Saimaa University of Applied Sciences Business Administration Lappeenranta Degree in International Business

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The Way to Effective and Sustainable Supply Chain Management in the Pharmaceutical Industry

#### Abstract

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The Way to Effective and Sustainable Supply Chain Management in the Pharmaceutical Industry, 55 pages, 2 appendices

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The purpose of the thesis was to examine the importance of Supply Chain Management (SCM) in developing and delivering effective and sustainable supply chains and value chains in the Pharmaceutical Industry. In addition, it was a goal to gain an understanding of the likely future trends and threats to the industry, and analyse how SCM can be used to address these.

The information for the theoretical framework was gathered from academic books, sector specific articles and journals, and recent studies. The empirical part was based on two structured questionnaires which were sent to 20 European based multi-national pharmaceutical companies and 7 European national pharmaceutical trade associations. Unfortunately only one response was received therefore, this company was used as a case study. For further analysis and formulation of recommendations the results from this response were compared to results of previous research into the subject conducted by respected research companies.

The results of the study show that sustainable SCM is of key importance to pharmaceutical companies and that they are taking actions to modernise their supply and value chains, so to deliver cost savings and value to both the company and the end-user. However, total sustainable SCM is not likely in the near future unless there is a move towards global consensus on legislation affecting the pharmaceutical industry.

Keywords: Supply Chain Management (SCM), Supply Chain, Value Chain, Pharmaceutical Industry, Pharmaceutical Company

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## **Abbreviations**

CSCMP - The Council of Supply Chain Management Professional

EFPIA - the European Federation of Pharmaceutical Industries and Associations

EU - European Union

HAI - Health Action International

R&D – Research and Development

SCM – Supply Chain Management

WHO - World Health Organisation

#### 1 Introduction

### 1.1 Background

In the modern global market place, every company no matter its size, business type or location is faced with increasing customer demands, competition, and rising development costs. As a result companies have to explore new methods of business operation to remain competitive and profitable, whilst delivering what the end-user wants, when they want it, where they want it and at an affordable price. As a means of doing this many companies are reviewing their supply and value chain management as a means of driving efficiency and delivering value.

This issue is of particular relevance to the pharmaceutical industry which is characterised by long product development and lead times, multiple supply chain networks at different stages of product development, and whose end product(s) has a direct real life impact on the final customer. Sector commentators have also suggested that most pharmaceutical companies currently have supply chains that are neither flexible nor cost effective (PricewaterhouseCoopers 2011, p. 3). This combined with reduced economies of scale that industry leaders previously enjoyed through the blockbuster drug "paradigm" due to the increase of generic competition, has led to many traditional Pharmaceutical Companies beginning to refine and redefine their supply and value chains, and their management.

### 1.2 Research Objectives and Research Questions

The objective of this study is to analyse the importance of Supply Chain Management (SCM) in developing and delivering effective and sustainable supply chains and value chains in the pharmaceutical industry. In addition, it is a goal of the thesis to examine the future trends and threats to the industry, and how SCM can be used to address these.

The thesis broaches the issue of the management of supply and value chains, in the Pharmaceutical Industry. Therefore the primary research question is:

How can the pharmaceutical industry achieve effective and sustainable (responsible) supply chain management?

Furthermore, the sub research questions will support the study and they are as follows:

- What do typical supply and value chains of pharmaceutical company's look like?
- What are the economic and commercial benefits of developing effective SCM to the pharmaceutical industry?
- What are the most important payoffs of a more sustainable supply chain?
- What are the key values of developing effective supply chains?
- What are the biggest challenges/obstacles to successful SCM in the pharmaceutical industry?

These research questions will help the author to find an answer to whether effective SCM can be used as a tool for delivering competitive advantage and added value during a period of increased economic and operating difficulties, and to address future business challenges.

#### 1.3 Delimitations

This research focuses on supply and value chains, and the development of SCM in pharmaceutical companies, and does not attempt to examine SCM in other business sectors as this would have made the research field too large, generalised and labour intensive in information gathering. It also only focuses on large multi-national pharmaceutical companies whose head offices are located in the European Union (EU), and does not examine smaller generic drug manufacturers as they tend not to have such dispersed supply chains. This is because European Community Regulations on SCM and sustainability cover all

companies no matter where they are located within the Union, and therefore made the gathering and comparison of information easier because they all have to operate according to the same set of regulations where ever they are located within the EU.

#### 1.4 Research Method

For the theoretical part about supply and value chains and SCM, sustainable SCM and supply and value chains in the pharmaceutical industry, the qualitative approach was chosen and thus the author gathered information from academic books, research papers and industry produced reports. Data was also acquired from internet sources, e.g. current figures of the size and value of the european pharmaceutical industry. The research methods of the empirical part are described in chapter 6.1.

## 2 Supply and Value Chains and SCM

To understand the importance of effective and efficient supply and value chains in the pharmaceutical industry as a means of developing competitive advantage and improving returns on investment and profitability; it is important to establish a high level understanding of what a supply and value chain, and its associated activities entail and incorporate.

The subject of supply and value chains and SCM is not a new one, and has been the subject of a number of academic studies and writings. However, its use as a tool for driving company differentiation, competitiveness and efficiency, whilst continuously delivering above and beyond the final customers' expectations; is still a relatively new issue in terms of the business world. Modern SCM emerged in the 1990's, and has been driven by a number of factors including the global nature of modern business operations, the growth of the internet, rapid advancement in technology, particularly in information technology; which has enabled companies to operate in real-time across large distances; a change in customer affluence, demands and sophistication, security threats and global

recessions. From this starting point it has rapidly grown and is now recognised as an essential factor in global competition.

Supply chains and value chains can be understood to consist of a series of activities and interactions in which a product or a material is transferred from its point of origin or source through the delivery to the end consumer. A value chain moves beyond the simple transferring of products, and includes the addition of certain values at various stages of its development in order to provide maximum satisfaction to the end consumer. The supply chain and the value chain are related to each other even though they move in opposite directions. Figure 1 provides an overview of this linkage.

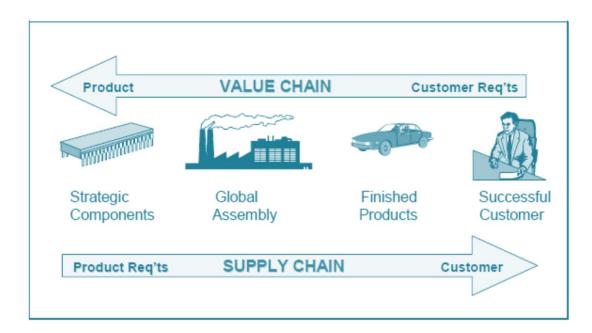


Figure 1. A comparison between a value chain and supply chain (Feller et al 2006)

From this simple diagram a supply chain can be said to be made up of a flow of products and services in one direction, whilst the flow of demand and cash in the other direction represents the value chain. This means that the primary difference between a supply chain and a value chain is a shift in focus from the supply base to the customer. In order for supply chains to be capable of generating maximum value, they must synchronise the flows of supply with the flows of value from customers in the form of rapidly shifting tastes, preferences, and

demand. Companies therefore need to stop viewing supply chains and value chains as different entities, but, rather, should integrate the two. (Feller et al 2006.) Supply chains, value chains and their management (SCM) are discussed in more detail in the following sections of this report.

#### 2.1 Supply Chains

There are many different definitions of the term "supply chain." Typically a supply chain can be defined as a 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 (Lysons & Farrington 2006, p. 93). The processes involved in a supply chain may include activities such as sourcing raw materials and parts, producing or assembling the products, storing the products, order processing and tracking, through to the distribution and delivery of the product to the final customer (Sanders 2012, p. 3). Figure 2 provides an overview of a simplified supply chain.

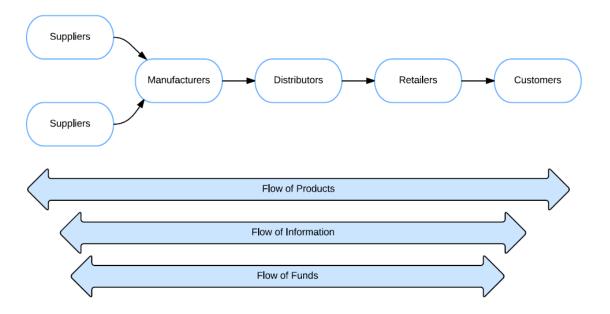


Figure 2. Simplified supply chain

However, a supply chain is much more complex than this image suggests and is a complex network of different trading partners, typically referred to as stag-

es; it includes suppliers, producers, wholesalers/distributors, retailers and customers. It also important to bear in mind that no one supply chain is the same, and each stage may not be present in every supply chain. Supply chains are also coming under increased financial pressure, which has resulted in many companies reviewing their supply chains, and as a result the companies are bypassing or removing stages that are not delivering value. As a result supply chains are often referred to as a "value chain" or a "value network." (Sanders 2012, p. 4.)

#### 2.2 Value Chains/Value Network

As mentioned in the previous section, supply chains are also commonly referred to as "value chains or networks," and the effective management of Supply chains can be used as a tool for deriving better returns on investment and outlay on product development and other associated costings. A value chain can be viewed as a linear map of the means by which value is added through a process from sourcing and processing of raw materials, to the assembly and delivery of the finished product to the end-user, including after delivery service (Lysons & Farrington 2006, p. 101.)

The most recognised and important value chain models have been developed by Michael Porter of the Harvard Business School, and Peter Hines of the University of Wales. In the 1980's Michael Porter reasoned that a company's' competitive advantage can only be understood by examining the costs that are created by the individual departments or team within a company, and how their supply chain activities affect the company as a whole. The primary and secondary value chain activities described by Porter (1985) are indicated in Figure 2.

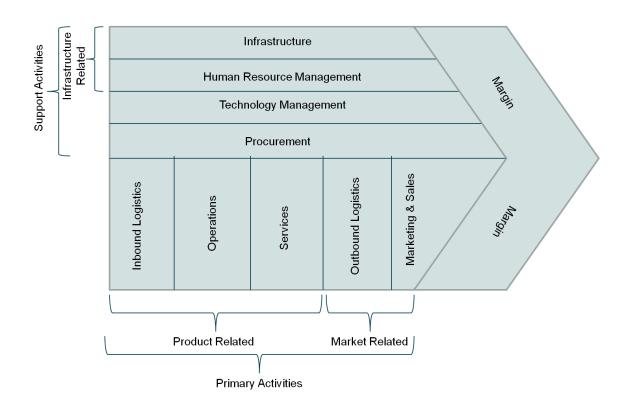


Figure 2. Michael Porter's "Value Chain Model" (Saha 2011)

Porter believes that business activities can be classified into five primary activities (inbound logistics, operations, outbound logistics, marketing and sales and service activities) and four supporting activities (firm infrastructure, human resource management, technology development and procurement activities); which if managed effectively can deliver a competitive advantage. The term "margin" is used to indicate that a company is able to make a profit that is more that than the combined cost of these activities (Lysons & Farrington 2006, p. 102-103.)

In 1993, Peter Hines published a critic on Porters original work which recognised Porters model in that it helps to improve the strategy of managers in areas such as materials management and customer relations and retention, which were placed in a very important position within the company. However by focusing primarily on profitability and profit generation, Porter fails to take into account the importance of consumer satisfaction. Porter's model provides a divided network within the company and with its partners, rather than highlighting the importance of integration across the whole network. Finally, as Porter's work

was based solely on American case studies his conclusions are not appropriate for modern day companies who are operating on an increasingly international playing field. To correct this Hines offers two models (1) "a micro integrated material's value pipeline" operating as one large flow pointing from consumer to raw materials source, based on a pull system process rather than a push process suggested by Porter; and (2) "a macro ten forces partnership model", in which teams are primarily concerned with marketing, materials, engineering, quality, R&D and design. Secondary activities include activity-based costing (ABC), HRM/training/education, Total Quality Management (TQM), Electronic Data Interchange (EDI) and profit. (Lysons & Farrington 2006, p. 103-104.)

#### 2.3 Supply Chain Management

Imperative to efficient and effective supply and value chain is supply chain management (SCM). SCM means different things to different people, and there is not one clear definition as to what SCM is. However, it can be generally accepted that SCM involves the design, coordination and management of flows of products, information, and funds throughout the supply chain. The Council of Supply Chain Management Professional (CSCMP) states that

"Supply chain management encompasses the planning and management of all activities involved in sourcing and procurement, conversion, and all logistics management activities. Importantly, it also includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third party service providers, and customers. In essence, supply chain management integrates supply and demand management within and across companies."

#### They additionally state that

"Supply chain management is an integrating function with primary responsibility for linking major business functions and business processes within and across companies into a cohesive and high-performing business model. It includes all of the logistics management activities noted above, as well as manufacturing

operations, and it drives coordination of processes and activities with and across marketing, sales, product design, finance, and information technology."

SCM is therefore can be viewed as an integrating function with the primary objective of linking major business functions and processes within and across companies and their partners, into a high-performing business model. It includes activities such as logistics management and manufacturing operations, and drives the coordination of processes across all business departments, thereby developing a more holistic approach to business operation rather than operating in silos. (Grant et al 2013, p. 3.)

It can be concluded that SCM is about the companies collaborating to leverage strategic positioning and to improve operating efficiency (Bowersox, et al 2002, p. 4). This is increasingly being achieved through collaboration and partnership agreements, which bring their own difficulties, particularly when operating at a global level. As a consequence a collaborative supply chain strategy agreed, by all links in a supply chain is essential to achieve efficient and desired outcomes and to manage risks.

#### 2.4 Increasing Importance of SCM

Modern SCM has can be traced back to the 1990's when difficult global economic conditions and an increase in uncertainty in business environments, made it necessary for companies to seek new ways of doing things. This has included activities such as customisation of products to customer specifications and reducing lead times between product design, manufacture and delivery to the customer; in order to make a profit and survive.

SCM has increasingly proven to be an essential element for successful global competitiveness. A number of forces have given rise to this trend. Firstly, companies have realised that they can make significant savings through planning and managing their supply chain activities better. Secondly, advances in technology, most notably the World-Wide-Web (WWW), have allowed companies access information critical to their business success, and to better manage their

supply chains, particularly as they becoming more international and widely spread. Thirdly, improved transportation methods have led to reductions in transport costs, whilst provided alternative and faster modes of transport than had previously been available. Finally, greater customer disposable income, sophistication and demands, has resulted in a greater variety of quality goods and services. (Sanders 2012, p. 15-17.)

### 2.5 SCM and Logistics

To this point this report has discussed SCM and supply chains. However, it is important to provide a definition of what is meant by the term "logistics," as people think that SCM and logistics is the same thing. The Council of Supply Chain Management Professional (CSCSP) succinctly summaries logistics management as

"... that part of supply chain management that plans, implements, and controls the efficient, effective forward and reverses flow and storage of goods, services and related information between the point of origin and the point of consumption in order to meet customers' requirements."

Logistics can be viewed as the work required to move and position inventory throughout a supply chain. However, logistics goes beyond transportation and it is a much more complex process, including issues such as planning and preparation; packaging; documentation; storage; insurance and import and export regulations. Logistics and logistics management can therefore be viewed as a supporting element of SCM, which is essential in ensuring that all links in a supply chain are joined up, and dictates how a SCM plan is formulated.

#### 2.6 The Bullwhip Effect

All elements of the supply chain are interconnected and interdependent. It is the role of the SCM to ensure that each link in the chain is integrated, cohesive and working towards shared goals and objectives, whilst remaining lean, responsive, innovative and profitable. Predictability and minimal disruption are im-

portant elements of a competitive, efficient and well working supply chain. It is therefore essential that all of those engaged in a supply chain are collaborating, sharing information and acting in coordination with one another. Inefficiencies or breakdowns in these areas at any stage of the supply chain can have a distorting effect on what is delivered to the final customer, and can lead to lower profitability throughout the supply chain, and what is commonly known as the "bullwhip effect." (Sander 2012, p.8.)

It has been witnessed that the distortion and fluctuation of information increases as it progresses up the supply chain from retailers, manufacturers to suppliers. This is what is referred to as the "bullwhip effect" as inaccurate and distorted information moves up the chain like a bullwhip uncoiling. In response to this, each stage in the chain progressively carries more stock to compensate for the lack of information. (Sander 2012, p.8.) The longer the supply chain becomes, the more likely the bull whip effect will occur, as manufacturers and suppliers are further away from the final customer, and breakdown in sharing information between links in the chain is more likely; this is particularly the case for companies operating at a global level. The results of the bullwhip effect are excessive inventory quantities, poor customer service, cash flow problems, stock outs and high material costs, overtime expenses and transport costs. (Lysons & Farrington 2006, p. 334.)

To avoid and resolve the bullwhip problem, it is important to ensure transparency and information sharing throughout the supply chain. The importance of information sharing and the management of such fluctuation have seen the onset of Enterprise Resource Planning (ERP) and SCM systems and software, which support internal and external integration and exchange of real time information, such as finance, manufacturing and distribution, at each level of a supply chain. (Simichi-Levi et al 2003, p. 272.)

#### 2.7 Future SCM Trends

As modern supply and value chains continue to develop as a result of rapidly evolving global and technological environments. A number of trends are emerg-

ing that are impacting the way supply chains are designed and managed, and are creating unique challenges for businesses. According to Nada Sanders and Sumantra Sengupta the top trends that are emerging include:

- 1. Increased globalisation and the spread of the global marketplace. Changes in information technology, transportation and government policies have meant that there is no avoiding the global economy. Whilst this has brought numerous advantages for companies and the consumer alike, such as a larger choice of product sources for companies; and more choice, higher quality and lower prices for the consumer. It has also created a number of challenges such as the distance barrier when shipping products over vast distances.
- Increased outsourcing, including the hiring of third and fourth parties to undertake activities that were traditionally the sole responsibility of the manufacturer.
- Lean supply chains, whereby companies in the supply chain that are directly linked by upstream and downstream flows will be required to work in coordination and cooperation with one another to reduce waste and cost.
- 4. Supply chain security and maintaining product integrity as goods are moved around the world and across multiple national borders. Modern stringent security requirements have resulted in more complex supply chains, and the ability to protect security while being efficient is a key issue. Other key issues in this area include increased risk of theft and product tampering. This is a particular issue in the area of pharmaceutical. Modern security methods include the use of electronic seals to prevent tampering, to using RFID and GPS technologies to track product movement.
- 5. Service chains will become more important than product chains. As consumer power grows and demands increase from pre- and post-sale, companies increasingly have to develop ways to effectively couple and manage activities in these areas. An important element in this will be a company's ability to listen to and react to customer feedback.

- Companies will have to fully report their supply chain externalities in an open and transparent manner, including their approach to sustainability and corporate social responsibility in the communities they operate.
- 7. Supply chains will be designed to serve the base of the pyramid, meaning that companies will have to adapt their products and methods to target and tap the market potential the larger number of consumers with low incomes. This will necessitate companies having to alter their traditional mind-set of a "cost-plus" model to a "not to exceed" cost model.
- 8. Product clock speeds/life cycles will determine the number and type of supply chains, with "fast clock speed" becoming more the norm than the exception. This has had the knock on effect that companies can no longer employ a single supply chain approach, and must have distinct product supply chains to meet each product's needs.
- 9. Technology to support SCM, such Enterprise Resource Planning (ERP) and the concept as Software as a Service (SaaS); will primarily be on tap, with users paying for the ability to use the capability rather than have to invest in costly fixed systems and their ongoing associated costs.
- 10. Artificial intelligence will be embedded in the mainstream supply chain activities, which allow systems to access algorithms that learn and retain past knowledge and experience, and thereby automatically update and improve (Sanders 2012, p. 20-25; Sengupta 2013.)

It is evident from these examples that the supply chain and value chain environment is changing rapidly, and will continue to do so in the future. It is therefore essential for any company no matter of their size or business type to continuously review and develop flexible SCM systems in order for them to adapt quickly and remain competitive, whilst delivering value to their end customer or user.

#### 3 Sustainable SCM

One of the biggest trends and factors effecting the design and management of supply chains is "Sustainable" business practices, which is of increasing importance to global governments, non-governmental and activist organisations and consumers; who are demanding, through means such as legislation and changes in buying habits, that companies operate in an ethical and appropriate manner. The Merriam Webster Dictionary (2015) defines "Sustainable" as being

"Able to be used without being completely used up or destroyed, involving methods that do not completely use up or destroy natural resources and being able to last or continue for a long time."

Figure 3 provides a high level overview of the three core spheres of sustainability, which are considered to be the key elements that enable companies and other societal players to develop process or management systems that contribute to the development of vibrant national and global economies, in addition to the raising of the quality of life in which they operate whilst respecting the need to sustain natural resources and protect the environment. (Vanderbilt University 2015.)

# The Three Spheres of Sustainability

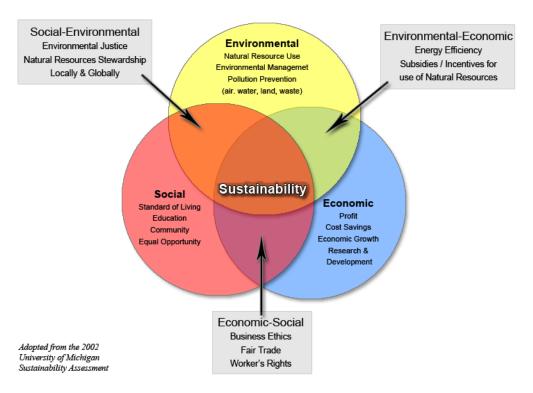


Figure 3. the Three Spheres of Sustainability (Vanderbilt University 2015)

Companies primarily exist to make money and a return on investment for their owners and stakeholders, but now they are increasingly expected to be "social responsible," and SCM's play a key role in this through effective, efficient purchasing and manufacturing. Through social responsible and sustainable business practices companies are producing better products, using fewer resources, appealing to a larger consumer audience and avoiding environmental regulations. At the same time such companies are able to stay ahead of competitors by forcing governments that enact competitors to develop similar results, invest in technology or pay heavy fines. However, it takes a committed organisation to develop a truly integrated and socially responsible supply chain and motivate suppliers to do the same.

#### Sustainable SCM

Most people do not think about how or where the products they purchase or use, were sourced from and produced. However, supply chains can have a sig-

nificant environment and social consequences, including environmental costs, health and human safety risks, and the cost of waste. Over recent decades the combination of heightened customer awareness and demand for ethically manufactured products and an increase in regulatory standards; companies now have to be more accountable for the impact that their actions and products and services, and the associated supply chains are having on the environment and the societies in which they are being performed. Focus on "green" and sustainability, and issues such as the environment and social responsibility; have therefore become key elements of SCM.

Essentially companies are there to make money, but now they are increasingly expected to be "social responsible," and SCM play a key role in this through effective, efficient purchasing and manufacturing. Through social responsible and sustainable business practices companies are producing better products, using fewer resources, appealing to a larger consumer audience and avoiding environmental regulations. At the same time such companies are able to stay ahead of competitors by forcing governments that enact competitors to develop similar results, invest in technology or pay heavy fines.

In addition there are four documented types of payoff that result from a company improving its sustainable performance. These are:

- Financial Payoffs these include reduced operating costs, increased revenue, lower administrative costs, lower capital costs, and stock market premiums.
- Customer Related Payoffs these include increased customer satisfaction, product innovation, improved reputation, increased market share and new market opportunities.
- Operational Payoffs these include process innovation, productivity gains, reduced cycle times and waste minimisation.
- Organisational Payoffs these include employee satisfaction, improved stakeholder relationships, reduced regulatory intervention, reduced risk and increased organisational learning (Sanders, N 2012, pp. 377.)

However, it takes a committed organisation to develop a truly integrated and socially responsible supply chain and motivate suppliers to do the same.

# 4 Supply and Value Chains and SCM in the Pharmaceutical Industry

The pharmaceutical industry includes activities such as the manufacture, development, marketing and distribution of drug products including quality assurance of these activities (University of Helsinki, 2006). In 2014, the global pharmaceuticals market was worth US\$300 billion a year, a figure expected to rise to US\$400 billion in the next three years. The ten largest drugs companies control over one third of this market, several with sales of more than US\$10 billion a year and profit margins of about 30%. Six companies are based in the United States and four in Europe. It is predicted that North and South America, Europe and Japan will continue to account for a full 85% of the global pharmaceuticals market well into the 21st century. (The World Health Organisation, 2014.)

Traditionally, the majority of the largest pharmaceutical companies operated using a simple supply chain model consisting of suppliers of raw materials/chemicals, pharmaceutical companies, wholesalers, retailers, in some places insurers and ultimately the final end-user. In most instances there was minimal communication between each party and there was no real desire to pursue efficiency gains. Regulatory constraints restricting the activities of smaller rival companies and favourable tax structures in a limited number of locations worked in the industry's favour. In addition, to steady profits from customers dependent on a limited number of companies' products made change undesirable or at least unnecessary. (Ehrhardt, Hutchens & Higgins, 2012.)

However recent developments and disruptions in the traditional operating environment, most notably the emergence and increasing influence of cheaper generic drug manufacturers, as well as changes in customer demand patterns, new and more agile and innovative rivals and increasingly restrictive global regulatory environment, have meant that traditional pharmaceutical companies

have had to change their game plan, to stay ahead of the field, remain profitable and deliver quality products that the customer wants.

#### 4.1 The European Pharmaceutical Industry

The presence of a viable, well-functioning and effectively regulated pharmaceutical industry is a major contributing factor in the betterment of the health and the quality of life of not only citizens of the European Union, but also in other countries and particularly those in the developing world; through the development and supply of remedies to an increasing number of patients, through a more timely, widespread and equal access to pharmaceuticals. It also acts as a catalyst to medical progress through researching, developing and bringing new medicines that improve health and quality of life for patients around the world.

In addition to delivering value to patients the pharmaceutical industry is also a key asset of the European economy, and the European Commission view it as one of Europe's top performing business sectors and a key driver of economic growth in a period of increased operational difficulties for most of the EU's business sectors. In 2013 Pharmaceutical Companies invested an estimated € 30,630 million in R&D in Europe, and directly employed more than 690,000 people and generated three to four times more employment indirectly – upstream and downstream – than it does directly. (European Federation of Pharmaceutical Industries and Associations 2014.)

It also provides a major source of growth and economic performance as reflected by its average annual growth rate. The production index increase amounts to 2.5% (between 2006-2011) and the growth in labour productivity per person employed is 3.6% over the same period. The European pharmaceutical industry serves as a major contributor to the EU's trading power. The EU is also one of the world's major traders in medicinal and pharmaceutical products. In 2013, its total trade amounted to € 156.9 billion (taking into account all 28 EU Member States) and the value of exports reached more than € 107.4 billion. Therefore a viable European pharmaceutical industry is important for European public

health, economic growth, trade and science. (European Commission 2014, p.3-4 & European Federation of Pharmaceutical Industries and Associations 2014.)

## 4.2 Major Drivers and Challenges Facing the Industry

However, the sector faces real challenges. As well as increasingly burdensome regulatory hurdles and escalating R&D costs, the sector has been severely hit by the impact of fiscal austerity measures introduced by governments across much of Europe since 2010 (European Federation of Pharmaceutical Industries and Associations 2014). In order to get an understanding of how effective and efficient SCM can be used to increase economic performance and deliver value both to EU pharmaceutical companies and their customers, it is important to have an overview of these challenges going forward and their key influences. The following list provides details of some of these issues according to the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA):

- 1. Demographic Change One of the key challenges facing the EU is Demographic change. Over the next 50 years, the number of EU residents aged 65 and over is expected to increase dramatically from 92 million in 2013 to 148 million in 2060. As health-related spending generally increases with the age of a person and the prevalence of chronic diseases like diabetes or dementia will rise with an ageing population, consequently such demographic transition is viewed as a major challenge for the financial sustainability of EU health and care systems. Public spending on health care already accounts for more than 7% of GDP in the EU, this is expected to increased significantly by 2060 public when expenditure on acute health care and long-term care measured as a percentage of GDP is expected to increase to between 8.5 and 9.1% of GDP.
- Resistance to Existing Diseases and the Emergence of New Threats A
  higher degree of urbanisation, migration of people from other EU and nonmember states, particularly from the developing world; better mobility increase the risk of epidemics of existing and new diseases, including those

that had previously been eradicated in the EU, and increasing resistance of diseases to existing medicines; have all contributed to new challenges for Pharmaceutical Industry. Additionally, changing life styles are expected to be a further driver in defining public health needs. Chronic diseases like coronary heart disease and diabetes are becoming more widespread and increasingly affect not only the older part of the population.

- 3. Investment in Pharmaceutical Research and Development Developing medicinal products is increasingly complex, expensive and risky. Consequently, R&D expenditures in the pharmaceutical sector have grown dramatically, which has resulted in a widely acknowledged decline in Pharmaceutical R&D productivity largely due to the increased costs associated with developing a new medicine. R&D costs in the pharmaceutical industry are estimated to amount to approximately € 1 billion for each new medicinal product entering the market, while in 1975 development costs amounted only to € 149 million (in 2000 prices). An increasing focus on more complex diseases has also led to increasing R&D costs and R&D projects targeting diseases have a lower average probability of successful development. Another reason relates to regulatory a factor which has led to higher demands by marketing authorisation agencies with regard to the quality, scope and scale of data submitted as a consequence of legitimate public health objectives.
- 4. Policy Consistency regarding the Pharmaceutical Sector The rules affecting pharmaceuticals is set at both EU and national level. The framework concerning the placing of a pharmaceutical product on the market in the EU and other related subject matters (e.g. the supervision of products after authorisation, the manufacturing, wholesaling or advertising of medicinal products for human use, clinical trials, and specific rules addressing the particularities of certain types of medicinal products and promoting research in areas like orphan medicinal products) fall under the competences of the EU. This combination of EU and national standards and regulations can often lead to confusion and extra cost for the Pharmaceutical Industry.

- 5. Ethical Behaviour Public awareness and demands, with regard to the social and ethical performance of enterprises is increasing and the sector has to respond to this challenge. Consumers are increasingly expecting the industry to go beyond a purely economic role and make a growing contribution to society as a whole, particularly in times of crisis. This increased interest of the public in the ethical conduct by all parties concerned, i.e. industry, healthcare professions, the distribution chain, hospitals, and public authorities, has also been reflected in the Commission's activities and demands on the industry in terms of performance and reporting. Consequently the pharmaceutical industry is subject to increased public scrutiny since a major part of its revenues is paid by public bodies, particularly in European welfare states. This issue and is role in delivering value to both the industry and the consumer is covered in more detail in Section 4.2 of this report.
- 6. Increased Competition from Emerging Economies There is rapid growth in the market and research environment, as well as a proliferation of generic medicines; in emerging economies such as Brazil, China and India. This has resulted in a gradual migration of economic and research activities from Europe to these fast-growing markets where lower research and development costs and a less stringent regulation environment, allow for a better return on investment. The IMS Retail Drug Monitor reported in 2013 that the Brazilian and Chinese markets grew by 17% and 14% respectively compared to an average market growth of 1% for the five major European markets and 3% for the US market (European Commission 2014, p.3-13 & European Federation of Pharmaceutical Industries and Associations 2014.)

#### 4.3 Role of SCM in Delivering Value and Profitability

Prior to the 1990's, the Pharmaceutical Industry supply chain and its subsequent SCM focussed on the sourcing and manufacture of test materials to be used in clinical trials of medicine and related products, for regulatory scrutiny. The justification for this was that manufacturers believed that there was little value in investing any more than necessary in a medicines supply chain before

they were granted approval. This approach resulted in a narrow and short-term mind-set leading to:

- A lack of focus on the performance of suppliers and their supply chain,
   when making decisions on procurement policies and practices
- Short-term tactical sourcing and outsourcing of decision making
- Carrying of large holding inventories to counter any lost sales
- Employing strategies of maximising batch sizes to minimise cost per unit
- Extensive off-line testing and checking of documentation
- A resistance to change

By focussing its supply chain primarily on cost and regulatory, the Pharmaceutical Industry failed to connect with its end consumer and tended to adopt a take it or leave it approach, and thereby failed to deliver value. (Rees 2011, p. 16.)

### 4.4 Modern Pharmaceutical Industry Supply Chains and SCM

Since the 1990's, major economic and operating changes and disruptions coupled with a more sophisticated consumer, has forced Pharmaceutical Companies to review and amend their approach to SCM and Value delivery, in order to remain competitive and fend off competition from emerging economies. The basic concept of interconnectedness still exists however SCM has become increasingly complex with the realisation those quick fixes are no longer a viable approach to long-term profitability and that the identification of root-cause issues and sustainable solutions is the way forward. (Rees 2011, p. 18).

The primary objective of Pharmaceutical Companies as well as Governmental and public sector pharmaceutical supply chains is to provide access to easy and on time access to medicines and associated supplies, promote the proper use of the medicines, and to ensure quality, safety and efficacy of these medicines. Whilst this can result in highly complex which vary according to national, and in the case of the European based companies Union legislations and mar-

ket structures; a general supply chain process exists, which can be attributed to every pharmaceutical company and is demonstrated in Figure 4.

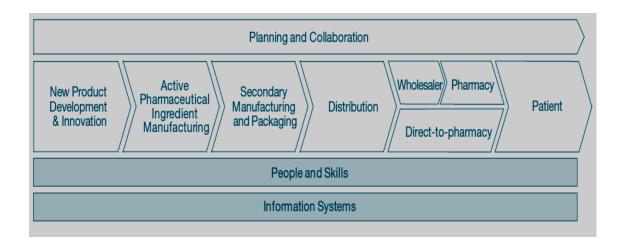


Figure 4. Pharmaceutical supply chain (PricewaterhouseCoopers 2011)

As has previously been highlighted, outsourcing is of growing importance to the European pharmaceutical industry, with Phoneix Group (one of the three large pan-European pharmaceutical companies) stating that "Today there is not a single country in Europe where it is not in manufacturers' interests to outsource their entire distribution and logistics requirements, whether for drugs, medical products or veterinary pharmaceuticals, to a specialist company operating within an efficient logistical system. This logistical partner takes over responsibility for distribution to all wholesalers (Cmolik 2012, p.18-19.)"

Increasingly modern pharmaceutical companies are outsourcing an increasing amount of their everyday activities to 3<sup>rd</sup> and 4<sup>th</sup> party service providers, and wholesalers. Typically a pharmaceutical company will manage its own supply chain activities such as planning, operational procurement and delivery functions regionally, and their enabling, manufacturing and assembly and strategic procurement functions globally. They outsource about 6% of their planning and sourcing activities; 25% of their new product development activities; and 20%-40% of their delivery activities. The most important value drivers for these companies are maximum delivery performance (100%), minimised costs (94%), maximum volume flexibility and responsiveness (78%) and minimised risks

(78%). An issue of increasing importance and focus for the leading companies is collaboration with key customers and suppliers and end-to-end supply chain planning. A great weight also continues to be placed weight on continuous improvements in manufacturing and its associated activities. (PriceWaterHouse 2013, p. 26.)

Additionally these wholesalers, as well as 3<sup>rd</sup> and 4<sup>th</sup> Party Service Providers; offers services such as professional storage and transportation in accordance to the necessary legislation and special requirement for drugs handling, as well as other tailor-made solutions required by the Pharmaceutical Industry. These tailor-made solutions include such things as product tracking, monitoring of temperature, humidity and exposure to light, and country specific packaging and labelling. (Cmolik 2012, p. 19.)

### 4.5 Development of a Pharmaceutical Product and typical Supply Chain

The development and bringing to market of new drugs is of ever increasing costs and reduced margins. Efficient supply chains and SCM provide an opportunity for EU pharmaceutical companies to increase their return on investment. A typical drug development supply chain can be broken-down into five stages, these being (i) preclinical development, (ii) preparing for phase 1 of clinical trial i.e. is the drug safe for human use? (iii) phase 2 and proof of concept, (4) phase 3 registration-orientated and pivotal clinical trials, and (v) commercial launch and supply and Phase 4 clinical trials after launch. These stages are typically referred to as "Commercial" and "Clinical" supply chains, each of which has its own characteristics and a drug development can be dropped at any stage without recouping any of the outlay that has been made. Therefore SCM is critical in developing products that come to market and produce a return on investment, and minimise costs for products that are dropped. Table 1 provides a summary of the main differences between "Commercial" and "Clinical" supply chains and their Value-Chain parameters (Rees 2011, p105-110.)

Value-Chain Parame- Clinical Value-Chain Commercial Value-

ter		Chain	
Inventory	Expensed	Balance Sheet Asset	
Demand/capacity	Determinate (set by	Uncertain (driven by pa-	
	clinical protocols)	tient markets)	
Working capital	Low	High	
Agreements	Investigator, Contract	Licensing, distribution,	
	Research Organisa-	quality/technical, and	
	tions, development,	commercial supply	
	quality/technical		
Compliance	Increasing Current	Validation, change con-	
	Good X Practice (X can	an trol, traceability, preap-	
	mean: Clinical, Labora-	proval inspections	
	tory, Manufacturing,		
	Pharmaceutical,) ap-		
	plies		
Insurance	Limited	Product liability, marine	
		insurance, etc.	
Supply base calibre	Support needs of spe-	Able to cope with long-	
	cific studies	term market supply	
Cost of Goods	High: immature pro-	Need to manage cost	
	cesses and low volume	reduction to leverage	
		higher volumes/process	
		maturity	
Distribution logistics	Mainly express couriers	Complex channel net-	
	to sites	works to wholesalers,	
		clinics, hospitals and	
		pharmacies	
International move-	Shipped as research	Liable to stringent as-	
ments	materials	sessment because of	
		implications for duty, tax,	
		etc.	
Packaging	Mainly regulatory driv-	Many stakeholders for	
	en, simple design and	approval and complex	

Table 1. Main differences between "Commercial" and "Clinical" supply chains and their Value-Chain parameters (Rees 2011, p105-110)

This table demonstrates how difficult it can be for a pharmaceutical company to develop and bring a product to market, and how critical effective SCM is in producing value for both the company and the consumer.

#### 4.6 Understanding the Pharmaceutical Industry Value Chain

As the cost of developing and bringing new products to market and regulatory burdens have increased the landscape of the European pharmaceutical industry has altered dramatically. The focus of the industry has moved from quick fixes and cash cows to become increasingly on understanding the effects of disease and infections at a molecular level in an attempt to develop better and more specifically targeted innovative products, which reduce the risk of product development failure and subsequent monetary and value for the company, and to deliver better products to the consumer.

Elements of the pharmaceutical value chain typically focus on the consumer/patients receiving the correct medicine, at the appropriate time and from a convenient location. Ensuring that these three core elements are achieved requires a complex value chain which includes the manufacturing of the medicine, distribution to the dispensing point and dispensing to the end-user. An initiative between the World Health Organisation (WHO) and Health Action International (HAI), has established a 6 key-stage methodology for classifying the level of medicine build up at each stage of the supply and value chain these being (i) the manufacturer selling price, (ii) cost, insurance, freight charges (CIF), import tariffs and charges, (iii) importer margin, (iv) distribution margins, (v) retailer margin, and (vi) taxes. The combination of the value added at each stage as well as their linked costs, provides a basis for understanding the pharmaceutical supply and value chains. The degree to which these occur depends on the sophistication and efficiency of these Chains and common commercial practices.

Table 2 provides a breakdown of the pharmaceutical/drug industry value chain by stakeholder (IMS Institute for Healthcare Informatics 2014, p.1-3)

Illustrative	Manufacturer of drug	Distribution	Dispensing
Cost Incurred	<ul> <li>R&amp;D</li> <li>Manufacturing     Costs</li> <li>Import duties &amp;     taxes</li> <li>Promotion &amp; education</li> </ul>	<ul> <li>Medicine acquisition</li> <li>Handling &amp; delivery</li> <li>Obsolescence costs</li> <li>Capital costs</li> <li>Promotion &amp; education</li> </ul>	<ul> <li>Medicine acquisition</li> <li>Labour facilities, equipment</li> <li>Medicine wastage</li> <li>Capital costs</li> <li>Education</li> </ul>
Value Added	<ul> <li>Innovation</li> <li>Regulatory documentation</li> <li>Quality assured manufacturing</li> <li>Education</li> </ul>	<ul> <li>Ensuring continuous medicine supply</li> <li>Waste management</li> <li>Order processing</li> <li>Education</li> </ul>	<ul> <li>Medicine availability</li> <li>Pharmacist advice</li> <li>Patient convenience</li> <li>Additional healthcare services</li> <li>Education</li> </ul>

Below the value added by each illustrative is examined in more detail:

• Value added by the manufacturer relates to new generation medicines and relates to the treatment of the consumer/patient. Advances may include tackling a new disease, improving health outcomes, treatment safety, reducing side-effects and ability to treat specific ailments and patient demographics. In addition, there are potential wider benefits to health systems including reducing the burden on health systems and overall benefits to society. Whilst the main cost in drug discovery and development is R&D, the value-added extends beyond the drug produced and includes advancements in scientific knowledge and technological advancements, which have the po-

tential to diffuse into other areas of industry. Additionally, promotional and educational efforts by the manufacturer can help those working directly with consumers to ensure the most appropriate, effective and quality standard of care. (IMS Institute for Healthcare Informatics 2014, p.7.)

- The key value added by distributors is the function to resolve the challenge of being able to meet the various needs of the consumer, through supplying the manufacturers' medicines, without requiring the retailer to carry large inventory levels. Another role of the distributor is to provide the required working capital for pharmacists to allow them to purchase the end products, before receiving payment from the end-user. Finally, wholesalers are also able to provide a wide variety of commercial support functions to independent pharmacists to improve their business, including sales training and education programmes for pharmacists. (IMS Institute for Healthcare Informatics 2014, p. 10.)
- A role of the retail pharmacist is that of logistics and being able to provide the correct drug, in the right quantity, at the right time and place. In addition, the pharmacist may also be required to correct prescription errors, processing prescriptions, labelling, etc. As well as advising consumers on product safety and possible side effects. Another recent phenomenon has been drug shortages. Although the EU can be considered as one of the most efficient producers and market for pharmaceutical products, countries such as the Netherlands has indicated a 3-5% unavailability of products at the time of order. Such shortages can result in adverse health outcomes and consumers switching products. Consequently pharmacists dedicate a large amount of their time sourcing drugs or finding alternatives. Finally, in recent years the role of the pharmacist has moved beyond the traditional role of dispensing drugs, but to advising on patient health related issues such as disease management, and nutrition and lifestyle factors. (IMS Institute for Healthcare Informatics 2014, p.14.)

# 5 Sustainable Pharmaceutical Supply and Value Chains in the EU

The pharmaceutical industry contributes many benefits to Europe and its citizens:

- Better quality healthcare and treatment choices;
- Value solutions that meet national healthcare and social security budgets;
- **Investment in innovation** in Europe, bringing highly skilled employment and contributing economic benefits.

Sustainable, integrated and collaborative business practices is of increasing importance in the development of a sustainable pharmaceutical industry within the EU, and many companies are coming together to work together on issues that will benefit the whole industry, as well as the customers it serves and the communities in which they operate. In the EU this has led to the establishment of the European Federation of Pharmaceutical Industries and Associations (EFPIA), who represents the pharmaceutical industry operating in Europe. It acts as a single voice on the EU scene of 1,900 companies, including some of the largest global companies such as GlaxoSmithKline (GSK), Pfizer and Roche; by fully engaging with the EU and, in the discussions on the formulation, revision and implementation of regulation and EU legislation. (EFPIA, 2015.)(1.) The EFPIA along with the European Generic Medicines Association (EGA) have identified three priority action points which they believe if implemented successfully will help build a healthier EU pharmaceutical and health industry, which benefits both the manufacturer and end-user. These priority areas are:

- Recognising that medicines are essential to improve patient outcomes and equity of access to healthcare across Europe;
- Supporting a more sustainable and predictable business environment to incentivise the pharmaceutical industry to invest in bringing better and more cost effective treatments to patients;
- Fostering an environment that will make the EU an attractive global hub for pharmaceutical research and manufacturing.

EFPIA is active in partnering in EU Research programmes, such as the IMI (Innovative Medicines Initiative), Europe's largest public-private partnerships. They also work on corporate social responsibility initiatives with others healthcare stakeholders, including patient groups and healthcare professionals (European Federation of Pharmaceutical Industries 2015.) (2.)

In addition to collaborative approaches to developing sustainable supply and value chains, pharmaceutical companies are increasingly recognising the importance of ensuring a reliable supply of drugs and other medical products, and as a result are no longer considering each action in the supply chain in isolation, and are employing systems that centralise and coordinate the entire supply chain activities, from raw material procurement to manufacturing to product shipment. In this way companies are able to operate in a more economic and sustainable ways which enable them to steadily reduce costs, increase their flexibility and delivery reliability, and maintain high standards of quality, safety and environmental protection on a global basis. It also enables them to meet increasingly stringent legislative and quality requirements such as completing regularly audits by internal experts, regulatory authorities and external consultants. (Bayer Healthcare 2015.) These sustainable practices are analysed in more detail in Section 6 of this report.

## 6 Empirical Research

The objective of the study was to examine how important SCM is in the European Pharmaceutical industry as a means for developing and delivering effective and sustainable supply chains and value chains. In addition, it also had the objective of identifying future trends and threats to the industry, and how SCM can be used to address these. Respondents were asked to give a brief overview of their current supply chain networks and SCM, and were then given an opportunity to provide their views and opinions on the key objectives that have been described in Section 1.2 of this report. Additionally, respondents were given an opportunity to provide any additional comments that they wished to make

on how more effective and sustainable SCM in the pharmaceutical industry can be achieved, which were not directly addressed in the questions posed to them.

#### 6.1 Data Collection

The data was collected using two structured questionnaires. One was sent to 20 European based pharmaceutical companies and another to 7 European national trade associations representing pharmaceutical companies in different European countries. The names of these Companies and Trade Associations, was obtained from EFPIA website and they represent all of the major large European pharmaceutical companies. The questionnaires were based on the same questions, but the questionnaire sent to pharmaceutical companies contained additional questions on the nature of the supply chains and SCM they used, and were therefore not relevant to the Trade Associations. Copies of the questionnaires can be found at Appendix A and B of this report.

A structured questionnaire was chosen as it enables a researcher to gather and analysis the opinions of a targeted group of contacts on a specific subject in a structured way, enabling them to produce hard facts and statistics on a number of predetermined questions on issues that had come to their attention, through their theoretical research. In each questionnaire the respondent receives exactly the same set of questions, in the same order. The researcher chose this form of empirical data collection as it enabled them to seek the views of a specific group of people located in a number of different European locations, which would have been difficult in terms of practicality (time and money) if other forms of data collection such as face to face interviews or telephone interviews had been used.

The questionnaires were created with the Google Forms system and a personal link to the questionnaire was sent through email to individuals responsible for SCM and corporate media handling. Google Forms saved all the answers and the received data was processed on Google Forms. This data was supplemented with additional information that had been gathered in prior surveys relevant to the objective of the study.

#### 6.2 Background to Respondents

The response rate to the empirical evidence gathering was very low with only one positive response to the questionnaire. In most cases the researcher received no response, or was informed that a response was not possible due the large number of requests that are received by companies on such issues. Therefore, the researcher has used the one response that he received as a case company and used previous empirical evidence that has been gathered on similar issues to back up their findings. Due to confidentiality issues the case company shall be referred to as Company X.

#### **Company X Case Study**

Case Company X provides a good representation of the target market that the researcher attempted to survey. It is a very large multi-national company located in the United Kingdom, and it is active in Asia, Africa, North America, South America, Oceania and other European Countries (Non-EU Members). They employ approximately 130,000 people directly, over 5000 of who are employed directly on supply chain related issues. Additionally it has a specialised supply chain management team located within its central headquarters, which is typical of most large multi-national Pharmaceutical Companies. Company X's supply chain network is made up of over 5000 partners/suppliers, and 25 to 50% of its SCM functions, including documentation handling and processing and freight booking; is outsourced to 3rd or 4th Party Service Providers who are required to commit to and apply Company X's supply chain objectives.

In section 4.3 of this report, the researcher describes a simplified version of a pharmaceutical company supply chain. As part of the questionnaire the researcher asked responders to briefly describe a typical supply chain in their company. Company X's typical supply chain is:



Figure 5. Company X typical Supply Chain

This description supports the theoretical evidence the researcher undertook, it also shows that pharmaceutical companies supply chains are now relatively short, and are moving towards supplying the end user (customer) directly rather than through wholesalers, which had often been the case in the past. By doing this Pharmaceutical Companies are able to obtain value/profits which had previously been lost at this stage in the chain. It also enables them to be in a better position to respond quickly to the end users demands and needs, and reduce wastage in the supply chain.

In section 4.1.2 the researcher examines some of the major drivers and challenges facing the European pharmaceutical industry, from the empirical evidence it was discovered that the biggest drivers and challenges facing Company X are worldwide drugs legislation, chemicals, animal by-products and medicine licensing. In addition they are also challenged by the multiple pieces of differing legislation in place in different countries; worldwide shipping and temperature controlled shipping are also an issue.

The major focus of this research paper was to examine how effective and sustainable SCM in Pharmaceutical Industry can be used to develop future competitiveness for traditional Pharmaceutical Companies. However, whilst sustainability is very important to Company X, they were unsure whether as to how this could be achieved within the current environment the Industry is operating in. That said Company X stated when asked to describe briefly how they thought sustainable and responsible agendas could be be used as a tool for competitiveness and better SCM, they felt that this could be achieved by embedding sustainability into their procurement and supply chain, and stopping being part of the problem through their purchasing behaviour. They stated that without a

unified message to suppliers over social and environmental practices they will not change. Turning hidden cost and risk into competitive advantage through supply base collaboration is of strategic importance, and an individual company cannot change an entire culture and infrastructure of an industry. In order to induce systemic change Pharmaceutical Companies and their partners need to overcome distrust and coalesce with peer companies in areas of mutual interest.

Company X consider the most important payoffs of a more sustainable supply chain are Customer Related Payoffs, including increased customer satisfaction, product innovation, and improved reputation; and the major drivers and challenges facing the European Pharmaceutical Industry in the future are customer demographic change, policy consistency regarding the Pharmaceutical Sector and ethical behaviour.

Finally Company X was given the opportunity to make any final comments on their supply chain. They stated that patients and consumers rely on them to provide an uninterrupted supply of medicines and products, manufactured to the highest-quality standards and spend over approximately €4 billion each year manufacturing and supplying products to help people do more, feel better and live longer. An effective and responsibly managed supply and distribution system is essential for them to get high-quality products to the right places at the right time. If they do not do this, people's health may suffer and their lives may even be at risk. To protect the interests of their patients and consumers, they aim to work with responsible suppliers who meet the same quality, social and environmental standards as themselves.

Ethical conduct is a priority and they are committed to performance with integrity. They have robust policies and compliance processes covering all their operations, including the way they reward their sales representatives, how they market their medicines and vaccines, and how they work with stakeholders. Their compliance programmes embed the same standards across their business units in different countries. These include a Code of Conduct, which outlines how all employees should apply our Values and Behaviours, and a Global Code of

Practice for Promotion and Customer Interactions, which applies to all employees involved in sales and marketing as well as third parties acting on their behalf. All employees have access to whistleblowing mechanisms that they can use to get advice and to report suspected cases of misconduct – anonymously if required.

### 6.3 Supporting Empirical Evidence

In order to support the reliability and consistency of this empirical evidence, the researcher has chosen to compare the response of Company X to similarly themed researchers that have been undertaken on the pharmaceutical companies by well-regarded and globally recognised industrial consultancy firms.

In a survey of the pharmaceutical industry in 2013, PricewaterhouseCoopers (PwC), which surveyed over 500 supply chain executives, including those involved in the Pharmaceutical industry, on the future trends in supply chains and SCM; discovered that the majority of pharmaceutical companies manage the planning, operational procurement and delivery functions of their supply chains regionally, and their enabling, manufacturing and assembly and strategic procurement functions globally. Approximately 6% of planning and sourcing activities; a relatively high 25% of new product development activities; and between 20%-40% of deliver functions are outsourced. In terms of supply chain performance the leading pharmaceutical companies on average achieve Earnings Before Interest and Tax (EBIT) margins of 16.9%; Inventory Turnovers of 16,3 and delivery performance of an impressive 97,4%.

In the same survey PwC identified the leading value drivers for pharmaceutical companies. 100% of respondents identified "Maximum delivery performance," which includes issues such as end-to-end supply chain planning and visibility, order fulfilment cycle-time reduction and improved manufacturing time and collaborative planning with key suppliers; as the most significant value driver. Other value drivers and supporting practices identified, included:

- Minimising costs (94%) including decreased manufacturing costs through waste reduction and inventory reduction.
- Maximum volume flexibility and responsiveness (78%) including outsourcing to 3<sup>rd</sup> and 4<sup>th</sup> party suppliers, and partner involvement in decision processes.
- Minimising risks (78%) including short-term supply visibility through measures such as traceability; multiplying sources and reducing the reliance on single sourcing and regular review of suppliers.
- Complexity Management (72%) including the use of distributors and channel partners, differentiation of distribution strategies and development of multi-skilled employees who can handle a varied number of responsibilities.
- **Sustainability (67%)** including responsible supply chain partners footprints and procurement and recycling returns through the supply chain.
- Tax optimisation (53%) –import and export optimisation, intellectual property and patent royalty optimisation and localisation of inventory ownership in tax efficient countries. (PriceWaterHouseCooper 2013, p. 26-27.)(1.)

In a separate survey of Global Pharmaceutical Companies Chief Executive, PwC found that respondents believed that the biggest change factor and priority area for the sector are advancements in technology and that is essential for them to take advantage of the benefits that these bring, which they believe that they are doing through their strength in using innovation in their day to day business. Other significant issues affecting the sector are regulatory focus and business integrity; and the battle for talent, particularly with changing consumer/patient demographics and shifts in wealth with 72% of respondents believing this movement will have a significant transformational effect on their business. Innovation and intellectual property are also key priority areas and 38% of respondents stated that they had completed or in the process of changing their R&D and innovation strategies to manage future business transformation (PriceWaterHouseCooper 2014, pp 4-5.)

It was also discovered that the main restructuring activities that are planned by the industry are new strategic alliances or joint ventures, with the sector more likely than other industries to seek alliances, joint ventures or outsourcing. However, the Pharmaceutical demonstrate less desire to do cross-border mergers and acquisitions (PriceWaterHouseCooper 2014, pp. 15).

### 7 Summary and discussion

The main purpose of this research was to examine the importance of SCM in developing and delivering effective and sustainable supply chains and value chains in the pharmaceutical industry, by specifically examining the situation within traditional European based pharmaceutical companies. In addition, it was an objective to gain an understanding of the likely future trends and threats to the industry, and analyse how SCM can be used to address these.

It is evident from this research that large multinational pharmaceutical companies, and not just those located within Europe; face a number of challenges in managing and developing their supply chains, in order to unlock there "Value" and to maintain a sustainable business. However, this can be difficult for pharmaceutical companies, particularly for large multinational companies who have complex supply chains and long product lead times.

Unfortunately the results of the industry questionnaire were very low. However, the response that was received was from a well-known multinational pharmaceutical company that represented the company structure and size the researcher was targeting. Therefore it provided a good representation of the pharmaceutical sector and the companies the researcher wanted to gain an understanding of, and the issues that Company X discussed would typically be the same for the other companies that the researcher contacted. The responses from Company X were also supplemented with results from similar surveys conducted by PwC on the pharmaceutical industry.

From this research it has become apparent through both the theoretical and empirical evidence that the pharmaceutical industry is going through a period of transition. It is no longer the case that a few very large companies can dominate the market with a limited number of block buster drugs. Numerous factors, including escalating R&D costs, the emergence of competitors in emerging economies such as Brazil and India; the emergence of generic drug manufacturers who can produce for like drugs at the fraction of the cost and a more knowledgeable and demanding consumer/patient; are forcing traditional pharmaceutical companies to think smarter and re-evaluate their existing supply chains and their management. However, it can be said that the biggest issue affecting the pharmaceutical industry is worldwide product legislation and licensing, and the multiple pieces of differing legislation in place in different countries. These multiple pieces of legislation create additional procedures and related costs for these companies, and subsequently restrict their efficiency and return on investment.

As the pharmaceutical sector is increasingly more global in its make-up and target markets, supply chains, their interlinked activities and management is becoming one of the most pressing business issues for pharmaceutical companies. One of the most pressing issues is partnerships between pharmaceutical companies and logistic service providers. It is imperative that there is a clear and accepted understanding between all the parties involved and a trust that the supply chains will work at all connections in the links, deliver value and meet the expectations of the consumer/patient. It was therefore interesting to receive Company X's views on this issue, which supported this opinion. Company X stated that without a unified message to suppliers over social and environmental practices they will not change. Turning hidden costs and risks into competitive advantages through supply base collaboration is of strategic importance, and an individual company cannot change an entire culture and infrastructure of an industry. In order to induce systemic a change you need to overcome distrust and coalesce with peer companies in areas of mutual interest.

Through the theoretical research conducted as part of this study it is evident that this collaborative approach is becoming of increasing strategic importance. For example, a number of industry representative bodies, such as the EFPIA, has been established and the writing of pan-industry implementation guidance on "Pharmaceutical Industry Principles for Responsible Supply Chain Manage-

ment," which has been developing through joint working between all of the major pharmaceutical companies.

It is also evident that one of the most important benefits resulting from developing sustainable SCM is delivering value to the customer/end user, and the ability of getting drugs to the end-user (patient) efficiently, on-time and in perfect condition. As ultimately increased customer satisfaction, product innovation, and improved reputation are key drivers to future customers and economic growth. If the customer is unhappy with a product they will seek an alternative from your competitor.

It can therefore be concluded that whilst sustainable SCM is of key importance to pharmaceutical companies and they are taking actions to modernise their supply and value chains, as a means to deliver cost savings and value to both the company and the end-user. It is difficult to foresee totally sustainable SCM in the near future unless there is a move towards a global consensus on legislation on the pharmaceutical industry, using mechanisms such as the World Trade Organisation (WTO).

# **Figures**

Figure 1. A comparison between a Value Chain and Supply Chain (Feller et al 2006)

Figure 2. Simplified Supply Chain

Figure 3. The Three Spheres of Sustainability (Vanderbilt University 2015)

Figure 4. Pharmaceutical Supply Chain (PricewaterhouseCoopers 2011) (2).

Figure 5. Company X typical Supply Chain

# **Tables**

Table 1. The main differences between "commercial" and "clinical" supply chains and their value-chain parameters (Rees 2011, p105-110.)

Table 2. A breakdown of the pharmaceutical/drug industry value chain by stakeholder (IMS Institute for Healthcare Informatics 2014, p.1-3)

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# Appendix A

# The way to effective and sustainable Supply Chain Management in Pharmaceutical Industry

The objective of this questionnaire is to gain an understanding of the importance of Supply Chain and Value Chain Management within European Pharmaceutical Companies, and how it can be used to build a "Sustainable" business.

### **Company Name**

(Your company legally registered name)

### In which country is your company/organization based?

(Location of registered headquarters)

### In what other regions is it mainly active?

(Where does your company have offices/manufacturing sites outside of the EU)

Asia

Africa

North America

South America

Oceania

Other Europe (Non-EU Members)

How many people are employed directly by your company?

How many people does your company employ directly on Supply Chain related issues?
Does your company/organisation have a specialised Supply Chain Management Team?
Yes
No
N/A
If "Yes" is your Supply Chain Management coordinated centrally or from each of your company's/organisations locations
How many supply chain partners/suppliers does your company interact with?
Approximately how much of your Supply Chain Management outsourced to 3rd or 4th Party Service Providers?
(Does your company/organisation employ others to undertake Supply Chain functions on your behalf)
0-25%
25-50%
50-75%
75-100%
100%

If you outsource Supply Chain related activities please provide examples of the type of activities.
Are your partners/suppliers required to commit to/apply your own companies Supply Chain objectives
Yes
No
Please describe briefly a typical Supply Chain in your company
(This could include a typical Supply Chain in drug production or delivery of a product to the end-user)
What are the biggest challenges/obstacles to successful Supply Chain Management in the Pharmaceutical Industry?
Please describe briefly how you believe a more sustainable Supply Chain can be achieved
How important is sustainability in your companys/organisations Supply Chain Management
(This includes issues such as social responsibility and business efficiency and delivery of objectives)
1 2 3 4 5
Not Important C C C C Very Important

What has been the impact of sustainable and responsible business agenda's and regulatory requirements on your company/organisation and your Supply Chains

1	2	3	4	5	
Has not impacted at all O	0	0	0	0	Impacted signicantly

Please describe briefly how you think sustainable and responsible agendas can be used as a tool for competitiveness and better Supply Chain Management?

What do you/your company/organisation consider to be the most important payoffs of a more sustainable supply chain

Financial Payoffs – these include reduced operating costs, increased revenue, lower administrative costs

Customer Related Payoffs – these include increased customer satisfaction, product innovation, and improved reputation

Operational Payoffs – these include process innovation, productivity gains, reduced cycle times and waste minimisation

Organisational Payoffs – these include employee satisfaction, improved stakeholder relationships, reduced regulatory intervention, reduced risk

Other

If "Other" please specify

What do you believe are Major Drivers and Challenges Facing the European Pharmaceutical Industry in the future?

Customer Demographic Change

Resistance to existing diseases and the emergence of new threats

Investment in Pharmaceutical Research and Development

Policy Consistency regarding the Pharmaceutical Sector

Ethical Behaviour

Increased Competition from Emerging Economies

Other

If "Other" please specify

Please add any additional comments you would like to make on how more effective and sustainable Supply Chain Management in Pharmaceutical Industry can be achieved

# Appendix B

The way to effective and Sustainable Supply Chain Management in the European Pharmaceutical Industry

The objective of this questionnaire is to gain an understanding of the importance of Supply Chain and Value Chain Management within European Pharmaceutical Industry, and how it can be used to build a "Sustainable" business.

Trade Association full name

**Country of Location** 

How many Pharmaceutical Company Members do you have?

What is the typical size of your Members?

(i.e. What is the average number of employees?)

What do you consider to be the biggest challenges/obstacles to successful Supply Chain Management in the Pharmaceutical Industry?

Please describe briefly how you believe a more sustainable Supply Chain can be achieved

What has been the impact of sustainable and responsible business agenda's and regulatory requirements on your members and their Supply Chains

	1	2	3	4	5	
Has not impacted at all	0	0	0	0	0	Impacted Significantly

How important is sustainability in your members Supply Chain Management

(This includes issues such as social responsibility and business efficiency and delivery of objectives)

Please describe briefly how you think sustainable and responsible business practices and agendas can be used as a tool for competitiveness and better Supply Chain Management?

What do you/your company/organisation consider to be the most important payoffs of a more sustainable supply chain

Financial Payoffs – these include reduced operating costs, increased revenue, lower administrative costs

Customer Related Payoffs – these include increased customer satisfaction, product innovation, improved reputation

Operational Payoffs – these include process innovation, productivity gains, reduced cycle times and waste minimisation

Organisational Payoffs – these include employee satisfaction, improved stake-holder relationships

Other

If "Other" please specify

What do you believe are Major Drivers and Challenges Facing the European Pharmaceutical Industry in the future?

Customer Demographic Change

Resistance to existing diseases and the emergence of new threats

Investment in Pharmaceutical Research and Development

Policy Consistency regarding the Pharmaceutical Sector

**Ethical Behaviour** 

Increased Competition from Emerging Economies

Other

If "Other" please specify

Please add any additional comments you would like to make on how more effective and sustainable Supply Chain Management in Pharmaceutical Industry can be achieved