

**AN ANALYSIS OF THE KEY DRIVERS, DECISION MAKING AND STRATEGIC ISSUES
WITH RESPECT TO OUTSOURCING IN THE SA PHARMACEUTICAL
MANUFACTURING INDUSTRY**

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**By
I Govender
Student no: 70792925
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ABSTRACT

“Outsourcing has been touted as the ideal way for organisations to reduce cost, focus on core business processes, improve services, enhance skills, reduce time-to-market and increase overall competitive advantage,” (Power, Bonifazi and Desouza, 2004). A pertinent question is therefore ‘Can South African companies in the pharmaceutical industry remain competitive by outsourcing, what is driving these companies to outsource and how effective has the initiative been?’

The purpose of the study is to identify the extent to which various key factors play an influential role in motivating pharmaceutical companies in SA to outsource. South African pharmaceutical companies as part of the global arena, have to continually assess the feasibility of manufacturing their products in-house or allowing contract manufacturers to manufacture and or pack on their behalf. The research questions posed in this research were: why are companies outsourcing, what is outsourcing and what is happening amongst the South African pharmaceutical companies? The results of this qualitative rich study have shown that outsourcing in SA is not just about cost savings or reduction in product costs but that this process is able to afford the contract giver the ability to tap into additional capabilities (facilities, technology and skill) of their outsourcing partner.

Outsourcing has enabled the contract manufacturers in SA to assist the contract givers in numerous areas such as cost reduction, cost saving, reduction in capital investment, increased flexibility and allowed the contract givers to focus on their core competencies. The implementation of off shoring may result in South African contract givers incurring additional ‘hidden costs’ which may be attributed to quality problems, reduced flexibility of transport, product write-offs (due to large volumes ordered), currency fluctuations and additional resources that may be required (technology transfer, documentation review, and validation). The responses from the research questionnaires indicate that the key drivers of outsourcing in South African are aligned with those identified in global

marketplace by Jiang and Qureshi; Copestake and Lau and Zhang (2006). The main drivers being **profitability increase** (cost reduction, cost saving and capital reduction), **strategic considerations** (focus on core competence, increased flexibility and to facilitate market penetration) and access to **knowledge and skills**.

The key for the South African outsourcing service providers lies in ensuring that their clients are kept satisfied so that they can minimise the threat of offshore providers. The results of the study are line with Momme and Hvolby (2001) suggestions in which they advocate that organisations only outsource when suppliers have a comparative advantage and that an organisation proactively have a stronger focus on its internal core business areas. In SA governmental changes in regulations/ laws such as those addressing parallel importation, patents, foreign investors and trade would impact on the countries national competitive advantage. However although outsourcing is highly beneficial, organisations need to carefully manage the process, identify hidden costs, risks and initiate preventative measures to ensure success.

This study was the first step towards conceptualising the impact of the key drivers, decision making and strategic issues on the South African pharmaceutical manufacturing industry.

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DEFINITION OF TERMS

Anti- retroviral (ARV's) – medication that is administered to HIV positive people. It works by slowing down the replication of the HIV virus.

Contract Giver (CG) is responsible for assessing the competence of the contract manufacturer to carry out successfully the work required. The CG outsources the manufacturing and or packing to the contract manufacturer.

Contract Manufacturer (CM) is a firm that manufactures products and or packs for another company that is the 'hiring' company/ contract giver.

Capability in the context of the current research includes an organisation facility, equipment, processes, systems, capacity, experience and skills

Economies of scale can be accomplished because as production increases, the cost of producing each additional unit falls.

Food and Drug Administration is regulatory body that governs the manufacture, sale and distribution of medication the United States

Generic manufacturer manufactures drugs that contain the same active ingredient as the original formulation. The generic drug is considered bioequivalent to its branded counterpart with respect to pharmacokinetic and pharmacodynamic properties (wikipedia)

Incoterms are internationally accepted commercial terms defining the respective roles of the buyer and seller in the arrangement of transportation and other responsibilities and clarify when the ownership of the merchandise takes place. They are used in conjunction with a sales agreement or other method of transacting the sale.

Key success factors (KSF) as those competitive factors that most affect industry members ability to prosper in the marketplace (Thompson, Strickland and Gamble (2005).

MCC is the regulatory body responsible for determining which medicines can be sold in South Africa. It governs the manufacture, sale and distribution of medicines in SA

Off shoring maybe simply defined as outsourcing to “countries other than your own.”

Open- ended questions are those require additional information from respondent and are sometimes referred to as infinite type questions.

Closed –ended questions are those questions that may be answered finitely by either a “yes” or “no.”

Pharmaceutical Company – an independent company that is involved in developing, manufacturing, packing and distribution of registered medicines

Pharmaceutical Inspection Co-operation Scheme (PIC/S) provides an active and constructive co-operation in the field of GMP (Good Manufacturing Practice) for drugs. It will assist in the facilitation of the networking and cooperation between participating regulatory authorities.

Process optimization is the practice of making changes or adjustments to a process to improve the process.

Realignment of Product – the manufacturing of a product that has been moved from one facility to another. Product could have been previously manufactured in house or at another contract manufacturer.

Strategic Alliance according to Hill (2005) is defined as a cooperative agreements between potential or actual competitors and attributes the following advantages to strategic alliances.

Strategic Sourcing encompasses a disciplined, systematic process for reducing the total costs of externally purchased materials, goods and services. (Everbusch and Hill, 1997)

Value chain analysis will assist an institution determine which type of competitive advantage to pursue, and how to pursue it.

ABBREVIATIONS

AMT	Advanced manufacturing technology
BEE	Black economic empowerment
CG	Contract giver
CM	Contract Manufacturer
FDA	Food and Drug Administration
GMP	Good Manufacturing Practices
JIT	Just in time
MCC	Medicines Control Council
MNC	Multinational company
PIC/S	Pharmaceutical International Convention/ Pharmaceutical Inspection Co-operation Scheme
RA	Regulatory Affairs
SA	South Africa
SLA	Service Level Agreement
TGA	Therapeutic Goods Association
TQM	Total quality management
WHO	World Health Organisation

CHAPTER 1: INTRODUCTION TO RESEARCH

1.1 Introduction

This study will aid in the understanding of the outsourcing process. It is intended to focus on factors which influences the decision making process of South African pharmaceutical companies. Pharmaceutical manufacturers are faced with the 'make or buy' decision which may ultimately lead to outsourcing and according to Canez, Platts and Probert (2001), "the make-or-buy question represents a fundamental dilemma faced by many companies."

The research also looks at the obstacles that South African pharmaceutical companies are facing with respect to manufacturing in comparison with the situation in Western developed countries. The study will attempt to investigate if South African organisations could fall under the category of becoming a popular outsourcing destination such as India and China or will the organisations inside of South Africa (SA) follow the trend of their American counterparts and outsource offshore.

1.2 Background to the Study

The changes in the South African pharmaceutical industry are similar to those in other industries throughout the world. Consequently a shift has been observed towards economies of scale (large volumes, low cost) to bring in the profits compared to previously when small volumes with enormous mark-up's brought in the huge profits. The industry although very competitive (Kermani, 2004) and with its share of difficulties (table 1), has a huge growth potential. In SA two of the major reasons for the continuous growth can be attributed to:

- The increasing incidence of HIV/AIDS and the provision for Antiretroviral's (ARV's) and other medication for opportunistic infections within SA, Africa and other international markets and
- Treatment for chronic illnesses due to people living longer.

Table 1.1: Significant Pressures in SA's Competitive Landscape

Significant Pressures in SA's Competitive Landscape	
<ul style="list-style-type: none">• Changes in Legislation• Globalisation• Parallel Importation• Technology• Alliances and Production Sharing	<ul style="list-style-type: none">• Pressure Groups• Black Economic Empowerment• AIDS and Multi-Drug Resistant TB• Baby Boomers

There is immense pressure (local and international) on the SA government to provide ARV's. This has forced the government to reassess its role in the provision of ARV's for HIV infected patients. Globalisation and parallel importation means that South African pharmaceutical companies are now competing with other pharmaceutical company's throughout the world for government tenders in SA and other African countries.

The pharmaceutical industry is highly regulated and thus the manufacture and release of pharmaceutical products in SA will be governed by adherence to strict regulations as set out by organisations such the Medicines Control Council (MCC) and other similar regulatory bodies in other countries such as the Food and Drug administration (FDA) in the United States and World Health Organisation (WHO). Quality assurance needs to ensure that adequate controls are in place at approved manufacturing sites to ensure that manufacturers consistently produce pharmaceuticals of high quality that conform to approved specifications.

The pharmaceutical industry is generally characterized by low switching costs (time, inconvenience and reliability of the substitute) and therefore it is always under intense competitive pressure from competitors with substitute products. According to Thompson, Strickland and Gamble (2005) the strength of competition from substitutes is significantly influenced by how difficult or costly it is for the industry's customers to

switch to a substitute. The industry is never stagnant with new drugs being discovered and novel drugs delivery systems are fast replacing former dosage forms.

Outsourcing is one of the most recent management strategies to emerge in response to demand for more efficient ways to address competitiveness (Jiang and Qureshi, 2006). According to Porter (1996: 61), “the popularity of outsourcing and the virtual corporation reflect the growing recognition that it is difficult to perform all activities as productively as specialist.” Mariotti (1999) defines outsourcing as a strategic decision to obtain goods or services from an independent organisation outside of a company’s legal boundaries; to purchase goods or services instead of making or doing them.

“Outsourcing has been touted as the ideal way for organisations to reduce cost, focus on core business processes, improve services, enhance skills, reduce time-to-market and increase overall competitive advantage,” (Power *et al*, 2004). Increased outsourcing of products to contract manufacturers (CM) can also be attributed to **capacity constraints** (increase in demand for products), **diversification** (increase in product offering and market share) and **strategic or collaborative partnerships** with CMs that are mutually beneficial.

Juma'h and Wood (1999) suggest that companies that outsource may enter into outsourcing agreements for **tactical** (short-term) or for **strategic** (long-term that is concentrating on core business and increasing the efficiency of the outsourcing company) motives. Strict regulations in SA prevent pharmaceutical companies from outsourcing to CM’s who are not registered with the MCC in SA. The registering of an alternative manufacturer with the council may take as long as six to nine months which makes it difficult for the CG to switch from one CM to another.

Kannan and Tan (2006) make clear that although outsourcing allows firms to exploit the capabilities, expertise, technologies, and efficiencies of their suppliers, the firm becomes more reliant on their suppliers. Some pharmaceutical companies have since

recognised the competitive or cooperative duality of business relationships and no longer view inter firm relationships as exclusively competitive in nature. Strategic alliances and collaborative partnerships form a major part of their strategy.

The pharmaceutical industry in SA has to remain competitive to compete in the global marketplace and when faced with the decision on whether to outsource or not they need to consider the key drivers and strategic issues prior to finalising their decision.

1.3 Problem Statement

This research focuses on identifying strategic factors such as cost, quality and capability that would assist an organisation to make the correct decision that is whether to make or buy medicines, so that the organisation can amongst other things increase its market share, improve profitability and decrease the time its takes to launch new products (first to market).

South African pharmaceutical companies are no longer operating in a vacuum and need to focus on ensuring that their products are put onto the market first whilst simultaneously reducing costs of medication and retaining product quality. Strategic decisions need to be finalised when addressing capacity issues such as:

- Which products will be manufactured?
- Which countries to supply?
- Should investments be made to increase capacity?
- Should additional capacity be gained through outsourcing?
- What level outsourcing is needed?
- Which products should be outsourced?
- If capacity is increased what happens if demand falls away?

Many pharmaceutical companies in SA are faced with the make or buy decision in trying to launch new products faster thereby continuously increasing shareholder

value. Pharmaceutical companies thus need to find ways to reduce costs maintain high quality standards and meet the market demands for product.

1.4 Research Objectives

- a) To understand why companies are outsourcing (**why** outsource)
- b) To elaborate on outsourcing as a strategic initiative (**what** is outsourcing) and
- c) To identify current outsourcing practices in the pharmaceutical industry (**what** is happening).

The responses from questionnaires and interviews with both the contract givers and manufacturers will be analysed to identify these drivers and factors mentioned in the objectives. The qualitative research methods adopted will also enable the researcher to gain an understanding of the current situation that is how the decisions at present are being made. Recommendations will then look at what should be done.

1.5 Purpose of the Study

The purpose of the study is to identify the extent to which the various key factors play an influential role in motivating companies to outsource. South African pharmaceutical companies as part of the global arena, have to continually assess the feasibility of manufacturing their products in-house or allowing contract manufacturers to manufacturer and or pack on their behalf.

Dubourg (2003) explains that as outsourcing in the industry matures, pharmaceutical manufacturers will select their outsourcing partners strategically and will consider their partnership to be a competitive advantage.

1.6 Assumptions

This research is focused on identifying key factors that play a role in the decision to outsource. The assumptions to this research are as follows:

The first assumption is that outsourcing is an important facet of the pharmaceutical industry.

The second assumption is that there are common factors that can be identified which influence the decision to outsource within the pharmaceutical industry.

The third assumption is that the decision to outsource is not only based on reducing costs and solving capacity problems but on other important factors such as a CM having the required expertise and technology that is needed.

The fourth assumption is that the participants are willing to share their knowledge and are truthful in the information they provide.

1.7 Delimitations and Limitations

a) Delimitations

This research is considered part of the ground work in identifying key factors that influence the decision to outsource. This research focuses on pharmaceutical outsourcing and relates to SA companies who outsource and those who engage in contract manufacturing.

This study will investigate or focus on the following:

- Outsourcing in the pharmaceutical industry. However while investigating the pharmaceutical industry in this study, the commonalities in the literature from other industries such as the Information technology (IT) and motor industry will be reviewed and the learning's will be applied. Participation of organisations in this study is thus limited to those the pharmaceutical industry
- Outsourcing of pharmaceutical manufacture and or packing. The outsourcing of departmental functions such as IT, human resources (HR) and procurement within an organisation will not be investigated
- Research on contract manufacturers who are registered with SA's MCC and
- The effect outsourcing has on job losses in SA and the morale of staff when jobs are outsourced will not be researched.

b) Limitations

- The researcher has not established a working relationship with those who will be requested to complete the questionnaire and respondents may not be keen to divulge certain information
- The sample size is small and intentionally non-random i.e. purposeful. The sample was identified according to the research questions
- Some pharmaceutical companies based in SA will not be able to assist with the study due the fact that strategic decisions are taken by the parent company which is based outside of SA
- Due to location, time and financial considerations the researcher would not be able to conduct in-depth interviews with all pharmaceutical companies that outsource in SA and
- Since the research is focusing on identifying factors that influence the decision to outsource it would not be possible at this stage to establish financial measures that monitor and assess the situation once the decision has been made to outsource.

1.8 Significance of the Study

The pharmaceutical industry is a highly regulated industry. Thus the decision on whether to outsource or not is one that needs careful consideration. If a contract manufacturer (CM) is selected by the organisation, then the approval process may take up to a year for the CM to be approved by the MCC for manufacture and or packing of a product. If the performance of the CM is later found to be unsatisfactory, the organisation needs to consider other CM's and restart the approval process. Therefore correct vendor selection vital in the outsourcing process.

The current study looks at the ability of outsourcing to provide industry key success factors (KSF) which impact on quality, flexible capacity and low costs. Absence or inadequate quality control management by the contract giver (CG) and CM from the initial stage of purchasing of the raw materials to the manufacturing and packaging of the finished product could be detrimental to the company. Quality related problems can result in product recalls which are not only expensive but also affects patients, the CM and the reputation of the CG. Organisations need to strive for “overall low costs (not just manufacturing) so as to be able to meet low price expectations of customers,” (Thompson, Strickland and Gamble, 2005: 81).

1.9 Outline of the Research Report

Chapter 2 reviews theoretical models and frameworks that will focus on defining an organisations strategy and then reviewing the organisations resources and capabilities. Finally look at outsourcing as a strategic action to complement the organisations basic strategy.

Chapter 3 is the literature review which assists in gaining a better understanding of the pharmaceutical industry, strategic issues in manufacturing and outsourcing in the pharmaceutical industry. It also looks at the impact of outsourcing other industries.

Chapter 4 outlines the research methodology which has two primary functions, “(1) to control and dictate the acquisition of data and (2) to corral the data after their acquisition and extract meaning from them,” (Leedy and Ormond, 2005: 6).

Chapter 5 presents the research results from the completed questionnaires from both the contract manufactures and the contract givers who express their views on the various aspects of outsourcing in the pharmaceutical industry.

Chapter 6 links the findings of research to the previous chapters and discusses the results

1.10 Summary

This chapter provided a foundation for the research on outsourcing in the pharmaceutical industry SA. The study will use a qualitative method to explore the relationship between outsourcing and key drivers such as cost, capacity, flexibility and quality. The background to the research was presented leading to the statement of the research problem and the purpose of the study. The limitation and delimitations of the study was enumerated. Finally the significance of the study was discussed and the chapter ended with a brief outline of the remaining chapters.

CHAPTER 2: Theoretical Considerations

2.1 Introduction

This chapter reviews the theory and exploits relevant conceptual models by focusing on three questions which are linked to the research objectives namely:

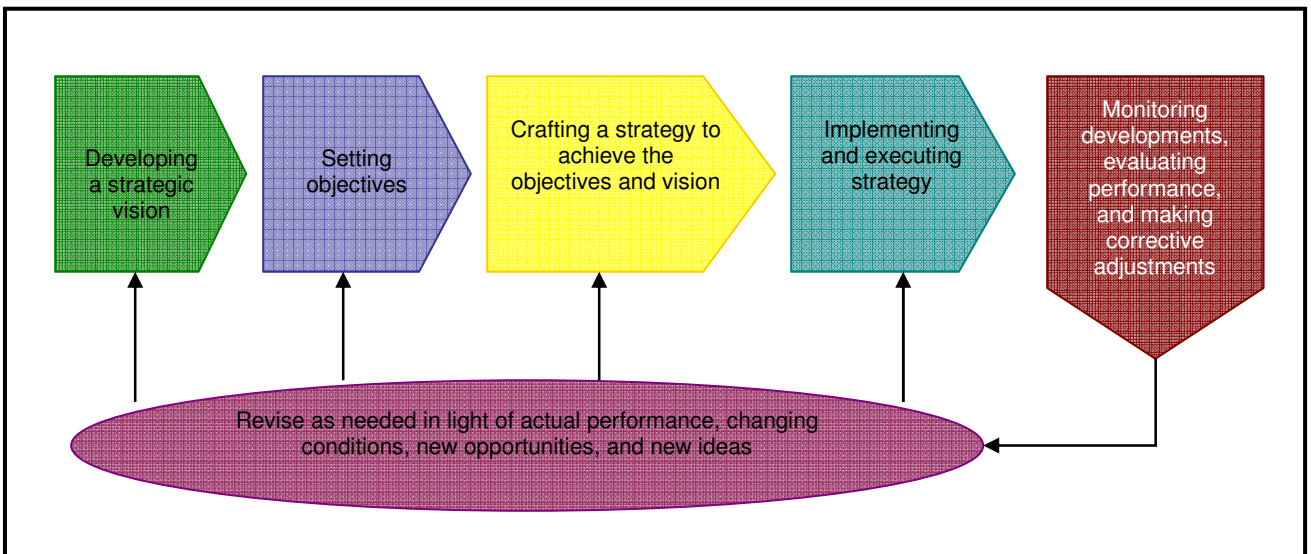
- Why are companies outsourcing
- What is outsourcing
- What is currently occurring with respect to outsourcing in the pharmaceutical industry?

Models will be reviewed that elucidate the role that strategic issues (competitiveness of the industry, **quality**, low **cost**, **capability**, flexible manufacturing **capacity**, efficiency of processes and strategic alliances) play within an organisation. The link between the organisational strategy and the build up to the make or buy decision and outsourcing is also illustrated.

2.2 Outsourcing Issues

There are many reasons why companies are currently riding the worldwide outsourcing wave. Outsourcing maybe viewed as a solution to the problems faced by South African pharmaceutical companies but how does an organisation determine if it is the correct solution. A prerequisite to the process is a review of the organisations strategy and objectives. Grant (2005) defines **strategy** as a unifying theme that gives coherence and direction to the **actions and decisions** of an individual or organisation. The process (figure 2.1) outlined by Thompson, Strickland and Gamble (2005) is the referred to the strategy- making, strategy- executing process and will be the starting point of understanding why companies are outsourcing.

Figure: 2.1 Strategy-Making, Strategy-Executing Process



Source: Thompson, Strickland and Gamble (2005: 18)

This process starts with developing a strategic vision, setting objectives and developing plans to achieve these objectives. This is then followed by the implementation and execution together with the continuous monitoring and evaluation of the organisations progress. Corrective actions are undertaken and the process continues in an environment which is rapidly changing and offers new opportunities.

Pharmaceutical manufacturers need to know:

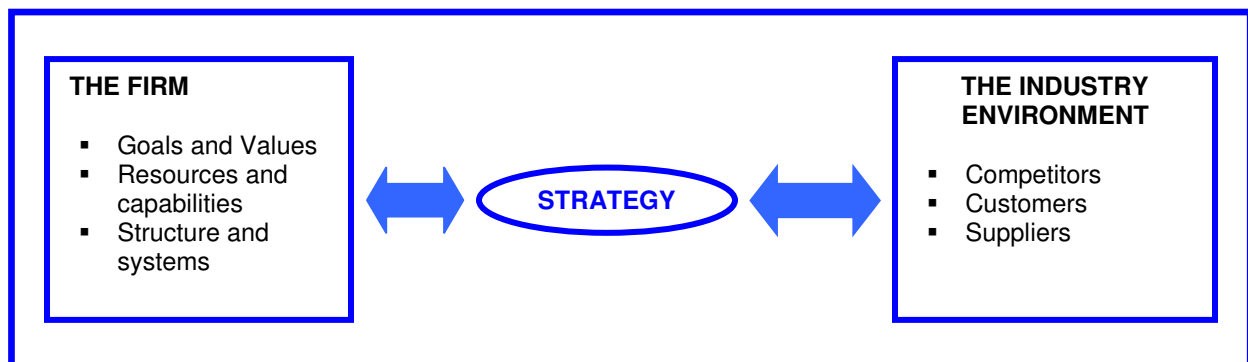
- Who are their competitors? What are their competitors doing?
- Who are their customers? What do customers want? How does the organisation satisfy this demand?
- Are their current suppliers able to meet their requirements? Is the organisation satisfied with their suppliers?

Despite all the different definitions of strategy, the one basic commonality is that strategy is about choice, that is where to compete and how to compete (Grant, 2005). This is reiterated by Thompson, Strickland and Gamble (2005:3), "A company strategy thus indicates the choices its managers have made about **how** to attract and please

customers, **how** to respond to changing market conditions, **how** to compete successfully, **how** to grow the business, **how** to manage each functional piece of the business and develop needed capabilities, and **how** to achieve performance targets.” These questions can be answered by the organisation on completion of a situational analysis by using the different tools such as the PESTLE analysis and Porters Five Forces. These tools enable an organisation to be aware of **change** and prompt a response which may then results in a possible change in strategic direction.

Grants (2005) framework (figure 2.2) views strategy as forming a link between the firm and its external environment. As a start the organisation needs to analyse its resources and determine their capabilities.

Figure 2.2: The basic framework: strategy as a link between the firm and its environment.



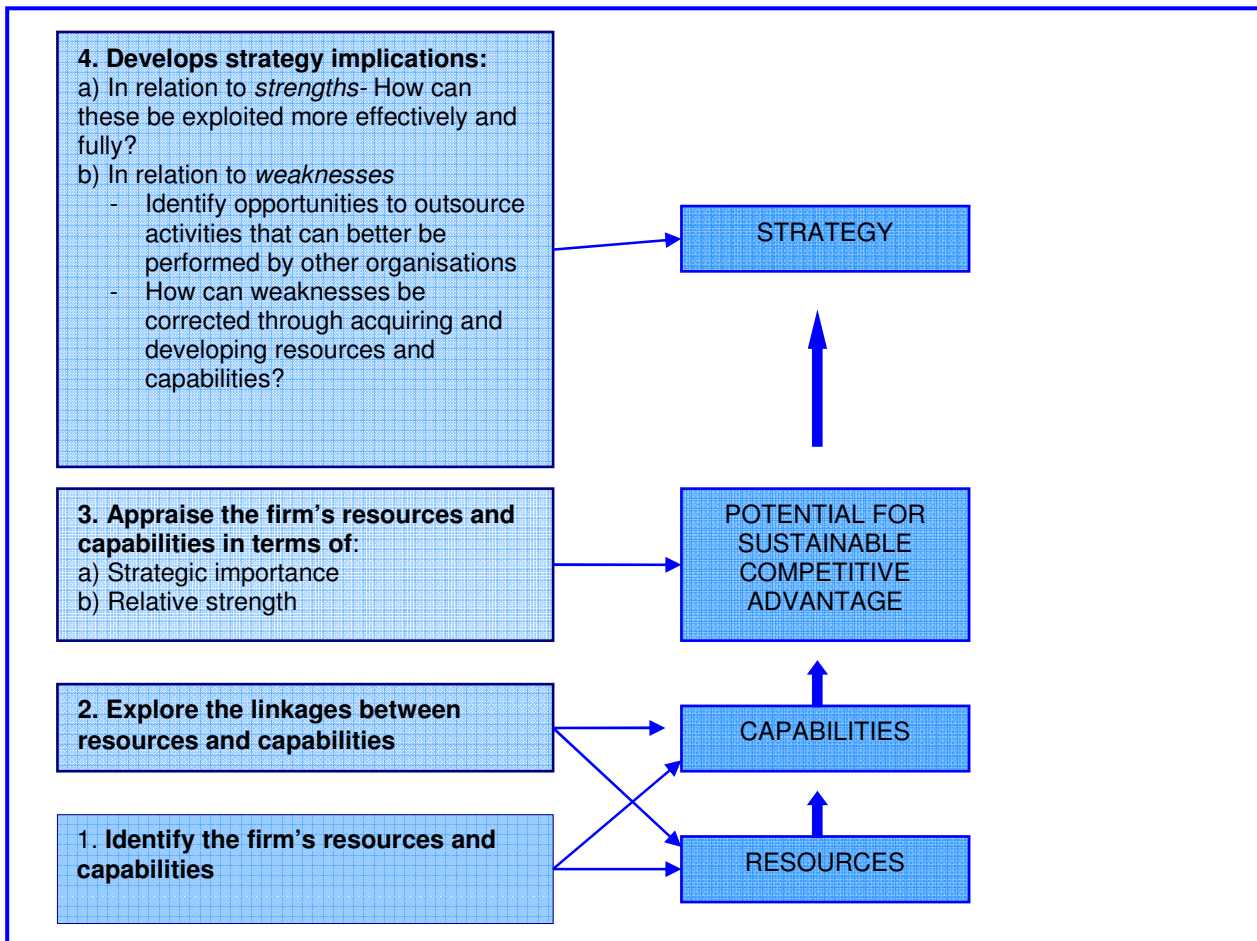
Source: Grant (2005: 12)

Canez *et al.*,(2001) stress that current global competition forces manufacturing companies to re-evaluate their existing processes, technologies, manufacturing and services in order to focus on strategic activities. Due to having **finite resources** it would not therefore be beneficial or possible for all the activities to be performed by an organisation.

Grants (2005) framework (figure 2.3) then shifts the organisations focus from the external to internal environment and basically answers what can the firm do. As

indicated below once the capabilities are established, the organisation then needs look at creating a sustainable competitive advantage. At this stage the organisation can start thinking about outsourcing to address the organisations needs in acquiring the required capabilities.

Figure 2.3: Framework for analyzing resources and capabilities



Source: Grant (2005: 171)

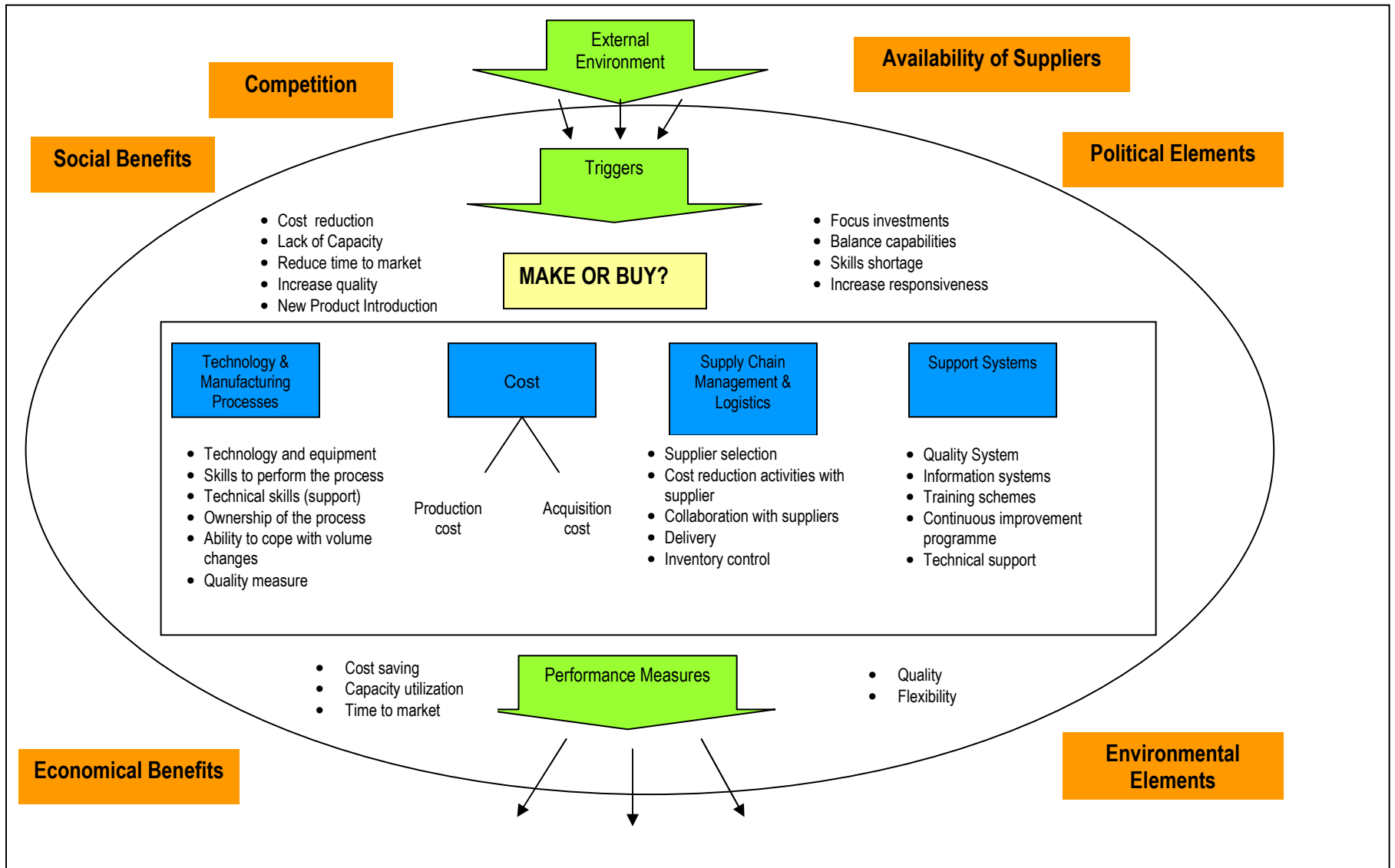
The model proposed by Canez *et al.*, (2001) in figure 2.4 is a comprehensive model which summarises why some organisations are outsourcing. The external environment becomes the trigger to the organisation to review important issues such as **cost, quality, and capability**. According to Canez *et al* (2001) the triggers become the reason for under taking the make or buy review. The organisation needs to proactively

respond to **changes** that occur outside of their environment as depicted in the model. Triggers must not be analysed in isolation because issues like cost and quality are related and both important.

Ultimately whether an organisation decides to outsource or not, performance measures are to be put in place to continuously evaluate the performance of the organisation, the process and the contract manufacturer. Thus Canez *et al.*, (2001) have closely linked the performance measure to the initial triggers which start the make or buy decision. The outcome of the performance evaluation will “feed back into the external environment and possibly activate other triggers that again raise the make or buy question” Canez *et al.*, (2001).

According to Porter (1996: 77), “strategy renders choices about what not to do, is as important as choices about what to do.” Porter (1996) advocates the importance of the role of leadership which undertakes the challenge of developing or re-establishing a clear strategy through discipline and clear communication. He emphasises that a clear distinction needs to be made between operational effectiveness and strategy.

Figure 2.4: Make or Buy Model



Adapted: Canez *et al* (2001)

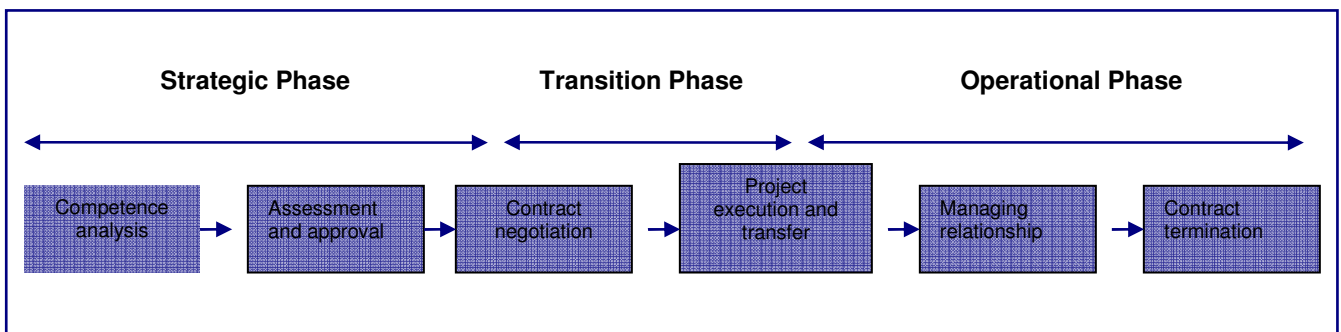
2.3 What is Outsourcing?

According to Gnuschke, Wallace, Wilson and Smith, (2004: 1) outsourcing “occurs when an organisation transfers some of its tasks to an outside supplier and offshore outsourcing occurs when these tasks are transferred to other countries.” In this section outsourcing will be reviewed by looking closer at the **outsourcing process** and its role in as part of an organisations **complimentary strategic initiative**.

- **The Outsourcing Process**

Momme and Hvolby (2001) present a conceptual framework that has identified six generic steps of the outsourcing process (figure 2.5). They view outsourcing as a dynamic process in which related decisions and actions must continuously be adapted to changes in the organisations strategic direction. Their framework “aims to facilitate start up, operations and maintenance operations of the buyer supplier relationship by linking operational and tactical considerations to strategic planning” Momme and Hvolby (2001). One phase provides input for the next phase.

Figure 2.5: Outsourcing Framework



Adapted: Momme and Hvolby (2001: 194)

Momme and Hvolby (2001) advocate the following:

- Company retains or in sources those manufacturing resources and capabilities that most critical to the organisation and that it is distinctively good at maintaining
- Company only outsource when suppliers have a comparative advantage such as greater scale manufacture, fundamentally lower cost or stronger performance incentives and
- That the organisation use outsourcing proactively through a stronger focus on the internal core business areas as a way to improve manufacturing performance, generate employee commitment and consequently increase competitiveness and profitability.

- **Outsourcing as a Complimentary Strategic initiative**

According to Thompson *et al.*, (2005: 115) “there are many routes to competitive advantage; however they all involve giving buyers what they perceive as superior value.” Initially a choice (Thompson *et al.*; 2005) must be made by the organisation to pursue one of the following:

- **A low-cost provider strategy** – gaining a cost-based competitive advantage over rivals. An organisation must be more skilled than rivals in controlling cost drivers and eliminating cost-producing activities.
- **A broad differentiation strategy** – this strategy seeks to produce a competitive edge by incorporating unique attributes and features into the companies products
- **A best-cost provider strategy** – create competitive advantage by giving buyers more value for money
- **A focused (or market niche) strategy based on lower cost** – deliver competitive advantage by achieving lower costs in this niche market
- **A focused (or market niche) strategy based on differentiation** - deliver competitive advantage by the ability to offer niche buyers something unique.

Once a company has decided which of the five generic strategies (Thompson *et al.*, 2005) to employ they need to turn their attention to what other strategic actions must be undertaken to complement their choice of a basic strategy:

- **Strategic Alliances and Collaborative Partnerships**
- Acquisitions & Mergers
- Integrate backwards and forward
- **Outsource selected value chain activities**
- Initiate Offensive Strategic moves
- Defensive Strategic moves.

Value chain analysis reviews what an organisation does with its resource inputs, by identifying activities, the way in which activities add value and the linkages between activities. “Positioning choices determine not only which activities a company will perform and how it will configure individual activities but also how activities relate to one another,” Porter (1996:70). Therefore the decision to outsource will be dependant on important considerations such as choice of basic strategy, competitive advantage, sustainability, and value chain activities.

According to Grant (2005) one of the greatest benefits of the game theory is its ability to view business interaction as comprising of both competition and cooperation. He further elaborates that a key deficiency in Porters Five forces framework is the viewing of inter-firm relations as exclusively competitive in nature. Hill (2005) defines strategic alliances as cooperative agreements between potential or actual competitors and attributes the following advantages to strategic alliances:

- Facilitate entry into foreign a market
- Allow organisations to share fixed costs (and associated risks) of developing new products or processes
- Bring together complementary skills and assets that neither company could easily develop on their own and

- Help an organisation establish technological standards for the industry that the organisation may benefit from.

However Hill (2005) also mentions possible disadvantages to alliances and suggests that in order for alliances to work there needs to be careful partner selection, a good alliance structure and the alliance needs to be properly managed.

2.4 Outsourcing in the pharmaceutical industry

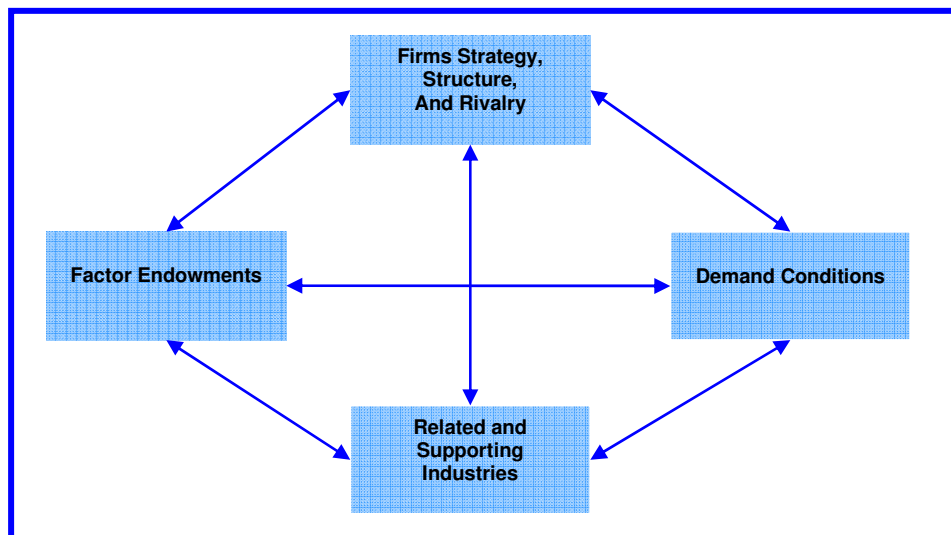
Kannan and Tan (2006: 755) emphasize that “competitive forces are putting firms under pressure to improve quality, delivery performance, and responsiveness while simultaneously reducing costs.” Pharmaceutical manufacturers are thus exploring new ways to react to these forces. Companies are increasingly using innovative decisions (management-buy-outs, business process re-engineering and outsourcing) to increase efficiency and profitability (Juma'h and Wood, 1999). Strategic alliances and collaborative partnership play a vital role in the pharmaceutical industry with organisations working together on projects such as research and development (R&D), drug trials, outsourcing of manufacturing and or packing, ethical companies selling intellectual property (IP) of drugs that have come off patent, ethical companies allowing generics to be manufactured for products that are still on patent.

Michael Porters diamond model (Hill, 2005) has four broad attributes (figure 2.4) that individually and interactively determine national competitive advantage. Differences in management ideology in different countries help a country to build national competitive advantage and intense domestic rivalry forces firms to look at ways to improve efficiency (Hill, 2005).

Porter also emphasises that government and chance play an important role in influencing these four determinants. Thus in SA like other counties in the world, governmental changes in regulations/ laws impacting on the pharmaceutical industry

(parallel importation, patents, foreign investors and trade) would impact on the countries national competitive advantage. Organisations within the pharmaceutical industry therefore have to continuously reassess their target markets both internationally and locally. If a company cannot manufacture a product at a lower cost than its competitor then the company will need to consider outsourcing to a contract manufacturer who can manufacturer at a lower cost. A competitor may be a local or a pharmaceutical manufacturer outside of SA.

Figure 2.6: Determinants of National Competitive Advantage: Porter's Diamond



Source: Hill (2005: 165)

When pharmaceutical companies tender to supply the state (government) they are effectively targeting a market that requires high volumes, low prices (small profit margin) and continuous supply. Although the demand may be erratic, failure to supply will result in severe financial penalties thus **capability** (flexible capacity) becomes an important issue because the organisation and its CM need to commit to continuous supply on being awarded the tender.

The model (figure 2.4) proposed by Canez *et al.*, (2001) provides a holistic picture of what the organisation needs to focus on by clustering the factors relevant to the make or buy decision into four areas: **technology and manufacturing processes; cost, supply chain management and logistics; and support systems.** In the pharmaceutical industry there should be an additional focus area which is **compliance or regulatory affairs (RA)**. Compliance with what is registered with the relevant regulatory body is non negotiable. In SA all manufacturing changes especially the change to a new manufacturer must be evaluated and submitted to the Medicines Control Council (MCC) by RA and thus RA plays an important role in the manufacture and movement of product from one site to another.

2.5 Summary

The aim of the chapter was to review the theory to create an understanding of outsourcing. A start was made by trying to understand outsourcing that is why organisations outsource and the outsourcing process. Finally the current situation in terms of outsourcing in the pharmaceutical industry was also discussed. Models were used to both graphically illustrate the processes that theorists suggest companies should follow and to create a baseline understanding of outsourcing. The significance of MCC is also explained where no manufacturing licence is granted unless the necessary documentation is submitted.

CHAPTER 3: LITERATURE REVIEW

3.1 Introduction

Chapter 1 and 2 have opened up a number of core issues with respect to outsourcing. Outsourcing in the pharmaceutical industry has largely been limited to the outsourcing of research and clinical trials to contract organisations. This review will explore these issues further and at the same time open up issues of outsourcing in other industries. The purpose of this chapter is to familiarise the reader with all the concepts concerning outsourcing in an unbiased manner and to familiarise the reader with some of the hype concerning outsourcing.

The chapter begins with a literature review of the pharmaceutical industry to acquaint the reader with this particular industry. This is followed by a review of the current views on strategic outsourcing, to gain insight into what outsourcing entails. In addition the key drivers (motivation factors) which influence companies to indulge in outsourcing are mentioned. Finally the chapter concludes by looking at current outsourcing practices amongst pharmaceutical companies.

3.2 The Pharmaceutical Industry

The pharmaceutical industry has previously been characterised by questionable capacity utilisation, with plants often running well below forty percent of capacity (Tilton, 1996). This practise was acceptable when small volumes of manufactured medicines with high mark-ups brought in huge profits but today there is a shift towards economies of scale (large volumes, low cost) to bring in the profits.

According to Shanley (2007a) pharmaceutical manufacturing can only advance if the manufacturers, regulators, academics and vendors join forces. The pharmaceutical industry differs from other industries due to its emphasis on **regulatory compliance**, the importance of successful **technology transfer processes** and the differences in its

supply chain. Each of these important focus areas are discussed together with a review of the relevant literature:

- **Regulatory Compliance and Legislation**

In addition to the normal group of stakeholders (customers, employees, shareholders) that is common among all industries, pharmaceutical companies must also address the needs of the relevant regulatory bodies (Martin, 2002). Compliance to particular regulatory bodies will depend on the markets that the pharmaceutical company intends serving. Additional compliance to other regulatory bodies will ensure a larger geographical area for sale of products.

In the United States (US) pharmaceutical companies would have to comply to the Food and Drug Administration (FDA), similarly in SA pharmaceutical companies will need to adhere to Medicine Control Council (MCC) guidelines. All pharmaceutical products must be manufactured in accordance with good manufacturing practices (GMP). Regulatory compliance thus determines what is imported into a particular country and to which countries product can be exported. In SA the MCC has recently joined an international regulatory body and will now subscribe to the stricter Pharmaceutical International Convention/ Pharmaceutical Inspection Co-operation Scheme (PIC/S) guidelines and this may result in some of the South African pharmaceutical manufacturer's licences being revoked due to non-compliance to the new PIC/S standards.

According to Martin (2002: 54) pharmaceutical companies "can use compliance as a regulatory platform to initiate system-wide changes with results that extend beyond compliance" and he emphasises the importance of **people** (culture within the organisation), **core processes** and **strategy** in achieving and sustaining compliance.

As discussed in chapter two (Porter's Diamond model), legislations like those in SA such as generic substitution, single exit pricing (SEP), Black Economic Empowerment (BEE),

professional fees and parallel importation will affect pharmaceutical manufacturers in terms of their attractiveness to potential customers. Compliance especially to regulations plays a major role in this industry.

- **Technology Transfer**

Technology transfer whether internally (in-house lab to production facility) or from one manufacturer to another is now seen as an indicator of manufacturing excellence and a core competency for drug innovators (De Palma, 2006). The significance of technology transfer is magnified as more products are outsourced through alliances and manufacturing only relationships according to De Palma (2006) and he advocates the following to companies:

- Face to face communication
- Be aware of the implications of scale up of batch size
- The use of platform technologies whenever feasible and
- Have a dedicated, multidisciplinary tech transfer team consisting of quality, engineering, supply chain, development, quality assurance, quality control, regulatory and operations personnel.

Successful technology transfer also plays an importance role in ensuring that products are launched on time to capture the targeted market share.

- **Supply Chains and Value Creation**

“The integrated supply chain structure seeks to minimise non-value-add activities and their associated structure, because this drives investment cost, operating cost and timeout of the supply chain process, ” (Stewart, 1995: 38). Pharmaceutical companies which are faced with empty pipelines, expiry patents, pricing pressures, generic competition, and growing government and consumer challenges have to progressively transform their product value chains in order to increase profitability (Hagen, Manganelli and McGruk, 2007).

According to Hagen *et al.*, (2007) on the one side large pharmaceutical companies are deconstructing their vertically integrated value chains (selling manufacturing facilities or divesting mature products which are not part of their core business) while the smaller companies are creating supply chains that can accommodate expected growth as the demand for their products outstrips their current value chains. Stewart (1995) emphasises that integrating a supply chain (SC) requires philosophical, operational and systems changes (table 3.1). Complex decisions (in source, outsource or to license) need to be made irrespective of whether a company is growing or disaggregating their value chain (Hagen *et al.*, 2007).

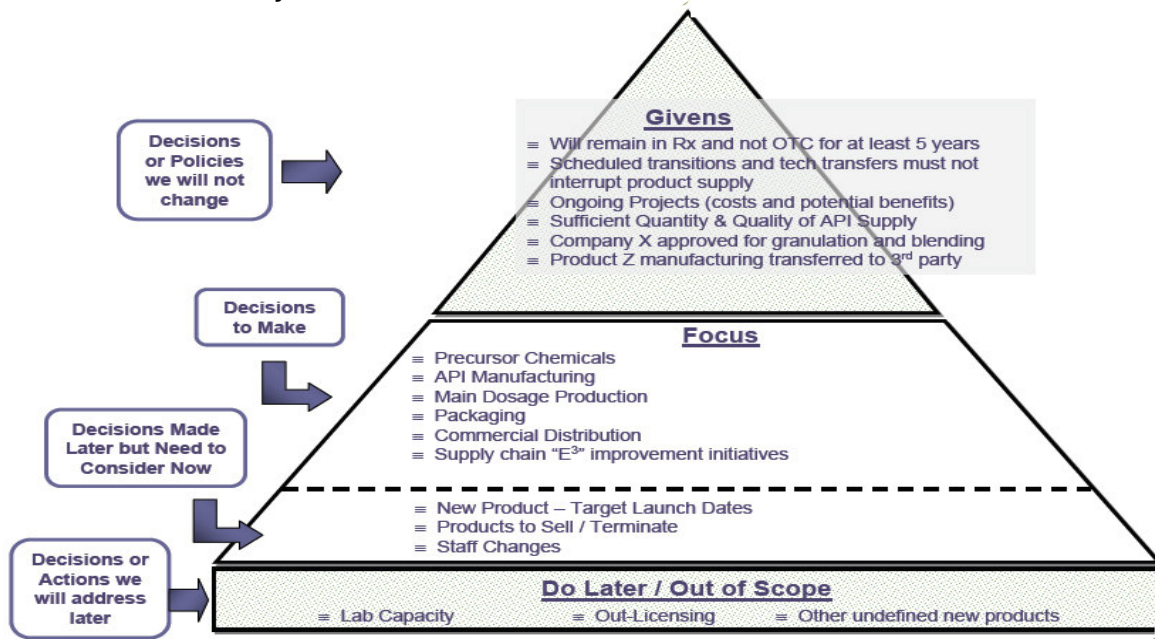
Table: 3.1 Four Categories of Operational Change

Policies, practices and procedure	Management approaches/ methodologies which define how to perform activities (task, sequence, timing, etc); balance performance metrics which reflect process performance; knowledge of industry best practices that enable best performance.
Organisation	Organisational structure and degree of cross-functional integration; roles and responsibilities for each policy, practice or procedure; skills/training available as well as required to perform activities
Structure	Assembly value add or distribution centre rationalisation; flow of material from source of supply to end customer; flow of data from customer to manufacturer/distributor
Systems	Use of systems to enable best practice performance; the effective management of data and analysis across the supply chain (speed of flow, one touch quality, appropriate access)

Source: Stewart (1995)

Hagen *et al* (2007) have added a third dimension to the usual supply chain objectives of **efficiency** (doing things right) and **effectiveness** (doing the right things). The third dimension which they have termed **excellence** is doing “the right things right” and achieving the highest quality. Hagen *et al* (2007) advocate the use of decision hierarchy (figure 3.1) and a strategic options table (figure 3.2) when executives are faced with different options on how to structure the overall supply chain.

Figure 3.1: Product Value Chain Decision Hierarchy



Source: Hagen *et al* (2007)

Figure 3.2: Example of a Strategic options table

Strategic Options						
Theme	Precursor Chemicals	API Mfg	Main Dosage Production	Packaging	Commercial Distribution	Supply Chain "E ³ " Initiatives
CC&S	In-House	In-House	In-House	In-House	In-House	Distribution Network Optimization
Vertically Integrated	Outsourced	Outsourced	Outsourced	Outsourced	Outsourced	Lean Initiative
Virtual Business	Build	Build	Build	Build	Build	Customer Service Improvement
Other	Acquire	Acquire	Acquire	Acquire	Acquire	Compliance Risk Reduction
	Partner	Partner	Partner	Partner	Partner	
	JV	JV	JV	JV	JV	
	Divest	Divest	Divest	Divest	Divest	None

Source: Hagen *et al* (2007)

Since 2006 about 30 000 pharmaceutical industry professionals in the US have lost their positions through mergers and acquisitions and organisational restructuring (Shanley, 2007c). The rationale is that pharmaceutical companies are under immense pressure (from competitors and shareholders) and need to react.

3.3 Strategic issues in Manufacturing

“Manufacturing flexibility has been heralded as a major competitive weapon for manufacturing organisations operating in increasingly uncertain environments and turbulent markets” Oke (2005: 974). This view is further supported by Beach, Muhlemann, Price, Patterson and Sharp (2000). Oke (2005) attempts to get a better understanding of what he terms a paradoxical concept - What is flexibility? When should a company strive for it? How can it be measured? How can it be implemented?

In trying to contribute to a better understanding of the different directions of manufacturing strategy research, Dangayach and Deshmukh (2001) have categorised the articles they have reviewed into six sub-streams of manufacturing strategy (table 3.2). These categories provide an outline of the important strategic issues in the manufacturing sector and draws focus to issues such as the shift towards “green productivity or eco-efficiency” due to pressure from stakeholders to be eco-efficient or the impact of organisational culture on the firms performance.

Lindman, Callarman, Fowler and McClatchey (2001: 47) point out that “new technologies and processes could distort the traditional trade-off between process flexibility and lower unit cost by providing additional benefits, such as increased flexibility, improved product quality, and lower unit costs.” Failure of companies to recognise the relationship between their manufacturing strategy and corporate strategy may result in their organisation having non-competitive production systems which are both expensive and time consuming (Dangayach and Deshmukh; Lindman *et al* 2001)

Table 3.2: Manufacturing Strategy

Manufacturing Strategy	Related Literature
1. Manufacturing capabilities	Competitive priorities, i.e. cost, quality, delivery and flexibility.
2. Strategic choices	Specific structural and infrastructural criteria like human resource, technology, information technology, organisation and management and environmental aspects.
3. Best practices	Advanced manufacturing technologies (AMT) and better management Practices like just in time (JIT) and total quality management (TQM).
4. Trans-national comparisons	Includes cross-country wide studies comparing various nations'/continents' manufacturing strategy practices.
5. Performance measurement	Performance measurement system design, development and assessment methodologies
6. Literature survey	Literature looks at developments such as : effects of organisational culture on firms performance; increasing awareness about environmental issues; role of small and medium enterprises in a nations economy; resource based operations strategy

Source: (Dangayach and Deshmukh, 2001)

According to Van Mieghem (2003: 270) “capacity is a measure of processing abilities and limitations that stem from the scarcity of various processing resources and is represented as a vector of stocks of various processing of resources.” Capacity utilisation plays a major role in many manufacturing industries such as the automobile industry (Roegner, 2004) and impacts on profitability. Hannon (2005) explains that issues such as mergers and acquisitions, the fluctuating value of the US dollar globally, price of crude oil, the increasing logistical costs and commodity pricing have all resulted in the procurers job becoming more complicated and suggests procurement professionals develop closer relationships and better communication with strategic suppliers.

Masacrito (Bernstein, 2007) explains that there are both **advantages** (mass production capabilities and lower costs, more competitive suppliers in low- cost regions, good work ethic from different cultures) and **disadvantages** (distance from product supply to point of need is increased, logistics costs are raised and product intervals are lengthened) when shifting to international sourcing.

3.4 Outsourcing – Cross Industry Analysis

According to Fahey (2003) scenarios are proven means to identify and examine pathways into alternate futures. Fahey (2003) further elaborates on competitors by explaining that they employ scenarios to better understand both current competitors' potential moves as well as the possible emergence of new rivals. "Resources in and of themselves do not confer a sustainable competitive advantage. The essential elements of the resource-based view of the firm are the firm's key resources and the role management in converting these resources into positions of sustainable competitive advantage, leading to superior performance in the marketplace" (Fahy, 2000).

Gnuschke *et al.*, (2004) have examined reasons why outsourcing is likely continue to increase in manufacturing sectors and expand significantly into service sectors and further question what factors are driving outsourcing of an organisations production and employment. According to their findings (Gnuschke *et al.*, 2004:4), "the decision to outsource is based upon the following factors:

- The demand of the customer
- The type of tale available
- Cost
- Productivity
- Political risk and
- Infrastructure delivery."

They further elaborate on the "push" factors in outsourcing that are cost driven and the "pull" factors that are provided by countries. These "pull" factors (Table 3.3) can be

linked to Porters diamond model discussed in chapter two and would result in “significant cost savings by taking advantage of skilled, quality labour at a fraction of the cost associated with producing domestically” (Gnuschke *et al.*, 2004:4).

Table 3.3: “Pull” Factors for Outsourcing

“Pull” Factors
<ul style="list-style-type: none">• Widespread acceptance of English as a medium of education, business, and communication• A common accounting and legal system, with the latter based on either U.K or US common law structure.• General institutional compatibility and adaptability• Time differential determined by geographical location leading to a 24/7 capability and overnight turnaround time and• A steady and copious supply of technical graduates

Source: Gnuschke *et al.*, 2004:4

McCormick (2006) questions which competitive advantage (technology or cost) should a company pursue. **Technology** involves a lot of capital investment and the desired improvement in productivity and quality might not happen. With **cost** on the other hand present benefit may be realised, but it is not easy to sustain as competitors would continue to seek for low cost vendors.

Haley and Haley (2006) propose a model for strategic success in emerging market (Mexico, China, India, Vietnam, Singapore and Malaysia). They argue that to succeed in emerging markets, managers must employ knowledge, speed and action; pursue results, relationships and quality; demonstrate passion; and be mindful of legacy. The senior managers that Haley and Haley (2006) interviewed stated strongly that companies must act responsibly when generating profits.

Power *et al.*, (2004) have indicated that as businesses struggle to lower cost and grow revenues, outsourcing initiatives are underway in small, medium, and large global companies. “Depending on the protagonist’s viewpoint, the delights or, more often the miseries of civil society, especially in developing countries, have been attributed to

globalisation” (O’Higgins, 2003: 52). O’ Higgins (2003) provides a brief summary (Figure 3.3) of the current globalisation drivers, globalisation practices and the benefits to corporations.

Figure 3.3: Globalisation strategy – antecedents and consequences

<i>Globalisation Drivers</i>	<i>Globalisation Practices</i>	<i>Benefits to Corporations</i>
<ul style="list-style-type: none"> • Global market convergence • Cost advantages • Global competition • Government influence 	<ul style="list-style-type: none"> • Major market participation • Product standardisation • Uniform marketing • Activity location/ concentration • Coordinated competitive moves 	<ul style="list-style-type: none"> • Economies of scale • Bargaining power • Labour and other factors costs and availability • Flexibility • Improved quality • Customer preference • Enhanced strategic positioning

Source: Global business mean global responsibilities (O’Higgins, 2003)

According to Mariotti (2009) in any strategic outsourcing decision one has to consider **strategic, operational** and **structural** issues. Power *et al.*, (2004) emphasise that in many situations organisations have not done their due diligence in defining and answering key outsourcing success factors such as the experience and skill levels of vendor personal; the vendors technical experience in the clients industry, vendor financial stability assessment; definition of service level agreements; implementation planning; intellectual property rights; data security; infrastructure definition; audit rights and dispute resolution process definition.

According to Jiang and Qureshi (2006: 46): “Research scope can be identified by three areas: outsourcing determinant, outsourcing process, and outsourcing result,” which these researchers proceed to define as:

- a. The **outsourcing determinant-orientated** research studies the drivers behind a firm outsourcing decision, that is the “**why**” issues.

- b. The **outsourcing process –orientated** research studies outsourcing contract negotiation, partner selection, implementation, control, monitoring that is the “**how**” issues.
- c. The **outsourcing result-orientated** research studies what an outsourcing decision brings the firm.

According to Jiang and Qureshi (2006) in reviewing the current literature, they have identified three main gaps which are the lack of objective metrics for outsourcing results evaluation; the lack of research on the relationship between outsourcing implementation and the firms’ value, and the lack of research on the outsourcing contract itself.

Jiang and Qureshi (2006) propose that much more outsourcing result-oriented research should be undertaken in the United States (US). However in SA, this would not be applicable as most pharmaceutical companies having only started outsourcing within the last few years or are still considering outsourcing into the future. Pharmaceutical companies must however start looking at possible ways in which the financial impact of outsourcing can be measured.

Jiang and Qureshi (2006) recommend that future research investigate how outsourcing is actually affecting operating performance with the use of appropriate measurable metrics by focusing on cost reduction, productivity growth, profitability increase, the firms’ value improvement and risk control.

Previously outsourcing was prevalent in administrative and support functions but the recent years organisations have been outsourcing value-creating activities that has reshaped the old sourcing model (Mariotti, 1999). According to Fahy (2000) the essential elements of resource-based view of a firm are the firm’s key resources and the role of management in converting these resources into positions of sustainable competitive advantage which then leads to superior performance in the marketplace.

The study conducted by Lau and Zhang (2006) found that Chinese companies that outsource in China have encountered obstacles and problems in the outsourcing process. Their findings have important implications for South African companies that are considering outsourcing not only to China but to other developing countries or to South African contract manufacturers. The difficulties experienced by Chinese companies (Lau and Zhang, 2006) include the lack of capable service providers, loss of control, poor transportation and IT infrastructure and the presence of local protection regulations.

Power *et al.*, (2004) emphasise that many organisations fail to realise the impacts of on their people, processes, methods and tools as they proceed down the outsourcing path. The table below summarises the ten outsourcing traps that Power *et al.*, (2004) insist must be avoided.

Table 3.4: The ten outsourcing traps to avoid

Ten Outsourcing Traps to Avoid
1) Lack of management commitment
2) Lack of an outsourcing communication plan
3) Minimal knowledge of outsourcing methodologies
4) Failure to recognise outsourcing business risks
5) Failure to obtain outside outsourcing professionals
6) Not dedicating the best and brightest internal resources
7) Rushing through the initiative
8) Not recognising the impact of cultural differences
9) Minimising what it will take to make the vendor productive
10) No formal outsourcing governance program

Source: (Power *et al.*, 2004)

Important drivers (table 3.5) have thus far been identified in the global marketplace. Lau and Zhang's (2006) identification and clustering of these drivers into three related, yet separate categories is an excellent classification which can possibly be used to rate factors thereby assisting the decision making process.

Table 3.5: Outsource Drivers

<p>Jiang and Qureshi (2006)</p>	<p>1) Cost Reduction</p> <ul style="list-style-type: none"> • CMs can spread fixed cost and thus achieve economies of scale. • Contract giver can reduce their operations expense and overhead expense. <p>2) Productivity Growth Company may review in house productivity and outsource only if CM can provide comparable service cheaper.</p> <p>3) Profitability Increase Outsourcing can boost profitability in many ways :</p> <ul style="list-style-type: none"> • Staffing • Capabilities • Facilities • Services • Payroll <p>4) Firm's Value Improvement</p> <ul style="list-style-type: none"> • Firm benefits from CMs capabilities. Target new markets • Firm is also kept abreast of fast changing technologies. • Firm also able to focus more on strategic issues.
<p>Copestake (2006)</p>	<p>1) Increase Efficiency and minimise cost</p> <p>2) Knowledge and experience</p> <p>3) CM good understanding of logistical regulatory environments.</p>
<p>Lau and Zhang (2006)</p>	<p>1) Economic factor is a strong motivation for outsourcing in China.</p> <ul style="list-style-type: none"> • Cost reduction, • Cost saving and • Capital investment reduction <p>2) Strategic considerations</p> <ul style="list-style-type: none"> • Accelerate re-engineering benefits • Focus on core competence, • Increase flexibility • Facilitate market penetration, are identified. <p>3) Environmental factors</p> <ul style="list-style-type: none"> • Information technology (IT) development • Capability of supplier

The total cost of ownership (TCO) together with the relationship of time and distance play an important role in outsourcing; many organisations are not thinking beyond the manufacturing process and make the mistake of only comparing the purchase price of the product from the new source against the price from the new source (Bernstein, 2007). In the evaluation the logistics costs need to be included, especially duties and

taxes at the point of import. Distance is an important factor that impacts on the delivery solution due to the additional interfacing with customs in the different countries and as a result the import/ export process adds time to the delivery process (Bernstein, 2007).

Mascaritolo (Bernstein, 2007: 58) brings attention to the fact that “the speed at which companies are ramping up production in low-cost regions is outpacing supply chain infrastructure. Often we see demand that is more than supply can handle. Cargo capacity remains in shortfall, especially from China.” Aves (2001) proposes twelve factors (table 3.6) that a company should analyse when entering into a an outsourcing venture and explains that “the migration of furniture manufacturing from the US to Asia is an accelerating change that is affecting every corner of the home furnishings industry – design, marketing, manufacturing, distribution and retailing.”

Table 3.6: Factors to consider when outsourcing

Managing Offshore Outsourcing
1. Design
2. Quality
3. Price
4. Delivery
5. Gross margin
6. Customs
7. Terms of Payment
8. Duty Drawbacks
9. Manufacturing ethics
10. INCO terms
11. Support Agencies
12. Global Risk

Source: (Aves, 2001)

3.5 Outsourcing in the Pharmaceutical Industry

Dubourg (2003) explains that a serious drain on productivity and financial resources may occur if a pharmaceutical company continues to maintain all its activities 'under one roof.'

Many pharmaceutical manufacturers were previously committed to full vertical integration that is from manufacturing their own active and non active chemicals compounds (raw materials) to packing of the finished product. This has arguably been non successful for many manufactures. The reaction to this is that currently only those activities that contribute to the company's competitive edge (Tilton, 1996) are performed in house with all other operations being undertaken by CMs i.e. outsourced.

The global contract manufacturing market for the pharmaceutical sector is forecast to increase about 8% per year and to exceed \$26 billion by 2011 (Scott, 2006). Scott (2006) discusses the findings of a marketing information group (Kalorama Information, New York) who concluded that in the future, growth in the industry will be driven largely by the need for services associated with high potency sterile drugs, protein - derived, and specialised production methods, such as chiral chemistry.

The Kalorama group further elaborates that the key growth driver today is the "unique, innovative, and state of the art processes and production technologies," offered by contract manufacturing firms (Scott, 2006). These findings arguably have important implications to current manufacturers because they will have to decide on whether they should start investing in new technology to enable them to manufacture such high potency and other specialised drugs themselves, or should suitable contract manufacturers be considered? Huge investments will be required by the manufacturer if they decided not to outsource and the return on their investment may not be immediately.

Copestake (2006: 61) emphasises that due to “changing market dynamics, Contract Research Organisations (CROs) must have the operational flexibility to be able to provide services in whatever manner is most appropriate for their customers”. In the US pharmaceutical companies who outsource want “no-frills production at the lowest possible price ... or if possible, below the lowest possible price” (McCormick, 2006: 12). Burcher and Lee (2000) explain that if there is no strategic thinking behind decisions to invest in advanced manufacturing technology (AMT), disappointment may occur when tangible benefits are not realised.

Copestake (2007) explains that some pharmaceutical companies are re-appraising their outsourcing models therefore there are signs of them migrating from a tactical view of outsourcing (driven by the need for additional capacity) to a more strategic approach to sponsor or CRO relationship. These new outsourcing models are important as it reflects how change can influence the strategic direction of a company especially one in SA. Thus Copestake (2009) has illustrated that it is not just about manufacturing medicines at a lower cost or sourcing additional production capacity.

In the US the Synthetic Organic Chemical Manufacturers Association’s Bulk Pharmaceuticals Task Force (Socma’s BPTF) have requested in a petition that the Food and Drug Administration (FDA) take actions to better manage drugs manufactured or produced at foreign facilities (Boswell, 2006). According to BPTF’s, there are significant disparities that exist in the FDA’s inspection of domestic manufactures and foreign manufactures (Boswell, 2006). This task force feels strongly that the FDA should actually be conducting more frequent inspections on foreign contract manufactures which certainly pose a greater risk to public safety.

As part of their **rationalisation processes** many the large multinationals (Hoechst Merrell Roussel, Glaxo Wellcome, Merck and Sanofi Sterling) have closed down some of their plants worldwide (Tilton, 1996). To these companies sourcing some of their requirements from CMs have become a viable alternative to in-house production.

A company such as Eli Lilly is willing to outsource manufacturing, particularly of more mature drugs, to free up capacity for new products (Wood, 2005). Eli Lilly's manager of Manufacturing Operations explained that they look for capacity within first and if not available they look at a CM who can combine speed, quality, and add value, with a close working relationship (Wood, 2005).

While some manufacturers have just trimmed their manufacturing base others have moved towards a virtual operation mode where they have entirely outsourcing their bulk requirements (Tilton, 1996). There has been an increase in the outsourcing trend due to the desire of pharmaceutical firms to bring in efficiency (Copestake, 2006).

Although cost is an important driver (Jiang and Qureshi; Copestake; Lau and Zhang; 2006), it is not only driver. In addition to cost and capacity issues, the literature also mentions other important factors (key drivers) that influence organisations to outsource and three which are important in the pharmaceutical industry that is expertise, fast cycle development and technology and performance will be briefly discussed.

- **Expertise**

Shanley (2007: 1) explains that "the need for speed and access to new markets is fuelling off shoring to Asia " and questions whether a shortage of U.S scientists and engineers are also driving this trend. Shanley (2007b) elaborates on the results of PriceWaterhouseCoopers survey (May 2007) of more than 185 global industry executives who agree that the global Pharma centre of gravity is shifting from previous U.S. and European domination to Asia

"While costs and savings may still be important in the pharma off shoring and outsourcing strategies, speed and access to new workforce's because markets are becoming equally critical" (Shanley, 2007). In the article by Shanley (2001) entitled *Pharma's Global Hunt for Talent* he also mentions the following:

- A 2006 Outsourcing Research Network survey and study entitled “Next Generation Outsourcing: The Globalization of Innovation,” found that drug and healthcare companies cited “expertise” as their reason for selecting an off shore location.
- Access to talent is becoming much more important.
- Booz Allen Hamilton, a consulting firm which conduct annual study found that from 2004 to 2006 the speed to market as an off shoring driver grew by nearly 70%, while costs savings as a driver only increased by 5% in the same period.
- Companies that have already outsourced are starting to see positive bottom –line results
- Outsourcing maybe seen as the easier alternative than recruiting talent in the U.S. Currently organisations in the U.S are taking about six to ten months to find the right person and important projects are therefore taking longer.

Initially what maybe seen as a shortage of graduates, could actually be viewed as shortage of people in the industry with the relevant skills and experience (Shanley, 2007). While 70 000 engineering degrees were awarded in the U.S in 2005, 600 000 were awarded in China and 350 000 in India (Shanley, 2007).

- **Fast –Cycle Development**

Pharmaceutical companies like others in the development industries are under increasing pressure to reduce drug development time and cost, and therefore need to execute fast-cycle development strategies to create a sustainable competitive advantage by integrating outsourcing within the internal organisation (Anik 2002). Outsourcing will ensure multitasking activities by allowing for parallel processing of the numerous drug development stages which can significantly reduce the development time (Anik 2002). According to Miller (2002) a contractor’s ability to offer additional closely related services may potentially have advantages over smaller, more focused competitors.

Within the generic segment of the pharmaceutical industry the first to market is crucial. Thus the period between the launch of the first generic after a patent expires and the second generic will impact on product market share.

- **Technological Advancement and Performance**

Innovative manufacturing methods and technology are important the pharmaceutical industry. Miller (2002: 22) explains that “contract manufacturers must demonstrate that they can do the job better, faster, and cheaper than their clients and their competitors to remain in the preferred ranks. Simply offering capacity or a one-stop-shop proposition is no longer sufficient.”

3.6 Summary

The aim of the chapter has been to provide the reader with a more comprehensive understanding of the current literature on the pharmaceutical industry, the strategic issues in manufacturing and outsourcing both within and outside of the pharmaceutical industry. This is to create an a better understanding of why companies are outsourcing, what is outsourcing, what is driving this initiative and what is currently happening in the pharmaceutical industry especially in the first world countries with respect to outsourcing. This is to enable the reader to make a comparison between these countries and SA. Finally additional literature has been reviewed to become familiar with the key drivers of outsourcing some of which are common to major industries and others which are unique to the pharmaceutical industry.

CHAPTER 4: RESEARCH DESIGN AND METHODOLOGY

4.1 Introduction

This chapter outlines a process that will be followed to gather data for the analysis of the key drivers, decision making and strategic issues in South African pharmaceutical manufacturing industry. The major research questions are presented. The research design is discussed as well as the sampling frame and method.

According to Leedy and Ormond (2005: 2), “Research is a systematic process of collecting, analysing and interpreting information (data) in order to increase our understanding of the phenomenon about which we are interested or concerned.” Due to data and methodology being interdependent, the researcher when selecting a methodology must always take into account the nature of the data that will be collected in the resolution of the problem (Leedy and Ormond, 2005).

4.2 Research Design

Although the researcher usually makes an informed decision (Leedy and Ormond, 2005) between quantitative and qualitative (table 4.1) approaches for a particular research question, Lee (1999) advocates the combination of qualitative and quantitative research in certain situations. Lee (1999) outlines three possible designs (two-phase, dominant-less dominant and mixed methodology design) and explains the advantages and disadvantages of these.

A qualitative approach will be adopted due the explorative and interpretive nature of the study. Leedy and Ormond (2005) explain that a qualitative study can help define what is important , when little information exists on a topic, when variables are unknown, when a relevant theory base is inadequate. All qualitative approaches have two things in common (Leedy and Ormond, 2005) namely:

- Focus on phenomena that occur in a natural settings
- Involve studying those phenomena in all their complexity.

Table 4.1: Distinguishing characteristics of Qualitative and Quantitative Approaches

Question	Quantitative	Qualitative
What is the purpose of the research	<ul style="list-style-type: none"> • To explain and predict • To confirm and validate • To test theory 	<ul style="list-style-type: none"> • To describe and explain • To explore and interpret • To build theory
What is the nature of the research?	<ul style="list-style-type: none"> • Focused • Known variables • Established guidelines • Predetermined methods • Somewhat context-free • Detached view 	<ul style="list-style-type: none"> • Holistic • Unknown variables • Flexible guideline • Emergent methods • Context-bound • Personal view
What are the data like, and how are they collected?	<ul style="list-style-type: none"> • Numeric data • Representative, large sample • Standardised instruments 	<ul style="list-style-type: none"> • Textual and/or image-based data • Informative, small sample • Loosely structured or non standardised observations and interviews
How are the data analysed to determine their meaning?	<ul style="list-style-type: none"> • Statistical analysis • Stress on objectivity • Deductive reasoning 	<ul style="list-style-type: none"> • Search for themes and categories • Acknowledgment that analysis is subjective and potentially biased • Inductive reasoning
How are the findings communicated?	<ul style="list-style-type: none"> • Numbers • Statistical aggregated data • Formal voice, scientific style 	<ul style="list-style-type: none"> • Words • Narratives, individual quotes • Personal voice, literary style

Source: Leedy and Ormond (2005: 96)

Case study, ethnography, phenomenological, grounded theory and content analysis are five common qualitative research designs (Leedy and Ormond, 2005). The research will entail an exploratory study using a case study methodology. The approach was chosen to focus on why and how companies decide to outsource (Lee, 1999). The researcher will record “details about the context surrounding the case, including information about the physical information, economic and social factors that have a bearing on the situation” (Leedy and Ormond, 2005: 135).

According to Lee (1999: 54) the “case study’s in-depth nature and emphasis on situationally embedded processes justify some level of casual inference.” Lee

(1999) explains that case study research has five primary components which are research questions, theoretical propositions, units of analysis, the logical linking data to these theoretical propositions, and the criteria for evaluation of these data.

The data collected will include the perspectives of the participants involved. The unit of analysis that the researcher is interested in this study is a combination of the following categories (Lee, 1999):

- a. A particular decision i.e. to outsource and
- b. Its enactment.

Outsourcing will be studied across about twelve pharmaceutical companies who either outsource their manufacturing or participate in third party manufacturing.

4.3 Selection and description of participants.

Senior managers at the strategic decision making level from the various pharmaceutical companies will be requested to participate in the study. Participation will be voluntary. The researcher has selected thirty pharmaceutical companies of the seventy four that is currently registered with the Medicines Control Council (MCC) in SA. These thirty pharmaceutical companies will each be sent a questionnaire to complete. The researcher will ensure that at least twelve companies will complete the questionnaire (six who are currently outsourcing and six who have manufacturing facilities). All participants will be linked to SA, either be a South African company that outsources or be a contract manufacturer (local or international) who manufactures for a South African company.

4.4 Data collection strategies

Two different questionnaires will be drafted namely:

- a. A questionnaire for a company involved in third party manufacturing (Appendix A).

- b. A questionnaire for a company that outsources its manufacturing and/or packaging (Appendix B).

The researcher will not use random sampling but rather a convenience sample (Haley and Haley, 2006) of senior managers who are involved in strategic outsourcing. Due to the specific emphasis of this study on collaborative relationships, a focused sample will be used. The selected managers will be sent a comprehensive questionnaire via email to complete. The questionnaire will contain mainly open-ended questions. Their responses will be accepted via email. Once the questionnaires have been reviewed, telephonic follow-ups may be conducted to get clarity on certain responses if necessary. The questionnaire will focus on the issues related to following:

- a. Outsourcing of manufacturing to local and international CMOs that is current Practices and strategic issues
- b. Participants' views on the advantages and disadvantages of outsourcing
- c. What is driving outsourcing in SA?
- d. Outsourcing in SA versus outsourcing to other countries.
- e. Future trends

The researcher will also conduct interviews with at least one or more with key role players in the outsourcing division at a pharmaceutical company. An unstructured interview method will be used to gain better insight into the subject matter.

4.5 Data Analysis Strategies

Data analysis would involve categorisation of data, interpretation of single instances, identification of patterns and synthesis and generalisations. The response from the questionnaires would be analysed to get an understanding of:

- a. The current situation of outsourcing in South Africa.
- b. Outsourcing in SA versus outsourcing in other countries. Is South Africa's pharmaceutical industry following the US footsteps in shifting of production to low cost manufacturers in India and China?

- c. Whether companies are benefiting from outsourcing?

4.6 Methods of Achieving Validity

Construct validity: Key informants will be asked to review the case study report to ensure its veracity, honesty, and clarity (Lee, 1999). The researcher will investigate the possibility of using multiple informants which then “implies internal consistency and potentially stability over time “(Lee, 1999: 155).

Triangulation will be used to assist with internal validity. Triangulation methods will minimise possible biases from respondents. According to Leedy and Ormond (2005), “ The external validity of a research is the extend to which its results apply to situations beyond the study itself.” The results of the study will be indicative of the South African situation and even though this research focuses only on a sample of pharmaceutical companies that outsource in the industry, the findings of the study will be applicable and have implications for other pharmaceutical companies in SA due to the fact that this is highly regulated industry and all are governed by the regulations of the country. Thus all the SA pharmaceutical companies who outsource have to abide to the regulations.

4.7 Anonymity and confidentiality

The names of the organisations or the participants will not be mentioned in the study.

4.8 Ethics

Participation in the study will be voluntary and participants will be informed about the nature of the study prior to being asked to participate. Refusal to participate in the study will be accepted at any stage during the course of the research. The primary data will at all times be treated as confidential information by the researcher. The primary data will then be analysed and the reviewed information that does not contain any names of organisations or the respondents can the viewed by others.

4.9 Summary

This chapter described the research methodology that is adopted in the study. It elaborates on the instruments used and the method which represents a means to accomplish the set objectives.

CHAPTER 5: RESEARCH RESULTS

5.1 Introduction

This chapter reports the results and findings of the qualitative research performed. The results will be presented in two sections i.e. the responses from the Contract manufacturers (CM's) and the Contract givers (CG's). The responses to the questions in each section of the study are grouped into four broad categories to facilitate the discussion and assist with the linking of the results to the research objectives. The four categories are:

- A. Current Practices and Strategic issues**
- B. Participants views on the advantages and disadvantages of outsourcing**
- C. Outsourcing In South Africa**
- D. Future trends**

The interviews and surveys covered aspects of the senior manager's perceptions of outsourcing as well as their reasons for outsourcing. The data collected was to enable the researcher to address each research objective. The data will be used to identify:

- Current outsourcing practices (what is done)
- Current outsourcing strategic issues (why it is done)
- Possibly future trends in outsourcing (what should be done).

The reader is reminded at this point that the questionnaire contained mostly open-ended questions. The quantitative data has been summarised below and will now be provided in conjunction with the responses to the close-ended questions.

5.2 Demographics

The study aimed to get senior managers from both multinational and generic pharmaceutical companies to participate in research. Feedback was received from twelve participants. Thirty three percent of the respondents were female and all respondents occupied senior levels within their organisation.

Table 5.1: Demographic Data

Personal Data			Organisation Status		
Sex	Yrs in Pharma Industry and Position in organisation		Manuf	Pack	Outsource
F	17	NPI Manager	√	√	√
M	14	Manager: Contract Manufacturing	√	√	-
M	15	Director	√	√	-
M	7	Manufacturing Executive	√	√	-
M	17	Logistics Manager	√	√	-
M	3.5	Third party Manager	√	√	√
F	20	Executive: Strategic Business Development	√	√	√
M	19	Director	-	-	√
M	36	General Manager: Outsource Division	√	√	√
M	20	Supply Chain and Logistics Manager	√	√	√
F	15	Strategic Sourcing Executive	√	√	√
F	10	Strategic New Business Development Manager	√	√	√

5.3 Questionnaire Responses: Contract Manufacturing

A total of six contract manufacturers (appendix A) completed the questionnaire that was used to determine key drivers, decision making and strategic issues related to outsourcing in the South African pharmaceutical industry.

A. Current Practices and Strategic issues

The reasons for outsourcing, its benefits and drawbacks are summarised (table 5.2) from the responses received.

Table 5.2: Outsourcing Reasons, Benefits and Drawbacks (Contract Manufacturer)

Reasons	Benefits	Drawbacks
<ul style="list-style-type: none"> • Financial- increase bottom-line, cost avoidance (deceased financial investment), reduce products costs • Capability of CM – due to lack of technology/ technical skills of the CG or they do not have the capacity or the facility to manufacture. 	<p>There are benefits (saving time and money, increased investment in new product development, reduces staffing requirements and risk of labour problems) provided that quality requirements of CG are met and there is no risk to patient's health or CG reputation.</p>	<ul style="list-style-type: none"> • Added outsourcing fee • Lack of control over lead-times • Risk

Respondents were queried on their capacity utilisation and all responded positively that they were achieving higher capacity utilisation by pooling of resources. A MNC explained that they are focusing on increasing capacity utilisation but not at the expense of their own products.

According to the CM's the expectations of CG's from outsourcing included professionalism, cost reduction, a quality product, delivery on time and in full. It is interesting to note that one CM listed only negatives expectations such as increased product lead times, possible risk of non-compliance and reduced control. The risk associated with outsourcing as elaborated on in Chapter two is important in the decision making process (Aves, 2001; Gnuschke et al., 2004; Jiang and Qureshi, 2006) Reasons listed for the large percentage of pharmaceutical companies that are seeking outsourcing vendors included:

- Pharmaceutical industry is lucrative and the "middle man" stands to make big profit without the capital expenditure, technical expertise and compliance issues. In addition generics are becoming more common
- Poor service levels and lack of capacity in facilities in SA

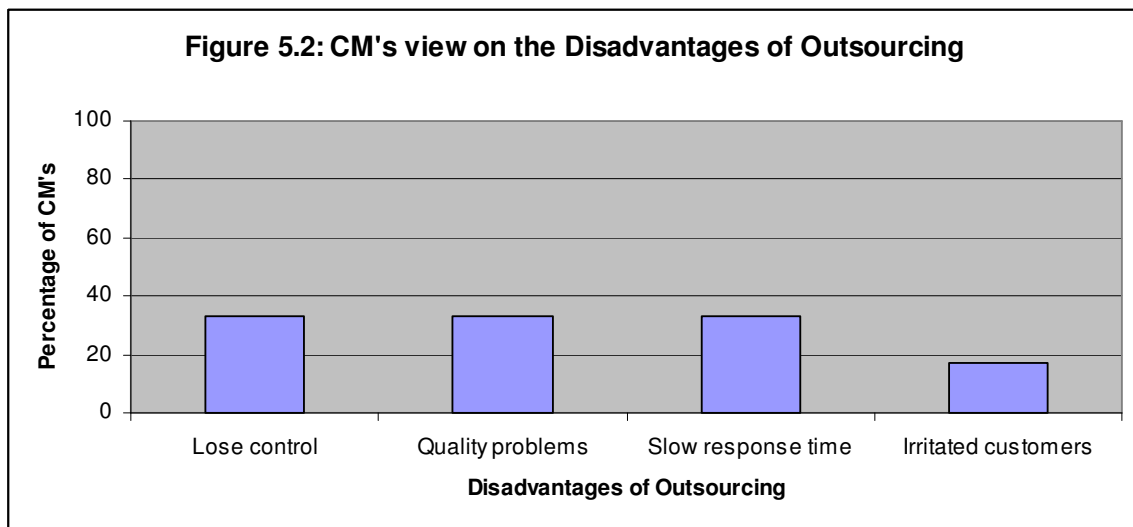
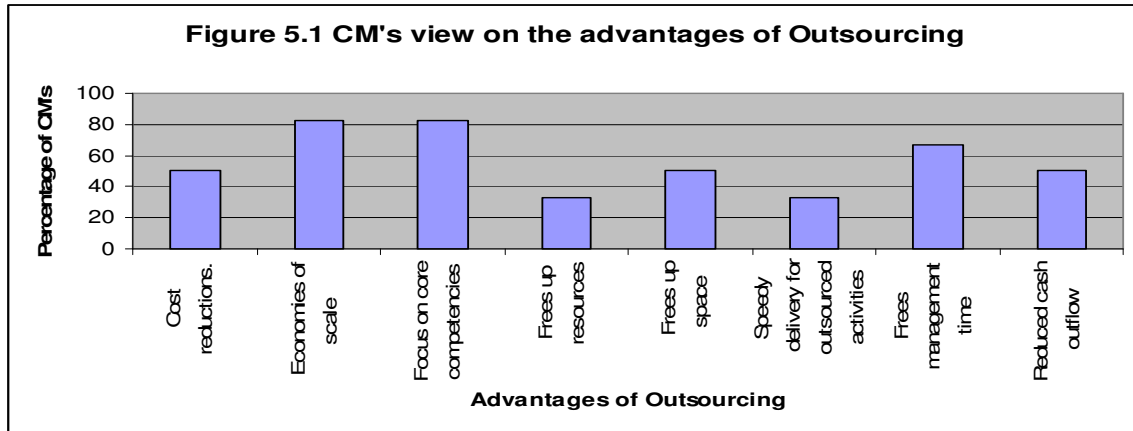
- New MCC requirements
- Cost, compliance and risk management driven and
- Due to advantages (free management time, focus on core competencies and benefit of economies of scale) of outsourcing.

CM's believed that the main criteria used by CG's in assisting with their make or buy decision included cost savings (price), review of core competencies, technical expertise, regulatory issues, capital, reduced financial outlay, hassle factor, service, quality (GMP standards), and lead times. Criteria that has been rated as of higher importance include cost saving, lack of financial outlay (capital) and lack of expertise. These criteria has been discussed in the literature review (Jiang and Qureshi; Copestake and Lau and Zhang, 2006).

B. Participants views on the advantages and disadvantages of outsourcing

Main advantages and disadvantages of outsourcing are graphically illustrated (figure 5.1 and 5.2) and the various managers also indicated the advantages which they believed CG's could still achieve and these included:

- Lowering personnel costs and other cost reductions.
- Focus on their core competencies
- Don't have to worry as much about keeping abreast with outsourced activities
- Increases the speed of delivery for outsourced activities and
- Free up management time to focus issues such as monitoring performance and focus on core competencies



CM's have listed a large number of disadvantages that they believe the contract givers are experiencing which is concerning and these include:

- Lose control
- Quality problems
- Slow response time
- Slow resolution times
- Can't produce desired results
- Reduced sales and
- Product recalls.

According to the responses from the CM's the three most important advantages of outsourcing **is reduction in costs, benefiting from economies of scale and the contract givers focusing being able to focus on core competencies**. The majority of the respondents agreed that **loss of control and quality related problems** deter contract givers from outsourcing. These responses can be compared to O'Higgins (2003) globalisation strategy (chapter 3, figure 3.3) and the outsource drivers (chapter 3, table 3.5) summarised.

C. Outsourcing in South Africa

The percentage of the CM's customers that did not have manufacturing facilities varied amongst the CM's and ranged from 5% to 85%. When CM's were questioned on reasons for not being awarded contracts in the past, their responses included issues such as their price being too high, capacity constraints, not having the appropriate technology, infrastructure and inability to assist with required processes.

In addition to having MCC approval the different CM's had approval from some of the other regulatory bodies such as the MHRA (UK), FDA (US), TGA (Australia), WHO and ISO accreditation. Manufacturers need approval from the relevant regulatory so that they can supply additional markets.

CM's are able to offer the following:

- Sophisticated and effective quality systems
- High levels of technical expertise, and an increasingly modern facility
- "One stop" manufacturing facility for the manufacturing and/or packing of liquids, ointments, tablets, capsules, toiletries, cosmetics, toothpastes and aerosols
- Competitive advantage – reputation, high service level, compliance with laws, lead times, flexibility, financially secure and stable
- Extensive manufacturing experience and capabilities for a wide range of products and dosage forms for the various markets and

- Able to manufacture smaller batch sizes

Respondents have cited numerous key drivers of outsourcing in SA such as **price, flexibility, capability, lack of expertise (technology), reducing complexity of operations, instability of country, regulatory environment (MCC and new regulations), small demands needing smaller batches sizes, IR issues, products with smaller profit margins and reduced investment in facilities.**

In terms of location domestic CM's are preferred due to avoidance of language problems and the increased transportation costs. Easier for CG to visit local CM's (accessibility is important especially if one requires stricter control of product manufacture). Many of the CM's are located in Gauteng and a large percentage of products are also sold there further reducing transportation costs. Fifty percent of the respondents have implemented improvement initiatives/ best practices (Chapter 3, Dangayach and Deshmukh, 2001) such as Kanban, JIT, Lean sigma principles, optimisation of production steps and information management.

According to the CM's the obstacles and problems faced by CG's in SA include regulatory issues, quality, lead time and delivery problems. There is a lack of capacity, lack of compliance and loss of control at some of the existing CM's and this further exacerbated due to the limited number of CM's in SA. In addition to these problems organisations that outsource outside of SA may experience logistical problems (long lead times), maybe forced to purchase larger volumes/ batch sizes, hold stock for longer, encounter language barriers, exchange rate fluctuations (price) and technology transfer issues.

Fifty percent of the respondents believed that the challenges that CG's are experiencing have limited the scope of outsourcing in SA and have cited reasons such as the new MCC guidelines on GMP which may result in a large number of facilities not meeting the new requirements while the others were positive about

outsourcing in SA and one respondents is optimistic and believes that SA can position itself as a low cost supplier to other countries.

The majority of the respondents have been able to assist the CG with the introduction of new technologies or materials, specialised expertise to manufacture products satisfactorily and expertise to speed up product development times. Many CM's however have not thus far assisted the CG's with geographic expansion. Currently CM's performance is monitored by reviewing of promised delivery times (adherence to forecasts), customer complaints, product quality reviews, measurement of customer service levels, audits of batch documentation and vendor facilities.

Responses on the hidden costs that should be expected when outsourcing outside of SA included currency fluctuations (price), quality, communication gaps, lead times, logistical issues (delivery) and understanding of INCOTERMS. A respondent indicated that with good cooperation there are no hidden costs due to "open calculations."

CM's have provided suggestions on what the SA government can do to further promote outsourcing in SA which included:

- Tax incentives to the manufacturers to attract business. Increase pharmaceutical industry exposure. Outsourcing is a question of capacities, know how and competitiveness, why not use global capacities when they are available.
- If government would like to help to increase the domestic business, than it should act pro industry (faster decisions, less bureaucracy...)
- Stabilise the MCC to give foreign investors confidence in quality. Advertise SA's ability abroad and
- Government must work closer with the pharmaceutical industries that have manufacturing capabilities and ensure they support and drive all

initiatives together with the manufacturers to make SA an attractive proposition for potential clients.

These are suggestions on what the government can do to assist manufacturers with service delivery and improve on the competitiveness of the pharmaceutical industry.

D. Future trends

The majority of the respondents are involved in collaborative partnerships with other pharmaceutical companies who may previously have just viewed each other as competitors. Respondents were requested to comment on the statement below:

While many companies benefit from sending work to places where labour is cheap, manufacturers often overrate the value of wage savings and underestimate the inventory, obsolescence, intellectual property and currency risks of off shoring. Some overlook the benefits of producing goods close to their markets so that customers can get them in days instead of months.

Feedback from respondents included the following:

- This is not necessarily the case. If the relationship between the contractor and the company is sound and conditions are clearly understood and good plans are in place then this arrangement can be very beneficial. Inventory must be properly managed and delivery dates must be adhered to.
- Correct. Often only trial and error shows this. Not being able to visit the facility and meet face to face cause's communication gaps, lack of control, and inevitably creeping costs and low yields and quality.
- Agree, but this can only be achieved if the necessary skills are in place and constantly developed to ensure the required end result is achieved throughout the process.

5.4 Questionnaire Responses: Contract Givers

A total of six Contract Giver questionnaires (appendix B) were completed either by email or by interviewing the manager. The responses from these questionnaires will be used to determine key drivers, decision making and strategic issues related to outsourcing in the South African pharmaceutical industry.

A. Current Practices and Strategic issues

The reasons for outsourcing and its benefits are summarised (table 5.3) from the responses received.

Table 5.3: Outsourcing Reasons and Benefit (Contract Giver)

Reasons	Benefits
<ul style="list-style-type: none"> • Financial- Cost Reduction • Capability (includes facility, equipment, processes, systems, capacity, experience and skills) - Niche manufacturing capability required, reduce own manufacturing capability/ complexity, make use of technology not available • Enhance flexibility by having more than one supplier • Focus on core business 	Benefits include better costs (savings), services, reduce own potential staff complications requirements, ability to deliver the desired results and BEE accreditation

In deciding to outsource, CG's had expectations which included:

- Cost efficient manufacture at comparable quality standards
- The ability of the CM to deliver directly to the customer through available networks.
- Organisations want to increase capacity and decrease costs.
- If processes are not efficient, then look at outsourcing.

Outcomes were achieved such as decreasing product costs. When questioned on whether their organisation's initial objectives/ expectations changed with time, the responses varied with some respondents agreeing with statement while other disagreed as illustrated in table 5.4.

Table 5.4: Outsourcing Objectives

Has the Organisations Outsourcing objectives Changed with Time?	
No	<ul style="list-style-type: none"> • If the basis for the decision is sound then objectives are unlikely to change • No although better communications are now being actively pursued and monitored. • However now aware that there is a cost associated with managing outsource
Yes	<ul style="list-style-type: none"> • Changes in legislation such as single exit pricing in SA has seen a resurgence of wholesalers. • Changes in organisational strategy and focus • The choice of partners is much more selective - look at quality and cost.

Respondents were asked to give possible reasons (table 5.5) why the 2006 Pharnasource Pharmaceutical Technology outsourcing survey found that 87% CG's were actively sourcing new vendors.

Table 5.5: Possible reasons for finding new vendors

Capability	Costs	Growth Of CG	Quality and Service	Other
<ul style="list-style-type: none"> • Absence of modern plants • Lack of appropriate skill sets • Capacity constraints at existing CM's • Innovation 	<ul style="list-style-type: none"> • Cost savings • Cost benchmarking 	<ul style="list-style-type: none"> • Expansion of product ranges • Growth in sales and reluctance to invest in capability 	<ul style="list-style-type: none"> • Not meeting quality standards • Looking for better service and reliability 	<ul style="list-style-type: none"> • Global market – flow and access of information • Focus on core business • Legislation

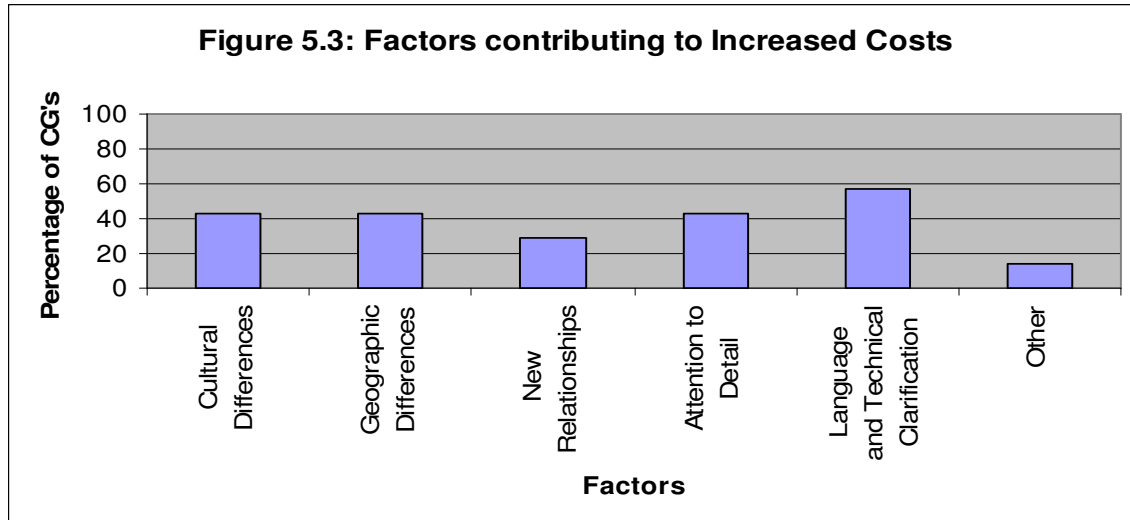
There is an agreement amongst the respondents that outsourcing will be dependant on more than just one criterion to ensure that outsourcing is successful. Important criteria include **cost**, **capability** (capacity, technology, and technical skills), **quality**, service and **compliance** with regulatory requirements. Realignment of products to a new outsource manufacturer also incurs additional costs and this must also be considered. Other criteria include issues such as product lead times for a new launch and the registration process for new manufacturer/packer.

While some CG's have indicated that the location of a CM should have no major impact on their choice of a CM if a total cost (transportation costs, etc) was considered, others have indicated that the location impacts on the choice of a CM due to:

- Accessibility to manufacturing site difficult due to distance, the closer the customer the better the control
- Communication, language barrier
- Certain countries are expected to be more cost effective and
- Not ideal to transport liquid i.e. transporting water.

Language and technical clarification (figure 5.3) was cited as an important factor contributing to the cost of setting up of a new vendor. Hidden costs when outsourcing outside of SA included:

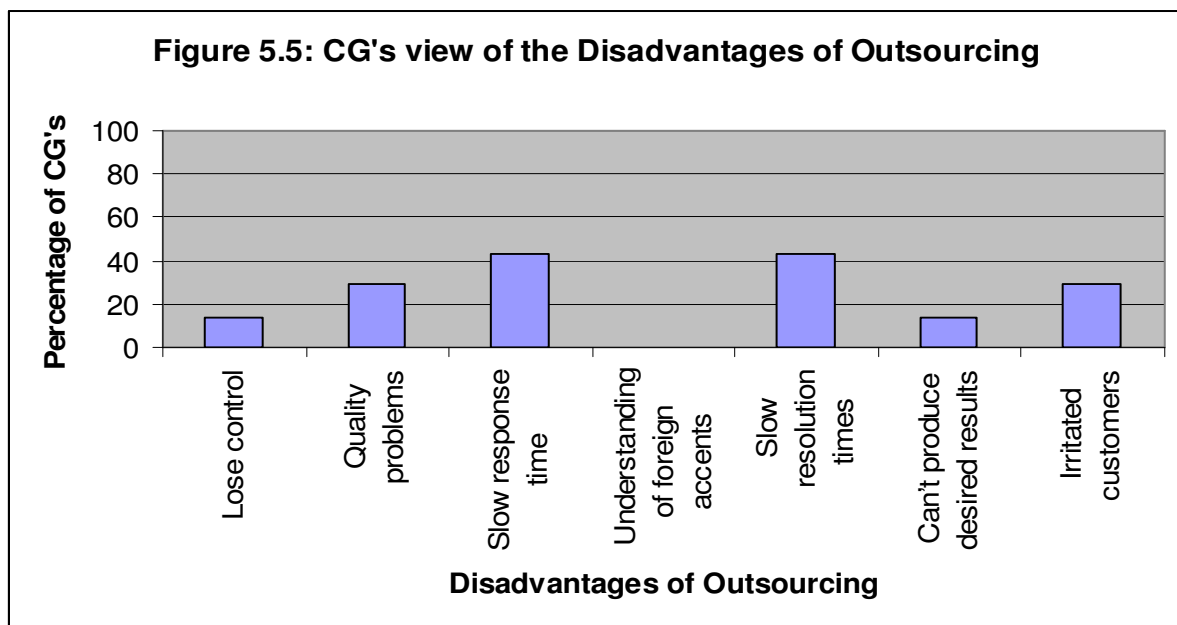
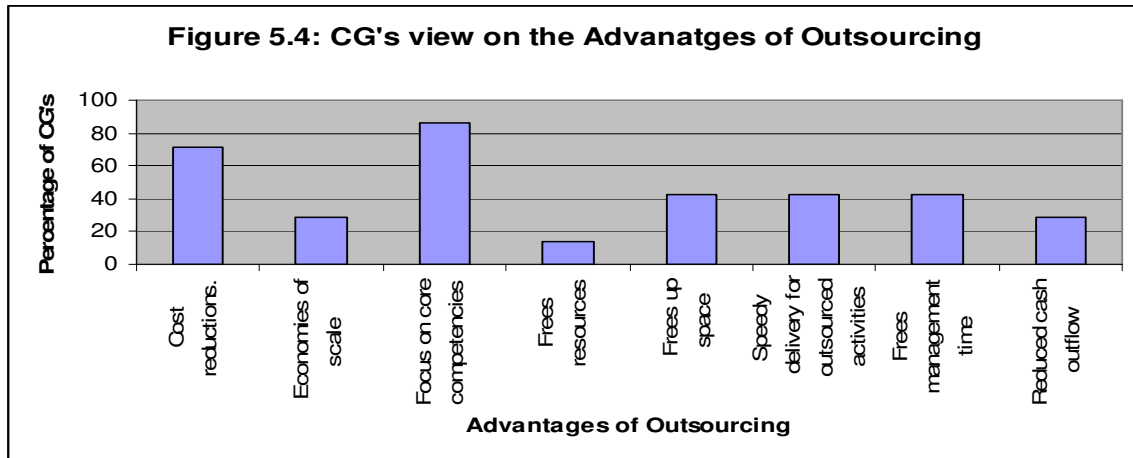
- **Cost of realignment** – Documentation, Legal issues (setup and negotiation time), regulatory compliance and associated costs
- **Cost of technical transfer, validation & stability**
- **Resources** to ensure change of site is compliant
- **Transport** - less flexible and this impacts transport costs when late deliveries have to be air freighted.
- **Minimum order quantities** are high
- **Quality** issues, counterfeits and
- **Currency fluctuation**



B. Participants views on the advantages and disadvantages of outsourcing

Respondents were questioned on the advantages and disadvantages that their respective organisations have thus far has encountered with outsourcing (figure 5.4 and 5.5). Responses varied in terms of advantages that their organisations still hoped to achieve. These included lower costs (gain economies of scale), reduce cash outflows, increase the speed of delivery of outsource activities, quicker response times to patient needs, optimising minimum order quantities with demand and reducing the risk around potential write off of expired stock. In addition it frees technical resources and CM's can assist the contract giver with the problem solving.

Slow resolution times and quality related problems were common disadvantages that were mentioned. Others mentioned were slow response time and CM not able to produce desired results/ not aligned to CG's expectations. Suggested plans to address these disadvantages include a structured plan to manage response times and expectations together with the completion of a technical agreement/ SLA, between the CG and CM to focus of communication channels.



Two main advantages listed by all respondents which strengthened their decision to outsource were lower costs (economic factor, Lau and Zhang, 2006) and organisation being able to focus on core competencies. The majority of the respondents indicated quality related problems as one of the main disadvantages that might deter organisations from outsourcing. Other disadvantages included

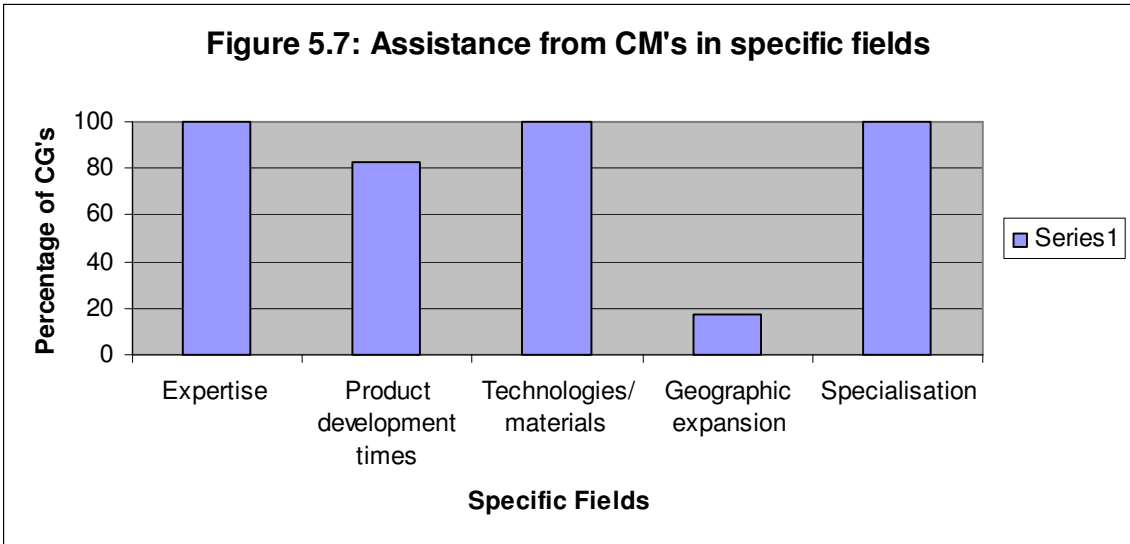
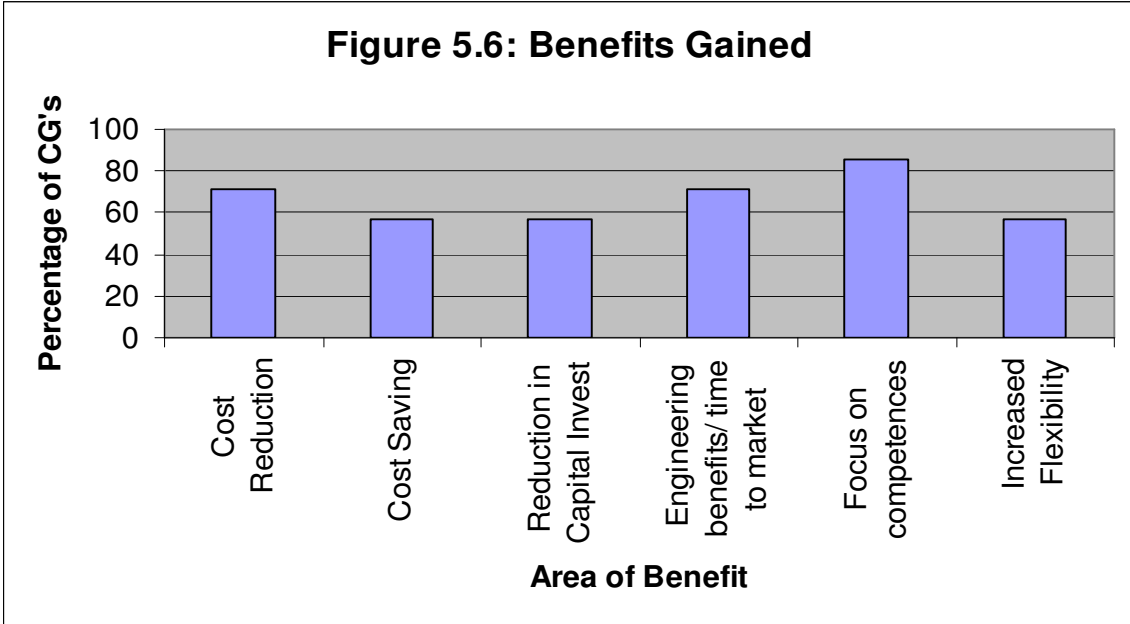
CM not producing desired results, loss of control, slow resolution and response times.

C. Outsourcing In South Africa

Key drivers include reduction in cost of goods/ cost savings, requirement for technological skills, labour problems and associated costs, manufacturing capacity, capability and small volumes/ demand in SA do not warrant the cost of manpower, materials and additional equipment. A problem in SA currently is that the country is not able to source raw (input) materials locally, which consequently increases product prices. This results in products not being as competitive as those from India and China. Currently South African CG's are experiencing numerous obstacles (table 5.6) with outsourcing; however these ventures have also resulted in benefits (figure 5.6 and 5.7) to the organisations thus far.

Table 5.6: Outsourcing Obstacles

Outsourcing to South African CM's	Outsourcing to CM's outside of SA
<ul style="list-style-type: none"> • Capacity with some local CM's accepting business because they need the revenue without having the requisite capacity available. • CM unwilling to invest in GMP upgrades, equipment, and people • Lack of expertise and capacity to run efficient & effective distribution channel • A smaller CG whose relative importance to the contract manufacturer versus some of their other bigger customers result in a drop in service levels as well as price competitiveness and focus is lost • Product costs higher • CM may have similar product or selling another generic that is equivalent to the CG's product and therefore both organisations may be competing for the same market share and • Difficult for CM in SA to source exact packing components when a CG moves manufacture of an overseas product to SA. 	<ul style="list-style-type: none"> • Inability to have face to face meetings regularly to resolve problems • Slow response and resolution times • SA volume/ demand for product are sometimes too small to get the attention of the CM; or to use as leverage for priority. • Quality and lack of understanding of SA regulations • Language and cultural barriers • Problems with meeting or missing deadlines for manufacturing and deliveries and • Price hikes due to exchange rate variances.



In selecting a vendor CG's are looking for

- Experience of CM in the required markets
- GMP Compliance, ISO, MCC, BEEE and
- Cost competitiveness of CM

Currently firms are using **vendor rating systems** (quality, due date performance) and annual inspection audits to appraise CM's. There is a focus on

both **service** (Customer service levels, product complaints) and **financial** (cost, waste, debtor days, and monthly savings for realigned products) indicators.

Respondents were asked to express their views on what the SA government can do to increase the amount of outsourcing of pharmaceuticals to contract manufacturers in SA:

- Export incentives
- Review of current regulations and red tape that has hampered industry growth and resulted in skilled professional leaving the country and the reduced competitiveness of medicines
- MCC registration process taking too long sometimes up to 4 years for the registration of a new product. Also aligning itself to PIC/S (chapter 3) standards which may mean possibly fewer local manufacturers will receive licences to manufacture products
- Introduce import duties or incentives to local manufacturers; and a barrier to entry via the registration process. Ultimately these are only temporary measures as global competitiveness is the only true assurance of survival and growth
- Trade tariffs – imported finished goods, exclude API's from tariffs
- Give more points to local manufacturers on tenders
- Improve skills base, ensure that university standards are high and
- Protection of local manufacturer, anti-dumping laws.

D. Future trends

Sixty seven percent of respondents have used or continue to use idle capacity to manufacture for other pharmaceutical companies who previously may have been viewed as just competitors. Respondents provided their view (table 5.7) on whether countries like India and China were only seen as attractive due to their low product costs and lowly skilled labour.

Table 5.7: India and China as Contract Manufacturers

India and China
These countries now experiencing skills shortages hence labour is becoming more expensive. They do have huge pharmaceutical/ technical expertise.
India offers high level of regulatory compliance and innovative technological skills for finished product manufacture. China is probably viewed as a source of APIs. The latter has more issues of cultural disparity and language problems.
They offer low cost and are keen to please and so there is an element of speed and flexibility.
They however need to be managed very closely at least initially.
Cost plays a role and quality standards are improving due to international focus.
India – No, have very good know how
Total cost of product is lower. India has a highly skilled labour force and the technical expertise.

Finally respondents were asked to comment on the statement below:

While many companies benefit from sending work to places where labour is cheap, manufacturers often overrate the value of wage savings and underestimate the inventory, obsolescence, intellectual property and currency risks of off shoring. Some overlook the benefits of producing goods close to their markets so that customers can get them in days instead of months.

According to the respondents proper planning is vital to avoid problems and an organisation needs to have a dedicated outsource division to manage the outsourcing to CM's. Manufacture is outsourced locally as long as it makes business sense. Currency risks must be managed. Local raw material availability is also a problem. Outsourcing is dependant on size and direction/strategy of the company. A CG explained that ideally one would like to manufacture locally using and employing local people to build the economy to make it self sufficient and reliant, but one needs to be also realistic and have supportive labour laws and relations to allow this to happen. Workers must not be exploited however they need to also know the importance of productivity, skills, reliability and honesty.

5.5 Summary

In this chapter the findings were presented. The results of the qualitative data analyses was gathered from threes sources, the survey questionnaires from contract givers, survey questionnaires from contract manufacturers and interviews with two managers involved strategic outsourcing. The surveys and interviews were content analysed to assist with research of objectives. These questions and detailed responses were grouped together and presented in four categories to which assisted in the determination of desired end states, success of partnerships and current practices amongst South African pharmaceutical companies.

Chapter 6: Discussion, Conclusions and Recommendations

6.1 Introduction

The purpose of the study is to identify the extent to which the various key factors play an influential role in motivating pharmaceutical companies to outsource. This was done in three ways. **First**, the theory (Chapter 2) and literature (Chapter 3) were examined for explanations on why companies are outsourcing, what the outsourcing process entails and what the current outsourcing Practices are in the pharmaceutical industry. **Second**, respondents were surveyed from two groups (CM's and CG's). **Third**, interviews were conducted with a pharmaceutical executive and a general manager who are involved in the strategic outsourcing process. Respondent's views are combined in the discussion that follows. The culminations of these efforts are discussed in this chapter, as well as directions for future research are presented in this area.

6.2 The drive to Outsource

The financial aspect and the capability (Anik 2002; Miller 2002; Shanley, 2007b) of CM's are the two broad categories listed as reasons for outsourcing by both the manufacturers and the contract givers. The CG's however have also mentioned **flexibility** and the **focus on core their business** (Wolpert, 2004). Important benefits are seen to be gained from outsourcing such as **reduced product costs, reduction in required resources** (staff, facilities), **compliance to regulations** and ability of the CG to meet the requirements of their shareholders, customers and the regulatory authorities. The responses indicate that the key drivers of outsourcing in South Africa are aligned with those identified in global marketplace by Jiang and Quresh; Copestake and Lau and Zhang (2006).

The expectations when outsourcing are linked to the reasons for outsourcing and the responses from the CM's indicate that they clearly understand the CG's objectives when they are awarded the business. Although basic expectations

may not have changed over time, responses however indicate that changes within the environment and organisation have fine tuned the needs of the outsourcing company.

Organisations are continuously looking at new vendors to assist them with **cost reduction, capability issues, quality and service problems**. In sourcing of these new vendors contract givers want reduce risk (Jiang and Qureshi, 2006; Wolpert, 2004), address compliance problems and simultaneously cope with changes within the company. In chapter three O' Higgins (2003) globalisation strategy (figure 3.3) was discussed and the research results indicate that SA is influenced by **globalisation drivers** (cost advantages, global competition, and government influence), **globalisation practices** (activity location/ concentration and coordinated competitive moves) and organisations want to achieve the **benefits of globalisation** (economies of scale, labour and other factor costs, flexibility and improved quality).

Results indicate that pharmaceutical companies in SA are influenced by outsource drives mentioned in chapter three (table 3.5) as identified by Jiang and Qureshi; Copestake; Lau and Zhang (2006). The main drivers being **profitability increase** (cost reduction, cost saving and capital reduction), **strategic considerations** (focus on core competence, increased flexibility and to facilitate market penetration).

Results concur with Jiang and Qureshi; Copestake; Lau and Zhang; (2006) in that it is not just about manufacturing medicines at a lower cost or sourcing additional production capacity but also about the important factors (key drivers) such as flexibility, expertise, fast cycle development, technology and performance elaborated on in the literature review. In SA the results indicate that the criterion used to assist with make or buy decision is not just based on cost but a combination of factors which also includes the contract givers current capability, their quality requirements and the need to comply to regulations.

Cultural and geographic differences (Power et al., 2004) together with language and technical difficulties add to the cost associated with outsourcing outside of SA (figure 5.3). The total product costs therefore need to be considered and with outsourcing there is also a cost associated with managing the process. Some of the organisations in SA understand the importance of looking at the **total cost of ownership** (product costs, logistical costs, import taxes and delays due to distance) as stressed by Bernstein (2007) when deciding to outsource.

6.3 Outsourcing as a Complimentary Strategic Initiative

Respondent's perceptions of advantages and disadvantages of outsourcing are linked to why pharmaceutical companies are outsourcing in SA. According to respondents the major **advantages** for outsourcing includes **cost reduction**, CG gaining benefits of **economies of scale** and **focusing on core competencies** while disadvantages include losing control, quality problems, irritated customers, slow response and resolution times.

According to the results there are still further advantages that can be gained from outsource activities which include lowering of costs, reducing cash outflows, quicker response time to customer needs and organisations being able to focus on core competencies. Although there are disadvantages to outsourcing, respondents have indicated the process needs to be managed, a structured plan needs to be in place to manage response times and expectations.

Chapter two introduced the theoretical link between an organisations strategy and the build up to the make or buy decision and Grants (2005) definition of **strategy** as a unifying theme that gives coherence and direction to the **actions and decisions** of an individual or organisation was discussed. The feedback from both groups of participants (contract manufacturers and contract givers) indicate that they understand what can be achieved from outsourcing however there little feedback of how the benefits (cost reduction, economies of scale and

focusing on core competencies) of outsourcing are linked to their organisational strategy.

Grants (2005) framework discussed in chapter two (figure 2.3) outlines the organisations shift in focus from the external to the internal environment so that the organisation can understand what it can do that it limitations based on its resources and capabilities. SA pharmaceutical companies like those in Europe and USA as identified by Scott (2006) are also looking for assistance with processes and production technologies from their CM's. CG's in SA seem to be aware that they should be only performing those activities (in house) that contribute to the company's competitive edge (Tilton, 1996) and all other operations should be undertaken by CMs i.e. outsourced.

6.4 Pharmaceutical Outsourcing in SA

The approval status of an organisation determines which markets the pharmaceutical manufacturer is able to supply. The majority of CM's in SA only have MCC approval and therefore can not supply the USA, Europe, Australia and WHO markets. The WHO market is important one because this approval would mean a pharmaceutical company in SA can supply other Africa countries which are funded by WHO initiatives and other donors which require WHO approval.

Results indicate that local CM's are able to provide a service that is compliant with the regulations, flexible production, smaller batch sizes, "one stop" manufacturing and expertise at an acceptable price. The MCC has recently joined PIC/S, a stricter European standard and many CM's in SA are concerned that they may not meet these new standards. To modernise their facilities local CM's requires capital. Although some CM's have improved their GMP standard others have been slow due to the huge financial investments that would be required as well as the possible interruption in production and revenue stream that will then arise.

Respondents have cited numerous key drivers of outsourcing in SA such as **price, flexibility, capability, lack of expertise (technology), reducing complexity of operations, instability of country, regulatory environment (MCC and new regulations), small demands needing smaller batches sizes, IR issues, products have small margins, reduced investment in facilities.**

There are also other issues that are all related to one of the main constructs that is the reduction in product costs include the current labour problems (productivity and higher labour costs when compared to other countries such as India and China) and the high cost raw materials in SA due these being imported. These results in higher input and conversion costs which ultimately lead to higher end product costs and the manufacturers price not being competitive. Outsourcing in SA to local CM's is not without problems which include:

- Accepting the business even though they have capacity problems
- Unwilling to invest in GMP upgrades because of the investment required
- Possibly also competing for the same product market share and
- Sourcing of components required for product manufacture and or packing.

However outsourcing to countries outside of SA presents a new dimension of problems which include:

- Inability to conduct regular face to face meetings
- Slow response and resolution times
- Difficult for the CM to understand SA regulations especially in third world countries like China
- Huge impact of cultural and language barriers
- Delivery problems due to distances and
- Currency fluctuations due to exchange rate variance and payments are made in US dollar or Euros.

Responses are indicative that in SA labours issues also plays an in important role in the decision to outsource similar to the western developed countries. South African CM's and CG's have indicated the importance of the speed to

market in the outsourcing initiative which is confers with the Booz Allen Hamilton study which found that this factor as a outsourcing driver grew by 70% from 2004 to 2006 when compared to cost savings which increased by only 5 % (Shanley,2007b).

Location of the CM may not be seen as a major hindrance to the process however it does impact on the initiative in terms of accessibility to the manufacturing site and communication problems due to distance, language and cultural issues. As indicated in chapter five (figure 5.3) these factors contribute to additional costs that have to be considered. Outsourcing to countries outside of SA may also incur additional 'hidden costs' such as quality problems, reduced flexibility of transport, resources (technology transfer, documentation review, and validation), product write-offs due to large volumes ordered and currency fluctuations. CG 's in SA seem to be aware that strategic sourcing must be evaluated in terms of the lowest total cost and the impact of indirect materials and services costs (Everbusch and Hill, 1997;Hagen *et al*,2007).

Respondents have been very vocal in their suggestions on what the SA government can do to increase outsourcing of pharmaceuticals to CM's in SA however the government must be careful not protect the local industry to an extend that it is not competitive in the global marketplace. A lot of the suggestions are practical however they need be driven by the government and the pharmaceutical industry must be seen as one of the key industries in SA. The SA government does currently offer a range of incentive schemes to encourage foreign investment and grow SA business. These incentives are for businesses that are part of the motor and textile industries and similar incentives should be rolled out to the pharmaceutical industry. According to Khanyile (2007) the SA government has been considering the idea of giving local pharmaceutical manufacturers tax incentives to increase the manufacture of pharmaceutical products in SA.

Outsourcing has enabled the CM's in SA to assist the contract givers in numerous areas such as **cost reduction, cost saving, reduction in capital investment, provided increased flexibility and allowed them to focus on core competencies**. For outsourcing to be effective the CM's performance is monitored with various measures (vendor rating and financial systems). Contract givers also face the directive of outsourcing to local manufacturers who are Black Economic Empowerment (BEE) compliant which also adds an additional dimension to the choice of an outsource partner.

The results indicate that the majority of the respondents are involved in collaborative partnerships with other pharmaceutical companies who previously may have just been viewed as competitors. This can be linked to Grant's (2005) praise of the game theory in which he emphasises its ability to view business interaction as comprising of both competition and cooperation. Although outsourcing to countries like India and China has its problems, these countries do have the required skill and expertise and the CG needs to carefully managed the initiative because outsourcing to local CM's can only take place as long as it is financially viable.

6.5 Conclusions

"Competitive forces are putting firms under pressure to improve quality, delivery performance, and responsiveness while simultaneously reducing costs" Kannan and Tan (2006: 755). In reacting to these pressures the pharmaceutical manufacturers are thus exploring new ways to respond to these forces. The make or buy dilemma is never an easy one decision for any organisation and will be influenced the strategic direction of the company.

Outsourcing in the pharmaceutical industry has become a common practise in US and in Europe. However, it is a rapidly growing and emerging industry in countries like South Africa. Successful outsourcing can provide significant

benefits to an organisation as is evident from the theory discussed in chapter two and the literature review. The results of this qualitative rich study have shown that outsourcing is not just about cost savings or reduction in product costs but that this process is able to afford the contract giver the ability to tap into additional capabilities (facilities, technology and skill) of their outsourcing partner. This partnership also enables the contract giver to focus on their core competencies that is “do what they do best” which could be research, drug development or even just manage their virtual company.

India seems to be an ideal contract manufacturer for South African pharmaceutical products due to its highly skilled labour force, pharmaceutical/technical expertise and its total product costs being lower than the CG's. India seems to have a lot of the Gnuschke *et al* (2004) “pull” factors such as a widespread acceptance of English as a medium of education, business, and communication together with a steady and copious supply of technical graduates. A vital role needs to be played by the SA government in creating these “pull” factors in SA. In SA governmental changes in regulations/ laws such as those addressing parallel importation, patents, foreign investors and trade would impact on the countries national competitive advantage (Chapter 2, figure 2.6: Porters Diamond model).

The results of the study are line with Momme and Hvolby (2001) suggestions in which they advocate that organisations only outsource when suppliers have a comparative advantage and that an organisation proactively have a stronger focus on its internal core business areas.

However although outsourcing is highly beneficial, organisations need to carefully manage the process, identify hidden costs, risks and initiate preventative measures to ensure success. The key for the South African outsourcing service providers lies in ensuring that their clients are kept satisfied so that they can minimise the threat of offshore providers.

The make or buy model proposed by Canez *et al.*, (2001) in chapter two (figure 2.4) should be used as a fundamental model by organisations that want to outsource or are currently outsourcing. The model indicates important focus areas for organisations to look at in their decision making process. The results of the current study concur with the importance of these particular focus areas (cost, quality, technology, processes, capability and support systems) and its applicability to the South African pharmaceutical industry. The emphasis placed on external environment ensures that there is a trigger in place for organisations to react to change. These triggers should then become the reason for organisations to continuously reviewing the make or buy decision (Canez *et al.*; 2001). Triggers must not be reviewed in isolation because issues like cost and quality are related and both important. For the pharmaceutical industry the current model needs to be adapted to include a focus on **regulatory compliance** which is linked to product quality and impacts on product costs and selling of product. The importance of regulatory compliance and its role in the pharmaceutical has been emphasised (Martin, 2002; De Palma, 2006 and Shanley 2007a) and discussed in chapter two and three.

Ultimately whether the organisation decides to outsource or not, performance measures are to be put in place which then continuously evaluates the performance of either the organisation or the contract manufacturer. Thus Canez *et al.*, (2001) have closely linked the performance measure to the initial triggers which start the make or buy decision. The outcome of the performance evaluation will “feed back into the external environment and possibly activate other triggers that again raise the make or buy question” Canez *et al.*, (2001).

It is evident that a large number of companies in South Africa are currently outsourcing and that many more will outsource in the near future. This represents positive growth for contract manufacturers in South Africa as companies spend substantially more on outsourcing. The demand for outsourcing services is

immense. The key for the South African contract manufacturers lies in ensuring that their clients are kept satisfied so that they can minimise the threat of offshore providers. However, this may not be easy within the unique South African context as companies face issues such as Black Economic Empowerment (BEE), which have been identified.

The study set to examine and evaluate the role of the various key drivers which play an influential role in outsourcing in South Africa. This was achieved through a comprehensive questionnaire distributed to pharmaceutical companies who can be classified as contract manufacturers or contract givers. It can be concluded that while some contract givers may still be using local contract manufacturers and remain content with local service providers, unsatisfied contract givers who do not want to renew contracts may look offshore to meet their needs.

6.6 Recommendations

Once a company has made the decision to outsource Trebilcock (2004) suggests that an organisation follow ten basic rules (table 6.1) to ensure both a successful relationship and outsourcing process. Trebilcock (2004) advocates that organisations follow clearly defined processes which place emphasis on proper partner selection (Hill, 2005). This is a vital step in the outsourcing process because selection of the incorrect partner will result in the contract giver incurring both lost time and extra costs.

Table: 6.1: Rules of Outsourcing

Ten Rules of Outsourcing	
1	Develop a strategy for outsourcing
2	Establish a rigorous provider selection process
3	Clearly define your expectation
4	Develop a good contract
5	Establish sound policies and procedures
6	Identify and avoid potential fiction points
7	Communicate effectively with your logistics partner
8	Measure performance , communicate results
9	Motivate and rewards providers
10	Be a good provider

Source: Trebilcock (2004: 59)

The South African government has a major role to play in the success of the local pharmaceutical industry. They need to ensure that the industry remains competitive and to enable the industry to compete in the global market place.

South African organisations including those in the pharmaceutical industry need to place greater emphasis risk reduction, integration of supply chain as advocated by Hagen *et al* (2007), executives need to make use of decision hierarchy (figure 3.1) and strategic options table (figure 3.2) when are faced with different options on how to structure the overall supply chain.

In chapter three De Palma (2006) has suggestion of a dedicated, multidisciplinary technical transfer team consisting of quality, engineering, supply chain, development, quality assurance, quality control, regulatory and operations personnel is mentioned. The successful technology transfer from the contract giver to the contract manufacturer forms an integral aspect of the outsourcing process and organisations must form similar multidisciplinary teams as suggested to both fast track the process and minimise problems that may occur.

Performance evaluation of the outsourcing initiative needs to be an ongoing process. Jiang and Qureshi (2006) recommend that future research investigate how outsourcing is actually affecting operating performance with the use of appropriate measurable metrics by focusing on cost reduction, productivity growth, profitability increase, the firms' value improvement and risk control.

6.7 Suggestions for Future Research

The study found that there were a number of key drivers, decision making and strategic issues that were promoting outsourcing of pharmaceutical products in SA. There exists a wide scope for future research that can be conducted due to the key drivers identified.

A quantitative study can be conducted by using a larger sample size to determine the relevant importance of each of the constructs identified. The factors mentioned in the make or buy model proposed by Canez *et al* (2001) can also be further tested to determine its applicability to the pharmaceutical industry and the results can then be used to modify the model and develop one that is specific to the pharmaceutical industry.

It may be also interesting to look at the social side of the partnership between the contract giver and the manufacturer because currently it seems that each is not concerned about the other side of the alliance as long as the operational side of the alliance is moving forward. This would include looking at fostering between supplier relations when outsourcing and what initiatives/process improvements the CM can undertake to ensure the CG get additional benefits from the joint venture.

An in-depth investigation needs to be conducted to look at whether SA companies that are outsourcing are aware of the outsourcing traps as cautioned by Power et al (2004) and what emphasis do these companies place on the factors mentioned by Aves (2001).

Table: 6.2: Outsourcing Recommendations

Ten Outsourcing Traps to Avoid	Managing Offshore Outsourcing
1) Lack of management commitment	1. Design
2) Lack of an outsourcing communication plan	2. Quality
3) Minimal knowledge of outsourcing methodologies	3. Price
4) Failure to recognise outsourcing business risks	4. Delivery
5) Failure to obtain outside outsourcing professionals	5. Gross margin
6) Not dedicating the best and brightest internal resources	6. Customs
7) Rushing through the initiative	7. Terms of Payment
8) Not recognising the impact of cultural differences	8. Duty Drawbacks
9) Minimising what it will take to make the vendor	9. Manufacturing ethics
Productive	10. INCO terms
10) No formal outsourcing governance program	11. Support Agencies
	12. Global Risk

Source: Power et al (2004)

Source: (Aves, 2001)

Finally additional research will need to be undertaken on measuring the performance of a companies outsourcing initiative to determine if current measurements are providing an accurate assessment of the process. The current study just noted what measurements companies are using.

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Appendix A: Questionnaire (Contract Manufacturer)

Position in the Organisation			
Age		Sex (M/F)	
Number of Years in current position		Organisation Current Status	
		Pharm. Manufacturer	Yes No
Number of Years in the pharmaceutical industry		Pharm. Packer	
Total number of years employed		Is the registered applicant for some of the products that are manufactured or packed on site.	

Due to the explorative nature of the study of the questions below must be answered with as much detail as possible. Questionnaire needs to be completed and emailed or faxed to the researcher via email. Researcher can be contacted on 082 3011088 / 041 407 2286(work)/ 041 407 2093(fax) or via email (igovender@aspenpharma.com) for clarity on any of the questions or for a discussion on the issues raised below.

1. Why do you think organisations outsource? Do you think the benefits of outsourcing outweigh the drawbacks? Please elaborate.

Response

2. Can you elaborate on reasons why your company was not awarded certain contracts in the past? What percentage of your customers does not have manufacturing facilities?

Response

3. Elaborate on the current status of your organisation in terms of outsourcing. What accreditations / approvals from the various regulatory authorities have your organisation thus far received? What expertise and advantages can your company offer organisations that want to outsource?

Response

4. Is your firm able to achieve high capacity utilisation through pooling (supplying many different contract givers)?

Response

5. What do you think are the key drivers for outsourcing in SA currently?

Response

6. Initially when an organisation decides to outsource, what do you think are their expectations from outsourcing?

Response

7. In the next section I would like to look at the advantages and disadvantages of outsourcing. Please refer to the table below and insert the appropriate letters in the space provided. If the table does not contain appropriate responses, then please elaborate in the additional space provided.

Advantages	Disadvantages
a) Lower personnel costs and other cost reductions.	j) Lose control
b) Gain economies of scale	k) Quality problems
c) Can focus on your core competencies	l) Slow response time
d) Don't have to worry as much about keeping curt in outsourced activities	m) Can't understand foreign accents
e) Frees up resource when equipment is sold?	n) Slow resolution times
f) Frees up space that can be put to alternative uses	o) Can't produce desired results
g) Increases the speed of delivery for outsourced activities	p) Reduced sales
h) Frees up management time	q) Irritated customers
i) Can reduce cash outflow	

Example:

What advantages and disadvantages have your organisation thus far has encountered?

Advantages	a	b	e	g	j				
Disadvantages	k	n	o						

7.1 What advantages and disadvantages have the companies that outsource to your organisation encountered thus far?

Response

Advantages									
Disadvantages									

Other advantages/ disadvantages

7.2 Which advantages do you believe they can still achieve?

Response

Other advantages

7.3 Which disadvantages are currently being experienced by organisations that outsource and how can your organisation assist to minimise the impact on the outsourcing initiative?

Response

Other disadvantages

7.4 Which do you think are the 3 most important advantages that strengthen the decision to outsource?

Response

Other advantages which are also important

7.5 Which do you think are the 3 important disadvantages which might deter an organisation from outsourcing?

Response

Other disadvantages which are also important

8. The 2006 Pharmasource Pharmaceutical Technology outsourcing survey found that 87% of companies are actively looking for new vendors. Why do you think this is so?

Response

9. What criteria do you think contract givers currently use to determine the make or buy decision? Are all criteria equally important or is some of greater importance? Explain

Response

10. What role does the location of a contract manufacturer (CM) and other logistical issues play in your choice of a CM?

Response

11. Third party logistics (3PL's) have made "build to order manufacturing systems possible in the computer industry where these would have otherwise been infeasible. The automotive industry often relies on a 3PL provider to perform functions associated just in time logistics. Has your organisation implemented any similar systems e.g. JIT, Kanban?

Response

12. What in your opinion are the various obstacles and problems that organisation who outsource face when outsourcing in SA and the rest of the globe?

Response

SA

Countries outside of SA

13. Do you believe that these challenges experienced by outsourcing companies limit the scope of outsourcing and the pace of development in SA?

Response

14. Has your organisation been able to assist the contract giver with any of the following :
(Indicate Yes in the appropriate boxes)

1) Expertise to manufacture of product satisfactorily	
2) Expertise to satisfactorily speed up new product development times	
3) Introduce new technologies or materials to the manufacturing process.	
4) Assist with geographic expansion – quickly and inexpensively	
5) Specialisation	
6) Other	

15. How do the different contract givers monitor your organisations performance?

Response

16. Is your organisation involved in collaborative partnerships with other pharmaceutical companies who in the past may have been seen solely as a competitor? Elaborate

Response

17. In your opinion and experience what are important hidden costs that outsourcing companies face when they outsource to countries outside of SA?

Response

18. Which products (off patent, new launches) does your organisation usually manufacture for contract givers?

Response

19. Discuss the following statement:

While many companies benefit from sending work to places where labour is cheap, manufacturers often overrate the value of wage savings and underestimate the inventory, obsolescence, intellectual property and currency risks of off shoring. Some overlook the benefits of producing goods close to their markets so that customers can get them in days instead of months.

Response

20. What do you think the SA government can do to increase the amount of outsourcing of pharmaceuticals to contract manufacturers in SA?

Response

Any further comments with respect to this research topic or questionnaire.

Appendix B: Questionnaire (Outsource Company)

Position in the Organisation			
Age	Sex (M/F)	Organisation Current Status	
Number of Years in current position		Yes	No
		Pharm. Manufacturer	
Number of Years in the pharmaceutical industry		Pharm. Packer	
		Outsourcing some manufacturing and or packing	
Total number of years employed		Not outsourcing currently but plan to do so in the future	

Due to the explorative nature of the study of the questions below must be answered with as much detail as possible. Questionnaire needs to be completed and emailed or faxed to the researcher via email. Researcher can be contacted on 082 3011088 / 041 407 2286(work)/ 041 407 2093(fax) or via email (igovender@aspenpharma.com) for clarity on any of the questions or for a discussion on the issues raised below.

1. Why do you think organisations outsource? Do you think the benefits of outsourcing outweigh the drawbacks? Please elaborate.

Response

2. What do you think are the key drivers for outsourcing in SA currently?

Response

3. Initially when your organisation made the decision to outsource, what were the organisation's expectations from outsourcing? What outcomes were expected and were they achieved? (Alternatively if your organisation is considering outsourcing what are the organisations objectives/ expectations?)

Response

4. Has your organisation's initial objectives / expectations changed with time? Elaborate.

Response

5. In the next section I would like to look at the advantages and disadvantages of outsourcing. Please refer to the table below and insert the appropriate letters in the space provided. If the table does not contain appropriate responses, then please elaborate in the additional space provided.

Advantages	Disadvantages
a) Lower personnel costs and other cost reductions.	j) Lose control
b) Gain economies of scale	k) Quality problems
c) Can focus on your core competencies	l) Slow response time
d) Don't have to worry as much about being well informed about the latest information with outsourced activities	m) Can't understand foreign accents
e) Frees up resource when equipment is sold?	n) Slow resolution times
f) Frees up space that can be put to alternative uses	o) Can't produce desired results
g) Increases the speed of delivery for outsourced activities	p) Reduced sales
h) Frees up management time	q) Irritated customers
i) Can reduce cash outflow	

Example:

What advantages and disadvantages have your organisation encountered thus far?

Advantages	a	b	e	g	j
Disadvantages	k	n	o		

5.1 What advantages and disadvantages have your organisation thus far has encountered.

Response

Advantages									
Disadvantages									

Other advantages/ disadvantages

5.2 Which advantages do you believe your organisation can still achieve?

Response

Other advantages

5.3 Which disadvantages have been discussed previously in your organisation and what action plans are in place to minimise impact on the outsourcing initiative?

Response

Other disadvantages

5.4 Which do you think are the 3 most important advantages that strengthen the decision to outsource?

Response

Other advantages which are also important

5.5 Which do you think are the 3 important disadvantages which might deter an organisation from outsourcing?

Response

Other disadvantages which are also important

6. The 2006 Pharmasource Pharmaceutical Technology outsourcing survey found that 87% of companies are actively looking for new vendors. Why do you think this is so?

Response

7. What criteria is currently being used to determine the make or buy decision? Are all criteria equally important or is some of greater importance? Explain

Response

8. What role does the location of a contract manufacturer (CM) play in your choice of a CM?

Response

9. What were the various obstacles and problems that your organisation encountered when outsourcing to other organisations in SA and the rest of the globe?

Response

SA

Countries outside of SA

10. Do you believe that these challenges limit the scope of outsourcing and the pace of development in SA?

Response

11. How has outsourcing benefited your organisation in the following areas?

a) Cost Reduction

b) Cost Saving

c) Reduction in Capital investments (Transportation, warehousing, employees, IT , & manufacturing)

d) Acceleration of engineering benefits or time to market

e) Focus on competences

f) Increased Flexibility

12. Have your outsource manufacturers been able to assist with any of the following :
(Indicate Yes in the appropriate boxes)

1) Expertise to manufacture of product satisfactorily	
2) Expertise to satisfactorily speed up new product development times	
3) Introduce new technologies or materials to the manufacturing process.	
4) Assist with geographic expansion – quickly and inexpensively	
5) Specialisation	
6) Other	

13. What does your organisation look for in a CM in terms of regulations and expertise? How readily available are CM's (local and international) that meet your organisations needs and what are the consequences of such CM's not being available ?

Response

14. In order to properly evaluate the functions of a CM, firms must develop clear guidelines for appraising the CMs outcomes. Monitoring is often difficult and requires resources such as time, money and expertise to be effective. What quantitative indicators of performance does your organisation use to assess the benefits of outsourcing?

15. Does your organisation use any of its idle capacity to manufacture pharmaceuticals for another pharmaceutical company or is it involved in collaborative partnerships with other pharmaceutical companies who in the past may have been seen solely as a competitor? Elaborate

Response

16. Which of the following would you attribute to costs becoming a significant factor when setting up with a new vendor:
(Indicate **Yes** in the appropriate boxes)

1) Cultural differences	
2) Geographic differences	
3) New relationships	
4) Attention to detail	
5) Language problems and technical clarification	
6) Other	

17. In your opinion and experience what are important hidden costs when outsourcing to countries outside of SA?

Response

18. When and for which products (off patent, new launches) does your organisation prefer to outsource?

Response

19. Do you think countries like India and China are only attractive because they offer only low cost and lowly skilled labour? Elaborate

Response

20. Discuss the following statement:

While many companies benefit from sending work to places where labour is cheap, manufacturers often overrate the value of wage savings and underestimate the inventory, obsolescence, intellectual property and currency risks of off shoring. Some overlook the benefits of producing goods close to their markets so that customers can get them in days instead of months.

Response

21. What do you think the SA government can do to increase the amount of outsourcing of pharmaceuticals to contract manufacturers in SA?

Response

Any further comments with respect to this research topic or questionnaire.

