, detailed exchanges. Using translators is one option, but they often do not have the technical background to address industry specifics. The risk of misunderstanding and communication impasse cannot be underestimated in global sourcing (Accenture, 2007).

2.4.4 Volatile economic and political environment in global sourcing

Local and regional economic environment can be a primary risk factor for global sourcing. Due to the cheap-labor and other factors, developing countries may be experiencing uncertain economic situation (Cook, 2006).

A pronounced financial crisis happened in 1999 leading to a decline in almost every Asian economy and currency decreased sharply over one weekend. Plenty of banks and companies went bankrupt in Asian countries. Even as late as 2006, although many Asian countries have seen their economies revived, some still have not totally recovered. Many European and American companies were financially stricken by this horrible occurrence. Many U.S. companies are not willing to invest in an overseas factory in Latin American and Africa because of the uncertainty of local economic environment (Cook, 2006). Therefore many strong enterprises engage experts to inspect local economies where they plan to source. The economic risks are more severe for the medium and small companies; they must find reliable way to cover this risk.

There are also some problems caused by political factors in global sourcing. For instance, events in the Middle East and North African show that local politics can dominate how companies set up commercial relationship with the companies in these countries (Cook, 2006). According the study of Thomas A. Cook, there are more than 50 countries around the world where the political environment is not conducive to deals with local businesses.

2.4.5 Fluctuation of currency exchange rate in global sourcing

In global sourcing, the money has to be moved between domestic countries and foreign partners. Stability of currency enables the international trade to be easier while instability makes it more complex and introduces risk. If trade amounts to tens of millions of dollars, a 0.5% deviation of exchange rate could affect the effectiveness of global sourcing strategy and profitability of the whole supply chain. Moreover, 4% deviation could result in a disastrous end (Cook, 2006).

For large multinational companies, they usually have specific personnel in the financial departments who are in charge of collecting and managing the information on currency valuations. But for the small companies planning to carry out global sourcing, normally they do not have the specific financial experts, but they still must set up an internal management system

or outsource the work in order to predict and hedge against currency fluctuations. But from another side, if the companies can make wise use of the risk from currency fluctuation, sometimes experienced companies can put themselves in a beneficial position by managing currency correctly. Hence, the opposition of risk from currency fluctuation is also present when discussing currency problems (Cook, 2006).

2.4.5 Supplier selection complexity in global sourcing

How to handle global sourcing effectively and efficiently are additional challenges. Supplier selection is a vital aspect in the performance of global sourcing implementation. Unlike dealing with domestic suppliers, the costs involved in identifying, selecting, and evaluating foreign suppliers can be prohibitive. Supplier selection and evaluation have an important role in the supply chain process and are crucial to the success of a manufacturing firm (Hartley & Choi, 1996).

There are several supplier selection methods which persist in the contemporary business world. Supplier selection is a fundamental decision that a buyer makes and also a very critical one. The process of selecting a group of competent suppliers for important materials, which can potentially impact the firm‟s competitive advantage, is a complex one and should be based on multiple criteria. Factors that firms should consider while selecting suppliers suggested by Wisner in 2005 are as follows (Wisner, Leong, & Tan, 2005): Product and process technologies, Willingness to share technologies and information, Quality, Cost, Reliability, Order system and cycle time, Capacity, Communication capability, Location, Service.

Different companies have different criteria based on their products, price offered, quality, on-time delivery, after-sales services, response to order change, supplier location and supplier's financial status, etc. (Ting & Cho, 2008). After determining which criteria should be involved in the selection process, choosing a method to calculate or evaluate right suppliers is a complex one.

For supplier selection method, AHP (Analytical Hierarchy Process) is a popular approach used for solving problems which have multiple criteria. This method is applied by a number of researchers and practitioners. It is a widely-used technique which has attained much attention as this process deals with both quantitative and qualitative criteria. It will provide the decision

makers with a way to structure this complicated process in the form of a hierarchy which includes three levels of stages: goal, dimensions and criteria (Narasimhan, 1983).

The AHP considers a set of evaluation criteria, and a set of alternative options among which the best decision is to be made. It is important to note that, since some of the criteria could be contrasting, it is not true in general that the best option is the one which optimizes each single criterion, rather the one which achieves the most suitable trade-off among the different criteria.

The AHP generates a weight for each evaluation criterion according to the decision maker's pairwise comparisons of the criteria. The higher the weight, the more important the corresponding criterion. Next, for a fixed criterion, the AHP assigns a score to each option according to the decision maker's pairwise comparisons of the options based on that criterion. The higher the score, the better the performance of the option with respect to the considered criterion. Finally, the AHP combines the criteria weights and the options scores, thus determining a global score for each option, and a consequent ranking. The global score for a given option is a weighted sum of the scores it obtained with respect to all the criteria.

Categorical method‟ (Timmerman, 1986; Wills & Huston, 1990) is an example of such methodologies. After establishing a list of attributes to be used in the evaluation process, this method seeks to assess the suppliers' performance by applying the labels "good," "fair," and "poor." A chosen supplier is the one who receives the most "good" ratings. Categorical supplier measurement is the easiest method to implement but suffers from subjectivity. It does not provide a detailed insight into the supplier's true performance because the attributes being measured are weighted equally. Also, because the representatives of the involved divisions assign the ratings, this method relies on an individual's perception about performance and not on quantitative data.

Cost-ratio method (Timmerman, 1986) ‟ is another method used in selecting suppliers. By this method, the total cost related to quality, delivery, and service are calculated and expressed as a proportion of the total firm's purchase price. The supplier selected to by decision makers is one that can provide the lowest cost. There are numerous other methods that a firm must consider and combine to determine the standards by which suppliers are selected. How many suppliers to use for each purchased item is another challenge for the purchasing manager. Theoretically,

firms should use a single source or as few as possible to enable the development of close relationships with the best suppliers. However, by increasing reliance on one supplier, the firm increases its risk that poor supplier performance will result in plant shutdowns or poor quality finished products.

Using the cost-based system, a buyer is able to quantify the additional costs incurred if a supplier fails to perform as expected. The total cost of doing business with the supplier can be calculated by the supplier performance index (SPI). This index is calculated for each item or commodity provided by the supplier and has a base value of 1. It is represented by the following formula: SPI = (Purchase Price + Nonperformance Cost) / (Purchase Price). As derived from the equation, the closer SPI is to 1, the better the supplier. Non-costs should include qualitative factors (Timmerman, 1986).

2.5 Empirical Studies Review

According to IBM global chief supply chain management officer study 2009, the key supply chain management challenges for life sciences supply chains include supply chain visibility, increasing customer demands, risk management, globalization and cost containment. According to Wilfried et al. (2009), the competitiveness of a supply chain is determined by many different factors and a resource based view of the firm, with attention to networks, knowledge management and environment. Challenges affect a supply chain by affecting one or more of its components. These components are either internal or external to the supply chain, and can be classified as belonging to the following realms or contributors to the functioning of the supply chain: Transportation, Utilities/Equipment, Communication, Suppliers, Customers, Labour and Finance (Stecke and Kumar, 2009).

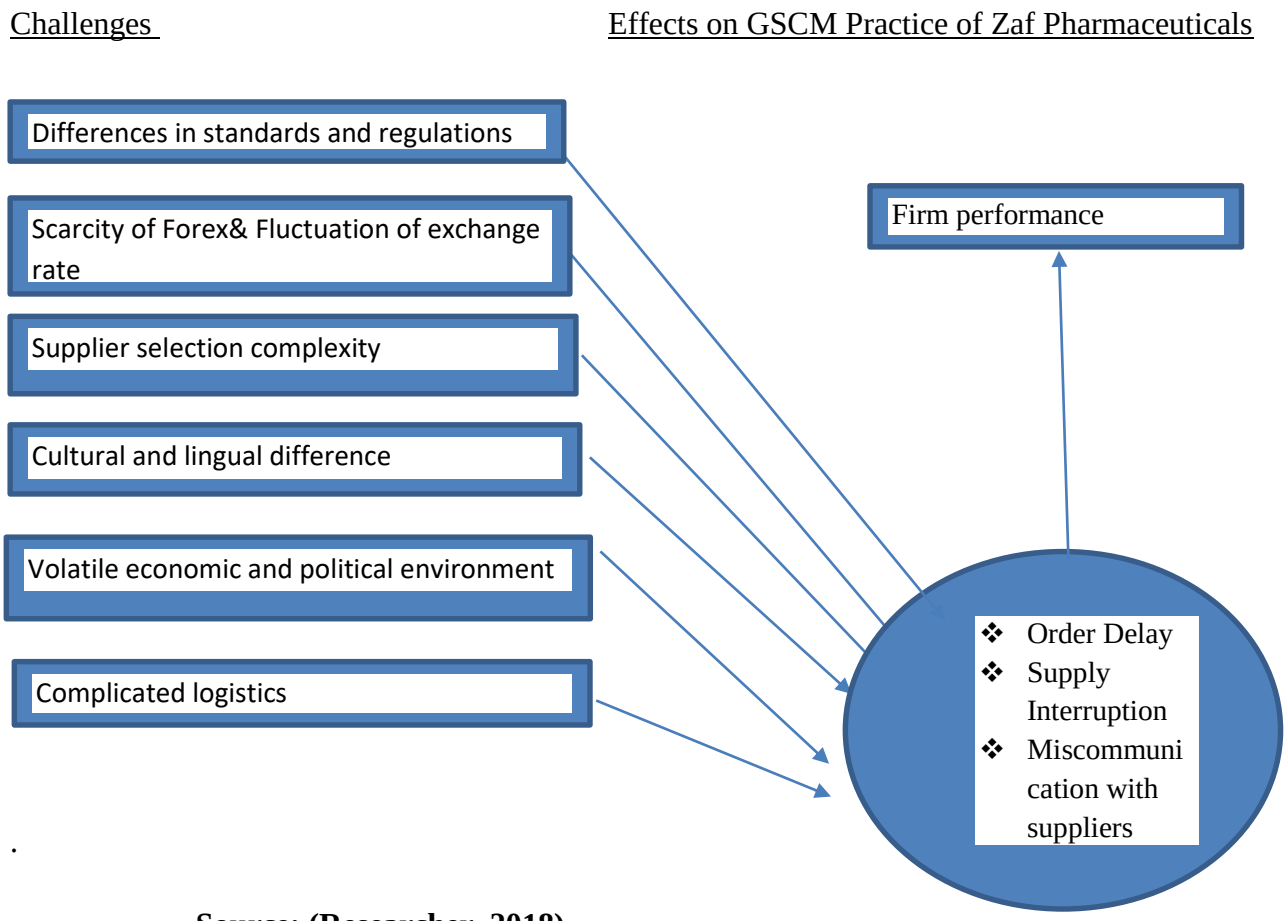
Apart from the Jaberidoost, & et al., (2013) study, there is a general lack of research in the area of pharmaceutical supply chain risks. In their systematic literature review, Jaberidoost, & et al., concluded that PSCs face a total of 50 main risks classified into seven categories, as follows: supply risk, organization & strategy risk, financial risk, logistical risk, market risk, political risk, and regulatory risk. They also emphasized the importance of identifying the potential risks in PSC, assessing their significance, and developing risk management strategies to handle them.

The pharmaceutical industry is plagued by numerous challenges that are threatening a major overhaul of the entire industry. Among the top issues is the concern of steadily increasing drug prices. Consolidation of healthcare management organizations along with the passage of the Medicare Modernization Act (MMA) is likely to exert downward pressure on the drug prices.
In addition, there is a huge push towards the use of generic drugs, which, unlike the branded drug segment, is very cost sensitive. As a result of these developments, the margins are expected to come under pressure, which will prompt the drug manufacturers to demand lower prices from distributors (Sing, 2005).

2.6 Conceptual frameworks

The researcher used the challenges of global pharmaceuticals supply chain management as conceptual framework to show their perceived effect on global supply chain practice of Zaf pharmaceuticals PLC. This study was done considering the following challenges.

Figure 2: conceptual framework



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Source: (Researcher, 2018)

CHAPTER THREE

RESEARCH METHODOLOGY

The chapter discusses the methodology that would be used in gathering the data, analyzing the data and reporting the results. It specifically presents the research design, population of the study data collection and data analysis.

3.1 Research approach and design

Descriptive research design was employed by this study. Both qualitative and quantitative data were collected at the same time (cross-sectionally) from May 05-12/2018.

A descriptive research design was employed in this study as it is appropriate to determine and report the way things were (Mugenda, 2008). The data collection was made to describe the challenges of global Pharmaceuticals supply chain management at Zaf Pharmaceuticals PLC, which is located at Gerji, Bole Sub city, Addis Ababa, Ethiopia, in a limited geographical scope. For this reason, the research design was found to be logistically easier and simpler to conduct considering the limitations of this study.

The justification for the quantitative approach was to quantify the data on the issue under study and to provide statistical information about problem (Creswell, 2009). The quantitative research design was cross- sectional design, because the data that gathered through questionnaire were collected once and it is significant to study. Qualitative approach was employed as it was found to be the best way to access the participants' ideas, memories and attitude in their own words rather than the words of the researcher (Cohen, 1994).

Therefore, the research used descriptive research design employing both qualitative and quantitative approach collecting data cross-sectionally at a limited geographical scope, Zaf Pharmaceuticals PLC, to describe challenges of global pharmaceuticals supply chain management on its organizational performance.

3.2 Unit of Analysis

Dul and Hak (2008) suggested that when conducting a descriptive case study, case selection should be governed by convenience, feasibility, and likely effectiveness.

Zaf Pharmaceuticals PLC is one of the largest private Ethiopian pharmaceutical importing companies, involved in importing of lifesaving medicines, with a complex global supply chain management experience. Currently its annual sales volume from its global supply chain operation reaches about 20 million USD. These aspects make the company appropriate for studying the complexity of global pharmaceutical supply chain management challenges. Moreover, willingness of top management of Zaf Pharmaceuticals PLC to cooperate further encouraged the selection of the company for this study.

3.3 Population of the study and data source

3.3.1 Population of the study

According to Hair *et al.* (2010), target population is said to be a specified group of people or object for which questions can be asked or observed made to develop required data structures and information. Therefore, for this study, the target populations was single company, Zaf Pharmaceuticals PLC, particularly those with education level, bachelor degree and above and who are familiar with global supply chain management were involved in responding to self-administered questionnaire and interview.

3.3.2 Sampling technique

Because the total population was finite and small in number, the study covered all the total population of the study and sampling technique was not applied.

However, the respondents that represent the company were selected using purposive sampling. Managers, supervisors or experts of concerned departments who involved in the global supply chain management, like Business development, marketing management, regulatory affairs management and procurement departments' staff from Zaf pharmaceuticals and Zaf's global suppliers' representatives were involved to fill on questionnaires.

The CEO and General Manager of Zaf pharmaceuticals PLC were interviewed purposively because the distribution agency agreement issues with suppliers were found to be managed by top level managers. Procurement officers, customs clearance officers, regulatory affairs officers,

officers and distribution managers were involved in the assessment. In addition, medical representatives of foreign pharmaceuticals suppliers of the company were involved to answer both open and close ended questionnaires.

3.4 Data Collection Techniques and Research Instruments

A data collection method, also referred to as a data generation method, provides a means of gathering research findings. Questionnaires and interviews are widely used methods for primary data collection (Oates, 2006:234).

In this study, data was collected by the researcher from top and middle level managers, procurement officer, marketing officers, regulatory affairs officers and suppliers representatives using structured self-administered questionnaires which have closed and open ended questions (appendix) . A total of 65 respondents were involved to fill questionnaires. Among them 5 (CEO, general manager, procurement manager, business development manager and marketing manager) were interviewed using close-ended questions in their office. Other 60 were approached to respond to self-administered questionnaire. The data was collected cross-sectionally from May 05-12/2018.

3.5 Data Analysis and Interpretation Methods

The collected primary data was checked for completeness to make it ready for the analysis. The responses from the field were put into categories and coded according to the themes so as to answer the research question and obtain the relevant information. The classified data in tables for ease of interpretation, understanding, reading and discussion. The researcher used descriptive analysis like mean, percentages and frequencies in order to describe the demographic and general information of the respondents.

Descriptive data analysis like percentage, mean and standard deviation through the use of Statistical packages for social science (SPSS) version 20 software was employed to analyze the data collected from self-administered questionnaires. The qualitative data collected through interview was used to strengthen discussion points and recommendations accordingly.

3.5.1 Validity and Reliability

In this study, a pilot test was conducted distributing 5 questionnaires to the sales and medical equipment service, Finance managers and officers at Zaf Pharmaceuticals PLC which were out of the researcher population. Feedback and necessary correction like grammatical errors were made to improve the validity of the research.

The reliability of the instruments was established following a pre-test procedure of the instruments before their use with actual research respondents.

To ensure reliability of this study, a Cronbach's Alpha test was performed as a measure to see if the study repeats the same results if the same experiment is performed. Cronbach's Alpha was used to test reliability of the study. In this study, the test was made on 7(seven) variables (challenges identified and rated using 5 Level Likert scale.

Table 3.1 Chronbach's alpha test result

Cronbach's Alpha	No. of items(N)
.713	7

Source: (own survey, 2018)

Cronbach's alpha reliability coefficient normally ranges between 0 and 1. The closer the Cronbach's alpha coefficient is to 1.0 the greater the internal consistency of the items in the scale and a value greater than 0.7 is acceptable (George & Mallery, 2003).

As indicated in table above, Cronbach's alpha test indicated that the instrument was found to be reliable as **0.713** value is in the acceptable range.

3.6 Ethical considerations

Ethical Clearance was obtained from ethical clearance committee of Addis Ababa University, School of Commerce, Department of Logistics and Supply Chain Management and permission was guaranteed from CEO of Zaf Pharmaceuticals PLC to conduct the study. Informed verbal consent was requested and obtained from each participant.

CHAPTER FOUR

RESULTS AND DISCUSSION

This chapter presents an analysis of data collected and discuss the findings on the challenges of global pharmaceuticals supply chain management in Zaf Pharmaceuticals PLC.

4.1 Response rate

Sixty (60) Self-administered questionnaires were distributed to respondents and interview was conducted with 5 Managers. Unfortunately 3 responses from self-administered questionnaires were found to be incomplete and rejected from analysis at editing stage. The remaining 57 responses (self-administered) were analyzed using SPSS Version 20. The response rate was 95.4%. According to Mugenda and Mugenda (1999), a response rate of 70% and above is excellent. Based on the assertion, the response rate this study was considered to be excellent.

4.2 Demographic information of respondents

Table 4.1: Demographic characteristics of respondents

Major information on respondents		Frequency	Percent (%)	Cumulative (%)
Sex	Male	43	75.4	
	Female	14	24.6	100.0
Educ. level	First Degree	34	59.6	
	Master's Degree	23	40.4	100.0
Department	Procurement	19	33.3	
	regulatory affairs	6	10.5	43.9
	suppliers' representative	12	21.1	64.9
	Business development &marketing mgt.	20	35.1	100.0
Experience	1-4 years	19	33.3	
	5-8 years	27	47.4	80.7
	9-12 years	9	15.8	96.5
	>12 years	2	3.5	100

Source: (Own survey, 2018)

The demographic profile of the respondents is presented and analyzed in the above table. The purpose of assessing respondents' sex, was to determine whether the researcher considered heterogeneity of sample units. Among 57 self-administered questionnaire respondents, 43(75%) were male and 14(25%) females. Among them 60% were first degree holders. Others held their Master's degree.

Respondents were selected from procurement department 19 (33%), business development and Marketing departments 20(35%) and 12(21.1%) from foreign suppliers' representative offices. Other 6 (10.5%) of respondents were working on regulatory affairs. In terms of work experience in the pharmaceuticals supply chain management, 27(47%) of the respondents found to have 5 to 8 years and 19(33%) had 1 to 4 years and remaining 11(19.3%) have more than 8 years' of work experience in the pharmaceuticals supply chain management. assessing the work experience and education level of the respondents' is that, when the respondents are more experienced and educated they have better opportunity to understand the case and give better response than else. In addition, assessing functional working areas of respondents' highlights on exposure of them to the case

4.3 Results, Findings, Interpretation and Discussion on challenges of global pharmaceuticals supply chain management at Zaf Pharmaceuticals PLC.

In this part of the study report, analysis conducted on data gathered to assess challenges of global pharmaceuticals supply chain management at Zaf Pharmaceuticals PLC is presented in relation to the objectives of the study. Descriptive statistics was used to analyze the data collected via self-administered questionnaires.

4.3.1 Suppliers selection complexity

The researcher wanted to know whether global suppliers' selection process is a challenge for Zaf Pharmaceuticals PLC in its global pharmaceuticals supply chain management practice. Respondents were asked to answer six questions pertaining to this issue. The first question was to know whether they are engaged in the suppliers' selection process or not. As indicated in Table 4.2 above, among the respondents, 37(65%) involved directly or indirectly in supplier selection processes. The rest, 20(35%) responded that they were not involved in supplier's

selection. This shows that 65% of the respondents were aware of challenges in suppliers' selection Process.

Table 4:2 Respondents perception on challenges of suppliers' selection

		Validity	Response	Frequency	Percent
1	Engagement in suppliers' selection		Yes	37	64.9
			No	20	34.1
2	Information source to find supplier	Valid	Trade fairs	4	10.8
			Suppliers' websites	4	10.8
			Recommendation	1	2.7
			Supplier's representative	15	40.8
			All	13	35.1
		Missing	NA	20	
3	Does your company have documented suppliers' selection criteria?	Valid	Yes	24	42.8
			No	29	51.8
			Under development	3	5.4
		Missing	I do not know	1	
4	Did you face the challenge of finding qualified foreign sources?	Valid	Not at all	8	14.3
			Yes, but little	29	51.8
			Yes, intensively	19	33.9
		Invalid	I do not know	1	
5	What is the most priority when you select a foreign supplier?	Valid	High quality	9	16.1
			Low price	5	8.9
			High technology	3	5.4
			After sale service	1	1.8
			All of them	38	67.9
			Total	56	100
		Invalid	I do not know	1	
6	Do you conduct an audit of potential suppliers overseas?		Not at all	28	49.1
			Yes, but occasionally	22	38.6
			Yes, frequently	7	12.3

Source: (Own compilation, 2018)

The second question was intended to know the information source to find suppliers. Trade fairs, suppliers' website, recommendation by others and suppliers' representative were mentioned as

an alternative choices. Among the 37 respondents who were involved in supplier selection process, 15 (40.8%) chose suppliers' representatives and 13(35.1%) mentioned all mentioned items as their information source to find suppliers. Trade fairs and suppliers' websites were individually chosen by 4 (10.8%) respondents. The least of all alternatives was recommendation by others was chosen only by 1(2.7%) respondent. In addition, the interviewed General manager, business development manager and marketing manager of Zaf Pharmaceuticals PLC confirmed that their main source of information about global pharmaceuticals suppliers were the suppliers' representative. This shows that majority of the respondents used suppliers' representatives as a major source of information which may not help to check the suppliers true performance history and lead to formation of wrong relationship.

The third question aimed to know whether Zaf Pharmaceuticals PLC has documented supplier selection criteria. More than 57% of the respondents answered that there is no documented supplier selection criteria whereas 24(42.9%) responded as there is such document in the company.

The fourth question was about the challenges of finding qualified foreign source. One of the 57 respondents answered as "I do not know" and considered as missing value. Among 56 respondents, 8(14.3%) answered as they did not face such problem at all. The other 29(51.8%) answered they faced the problem but with little occurrence and 19(33.9%) they faced intensive challenge in finding qualified foreign source. Interviewed marketing manager and Business development manager also assured there is no documented suppliers' selection criteria further. Another question which was forwarded to respondents regarding supplier selection complexity was to know the criteria of priority in suppliers' selection process. Among 56 respondents, 38(67.9%) responded that quality, price, technological capacity of suppler and after sale services will be considered, whereas 9(16.1%) respondents answered that priority is given to high quality products and 5(5.4%) responded that emphasis is low price; 3(5.4%) preferred high technology to others and 1(1.8%) after sales service over others.

The last question was intended to know whether Zaf Pharmaceuticals PLC conducts audit of potential overseas suppliers. Among 57 respondents, 28(49.1%) answered that they did not conduct an audit at all, 22(38.6%) of respondents answered that they conduct potential overseas suppliers occasionally. Other 7(12.3%) answered they did it frequently. But from the interview,

it has been found that the mandate of auditing overseas Pharmaceuticals suppliers it to FMHACA and Zaf pharmaceuticals PLC occasionally send its CEO and department managers for potential suppliers performance evaluation and bilateral plan on annual basis. The difference in the answers shows that most of the respondents (officers) did not know whether the company conduct it regularly.

4.3.2 Challenges faced due to differences in standards and regulation

Table 4.3 response on challenges faced due to differences in standards and regulation

		Validity	Response	Freq.	Percent
7	Which regulator standards of Ethiopia affects your Global Pharmaceuticals supply chain management practice?	Valid	Pharmaceuticals MA	4	7.1
			Foreign exchange permit directives	8	14.3
			Ethiopian multi- modal transport laws	0	
			All of them	44	78.6
			Total	56	100.00
		Missing	I do not know	1	
8	Do the different regulatory standards affect the processes of pharmaceuticals MA?	Valid	Not at all	4	7.0
			Yes, but little	32	56.1
			Yes, intensively	21	36.8
			Total	57	100.0
9	Do customs duties regulation affect the processes of global SCM in your company?	Valid	Not at all	11	19.3
			Yes, but little	28	49.1
			Yes, intensively	18	31.6
			Total	57	100.0
10	Does shipping laws affect the processes of global supply chain practice of your company?		Not at all	5	8.8
			Yes, but little	35	61.4
			Yes, intensively	17	29.8
			Total	57	100.0

Source: (own survey, 2018)

In this sub-topic, respondents were requested to select the regulatory standards of Ethiopia that affected the company's global supply chain management practice. Pharmaceuticals market Authorization (registration of medicine to be distributed in Ethiopia), Foreign exchange permit directive of National bank of Ethiopia, Ethiopian multimodal transport regulations were given as alternative choices.

Majority of the respondents, 44(78.6%) answered that all of the mentioned regulations affected the global pharmaceuticals supply chain management practice of Zaf Pharmaceuticals PLC. Another 8(14.3%) selected foreign exchange permit directives over others and another 4(7.1%) selected standard requirements for pharmaceuticals market Authorization affected the global pharmaceuticals supply chain operations.

The second question in this subtopic was designed to know the perception of respondents whether different regulatory standards between the suppliers' countries and Ethiopia affected the processes of pharmaceuticals Market Authorization process. Among 57 respondents, 32(56.1%) answered difference in regulatory standards between the suppliers' country and Ethiopia affected the pharmaceuticals market Authorization process but with little manner. The other 21(36.8%) of respondents answered that the difference affected the market Authorization process intensively. Of the respondents, 4(7%) answered the process could not be affected at all. In addition the regulatory affairs head confirmed that such issues are common challenges for the company.

Other two questions were delivered to know the perception of respondents if customs duties regulation and shipping laws had affected global supply chain management practice of Zaf Pharmaceuticals PLC. Among 57 respondents, 28(49.1%) answered that there was such challenge but they assumed it was little in affecting GSCM practice of Zaf Pharmaceuticals. Other 18(31.6%) responded that customs regulations were affecting global pharmaceuticals SCM intensively. The remaining 11(19.3%) responded as the customs regulations could not affect SCM practice of Zaf Pharmaceuticals PLC at all. Regarding Ethiopian shipping laws, 35(61.4%) respondents acknowledged that shipping laws affected GSCM practice of Zaf pharmaceuticals but the intensity is little. The other 17(29.8%) of respondents answered that shipping law affected global supply chain operation of the company intensively. Five of the respondents answered that shipping laws had not affected GSCM practice of Zaf pharmaceuticals PLC.

During the interview, the procurement manager explained that customs issues for pharmaceutical products are standard and such challenges are minimal in affecting Supply chain management process

4.3.3 Challenges due to Fluctuation of currency exchange rate

Table 4.4: Responses on challenges due to Fluctuation of currency exchange rate

		Validity	Response	Frequency	Valid present
11	Do you face scarcity of foreign exchange which affects your company Supply chain management practice?	Valid	Not at all	1	1.8
			Yes, but little	2	3.5
			Yes, intensively	54	94.7
			Total	57	100.0
12	Have you ever replaced your supplier because of the changes in exchange rates and price fluctuation?	Valid	Not at all	21	37.5
			Yes, but little	29	51.8
			Yes, frequently	6	10.7
			Total	56	100
		Missing	I do not know	1	
13	Do you face any supply delay due to lack of foreign exchange permit	valid	Not at all	1	1.8
			Yes, but little	10	17.5
			Yes, intensively	46	80.7
			Total	57	100.0

Source: (own survey, 2018)

Discussion

Obtaining foreign exchange permit is the basis to start and keep membership in a global supply chain. Product flow from suppliers follows financial flows from distributors like Zaf Pharmaceuticals PLC. Respondents were asked to respond on four related multiple choice questions under this subtopic. The first question was intended to know whether Zaf Pharmaceuticals PLC faced any challenge of foreign exchange scarcity which affects its global pharmaceuticals supply chain operations. Among 57 respondents, 54(94.7%) answered that this

challenge was obvious and affected the global supply chain management practice intensively. Other 2 (3.5%) acknowledge the problem but affected but the magnitude is little.

The second question was intended to know whether currency exchange rate fluctuation affected Zaf pharmaceuticals PLC relation with its suppliers. It enquires whether Zaf pharmaceuticals PLC, has replaced its supplier because of the changes in exchange rates and price fluctuation. Out of 56 valid responses, 21(370.5%) answered "Not at all" but 29(51.8%) answered yes but little occasion. The remaining 6(10.7%) respondents answered as the company replaced its suppliers frequently. The third question was to assess the presence of supply delay due to lack of foreign exchange permit. Among 57 valid responses, 46(80.7%) answered the challenge was confronted intensively. Other 10 (17.5%) of respondents answered that they face such challenge but little. Only 1 respondent responded as such challenge was not faced.

4.3.4 Challenges of Volatile economic and political environment

Table 4.5: challenges of Volatile economic and political environment

		validity	Response	Frequency	Valid %
14	Did you face any supply delay due to political crisis in you suppliers' country?	Valid	Not at all	24	42.1
			Yes, but little	31	54.4
			Yes, intensively	2	3.5
			Total	57	100
15	Did your company encounter the risk of a supply interruption from a foreign source of critical required materials?	Valid	Not at all	8	14.3
			Yes, but little	39	69.6
			Yes, intensively	9	16.1
			Total	56	100
		Missing	I do not know	1	

Source: (own survey, 2018)

This subtopic is intended to know whether the company faced supply delay and supply interruption of critically required materials due to unstable political and economic condition in the suppliers' country. Among 57 respondents, 31(54.4) confirmed they faced a little supply delay due to political crisis in the suppliers' country while other 24(42.1%) answered they did not face such challenge due to political crisis at all. Only 2(3.5%) responded they face supply delay due to political crisis intensively. The second question was to know if the company

encountered supply interruption of critically required materials due to economic instability in its suppliers. Among 56 respondents, 39(69.9%) answered that they faced such little problem; 9(16.1%) responded that the problem is intensive but the responses of 8(14.3%) respondents show that the company didn't face such challenge.

4.3.5 Challenges of cultural and lingual difference

Table 4.6: response on Challenges of cultural and lingual difference

		Validity	Response	Freq UENCY	Valid percent
16	Did you have any cultural issue between you and the supplier which led to instability of the relationship?	Valid	Not at all	36	63.2
			Yes, but little	19	33.3
			Yes, intensively	2	3.5
			Total	57	100
17	Did you face to the challenge of **logistics problems due to cultural differences** when you do engaged in GSCM?	Valid	Not at all	7	12.3
			Yes, but rare	39	68.4
			Yes, intensively	11	19.3
			Total	57	100.0
18	Do you face any language barrier to communicate suppliers from different countries?	valid	Yes frequently	5	8.8
			Yes, but occasionally	36	63.2
			Not at all	16	28.1
			Total	57	100.00
19	Has miscommunication with a foreign supplier ever led your company to a conflict with that supplier?	Valid	Not at all	28	49.1
			Yes, but occasionally	28	49.1
			Yes, frequently	1	1.8
			Total	57	100.0

Source :(own survey, 2018)

This subtopic was intended to know whether lingual and cultural differences are challenges of Zaf Pharmaceuticals PLC in managing its relationship with its suppliers. Table 4.6 shows percentage response on related questions put categorically.

The first question was designed to know the presence of cultural issue between the supplier and the company which affects the relationship. Response from 36(63.25%) showed that there was no such cultural issue which created instability of relationship. Other 19(33.3%) acknowledged the problem but the occurrence was little. The second question was to know whether there zaf pharmaceuticals PLC encountered logistics problem due to cultural differences. Majority of the respondents, 39(68.4%) answered that the company faced such problems but found to be rare. The third question was to assess whether language is barrier a barrier to communicate suppliers. Of 587 respondents, 36(63.2%) answered they face such problem occasionally and other 16(28.1%) answered no language issue is barrier to communicate suppliers. The remaining 5(8.8%) of respondents responded as they face language barrier frequently.

The last question in this category was delivered to know if any miscommunication with suppliers ever led to conflict with Zaf Pharmaceuticals PLC. About half of the 57 respondents answered that such miscommunications have not led to conflict at all but others responded that such miscommunication led to conflict occasionally.

4.3.6 Challenges of complicated logistics

Table 4.6 shows frequencies of respondents regarding challenges of complicated logistics in global pharmaceuticals supply chain management practice of Zaf Pharmaceuticals PLC. Among 57 respondents, 45(78.9%) answered they faced little logistics challenge during their company global sourcing and other 7(12.3%) respondents answered they faced intensive logistics challenge during their global sourcing practice but the rest, 5(8.8%) responded that they did not logistics problem at all.

Table 4.7: Challenges due to complicated logistics

		Validity	Answer	Frequency	Valid %
20	Did your company face to the challenge of logistics problems when you do global sourcing?	Valid	Not at all	5	8.8
			Yes, but a little	45	78.9
			Yes, intensively	7	12.3
			Total	57	100.0
21	Do you utilize a 3PL providers when you import Pharmaceuticals?	Valid	Not at all	7	12.3
			Yes, but occasionally	11	19.3
			Yes, always	39	68.4
			Total	57	100.0
22	Do you receive your consignments on time when you import from your suppliers?	Valid	Not at all	12	21.1
			Yes, but occasionally	25	43.9
			Yes, frequently	20	35.1
			Total	57	100.0
23	Do you face difficulties when clearing from customs upon arrival?	Valid	Yes	52	91.2
			No	5	8.8
			Total	57	100.0
24	If you face difficulties, which challenges do you face?	Valid	Damage	8	14.5
			Loss	8	14.5
			Unpredictable tax variation	5	9.1
			All	30	54.5
			Others(delay in inspection, warehouse charge)	4	7.3
			Total	55	100.00
		Missing	NA	2	

Source: own survey, 2018

Most of the respondents 39(68.4%) answered that they always utilize service of 3PL (Third Party Logistics Service Provider) when they source pharmaceuticals from foreign suppliers. Another 11(19.3%) answered they occasionally employed the service of 3PL but 7(12.3%) responded that they did not employ the service of 3PL at all. The third question was intended to know whether Zaf Pharmaceuticals PLC receives its orders as per its schedule when it imports from foreign suppliers. Among 57 respondents, 20(35.1%) answered that they receive goods as per the schedule, other 25(43.9%) responded they received imported goods occasionally as per the schedule. the remaining 12(21.1%) responded that they did not receive goods as per the schedule at all.

Respondents were asked to answer whether faced difficulties when clearing Pharmaceuticals from customs upon arrival. Among 57 respondents 52(91.2%) answered they faced such problems but other 5(8.8%) responded there was no such challenge. Among the difficulties faced in clearing pharmaceuticals from customs, damage, loss and unpredictable tax were mentioned as challenges by 30(54.5%) of respondents.

The analysis result, shows that majority of the respondents faced little logistics problem on the global sourcing practice of Zaf Pharmaceuticals PLC and they employed service of 3PL until they receive goods from their suppliers. They also faced damage, loss and tax increment on their products when they cleared from Customs area. These findings were also supported by interview procurement and technical managers.

Delay in inspection of products at customs area and unexpected warehousing charges were mentioned as a critical challenge by 4(7.3%) of respondents and procurement and technical managers.

4.3.7 Descriptive statistics on comparison of challenges of global pharmaceuticals supply chain management at Zaf Pharmaceuticals PLC.

Although all issues related to supplier selection complexity, differences in regulatory standards, scarcity and fluctuation of currency rates, complicated logistics, supply uncertainty, cultural and lingual differences, political and economic instability have their own effect on the success or failure of GSCM practice, this does not necessary mean that all issue have equal influence on SCM operation. Thus the table 4.8 below rank the level of influence of the major issue discussed before.

Table 4.8: Comparison of major challenges

Challenge	N(response)	Mean	Std. Deviation	Rank
Supply Uncertainty	57	3.30	.944	4
Finding Qualified Supplier	57	3.19	.934	5
Shortage of FOREX and Fluctuation Exchange Rate	57	4.77	.535	1
Long Lead-time to Receive Orders	57	3.68	.848	2
Pharmaceuticals Regulatory Laws for MA	57	3.67	.852	3
Cultural and Lingual Difference	57	1.93	.776	6
Unstable Political Environment	57	1.89	1.097	7

Source :(Own survey, 2018)

As can be observed from the above table 4.8 abve, shortage of Foreign exchange and fluctuation of exchange rate has very high influence on Zaf's global pharmaceuticals supply chain management practice. During interview, the general manger of Zaf Pharmaceuticals PLC, mentioned that his company sales plan for the budget 2017/18 was 500 Million Ethiopian Birr but could not achieve it because of this problem and the problem is exacerbating year-to-year.

Other critical challenges identified are longer lead time to receive orders and pharmaceutical regulatory laws to get market authorization to distribute medicines and related goods in Ethiopia. Supply uncertainty and finding new qualified suppliers are also big challenges For Zaf Pharmaceuticals in its global supply chain management practice.

Cultural and lingual differences scored low value from respondents of self-administered questionnaire and interviews. In addition, political and economic instability got less value from respondents as the ZAF sources from economically strong and politically stable countries. To summarize, comparison is made among perceived challenges and foreign exchange shortage and fluctuation of exchange rates (Mean=4.77) is found to be the most challenging issue. Followed by longer lead-time to receive orders (Mean=3.68) and pharmaceuticals regulatory laws of Ethiopia (Mean=3.67). The other challenging issues are found to be Supply Uncertainty (mean =3.30) and challenges of finding qualified suppliers (mean=3.19). Unstable political and economic environment followed by cultural and lingual differences found to have low effect in the global supply chain management practice of Zaf Pharmaceuticals PLC.

CHAPTER FIVE

SUMMARY OF FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

This chapter summarizes findings of the study, the conclusions and recommendations on challenges of Global Pharmaceuticals supply chain management in Zaf Pharmaceuticals PLC.

5.1 Summary of Findings

The purpose of this study was to assess challenges of global Pharmaceuticals supply chain identify challenges of global pharmaceuticals supply chain management. The research questions were raised with the objectives of identifying and prioritizing those challenges based on perceived impact level on the firm's performance and due to special nature of pharmaceuticals transaction to identify major Ethiopian pharmaceuticals supply chain management regulatory challenges on Zaf Pharmaceuticals PLC. The study identified challenges faced during global SCM practice of Zaf Pharmaceuticals PLC collecting and analyzing data from respondents of concerned departments.

Comparison was made among perceived challenges. As a result, foreign exchange shortage and fluctuation of exchange rates (Mean=4.77) was found to be the most challenging issue followed by longer lead-time to receive orders (Mean=3.68) and pharmaceuticals regulatory laws of Ethiopia (Mean=3.67). The other challenging issues were supply uncertainty (mean =3.30) and finding qualified suppliers (mean=3.19). Unstable political and economic environment followed by cultural and lingual differences found to have low effect in the global supply chain management practice of Zaf Pharmaceuticals PLC.

In addition, for majority of the respondents who had participated in supplier selection process, their main source of information about the suppliers was found to be suppliers' representatives. According to the answer of most respondents, Zaf Pharmaceuticals PLC has no documented suppliers' selection criteria but searching for high quality of products, low cost and high technology and after sales service were found to be considered as default selection parameters. Regarding audit of potential overseas suppliers, most of the respondents agreed that they did not conduct such audit but some answered they did it rarely.

Regarding challenges of global pharmaceuticals supply chain management due to differences in standards and regulations, most of the respondents considered Foreign exchange permit directives, foreign supplier's product market authorization processes and waiting for Ethiopian shipping vessels due to multimodal transport law of Ethiopia were respectively big challenges to distribute pharmaceuticals from overseas suppliers on timely basis. Shortage of foreign currency was found to be affecting the company relationship with suppliers and its downstream customers according to the interview with the General Manager of Zaf Pharmaceuticals PLC. Fluctuation in exchange rate was also found to be common which led to unpredictable cost mark up on medicines. More than 80% of respondents responded they faced supply delay due to lack of foreign exchange permit. According to the interview with the Marketing manager most of the time supplier replacement due to exchange rate fluctuation is not common as the case is severe from the company's side at home.

Among the challenges identified from different literatures and included in both open and close-ended questions, challenges of volatile economic and political environment if found to have less effect on the global pharmaceuticals supply chain management practice of Zaf Pharmaceuticals PLC. Most of the respondents answered that supply delay and interruption due to economic and political environment occurs rarely.

Challenges of cultural and lingual difference with suppliers is found to have very low effect on the global SCM practice of Zaf Pharmaceuticals PLC. If such problems are to be mentioned their intensity is rare but business development manager, marketing manager and regulatory affairs head of Zaf perceived this as a major challenge specially when dealt with Chinese and Japanese suppliers. In addition interviewees mentioned the occasion of supply delay due to cultural issues like Chinese and Europe long period annual vacations.

Complicated logistics is one of the major challenges of global pharmaceuticals supply chain management but majority of the respondents (78.9%) acknowledged the presence of the problem but the occurrence is rare. Majority of the respondents believe that Zaf Pharmaceuticals PLC uses 3PL service providers and such problem is minimized. More than 91% of respondents faced difficulties in clearing pharmaceuticals from custom area upon receipt from the supplier. Majority of the difficulties were, damage, loss, unpredictable tax and unnecessary warehousing charge due to delay to issue inspection release certificate from concerned regulatory bodies.

To summarize, based findings, shortage of Foreign exchange and fluctuation of exchange rates found to be the most critical challenge for Zaf Pharmaceuticals PLC. Supply uncertainty, regulatory standard to get market authorization to distribute pharmaceuticals were the second most challenges in global pharmaceuticals supply chain management practices. Longer and variable lead-times, supplier selection complexity were identified to be medium challenges whereas lingual and cultural differences and economical and political instability are found to be minor challenges in global supply chain management practice of company.

5.2 Conclusion

Global supply chain management integrates supply and demand management within and across companies (suppliers, intermediaries, third party service providers or customers) belonging to different countries. The planning of activities involving sourcing, outsourcing and supplying are subject to environmental conditions that compose the global market. Firms globalize the upstream side of their supply chain to have access to lower priced goods, higher quality goods, and worldwide technology and to benefit from delivery and reliability. They also globalize their downstream operations so that they are able to sell their products in new geographical markets.

However the global dimension has introduced complexity in the supply chain. The management of global supply chains poses more challenges than the management of domestic supply chains. These challenges comprise, for instance, an increase on transportation costs, lead times and inventories, new and more suppliers, the change of local policies, variability and uncertainty in currency exchange rates, economic and political instability, and changes in the regulatory environment. The case of global Pharmaceuticals supply chain management is one of the most difficult supply chain management operations as it is conducted in a highly government-regulated environment to protect human lives from adverse effects of medicines. All the above mentioned challenges can lead to difficulties in getting the benefits associated with globalization.

Zaf Pharmaceuticals PLC, frequently faced such challenges when sourcing pharmaceuticals from more than 26 global suppliers. These challenges negatively affected relationships with its suppliers and downstream customers. This study clearly identified major challenges of global pharmaceuticals supply chain management in Zaf Pharmaceuticals PLC. Managers and concerned officers may use the findings to set solutions for each challenge on priority basis.

5.3 Recommendations

Based on the findings of the study, the following intervention recommendations are forwarded:

- So as to minimize supplier selection complexity and uncertainty on future relationship, it is better for the organization to give due attention on having documented suppliers' selection criteria.
- In order to build mutual trust, it is helpful to the company to conduct periodic audit of its suppliers developing checklists to evaluate product and service delivery capacity.
- Though shortage of foreign exchange and fluctuation of exchange rate is a national challenge which cannot be alleviated by the company, it will be helpful to think of joint venture to produce medicine locally. In addition, the company has to work on supplier's base reduction working with only a few suppliers having multiple product portfolio will help to utilize foreign exchange permits effectively.
- In order to reduce Pharmaceutical Market Authorization processes it is better for the company to source from highly credible regulatory authorities approved manufacturers and suppliers.
- In order to minimize the challenges associated with longer lead-times, it is helpful to the company to place order calculating remaining months of consumptions. By far the company need to work closely with its suppliers.
- In order to minimize challenge of miscommunication, it is helpful to the company to work on narrowing lingual gaps and appreciate cultural differences.

5.4 suggestion for further research

In general, as the global pharmaceuticals supply chain management is broad and needs the involvement of supply chain members, pharmaceuticals regulatory bodies, 3PL service providers, banks and ultimately physicians and patients, the challenges faced at all levels need deep research so as to improve human health. This study tries to highlight major challenges taking only one case company but does not test the effect of each challenge on firm performance; similar researches must be conducted in other companies as there will be procedural, structural and supplier relationship management differences may occur which can bring different results in the study.

In addition, individual challenges must be studied separately to deeply understand their effect on the performance of the company. For example the following points can be recommended for further study.

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ADDIS ABABA UNIVERSITY

SCHOOL OF COMMERCE

QUESTIONNAIRE

Dear Participant,

My name is Bayew Liknaw, MA Graduate student in Logistics and Supply Chain Management in Addis Ababa University School of Commerce and I am conducting a study on Challenges of global pharmaceuticals supply chain management taking Zaf Pharmaceuticals PLC as a case study.

The objective of this project is to assess challenges in global pharmaceuticals supply chain management. I eventually hope to understand how logistics is practiced and the related challenges.

Enclosed with this letter is a brief questionnaire that asks a variety of close and open ended questions about your experience towards Global pharmaceuticals supply chain management and challenges in your respected firm.

I kindly request your cooperation to look into the questionnaire carefully and answer so as to help me to analyze, conclude and recommend on this topic

Please do not write your name on the questionnaire. Your responses will not be identified with you personally.

If you have any questions or concerns about completing the questionnaire or about participating in this study, you may contact me at 0912363682 or at liknawbayew@gmail.com.

Thank you in advance for your cooperation!

Part I: BACKGROUND INFORMATION OF RESPONDENTS

1. Sex of the respondent: 1. Male [ ] 2. Female [ ]

2. Level of education: 1. First Degree 2. Master's Degree 3. Other (specify) _____

3. What is your position/status in the organization? _____

4. How many years of experience do you have in Pharmaceuticals import business? ___

Part II. GLOBAL SUPPLY CHAIN MANAGEMENT CHALLENGES (Please encircle your choice)

A. Supplier selection complexity

1. Are you engaged in supplier selection process? 1. Yes 2. No

2. If "yes", what are the sources of your information to get suppliers?

1. Trade fairs 2. Suppliers' websites 3. Recommendation by others 4. Suppliers representatives 5. All 6. Others (Please specify)

3. Does your company have documented supplier's selection criteria?

1. Yes 2. No 3. It is under development

4. Did you face the challenge of finding qualified foreign sources when you want to source some pharmaceuticals? 1. not at all 2. Yes, but a little 3. Yes, and intensively

5. What is the most priority when you select a foreign supplier? 1. High quality 2. Low price 3. High technology 4. After sale service 5. All of them considered.

6. Do you conduct an audit of potential suppliers overseas? 1. Not at all 2. Yes, but occasionally 3. Yes, frequently

B. Differences in standards and regulations

7. Which regulator standards of Ethiopia affects your Global Pharmaceuticals supply chain management practice? 1. Pharmaceuticals Market Authorization, *2*. Foreign exchange permit directives 3. Ethiopian multi- modal transport laws 4. All. 5 others, specify……..

8. Do the different regulatory standards between your suppliers' countries and Ethiopia affect the processes of global pharmaceuticals market Authorization in Ethiopia?

1 .Not at all 2. Yes, but a little 3. Yes, and intensively

9. Do any regulations such as customs duties affect the processes of global sourcing in your company? 1. Not at all 2. Yes, but a little 3. Yes, and intensively

10. Do any regulations such as shipping laws affect the processes of global supply chain practice of your company? 1. Not at all 2. Yes, but a little. 3. Yes, and intensively

C. Fluctuation of currency& exchange rate

11. Do you face scarcity of foreign exchange which affects your organizational performance?

1. Not at all 2. Yes, but occasionally 3. Yes, frequently intensively

12. Have you ever replaced a preferred vendor because the changes in exchange rates and price fluctuation? 1. Not at all 2. Yes, but occasionally 3.Yes, frequently& intensively

13. Do you face any supply delay due to lack of foreign exchange permit?

1. Not at all 2. Yes, but occasionally 3.Yes, frequently& intensively

D. Volatile economic and political environment

14. Did you face any supply delay due to political crisis in you suppliers' country?

1. Not at all 2. Yes but little 3. Yes and intensively

15. Did you encounter the risk of a supply interruption from a foreign source of critical required materials? 1. not at all 2. Yes, but a little 3. Yes, and intensively

E. Cultural and lingual difference

16. Did you have any cultural issue between you and the supplier which led to instability of the relationship? 1. not at all 2. Yes, but a little 3. Yes, and intensively

17. Did you face to the challenge of logistics problems due to any cultural issue when you do global sourcing? 1. Not at all 2. Yes, but a little 3. Yes, and intensively

18. Do you face any language barrier to communicate suppliers from different countries?

1. Yes 2. Yes but occasionally 3.Not at all

19. Has a miscommunication with a foreign supplier ever led you to a conflict with that supplier? 1. not at all 2.Yes, but occasionally 3.Yes, frequently

F. Complicated logistics

20. Did you face to the challenge of logistics problems when you do global sourcing?

1. Not at all 2. Yes, but a little 3. Yes, and intensively

21. Do you utilize a Third party logistics providers (like Freight forwarders and custom clearance, shippers and transporters) when you import materials from other countries?

1. Not at all 2. Yes, but occasionally. C. Yes, always

22. Do you receive your consignments on time as per you schedule when you import from your suppliers? 1. not at all 2.Yes, but occasionally 3.Yes, frequently

23. Do you face difficulties in clearing Pharmaceuticals from customs upon arrival?

1. Yes 2. No

24. If yes, which challenges do you face? 1. Damage 2. Loss 3. Unpredictable tax 4. All

4. If any other, please specify…….

Part III.,' please 'tick" (X) only one box from the given box after reading the variable on the left hand. How do the underlisted issues affect zaf pharm in its activity for global supply chain mgt.

		Effect on Zaf pharmaceuticals PLC.				
	Challenges	Very low (1)	Low (2)	Average (3)	High (4)	Very High (5)
1	Supply uncertainty					
2	Finding qualified foreign sources					
3	Shortage& Fluctuation in FOREX rates					
4	Longer lead- time to receive goods					
5	pharmaceuticals Regulatory laws					
6	Culture/language difference					
7	unstable political environment					

Thank you very much for your time!

Open Ended Questions.

OPEN ENDED QUESTIONS ON CHALLENGES OF GLOBAL PHARMACEUTICALS SUPPLY CHAIN MANAGEMENT (for managers in related to global supply chain operations)

1. What are the major challenges your firm face in its global pharmaceuticals sourcing?
2. What are the most rate limiting factors on your organizational performance since you are involved in GSCM?
3. Is there any coping mechanism to overcome such challenges? explain
4. How do you measure the performance of the suppliers?
5. Do you have qualified professionals to handle global supply chain issues? In which fields?
6. Do you share global market experiences with your suppliers? How?
7. Have you set any conflict resolution mechanism in case of relationship failure with your supplier? How?
8. Do you get adequate and timely service from your carriers and freight forwarders?
9. Do you think that the pharmaceuticals registration process is rate limiting factor for your global operations?

Thank you very much for your time.