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PHARMACEUTICAL SUPPLY CHAIN: SUPPLY CHAIN OF ARTEMISININ-BASED COMBINED THERAPIES IN GHANA

BY

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PHARMACEUTICAL SUPPLY CHAIN: SUPPLY CHAIN OF ARTEMISININ-BASED COMBINED THERAPIES (ACTs) IN GHANA

by

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DECLARATION

I hereby declare that this submission is my own work towards the MBA and that, to the best of my knowledge, it contains no material previously published by another person nor material which has been accepted for the award of any other degree of University, except where due acknowledgement has been made in the text.

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ABSTRACT

In Ghana as well as the world over, the emergence and rapid spread of *P. falciparum* resistance to commonly used antimalarials such as chloroquine poses a serious challenge to the benefits of early diagnosis and prompt treatment as a priority within the current strategy for malaria control efforts. In this regard, the National Malaria Control Programme in collaboration with the Noguchi Memorial Institute for Medical Research studied the efficacy of chloroquine country wide in 2002 and found that treatment failure following chloroquine was in the range between 6% and 25% and parasite clearance rates were low and in some cases below 50%. These results brought to the fore the need to search for alternative treatment for uncomplicated malaria. Artemisinin is a compound derived from the sweet wormwood plant – *artemisia annua* and has been used for centuries in traditional Chinese medicine to treat fever. An Artemisinin-based Combined Therapy (ACT) is a combination of two or more drugs (one of which is an artemisinin derivative) that have different modes of action. Studies have shown that using two or more drugs in combination has the potential to delay the development of resistance (Ministry of Health 2009). The main purpose of the thesis is to develop a detailed map of the supply chain for Artemisinin-based Combined Therapies (ACTs) in Ghana to describe the process behind it from the farmer to the patient. The research also considers the dynamics of this chain; including actors, activities, financing, integration of functions and legislations. It also investigates to gain a more realistic understanding of the nature and prevalence of risk in the ACT Supply Chain. This thesis has been written with an inductive research approach. A qualitative research approach has been used in interviews with actors and experts in the ACT supply network. The study also looks at the subjective aspect which determines the degree of influence some selected factors have on the chain/network. This study demonstrated the use of AHP for capturing the knowledge of a pharmacy expert to rate the selected factors that are detrimental to the supply chain. The author believes that the method of pair-wise ranking of the factors – delay, disruptions and price increases, is a productive framework for capturing expert judgement. The AHP process used revealed a significant level of delay occurrences in the system among other factors such as disruptions and price increases. The research recommends an enterprise resource planning system that will be able to follow-the-pill. Thus if pharmacies enter information about its processes, data can be available to authorized wholesalers, importers, sponsors, manufacturers and other actors in the chain.

ACRONYMS AND ABBREVIATIONS

ACT	–	Artemisinin-based Combination Therapy
AHP	–	Analytical Hierarchical Process
BMGF	–	Bill and Melinda Gates Foundation
CMS	–	Central Medical Stores
DHA	–	District Health Administration
DHMT	–	District Health Management Team
F1 hybrid	–	First-generation plant obtained from crossing two selected pure breeding parents to produce uniform, vigorous and high-yielding offspring
F2 hybrid	–	Plant that results from the self- or cross-fertilization of F1 hybrids
FDB	–	Food and Drugs Board
GFATM	–	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	–	Good Manufacturing Practice
ICB	–	International Competitive Bidding
MoH	–	Ministry of Health
NMCP	–	National Malaria Control Programme
OTC	–	Over the counter drugs
PoMs		Prescription only Medicines
RBM	–	Roll Back Malaria
RFID	–	Radio Frequency Identification
RMS	–	Regional Medical Store
SDP	–	Service Delivery Point
SP	–	Sulfadoxine-Pyrimethamine
TQMH	–	Tetteh Quashie Memorial Hospital
UNICEF	–	United Nations Children's Fund
USAID	–	United States Agency for International Development
WHO	–	World Health Organization

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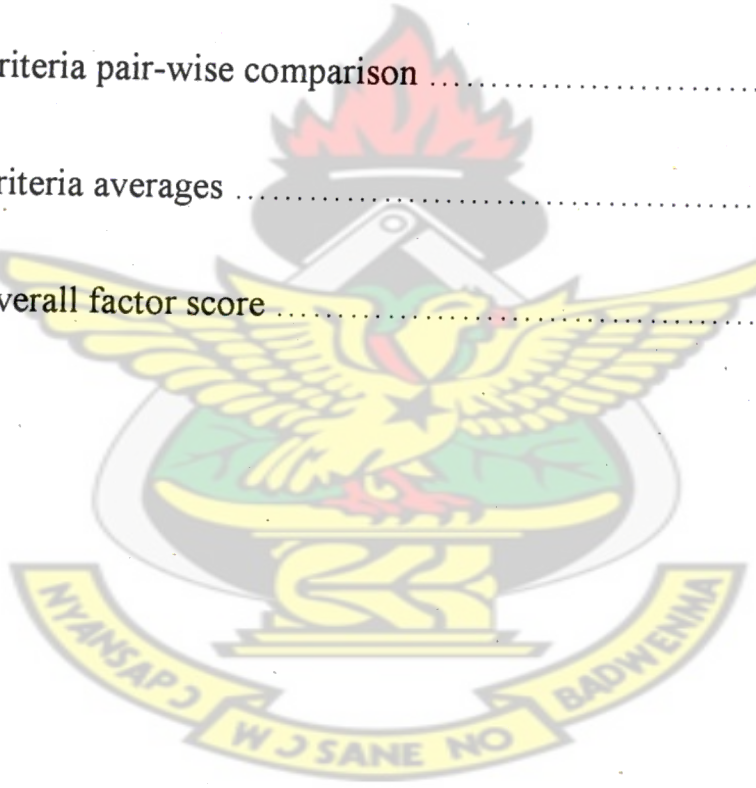

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CHAPTER ONE

RESEARCH INTRODUCTION AND CONTENT

1.1 Background

A recent study (Malaria No More, 2009) suggest that malaria claims the lives of more than one million people each year, most of them children under the age of five, virtually all in Africa. As many as 500 million malaria cases a year contribute to a vicious cycle of repeated illness and long-term poverty for families, communities and countries. In addition to its health toll, malaria places a heavy economic burden on many endemic countries. Africa alone is estimated to lose at least US$ 12 billion per year in direct losses (e.g. illness, treatment, premature death), and many times more than that in lost economic growth.

The widespread failure of chloroquine and sulfadoxine pyrimethamine (SP) in the treatment of malaria resulted in a hectic public health debate, which led to universal approval that mono-therapies that failed to cure up to one in four patients should be replaced by the highly efficacious artemisinin-based combination therapy (ACT). More than 40 countries in Africa have now adopted ACT as their first line treatment recommendation for uncomplicated malaria.

Beyond the difficulties of changing national treatment policies, a key benchmark of successful policy implementation, and thus effectiveness, is that the recommended drugs are available at the point of care. The effect of malaria on people of all ages is quite immense (WHO/UNICEF, 2003). It is however very serious among pregnant

women and children because they have less immunity. When malaria infection is not properly treated in pregnant women, it can cause anaemia and also lead to miscarriages, stillbirths, underweight babies and maternal deaths. Also, frequent cerebral malaria can lead to disabling neurological sequelae. Further, malaria in school children is a major cause of absenteeism in endemic countries. It is estimated that about 2% of children who recover from cerebral malaria suffer brain damage including epilepsy.

Hence, among young children, frequent episodes of severe malaria may negatively impact on their learning abilities and educational attainment. This is a threat to human capital accumulation, which constitutes a key factor in economic development. The debilitating effects of malaria on adult victims are very much disturbing. In addition to time and money spent on preventing and treating malaria, it causes considerable pain and weakness among its victims. This can reduce peoples working abilities.

The unfavourable impact of malaria on household production and gross domestic product can be significant. Malaria therefore is not only a public health quandary but also a developmental crisis. Apart from the negative effect of lost productivity on the major sectors of the economy, malaria has negative effects on the growth of tourism, investments and trade especially in endemic regions.

Malaria presents a major socio-economic challenge to African countries since it is the region most affected. This challenge cannot be allowed to go unnoticed since

good health is not only a basic human need but also a fundamental human right and a prerequisite for economic growth (Streeten 1981 cited in Asante & Asenso-Okyere 2003).The disparity in pharmaceutical access between developed and developing countries is stark. Developing countries make up approximately 80% of the world's population but only represent approximately 20% of global pharmaceutical consumption. Market failures, government failures and income differences account for this persisting inequity. Specifically, high drug costs, weak or corrupt institutions, contribute to less than effective pharmaceutical purchasing and distribution systems and the potential consequences of the Trade Related Aspects of Intellectual Property (TRIPS) Agreement all constrain drug access (Cohen et al, 2005).

One WHO certified artemisinin-based combination therapy, artemether–lumefantrine (Coartem, Novartis), is currently being produced and has a retail price of $2.40 per adult course (reportedly with little or no profit margin), as compared with 10 cents retail for chloroquine. Other formulations have also entered the market, e.g. Lonart, which sells at a lesser price than Coartem for an adult course. The poverty rate in Africa seeks to limit the number of patient able to procure these drugs even at their subsidised prices. Such a situation makes it difficult to completely eradicate the disease completely as majority of the people opt for the very cheap mono-therapies which militate against the global fight against the disease.

Ultimately, the effective management of pharmaceuticals in the National Health Service (NHS) is critical to patient welfare thus any risks attached to this must be identified and controlled. At a very basic level, risks in the pharmaceutical supply

chain are associated with product discontinuity, product shortages, poor performance, patient safety/dispensing errors and technological errors (causing stock shortages in pharmacies) to name but a few, all of which incur risk through disruption through the system.

1.2. Statement of the problem

Despite the fact that malaria drugs have long been distributed through a large number of sector channels including public, private, local chemical stores and on the streets, information on the integration and collaboration in this market is very minimal. There is very little evidence on the drugs' supply including distribution channels, interventions that are being implemented to influence its availability and prices, supply chain mapping and price mark-ups. The absence of data-driven market information has potentially significant consequences for a number of initiatives for scaling up access to ACTs in particular.

The weakness of data has implications for manufacturers, donors and national authorities, pharmacies, etc. in terms of clarifying total market, market share and availability of older drug classes, access through different outlet types, production planning and medium-term funding requirements among others. Improving access to good quality drugs is a crucial element of malaria control.

Ensuring high standards for medicines as well as medical treatment will be essential in preserving the efficacy of the current first line treatment – Artemisinin-based Combination Therapy (ACT). Although funding in the public sector has increased

remarkably over the years, most treatments are administered over the counter through general shops, pharmacies and hawkers. Because these outlets are poorly regulated, the distribution, quality, price and administration of anti-malaria drugs vary significantly. It is no doubt that drug resistance to artemisinin has already been established in South East Asia and could spread to Africa. According to a recent BBC report, Dr Delia Bethell stated that, the surprising resistance development in Cambodia can be attributed to inappropriate use of drugs, lack of medical supervision, weak public health system, shortage at government clinics and lack of access.

The problem now is how vulnerable is the ACT supply chain in Ghana. It is important therefore to increase understanding of the actors of the current anti-malaria supply chain, its finance, price components, the inefficiencies and the framework of the whole value network. This will help increase effective treatment rates of malaria by generating and disseminating evidence and recommendations to policymakers on methods to increase availability and to make consumer price of quality-assured artemisinin-based combination therapy (ACT) affordable.

Risks have been identified by some research which negatively affect the performance of the total supply chain (from raw material sourcing through to dispensation of medication). The aim of this study is to find out the dynamics of the ACTs supply chain and also how to efficiently fulfil orders.

1.3. Objectives of the study

The objectives of this research are to:

1. Develop a detailed map of the supply chain for Artemisinin-based Combined Therapies (Achieved on page 64).
2. Find out the dynamics of this chain; including actors, activities, financing, integration of functions and legislations (Achieved on page 44 - 57).
3. Gain a more realistic understanding of the nature and prevalence of risk in the ACT Supply Chain (Achieved on page 68 -74).
4. Use the findings to develop and communicate policy recommendations to improve access to ACTs (Achieved on page 78 - 79).

1.4. Relevance of the Study

A key goal of this research is to document the actors, price, availability, risk and synchronization in the ACT supply chain. Activities of actors are determined to a large extent by what happens further up the distribution chain. For example, availability will be affected by which anti-malaria drugs are being stocked by suppliers, marketing strategies used to promote these drugs, the registration of drugs and regulation of providers further up the chain. Retail prices will be influenced strongly by wholesale prices and by the cost of obtaining and storing the drugs. Actors' coordination and supply chain distortions will be determined by how information is disseminated throughout the supply chain.

To improve ACT availability, affordability and coordination we need to understand the distribution chain. However, relatively little is known about its operation and there is likely to be considerable variation across countries.

This study procedure aims to address these gaps by analysing the distribution chain for ACTs in Ghana. This will lead to the identification of policy recommendations in areas such as activities of actors (e.g., drugstores, importers and wholesalers), financing and credit facilities, risks (e.g., delays, price increase and disruptions), etc.

1.5 Limitations

Pharmaceutical supply chain management is a vast area of research, taking into account various aspects of the matter, such as Information technology, Network, Logistics, Finance, Price Mark-up, Risks, Regulations, Actors, Transportation, Wholesalers, Importers and many more. Unfortunately, due to constraints in accessibility, time and resources, it was impossible to go through all of these areas in detail. The researcher was therefore forced to concentrate more at the pharmacy level where the researcher believes most of the upstream shortcomings will be revealed.

Nevertheless, resource persons and experts were contacted for information where accessibility was denied especially with importers and wholesalers within the supply network. In the end, the network, supply chain, finance, regulations, actors, pharmacies and vulnerability of ACTs were investigated in depth. Drugs considered in the study were the WHO approved ACTs even though efforts were made to compile available antimalarials on the Ghanaian market too.

1.6 Outline of the research

After this introductory chapter, follows chapter two which would set the theoretical review of the research. This chapter would provide the reader with an outline of what previous researchers have contributed to the field of pharmaceutical supply chain. In chapter three, follows the methodology of the study and gives an insight into the procedures followed to completing the research. The chapter would provide the reader with an outline of the method chosen for the paper and why these methods were chosen. Chapter four is a narrative of the in-depth studies of ACT supply chain from the planting of the artemisia annua to the combined therapies delivered at the drugstores in Ghana. It gives the full description of the project and its activities. The chapter also embody an analysis which is related as far as possible to the background literature seen in chapter three.

Chapter five shows an overall conclusion to the whole study with recommendations suggested for the problems that were found in the research. Consequently, all the findings and results in the previous chapters were summarized and the outcome presented. Furthermore, recommendation for future work was also given.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

In this section, the researcher presents the theories for the study. As there is no single theory that explains and captures the characteristics of the ACT supply chain phenomenon as a whole, this section is based on different theories that cover different aspects of the observable fact. The researcher analyzed a wide range of theories before deciding which theories should be included in the project work. Based on the available knowledge regarding Artemisinin-based Combined Therapies *(ACTs)*, it is believed that the chosen theories together will cover the main characteristics of the phenomenon given the research objective. Important to highlight regarding the chosen theories is that they will be presented quite briefly. So, instead of examining a small number of theories in depth we will present several theoretical fragments that have been evolved from actual theories.

The researcher believes that this is the most appropriate approach since there is no single theory that covers and can describe the *Artemisinin-based Combined Therapies* phenomenon as a whole. The chosen theories are the following:

Network theory: An understanding of the ACT network and the relationship between the supply chain actors appears necessary to explain the ACT phenomenon.

Supply chain theory: This theory will be included since we intend to explain the ACT supply chain – manufacturer to customer – including all actors within the supply chain. Furthermore, the aim of the government and international health

organisations is to fight against malaria by making ACTs readily available. This ought to be reflected in a different supply chain for ACT compared to conventional pharmaceutical chain. Thus, this theory is found to be relevant to include in the study. Other theories are on legislations and risks.

2.2. Network

According to Schary et al. in 2003 (cited in Engström & Slivo 2008), because of the broad perspective network theory gives, with both internal and external perspective, it is closely associated to many other theories, which have a natural part in relations between the actors, such as supply chain management and relationship management. Lysons & Farrington (2006), identify a network structure as a series of strategic alliances that an organisation forms with suppliers, manufacturers and distributors to produce and market a product. It is the results of complex interactions within and between companies in relationships over time (Ford et al. 2003 cited in Lysons and Farrington 2006).

Lyson & Farrington (2006) further state that network allows organisations to bring resources, together on a long term basis to reduce cost, which is why enterprises in Europe and the USA are increasingly turning to global networking as a means of gaining access to low-cost overseas inputs. Network relates to all aspect of the supply chain, including marketing and distribution. Networks are made up by actors, the firms and the individuals within them perform a set of activities using a set of resources. The nodes represent the business or 'actors', such as suppliers, producers, customers and service providers. The links between the nodes he states represent the

relationships. Relationships between actors are like bridges as they give one actor access to the resources and competences of another. Networks are made up by actors, the companies and the individuals within them, that perform a set of activities using a set of resources.

Actors: In the process of developing activity links and resources ties, the individuals and companies interact with each other and actor bonds are formed.

Activities: The activities refer to the technical, administrative, commercial and other activities of a company which become connected to the other companies as the relationships develop.

Resources: Each company has its own set of resources, including manpower, equipment, plant, financial means etc., and relationships often provide a means of accessing resources which may have been unavailable to them previously. These three components are all interconnected. The existence of bonds between actors is necessary in order for any strong activity and resource links to develop (Baker 2003 cited in Engström & Slivo 2008). The firm's relations in a network imply a certain informational advantage compared to its competitors and this advantage could be referred to as a network resource (Gulati 1999 cited in Engström & Slivo 2008).

Harland's observations in 1996 (cited in Lysons and Farrington 2006), points out that some researchers use the term 'network' to describe a network of actors, while others use it to discuss a network of processes or activities. The study of networks can therefore be related to networks of actors (organisations and individuals), activities (or processes) and resources. When discussing networks, it is essential to specify

whether or not networks of actors or networks of activities are being considered. In this study network is considered as a resource, activity and actors.

NETWORK MODEL

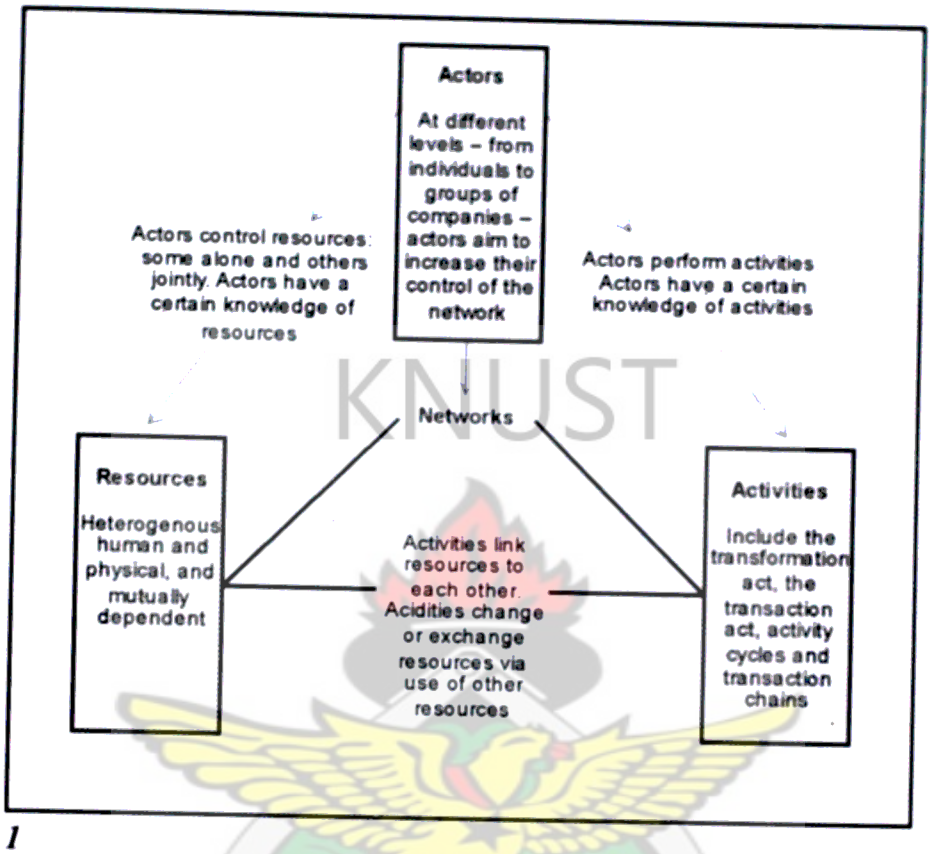

Figure 2.1
Source: Adopted from Lysons & Farrington, 2006

It is maintained that network represents a lateral and horizontal exchange, between independent partners, of resources and communication. In a definition, networks are classified around two key concepts: 1) a model of interaction based on exchange and relationships, and 2) a flow of resources between independent units (Powell 1990; Jones et al., 1997 cited in Perez & Martinez, 2007).

Authors like Omta et al. 2001; Harland, 1999; Dyer et al., 2001 (cited in Perez & Martinez, 2007) have emphasised the network character of SCM and proposed the analytical integration of SCM and the theory of networks approach. Under this

approach, Lazzarini et al. (2001) introduce the term 'Netchain' while Harland (1999) and Nassimbeni (1998) talk about 'Supply Network'. Defining supply chain as a chain of actors is seen as misguiding. Thus, Yücesan et al. (2005) (cited in Engström & Slivo 2008) define supply chain as a network consisting of actors with relationships to one another.

Snow et al. 1992 (cited in Lysons and Farrington 2006), make a distinction between internal, stable and dynamic structures. According to them, *internal network* firms own most or all of the assets associated with the business and endeavour to capture entrepreneurial and marketing benefits without engaging in much outsourcing. In *stable networks*, assets are owned by several firms but dedicated to a particular business. The suppliers nestle round a large core enterprise, either providing supplies or distributing its products. Dynamic networks are those with extensive outsourcing. The lead firm identifies and assembles assets owned wholly or largely by other enterprises on whose core skills it relies.

Lamming et al. (2000) (cited in Lysons and Farrington, 2006), clarify two distinctive types of supply networks relating, respectively, to products that are 'innovative-unique' (such as drugs, communication technology and electronics) and 'functional' (such as canned soft drinks, brake cylinders and car window wipers). Harland et al. (1996), provide a classification of supplier network based on two dimensions, which are, first, whether the supply network operates under dynamic or stabilised conditions and, second, whether the influence of the focal firm over other supply chain actors, such as customer and suppliers, is high or low.

Craven et al. 1996 (cited in Lysons and Farrington, 2006), offer two dimensions for the classification of network organisations: *volatility of environmental changes* and the *type of relationship* between network members, whether it is collaborative or transactional. For highly volatile situations, enterprises require flexible internal structures capable of rapid adjustment to new environmental conditions; and flexible external relationships that allow for alteration or termination in a relatively short time period.

Craven et al. (1996) again range network relationship from highly collaborative to largely transactional links. *Transactional* linkages imply discrete exchanges of values where a major issue is price, typified in the economics buyer-seller relationships. Transactional links are most likely to occur between parties that do not require collaboration. Collaborative links may involve various forms of inter-organisational cooperation and partnering, including the development of formal alliances and joint ventures; consider interactions between organisations to achieve common objectives; and continue relationships between the parties that, when they are long-term ones, are likely to involve strategic alliances as a networking method. Based on the two dimensions of volatility and relationships, he classifies networks as hollow, flexible, value-added and virtual.

Sang et al. (2008) categorize supply chain as three distinctive networks which are supply network, conversion network and distribution network, and also investigates

five dimensions of SCM activities, such as organizational capacity, revitalization support, collaboration, appraisal & responsibility and information system.

The organizations, which concentrate on *supply networks,* produce very complicated goods with the process, which many materials, parts and components are purchased produced and/or transported. The organizations, which concentrated on *conversion* networks, produce small, light, innovative and sophisticated products that require high technology and delicate processes. The organizations, which concentrate on *distribution* networks, are competed in consumer-goods industry having many distribution tiers and agencies.

The groups study confirm that there are distinct and separate categories of supply chain management (SCM) networks (supply networks, conversion networks and distribution networks); and identify five critical activities which could lead to a successful introduction of SCM. The dimensions of activities were identified as organizational capacity; revitalization support; collaboration; appraisal and responsibility; and information system.

Many organisations today have built strong networks with specific partners both upstream and downstream to create a superior *value delivery network* described as supply chain. They are able to achieve this network fulfilment through managing and linking their core business processes. The most important issue here is not about managing the stocks of goods, but about managing the flow of the goods, there should be enough visibility for one to take charge of the supply network. It is in this

vain that Wal-Mart turned such important responsibility to its leading vendors in a system known as Vendor-Managed Inventory (VMI).

A concluding remark is that although a network must establish relations that results in greater benefits than what can be accomplished individually, networks in some cases have negative effects on related parties. For instance, it could lock companies into unproductive relationships or exclude partnering with other possible actors. In other words relationships in a network could be a source of both opportunities and constraints.

2.3. Supply Chain Management

The Institute of Logistics (1998) claims that supply chain is a sequence of events intended to satisfy a customer. It virtually includes procurement, manufacture, distribution and waste disposal, together with associated transportation, storage and information technology. A supply chain is that network of organisations 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 (cited in Lysons & Farrington, 2006). It emphasises supply chains as networks, upstream and downstream activities and coordination of processes and relationships that creates value to the customer. Value as defined by Porter (1985) (cited in Perez & Martinez, 2007) is 'what buyers are willing to pay'. He also proposed the value chain as a tool for identifying ways to create more customer value.

The Supply chain approach developed from *logistics* which is the process of managing both the movement and the storage of goods and materials from the source to the point of ultimate consumption and the associated information flow (Crompton and Jesspon, 2001). Logistics essentially is an integrative process that seeks to optimise the flow of materials and supplies through the organisation and its operations to the customer. It is also a planning process and an information based activity. Supply chain therefore is a series of linked suppliers and customers; every customer is in turn a supplier to the next downstream organisation until a finished product reaches the ultimate end user. It is now being recognised that for the real benefits of the logistics concept to be realized, there is a need to extend the logic of logistics upstream to suppliers and downstream to final customers. This is the concept of supply chain management.

Supply chain management is a fundamentally different philosophy of business organisation and is based upon the idea of partnership in the market channel on a high degree of linkage between entities in that channel. Traditional models of business organisations were based upon the notion that the interests of individual firms are best served by maximising their revenues and minimising their costs. If these goals were achieved by disadvantaging another entity in the channel, then that was the way it was.

Under the supply chain management model the goal is to maximise profit through enhanced competitiveness in the final market – a competitiveness which is achieved by a lower cost to serve, in the shortest time-frame possible. Such goods are only

attainable if the chain as a whole is closely coordinated in order that total channel inventory is minimised, bottlenecks eliminated, time compressed and quality problems eliminated.

This new competition model suggests that individual companies compete not as company against company, but rather as supply chain against supply chain. Thus the successful companies will be those whose supply chains are characterised by cost-effectiveness, quality and speed than those of their competitors.

SUPPLY CHAIN LINKAGES

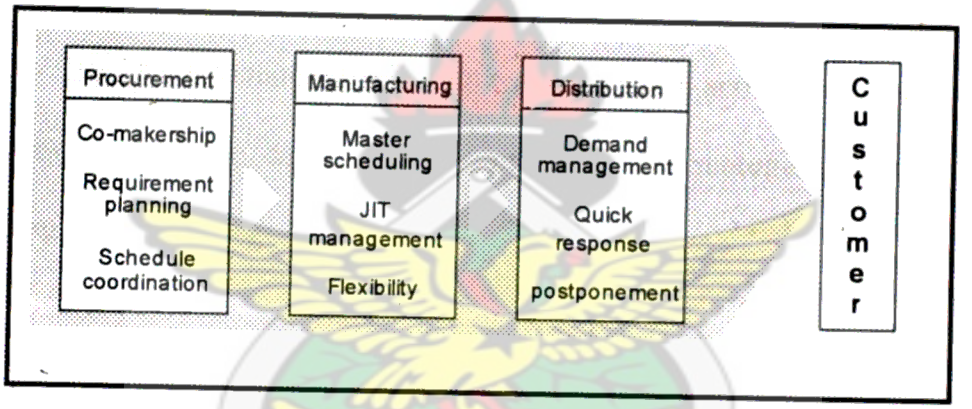

Figure 2.2
Source: Adopted from Crompton & Jesspon 2001

Figure 2.2 outlines the critical linkages that connect the supply chain to the customer. The key linkages are between procurement and manufacturing, and between manufacturing and distribution. Each of these activities, while part of a continuous process, has a number of critical elements. In this study, the researcher proposes the term 'Supply Chain Network Management' (SCNM) which puts in a nutshell a management concept that integrates a set of horizontal and vertical inter-

organisational relationships that are sequentially organised through vertical inter-organisational links throughout the production and distribution chain.

2.3.1. Supply Chain Components

A Successful Supply Chain Management (SCM) requires a change from managing individual functions to integrating activities into key supply chain processes. The three Primary Components of SCM are:

Information – A vital component for an SCM to be responsive to the market demand and for the supply chain to be competitive with others.

Logistics – The primary material flow and transformation activities in supply chain, including e-procurement, design, supply of parts and materials, manufacturing, warehousing and delivering.

Finance – The primary finance transaction of a supply chain including pricing, invoicing, payment, and account transaction within supply chain, among others.

According to Lambert and Cooper (2000) operating an integrated supply chain requires continuous information flow. Advanced information technology (IT), which has turned the world into a global village through ''speed of light'' transfers of information, data and files, is a major driver of supply chain integration. Through the Internet, a single data file can be accessed simultaneously by spatially distributed entities. Although earlier IT applications were in support of secure and evidential transfers of trading reports, cash and other assets and obligations, the applications

were eventually extended to logistics management (Russ and Camp 1997; Yusuf et al., 2003).

According to Fasanghari et al. (2008), the impact of IT on SCM is much larger as it facilitates inter-organisational communication and in turn reduces cycle times and develops collaborative work. It provides opportunities for an organisation to expand their markets worldwide; and also enhanced team work and customer relationship management. Russell and Taylor (2003), indicate that Information is the essential link between all supply chain processes and activities, including suppliers, manufacturers/ products, distributors, retailers and customers. He elaborates further that information technology allows real-time, on-line communications throughout the supply chain. Seamless flow of physical and non-physical assets amongst companies would lead to pooling synergy and optimisation of tangible and intangible assets that are potentially available to the individual companies (Kasarda and Rondinelli, 1998; Upton and McAfee 1996).

Financing a value chain as well as a supply chain is financing provided to or by a supply chain actor in order to increase supply chain growth and competitiveness. Whether provided by a bank, a buyer or an input supplier, supply chain financing allows firms to operate, to transact with others and to upgrade. Supply chain finance is neither a separate subset of finance, with unique or distinct products, nor is it a complex new field (Briefing Paper, USAID 2007).

Supply chain finance includes a wide range of products. While firms may self-finance at times, producers also receive trader credit in the form of in-kind loans from input providers, and seasonal loans from buyers. Buyers use credit not only to secure future products; in out-grower schemes they ensure that products meet standards by monitoring the farmer, providing inputs and credit effectively in the process. To manage risk, supply chain participants take advantage of their business relationships to screen borrowers for their ability and willingness to pay. They also use relationships as a modified form of collateral, for informal or contractual commitments to deliver future products (Ibid.).

2.3.2. Supply Chain Mapping

Described in Lysons and Farrington (2006), a map is a visual representation of some actuality. As supply chain and value mapping is undertaken for a specific purpose – normally for supply chain redesign or for modification or the elimination of waste – the number of options for mapping to meet the needs of users is large. Gardner and Cooper (2003) state that a well-executed strategic supply chain map can enhance the strategic planning process, case distribution of key information, facilitate supply chain redesign or modification, clarify channel dynamics, provide a common perspective, enhance communications, enable monitoring of supply chain strategy and provide a basis for supply chain analysis.

A supply chain map may be linked to or built directly from database or built by hand. Gardner and Cooper (2003) again state that 'the complexity of mapping is influenced

by three supply chain map attributes: geometry, perspective and implementation issues'.

A distinction can be made between traditional supply or value chain and value streams. The former include the complete activities of all the companies involved, while the latter refers only to the specific parts of the firms that actually add value to the product or service under construction. They identified seven mapping tools designed to reduce or eliminate seven forms of waste in a manufacturing organisation – overproduction, waiting, transportation, inappropriate processing, unnecessary inventory, unnecessary motion and defects. These take three forms, which are product (not identified and passed on to customers), service (not directly relating to products but to service, such as late delivery or incorrect documentation) and internal scrap (defects indentified during inspection). The map or chart can there be used identify where savings can be made or value added (Hines & Rich 1997, cited in Lysons & Farrington 2006).

2.4. Legislations

According to Lysons and Farrington (2006) Commercial or mercantile law includes agency agreement, contract for sale of goods and services, insurance, negotiable instruments and carriage by land, sea and air. Clearly all such legislation together with that relating to electronic trading and European procurement is applicable purchasing. Let us not forget here that in the supply chain is a series of linked suppliers and customer; every supplier is in turn a customer to the next upstream

organisation. This therefore point to fact that every member of the supply chain should be abreast with the laws and regulation of the network.

There are at least three good reasons why for all to have a working knowledge of the regulations. First, the principle of *ignorantia juris non excusat* (ignorance of the law does not excuse). Second, all purchasing specialists should have an awareness of the possible legal consequences of their actions. Third, 'a little knowledge is a dangerous thing' and a knowledge of the law should indicate when it is advisable for buyers to seek professional advice.

2.5. Risks

Laysons and Farrington (2006) agree supply chains are vulnerable due to external and internal risks. External risks are those attributed to environmental, economic, political and social causes, such as storms, earthquakes, terrorism, strikes, wars, embargoes and computer viruses. Internal risks are those attributable to interactions between organisations in the supply chain. According to them, a Cranfield University report identifies five categories of supply chain risk. Firstly, *lack of ownership* due to the blurring of boundaries between buying and supplying organisations arising from factors such as outsourcing and the creation of complicated networks of business relationships with confused lines of responsibilities.

Secondly, *chaos risks* due to mistrust and distorted information throughout the supply chain. An example is the bullwhip effect, in which fluctuations in orders increase as they move upstream from retailers to manufacturers to suppliers. Thirdly,

decision risks due to chaos that makes it impossible to make the right decision for every player in the supply chain. Fourthly, *JIT relationship risks* due to the fact that an enterprise has little capacity or stock in reverse to cater for disruptions in the supply chain due to late deliveries, such as transportation break downs. Fifthly, *inertia risks* due to a general lack of responsiveness by customers or suppliers to changing environmental conditions and market signals with consequential inability to react to completion moves or market opportunities.

To the above may be added *supplier base reduction*, especially single sourcing in which an enterprise is dependent on one supplier; *globalisation* in which advantages of sourcing abroad may be offset by extended lead times, transport difficulties and political events; and *acquisitions*, *mergers* and *similar alliances* that may reduce supply chain availability. Supply chain risk is a fact of life – supply interruptions, fluctuations in demand and spikes in commodity prices has now alerted companies to focus on supply chain risk management as a discipline to minimize the bottom-line impact of potential disruptions. From the Cranfield report, the researcher believes that supply chain vulnerability is due to five main factors – delays, disruptions, operations, price increases and legislation; and ranking these factors against the occurrence, controls and impact we will be able to identify the factor which most identifies with the vulnerability.

2.5.1. **Disruptions** – Supply chain disruptions are unplanned and unanticipated events that disrupt the normal flow of goods, information and materials within a supply chain and as a consequence, expose firms within the supply chain to some

degree of vulnerability. Pochard (2003), states that risks that can lead to supply chain disruptions are as different as natural catastrophes, strikes, political instability, fires or terrorism. Vulnerability of supply chains to these risks has increased because of modern practices such as lean management and just-in-time inventory.

Researchers have identified that many of the key risks factors have developed from a pressure to enhance productivity, eliminate waste, remove supply chain duplication and drive for cost improvement" (Stauffer, 2003). But this list is not comprehensive and we can find many other reasons. For example market has put a lot of pressure on firms to differentiate their products. This has led companies to rely on several third parties and has consequently increased the risks. Vulnerability has also increased because of the growing complexity of supply networks. Indeed the probability that something happens at a particular node or connection is higher than for a small and simple network. Supply chains that comprise hundreds or even thousands of companies present numerous risks.

The inconvenience to firms expecting to ship or receive goods and materials is, however, not the entire story; disruptive events within a supply chain can also significantly hurt the financial bottom line for affected entities in the supply chain. Publicly traded firms experiencing supply chain disruptions, for example, have reported negative stock market reactions to announcements of such disruptive events, and the magnitude of the decline in market capitalization has been as large as 10 percent. As a matter of fact, Ericsson reported a $400 million loss because it did not

receive chip deliveries from the Philips plant in a timely manner (Ringstrom & Soderpalm 2009).

2.5.2. Delays – Supply chain have a direct impact on a company's profit. As mentioned in the opening section, the average cost of shipping time has been estimated to be approximately 0.5 percent of the value of goods per day. For a company importing $500 million, an average delay of just one additional day could squander as much as $2.5 million per year from the bottom line (Gersper & Carr 2006). Another study, by the Boston Consulting Group cited by Gersper & Carr (2006), reports that waiting times at ports are already getting much longer and less predictable. The study, Avoiding Supply Chain Shipwrecks: Navigating Outsourcing's Rocky Shoals, concluded that backlogs at ports and at railroads were at all time highs in 2005, stating, "With freight volumes increasing faster than the ports can handle them, the situation will only worsen."

2.5.3. Price increases – Price can be defined as the value of a commodity or service measured in terms of the standard monetary unit (Lysons & Farrington 2006). They explained further that when comparing two quotations, price enable us to appraise the relative value offered by each supplier. Economic theory shows that demand and supply are balanced by the influence of price, the equilibrium price indicating the point at which demand and supply are equal. A seller's market exists when demand exceeds supply, so price generally rise. Conversely, a buyer's market exists when supply exceeds demand, so the price generally falls.

Kotler et al. (2002) add that a considerable factor in price increase is cost inflation. Rising cost squeeze profit margins and lead companies to make regular rounds of price increases. Companies often raise their prices by more than the cost increase in anticipation of further inflation. Another factor leading to price increases is over-demand: when a company cannot supply all its customers' needs, it can raise its prices, ration products to customers or both.

2.5.4. **Operational risk** – According to Comtroller's Handbook (1994) (cited in Young, 2001), operational risk is defined by as the risk of loss occurring as a result of inadequate systems and control; human error; or management failure. Schwartz and Smith (1997) confirm this by stating that operational risk is the risk of loss arising from human errors, management failure and fraud; or from shortcomings in systems or controls. They also state that operational risk management is sometimes seen as a discreet aspect of overall risk management. According to Standard Bank's Annual Report (1998), the breakdown of controls and procedures for efficient functioning of human, physical and operating resources is regarded as the prime source of operational risk. It is therefore defined as a potential loss arising from malfunctions in automated systems; failure in internal financial and administrative controls; and not compliance with policies and procedures. It is also refers to losses as a result of error, fraud and other criminal activities.

2.5.5. **Legislation** – Government regulations and compliance is a sticky and complex issue for pharmaceutical supply chain management. There can be many legal requirements to be adept at understanding and ensuring compliance with the

applicable statutes and regulations in all of the jurisdictions especial where the pharmacy chain operates an outlet or store (Zhang & al., 2008). A pharmaceutical supply chain is a highly regulated environment requiring extensive data collection and information exchange to ensure a chain of custody and monitoring of various controls (Zhan et al., 2008).

2.6. Pharmaceutical Supply Chain

The pharmaceutical supply chain is the means through which prescription medicines are delivered to patients. Pharmaceuticals originate in manufacturing sites; are transferred to wholesale distributors; stocked at retail, mail-order and other types of pharmacies; subject to price negotiations and processed through quality and utilization management screens by pharmacy benefit management companies (PBMs); dispensed by pharmacies; and ultimately delivered to and taken by patients. There are many variations on this basic structure, as the players in the supply chain are constantly evolving, and commercial relationships vary considerably by geography, type of medication and other factors. (The Health Strategies Consultancy (LLC), 2008).

The unique nature of the supply chain for pharmaceuticals makes managing complex information for supply chain effectiveness challenging, but clearly the rewards for doing so are significant. A typical Pharmaceutical supply chain is shown in *Fig 2.3.* It consists of one or more of the following actors: a) Manufacturer and/or contract manufacturer, b) Wholesaler; c) Pharmacy; and d) Consumer.

A TYPICAL VISIBLE PHARMACEUTICAL SUPPLY CHAIN

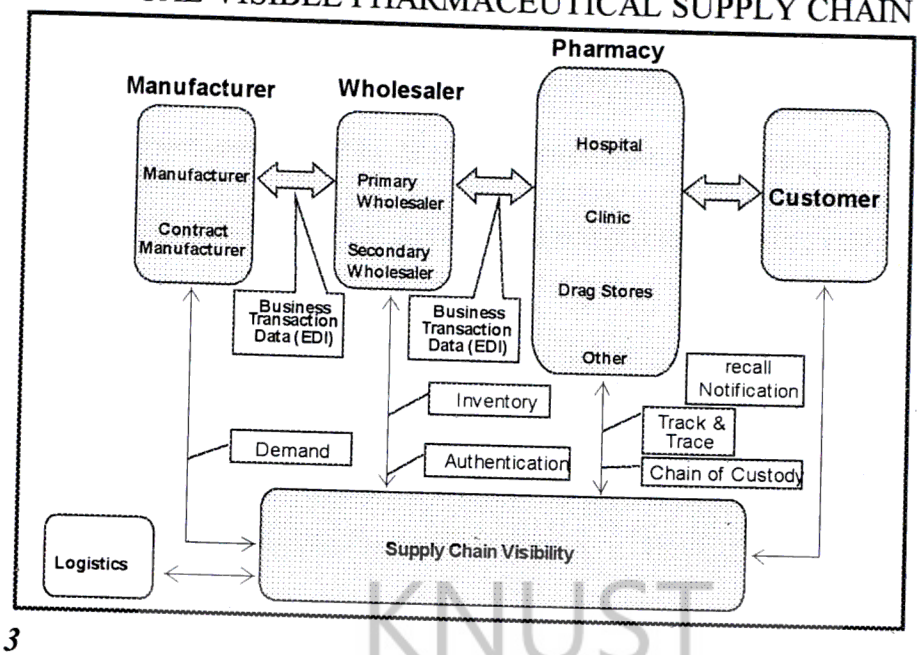

Figure 2.3
Source: Adopted from Zhang et al. 2008

Pharmaceutical Manufacturers are the source of the prescription drugs in the pharmaceutical supply chain. The pharmaceutical manufacturing industry is composed of two distinct business models: manufacturers of brand-name drugs (e.g., Pfizer, Merck, and Novartis) and manufacturers of generic drugs (e.g., Mylan, Roxane, and Barr). Most brand manufacturers devote a portion of their expenses to the scientific research and development of new drug therapies. Generic drug manufacturers typically do not develop new drug therapies, but instead manufacture generic compounds that compete directly with the original branded version of a drug once the brand product's patent protection has expired.

Manufacturers manage the actual distribution of drugs from manufacturing facilities to drug wholesalers, and in some cases, directly to retail pharmacy chains, mail-order and specialty pharmacies, hospital chains, and some health plans. Manufacturers may also distribute products directly to government purchasers and wholesale distributors

who are the manufacturers' largest purchasers. Very few drugs are distributed directly to consumers. Manufacturers also play an important role in ensuring the safety of the pharmaceutical supply chain by producing informational labelling for prescribers and consumers that is consistent with the terms and conditions of a drug's approval.

Pharmaceutical manufacturing is a large global industry. In 2003, worldwide pharmaceutical industry sales totalled $491.8 billion, an increase in sales volume of 9 percent over the preceding year (IMS Health, 2004). The U.S. represents the largest single national market for pharmaceuticals, accounting for 44 percent of global industry sales in 2003, or a total of $216.4 billion, which was an increase of approximately 12 percent from the previous year's figure (IMS Health 2004).

Wholesale distributors purchase drugs from manufacturers. For branded products, the purchase price is fairly uniform, with little negotiation on the part of the wholesale distributor. The distributor typically purchases branded products for a discounted rate off of Wholesale Acquisition Cost (WAC). Examples of discounts for branded products include volume discounts, prompt pay discounts, and discounts related to the sale of short-dated products (because the wholesaler is assuming a risk that the product will expire before it can be resold). The wholesale distributor then sells the product to its end consumer, typically a pharmacy, at WAC plus some negotiated percentage.

For generic products, the purchase price is highly variable, largely depending upon competition in the class and the ability of the wholesale distributor to drive market share or increase the volume sold. In this case, wholesale distributors play a larger role in the negotiation of the price of the product. The price to the end consumer also is highly elastic depending upon the negotiated contracts with the retail pharmacies.

Pharmaceutical retail business in Ghana is fully privatised and is conducted by (i) Pharmacies that employ registered pharmacists and which can dispense Prescription only Medicines (PoMs); and (ii) Chemist shops; managed by pharmacy technicians and which dispense OTC products solely. Given the high popularity and 'cash cow' nature of OTC products in Ghana, reportedly even the principal teaching hospital in Accra has commenced selling OTC products. Pharmacies are regulated by the Ghana Pharmacy Council, but it is not clear who regulates Chemist shops. Many countries in the sub-region have a problem with street peddling of pharmaceuticals. According to the Ghana FDB, Ghana has a 'relatively' safe retail pharmaceutical supply chain and does not have a major problem with street trading of pharmaceuticals, although this does occur to some extent in rural and peri-urban areas.

CHAPTER THREE

METHODOLOGY

3.1 Introduction

This chapter discusses the basic concept central to research methodology as well as presents the methods that have been used in the study. The intention is to give a representation of the plan for the study used as a guide in collection and analyzing data. The purpose of selecting these methods is to ensure the study is cost effective and relevant to the problem

3.2 Research approach

The consideration for the study was weather to use a *deductive* or an *inductive* research approach. The deductive approach implies that a number of hypotheses are formed based on existing theories and are therefore tested in reality; this is in order to examine if theories have any accordance with reality. The inductive approach implies that general conclusions are made with empirical facts as a base. This means that empirical data first is studied and then connected to the theory.

Pharmaceutical supply chain is a complex phenomenon that has experienced rapid growth in present times. As the researcher decided to study a complex phenomenon, that has experienced a rapid growth the recent years, the inductive approach was found most appropriate, i.e. empirical data was first collected and then sought to explain the empirical data by finding relevant theories. By choosing the inductive approach, the researcher was able to gather information about the phenomenon that was not determined or specified by a certain theory, thus the researcher was able to

investigate the phenomenon in depth, without any pre-determinant view on the phenomenon compared to the deductive approach (Yin 2003; Saunders 2000; Holme & Solvang 1997 cited in Jalal 2007; Engström & Slico 2008)

3.3 Quantitative and qualitative methods

In conducting a research, one is faced with the option of using either a quantitative and qualitative method (Holme et al., 1997; cited in Engström & Slico 2008). The quantitative method is structured and formalised, and recognized by selectivity and distance in relation to the source of information. A researcher using quantitative data examines many objects in few considerations, with an objective perspective. By doing this the researcher strives to generalize the gained knowledge and reality. Consequently the method's result is broad and can be used in statistical manner.

The qualitative method is much less formalized and its primary purpose is to create a deeper understanding about the problem area. In contrast to quantitative methods the researcher examines one or a few objects in many considerations. Further the researcher strives to describe the objects in its entirety with a subjective perspective. Qualitative methods are recognized by the nearness to the source of information. Information, which is mediated through words, can be called quantitative.

The problem under study is rather more complex and could vaguely be expressed in quantitative terms. Further we want to get a deeper understanding of the ACT supply chain and also get to describe the objects in its entirety. Consequently the study requires a qualitative method. Using a quantitative method will not be justified in this

study, first because it will be far too complicated and time consuming. Second, ACTs supply chain is a new phenomenon, it will be difficult to find enough respondents in order to perform a quantitative research. All the same, risks in the chain will be ranked and used in an analytical hierarchy process model.

3.4 Types of Research

Depending on the nature of the problem and its structure, the research will be determined as an *explorative*, *descriptive* or *causal* research. Explorative research is conducted to get a better understanding and clarify the nature of ambiguous problems. Similarly, an exploratory research is appropriate when the problem is difficult to demarcate and when there is no a clear apprehension about what model should be used. It is particularly helpful in breaking broad and vague problems into smaller sub-problems, helps to eliminate ideas that are not practical and establishes priorities for further research (Zikimund & William 1994; Holme et al.1997 cited in Engström & Slico 2008).

The main purpose of descriptive research, as the name implies, is to describe characteristics of a population. It is concerned with determining the frequency in which something occurs or the relationship between two variables. A descriptive research seeks to answer questions like who, what, when, where and how. Unlike exploratory research, descriptive studies are based on some previous understanding of the nature of the research problem (Zikimund & William 1997). The main goal of causal research is to identify cause-and-effect relationship between variable. Exploratory and descriptive researches normally precede cause-and-effect

relationship studies. In causal studies researches typically have a expectation about the relationship to be explained (Zikimund & William 1994).

The nature of this research determines an exploratory research. This is due to the rather vague research and the difficulties to demarcate. It is concluded that there is the need to gain better understanding of the dimensions of the problem as well as to receive a fundamental knowledge of ACT supply network. However, the study will also contain descriptive elements.

3.5 Research Design

The choice of research design depends on how the information should be gathered and analyzed. It can be described as a choice between depth, width and time span of a research. A researcher may choose from four general categories of explanatory research methods, in order to obtain insight and gain a clearer idea of the problem: *(1) Literature search, (2) focus group interviews, (3) case studies, (4) experience surveys.*

A *literature search* is a search of statistics, books and articles in order to obtain data or get insights into the problem. *Focus group interviews* are an elaborate kind of study, where six to ten people are brought together in a loosely structured format with the purpose to discuss a certain issue. The discussion is lead by a moderator and the people in the focus groups are consequently exposed to each other's ideas. Information obtained in these studies is qualitative and serves to guide subsequent quantitative study. The third method is *case studies*. This exploratory research

technique implies that the researcher intensely investigates one or a few situations similar to the problem situation. The primary advantage of the case study is that a complex situation or entity can be investigated in depth with meticulous attention to detail (Zikimund & William, 1994; Yin 1994). An *experience survey* implies that individuals who are knowledgeable about a particular research problem are questioned. The purpose is to help formulate the problem and clarify concepts rather than develop conclusive evidence.

Since we have a limited amount of experience and knowledge about pharmaceutical supply chains, and ACT supply chain in particular, there was a great need of performing a literature search as well as an experience survey. Initially, we studied a large amount of books, articles and exiting studies on ACTs supply chain. Then we perform experience surveys, in which we talk to knowledgeable individuals in the field of ACTs. Through this exploration, the researcher gain a great knowledge of the actors, flow processes, activities, resources and the managerial processes mapping of the chain.

Before each experience survey interview we sent the questions via mail to the interviewee, and explained the purpose of the research. During the interview, the interviewee was allowed to talk freely and the researcher was careful not to ask leading questions or negative questions and not to influence the interviewee with body language. This was to ensure an objective and neutral interview as possible. The interviews were not recorded but short notes were taken and immediately after the interview the full findings were wrote with intermittent call back via phone for

answers that were not clear In total, 12 interviews were conducted during the study period in addition to a considerable number of articles The interviews were held either personally and via phone which lasted between one and two hours each Seven questionnaires were also administered to local drug stores, upon which KAMA Pharmacy Division – KNUST was chosen for an Analytical Hierarchy Process to determine which factors are detrimental to the ACT supply chain The choice of KAMA pharmacy was made because it was found to have a perfect linkage with a sole partner upstream and was practicing a single source strategy which was a good structure for the study All the others were loosely networked to their supply source

At the end of each interview, the interviewees were asked of other people they could recommend us to interview After administering the 7th questionnaire the researcher felt that the following interviews did not contribute with any additional relevant information, and thus, decided to stop there

3.6 Analytic Hierarchy Process

The Analytic Hierarchy Process (Saaty, 1980, cited in Coyle, 2004), is a powerful tool that may be used to make decisions when multiple and conflicting objectives/criteria are present and both qualitative and quantitative aspects of a decision need to be considered The AHP considers a set of evaluation criteria and a set of alternative scenarios among which the best decision is to be made It generates a weight for each evaluation criterion and scenario according to the information provided by the decision maker The AHP combines the objective and scenario evaluations determining a ranking of the scenarios An example of such a hierarchy

is presented in *Figure 3.1*. At the top level, a goal is specified, in this case ACT supply chain vulnerability.

The STUDY'S AHP STRUCTURE

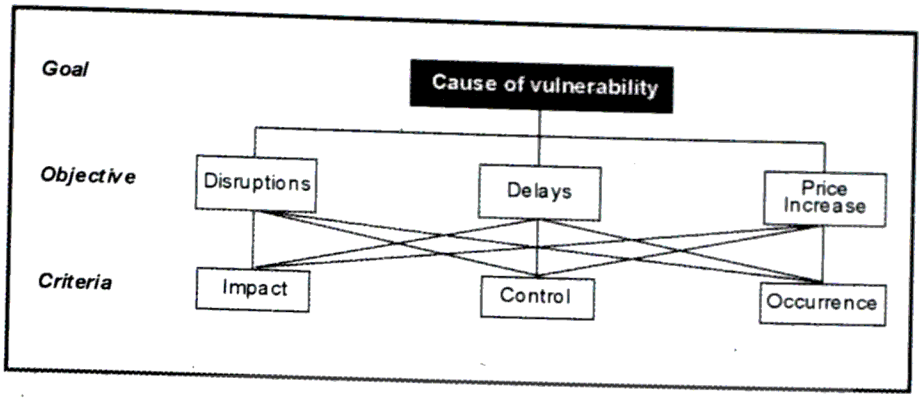

Figure 3.1
Source: Adopted from Coyle 2004

The AHP was used to select the factor among the three stated factors that affects the ACT supply chain worst of all based on a given decision criteria – control, occurrence and impact. Criteria are regarded as mutually exclusive and do not depend on the elements below them in the hierarchy. Criteria can be subjective (such as impact of trees price increases on ACT supply chain venerability) or objective (such as disruptions cost), depending on the means used in evaluating the contribution of those criteria below them in the hierarchy. The study looks at the subjective aspect which determines the degree of influence the factors have on the chain/network. The AHP combines the objective and scenario evaluations determining a ranking of the scenarios.

The essence of the AHP in this study is to construct a matrix expressing the relative values of a set of attributes. For example, what is the relative importance to the ACT supply chain vulnerability of disruptions as opposed to price increases? Selected

actor is tasked to choose whether disruptions are very much more important, rather more important, as important, and so on down to very much less important, than price increases. Each of these judgements is assigned a number on a scale. One common scale (adapted from Saaty) can be found in on *Table 3.1*. A basic, but very reasonable, assumption is that if attribute A is absolutely more important than attribute B and is rated at 9, then B must be absolutely less important than A and is valued at 1/9.

These pair-wise comparisons are carried out for all factors to be considered, usually not more than 7 and the matrix is completed. The next step is the calculation of a list of the relative weights, importance, or value, of the factors, such as disruptions and delays, which are relevant to the problem in question (technically, this list is called an eigenvector). Further, a Consistency Ratio (CR) is calculated to measure how consistent the judgements have been relative to large samples of purely random judgements. If the CR is much in excess of 0.1 the judgements are untrustworthy because they are too close for comfort to randomness and the exercise is valueless or must be repeated.

The final step is to use standard matrix calculations to produce an overall vector giving the answer we seek, namely the relative merits of control, impact and occurrence vis-à-vis the delays, disruptions and price.

Table 3.1: Saaty's scale

Intensity of importance	Definition	Explanation
1	Equal importance	Two factors contribute equally to the objective
3	Somewhat more important	Experience and judgement slightly favour one over the other.
5	Much more important	Experience and judgement strongly favour one over the other.
7	Very much more important	Experience and judgement very strongly favour one over the other. Its importance is demonstrated in practice.
9	Absolutely more important.	The evidence favouring one over the other is of the highest possible validity.
2, 4, 6, 8	Intermediate values	When compromise is needed

Source: Adopted from Saaty 1980 cited in Coyle 2004

3.7 Research Quality

To be able to determine the quality of the research, the validity and reliability of the research must be examined. The researcher has consciously worked throughout the process of writing the thesis with the aim of attaining high quality on the research.

3.7.1 Validity: Validity can be defined as to what extent the research is measuring what it is supposed to measure. There are three forms of validity; construct, internal and external (Yin 2003, p34 cited Engström & Slico 2008).

The construct validity is defined as establishing the correct operational measures for the concept being studied (Yin 2003, p35). By having triangulation, i.e. multiple sources of evidence, we can ensure increased construct validity in the research. The researcher interviewed several actors and reviewed many articles within the ACT supply chain to obtain different perspectives, and thus, different views could be

analyzed with each other and able to obtain a deep insight in the phenomenon. Moreover, the key interviewees were contacted via phone after the interview for clarification to guarantee that no misinterpretations or misunderstandings of the interviews have occurred. The internal validity is defined as the extent to which the results obtained within the study are true (Ghauri et al 2005 cited in cited Engström & Slico 2008). The internal validity should only be considered in causal (or explanatory) studies, in which an investigator wishes to determine whether event x led to event y (Yin 2003, p36). As our study is neither causal nor explanatory, we will not discuss the internal validity further.

The external validity is defined as the domain to which a study's findings can be generalized (Yin 2003, p36). Generalization in terms of inferring conclusions to a greater population is not of interest in a case study (Saunders et al 2003 cited Engström & Slico 2008). The purpose of this research is to understand a specific phenomenon in depth. Thus, it is not possible for us to generalize the conclusions as we can only draw conclusions specific for the ACT supply chain. One might argue that our conclusions might be applicable to all antimalarials, but the researcher believe that this is not the case as the WHO approved ACTs differ from other antimalarial supply chains, such as locally manufactured antimalarials, with respect to different supply chain, key actors in the network and ACT trade not progressing equally successfully in all markets. However, generalization is not relevant in our case as it is not within our interest to generalize the conclusions.

3.7.2 Reliability: Reliability is defined as to what extent the study can be repeated with same results. The goal of reliability is to minimize the errors and biases in the study. One prerequisite to achieve reliability in a case study is to document the procedures (Yin 2003, p37-39 cited Engström & Slico 2008). To reach a high reliability in the study, we have carefully documented the whole process throughout the research. To minimize the risk of biases from the interviews, interviewees were called for further clarification. The key interviewees were high level personnel in the ACT supply chain whose information the researcher believe are authentic. The study also found that the reliability increased with one of the interviewee knowing the ACT network as a result of earlier survey conducted in the private channel of the network. This facilitated obtaining richer information from key actors.

Reliability can be referred to the construct validity, where the reliability increases when the construct validity is high. Consequently, we claim that the reliability of the research is high as well and that another researcher would obtain the same result conducting the same research with same method (Yin 2003, p 105). The sources of information can always be questioned in a study. The reliability and validity in the conclusions can always be influenced during the research. However, the researcher believes that we have chosen a satisfactory method given our purpose and resources.

The researcher is aware of the fact that a study, which on such a high level is dependent on interviews, may not reflect an entire objective perspective of the Artemisinin-based Combined Therapies supply chain as each actor is driven by personal interests. By being aware of this, and interviewing a wide range of actors

with different perspectives, the researcher believes that a reasonable insight into the ACT supply network has been captured.

CHAPTER FOUR

FINDINGS AND ANALYSIS

4.1 Introduction

In this section, the empirical findings will be presented based on three main research themes namely network, legislation and risks. The ACT supply chain network will be presented by explaining the actual activities for each actor within the chain.

The section will also present a qualitative analysis of the empirical data and the theories. This will validate the adoption of an inductive approach stated in chapter 3. Thus the general conclusion will be made with empirical facts as a base. The analysis as much as possible will be presented in the same order as the theories. Starting with the ACT network; continuing with the supply chain, the legislation and finally risks in the chain.

This presentation will therefore allow interested parties to obtain a comprehensible overview of the processes behind ACT supply network and also understand the phenomenon through the perspective of each actor – from farmer to patient.

4.2 FINDINGS

Artemisinin-based combination therapy (ACT) uses a combination of anti-malaria drugs, one of which is an artemisinin derivative. The physical ACT flows downwards through the supply chain and consequently the drug payments flow upwards. The WHO monitors that all supply chain actors follow the agreed

international standards. WHO experts convened in Geneva on 4-5th April 2001, have reconsidered all current antimalarial drug combination therapies and recommended a short list of therapeutic options with potential for deployment. This preference was based on available safety and efficacy data. The following drug combinations available now, have the potential for deployment, if costs were not an issue: 1) artemether-lumefantrine; 2) artesunate (3 days) plus amodiaquine; 3) artesunate (3 days) plus sulfadoxine-pyrimethamine (SP) in areas where SP efficacy remains high; 4) SP plus amodiaquine in areas where efficacy to both SP and amodiaquine remains high.

4.2.1 Sources of Artemisinin

4.2.1.1 Cultivation - Artemisinin can only be extracted from ***Artemisia annua*** (sweet wormwood or Chinese wormwood), although efforts are being made to mimic the artemisinin biosynthetic process in a micro organism. Under the name 'Qinghaosu', it has been used in traditional Chinese medicine to treat fever for over 2000 years. The active molecule is a sesquiterpene lactone containing a bridged endoperoxide. The following chemical derivatives are important:

- two lipophilic derivatives : artemether and arteether;
- a hydrophilic derivative : artesunate;
- a metabolite : dihydroartemisinin.

These four derivatives have approximately five times higher potency than artemisinin, but a shorter shelf-life. Artemisinin and its derivatives work against

malaria parasites by being schizontocidal and gametocidal, with rapid action on all blood stages.

Artemisia annua is an annual herb endemic to Asia, most probably China. It occurs naturally as part of steppe vegetation in the northern parts of Chahar and Suiyuan provinces at 1,000 to 1,500 m above sea level. *Artemisia annua* is cultivated as an annual crop in China and Vietnam as a source of artemisinin, and in Romania and Bulgaria for its essential oils. It is also cultivated on a small scale in the United States as a source of material for aromatic wreaths (Janick, 1995). The best plants are found in the wild only in certain parts of China, such as Guangxi and Hunan, which (along with Vietnam) produce most of the world's supply. In China, firms such as Guilin Pharmaceuticals are stimulating the cultivation of the plant, both on their own plantations in Chongqing and through contracts with local farmers, rather than relying on the collection of leaves from wild sources.

Chinese scientists started to domesticate the wild species of *Artemisia annua* after the curative effect of artemisinin was discovered in 1972. Vietnam and Thailand followed in the 1980s. In 2004, China claimed that it was growing a total acreage of 2,000 hectares of *Artemisia annua*. Recently, Novartis stated that China is taking the lion share in a total cultivated area in Asia of 9 000 hectares, but this statement has not been verified. It is generally thought that China still collects some of its *Artemisia annua* from the wild. Vietnam is growing *Artemisia annua* on some 1,500 ha through three main producers, while some production is also reported from India.

Production has also started in West Africa, notably Ghana and Gambia, and an extraction plant is planned for Senegal. In Brazil, the production of *Artemisia annua* is being promoted, while the crop has been grown in the United States and Australia on an experimental scale. *Artemisia annua* is also collected in Eastern Europe for the extraction of essential oils for the perfume industry. The plant is increasingly grown for this purpose in such countries as Romania and Bulgaria.

Table 4.1: Estimated production of *Artemisia annua*

Country	**Acreage in 2004 (ha)**	**Total acreage in near future (ha)**
China	2 000	5 000
Vietnam	1 500	2 000
India	100	200
Kenya	400	2 000
Tanzania	200	1 000
Uganda	0	500
Eastern Europe	500	500
Total	**4 700**	**11 2000**

Source: Adopted from Heemskerk et al. 2006

Artemisia annua was introduced in Tanzania in 1994. Since then, large-scale farmers have been experimenting with its production elsewhere in East Africa, notably Kenya, Tanzania and Madagascar. In recent years, experiments have taken place in other 20 or so countries, mainly in sub-Saharan Africa; however, most of the efforts have remained rather small scale, sometimes for the local consumption of *Artemisia annua* tea.

4.2.1.2 Cultivation requirements of Artemisia annua – A. annua is a labour-intensive crop whose cultivation requires close attention to detail, especially at planting and harvesting time:

- it has a tiny seed (12-14 thousand seeds per gram) which must be germinated in a well-managed nursery;
- the seedlings are delicate and must be planted out with great care into a well prepared seedbed, at a density of 3-4 plants per square metre (30-40 thousands plants per ha);
- control of weeds around the young seedlings is critical: weeding may need to be done 3-4 times by hand before the canopy is formed;
- irrigation may be needed if there is any risk of water stress, especially in the four weeks after transplanting;
- harvesting, which is normally done by hand, must be precisely timed for just before the plants begin to flower; if left too late, the artemisinin content in the leaves falls off rapidly; and
- the crop must be dried in the field or store: the leaves are then stripped off by hand or stick or by driving a tractor over the plants. The process must be rapid to avoid the deterioration and loss of the artemisinin content.

Yields of *Artemisia annua* vary according to the variety planted and various growing factors, such as altitude, precipitation, soil moisture, soil type and farmer management. One of the major determinants of the yield is the quality of seed: '*pure*' F1 seed of a superior hybrid produces significantly higher yields in terms of leaf foliage, which also has higher concentrations of artemisinin than the second-

generation F2 hybrid seed. If all these factors are averaged and applied by quality of seed, then a world peak demand of 400 million adult treatments will require between 17 000 and 27 000 ha.

4.2.1.3 Production in micro organisms - Several universities (e.g. Wageningen University Research Centre and UC Berkeley) are carrying out research on the process of biosynthesis of artemisinin in plants. The common aim is to discover the biosynthetic process and the various enzymatic steps and the corresponding *Artemisia annua* genes. The elucidation of the biosynthesis of artemisinin can contribute to enabling artemisinin production in micro organisms as well as the breeding of new varieties of *Artemisia annua*, which are more efficient producers of artemisinin. Presently the plants are relatively inefficient producers of artemisinin, but the content can potentially be doubled.

Three San Francisco Bay Area entities have teamed up with France based pharmaceutical company sanofi-aventis to combine their unique, complementary expertise to develop semisynthetic artemisinin. Their synergistic approach applies cutting-edge technology to create a source of semisynthetic artemisinin for use as a raw material in artemisinin-based combination therapies, the most effective—but presently too expensive of the known antimalarial treatments.

The Institute for One World Health is the product development lead and has responsibility for directing this collaborative effort; as well as lead the project's public policy and global access goals. *Amyris* is optimizing the microbial strain and

using it in the development of a manufacturing process to make high quality semisynthetic artemisinin. *Sanofi-aventis* is providing fermentation and chemistry process development expertise, and if technical benchmarks are achieved, will develop an industrial manufacturing process for semisynthetic artemisinin. *The University of California at Berkeley* has utilized synthetic biology to develop a microbial strain to produce artemisinic acid. The University of California at Berkeley completed its portion of the development efforts in December 2007. By combining their capabilities, the partners will work together to develop a manufacturing process for semisynthetic artemisinin. Ultimately, the goal is to produce hundreds of metric tons of artemisinic acid by fermentation, for subsequent chemical conversion to artemisinin. Together, this unique partnership will help ACT producers deliver life-saving medicines into the hands of people with malaria in the developing world.

The consortium of UC Berkeley (for the technology), Amyris Biotechnologies of the Albany Company (for the manufacturing) and One World Health Institute (for the clinical trials) is funded (USD 43 million) by The Bill and Melinda Gates Foundation (BMGF). Using this technology, the partnership expects to bring down the cost of artemisinin combination drugs to a fraction of the US$ 2.40 per adult course of treatment for patients in developing countries.

4.2.1.4 Synthetic production - The University of Nebraska Medical Centre (Vennerstrom et al., 2004) has come up with a five-step chemical process to make compounds that can mimic the action of artemisinin derivatives. One of them, OZ-277, a synthetic ozonide derivative of artemisinin, has proved more effective than

artemisinin itself in both the test tube and in animal models of malaria. The target is to produce OZ-277 as cheaply as possible (at less than one-tenth of the cost of present ACTs). Difficulties with making a water-soluble version that can be swallowed have been overcome, and the drug is being tested in Thailand. Regulatory submission was expected to be filed in late 2007 or early 2008, with approval taking a further 12 months. The drug is expected to be on the market in 2010, if all clinical stages of the trials go as expected. Participants at the meeting were very interested in the possibilities for other sources of active pharmaceutical ingredients for ACTs.

4.2.2 Extraction and Manufacturing of ACTs

After a successful production of the *Artemisia annua* plant, the next stage is the extraction and further manufacturing of the drug. The extraction is to take place in the country of production, mainly because, the export of the bulky leaves would be too costly, although some suggest that this could be offset by enhanced quality when extracted in Europe (e.g. UK experience with the extraction of leaves from Tanzania). Interviews with Novartis and GlaxoSmithKline indicate that companies are keen to recover their costs only and are not expecting major returns except in terms of goodwill. The company's definition of recovering costs could however not be pursued, notably whether these costs include all investments in Research & Development, as well as activities to compile a file for compliance with the pre-qualification criteria. Other (smaller) companies have however to compete in this market in which profits are necessary to survive

4.2.2.1 Extraction - TechnoServe has compared different extraction methods relevant for the establishment of plants in Uganda, Kenya and Tanzania. Each extraction plant will be able to process 2 500 tons of dry leaves, with a potential extraction capacity of 25 000 kg of artemisinin each. The plants are being established by Advanced Bio-Extracts and financed and technically supported by Novartis, also to make the process GMP certified. According to TechnoServe the investment costs are USD 6 million for each plant; the annual operating costs will amount to approximately USD 3 million. Mixed solvent extraction and carbon dioxide extraction have shown the best internal rates of return (IRR), namely of 41 % and 26 %, respectively, which were subjected to sensitivity analysis for raw artemisia leaves.

4.2.2.2 Manufacturing - In May 2002, in collaboration with other United Nations agencies, WHO established an international mechanism to pre-qualify manufacturers of artemisinin compounds and ACTs on the basis of compliance with internationally recommended standards of manufacturing and quality. Products and manufacturers that meet these standards are included in a list considered acceptable for procurement by United Nations agencies. The list is published as a guide to governments, NGOs and other partners, e.g. the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), procuring ACTs. To date, one ACT – artemether–lumefantrine (Coartem®) – has been pre-qualified (WHO, 2006).

WHO and UNICEF place regular calls for tenders of co-blistered combinations of the following products for which there are not yet pre-qualified manufacturers: i)

artesunate plus amodiaquine; ii) artesunate plus sulfadoxine/pyrimethamine; iii) artesunate plus mefloquine; and iv) amodiaquine plus sulfadoxine/pyrimethamine. Several manufacturers have been inspected by WHO and GMP-certified products for all of the above ACT are being procured by both WHO and UNICEF, including for GFATM supported programmes.

Since 2001, Novartis has supplied more than six million treatments of artemether-lumefantrine on a non-profit basis for distribution to the public sector in malaria-endemic developing countries. Production of Coartem, currently the leading artemisinin-based combination therapy (ACT), has increased from 100,000 treatments in 2002 to a projected 30 million treatments in 2005. The original 2001 agreement between Novartis and the WHO forecast demand for Coartem at just over two million treatments in 2005. Since then, non-binding demand forecasts provided by WHO have continuously increased, including a six-fold jump in the 2005 demand forecast between December 2003 and March 2004. In this three month period, the WHO demand forecast surged from 10 million to 60 million treatments.

4.2.3 Artemisini-based Combined Therapy pipelines in Ghana

There are basically two main supply channels through which ACTs enter the Ghanaian pharmaceutical system. These are the formal (public) and the informal (private) conduits. The *public sector* operates a formalised three-tier system for the management of ACTs. The Central Medical Stores (CMS), the Regional Medical Stores and service delivery points (SDPs) together with the transportation network constitute the pipeline for the supply chain. The customers here are either internal

(for CMS the customers are the RMSs, and for the RMSs the customers are the SDPs), or external (patients and clients who seek services at the health facilities). The interactions within the tiers lead to the exchange of health commodities (goods) and/or services, and these transactions have to be properly documented, followed, audited, and/or reviewed through a systematic supervisory and monitoring schedule. Currently, Artemisinin-based Combined Therapies are purchased by the CMS through international competitive bidding (ICB). The RMSs and teaching hospitals are meant to procure medicines through the CMS and from the local private sector in cases of unavailability. All the regional hospitals and SDPs are in turn meant to procure from the RMS in their respective regions. The budget for antimalarials is currently provided through the Global Fund to Fight AIDS, Tuberculosis and Malaria.

The *private ACT distribution* pipeline comprises the importers, wholesalers, the retail outlets and the transportation network linking all three levels. It is not unusual to have a combination of wholesale and retail units operating as a conglomerate or a business concern that has an importing unit as well as wholesale and retail outlets.

Global initiatives are taking place to ensure access to essential medicines; particularly Artemesinin-based Combination Therapy (ACTs). One of the initiatives being distribution of subsidised ACTs through the private sector (particularly drug shops). Malaria in Ghana is now largely treated outside of the public health system and through chemist shops due to traditional consumer health seeking behaviour and costs of accessing qualified medical practitioners. ACTs were recently removed from

the Ghana Prescription only Medicine (PoM) list and declassified to Over the Counter (OTC) for this reason, so as to enable better population access to medicines including the promotion of home-based care. The private sector supply chain actors are mostly funded through rebate and other credit facilities. Mission hospitals and NGOs may choose to procure from the formal route or the private streams. They have no prescribed routes although many of such institutions may adopt the formal; but quickly change to the private route when shortages and delays set in.

4.2.4 Drug Legislations and regulations

The Food and Drugs Board is the national regulatory body under the Ministry of Health with the responsibility of implementing Food and Drugs Law of 1992, (PNDCL 305B) to regulate the manufacture, importation, exportation, distribution, use and advertisements of food, drugs, cosmetics, medical devices and household chemicals with respect to ensuring their safety, quality and efficacy. In exercising this mandate, the Board ensures the safety and wholesomeness of foods we eat. It is in this capacity that the board, as a follow up to the press conference of 6th July 2009 held in Kumasi, warned the public of the fake Coartem tablets circulating in Kumasi. This fake Coartem does not to contain Artemether and Lumfantrine – the main active ingredients of the original Coartem (Food and Drugs Board, 2009).

The Doha Declaration Paragraph 6, offer Ghana an option if Ghana decides against using its local industry for the production of generic medicines. While some critics have viewed this provision favourably, others have criticized it as too administratively complex for developing countries. The implementation of the

Paragraph 6 Decision requires a number of steps, among which include: 1) in most cases, compulsory licenses issued by importing and exporting countries, 2) the importing country's establishment of insufficient or no local manufacturing capacity in the specified pharmaceutical sector, 3) importer notification to the WTO of its intention to use the system detailing product(s) requested and quantities (accompanied by confirmation of insufficient manufacturing capacity and that a compulsory license is or will be granted) and 4) notification of the exporting country's compulsory license to the WTO and the conditions attached (Republic of Ghana: Act 657). Paragraph 4 of the Decision requires the importing country to "take reasonable measures within their means ... to prevent re-exportation"; this requires countries to implement anti-diversion measures including special marking and labelling of the product(s).

4.2.5 Information systems and transportation

In the public sector information flow of reporting is from the lower levels to the upper levels. Information on consumption and stock balances is communicated to the Regional Directorates after submissions are made to the DHMTs. The reports are also forwarded to the Office of the Chief Pharmacist on a quarterly basis. Reporting of this information needs to be synchronized with the reports required to be sent NMCP. Information on consumption for all health commodities for the management of malaria needs to be channelled to NMCP and the medicine component should go to the Office of the Chief Pharmacist and the Director, Procurement and Supply Directorate. The private starts with the drug stores/pharmacies to the wholesaler; then to the importer who orders from Novartis or other foreign prescribed outlet.

The transportation network is not fixed in the informal sector. Pharmacies most often pick their orders by their own means; but at times when bulk purchases are made they are cart to the pharmacies for free or as per the negotiation. In the public sector, lower-level facilities (especially the health centres) rely on the District Health Administrations (DHAs) to provide transport. The DHAs usually use a four-wheel-drive double cabin pickup truck. Each DHA has at least one double cabin pickup truck. At the regional level, all Regional Health Administrations – to which the RMSs are administratively linked – have 7-ton trucks to cart health commodities from the CMS to the RMS.

The CMS is currently working toward providing no-charge transportation to the RMS through a scheduled delivery system using 7-ton trucks. The RMS in turn would focus the use of its trucks to transport health commodities to the SDPs. At present, however, the CMS has only five 7-ton trucks and a 35-ton articulated truck, which are used to transport all health commodities to the regions. No contract arrangements exist for transport for the Regional or District Health Administrations with parastatal or commercial agencies.

4.2.6 ACT network from the Pharmacy Perspective

Kama Health Services Ltd. was established on 24th January, 1983, to carry out the business of manufacturing of drugs, animal and vegetable farms for protein and vitamins, operating a clinic and management consultancy on health services. Within the period of a decade, the Company have established four large branches in Kumasi. Kama Health Services hold distributorship license for 8 international manufacturers

including Almiral Prodesfarma (Spain) Phargon (Holland) XL Laboratories PVT (India) etc. The KAMA pharmacy division on Kwame Nkrumah University of Science and Technology serves the pharmaceutical needs of the university community. With just about a staff of three, the outlet retails lots of drugs including KAMA's own brands or manufactured items. One of these drugs is an antimalarial called Lumet. ACTs on sale at the time of conducting the study include Lonart, artesunate+amodiaquine, artesunate+sulfadoxine-pyrimethamine(SP). Coartem was available due to the speculation of fake ones on the market.

Artesunate+sulfadoxine-pyrimethamine, Artesunate+amodiaquine and artesunate+sulfadoxine-pyrimethamine(SP) were out of stock and restocking was not in the know because it is believed the introduction of the Coartem has led to the poor patronage of the three combined co-blister packs. Coartem was not on the shelves possibly due to a recent press release on fake Coartems on the Kumasi market by the Foods and Drugs Board. Demand almost always outstrips supply for Coartems. The pharmacy admits Coartem is in high demand even at a high price of GHC 9.00 which represents mark-up of 20% of the wholesale price. It is believed the drug sells as high as 45% of wholesale value elsewhere (This fact was identified through price tags on used packets that were brought into the pharmacies for repurchase).

The pharmacy takes its orders from the KAMA wholesale division on credit bases since they represent the forward integral group of the wholesale division. Payments are effected after sale of the drugs. Other retail outlets negotiate differently. Credit facilities and discounts are admittedly given to some family relations, friends and

doctors. The wholesale division procures Coartems from an importer (East Cantonment Health) and redistributes to the various KAMA pharmacy points including other pharmacies and chemical stores which are not under the umbrella of KAMA. Although, the company does not inform the wholesale division about the state of stock in real time, they have a personal computer with its accompanying software –Medbiz which takes care of their inventory and prompts them when they reach re-ordering points. Requisitions are done over the telephone or personal presences at the wholesale premises.

A quick survey of eight pharmacies in the Akwapim South district revealed slightly different picture from the KAMA pharmacy. The study revealed a significant number of chemical stores over pharmacies. These chemical outlets are not allowed to sell class A and B drugs, but thanks to the drug policy, ACTs are allowed to be sold as counter drugs so most of them retail some ACT drugs accept for Coartem. The reasons for not stocking Coartem were due to the high price and the fake drug scare.

Almost all of outlets procure from multiple sources and these include: Ernest Chemist, Tobinco Pharmacy, Osons Chemist, M&G Pharmaceuticals, Danadams Pharmacy, Delight Pharmacy, Darose and Komsam Pharmacy. The relationship between the chemical stores and the wholesale is basically weak but a wholesaler like Tobinco goes the extra mile to give out 14-day credits to clients and also provide transportation through its distribution vans every other week. The Tetteh Quarshe Memoial Hospital (TQMH) pharmacy enjoys up to 30 days credit period on ACTs delivered to them. On the shelves, the study found a combination of both mono and combined therapies. These included Artesunate, Artemos, Lonart, Alaxin,

Artesunate-Amodiaquine, Metakelfin, Camosunate, Malafan, Gvither and Fansidar. Drugs are sold at mark-ups ranging between 5 and 10%. Communication between partners was found to be through phone call or face-to-face interactions. Transactions at the stores are done manually except for the TQMH pharmacy which uses a clinical analysis software. Known regulatory requirements include the chemical & pharmacy act. Other regulatory requirements revealed were the internal revenue and district assembly levies which are thought to be too high and unnecessary respectively.

On the technical issues of expired drugs, the study found out that no appropriate measure is in place for the return of expired drugs for appropriate disposal. Wholesales do not retrieve from the shelves expired drugs and it becomes the burden of the chemical stores to dispose of it in their own way – mostly by burning which might not be environmentally friendly. In terms of risk, the pharmacy/chemical stores experiences virtually no encounter with drug related regulations directly. Importers and manufacturers are the most hit heavily when it comes to legislation; all the same the ramifications of such actions trickles down the chain in the form of shortages and high prices. Disruptions hardly occur, but when it does the impact is very significant.

The incidence of shortages recalled in the study has been to fuel shortages, especially with the public sector and the FDB fake drugs announcement. Price increases do happen but not very frequent and even when it does demand is affected less than proportionately, so the impact does not posse much of a problem to the supply chain. Operational risk was admitted to be very minimal based on the fact that there is weak

interdependence and collaboration between most of the pharmacies/chemical stores and the wholesale facility; and also because most of them adopt the multiple sourcing approach. Delays were also seen to occur more often. A consensual set of factors compiled based on views and comments under the circumstance revealed the following ranked on the scale of 1 to 5. The researcher believes that risk factors affecting the activities downstream are as a result of upstream activities. In this vain, a critical look at downstream risks will give us a greater insight into what risk factors to expect throughout the chain. The following risk factor rankings were derived from the study:

Table 4.2 Mean factor ranking

Pharmacy/Chemical Store	Op	De	Pi	Di	Lg
J. B. Tetteh Chemical Store	1	2	4	3	1
TQMH	1	3	3	1	1
Kama Pharmacy Division	1	3	2	4	1
Had Chemicals Store	1	3	3	2	1
M.B.A. Asiedu Chemicals Store	1	3	4	2	1
M.Mamfo Chemical Store	1	2	4	1	2
Doro Okyere Chemical Store	1	3	3	2	2
Finco Pharmacy	1	3	2	1	1
Mean ranking	**1**	**2.63**	**3.13**	**2**	**1.25**

Source: Author's field survey, 2009

OP – Operations De – Delays Pi – Price increases
Di – Disruptions Lg – Legislations

4.3 ANALYSIS

4.3.1 The ACT Supply Network

Although pharmaceutical standards do not stipulate that organisations that buy directly from upstream partners should sign contracts that allow for long-term planning and sustainable practices, the network is well integrated. Due to product quality, prompt delivery and rebates, bulk discounts, etc., pharmaceutical companies worldwide collaborate with one another to achieve a certain goal. From the empirical findings, WHO and Novartis collaboration with artemisia annua farmers help procure high content artemisinin for the production of Coartem. These and other benefits stress the importance of relationship and coordination between the actors within the ACT supply network.

The network theory also ranges network relationship from collaborative to largely transactional links. The transactional links are said to imply discrete exchanges of values where the major issue is price, epitomized in the economics buyer-seller relationships. Collaborative links may involve various forms of inter-organisational cooperation and partnering. From the findings the study showed that Novartis manufactures drugs on no-for-profit bases and most developing countries buy these drugs at extremely subsidized prices, giving a picture of a more collaborative nature of the network.

Again the ACT network depicts a strong evidence of actor interdependence and long-term relationships. This builds trust and collaboration as a key to a network robust 'netchain'. A lot more organisations end up taking part in different levels of the

network in a bid to control and strengthen their supply base. One such company is KAMA Health Services as stated in the findings. KAMA wholesale division has so much trust and keen in keeping the relationship with East Cantonment Pharmacy for their supply of Coartem that they will refuse to procure from any other importer even in the face of a shortage. They are prepared to wait and buy only from one source to avoid reselling fake drugs.

The network theory states that networks consist of a number of actors that engage in various activities. Each actor has its own set of resources. Analyzing the empirical findings, key actors for the ACT network can be identified; the WHO, Novartis farmer, importer, wholesaler, pharmacy and finally consumer. Figure 4.1 illustrate an overview of how the actors are related to each other. The activities that the actors engage in are the production and actual trading of the ACTs. Novartis is the only company manufacturing the fixed dose Coartem, other combination blister packs are subject to WHO/UN approval and procurement for onward supply to needy countries. Governments in the various countries also aid the smooth distribution of the drugs and makes sure they don divert to the private routes. Resources that the actors benefit from when engaging in these activities can be such as the payment in advance to the farmer, The Bill and Melinda Gates Foundation, credit facilities to distributors, etc.

Again net work theories clarify two distinctive types of supply networks relating to products that are 'innovative-unique' (such as drugs, communication technology and electronics) and 'functional' (such as canned soft drinks, brake cylinders and car

window wipers). ACTs are innovative and unique drugs due to their efficacy in dealing with the malaria situation currently worldwide and the fact that it is by approval of a world body – WHO. ACTs are drugs that can be traced to only one source.

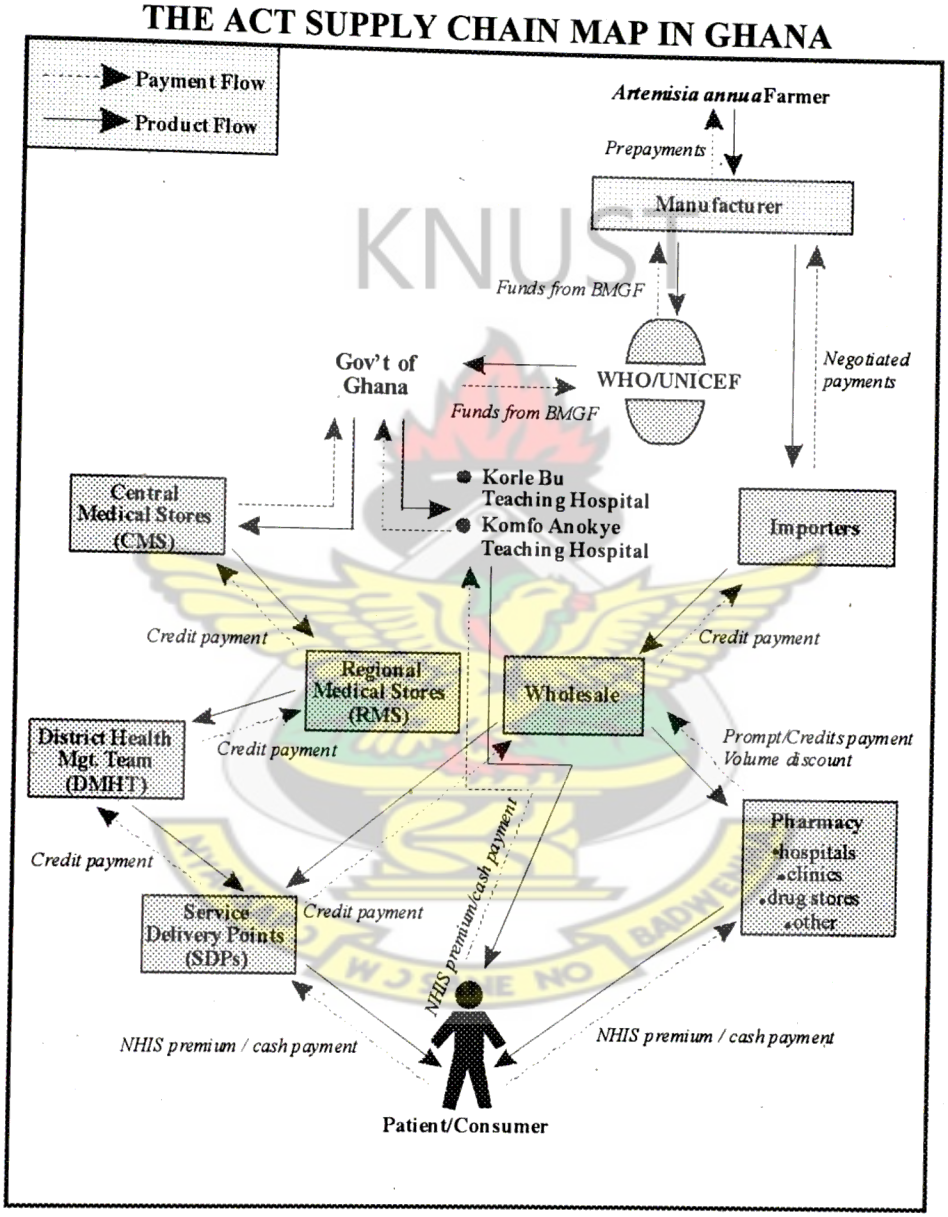

Figure: 4.1
Source: Author's construct, 2009

To sum up, the network theory is consistent with the empirical data when it comes to the fact that the network of ACT depicts strong collaborative relationship among actors. However, the network theory does not consider the characteristics in the relationship between the partners in the network. Since there is an excess demand over supply, the pharmacies are dependent on the wholesaler to engage in a relationship. This is also depicted further in the generally loose relationship between retail outlets and wholesalers from the study.

The supply chain theory states that supply chain is a sequence of events intended to satisfy a customer; and it includes procurement, manufacture, distribution and waste disposal, together with its associated transportation, storage and information technology. A robust supply chain requires a change from managing individual functions to integrating activities into key supply chain processes. The key enablers are information flow, logistics and funds flow.

The supply chain starts with the farmer. The farmer produces the Artemisia annua which includes planting, harvesting and extracting. After extracting, it is sold to the Manufacturer (Novartis and GlaxoSmithKline) who plays a key role in the supervision of the farmer. The manufacturer processes the raw materials into finished Coartem and co-blistered combinations funded by BMGF. Certified ACT are procured by both WHO and UNICEF, including for GFATM supported programmes.

The drug then enters Ghana through two known channels: private and public. The public routes make use of the CMS, RMS, DHMT and SDPs; whilst the private route

involves the importer, wholesaler and pharmacies (private clinics, drugstores, mission hospitals/NGO, etc). The pharmacies and the SDPs are the ones the end-customer meet when buying the drugs. From the study, it was released also that SDPs do procure from the private channels. This could be seen where TQMH makes orders from M&G pharmaceuticals, Ernest Chemist and Danadams pharmacy at credits ranging between 15 to 30days. This is can be made possible through the provision of a non-availability certificate and tendering.

The financial flows are all the money that each buying actor pays to the selling actor within the supply chain. Most of the finances in this particular chain are in credits, prepayments (to farmers) and funds from BMGF. The information flows represent orders of ACTs and the coordination of the ACT. Hence, these flows include information about the price, the delivery and the quality. In many of the ACT consuming countries fake drugs are common and this is something that importers, wholesalers, pharmacies and consumers are on the lookout for when evaluating received information. The material flows represent the flow of the physical ACT from the farmer via the manufacturer, the importer, wholesaler and pharmacy to the end-consumer. The physical ACT does not differ from other similar drugs in terms of characteristics.

The supply chain network, is supported by three pillars; *processes*, *organizational structures* and *enabling technologies*. The *processes* encompass all value-adding activities within the supply chain. The Artemisia annua farmer adds value to the product through planting, harvesting and extracting. Novartis/GlaxoSmithKline adds

value through processing the extracts. The importer adds value through shipping the ACT from abroad to the wholesaler. The wholesaler adds value by selling in bulk to the pharmacy. Finally, the pharmacy in turn forwards the ACT to the end-customer.

The *organizational structures* of the ACT supply differ from the other drugs. Although ACT prices are pre-stated, the final figure transferred to the final consumer depends on the negotiations made between the main purchaser and the manufacturer. Then also only pre-qualified manufacturer are used as source and the drugs are sold out to international organizations like WHO and UNICEF for onward distribution to developing countries like Ghana.

Regarding the *enabling technologies*, the Artemisia annua is a labour-intensive crop whose cultivation requires close attention to detail, especially at planting and harvesting time. Yields of *Artemisia annua* vary according to the variety planted and various growing factors, such as altitude, precipitation, soil moisture, soil type and farmer management. One of the major determinants of the yield is the quality of seed: '*pure*' F1 seed of a superior hybrid produces significantly higher yields in terms of leaf foliage, which also has higher concentrations of artemisinin than the second-generation F2 hybrid seed. The extraction must be perfect to meet GMP certification; then the high tech-processing is taken over by Novartis.

A concluding remark regarding the definition claimed by The Institute of Logistics made mention of waste disposal which is also captured in the findings. The researcher believes that since the drug has a shelf life of 24 months, there should be a

reverse logistics policy to take care of any expired drugs and any other eventualities. Nevertheless, Coartem and the other ACTs are always in short supply.

4.3.2 The ACT Legislation

The theory admits government regulations and compliance are cumbersome in dealing with due to the many requirements to be adept at understanding and ensuring compliance with the applicable statues and regulations. Importers especially must make do with a lot of legislative bottle necks before they can successfully register or partner a manufacturer for the right to ship in ACTs. The Doha Declaration Paragraph 6 Decision requirements are too administratively complex for the importer to be able to comprehend with. It is therefore not surprising there are just a handful of private ACT importers. We should not forget too that a majority of the people acquire their ACT drugs over-the-counter contributing to shortages with its admitted influx of fake drugs. Local manufacturers who can also be a relief for us are faced with WHO's international mechanism for pre-qualify of artemisinin compounds and ACTs on the basis of compliance with internationally recommended standards of manufacturing and quality.

4.3.3 Vulnerability of the ACT supply chain

According to theory, supply chains are prone to internal and external risks. Even from the pharmacy level as evidenced in the findings, a press release on fake Coartem in Kumasi by the Food and Drugs Board alone caused shortage of Coartem, thereby disrupting the flow of the drug to final consumers. Again, one of the major problems that the introduction of Artesunate-Amodiaquine combination faced some

time ago was the management of negative press reports of adverse events which nearly derailed the programme. A disruption of the ACT supply chain can also be caused as remotely as from the farmer level or from any of the stakeholders in the chain.

Ranking the various factors believed to militate against the supply network, the findings (Table 4.1) showed that disruption (Di), delays (De) and price increases (Pi) significantly contribute to the vulnerability of the supply chain. We can now consider the three major factors and use the AHP based on the criteria: control, occurrence and impact, to find out the factor which most affect the seamlessness of the ACT supply chain from the pharmacy level (KAMA pharmacy division was used as the yardstick for the AHP process due to their level of collaboration, relationship with wholesale division and the level of understanding of the research respondent at post).

The following data were gathered in the research and the pair-wise comparison ratings for each of the three criteria are summarized in the following matrices:

Table 4.3 Factor pair-wise matrix

Impact	Di	De	Pi
Di	1	3	7
De	1/3	1	5
Pi	1/7	1/5	1

Occurrence	Di	De	Pi
Di	1	1/7	1/3
De	7	1	5
Pi	3	1/5	1

Control	Di	De	Pi
Di	1	5	7
De	1/5	1	3
Pi	1/7	1/3	1

Source: Field survey, 2009

The 'impact' matrix indicates that disruption is very strongly detrimental to price increases; price is moderately detrimental to disruption in the 'occurrence' matrix, disruption is strongly detrimental to delays and also very strongly detrimental to price increase in the control matrix. Note that any factor compared to itself must be equally detrimental, this makes the values along the matrix diagonal all equal to 1.

The next step in AHP is to prioritize the factors within each criterion. This means we can determine which factor is the most detrimental, the second most detrimental factor and the third most detrimental factor within each of the three criterion. The synchronization is mathematically complex, but we can use an approximation method that provides a reasonably good estimate of detrimental scores.

The first step in doing this is to sum the value in each column of the pair-wise comparison matrix; and the values in each column are divided by the corresponding column sums as depicted on table 4.3.

Notice that the values in each column sum to 1. Next the values in each row are averaged and the row averages provide the company with their preferences for each criterion, summarized in the following matrix. For example, for the impact criterion disruption is the most detrimental; delay is the most detrimental in the occurrence criterion and finally in the control criterion disruption is the most detrimental to the ACT supply chain.

Table 4.4 Factor pair-wise summation matrix

Impact

	Di	De	Pi
Di	1	3	7
De	1/3	1	5
Pi	1/7	1/5	1
	11/2	**41/5**	**13**

Occurrence

	Di	De	Pi
Di	1	1/7	1/3
De	7	1	5
Pi	3	1/5	1
	11	**11/3**	**61/3**

Control

	Di	De	Pi
Di	1	5	7
De	1/5	1	3
Pi	1/7	1/3	1
	11/3	**61/3**	**11**

Impact

	Di	De	Pi
Di	0.68	0.71	0.54
De	0.23	0.24	0.38
Pi	0.10	0.05	0.08
	1	**1**	**1**

Occurrence

	Di	De	Pi
Di	0.09	0.11	0.05
De	0.64	0.74	0.79
Pi	0.27	0.15	0.16
	1	**1**	**1**

Control

	Di	De	Pi
Di	0.74	0.79	0.64
De	0.15	0.16	0.27
Pi	0.11	0.05	0.09
	1	**1**	**1**

Source: Field survey, 2009

Table 4.5 Criteria pair-wise row averages

	CRITERIA		
Detrimental Factors	Impact	Occurrence	Control
Disruption	**0.64**	0.08	**0.72**
Delays	0.28	**0.72**	0.19
Price increase	0.07	0.19	0.08
	1	1	1

Source: Field survey, 2009

Next, we also need to rank the criteria in order of how detrimental they are to the supply network. This is accomplished in the same way the suppliers were ranked within each criterion previously, by using pair-wise comparisons. The following matrix thus shows the pair-wise comparisons for the four criteria.

Table 4.6 Criteria pair-wise comparison

Criteria	Impact	Occurrence	Control
Impact	1	1/3	1/5
Occurrence	3	1	1/5
Control	5	5	1

Source: Field survey, 2009

The values in each column in the matrix are summed, then the column values are divided by their corresponding column sums and the rows are averaged, resulting in the following matrix:

Table 4.7 Criteria averages

Criteria	Impact	Occurrence	Control	Row averages
Impact	0.11	0.05	0.14	0.10
Occurrence	0.33	0.16	0.14	0.21
Control	0.56	0.79	0.71	0.69

Source: Field survey, 2009

Clearly control is the most detrimental criterion, occurrence and impact following in that order. Evidently if organizations cannot control disruption, delays and price increases then ACT supply chain is definitely heading for disaster. An overall score for each factor is computed by multiplying the matrix summarizing the detriment for each factor for each criterion we developed previously by the row averages for the three criteria.

Table 4.8 Overall factor score

	CRITERIA				
	Impact	*Occurrence*	*Control*	*Criteria*	
Disruption	0.64	0.08	0.72	Impact	0.10
Delays	0.28	0.72	0.19	× Occurrence	0.21
Price increase	0.07	0.19	0.08	Control	0.69

Source: Field survey, 2009

Disruption score **= 0.10(0.64) + 0.21(0.08) + 0.69(0.72)** **= 0.58**

Delay score = 0.10(0.28) + 0.21(0.72) + 0.69(0.19) = 0.31

Price increases score = 0.10(0.07) + 0.21(0.19) + 0.69(0.08) = 0.13

Based on these scores, disruption is identified as the most detrimental factor to the ACT supply chain from the pharmacy level. In terms of the frequency, delays happen far more times than disruptions as we can see from the above Table 4.5 where delays ranked 0.72 as against disruption 0.28. This affirms the fact that the impact and occurrence of disruption if not controlled can lead to a highly vulnerable ACT supply chain. All said and done, in order to rely on such a result one must have confidence in the judgment made in developing the pair-wise comparisons.

Disruptions within the supply chain are a major source of risk. The findings indicated that supply disruptions could be seen in the form of non-availability of raw materials, transportation and lack of knowledge regarding the source of supply. Any of these could restrict or stop the flow of products through the supply chain, increasing the risk to the patient. Risks that can lead to supply-chain disruptions are as different as natural catastrophes, strikes, political instability, fires or terrorism. Vulnerability of supply chains to these risks has increased because of modern practices such as lean

management and just-in-time inventory. Vulnerability has also increased because of the growing complexity of supply networks. Indeed the probability that something happens at a particular node or connection is higher than for a small and simple network. Supply chains that comprise hundreds or even thousands of companies present numerous risks.

Nevertheless, the structure of the pharmaceutical supply chain is such that an examination focusing on risk needs to encompass the complete supply chain and composite network of buyers and suppliers. In which case the total supply chain needs to be the subject of assessment as opposed to individual entities or parties e.g. risks attached to a supplier, pharmacy or purely to patients. Adopting a broad and encompassing view on this issue and not focusing on individual entities is critical in examining this area.

CHAPTER FIVE

SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

In the analysis we were able to analyze the ACT supply chain via five theories, network theory, supply chain theory, legislation theory, risk theory and analytical hierarchy processes theory The analysis explained three themes - network, legislation and risk that give an overall description of the phenomenon

5.2 Summary

It is noticeably obvious that the artemisinin-based combined therapies network enables the actors within the network to build close relationships to each other that help the flow of material, information and payments among actors Collaborative links within the network cannot be over emphasized, this involves various forms of inter-organizational cooperation and partnering which help actors involved In a bid to bring down the price of ACT drugs a consortium of UC Berkeley (for the technology), Amyris Biotechnologies of the Albany Company (for the manufacturing), One World Health Institute (for the clinical trials) and The Bill and Melinda Gates Foundation (funding to the tune of USD 43 million) was fostered to achieve this goal The fact that the actors are involved in different stages in the supply chain of ACT and engage in different activities with motives and incentives disparate from each other, adds on to the complexity of the network

Within the ACT supply chain there are several actors; including the farmer, manufacturer, international organizations, importers, government, wholesalers and pharmacies. The numbers of actors can of course vary but a typical developing country ACT supply chain includes all actors. The information flows represent orders of ACTs and the coordination of the drug, for instance information about price, delivery and quality. The material flows include the flow of the physical ACT from the Artemisia annua farmer to the service delivery outlets of pharmacies who then forward them to the final consumer. Regarding the financial flow of the chain, a large chunk of the supply chain cost is funded by international organizations and manufacturing outfits. The local chain members also benefit from credits from immediate upstream partners.

Furthermore, every single actor within the supply chain adds value to the product. The organizational structure of the ACT supply is such that international organizations play a major role by negotiating the purchases of these drugs for developing countries. Regarding the enabling technologies, the Artemisia annua is a labour-intensive crop whose cultivation requires close attention to detail, especially during planting and harvesting time.

The ACT supply chain is very complex and recent lean practices have resulted in these networks becoming more vulnerable. For instance, there is often little buffer inventory and any disruption can have a rapid impact on the supply process. Evidently disruption was found out to be the main detrimental factor to the supply chain although delay was found to be occurring more frequently. Price increases

indicated a low effect on the supply network at the pharmacy level. The pharmacy level is the point where the final material flow gets to the consumer/patient. The researcher then believes that all shortcomings of the various actors in the supply chain are reflected at this part of the chain. However, it was realized that the structure of the pharmaceutical supply chain is such that an examination focusing on risk needs to encompass the complete supply chain and composite network of buyers and suppliers. In this case the total supply chain needs to be the subject of assessment as opposed to individual entities or parties to the supply network.

5.3 Conclusion

Access to reasonably priced, quality-assured ACTs is critical to the effectiveness and impact of national malaria programmes. The key challenge to the supply of malaria drugs according to research is predictability – ensuring a predictable supply of commodities – and securing multi-year financing. Serious but common breakdowns in the ACT supply chain creates the conditions for accelerated drug resistance mostly attributable to activities prevailing at any given time – from drug development and procurement to regulatory requirements right down to providers' prescribing patterns. Those that most directly affect resistance arise from weak regulation, poor supply chain management, a lack of knowledge and training among providers, inadequate monitoring and control systems in hospitals and other care facilities and insufficient human and other resources. Ultimately, these weaknesses affect patient access, drug affordability and compliance with treatment regimens – which are key factors in the prevention and containment of drug resistance.

5.4 Recommendations

The supply chain must be optimized to tackle supply chain issues which include counterfeit drugs, which are a major problem, as well as ensure efficient procurement, delivery of products and information dissemination throughout the chain. Because ACTs, especially Coartem are high-priced, there is always the possibility of counterfeit. Several recent cases of counterfeit medicines have raised Ghanaian awareness of the problem. Auto-ID technology can provide an effective information infrastructure to detect and control counterfeit drugs through track and trace and drug verification capabilities.

Actors in the ACT supply chain should realize that the only winning strategy in this ultra-modern environment is to build a responsive supply chain, one that's more capable of dealing with severe positive changes in risk profiles and patient satisfaction, by building a visibility foundation through IT and trading partner collaboration.

Most actors according to the research believe that delay is actually what retards their material flow because of its frequency, but they should know that disruption risks exist and are very detrimental to the seamlessness of the supply chain, so managers must not ignore them. It is necessary to introduce a culture of risk awareness within the organization in order to face this problem. The elimination of delays in the information infrastructure can significantly reduce the cost of disruptions too. This, in turn, will result in improvement in drug quality and reductions in cycle time (the maximum amount of time an item is allowed to spend at a node within the network).

To achieve the benefits in terms of optimizing the supply chain, two things must happen. First, an enterprise-wide *item-level* visibility must be possible through the supply-chain information infrastructure – real time tracking through the use of RFID for instance. After the Coartem counterfeit scare stakeholders in the pharmaceutical industry proposed the checking of the quality of the drugs through the use of the mobile phone. This is a laudable idea which can arrest the situation in the short term. An ideal situation can be what is shown in Figure 2.3.

The ACT supply chain is a complex one. Not knowing the process by which items make their way to pharmacy shelves leads to difficulty in satisfying people on a make-to-order basis. This is necessary in the face of the short shelf-life of ACTs. The system should not be flooded with the drug and it should also not be scarce so as to scale up counterfeiting. Auto-ID lays the foundation for the management of this complexity and provides the framework for a safer and securer Supply Chain. Auto-ID technology can help manage risk and maintain lineage by labelling ACTs with radio frequency identification. This allows products to be tracked, traced and recalled if necessary.

Second, the risks inherent in supply chain systems can be mitigated or avoided, this can be achieved by adopting a structured approach to understanding the nature of risk in the total ACT supply chain in order to effectively manage it. This would involve detailed analysis of the successes of the various parties and agencies. Presently the researcher could find little evidence of this being done. Consultations should be

performed on a continuous basis with actors of the total supply chain. Adequate training packages also need to be developed and disseminated to decision-makers within the chain concerning the presence of risk and its mitigation strategies. This would involve strategists, policy makers, procurement bodies/staff and key pharmaceutical personnel e.g. pharmacy specialists.

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APPENDIX

Appendix 1

AHP pair-wise comparison sheet

Company Name: *KAMA Pharmacy – KNUST, Kumasi*

Personnel-in-charge: *Opoku Christian*

Position: *Pharmacy Technician*

Factor pair-wise comparison ratings for each of the three criteria
(1=EQUAL 3=MODERATE 5=STRONG 7=VERY STRONG 9=EXTREME)

	Impact			
		Disruptions	Delays	Price increases
1	Disruptions	1	*3*	*7*
2	Delays		1	*5*
3	Price increases			1
	Occurrence			
		Disruptions	Delays	Price increases
1	Disruptions	1		
2	Delays	*7*	1	*5*
3	Price increases	*3*		1
	Control			
		Disruptions	Delays	Price increases
1	Disruptions	1	*5*	*7*
2	Delays		1	*3*
3	Price increases			1

Criteria pair-wise comparison
1=EQUAL 3=MODERATE 5=STRONG 7=VERY STRONG 9=EXTREME

		Impact	Occurrence	Control
1	Impact	1		
2	Occurrence	*3*	1	
3	Control	*5*	*5*	1

Appendix 2

Primary & Secondary Empirical Sources

	Interviews			
	Name	Position	Organisation	Place
1	Allotey, Naa-Korkor Tel: 0244462747	Programme Manager	National Malaria Control Programme	Miklin Hotel, Kumasi
2	Franklin Donkor Tel: 0244388377	Pharmacist	Komfo Anokye Teaching Hospital	Phone
3	Sackey, Raymond Tel: 0249709782	Supply/Procurement Officer	District Health Management Team, Mampong-Akwapim	Mampong – Akwapim
4	Opoku Christian Tel: 0243843166	Pharmacy Technician	KAMA pharmacy division - KNUST	KNUST Campus, Kumasi
5	Eghan, Emmanuel Tel: 0244357106	Management Sciences for Health	Country Director	Miklin Hotel, Kumasi
	Questionnaires			
6	J. B. Tetteh 0285086861	Store Owner	Tetteh Chemical Store	Akropong - Akwapim
7	Antwi Boateng 0246893448	Pharmacist	Tetteh Quarshie Memorial Hospital	Mampong, Akwapim
8	Adu Magaret 0240862984	Pharmacy Assistant	Finco Pharmacy	Mampong, Akwapim
9	Awuku Boateng 0242258829	Store Owner	Had Chemical Store	Mampong, Akwapim
10	Christian Opoku 024360870	Pharmacy Technician	KAMA (Pharmacy Division – KNUST)	KNUST Campus, Kumasi
11	Dorothy Okyere 0246609728	Store Owner	Dorothy Okyere Chemical Store	Mampong, Akwapim
12	Samuel Mamfo 0208187411	Store Owner	M. Mamfo Chemical Store	Mampong, Akwapim

	Presentations	Organisation	Topic	Venue
13	Dr. Andrew Kitua Tel: +255 22 212 1400 Fax: +255 22 212 1380 Email: akitua@nimr.or.tz	National Institute for Medical Research, United Republic of Tanzania	**Topic:** "The role of artemisinin-base Products in Current treatment of Malaria and National Policies"	Meeting on the production of artemisinin and artemisinin-based combination therapies 6–7 June 2005, Arusha, United Republic of Tanzania
14	Dr. Ian Bathurst Tel: +44 22 799 4084 Fax: +44 22 799 4061 Email: bathursti@mmv.org	Medicines for Malaria Venture	**Topic:** "Potential impact of new developments, including alternatives to ACTs, vaccines and increased vector control coverage"	-do-
15	Dr Clive Ondari Tel: + 41 22 791 4439 Fax: +41 22 791 1587 Email: ondaric@who.int	WHO	**Topic:** "National regulation and artemisinin-based products"	-do-
	Articles			
17	Willem Heemskerk, Henk Schallig and Bart de Steenhuijsen Pite	THE WORLD OF ARTEMISIA IN 44 QUESTIONS		2006
18	Olliaro, P.L. & Taylor, W.R	Developing artemisinin based drug combination for the treatment of drug resistant falciparum malaria		2004
19	J. Janick	Horticultural reviews, volume 17		1995
20	Wright Colin W	Artemisia		2002
21	Duke, S.O., K.C. Vaughn, et al.	Artemisinin, a constituent of annual wormwood (Artemisia annua), is a selective phytotoxin.		1987
22	Bouwmeester, H.J., T.E. Wallaart, M.H.A. Janssen, B. van Loo, B.J.M. Jansen, M.A. Posthumus, C.O. Schmidt, J-W. de Kraker, W.A. König and M.C.R.	Partial purification and characterization of amorpha-4,11-diene synthesis. The sesquiterpene synthase catalyzing the first probable step in the biosynthesis of artemisinin.		1999

	Franssen		
23	Prof. Michaela von Freyhold, Dr Charles Lugt, Laughlin et al.,	Medicines for Malaria Venture	2002
24	Vennerstrom JL, Brun R, Charman SA, Chiu F, Chollet J, Dong Y, Dorn A, Hunziker D, Matile H, McIntosh K, Padmanilayam M, Santo Tomas J, Scheurer C, Scorneaux B, Tang Y, Urwyler H, Wittlin S & Charman WN	Novel antimalarial peroxides: Identification of a trioxolane drug development candidate	2004
25	WHO	World Health Organisation, Facts on ACTs	2003
26	Gladys Tetteh Ben Botwe Peter Gyimah	Assessment of the Availability and Quality of Antimalarials in the Public and Private Sectors of Ghana	2006
27	Jonathan Harper & Martha Gyansa-Lutterodt	The viability of pharmaceutical manufacturing in Ghana to address priority endemic diseases in the West Africa sub-region	2007
28	JC Cohen, M Gyansa-Lutterodt, K Torpey, LC Esmail and G Kurokawa	Globalization and Health TRIPS, the Doha Declaration and increasing access to medicines: policy options for Ghana	2005

Appendix 3

Questionnaire (Local Pharmacies)

The Supply Chain for Artemisinin-based Combination Therapies

1. Regarding the interviewee's role in the antimalarial supply chain:

a. Name & Position: ..... Phone:.....

b. Organisation: .....

c. Status: Drug store / Pharmacy / Other specify .....

d. Please state the main ACT medications that are available .....

.....

2. Regarding the overall ACT supply chain:

a. List companies that supply you ACTs?

.....

b. How strong is your relationship with them?

[1] Weak [2] Strong [3] Very strong

c. Do you have software that takes care of inventories? No / Yes.

What other task does this software perform if any .....

.....

d. How do you communicate with your suppliers?

[1] By phone [2] via e-mails [3] face-to-face [4] Other.....

e. How do supplies get to your premises?

[1] By road [2] on foot [3] Other, specify .....

f. How do you pay for the ACTs you buy?

[1] Credit (1-14 days, 15-30days, 31-60days, 61-90days, 91days +)

[2] Cash [3] Advance payment [4] Other, specify .....

g. What is your average mark-up?

[1] 5-10% [2] 11-20% [3] Other, specify .....

3) Regarding legislation

a) Which regulatory requirement is best known to you?

.....

b) What are your views on these regulatory requirements?

i) Do you think they are reasonable? Yes/No (Please comment)

.....

Do they obstruct your business activities in any way? Yes/No

Please specify if yes .....

c) Would you like to see changes in the regulatory system? What aspects would you like to see changing? .....

.....

5. Regarding Risks

a) What disruptions have you encountered so far (strikes, fuel shortage, natural events, theft, etc.)? ..... b) Have you had any issues with delays recently/in the past? Yes/No

What were the cause(s) if any?.....

.....

c) What about price increase? Can you recollect any incidence of price increases affecting your business?

d) Do you encounter problems as a result of a relationship with partners? Specify if any .....

e) For each of the following risk it on the scale of **1** to **5**

Disruptions ☐ Delays ☐ Price increases ☐

Legislation ☐ Operations ☐

f) Please state the name and location of any other drug shop near your place.

.....

Thank you for been so helpful.

Appendix 4

General Interview Guidelines

The Supply Chain for Artemisinin-based Combination Therapies

1. **Regarding the interviewee's role in the antimalarial supply chain:**
   a. Please tell me about your organization and the role it plays in the ACT supply
   b. Please tell me about yourself, your position in the organization and your role.
2. **Regarding the overall ACT supply chain:**
   a. What are the key stages of the ACT supply chain and what happens at each stage?
   b. Who are the main actors at each level of the supply chain (i.e. businesses, NGOs, procurement agencies, international organizations and donors)?
   c. What are the roles and main activities of these actors?
   d. How do you move supplies along the network? Do you recall any incident pertaining to movement of supplies?
   e. How do you fund your activities? Do you recall any problems with your financing?
   f. How do you get/send information about the drugs?
3. **Regarding the price and availability of antimalarials.**
   a. Please name the main ACT medications (both generic and brand names) that are available in the country.
   b. What is your average mark-up?
   c. To the best of your ability and being as specific as you can, please estimate the price mark-ups at each level of the supply chain.
   d. Please comment on the availability of the ACT that you mentioned before. For example:
      i. Are some products more readily available compared to others?
      ii. Are there currently or have there recently been problems with the availability of antimalarials

4) Regarding legislation

a) Which regulatory requirement on ACT availability is best known to you? What are your views on these regulatory requirements?

i) Do you think they are reasonable? If not, why not?

ii) How do they influence the way you run the business?

b) What are your views on the capacity of the regulators to enforce their regulations?

i) Do you feel that most people comply?

ii) Do you feel that sanctions are enforced?

iii) Have you had any personal experiences of dealing with the regulatory authorities? Can you describe them?

c) Would you like to see changes in the regulatory system? What aspects would you like to see changing?

5. Regarding Risks

a) What disruptions have you encountered so far (strikes, fuel shortage, natural events, etc.)?

b) Have you had any issues with delays recently/in the past? What were the cause(s) of the delays if there was any?

c) What about price increase? Can you recollect any incidence of price increases – i.e. rise in price of fuel, foreign currency, etc. – affecting your business?

d) How do individual activities coming together help you to achieve efficiency? Recall an instance when a supply chain activity disrupted your effort to make ACTs available

6. Is there anything else that you want to say about your experience in dealing with ACTs? Do you have any questions to ask?