REGIONAL VALUE CHAINS AND DEVELOPMENT INTEGRATION IN THE SADC REGION: THE CASE OF THE PHARMACEUTICAL INDUSTRY

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By

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ABSTRACT

This thesis investigates how regional value chains (RVCs) can be used to further development integration in the Southern African Development Community (SADC) region with a focus on the pharmaceutical manufacturing industry. The study is motivated by the apparent lack of attention given to the development of the pharmaceutical manufacturing industry in Southern Africa, the region's high disease burden and the identification of the industry as economically and socially important by the SADC (2015) Industrialisation Strategy and Roadmap and the Department of Trade and Industry (DTI) (2017a) Industrial Policy Action Plan (IPAP). At the same time, South Africa and other countries in the region are exploring alternative approaches to regional integration, given the failure or stagnation of numerous formal integration arrangements throughout Africa, which have often lead to polarised rather than balanced development. This thesis argues that the development of RVCs within SADC may be an effective tool for development integration in the region, particularly in sectors such as pharmaceuticals.

The study employs a value chain framework for the analysis and discusses development integration options, drawing on the East Asian experience with RVCs and on case studies involving India in the case of the pharmaceutical industry. It provides a sector profile of the industry in South Africa, due to its dominant status in the region, and also of Zimbabwe, due to that country's potential to become a pharmaceutical industry leader in the region once again.

The thesis first explores the important theoretical aspects underlying value chain analysis, namely governance and upgrading, while also outlining the rise of global value chains (GVCs). It analyses the complex relationships between RVCs and GVCs, and RVCs and regional integration. From this it concludes that RVCs are a stepping stone to participation in GVCs and that RVCs should be promoted within a development integration framework through strong regional

cooperation. Value chain analysis is applied to the entire pharmaceutical manufacturing industry with a focus on SADC. The thesis examines how the sector is evolving with manufacturing multinational corporations (MNCs) outsourcing production and setting up centres of excellence in regional production hubs. The study argues that with the application of recommended policies, RVCs in sectors such as pharmaceutical manufacturing may provide a tool for achieving balanced development in the region.

However, the study also finds that the pharmaceutical industry in SADC lags a long way behind the rest of the world and that many countries and firms will need to begin at the bottom of the value chain, with formulation, in order to contribute to the development of RVCs. The thesis concludes with recommendations on what policies are needed to foster the growth and development of pharmaceutical RVCs in the SADC region. These include strengthening public procurement, providing incentives for investment into the industry, incremental production and incremental export volumes, as well as certainty and predictability around the regulatory and business environment. Further, policy should aim to construct synergies and linkages on the ground between health systems and industrial developments; regulate service links important to pharmaceutical manufacturing; develop a coherent regional policy agenda; remove unnecessary non-tariff barriers to trade in the region and, in line with development integration, implement trade policy along with trade infrastructure that is efficient and includes airports, rail, roads and ports, as well as effective access to the internet.

DECLARATION

Except where explicitly stated otherwise and acknowledged, this thesis is wholly my own work and has not been submitted to any other University, Technicon or College for degree purposes.

Signed: ……Sean Ernest Faydherbe……

Date: ……18 March 2018……..

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LIST OF ACRONYMS AND ABBREVIATIONS

AfDB	African Development Bank
AGOA	African Growth and Opportunity Act
AIDS	Acquired Immunodeficiency Syndrome
API	Active Pharmaceutical Ingredient
ARV	Anti-retroviral
AU	African Union
CEO	Chief Executive Officer
CSR	Corporate Social Responsibility
CZI	Confederation of Zimbabwe Industries
DTI	South African Department of Trade and Industry
EML	Essential Medicine List
EOI	Export-oriented Industrialisation
EPZ	Export Processing Zone
EU	European Union
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FTA	Free Trade Area
GDiP	Good Distribution Practice
GLP	Good Logistics Practice
GMP	Good Manufacturing Practice
GVC	Global Value Chain
GWP	Good Warehousing Practice
HIV	Human Immunodeficiency Virus
HS	Harmonised System
ICT	Information and Communications Technology
IDC	Industrial Development Corporation

IPAP	Industrial Policy Action Plan
ISI	Import-substituting Industrialisation
ITC	International Trade Centre
MCA	Medicine Control Agency
MCAZ	Medicines Control Authority of Zimbabwe
MCC	Medicines Control Council
MNC	Multinational Corporations
NAFTA	North American Free Trade Agreement
NDP	National Drug Policy
NGO	Non-Governmental Organisation
NMRA	National Medicines Regulatory Authorities
NSI	National Systems of Innovation
OBM	Own-Brand Manufacture
ODM	Own-Design Manufacture
OEA	Original Equipment Assembly
OECD	Organisation for Economic Development
OEM	Original Equipment Manufacture
PMPA	Pharmaceutical Manufacturing Plan for Africa
PTA	Preferential Trade Area
PwC	PricewaterhouseCoopers
R&D	Research and Development
RVC	Regional Value Chain
SACU	Southern African Customs Union
SADC	Southern African Development Community
SADCC	Southern African Development Coordination Conference
SAHPRA	South African Health Products Regulatory Authority
SEP	Single Exit Pricing

SEZ	Special Economic Zone
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organisation
VAT	Value Added Tax
VSI	Vertically Specialised Industrialisation
WHO	World Health Organisation
WTO	World Trade Organisation

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CHAPTER 1: INTRODUCTION

1.1 Context of the Research

The global economy is increasingly structured around global value chains (GVCs) (Gereffi and Fernandez-Stark, 2016). The organisation of trade into GVCs has been a major driver of recent economic development (OECD, 2012). According to Barnes (2017), GVCs are contributing an increasing amount to global trade, estimated to be between US$5 trillion and US$19 trillion annually. The origins of GVCs can be traced back to new forms of corporate organisation that emerged in the 1970s and 1980s which involved firms outsourcing non-core activities while retaining core competencies in-house, leading to a fragmentation of production (Kaplinsky, 2016: 2). Outsourcing initially occurred close to the outsourcing company which Barnes (2017) refers to as near-sourcing. However, as the technology improved in both transport and communications, outsourcing became offshoring and therefore global in nature. More recently, it has been suggested that the emergence of regional value chains (RVCs) has reversed this trend to some extent, as companies are turning to outsourcing non-core competencies to regional rather than global firms (Barnes, 2017).

The value chain describes the full range of activities required to bring a product or service from conception, through the different phases of production (involving a combination of physical transformation and the input of various producer services), delivery to final consumers, and final disposal after use (Kaplinsky and Morris, 2015: 4). A value chain becomes global when value chain activities are carried out in different countries around the globe and regional when participating countries all occur in the same area or region. These value chain activities include research and development (R&D), production, marketing and distribution and consumer support, among others. According to Kaplinsky (2016) in excess of two-thirds of global trade now takes place in intermediate products within GVCs which has led to an overestimation of the value of trade by as much as 28 percent. Items are double or triple counted as intermediates cross borders to be assembled into a final product.

The emergence of GVCs has provided firms with the opportunity to participate in the global economy, changing the nature of production, trade and employment. It has been argued by Gereffi and Fernandez-Stark (2016) that the ability of firms to insert themselves into GVCs is crucial for their further development. Value chain analysis provides a holistic view of global and regional industries with a focus on value-added from beginning to end and by examining the related

standards, regulations, job descriptions, technologies, processes, products and markets (Gereffi and Fernandez-Stark, 2016).

The traditional typology used to distinguish between types of value chain, how they are organised and what role the lead firms play is that of producer- versus buyer-driven value chains (Gereffi, 1994). A more recent classification which plays an important role in policy making and the discussion of rent seeking has been introduced by Kaplinsky and Morris (2015). They differentiate between chains that are 'vertically specialised' and those that are 'additive' in nature. According to Barnes (2017) markets are undergoing significant change due to GVC disruption and are becoming increasingly important. The nature of end markets affects the structure of GVCs due to the requirements that must be met by firms supplying each specific market (Kaplinsky, 2016).

In the literature on value chains, two of the most important theoretical aspects are governance and upgrading. Governance refers to how authority and power relationships determine the flow and allocation of financial, material and human resources within a chain (Gereffi, 1999). The actors in the chain who have the most influence are the lead firms, whereas the first, second or third tier suppliers tend to have less power and influence respectively (Moyer-Lee and Prowse, 2015). Linked to governance is the role of standards in GVCs. The growing awareness of consumers, especially in developed markets, means firms must often adhere to a strict set of rules enforced by several role players in order to participate in GVCs (Morris, 2016). Economic upgrading within a value chain is defined as firms, countries or regions moving to higher value activities within the value chain to increase the benefits, such as security, profits, value-added and capabilities, from participating in global production (Gereffi, 2005: 171). The type of governance within a chain affects both the opportunity to upgrade and path for upgrading within GVCs (Gereffi and Fernandez-Stark, 2011).

According to the World Bank (2016: 2) value chains can be defined according to several different contexts, one of which is a geographical context. The regional rather than global nature of many value chains is the reason for this classification. The lead time and flexibility requirements, the economics of production and distribution and the need for close interaction often work against complete dispersion in the case of most tasks and value chains which leads to the rise of RVCs (World Bank, 2016). Regional integration and RVCs provide the opportunity to pool resources and increase the level of value addition in exports (Banga, Kumar and Cobbina, 2015: 6). RVCs differ from GVCs as in RVCs the finished product is exported by a country within the

region offering the country the opportunity to climb the value chain using the region's competitiveness (Banga *et al.*, 2015). It has been suggested that established RVCs allow local firms to link into successful GVCs, increasing their bargaining power with lead firms. As Southern Africa has limited global scale economies, its potential to participate in GVCs without the interim learning that could be provided within RVCs may be limited.

South Africa is at the forefront of fostering an approach to regional integration that has become known as 'development integration', both for the Southern African Development Community (SADC) region and the continent more broadly (Davies, 2011). According to Davies (1996) development integration is one of three paradigms of regional integration, the other two being market and functional integration. Development integration proponents criticise a purely trade-driven market integration approach as inadequate for achieving effective integration or a more balanced rather than polarised development path. It stresses the need for "both macro and micro co-ordination in a multi-sectoral programme embracing production, infrastructure and trade," as well as early stage political cooperation and an equitable balance of the benefits of integration achieved through compensatory and corrective measures particularly orientated towards least developed regions (Davies, 1996: 4). South Africa's focus on development integration is an important response to pressure from its SADC partners for the country to do more to balance its dominant economic position in the region. South Africa has therefore prioritised the infrastructure and industrial development pillars of development integration, as highlighted in its trade and industrial policy documents (Davies, 2011; DTI, 2010a; DTI, 2017a). The growth and expansion of RVCs is seen as a key component of the development integration approach.

The 2015-2063 SADC (2015) Industrialisation Strategy and Roadmap has identified the development of the pharmaceutical value chain as a core component of its RVC strategy. The pharmaceutical industry is particularly relevant to Africa due to the continent's disproportionate burden of disease. The African Union (AU) (2007) Pharmaceutical Manufacturing Plan for Africa (PMPA) argues that increasing the ability of SADC and other African countries to produce affordable and high quality essential medicines will contribute to improved health outcomes and the realisation of direct and indirect economic and developmental benefits. According to the South African Department of Trade and Industry (DTI) (2017a), role players in the South African pharmaceutical industry consider that they are able to make a meaningful contribution to stimulating domestic and regional growth and attracting foreign direct investment. The

pharmaceutical industry is also identified by the World Bank (2016: 52) as important for bilateral investment promotion and establishing RVCs in Southern Africa. However, limited research has been conducted on the possibilities for and constraints to successfully establishing and upgrading the pharmaceutical industry in a Southern African context (Haakonsson, 2009a). This suggests that RVCs as part of a development integration strategy, with a focus on the pharmaceutical sector, provide a relevant and productive area for further research.

1.2 Goals of the Research

The primary goal of the research is to investigate how RVCs can be used to further development integration in the SADC region with a focus on the pharmaceutical industry. To achieve this, a number of sub goals are addressed including:

- Investigating the relationship between RVCs and GVCs, as well as understanding whether RVCs should be used as a tool for insertion into GVCs or whether they are better utilised as a standalone development strategy.
- Examining whether the development of RVCs can contribute to a more balanced developmental path for the SADC region.
- What the SADC region needs to do, in terms of policy responses, infrastructure development and regional integration, to attract and establish RVCs.
- Exploring the development of pharmaceutical RVCs as part of a strategy to achieve development integration in the SADC region.

1.3 Methodology

This study utilises the value chain framework to identify the opportunities, barriers and policy responses which will enhance the benefits of regional integration with a focus on the national and regional pharmaceutical industry in the SADC region. According to Daly, Abdulsamad and Gereffi (2016), the analysis of a value chain includes the identification of the input-output structure, geographic scope, and governance, or lead firm dynamics, of a particular chain. This is in order to understand how information, materials and financial resources flow between firms and other stakeholders in the chain. The value chain is then mapped according to the activities and firm location before comparative benchmarking is undertaken to assess the position of a specific firm,

cluster or country relative to competitors. This also helps identify potential trajectories for expanding exports and moving into higher value-added positions in the chain, more commonly known as upgrading (Daly *et al.*, 2016).

The overarching method utilised in the research is value chain analysis. Both qualitative methods and quantitative data analysis are used. The qualitative analysis includes a review of the literature on GVCs and RVCs with a focus on their interaction, and an examination of key policy documents such as the 2015-2063 SADC (2015) Industrialisation Strategy and Roadmap and the AU (2007) PMPA. This is along with a pharmaceutical sector profile on South Africa and a pharmaceutical sector trade profile on Zimbabwe. These countries were chosen because both countries are members of SADC and both have strong (relatively strong in Zimbabwe's case) domestic pharmaceutical manufacturing industries created by local investment. South Africa has the leading pharmaceutical manufacturing industry in SADC and Africa and is therefore included as a focus country. According to Mulumba and Machemedze (2015) despite its economic downturn, Zimbabwe has the second largest pharmaceutical manufacturing industry in SADC. Further, up until 2001 Zimbabwe accounted for 50 percent of South African pharmaceutical exports (DTI, 2011). It therefore has the ability to be a significant producer in the region in the future and provides a link between South Africa and a number of SADC countries. For this reason, it is included as a focus country in this thesis.

Furthermore, a key informant interview was conducted with an industry expert from South Africa who has extensive professional and policy experience in the sector. A purposive sampling method, which was applied on the basis of expertise in this field, was used in the selection of participants. However, a number of industry and policy experts were not available to participate in the study and the focus was on the other qualitative and quantitative data techniques used. The interview process was approved by the relevant University ethics committee.

Quantitative data was collected on selected pharmaceutical value chains in the SADC region with a focus on South Africa and Zimbabwe. This data includes pharmaceutical manufacturing employment, total exports and imports of harmonised system (HS) Chapter 30 pharmaceutical products, growth in the industry and its current size and pharmaceutical trade balance between 2007 and 2016. This data was collected online from sources such as the International Trade Centre Trade Map Database (ITC, 2017) and from documents such as the DTI Industrial Policy Action Plans (IPAPs), the DTI (2017b) Overview of the South African Pharmaceuticals Industry, the

Confederation of Zimbabwe Industries value chain mapping study (CZI, 2014) and the United Nations Industrial Development Organisation (UNIDO) (2011) Pharmaceutical Sector Profile for Zimbabwe. The information gathered is used to construct a value chain framework similar to that of Moyer-Lee and Prowse (2015) and described by Kaplinsky and Morris (2001).

1.4 Thesis plan

The thesis is structured as follows. Chapter 2 begins with a brief outline of the rise of GVCs before providing a deeper analysis of the theory briefly introduced in Chapter 1. This includes the main value chain typologies distinguished, namely buyer- versus producer-driven and vertically specialised versus additive value chains, as well as the concepts of governance and upgrading. The governance section examines the role of governance, the different governance structures within GVCs and the relationship between governance and standards. The discussion on upgrading explores the different types of economic upgrading, the importance of social upgrading and the 'smile curve' theory of the distribution of value-added in value chains. Chapter 2 also discusses the importance of end markets in GVCs.

The focus of Chapter 3 is on RVCs and development integration. It provides a discussion on the use of RVCs as a tool to foster development integration in SADC in order to achieve more balanced economic development. Further, Chapter 3 includes an analysis of the relationship between RVCs and GVCs and how RVCs can be used as a tool for later insertion into GVCs. The different integration paradigms are explored along with the debate surrounding RVCs and formal integration arrangements in the context of countries at unequal levels of development. The chapter concludes with a critical analysis of two key policy documents, namely the 2015-2063 SADC (2015) Industrialisation Strategy and Roadmap and AU (2007) PMPA.

Chapter 4 provides a value chain analysis of the pharmaceutical manufacturing industry in selected SADC countries with a focus on South Africa and Zimbabwe. A pharmaceutical sector profile on South Africa and a pharmaceutical sector trade profile on Zimbabwe, based on available information, is included in this chapter. The South African profile includes pharmaceutical manufacturing employment, exports, imports, trade balance and the size of the South African market as a percentage of the global market, where available. The Zimbabwean trade profile is limited to pharmaceutical exports, imports and trade balance. Chapter 4 also explores the governance structure of the pharmaceutical manufacturing industry.

Chapter 5 develops the discussion around upgrading by considering two case studies, on Uganda and India, in order to identify lessons regarding upgrading opportunities for the SADC pharmaceutical manufacturing industry. Further, it discusses industrial policy within a GVC framework as compared to traditional industrial policy. It concludes by providing recommendations to governments and other regulatory bodies on which policies should be implemented to achieve development integration in SADC through regional pharmaceutical value chains.

Chapter 6 synthesises the key points throughout each of the first five chapters to provide a conclusion to the thesis.

CHAPTER 2: GLOBAL AND REGIONAL VALUE CHAIN THEORY

2.1 Introduction

The aim of Chapter 2 is to provide a deeper analysis of the different theoretical aspects of value chains introduced in Chapter 1. The chapter begins with a brief overview of the rise of GVCs providing some detail on the fragmentation of the production process which ultimately led to their emergence. Thereafter important theoretical concepts such as value chain typologies, governance and upgrading are examined. Section 2.2 explores the rise of GVCs and the fragmentation of the production process while Section 2.3 expands upon both the traditional buyer- versus producer-driven and more recent vertically specialised versus additive value chain typologies. It ends by highlighting the importance of end markets in value chains. In Section 2.4 the role of governance and different governance structures in GVCs is analysed along with the relationship between governance and standards in GVCs. Section 2.5 identifies the different types of upgrading that take place in value chains while making a link between governance and upgrading. Both economic and social upgrading are analysed as well as the notion of the changing pattern of the 'smile curve' in modern GVCs. Section 2.6 concludes the chapter.

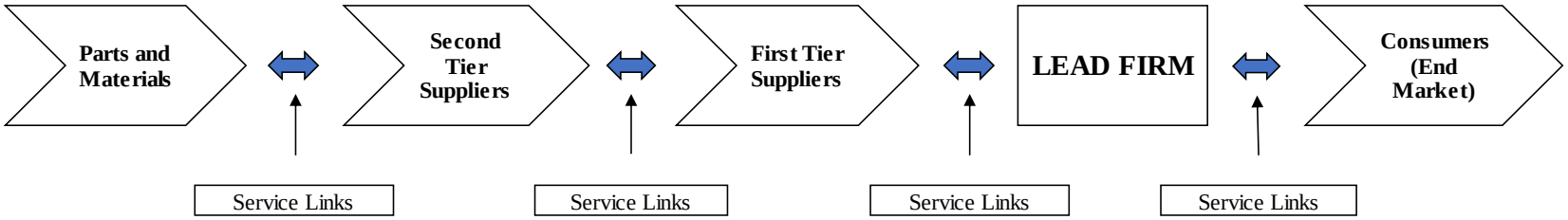
2.2 The Rise of Global Value Chains

The fragmentation of production into different geographical areas arises due to certain areas having a comparative advantage in different aspects of the production process, among other factors (AfDB, OECD and UNDP, 2014). The specialisation in core competencies is, according to Barnes (2017), driven by the search for rents and subsequently drives the division of labour. According to Cattaneo (2009), this fragmentation has been made possible through the advancement of service links including transport, communications, insurance, quality control and managerial coordination. Advancements in communication and transaction technologies, as well as the trend towards deregulation of domestic and international capital market activities and the creation of new financial products, have increased the global trade in financial assets. Capital mobility enables the quick and efficient movement of finances worldwide, contributing to the separation of production and ultimately the rise of GVCs (Obstfeld, 1993).

The separation of production is not new, but its intensity and geographical spread has increased dramatically in recent decades (World Bank, 2016). Baldwin (2012: 1) calls this the 'second

unbundling' or "the geographical unbundling of the production process." This is the offshoring of outsourced activities expanding due to improved shipping technology, global trade liberalisation, global capital market liberalisation and revolutionary changes in information and communication technology. This fragmentation, specialisation and division of labour has led to the emergence of GVCs. Figure 1 provides a graphical representation of the fragmentation of production that occurs in GVCs.

Figure 1: Fragmentation of Production.



Source: Adapted from Barnes (2017).

Figure 1 illustrates the fragmentation of production within value chains. As shown, a general value chain begins with the inputs, namely parts and materials. These inputs move through the processing stages of the chain from second tier suppliers to first tier suppliers[1] and then lead firms and finally onto consumers. An important note is that this is a generic value chain and in practice value chains may be longer or shorter and are often more complex. Each stage in the chain is linked to the next by service links. These links are an integral part of the chain and include logistics, communications, insurance, quality control and managerial coordination (Cattaneo, 2009).

2.3 Value Chain Typologies

As noted in Chapter 1, the traditional value chain typology distinguishes between buyer- and producer-driven value chains. This section analyses both the traditional and more recent value chain typologies, as well as the importance of end markets. This will facilitate the discussion of governance and upgrading in subsequent sections.

2.3.1 Buyer- versus Producer-Driven Chains

According to Barnes (2017) the traditional divide of buyer- versus producer-driven chains is based on the role lead firms play. This typology therefore has implications for governance (Gereffi, 1994). The categorisation of value chains into buyer- and producer-driven, which is still relevant today, arose to highlight the emergence of global buyers in the 1970s and 1980s (Gereffi, 1999). Buyer-driven chains are those in which large retailers, branded marketers and branded manufacturers are the lead firms (Gereffi, 1994). Barnes (2017) describes these chains as being driven by non-manufacturing buyers or commercial capital specialised in design and marketing. The value chain leaders outsource production to decentralised production networks generally located in developing countries and owned by local firms (Barnes, 2017; Gereffi, 1994). This type of chain is common in the consumer non-durables industry such as apparel, toys and footwear. Economies of scope is the main barrier to entry in these value chains while the main network links are trade-based and the predominant network structure is horizontal (Barnes, 2017).

Producer-driven chains are described by Gereffi (1994) as being dominated by large multinational manufacturing firms with a competitive advantage in specific production

[1] A first tier supplier supplies completed components directly to a lead firm for final assembly while a second tier supplier supplies goods to first tier suppliers which are used to produce the components (Financial Times, 2017).

methodologies and mainly engaging in intra-firm trade located towards the end of the chain. According to Barnes (2017) producer-driven chains are driven by industrial capital which is the main technology holder in the chain with core competencies in R&D and production. This type of chain is most characteristic of sectors that are capital and technology intensive such as consumer durables, capital goods and intermediate goods, which includes, among others, industries such as automobiles, computers and aircraft (Gereffi, 1994; Barnes, 2017). The most relevant barrier to entry in producer-driven chains is economies of scale. The main network links in these chains are investment-based and their predominant network structure is vertical (Barnes, 2017).

2.3.2 Vertically Specialised versus Additive Value Chains

A more recent value chain typology introduced in Section 1.1 above, that of vertically specialised versus additive value chains, reflects the dominant trends in modern GVCs rather than each value chain's specific characteristics. The trend of outsourcing non-core competencies while retaining and focusing on core competencies has led to a fracturing of value chains and gives rise to vertically specialised chains. Each process that has been created as a result of this fragmentation can be completed simultaneously. Global dispersion of production has increased as a result, aided by the reduction in transport costs, small processing volume losses and the increased durability of inputs. Chains with a larger number of processes, such as the automotive industry, which includes approximately 3000 processes, are more likely to be classified as vertically specialised (Morris, 2016). Vertically specialised chains mainly occur in the manufacturing industry (Barnes, 2017).

Additive GVCs are characterised by the addition of value at each stage of production along a value chain. While production activities in vertically specialised chains can be carried out simultaneously, in additive chains one production stage cannot begin without the last being completed. According to Kaplinsky and Morris (2015), additive chains usually occur in the resource and commodities sector. This is because primary inputs make up a significant proportion of the final product, the primary input may be varied due to the characteristics of the resource and an important component of the overall product value is made up of processing losses. According to the World Bank (2016), the introduction of the additive typology brings the discussion on the beneficiation of natural resources, which is especially relevant to Africa, into the GVC framework.

It is important to note that while these classifications represent the dominant trends in GVCs, there is no clear-cut distinction and may be some overlap between vertically specialised and

additive chains. According to the Organisation for Economic Development (OECD) (2014) the growth in vertically specialised chains is faster than growth in additive chains. However, additive value chains seem to be more important in low- and middle-income countries in Africa, Latin America and parts of East and South-East Asia, accounting for up to 75 percent of all exports in Africa while vertically specialised chains only account for 25 percent. This is seen to be a result of the continent's dependence on the resource sector (OECD, 2014). By contrast, for the rest of the world, vertically specialised chains make up 75 percent of exports while additive chains only account for the remaining 25 percent (OECD, 2014; Barnes, 2017). According to Kaplinsky and Morris (2015), these two families of GVCs require different corporate strategies and different forms of policy support. This is discussed further in Chapter 5.

2.3.3 The Importance of End Markets

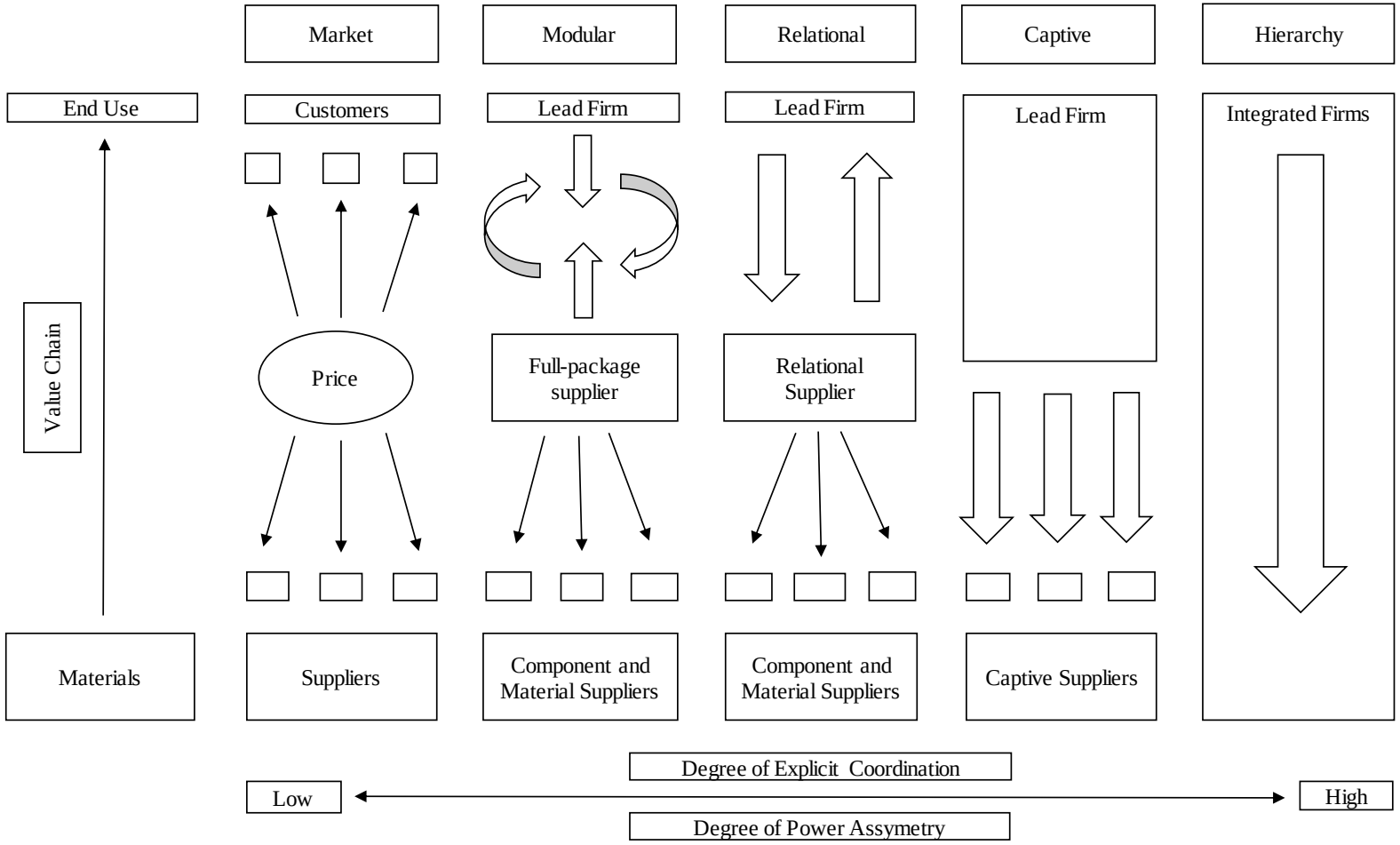
The market, namely the end users or consumers, is becoming increasingly important in a GVC context. Different markets have different criteria for insertion and offer scope for different margins (Kaplinsky, Terheggen and Tijaja, 2011). Markets can be broken down into global, regional and domestic markets as well as low-, middle- and high-income markets and are important to GVCs as they influence what is produced in the value chain. In high-income markets in particular, there is increasing fragmentation and volatility, and characterisation by critical success factors (Kaplinsky *et al*., 2011; Barnes, 2017). According to Kaplinsky *et al*. (2011) low- and middle-income markets are also starting to exhibit these traits of fragmentation and volatility; however, they are generally less price and quality sensitive and less defined by standards than high-income markets. The high growth of disruptive poor markets is important in GVCs as it allows the potential for new entry due to the lower standards required, among other factors (Barnes, 2017).

2.4 Governance and Standards

Governance is defined as the organising of activities to achieve a specific functional division of labour along the chain which would result in the specific allocation of resources and distribution of gains (Gibbon and Ponte, 2005: 3). As noted in Section 2.2.1, the buyer- versus producer-driven value chain typology has implications for governance as it is based on the role lead firms play in the chain. However, Gereffi, Humphrey and Sturgeon (2005) suggest that this typology became too broad to capture the more complex range of governance structures that had begun to emerge

globally. They therefore introduced a new typology of GVC governance structures made up of market, modular, relational, captive and hierarchal governance structures (Gereffi *et al.*, 2005: 89).

Figure 2: Governance Structures within Global Value Chains.



Source: Gereffi *et al*. (2005).

Figure 2 provides an illustration of the five governance structures and the interaction between lead firms, suppliers and customers. Gereffi and Fernandez-Stark (2011: 8-10) describe the governance structures as follows. Simple transactions occur under market governance and there is a smooth flow of information. This type of structure is characterised by low switching costs and there is little formal interaction between buyers and suppliers. Modular governance includes more complex transactions that are easily codified. Suppliers are responsible for process technology while firms use generic machinery to make products to specification. There is a large information flow between suppliers and buyers, but there are still low switching costs. With relational governance, information is difficult to transmit or learn and lead firms maintain power over production which includes production of differentiated products with unique characteristics. Information sharing is common in this structure and there is frequent interaction between actors. Switching costs are higher due to the time it takes to build relational linkages. Monitoring and control by buyers over suppliers is a distinguishing characteristic of captive governance. Small suppliers depend on a limited number of buyers with great power who have limited involvement in production but significant control over decision-making. There are high switching costs in captive chains. Lastly, in hierarchical chains products are complex and not easily codified. Lead firms control suppliers who, through vertical integration, produce products in-house. This type of chain is common when highly competent suppliers cannot be found (Gereffi and Fernandez-Stark, 2011).

The fragmentation of production requires coordination as value chains are more than just input-output relationships. Lead firms are described by Moyer-Lee and Prowse (2015) and Barnes (2017) as the actors in the chain who have the most influence, while the first, second or third tier suppliers tend to have less and less power and influence. These lead firms are responsible for value chain coordination and allocation of resources as well as making decisions such as where products are made using what inputs, how they are made and what markets they are made for (Barnes, 2017). They are also responsible for another important aspect of governance, namely ensuring that firms in the value chain meet the required standards needed to deliver the final products into the specific market.

The importance of standards has grown recently due to the increased awareness of consumers about the circumstances around how products are being manufactured and the actions of the firms producing them. Governments have also increased the pressure on firms to conform to certain

standards with global industry focusing more time and effort on ensuring all firms in the value chain conform (Morris, 2016). According to Morris (2016: 3) and Barnes (2017) standards include corporate standards internal to a chain which address quality, cost, delivery and, increasingly, environmental processes, detailing lead firm requirements to ensure systemic competitiveness; generic standards which are industry specific or relevant across a range of sectors; government regulatory standards which usually focus on issues such as health, food safety, energy efficiency, including regulations set by international bodies; and finally civil society standards which include certifying labour, organic, environmental and fair trade standards. Lead firms ensure value chain participants conform to these standards by utilising rewards and penalties, and standards provide guidance on who participates in a chain, how they participate and what they do (Morris, 2016).

Standards go hand in hand with corporate social responsibility (CSR). While CSR is a multifaceted notion, it generally refers to "the responsibility of enterprises for their impacts on society" (European Commission, 2011: 1). It encompasses a wide range of efforts through which firms seek to integrate social, environmental, ethical, and human rights as well as consumer concerns into their core business practices. The goal is to maximise the benefit of shared value for a broad set of stakeholders, including owners, shareholders, and the wider society, while reducing potential negative impacts of corporate business practices to a minimum.

The use of standards is becoming more important, especially in high margin sectors, for example, organic foods. Standards are vital in the pharmaceutical sector due to the demand for high quality medicinal products (see Chapter 4). Kaplinsky (2010) explains that while standards have been found to be increasingly important in high income countries where consumers can afford to pay for differentiated products and governments have the funding to police rules, it is a different case altogether in lower income countries. These countries tend to enforce standards to a lesser extent. Morris (2016) argues that this is due either to less priority on social and environmental issues, more relaxed government regulations or the reality that the lower spending power of consumers does not allow them to pay for the higher costs associated with meeting the higher standards. This discrepancy in enforcing standards affects the governance within value chains as lead firms of chains targeting lower income countries will not necessarily enforce the rules in the chain in as strict a manner as those targeting higher income countries. High standard markets generally have higher cost and informational barriers to entry, potentially allowing easier entry into businesses in less developed markets (Morris, 2016).

2.5 Upgrading

The second important theoretical aspect in the GVC framework is upgrading. According to Gereffi and Lee (2016) the ability of firms or countries to upgrade in a value chain is directly affected by the governance structure of the chain. Factors including external pressures and conditions set by global buyers as well as the standards associated with value chain participation affect both social and economic upgrading (Gereffi *et al*., 2005).

2.5.1 Economic Upgrading

As noted in Chapter 1, economic upgrading within a value chain is defined as firms, countries or regions moving to higher value activities within the value chain to increase the benefits, such as security, profits, value-added and capabilities, from participating in global production (Gereffi, 2005: 171). Participating in higher value-added activities and market segments is generally expected to generate larger economic benefits, including high-wage employment and higher incomes (OECD, 2012: 37). Value chains allow countries and firms easier access to global trade while also providing opportunities to upgrade these positions. Economic upgrading patterns differ by both industry and country based on the input-output structure of the value chain and the institutional context of each country (Gereffi and Fernandez-Stark, 2016). Intense competition and the dispersion and fragmentation of production mean that upgrading is important for economic development and job creation in the global economy (Gereffi and Lee, 2016).

According to Humphrey and Schmitz (2002: 1020), there are four types of economic upgrading, namely process, product, functional and chain or inter-sectoral upgrading. Process upgrading involves the efficient transformation of inputs into outputs through the reorganisation of production techniques and/or the use of better technology. In product upgrading, there is an increased sophistication of the product lines. Increasing the skills needed to do a job through introducing or abandoning functions is called functional upgrading, and chain or inter-sectoral upgrading refers to firms moving into new but often related industries (Humphrey and Schmitz, 2002: 1020). Several additional types of upgrading include entry into the value chain, whereby firms enter the regional or global value chain for the first time. This is considered one of the most challenging upgrading steps. Others are backward linkages upgrading, where local firms in one industry start to supply tradeable inputs and/or services to companies - usually multinational corporations (MNCs) - that are located in the country and are already inserted in a separate GVC;

and end market upgrading, which can include moving into more sophisticated markets that require compliance with new, more rigorous standards or into larger markets that call for production on a larger scale and price accessibility (Gereffi and Fernandez-Stark, 2016: 13)

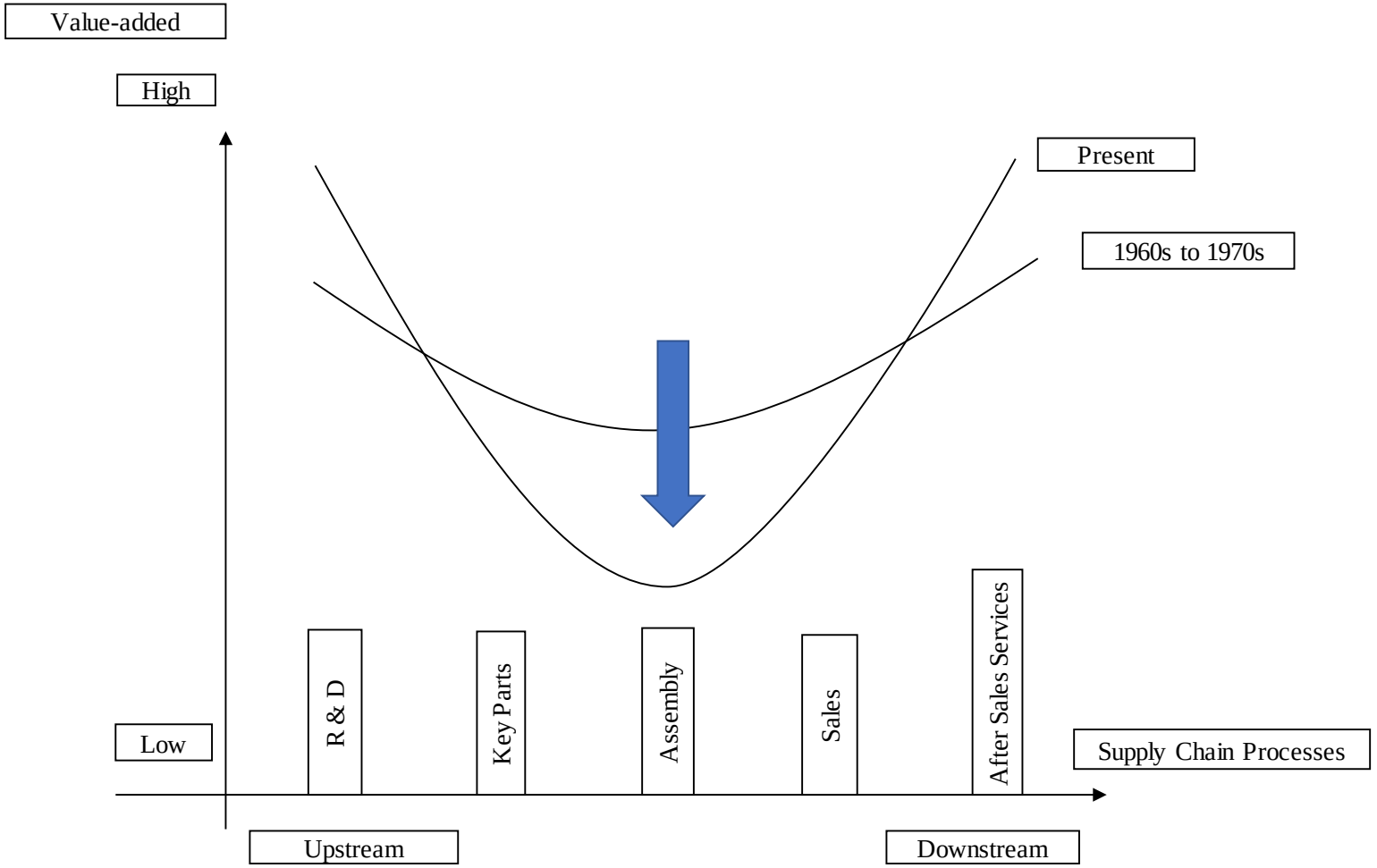
The process of economic upgrading is often not a natural progression and requires fostering the correct conditions by establishing a conducive environment and implementing the appropriate policies. This role falls largely to government and the relevant standards and regulatory authorities and government policies are crucial (see Chapter 5). However, a diverse mix of corporate strategies, government policies, technologies, worker skills and institutions go hand in hand with successful upgrading (Gereffi and Fernandez-Stark, 2016). Identifying the correct conditions for successful economic upgrading and under which firms can climb the value chain is the major challenge. Conditions need to allow firms to move from basic assembly using low cost, unskilled labour to increasingly advanced forms of full package supply and integrated manufacturing (Gereffi and Fernandez-Stark, 2016). The World Bank (2016: 88) highlights a list of policy proposals that could help developing countries upgrade and establish higher value-added positions in GVCs. The proposals include the support of multi-chain upgrading, clustering, the investment in information and communications technology (ICT) and supporting regional scale economies to name a few (World Bank, 2016).

The importance of upgrading can be illustrated with reference to the 'smile curve' which has been used to depict the consequences of the offshoring of the fabrication stages of production in GVCs. According to Baldwin, Ito and Sato (2014), the smile curve was proposed by Acer founder and CEO Stan Shih in the early 1990s. The curve is used to describe a shift in value-added in the manufacturing industry from fabrication stages to pre- and post-fabrication services over time (see Figure 3). It has been argued that the smile curve is deepening and that the shift of value-added away from fabrication stages is increasing (Baldwin *et al*., 2014; Barnes, 2017). The concern for developing nations is that the high value, high wage jobs in pre- and post-fabrication services such as R&D, marketing and design for example, are captured by, and remain in, developed countries while low value, low wage jobs in fabrication are offshored to developing nations. These low value jobs are additionally attracting an even lower share of value over time (Baldwin *et al*., 2014).

The role of manufacturing in development strategies is therefore not as clear-cut as previously thought and countries may need to upgrade away from manufacturing and towards high-end services in the future to create more value and achieve higher levels of development (Baldwin,

2012; Gereffi and Fernandez-Stark, 2016). The question of whether countries can do this without having passed through a significant manufacturing stage is however controversial as the ability to engage in design and other high value service activities has been linked to production experience in manufacturing. Developing country policy-makers are concerned about being caught in low-end service segments of value chains, characterised by precarious and informal work with limited prospects for upgrading (Cattaneo, 2017).

Figure 3: The ‘Smiling’ Curve of Value-Added.



Source: Baldwin (2012).

Figure 3 graphically represents how the share of value-added in the middle stages of the value chain such as assembly is significantly lower than stages at the beginning and end such as R&D and after sales services. An important aspect to note from Figure 3 is the deepening of the smile curve over time which highlights the increasing gap between value-added in the middle and at the end stages of the value chain.

2.5.2 Social Upgrading

According to AfDB *et al*. (2014: 129), in order for economic upgrading to become more inclusive it should be linked to social upgrading. While participation in GVCs in labour intensive industries has created more employment, especially for women and migrant workers, these jobs are often insecure and unprotected. For this reason, and others discussed below, it is argued that economic upgrading should lead to social upgrading, the so called 'win-win' scenario. In the literature, social upgrading not only includes access to better work through upgrading (such as acquiring skills in one job in order to move to a better job) but also the enhancement of working conditions, rights and protection which improves the wellbeing of workers. Barrientos, Gereffi and Rossi (2011: 324) formally describe social upgrading as "the process of improvement in the rights and entitlements of workers as social actors and the enhancement of the quality of their employment." It can be divided into two components: measurable aspects, such as increases in wages and employment, and less readily quantifiable aspects such as empowerment or improved conditions. The extent of social upgrading will be affected by factors such as sector specificities, public policies, GVC governance and firm level efforts (Bernhardt and Pollak, 2016).

Many studies assume that economic upgrading will automatically translate into social upgrading. This is often not the case as the employment created may be exploitative or insecure. The translation of economic upgrading into social upgrading also depends on the upgrading path taken; if a firm follows the low road to economic upgrading, which focuses on cost cutting measures, the jobs created may be low paid, informal or part-time jobs that do not provide security. In such cases economic upgrading may not translate into social upgrading. On the other hand, if a firm follows the high road to economic upgrading the jobs created would be full time, high skilled high wage jobs aligning economic with social upgrading. According to Barrientos *et al.* (2011: 333) firms that adopt the low road risk losing out on quality and those taking the high road risk losing out on price competitiveness. Firms therefore often adopt a mixed approach of high quality

and low-cost employment to take advantage of both quality and price competitiveness. This is reflected in the employment of full time and part time employees across work sites.

It is clear, therefore, that a number of different factors affect whether economic upgrading will translate into social upgrading. It is often the case that different employees may have different experiences, especially in a situation of mixed high and low roads to economic upgrading. CSR is another aspect of social upgrading. Some firms have become more active in undertaking CSR to develop good standing between themselves and stakeholders; relationships which are of ever-increasing importance. External standards and government policy also have an important role to play in promoting social upgrading. This is considered further in Chapter 5.

2.6 Conclusion

This theoretical chapter has considered important aspects of value chain analysis including value chain typologies, governance and upgrading. It began with a brief discussion on the rise of GVCs and also considered the importance of end markets, the role of standards in governance and the change in value-added spread along the chain signified by the smile curve. This paves the way for the analysis of the pharmaceutical sector from Chapter 4 onwards. Characterising the pharmaceutical manufacturing chain in SADC in terms of the typologies discussed in this chapter, along with its governance structure and upgrading opportunities, provides a basis for considering upgrading prospects and policy for the sector. Chapter 3 lays further groundwork by expanding the discussion of RVCs and their link to GVCs, as well as the alternative approaches to regional integration in the SADC region.

CHAPTER 3: REGIONAL VALUE CHAINS AND DEVELOPMENT INTEGRATION

3.1 Introduction

The previous chapter provided an analysis of the main elements of value chains including the different value chain typologies, specialisation and outsourcing, governance and standards, and upgrading. Against this background, the present chapter develops the discussion around RVCs, and seeks to provide an argument that links RVCs to development integration in order to examine how RVCs could be used as a tool for fostering development integration in the SADC region. Section 3.2 explores the RVC approach and attempts to understand the link between RVCs and GVCs, and why RVCs could be useful to developing countries. Section 3.3 introduces the alternative approaches to regional integration and explores the debate surrounding RVCs and formal integration arrangements in a context of countries at unequal levels of development. Section 3.4 aims to understand how RVCs can be used to further the development integration agenda in SADC and concludes with a critical analysis of two key policy documents, namely the 2015-2063 SADC (2015) Industrialisation Strategy and Roadmap and AU (2007) PMPA. Section 3.5 concludes the chapter.

3.2 Rationale for a Regional Value Chain Approach

As noted in Chapter 1, a value chain is described as the full range of activities required to bring a product or service from conception, through the different phases of production (involving a combination of physical transformation and the input of various producer services), delivery to final consumers, and final disposal after use (Kaplinsky and Morris, 2015: 4). The chain becomes global when it spans many borders around the world while it is regional when participating countries are all located in the same region. Issues such as the need for proximate interaction, the economics of production and distribution, flexibility requirements and lead times often work against the complete dispersion of tasks and activities in value chains and lead to the rise of RVCs (World Bank, 2016). While it has been suggested that participating in GVCs may be advantageous for developing countries, the strict governance and control measures of lead firms make successful and efficient participation a difficult prospect (Ncube, Roberts and Zengeni, 2017). Acknowledging the opportunities and challenges of participating in GVCs highlighted in the literature, in particular the tightly controlled and hierarchical types, Keane (2015) hypothesises

that in developing nations firms may find regional markets and value chains more conducive to some types of upgrading. Cooperation on issues such as border controls or harmonising standards may also be easier to overcome when a border is shared (Keane, 2015). However, an important question for this thesis is whether countries are better off utilising RVCs as a tool or stepping stone to insertion into GVCs or whether developing countries would benefit more from using RVCs as a standalone development strategy.

According to Keane (2015), the majority of value chain studies focus on the use of RVCs as a tool to prepare a country for insertion into GVCs and studies on African GVC participation generally imply that building RVCs aims to prepare firms for global export. The World Bank (2016) and Morris and Fessehaie (2014) suggest that countries should first participate in RVCs in order to acquire the capabilities needed to participate successfully in GVCs. According to Kaplinsky and Morris (2015), RVCs can be used as a means to an end as they provide African suppliers aiming to enter global markets with an important learning base. The World Bank (2016) suggests using the gateway model for the development of RVCs in the Southern African Customs Union (SACU), led by South African-run firms, which can then be inserted into the global economy.

According to the United Nations Conference on Trade and Development (UNCTAD) (2013) RVCs play an important role in expanding the manufacturing base of African countries, improving the productive capacity of domestic firms which have export potential as well as those firms which produce goods and services for the nation and region while also boosting intra-African trade. UNCTAD (2013) therefore suggests that RVCs provide upgrading opportunities which help firms to achieve international competitiveness, providing easier access for these firms into global markets. In their perspective, RVCs, while boosting the productivity of domestic firms with and without global export potential, should be utilised to provide firms with the opportunity to learn and develop productive capacities before insertion into GVCs. On the other hand, Keane (2015) suggests that, due to limited domestic capabilities, entering RVCs and attracting regional foreign direct investment (FDI) as an economic development strategy may be an end in itself for some developing countries at the early stages of economic development. FDI sources and investor intentions would need to be scrutinised and integration processes carefully managed in this situation (Keane, 2015).

Acknowledging that there may be specific cases where entering RVCs may be the end goal for a country, the literature appears to weigh heavily in favour of utilising RVCs as a gateway to insertion into GVCs. This is in line with trends in the globalisation of the world economy and therefore this thesis takes the stance that RVCs are not a standalone strategy, but one used to build capabilities for global participation.

3.3 Regional Value Chains and Regional Integration

Section 3.2 has argued that the development of RVCs is an important aspect of development strategy in order to facilitate participation in GVCs in the current global environment. This allows the focus of the discussion to shift to the debate surrounding the relationship between RVCs and regional integration. More specifically, the question is whether formal integration is necessary for the development of RVCs or whether formal integration tends to follow the emergence of RVCs. This is tied to the issue of the appropriate depth of and approach to regional integration in a context of countries at unequal levels of development. Formal integration refers here to one of the five levels of economic integration usually defined in the mainstream literature on integration, namely a preferential trade area (PTA), free trade area (FTA), customs union, common market or economic union (McCarthy, 2007).[2] An important aspect of regional integration that this thesis examines is that it is usually uneven or unequal in its impact and therefore steps need to be taken to achieve balanced rather than polarised economic integration. This is explored further in Section 3.3.1. One of the main challenges of regional integration is to find a balance between exploiting the advantages of growing markets and freer trade and at the same time ensuring that the state retains its ability to mitigate any negative aspects of regionalisation through implementing social and developmental policies (Soko, 2007).

According to Cattaneo (2009), in regional arrangements such as the European Union (EU) and North American Free Trade Agreement (NAFTA), production sharing developed within formal economic integration arrangements. However, in East Asia, even though there was strong regional cooperation and a strong regional dimension to production sharing, it developed outside of these

[2] The formal economic definitions are as follows. In a preferential trade area, tariffs are removed only on selected products, while in a free trade area there is unrestricted movement of goods between member states, but each retains its own trade barriers against the rest of the world. A customs union is a free trade area with a common external tariff, while a common market is a customs union with free movement of capital and labour between member states. An economic union is a common market with harmonised fiscal and monetary policies (Appleyard and Field, 2017).

formal arrangements. According to Haddad (2007) this growth path in East Asia was largely due to low barriers and transport costs which arose naturally between countries as a result of the efficiency of regional service linkages as well as the emergence of China as a low-cost assembler. This suggests that deep formal regional integration is not always necessary for the development of RVCs. In fact, it could be argued that it is more beneficial for regions where polarised development is an issue to focus on developing RVCs as a tool to achieve more balanced economic integration.

SADC, for example, has therefore turned its attention to promoting what has become known as development integration. Prioritising the development of RVCs through regional industrial policies, infrastructure development and regional cooperation is one of the main tools of development integration. The argument is that improving infrastructure and increasing industrialisation through the development of RVCs will achieve more balanced economic development and integration. Section 3.3.1 compares and contrasts development integration with the other forms of economic integration and provides some insight into SADC's latest strategy to achieve balanced economic integration. Section 3.3.2 expands on the argument that regions such as SADC should focus on developing RVCs before engaging in deep formal regional integration arrangements and provides evidence for this based on the East Asian experience.

3.3.1 Approaches to Regional Integration

Davies (1996) identifies three different paradigms of regional integration. The first is the conventional trade or market integration paradigm. This is characterised by the linear progression from a PTA through a FTA, customs union and common market, to an economic union. In the basic market integration approach, emphasis is placed on the static trade creation and trade diversion effects of integration. With trade creation a country substitutes the production of a product in which it does not have a comparative advantage with relatively cheaper imports from a partner country. Trade diversion occurs when a country turns from lower cost suppliers in a country outside the union to relatively higher cost partners within the union due to an 'artificial' advantage gained through trade preferences. Market integration is said to be economically desirable when trade creation effects outweigh trade diversion (Davies, 1996). Although the analysis has been extended to incorporate benefits from economies of scale in a larger regional market, the static approach has been criticised as inappropriate in a developing country context, with polarisation and an unequal distribution of the benefits of integration often the result (Cattaneo, 2009).

The second paradigm, and an alternative to market integration, is functional integration. In this case, cooperation and joint execution of projects that aim to remedy underdevelopment of production and infrastructure are the priority. This is seen not only as a means of reducing regional non-tariff barriers to trade but also as a way to create a regional identity, setting in motion interaction leading to better grounds for more secure integration, as opposed to hasty liberalisation which would benefit stronger partners leading to a polarised development path (Davies, 1996). Mutambara (2009) explains that the emphasis of the approach on functional cooperation in sectors such as transport, communications, water and energy can also be seen as a basis for facilitating more formal economic integration in the future.

The third paradigm is development integration which criticises a purely trade-driven market integration approach as inadequate for achieving effective integration among developing countries or a balanced development path. Development integration focuses on coordinating a programme between countries which places emphasis on industrial policy, production, infrastructure and trade. Both early stage political cooperation and measures to promote an equitable balance of the benefits of integration through compensatory and corrective measures particularly orientated towards least developed regions are important in development integration (Davies, 1996). According to Cattaneo (2009), development integration is seen as an option for economic integration whereby regional industrial development is promoted through reducing the cost of protection of the industrial sector, increasing the size of the regional market and cooperation in transport and infrastructural development.

According to Davies (1996) and Cattaneo (2015), the development integration perspective suggests that in order to be successful market integration needs to be complemented by certain policies, relationships and institutions. Firstly, there must be coordinated regional industrial development policies between member states. South-South production and trade networks should be developed along with regional transport networks and infrastructure. Setting up regional development banks is important for funding purposes while implementing policies and mechanisms that will ensure the equitable distribution of benefits is critical to the smaller, less developed economies in the region. Lastly, introducing asymmetric tariff reductions, ensuring the availability of special payments mechanisms, and ensuring that investment that is aimed at development and will help enable effective development integration. RVCs are an important component of this integration strategy.

Development integration is viewed as providing a framework within which gross economic and social imbalances within and between countries in the SADC region and most importantly between South Africa and surrounding countries can be reduced (Keet, 1999: 35). SADC was established in 1980 as the Southern African Development Coordination Conference (SADCC). It was a loose organisation adopting a functional integration approach to economic integration in its first decade (Davies, 1996). The 1992 SADC treaty transformed it into the Southern African Development Community and there was a shift towards greater market and trade integration, and the 1996 Trade Protocol moved the grouping towards an FTA. More recently South Africa has attempted to position development integration more centrally as the economic integration strategy of SADC and also of broader groupings such as the Tripartite Free Trade Area and Continental Free Trade Area. The current South African view appears to favour an emphasis on the three pillars of trade integration (at the FTA level), infrastructure development and regional industrial development. Proposals for SADC to move to a customs union are not favoured at present, as they reduce the ability of individual countries to use the tariff as a policy tool.

Soko, (2007: 2) argues that the only way development integration will succeed in the SADC region is if South Africa discharges its responsibilities in accordance with its hegemonic status. As noted earlier, South Africa's focus on development integration is an important response to pressure from its SADC partners for the country to do more to balance its dominant economic position in the region. South Africa has therefore prioritised the infrastructure and industrial development pillars of development integration, as highlighted in its trade and industrial policy documents (Davies, 2011; DTI, 2010a; DTI, 2017a).[3] Since the implementation of the SADC FTA by most member states, it has become increasingly evident that the main barriers to growing intra-regional trade and developing RVCs are often not tariffs but non-tariff barriers such as poor transport infrastructure. Therefore, the South African DTI's approach is focused on implementing policy which will build the productive capacity and infrastructure in the region (DTI, 2010a: 30). The development of RVCs is seen as an important aspect of a development integration strategy.

[3] Many economic integration initiatives in Africa suffer from issues such as uneven levels of development of member states, overlapping membership of regional economic organisations, lack of political will, inadequate human and institutional capacity to implement obligations and tensions between agreements on the continent and those negotiated with external countries or blocs (Cattaneo, 2009).

3.3.2 Regional Value Chains and Regional Integration in Practice

The East Asian experience provides some lessons for other developing regions of how the relationship between RVCs and formal regional integration may unfold when building regional production networks. As noted in Section 3.3, formal regional integration is not a necessary pre-requisite for meaningful growth of production sharing and fragmented trade. While growth in fragmented trade and production sharing had a particularly important regional dimension in East Asia it arose outside of formal regional integration arrangements (Cattaneo, 2009). Despite this, it is important for there to be strong regional cooperation between nations. In the East Asian case high levels of regional cooperation along with low 'natural' barriers allowed RVC development to precede the introduction of formal regional integration. Apart from 'naturally' low barriers and transport costs, East Asia was also able to foster the development of regional production-sharing networks as a result of the emergence of China as a low-cost assembler (Haddad, 2007). According to Cattaneo (2009), there are however a number of advantages to production sharing within FTAs and custom unions which is the direction in which East Asia subsequently moved as formal trade agreement activity increased globally.

As Mutambara (2009) points out, the SADC region does not share the same advantages of low barriers and transport costs as East Asia. Non-tariff barriers and, in particular, high transport costs are significant inhibitors to trade in the region. The development integration approach would prioritise the removal of such barriers and is therefore arguably able to achieve more than a purely market integration approach. Its focus on building infrastructure and developing effective industrial policy is key to overcoming these issues. The removal of non-tariff barriers would facilitate the development of RVCs and growth in fragmented trade across the region. According to Cattaneo (2009) the service linkages that facilitate production sharing are crucial for the development of regional trade. For example, improving the efficiency of transport between countries and streamlining border crossings will promote trade and enable the development of RVCs. Therefore Cattaneo (2009) suggests the development of a coherent agenda for the services sector in Southern Africa and at the same time the region needs to identify the best framework for regional cooperation in services due to the importance of services in supporting manufacturing production and trade in a value chain context.

3.4 Regional Value Chains as an Instrument of Development Integration in the SADC Region

The two conclusions made in this chapter so far are firstly that regional value chains should be used by developing countries and regions to build capabilities for the end goal of insertion into the global market and secondly that regions that face issues of polarised development should focus on utilising RVCs as a tool to achieve balanced economic development through a development integration framework. The study turns next to explore how SADC can use RVCs as a tool to achieve development integration, with a focus on the pharmaceutical manufacturing industry. The literature that introduces development integration in Section 3.3.1 emphasises that industrial policy, production, infrastructure and trade are important aspects of a development integration approach. This section introduces two key documents that highlight the importance and potential role of the pharmaceutical industry in furthering economic development in Africa, and SADC in particular, within a development integration framework.

3.4.1 The SADC Industrialisation Strategy and Roadmap

The 2015-2063 SADC Industrialisation Strategy and Roadmap (the Strategy) was formulated at the August 2015 SADC meeting in Victoria Falls, Zimbabwe. The primary orientation of the Strategy focuses on upgrading and regional integration, among other issues, such as industrialisation and modernisation. Value chains are a key tool of the Strategy and, importantly, are identified as having the potential to expand production whilst enabling cross-border utilisation of natural and human resources and realising regional sectoral strategies. Mention is also made of RVCs as a tool for interaction in GVCs, in line with the theory above. Identifying the removal of intra-regional trade barriers and regional consultation as important is a positive move for the development of RVCs in SADC. The Strategy also acknowledges the poor level of infrastructure and ICT services in the region, and aims to develop both in line with a development integration strategy.

It is likely that the SADC (2013) Industrial Policy Framework is a precursor document to the Strategy. SADC (2013) highlights three important value chain focus areas for the region, namely pharmaceuticals, agriculture and minerals beneficiation. Whilst the formal 2015 Strategy identifies that special attention needs to be paid to the development of pharmaceutical products, there is only a single mention of the pharmaceutical value chain and details of the proposed development of the value chain are not included in the document. This is in contrast to policy documents such as the

DTI (2017a) which identifies pharmaceuticals as a sectoral focus area, provides a brief analysis of the South African industry while identifying opportunities and weaknesses, and importantly provides key action programmes. It is unfortunate that the 2015 SADC Strategy does not provide sector specific recommendations for the development of pharmaceutical RVCs within SADC. However, SADC did release the 2007-2013 SADC (2007) Pharmaceutical Business Plan in 2007 which provides a more detailed plan for the pharmaceutical industry and is discussed further in Chapter 4.

The identification of government as a developmental agent, along with the regional integration thrust, signifies an intention of this strategy to promote a development integration agenda. The regional integration path that the Strategy aims to follow utilises regional integration to promote industrialisation while recognising the sovereignty of countries through allowing each government to develop its own policy. The fact that access to finance is identified as a weakness in the Strategy is important for the pharmaceutical manufacturing industry due to its capital-intensive nature. The Strategy does, however, highlight that growth should be aimed at the medium- and high technology sectors and pharmaceuticals falls into this category. The skills shortage identified by the Strategy is a hindrance to the pharmaceutical industry as it requires highly skilled personnel. Other tools identified by the Strategy and relevant to this thesis are regional economic clusters and upgrading.

The Strategy is a positive move by SADC towards the development of RVCs and the pharmaceutical industry and, while it has fallen short on prescribing recommendations to the pharmaceutical industry, it has been a useful guiding document for the arguments developed in this thesis.

3.4.2 The AU Pharmaceutical Manufacturing Plan for Africa

The AU (2007) PMPA is the second guiding policy document for this thesis. The PMPA, developed in 2007, aims to ensure that all flexibilities within the Doha declaration on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Public Health and in the TRIPS Agreement are made use of in developing the production of generic medicines on the African continent (UNIDO, 2011). The PMPA is a useful document for this thesis as it includes more significant detail on pharmaceutical manufacturing in an African context. As in DTI (2017a), the PMPA includes a brief situational analysis for pharmaceutical manufacturing on the continent as well as the potential benefits and issues involved with developing generic manufacturing.

Importantly, and in line with SADC (2015), the PMPA acknowledges that legislation must cater for regionalised local production. Unfortunately, the PMPA falls short in addressing GVCs, RVCs and the use of the pharmaceutical industry as a tool for achieving balanced development integration. Brief mention is made of infrastructure development, particularly with respect to manufacturing and distribution. This suggests some recognition of development integration, as infrastructure development is an important tool in this approach, but the document does not provide a clear strategy for developing pharmaceutical RVCs on the continent. Another important point the PMPA highlights that is of significant importance to the pharmaceutical industry is the issue of technology transfers. This is highly dependent on the owner of the technology and often only occurs when the product is no longer profitable. The PMPA is useful in that it identifies these critical issues for the industry. As one of the main aims of this thesis is to provide policy recommendations it is fitting that the PMPA provides guidance on policy issues. Tensions between trade and health policy are a stumbling block to the manufacturing industry and streamlining these to match the development strategy of the region will, according to the PMPA, lead to the desired results.

One of the African Union's largest concerns in the pharmaceutical sector is the continent's significant dependence on China and India for generic medicines. The document entitled the PMPA Business Plan, released in 2012, provides the framework for the implementation of the PMPA and alleviating this reliance on India and China. The focus of SADC (2015), released seven years after the PMPA, on the manufacture of pharmaceuticals as well as the pharmaceutical value chain is understandable as these are two key areas that the PMPA identifies as important for Africa. The discussion on the pharmaceutical manufacturing industry and its importance to SADC is developed further in Chapter 4.

3.5 Conclusion

Important theoretical issues considered in this chapter include RVCs and regional integration. In the discussion on RVCs, this chapter explored the relationship between RVCs and GVCs and whether RVCs are likely to be more successful within formal or informal integration arrangements. The chapter concludes that while in some developing countries in the early stages of development RVCs may be an end in themselves, RVCs should generally be used as a means of building capabilities to eventually enter GVCs as they often provide an easier upgrading path for developing

nations. This has important repercussions for the discussion on the development of pharmaceutical RVCs in Chapter 4 and Chapter 5. Furthermore, this chapter concludes that, based on the East Asian experience, RVCs do not require formal integration arrangements to be successful.

The second half of the chapter introduced the three regional integration paradigms, namely market, functional and development integration. It concludes that development integration is likely to achieve a more balanced development path than market and functional integration. Both SADC and South Africa have adopted a development integration approach to foster balanced development in the region. The development of RVCs is seen as an important component of a development integration strategy. Finally, the chapter examined two important policy documents for this thesis, SADC (2015) and AU (2007). SADC (2015) was found to be an important document given the theoretical framework of this thesis, however the Strategy fails to provide a roadmap or recommendations specific to the pharmaceutical industry. The AU (2007) PMPA provides important insight into critical pharmaceutical manufacturing related issues in Africa, however it falls short in addressing regional integration and pharmaceutical manufacturing RVCs. Chapter 4 of the thesis therefore moves to discuss the pharmaceutical sector in a value chain framework in more detail, and then draws on case studies to explore how pharmaceutical manufacturing RVCs could contribute to development integration in the SADC region.

CHAPTER 4: THE PHARMACEUTICAL VALUE CHAIN

4.1 Introduction

Chapter 3 examined the 2015-2063 SADC (2015) Industrialisation Strategy and Roadmap, and noted its emphasis on value chain development in the pharmaceutical manufacturing industry. The promotion of pharmaceutical product development is important in the light of the numerous challenges faced by the African healthcare system including, among others, a growing chronic disease burden, a disproportionately high infectious disease burden, a shortage of the necessary human resources and infrastructure as well as significant financial constraints (AU, 2012; Industry expert, 2017: interview). It is for this reason that the AU developed and adopted the PMPA in 2007 which has a vision to develop a pharmaceutical manufacturing industry in Africa that can provide the continent with a secure and reliable supply of affordable, high quality, safe, accessible and efficacious medicines (AU, 2012). The plan focuses on promoting a local pharmaceutical manufacturing industry which provides an increase in access to affordable medicines as well as a sustainable supply of these medicines while at the same time improving public health outcomes and stimulating industrial and economic development.

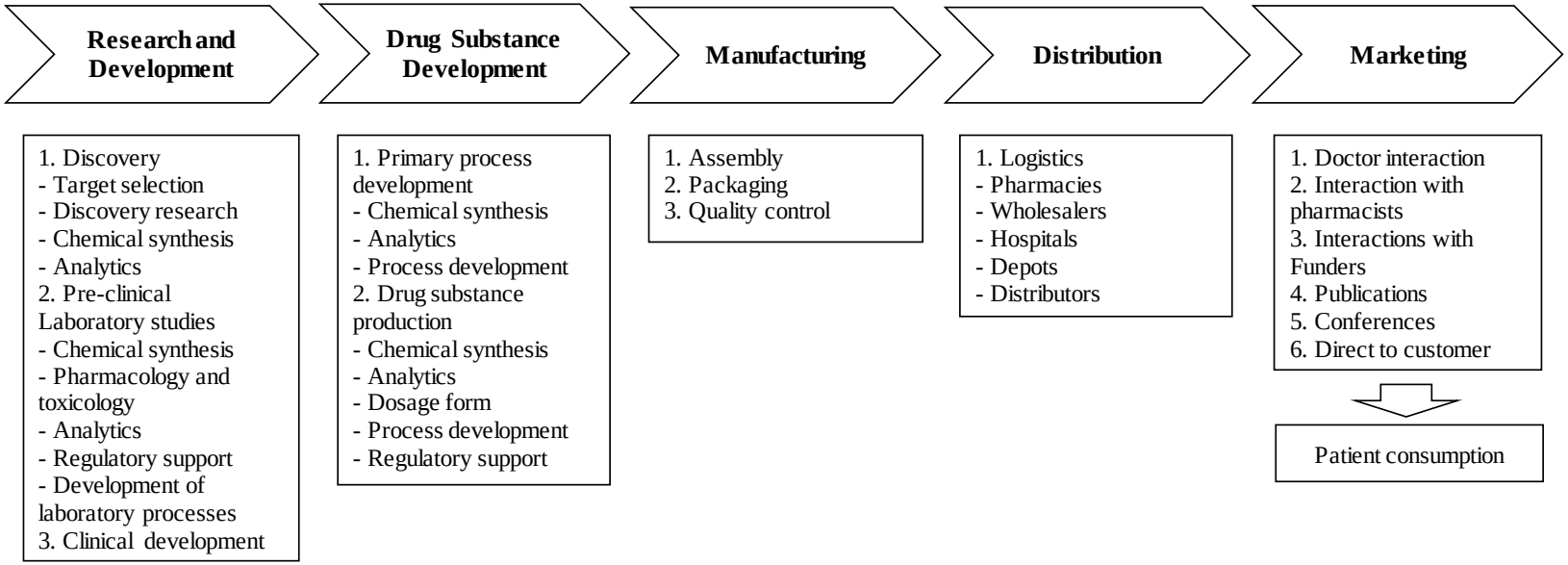
Based on the theoretical background set out in previous chapters, this chapter provides an overview of the global pharmaceutical industry from a value chain perspective with a focus on both manufacturing and the SADC region. Each stage of the value chain identified in Figure 4 is expanded upon below. Section 4.2 provides an introduction to the industry and the value chain in its entirety. It analyses each stage of the value chain with a focus on the manufacturing portions of the value chain as well as providing sector profiles for South Africa and Zimbabwe. Zimbabwe and South Africa are both SADC member states and according to DTI (2011) up until 2001 Zimbabwe accounted for 50 percent of South African pharmaceutical exports. South Africa has the largest pharmaceutical manufacturing industry in Africa, and with the development of RVCs South Africa and Zimbabwe could together potentially provide the hub for pharmaceutical manufacturing in the SADC region. Section 4.3 outlines the governance structure of the pharmaceutical value chain in line with the theory set out in previous chapters. Section 4.4 concludes the chapter.

4.2 The Pharmaceutical Industry and Value Chain

According to the DTI (2017a) the global pharmaceutical industry is worth US$300 billion per year and this is expected to rise by 33.3 percent to US$400 billion per year by 2019. Six of the top ten companies in the world are American owned and therefore the USA is the dominant player in the market. As much as 85 percent of the global market is accounted for by North America, South America, Europe and Japan. Given the advantages gained through economies of scale and patent protection, this trend is expected to remain constant (DTI, 2017a). Most global trade remains between OECD countries, however there has been a rapid rise in the participation of the Indian pharmaceutical industry of late. Indian exports to the United States rose from US$855 million in 2007 to US$5.1 billion in 2016 and exports to South Africa rose from US$109 million to US$417 million in the same period. Sub-Saharan Africa, however, remains marginalised in global trade, importing mostly from low-cost companies in Europe, mainly tied to donor and aid programmes, and from India (Haakonsson, 2009b).

According to AU (2012), numerous stakeholders determine the context within which the pharmaceutical manufacturing industry operates in a country. At the broad level, the value chain consists of five main steps in the process of supplying finished medicines to the final consumer. These include R&D, drug development/primary manufacturing, manufacturing, distribution and marketing (Figure 4). However due to the complexity of the industry each stage contains many sub-processes with supporting industries and numerous smaller value chains. Therefore, the industry involves many key actors such as the manufacturers themselves, national regulators, government ministries and wholesalers among others (AU, 2012). According to UNIDO (2011) the development of the industry requires the input of all stakeholders to foster a conducive environment for the industry to reach its potential as an asset for economic and social development. Figure 4 outlines the main tasks in the broader value chain as well as the major sub-processes involved in each primary stage. Whilst this thesis focuses on pharmaceutical manufacturing, each primary step will be evaluated from a global and SADC perspective. This will assist in understanding the importance of this complex industry with a view to assessing the prospects for pharmaceutical RVC development in the SADC region, and the role of regional integration and productive sector policy in this regard.

Figure 4: The Pharmaceutical Value Chain.



Source: DTI (2017b).

Figure 4 outlines the five main stages of the pharmaceutical value chain at the broad level. These include R&D through drug substance development, manufacturing, distribution, and finally, marketing. Figure 4 includes the numerous primary and sub-processes carried out within each major stage of the chain highlighting the complex nature of the pharmaceutical industry. This figure paves the way for a deeper analysis of the value chain conducted around Figure 6 further below.

4.2.1 Research and Development

The pharmaceutical value chain begins with R&D, the first stage in the process of providing consumers with a wide variety of new medicines to treat numerous medical conditions. R&D is characterised by the high cost of discovery and development of new products which has continued to rise since the 1980s. According DiMasi, Grabowski and Hansen (2016: 20) the cost of developing a new drug and bringing it to market was estimated to be US$2.87 billion in 2013. This figure has likely risen. The term 'billion-dollar drug' has been coined to illustrate this high cost of R&D, clinical trials and final approvals (DiMasi, Hansen and Grabowski, 2003). There has also been a significant decline in the number of new drugs being approved, down two-fifths from last decade. Part of what makes R&D so expensive is that only one in roughly 5000-10000 chemical compounds researched makes it through to the consumer while the development of a new drug generally takes between 10 and 15 years. These issues outlined above emphasise the importance of patent protection to research-based companies (DiMasi *et al*., 2003). The debate around the TRIPS Agreement and patent protection in the context of pharmaceutical drugs is discussed further in Section 4.3 below.

There has not been significant investment in research-based pharmaceutical companies in SADC and Africa, largely due to the cost issues identified above and a relatively small market for branded medicines. While the DTI (2017a) and AU (2007) identify investment in R&D as a future goal, the focus at present is on increasing the efficiency of the industry in SADC and expanding the manufacturing of generics.

The emergence of the pharmaceutical manufacturing industry post World War II, due to breakthroughs in final product formulation and innovation, led to formalised, in-house R&D facilities, rapid new drug discovery, and the emergence of global blockbuster drugs (Gereffi, 1983; Haakonsson, 2009b). Barriers to entry such as high costs resulted in an international, research-

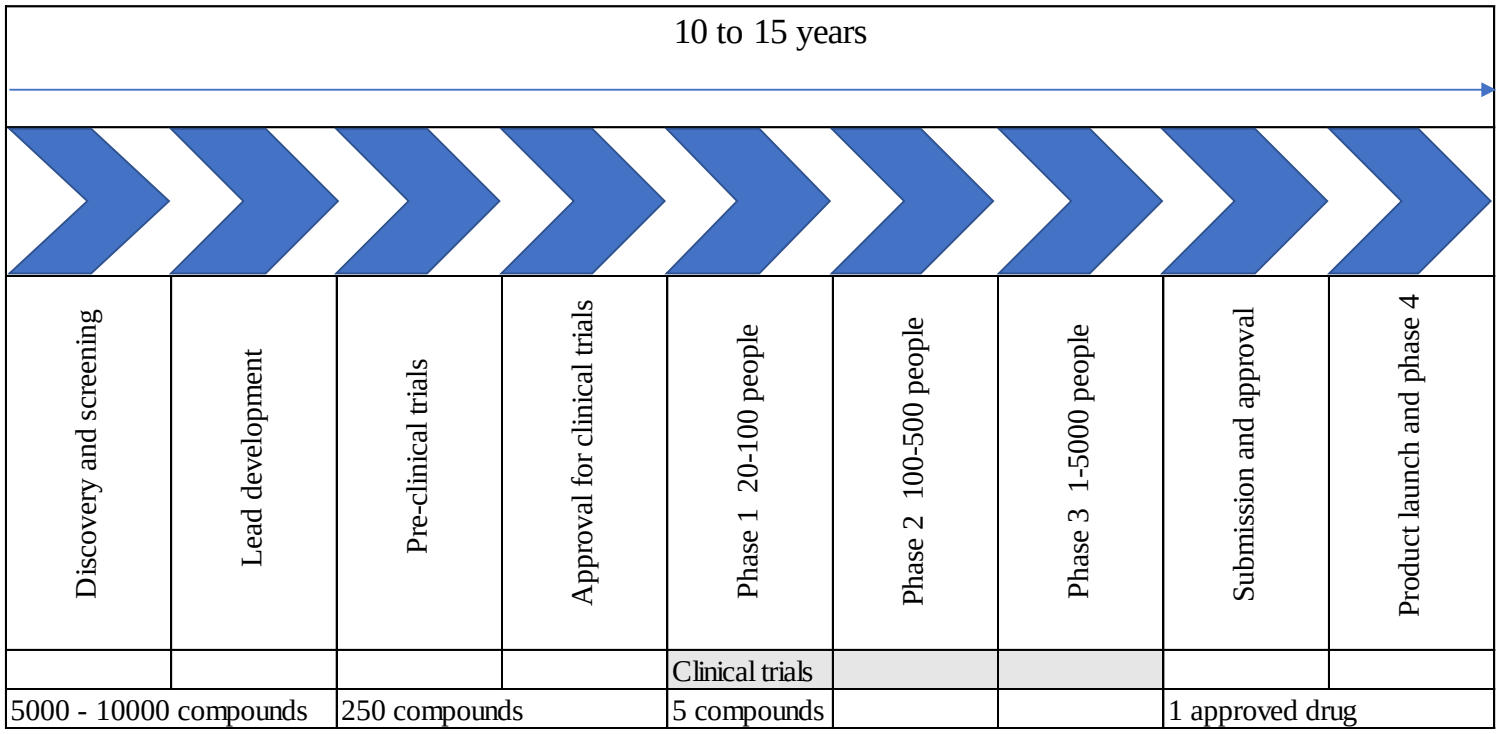
intensive industry consisting of large, vertically-integrated corporations dominated by large firms. Mergers and acquisitions have become increasingly common as firms attempt to gain economies of scale and, in the process, acquire R&D knowledge from other firms (Haakonsson, 2009b).

Wadhwa, Rissing, Gereffi, Trumpbour and Engardio (2008) find that MNCs, in order to broaden their R&D activities without increasing costs, are forging partnerships and research collaborations with companies in India and China, increasing the ability of Indian and Chinese firms to innovate. R&D is not limited to high value drug development processes but also includes lower value activities such as clinical trials. These low value activities are increasingly outsourced to contract researchers in low cost countries such as India. In Haakonson's (2009b) view, the changing nature of activity in the R&D strand of the value chain, together with increasing costs of drug development, are likely to alter the governance structure of this section from a producer-driven to a buyer-driven strand.

Most R&D is carried out in search of new branded products while minimal R&D is carried out on quality generics and almost none on low value generics. The branded strand of the pharmaceutical GVC has three major characteristics. Firstly, operations that are not the core business of companies are being outsourced. Secondly, branded product producers have been focused on finding the 'billion-dollar drug' or 'golden egg' and therefore all focus their efforts in similar areas of competence. Thirdly, MNCs are buying biotechnology companies to externalise their R&D activities. These biotechnology companies have the ability to identify new products but do not have the financial backing or distributional systems to market them. MNCs are always searching for new drugs to ensure there is a constant pipeline of new products due to the steep decline in price once off patent. Although the producers of quality generic drugs are generally not involved in R&D, many are involved in process development to improve their product or improve the efficiency of production and distinguish their product from others (Haakonsson, 2009b).

The diagram below highlights the R&D process in the pharmaceutical industry, from discovery through clinical trials to product launch.

Figure 5: The Research and Development Process.



Source: Adapted from PhRMA (2016: 48).

The two stand out features of Figure 5 are firstly the number of compounds that are discovered (5000 – 10000) in order to bring one approved drug to market and secondly, the lengthy time span (10 – 15 years) that it takes to do so.

Section 4.2.2 below moves on from R&D to explore the two subsequent steps of the broad pharmaceutical value chain in more detail, in line with the focus of this thesis, namely drug substance development and manufacturing.

4.2.2 Drug Development and Manufacturing

The South African Medicines and Medical Devices Regulatory Act (SAMMD) (1998: 7) defines 'manufacture' as "all operations, including purchasing of material, processing, production, packaging, quality control, release and storage of medicinal products and related control." According to Shah (2004) the manufacturing process in the pharmaceutical industry is separated into two activities, primary and secondary manufacturing. Fridge (1999) makes a similar distinction between the manufacture of 'pharmaceutical chemicals' and 'pharmaceutical preparations'. These typologies are only different in name and the primary and secondary manufacturing typology is used in this thesis. Primary manufacturing involves the manufacture of active pharmaceutical ingredients or APIs in the fine chemical industry. It involves several stages of chemical synthesis and separation to build complex molecules or, in the case of biochemicals, fermentation, product recovery and purification (Shah, 2004; Fridge, 1999).

The secondary manufacture stage involves adding excipients to the APIs as well as further processing and packaging to produce the final product. For example, a medicine in the form of a pill would undergo granulation, with addition of all the excipient materials, followed by compression (forming the pills, coating), then quality control and packaging (Shah, 2004; Fridge, 1999). According to Shah (2004) primary and secondary manufacturing locations are often geographically separate as firms take advantage of tax benefits and transfer price optimisation. Due to the nature of primary manufacturing plants discussed below there are generally many more secondary manufacturing sites than primary ones, serving local or regional markets (Shah, 2004).

Many different classes of drug manufacturers are involved in the pharmaceutical industry. These include large, R&D-based MNCs who have a global presence in both prescription and over-the-counter branded products with manufacturing sites in many locations. Secondly, there are large generic manufacturers specialising in the production of out-of-patent over-the-counter and

prescription products (Shah, 2004). The third type of manufacturer is local manufacturing companies that produce both generic and branded products in their home country under licence or contract. Contract manufacturers produce either APIs or intermediates but do not have their own product portfolio. They may also produce final products through outsourcing arrangements with other companies. Lastly, there are drug discovery and biotechnology companies which are often start-ups with little capacity but are capable of identifying new molecules (Shah, 2004).

In line with the AU (2007) PMPA the focus in Africa and, more specifically in SADC, is on the production of high quality generics. According to the AU (2012) generics do not require large clinical trials and are provided marketing authorisation based on evidence of their equivalence to the originator product. This is attractive to developing countries as it avoids the large cost of developing new drugs noted in Section 4.2.1 above. Having reliable access to high quality and competitively priced APIs is critical for commercial viability in the generic manufacturing industry. Fridge (1999) argues that having a viable API industry is a major asset for a country seeking to become a successful generic producer. The production of generics often occurs close to the end markets due to the relatively cheap and easy manufacturing process involved. Generic companies are increasingly outsourcing production to developing countries and therefore generic manufacturers may produce the same product for competing brands leading to a concentration of API manufacturers and, therefore, consolidation (Haakonsson, 2009b; Fridge, 1999). Outsourcing is a source of convenience for research-based and generic companies alike as it allows them to focus on core business activities (Shah, 2004). All indications are that this generics strand is buyer-driven (Haakonsson, 2009b).

Generally, each drug requires only one API but some may require several. Primary manufacturing sites may be able to produce more than one API, however, there needs to be strong demand for this arrangement to be cost effective and a logical investment. A country or region therefore needs a large pharmaceutical manufacturing base to demand these APIs otherwise there is no business logic for multiple production of APIs. Hence it can be argued that producers should concentrate on the manufacture of a single API (Maloney and Segal, 2007). Economies of scale play a larger role in the primary sector as opposed to the secondary sector as there are less primary manufacturers than secondary manufacturers. This provides a barrier to entry for smaller countries and is therefore a relevant aspect to consider in the case of SADC countries (Haakonsson, 2009a). One of the reasons that African countries (with South Africa as a good example) are so import

dependent in the pharmaceutical sector is the need to import these APIs. However, this is changing as there is investment in a new API plant in South Africa among other projects. This is expanded on in Section 4.2.2.4.

4.2.2.1 Trends in Pharmaceutical Manufacturing

The global pharmaceutical industry has undergone a restructuring in the last few decades which has affected the manufacturing portion of the value chain. Rising R&D costs and a 'thinning of the drug pipeline' has led to a consolidation of primary and secondary manufacturing facilities into 'centres of excellence' (Maloney and Segal, 2007). Naude and Luiz (2013) identify two different objectives MNCs aim to achieve from centres of excellence. Firstly, consolidating the manufacturing of large volumes into a single factory allow firms to gain economies of scale. Secondly, production in one facility allows for more efficient control over the quality and standards of drugs produced. Pharmaceutical manufacturing companies aim to position themselves close to their markets in regions with specific qualities such as cost reductions and tax and other government incentives offered to attract investment to these regions. Certain centres have an advantage over others if they can provide firms with an educated and skilled workforce as well as low cost labour, a stable political climate, good infrastructure and an attractive economy (Naude and Luiz, 2013).

The emphasis on high drug quality standards has become both a requirement and an expectation globally, regardless of whether the drug is a new, innovative drug or a generic drug (Naude and Luiz, 2013**).** Manufacturing sites in the pharmaceutical industry are generally adhering to minimum standards of manufacturing laid down by various regulatory authorities such as the Food and Drug Administration (FDA) and Medicine Control Agency (MCA). Globally the minimum standards for current Good Manufacturing Practice (GMP) as prescribed by the World Health Organisation (WHO) are becoming the norm, especially for operations involved in exports. In countries such as India there are government incentives in place to promote GMP compliance by manufacturers (Fridge, 1999).

Consolidation provides a unique opportunity for pharmaceutical manufacturers in less economically developed regions, such as SADC, who generally rely solely on generic production. This involves taking advantage of pharmaceutical MNCs outsourcing and offshoring major parts of the value chain, including manufacturing, to low cost firms in developing regions as has

happened in China and India (Maloney and Segal, 2007). The consolidation trend has also increased the number of mergers and acquisitions in the pharmaceutical manufacturing industry improving cost effectiveness and profitability. India in particular has benefitted from this reorganisation largely due to providing the correct environment to attract pharmaceutical MNCs. This has allowed India to gain an advantage in the industry and take advantage of technology and knowledge transfers from these MNCs (Haakonsson, 2009b). The capability of the Indian pharmaceutical industry has resulted in its ability to attract contract-manufacturing opportunities from large MNCs that have outsourced their production activities in order to focus on R&D. India has the largest number of FDA-approved production facilities outside of the United States and has become the 'pharmacy to the world' (Naude and Luiz, 2013). With this advantage, Indian companies have recently re-organised their production by setting up production facilities internationally, either in developed countries to overcome market barriers or in least-developed countries where there is no manufacturing capability (Haakonsson 2009b).

4.2.2.2 The Pharmaceutical Manufacturing System

While Figure 4 above provides a broad view of the pharmaceutical value chain, Figure 6, around which this section is based, is a segment of this chain which includes inputs, manufacturing, distribution, end markets and the role of external actors. Figure 6 highlights the manufacturing portion of the chain in line with the emphasis of the thesis on pharmaceutical manufacturing. This is to allow for a more detailed discussion of this segment of the chain. A number of stakeholders key to the pharmaceutical manufacturing industry along with their influence and roles are identified in this schematic representation. These include regulators, government ministries and trade associations. Regulators, such as the Medicines Control Authority of Zimbabwe (MCAZ) and the Medicines Control Council in South Africa (MCC, which will shortly become the South African Health Products Regulatory Authority, SAHPRA) should ideally be entrusted with oversight of quality within the production and distribution sections of the value chain (AU, 2012).

Figure 6 identifies the roles of and tools available to ministries in government including health, finance, industry and trade at each stage of this segment. Some tools include tariffs on inputs, manufacturing incentives, procurement and national drug policy. These ministries, as is discussed further in Chapter 5, need to formulate and implement a cohesive policy action plan using all available tools to provide a conducive environment for the industry to flourish. The role of trade

associations is not forgotten as they play an important role on behalf of the industry, engaging in lobbying government, dissemination of best practices and partnership brokering (AU, 2012).

Due to the focus on generic manufacturing by AU (2012) and other stakeholders such as the DTI (2017a) this diagram deals with the system surrounding generic manufacturing. To keep the diagram simple, important stakeholders such as the developers of human capital and financiers have been excluded. As the pharmaceutical manufacturing industry is capital intensive, finance warrants a short note before moving further. The ability to access financial investment is crucial, however the desire of investors, who include, for example, equity investors, providers of debt and foreign direct investment, to provide funds is determined by the dynamics of the rest of the pharmaceutical manufacturing system in a country, among other issues.

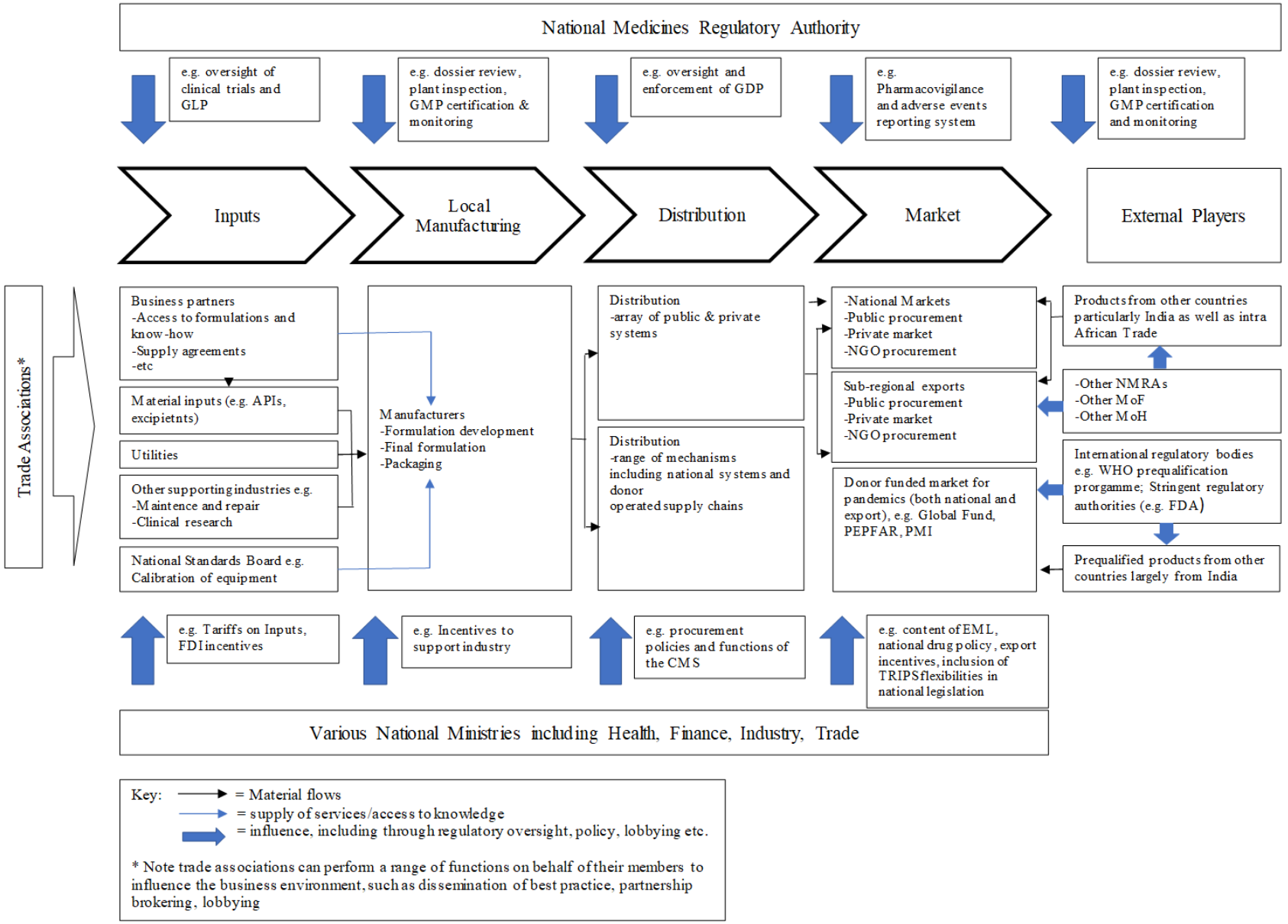
Beginning with inputs, Figure 6 outlines access to materials, a secure supply, knowledge, supporting industries and standards as important. The supply of inputs into the manufacturing industry is a key determinant of the proper functioning of manufacturing so emphasis must be placed on the efficient operation of this stage. The specialised manufacturing process is omitted from this schematic, however, is discussed in greater depth in Section 4.2.2 above. The AU (2012) echoes the Industry expert's (2017: interview) view that developing countries must start with formulation before working their way up the pharmaceutical manufacturing value chain. Formulation development, final formulation and packaging are identified as important in Figure 6.

The distribution of medicines is complex in an African context due to factors such as a lack of transport infrastructure and the rural location of much of the population. From a pharmaceutical point of view, the AU (2012) argues that an array of public and private systems must be developed for efficient distribution. These include national systems and donor-funded supply chains. Distribution is expanded upon further in Section 4.2.3 below. According to Kaplinsky and Morris (2015) while markets in developing regions are still less quality sensitive and more price sensitive this is slowly changing. Figure 6 identifies that markets for pharmaceuticals include private markets, public procurement, national markets and non-governmental organisation (NGO) procurement. Another important market is the export market, mainly to the region in this case, but South African firms are also targeting exports to global markets due to their WHO GMP standards (Industry expert, 2017: interview). The final link in this segment is external players. The domestic pharmaceutical industry is not limited to the home country as local producers compete with

imports while the decisions of other governments and medical regulatory authorities, such as the implementation of defensive tariffs, may affect the local industry. Meeting the required standards of organisations such as WHO GMP standards provide firms and countries with an advantage and access to more productive markets. Therefore, manufacturing industries should take into consideration the actions and influence external actors have upon their respective domestic industries (AU, 2012).

The importance of having an integrated quality system built into the pharmaceutical manufacturing industry while remaining competitive is considered after Figure 6 below.

Figure 6: The Manufacturing Portion of the Value Chain.



Source: AU (2012).

4.2.2.3 Quality and Competitiveness

Quality is a fundamental issue in the pharmaceutical manufacturing industry and is a function of many dimensions including product degradation, contamination, mislabelling and level of API content to name a few. These issues are minimised through regulatory oversight which seeks to ensure that practices such as GMP, Good Logistics Practice (GLP), Good Warehousing Practice (GWP) and Good Distribution Practice (GDiP), for example, are carried out along with establishing an 'adverse event reporting system' and conducting 'pharma-vigilance activities' (AU, 2012). The regulatory officials, as well as all other stakeholders in each pharmaceutical industry, should ensure that each stage of the supply chain focuses on manufacturing quality into the product. Checking quality at the end of the process should be just one step in the broader integrated quality system (AU, 2012).

Competitiveness is another important aspect of the industry. Compliance to GMP and other quality control practices increases the cost of investment and operations but does not mean that pharmaceutical manufacturing in compliant facilities is out of reach for SADC countries. Pharmaceutical production operates in a batch process and the same machinery is used to produce different products. Downtime can therefore occur either if the changeover is not efficient, if the production line is unbalanced or if breakdowns occur. This is countered with modern business practices to keep downtime to a minimum such as maintenance programmes and manufacturing batches of the same product, which is to some extent the function of the market and working capital (AU, 2012).

The system in Figure 6 can produce most off-patent products and utilising TRIPS flexibilities even allows some products, such as anti-retrovirals (ARVs), still under patent to be produced. The WHO Essential Medicine List (EML) provides 300 medicines which countries can adopt from a public health perspective and adapt for their own needs (AU, 2012).

4.2.2.4 Pharmaceutical Manufacturing in the SADC Region

There is a large divide between the levels of development of the pharmaceutical manufacturing industry within SADC with South Africa being well ahead of all the other members (AU, 2012). Most African countries aim to become more independent and less dependent on aid and donations, and one way of achieving this is to increase the production of high quality drugs. The SADC pharmaceutical manufacturing industry is heavily reliant on the import of many pharmaceutical

inputs such as APIs and packaging, as well as generics. For example, Zimbabwe imports 100 percent of the APIs it uses in manufacturing while South African pharmaceutical manufacturing companies almost exclusively produce generic products and are import dependent (DTI, 2017a; Maloney and Segal, 2007).

AU (2012) identifies the import of generics by many African states from China and India as an important challenge that needs to be overcome as it affects the cost of the drug and negatively affects a country balance of payments. The Plan aims to consolidate local production of much-needed generic medicines in Africa while ensuring economic and technical viability (AU, 2012). UNIDO (2011) echoes the concerns of the AU, stating that a problem on the continent is the lack of backward vertical integration into the manufacturing of competitively priced APIs on a large scale. African states need to ensure that they achieve increased API manufacturing through innovation and technology transfer just as India and China have done. Partnerships with both international and local players are therefore key in order to benefit from these knowledge transfers. The size of the SADC population provides an opportunity to produce APIs in the region as it offers significant demand making investment in API production viable.

The DTI (2017a) predicts significant growth in the African pharmaceutical market and argues that this will lead to an increase in pharmaceutical MNCs (generic producers) in South Africa using the country as a stepping stone into the African market. This provides opportunities for South Africa to become a 'centre of excellence' in the SADC region. In order to benefit from this trend, the country and region must provide the correct environment for FDI. Government and pharmaceutical policy makers have a role to play in attracting FDI and stimulating domestic growth. Policies that could be used to achieve this are explored further in Chapter 5.

Improving the quality of medicines in Africa is a major goal for policy makers as there are many counterfeits and low-quality products at present and sufficient regulatory oversight is required to meet this objective. Lack of regularity oversight is prevalent throughout the African industry. Meeting international standards and adhering to GMP, GLP, GWP and GDiP is an important step in ensuring high quality drugs in Africa. Cooperation and good relations between industry actors is essential to the success of the industry and the ability to produce medicines to international quality and have a sustainable industry. These actors are the national medicines regulatory authorities (NMRAs), manufacturers, the various government ministries, trade associations and an array of distribution channels. Institutions that develop the human capital for

this knowledge intensive industry are also key actors (AU, 2012). Cooperation is necessary between government ministries which have influence in order to develop the appropriate policy tools to grow the industry. An example of how a breakdown in communication and cooperation between policy makers can affect the industry is found in the duties on imports. Some African countries allow the import of generics from India and China duty free but charge 25 percent tax on the import of raw materials by local producers highlighting the policy inconsistency between various departments (AU, 2012).

The production of APIs in Africa is very limited except to a certain extent in South Africa, Ghana and Egypt and most African companies focus on packaging and final formulation of drugs. The African industry faces numerous challenges in developing its pharmaceutical manufacturing industry including a skills vacuum, limited funding opportunities, the limited ability to upgrade or design new plants, high costs in new product development, policy incoherence and underdeveloped supporting industries (AU, 2012).

This broad level overview of the pharmaceutical manufacturing industry globally and in SADC paves the way for a focused discussion on the pharmaceutical sector profiles of South Africa and Zimbabwe below. Table 1 below provides a sector profile for the South African pharmaceutical sector between 2007 and 2016.

Table 1: South Africa Pharmaceutical Sector Profile

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Manufacturing employment	9,500	9,500	9,650	9,625	9,650	9,630	9,600	9,500	9,500	9,500
Downstream employment	na	na	na	na	na	25,000	25,000	25,000	25,000	25,000
Indirect employment	na	na	na	na	na	na	11,000	na	na	na
Total market value (ex-factory price level)	na	na	na	2,240	2,408	2,890	3,194	3,533	3,533	na
Exports - HS Chapter 30	142.396	177.867	178.183	386.785	462.146	431.646	432.770	428.750	348.655	419.228
Percentage change (%)	-	24.91	0.18	117.07	19.48	-6.60	0.26	-0.93	-18.68	20.24
Total change	-	35.471	0.316	208.602	75.361	-30.5	1.124	-4.02	-80.095	70.573
Imports - HS Chapter 30	1,475.429	1,569.555	1,588.134	2,070.736	2,200.337	2,365.966	2,274.896	2,069.625	1,890.225	1,887.972
Percentage change (%)	-	6.38	1.18	30.39	6.26	7.53	-3.85	-9.02	-8.67	-0.12
Total change	-	94.126	18.579	482.602	129.601	165.629	-91.07	-205.271	-179.4	-2.253
Trade balance - HS Chapter 30	-1,333.033	-1,391.688	-1,409.951	-1,683.951	-1,738.191	-1,934.320	-1,842.126	-1,640.875	-1,541.570	-1,468.744
SA market as a percentage of the global market (%)	na	na	na	0.35	0.4	0.4	0.4	0.4	na	na

Source: DTI (2007, 2011-2016, 2017a, b); ITC (2017).

Notes: Market value and trade data in US$ millions

na = not available

South Africa

According to Fridge (1999) South Africa's pharmaceutical manufacturing industry was already well developed and the largest in Africa by the late 1990s. Despite numerous challenges it continues today as the most developed pharmaceutical sector in Africa and at the forefront of technological and manufacturing advancements (DTI, 2017a). However, the country faces one of the highest disease burdens in the world, along with a widening pharmaceutical trade deficit, making the further development of pharmaceutical manufacturing a priority (Industry expert, 2017: interview). The industry includes both local and multinational corporations focusing on the production of generic drugs mainly aimed at infectious diseases such as HIV/AIDS, tuberculosis and malaria and lifestyle diseases such as cardiovascular deficiencies and diabetes (Viviers, Lubbe, Steenkamp and Olivier, 2014).

According to (Maloney and Segal, 2007) pharmaceutical production declined by 50 percent in South Africa between the 1980s and mid-2000s resulting in a decline in pharmaceutical manufacturing employment. Both the restructuring of the industry and increase in production of generics by India in the late 1990s contributed to this reduction. Between 1994 and 2007 a total of 35 pharmaceutical plants closed down in South Africa, the majority being multinational R&D companies resulting in a fall in manufacturing employment from 16,000 in 1999 to 9,500 in 2007 (Maloney and Segal, 2007; DTI, 2012). According to Naude and Luiz (2013) some of the main reasons for company closures included the downsizing of operations, mergers and acquisitions, rationalisation, the increase in imported drugs and increasing costs due to the lengthy registration of medicines times. As evidenced in Table 1, according to the DTI's IPAPs (2007, 2010-2016, 2017a) pharmaceutical manufacturing employment has been stable at around 9,500 between 2007 and 2016. Figures for downstream employment are only available between 2012 and 2016 and remains stable at 25,000 while indirect employment in the industry was 11,000 in 2013 (DTI, 2014-2016, 2017a).

According to the DTI (2017a) the total market value at an ex-factory price level in 2015 was estimated at US$3,533 million which is a US$1,293 million or 57.7 percent growth from an estimated value of US$2,240 million in 2010. The export of pharmaceuticals under HS Chapter 30[4] from South Africa grew from US$142.396 million to US$419.228 million between 2007 and 2016. This is a 194.41 percent increase. The percentage change for HS Chapter 30 exports from

[4] Chapter 30 includes all pharmaceutical products (ITC, 2017).

South Africa shows erratic but positive growth between 2008 and 2011 and then negative growth in 2012, 2014 and 2015. This fall in the value of exports may be affected by the weakening rand to dollar exchange rate in that period. HS Chapter 30 imports grew from US$1,475.429 million to US$1,887.972 million between 2007 and 2016, an increase of 27.96 percent. Imports showed growth between 2007 and 2012 with the biggest increase coming between 2009 and 2010. However, between 2013 and 2016 there has been a steady decline in the United States dollar value of South African imports which can again be partly attributed to the depreciation of the South African rand.

It is important to note the large difference between imports and exports which contributes to the widening trade balance for South Africa. While it seems that the negative trade balance is shrinking post-2012, this is mostly due to the weakening rand and if quoted in rand terms the trade balance has widened dramatically between 2012 and 2016. This widening deficit in rand terms in the pharmaceuticals sector is a major problem as it leads to exchange rate vulnerability and a reduction in foreign currency reserves. This is part of the reason that South Africa is prioritising the development of the pharmaceutical manufacturing industry.

Approximately 276 companies are licensed by the Department of Health (DoH) and the MCC to import, export, manufacture or distribute pharmaceuticals in South Africa (DTI, 2017b). According to the DTI (2015) there are 23 pharmaceutical manufacturing plants in South Africa and the two largest, Aspen Pharmacare and Adcock Ingram, are South African owned. Aspen is the largest pharmaceutical company in the Southern hemisphere and the world's 6th largest generic manufacturer with a market capitalisation of R72 billion (DTI, 2013, 2015). Aspen's manufacturing plant in Port Elizabeth has formulation capacity of 12 billion units (tablets and capsules) per year. In 2013 Aspen's market share was 16.2 percent and Adcock Ingram's 8.9 percent (DTI, 2017b). Adcock Ingram's market capitalisation is R10 billion (DTI, 2013). Other main players include Cipla, which is locally owned and Sanofi, Pfizer and Novartis which are foreign owned MNCs (DTI, 2017b).

The industry in South Africa faces some major challenges. Firstly, pharmaceuticals and medical devices are the largest contributors to South Africa's large total current account deficit (Industry expert, 2017: interview). According to the DTI (2017a), 85 percent of trade in pharmaceuticals was attributed to imports in 2015. This heavy import dependence means that the industry is exposed to currency weakness (Industry expert, 2017: interview). The limited manufacture of APIs

used in manufacturing generic medicines in South Africa, as well as a shortage of specialised equipment, has led to this import dependence. According to the DTI (2013) ventures such as Project Ketlaphela aim to promote local manufacture of anti-retroviral APIs to supply 40 percent of South Africa's projected peak demand for ARVs in 2016-2017. Developing the API manufacturing industry is in line with the suggestion made above by Fridge (1999) that a viable API industry is a major asset for a country seeking to become a successful generic producer. This project will be a State controlled enterprise with the State controlling 60 percent via the Industrial Development Corporation (IDC) and Pelchem, while it will be jointly operated with a private investor and technology provider (DTI, 2014). However, according to DTI (2015), attempts to manufacture APIs locally through Project Ketlaphela and other projects have not been successful mainly due to issues such as a lack of vertical integration into the local manufacture of fine chemicals and intermediates for API synthesis and competition from large Chinese and Indian API manufacturers.

Compounding the import dependence issue is the single exit pricing (SEP) model in which increases often do not cover the increasing cost of imports when the rand weakens, a situation which the DTI recognises as unsustainable (DTI, 2017a). Another significant challenge is the lengthy time it takes the MCC to register medicines and conduct clinical trials which is mainly due to a skills shortage (DTI, 2017a). It is important for the relevant authorities to deal with these challenges as role players in the industry argue that they can make a significant contribution to economic growth, attracting FDI and increasing employment, claims that are backed up by the DTI identifying the pharmaceutical industry as a sectoral focus area. Another challenge identified by the Industry expert (2017: interview) is an insecure supply of medicines, especially those required by chronic patients.

Zimbabwe

In post-independence Zimbabwe, the approach government has taken to healthcare has been a combination of industrial development and primary care (Russo and Banda, 2015). In 1987 government introduced the National Drug Policy (NDP) which focused on promoting the use of generics. The NDP was updated in 1999 to include the promotion of the local manufacture of essential drugs, local R&D and collaboration with the region (UNIDO, 2011). Russo and Banda (2015) estimate that Zimbabwe spent US$223 million on pharmaceuticals in 2013, an increase

from US$213 million in 2012. 68.5 percent of the market is made up of generics while over the counter drugs make up 22.5 percent of total supply. According to UNIDO (2011) the local industry can supply 122 products out of 260 essential drugs in the country, or 46 percent, and is therefore moderately self-sufficient. The increase in imports from US$60.632 million in 2008 to a peak of US$258.328 million in 2014 reflects the low domestic capacity utilisation caused by hyperinflation, a shortage of foreign currency and infrastructural failure.

Table 2: Zimbabwe Pharmaceutical Sector Trade Profile

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Exports – Chapter 30	1.645	0.934	1.976	3.046	3.537	2.549	1.984	2.350	2.403	1.514
Percentage change (%)	-	-43.22	111.56	54.15	16.12	-27.93	-21.17	18.45	2.26	-37.00
Total change	-	-0.711	1.042	1.070	0.491	-0.988	-0.565	0.366	0.53	-0.889
Imports – Chapter 30	75.099	60.632	80.802	80.680	110.333	193.755	220.171	258.328	231.398	201.997
Percentage change (%)	-	-19.26	33.27	-0.15	36.75	75.61	13.63	17.33	-10.42	-12.71
Total change	-	-14.467	20.170	-0.122	29.653	83.422	26.416	38.157	-26.930	-29.401
Trade balance	-73.454	-59.698	-78.826	-77.634	-106.796	-191.206	-218.187	-255.978	-228.995	-200.483

Source: ITC (2017).

Notes: Trade values are in US$ millions

Market value and employment data time series for Zimbabwe were not readily available for consecutive years across the period 2007-2016

The Zimbabwean pharmaceutical industry began in 1953, the period of early industrial development in the country, and in 1990 Zimbabwe was seen as the African country with the most potential to become industrialised, mainly due to its large manufacturing industry (Russo and Banda, 2015). According to the most recent Register of Licensed Pharmaceutical Manufacturing Premises published by the MCAZ (2017) there are nine[5] pharmaceutical manufacturing companies including five major generic manufacturers producing 90 percent of the generic formulations in Zimbabwe (UNIDO, 2011). Zimbabwe's pharmaceutical firms are classified as national small- and medium-sized generic companies which focus on the production and development of formulations and packaging activities (Seiter, 2010). According to UNIDO (2011) there is no local manufacturing of bulk drugs in Zimbabwe and formulations make up 100 percent of the market. CAPS Pharmaceuticals employed 200 people and Plus Five Pharmaceuticals 91 in 2011 (UNIDO, 2011) while according to ITC (2017) Datlabs (Pvt) ltd currently employs 155 people and Varichem Pharmaceuticals 154.

According to Table 2, the export of pharmaceuticals from Zimbabwe has fluctuated during the period 2007 to 2016 from a low of US$0.934 million in 2008 to a high of US$3.537 million in 2011. This increase up until 2011 is not surprising as the economy stabilised during the period of the Government of National Unity between 2009 and 2013. However, exports fell off sharply to a low of US$1.514 million in 2016 due to unfavorable economic and business conditions. During the same period, there was a steady, rapid increase in the import of HS Chapter 30 pharmaceutical products from US$75.099 million in 2007 to a high of US$258.328 million in 2014 and falling to US$201.997 million in 2016. These increases may be due to the worsening economic and manufacturing environment in the country resulting in a fall in the local production of pharmaceuticals. The rapid increase in imports into Zimbabwe is negatively affecting the trade balance and the deficit has widened significantly from US$59.698 in 2008 to US$255.978 in 2014 and the falling slightly to US$200.483 in 2016. This is having a negative effect on the liquidity shortage in Zimbabwe due to foreign currency leaving the country and needs to be rectified through increasing the local production of pharmaceuticals in Zimbabwe.

[5] Datlabs (Pvt) ltd, CAPS Pharmaceuticals, Plus Five Pharmaceuticals, Varichem Pharmaceuticals, Zimbabwe Pharmaceuticals, Pharmanova, Ecomed Manufacturing, Graniteside Chemicals and the Gulf Drug Company (MCAZ, 2017).

While no companies in the country manufacture APIs, the excipients can be obtained locally, regionally and internationally and some companies are involved in packaging manufacture in the country (CZI, 2014). However, duties of up to 40 percent and value added tax (VAT) of 15 percent is charged by the authorities on the import of pharmaceutical raw materials and packaging. Roughly 20 percent of local products are exported and South Africa is the largest export market for Zimbabwean pharmaceuticals. The value of pharmaceutical products consumed in Zimbabwe increased by 7.5 percent from US$233 million in 2013 to US$251 million in 2014. A challenge faced by all African countries and identified by the AU (2007) PMPA is competition with cheap imports from India and China while relatively cheap South African imports also affect the competitiveness of the Zimbabwean industry (CZI, 2014). The high tariffs on inputs further reduce the industry's competitiveness. Donor funding provides a larger proportion of drugs into the market than the industry produces which further hampers competition. UNIDO (2011) argue that the industry has the potential to supply at least 70 percent of the country's medicine needs. However, Banda (2012) identifies a number of challenges for the pharmaceutical industry in Zimbabwe. These include policy and practice challenges as well as a lack of technological upgrading and innovation. Further challenges include accessing finance, a decline in the procurement capacity by government and unreliable supply of important manufacturing inputs such as water and electricity.

The SADC (2007) Pharmaceutical Business Plan is one policy document released to assist South Africa, Zimbabwe and all other SADC nations enhance pharmaceutical production and high quality medicine coverage. SADC (2007) aims to provide Member States with the tools to treat and prevent disease by increasing manufacturing and providing access to high quality and affordable essential medicines at both a national and regional level. Within the regional cooperation and integration agenda, SADC has identified health as a priority area which includes enhanced regional capacity for pharmaceutical manufacturing. This pharmaceutical programme has been developed in line with the SADC (1999) Health Protocol and regional policy frameworks. One of the main goals is to facilitate the trade in pharmaceuticals within SADC, and while not mentioned, RVCs are a useful tool to promote this trade. Strong linkages between all Member States is critical for an effective regional industry and RVCs and SADC (2007) identifies that this will occur through the various National Health Ministries.

The major highlight from the South African sector profile is the widening trade balance (in rand terms) which the Industry expert (2017: interview) identifies as a major challenge to the industry. Zimbabwe is also experiencing a widening trade deficit which provides incentive for further development of pharmaceutical manufacturing in both countries. Import dependence and a negative trade balance in pharmaceuticals was identified by SADC (2007) as issues that needed to be rectified. A combination of both macro and microeconomic policy instruments are likely to be needed to address both the trade imbalance and the performance of the sector. It seems this hasn't been achieved in the last 10 years and hopefully this thesis can contribute to the narrowing of the deficit in both countries. If South Africa prioritises the development of pharmaceutical manufacturing RVCs in the region it will benefit its industry through the regional procurement of APIs and other inputs whilst using its hegemonic status to help address health and economic issues in other nations. The Zimbabwean trade profile shows the poor level of pharmaceutical manufacturing in the country reflected by the low level of exports. Zimbabwe therefore needs to address this issue, along with its widening trade deficit, through promoting pharmaceutical manufacturing and RVCs. All SADC nations should lobby the South African government to promote pharmaceutical RVCs as it will provide them each with developmental benefits if fostered correctly. This is discussed further in Chapter 5.

4.2.3 Distribution

One of the main tasks of regulators in the pharmaceutical manufacturing industry is to ensure compliance with GDiP and GWP. The industry includes a number of distribution channels across public and private actors including national systems, procurement policies and donor operated supply chains. Recent trends of consolidation in the pharmaceutical industry have affected the distribution and storage of medicines. Centres of excellence are commonly located in places which provide, among other factors, the best access to major markets. Manufacturing in these locations allows for simpler more cost-effective distribution channels and ensures more efficient distribution and warehousing of medicines. Well-developed related and supporting industries and infrastructure are required to ensure a sound logistical system for distributing both inputs and the finished products (AU, 2012). According to IMS (2014) importers and wholesalers provide a link between retailers and manufacturers and supply medicines across most markets. Channels in the

rural areas of Africa often include extra links in the chain such as sub-contractors which increases the complexity of the distribution channel (IMS, 2014).

The AU (2012) identifies increased distribution efficiency as a key factor in developing a more successful pharmaceutical industry. However, a number of challenges to the effective distribution of medicines need to be overcome to achieve this. These include the fragmentation and gross inefficiency of many distribution chains and poor regulation. Africa also has inadequate distribution infrastructure causing some donated medicines to expire on the shelf, and rural areas often do not get sufficient access to medicines (AU, 2012).

4.2.4 Marketing

The final link in the pharmaceutical value chain is the end market. Pharmaceutical companies need to conduct marketing exercises to ensure the final product reaches the end market, being the consumers or patients. The main supply chain at present is either directly from pharmaceutical companies to hospitals and pharmacies or through wholesalers before distribution to pharmacies and hospitals (PwC, 2011). This is however expected to change in the future with the supply chain becoming more fully integrated and including manufacturer to consumer and direct to consumer distribution (PwC, 2011). Challenges faced in African markets include small end markets and a fragmentation of regional markets which hamper the efficient distribution of medicines to consumers (AU, 2012).

According to PwC (2011) the growth of the developing market provides both opportunities and challenges for the industry. The increase in wealth in these nations increases the opportunity for sales, however, due to inefficient public procurement schemes and low medical insurance coverage, these consumers tend to pay for more than half of their medicine costs themselves. Further, the ability to buy medicine regularly, weekly or even daily, and at low cost are more important than convenience for these consumers. Pharmaceutical companies therefore need to adapt to the needs of people living in developing markets and according to PwC (2011) lessons can be learnt from the medical devices sector. These companies are tapping into the developing market by offering products which, for example, can survive harsh conditions.

Another issue in developing nations is the limited reach and insecurity of supply chains. Counterfeiting of medicines is a major problem in developing regions and this needs to be monitored through increased regulatory oversight which at present is insufficient to protect consumers (PwC, 2011; AU, 2012). In conclusion, efforts need to be taken in regions such as

SADC to enhance sales and marketing efforts and adapt them to the needs of consumers in these areas. The supply chain needs to become more secure, less fragmented and more geographically dispersed to ensure medicines reach their intended consumers effectively and efficiently.

4.3 Governance in the Pharmaceutical Industry

Prior to the signing of the TRIPS Agreement in 1994, the global pharmaceutical industry was led by MNCs which were vertically integrated and technology intensive. The pharmaceutical value chain was split into two strands, the first focused on the production of branded and patented products for the Northern markets. It was producer-driven and had high barriers of entry due to R&D and marketing expenditure. The second value chain strand targeted developing countries with re-engineered drugs entering markets with little enforcement of property rights or patents. However, there was a focus by firms on production for their home countries and FDI into often larger foreign markets was low (Haakonsson, 2009b).

The establishment of the World Trade Organisation (WTO) in 1995 was a major turning point for the pharmaceutical industry. The signing of the TRIPS Agreement which required across the board harmonised patent protection on products and processes to be implemented by all members for 20 years brought about significant changes. The industry became globalised as patents were harmonised and according to Haakonsson (2009b) the value chain was reorganised into three strands. These strands are separated as follows: branded or innovative products form the first strand, high quality generics for high end markets the second and finally low value generics form the third strand. Northern based pharmaceutical companies, which lobbied for harmonised patent standards, argue that they are a necessity for further global expansion. There is however debate around whether harmonisation of patent standards brought about by TRIPS allowed firms to enter global markets or not. Bedi, Bedi and Sooch (2013) argue that TRIPS has negatively affected the Indian pharmaceutical industry, suggesting that it has become an arm of the western MNCs as opposed to developing its own high-end industry while endangering Indian SMEs due to their lack of resources needed to develop patents. The reorganisation of the industry, as described below, is therefore not seen as developmental by all. TRIPS may therefore hamper development of the industry rather than promote it and not necessarily all actors are benefiting from tech spillovers due to patents.

This period was also characterised by an increase in concentration in the sector with the ten largest firms accounting for 48 percent of the market in 2004. Mergers and acquisition became more frequent to increase capital needed for R&D and gain vital knowledge. The three strands that the pharmaceutical industry was reorganised into post-TRIPS are described as follows. Branded products: Developing innovative new branded products and their subsequent marketing is a costly exercise and therefore these manufacturers enter global developed markets to recover their costs with the protection of patents. Branded manufacturers face high barriers to entry as this strand requires extensive clinical trials and extremely costly R&D and marketing of innovative new medicines. Due to these factors, there are generally very few new members entering this segment (Haakonsson, 2009b). This strand is producer-driven and it includes a complex vertically integrated hierarchy led by MNCs operating in a network of strategic alliances, multi firm alliances and cross licensing agreements (Haakonsson, 2009b).

Quality generics: This strand is newer than the first and is dominated by medicines that have recently (or not so recently) ended their patent period and for which no suitable alternative has been found. These medicines are generally aimed at developing countries and their production provides an opportunity for the pharmaceutical manufacturing industries of these countries. Contrary to branded products, this GVC strand is buyer-driven and more often than not MNCs will retain the ownership of these products but outsource their production. India has built its pharmaceutical manufacturing industry on the production of these quality generics and low value generics alike which have been outsourced by developed nation MNCs. Barriers to entry are lower in this strand and include reputation, quality and price (Haakonsson, 2009b). While not involved in R&D, firms that specialise in the production of outsourced generics use process development to improve on the branded products and increase the efficiency of production.

Low value generics: these products are mainly manufactured for developing countries, low income markets and for procurement by government policies in third world nations. The strand has low margins and is very price sensitive but there is growth in terms of volume in this strand. The quality of the medicines is not a major barrier in this strand however firms must adhere to WHO good manufacturing practices (Haakonsson, 2009b).

Lead firm's strategies have again changed recently due to new processes such as 'drug development by design' (Malerba and Orsenigo, 2002) and mapping of the human genome. A reduction in the discovery of new chemicals and a change in the technology regime brought further

change to the industry. Large pharmaceutical firms started entering into mergers and acquisitions with medium and small entities. These enterprises are generally set up by university researchers as research centres for new biotechnology discoveries. With limited funding to access markets and develop new drugs this partnership provides advantages for the large company, they get access to new biotechnology products, and small firms which now have the resources and knowledge to take their product to market (Haakonsson, 2009b). Note that this is discussed in more detail in Chapter 5.

4.4 Conclusion

Using the theory introduced and explored in Chapters 1 to 3, Chapter 4 provides a detailed analysis of the entire pharmaceutical value chain. It begins with a broad outline of the pharmaceutical GVC before analysing each of the value chain stages. Due to the emphasis of this thesis on pharmaceutical manufacturing, drug substance development and manufacturing, the primary and secondary stages of manufacturing, are explored in the greatest depth of all the value chain stages in Chapter 4. This section includes profiles, analysed with available data for the period 2007 to 2016, on the South African pharmaceutical sector and trade in the Zimbabwean pharmaceutical sectors.

The South African sector profile shows that the trade balance in widening, a situation which the authorities hope to amend through increasing the manufacturing of intermediates. This is dealt with in Chapter 5. Further, manufacturing employment in South Africa remained steady between 2007 and 2016 while exports are rising suggesting growth in exports has not lead to a concomitant growth in employment. This may be due to a shift from local sales to exports while production remains constant or that jobs are being substituted by technology. A deeper analysis of the sector, with production figures, is needed in the future to understand this dynamic better. The Zimbabwean sector trade profile highlights how the economic challenges in the country have affected the sector. However, it seems as if due to the country's past industrial base in the sector, there is potential for it to re-emerge as a manufacturing hub with the implementation of the correct economic and industry specific policies. This would allow Zimbabwe to contribute significantly to the development of regional pharmaceutical value chains. Policy recommendations in a value chain context are considered in more detail in Chapter 5.

Chapter 4 concludes with a section on governance in the pharmaceutical manufacturing industry in which Haakonsson's (2009b) research is the main contribution. She identifies the generic strand, which dominates the South African and Zimbabwean industries, as being buyer-driven as MNCs retain ownership of products and outsource production to manufacturing facilities. The impact of these governance structures for upgrading, and the role of industrial policy in the value chain environment, are the subject of the following chapter.

CHAPTER 5: UPGRADING AND PRODUCTIVE SECTOR POLICY IN THE PHARMACEUTICAL MANUFACTURING INDUSTRY

5.1 Introduction

As noted in Section 2.5.1 economic upgrading within a value chain is defined as firms, countries or regions moving to higher value activities within the value chain to increase the benefits, such as security, profits, value-added and capabilities, from participating in global production (Gereffi, 2005: 171). The varied levels of development of the pharmaceutical industry within SADC member states suggests that individual countries may have to approach upgrading at different levels to begin with. According to the Industry expert (2017: interview), due to the lack of development of the regional pharmaceutical industry in SADC, many countries will need to start at the bottom if a sustainable regional industry is to be built and the best place to start would be with formulation. Upgrading would then amount to the gradual movement up (or down) the value chain as described below. However, a characteristic of the global pharmaceutical industry is the need for firms to upgrade constantly to meet both competitors' quality standards and rising international standards which are requirements for different levels of market entry (Banda, Wangwe, and Mackintosh, 2016). Firms need to ensure their technology is constantly upgraded to retain market access and sustain quality at a competitive price. The challenge for firms is to adhere to WHO GMP standards as this provides a significant advantage in this highly regulated market and allows for accessing donor funds (Banda *et al*., 2016).

Upgrading in SADC will therefore take many forms, and as discussed below, is based on what governance structure the industry exhibits. An important aspect for successful upgrading in any industry is government policy. According to Banda *et al.* (2016), it is critical that an active policy is designed and implemented by government which focuses on attracting investment and fostering upgrading by creating a conducive environment. Therefore, this chapter considers not only upgrading and development strategies but also the policies required to foster this development. A further priority for SADC governments is to facilitate the ability of firms to access the finance required to upgrade their processes and product portfolios as well as their quality and standards.

Section 5.2 uses case studies on two developing nations, Uganda and India, to provide lessons for SADC on possible upgrading trajectories in the pharmaceutical manufacturing industry. Section 5.3 discusses industrial policy within a GVC framework as compared to traditional industrial policy and provides recommendations to governments and other regulatory bodies on

which policies should be implemented to achieve development integration in SADC through regional pharmaceutical value chains. Section 5.4 concludes.

5.2 Upgrading

Merely establishing pharmaceutical manufacturing RVCs is not likely to lead to development integration in SADC. Firms within these RVCs, and especially so in the pharmaceutical industry, require constant upgrading to ensure not only survival within the industry but also the development of the industry to a point where it can effectively contribute to development integration. The linkages built within both RVCs and GVCs provide opportunities for companies and industries to upgrade through transfers of knowledge and technology. The Ugandan case below highlights these South-South linkages with Indian and Chinese firms, mainly due to their advanced position in the industry which firms in most African countries do not currently possess. This means firms in SADC may first need to link up with GVCs before successfully developing RVCs. South African firms could provide a leading role in this regard. Two cases are discussed below which provide learning opportunities for SADC pharmaceutical manufacturing firms.

In the first case, Haakonsson (2009a) discusses the possibilities for upgrading in the Ugandan pharmaceutical industry via South-South linkages. Lessons for upgrading pharmaceutical manufacturing in SADC can be drawn from the Ugandan case as both share numerous characteristics. These include being a developing nation (as are all SADC nations), having a high demand for low-value generics and small market for high-value patented products due to the price sensitive market, having a skills shortage and financing issues among others (Haakonsson, 2009a).

The industry in Uganda has upgraded via South-South linkages, mainly with China and India, by 'learning through importing'. Even though building linkages are a focus in additive value chains and the pharmaceutical industry is vertically specialised, Haakonsson (2009a) identifies these linkages to global information or production networks as being crucial to the ability of developing nation firms to upgrade as it allows access to reliable sources of technology and knowledge. Linkages in the pharmaceutical industry allow for technology transfer through the supply of machinery, through supplying intermediates or supplying knowledge needed to produce new products or through suppliers assisting with the improvement of firm level technologies (Haakonsson, 2009a). This is a lesson for SADC nations as forming ties provides upgrading opportunities through these transfers. However, as noted in AU (2012) countries must be aware of

the dangers of cheap imports from these nations which can hamper the development of the domestic industry and significantly affect the trade balance.

According to Haakonsson (2009a) Ugandan pharmaceutical firms have, since the 1970s upgraded from importers of medicines to importers of formulations which are then repackaged to the assembly of intermediates and finally original equipment manufacturers (OEM). While Uganda started with importing, their domestic pharmaceutical production began with formulation, providing evidence for the claim by the Industry expert (2017: interview) that this is where SADC countries need to start in their quest to build a regional pharmaceutical industry.

The upgrading trajectory that Ugandan pharmaceutical firms have followed, from importing finished products to packaging and assembly and finally to OEM, has allowed the industry to become a tool for economic development in the country. The trajectory followed by the Ugandan industry is similar to the upgrading path taken by Asian economies with vertically specialised value chains, identified by Kaplinsky and Morris (2015). This provides support for the view that the pharmaceutical value chain is vertically specialised. Therefore, policy crafted and implemented towards establishing the industry and building the value chain through upgrading should be 'thinning'. Thinning refers to firms reducing their share of value-added through outsourcing non-core activities to focus on core activities and occurs in vertically specialised value chains (Kaplinsky and Morris, 2015: 12). This debate between policy and upgrading is expanded upon in Section 5.3.2 below.

According to Gereffi (1999) the movement of firms from assembly to OEM then to own-design manufacture (ODM), and lastly own-brand manufacture (OBM) represents the 'high road' to industrialisation. The ability of larger firms in Uganda to access knowledge and technology and attract investment, mainly from India, plays a key role in their ability to upgrade to OEM. Strong upstream linkages through partnership and joint ventures allow for the initiation of production of low value drugs such as ARVs for which there will continue to be a high demand. The continuation of the upgrading trajectory into design and branded manufacturing is unlikely in Uganda due to barriers such as skills deficits and a small market (Haakonsson, 2009a). Firms in SADC may face similar issues due to the lack of demand for patented products in this price-driven market along with the skills shortage, financing issues and small market. However, over time this may change. As Africa grows and incomes rise, increasing demand for higher-value products, firms may be able to functionally upgrade into ODM and OBM. Functional upgrading in Uganda's

pharmaceutical industry is a case of importing existing production technologies and copying suppliers rather than learning production methods. Therefore, the use of low level technologies to produce low value goods has not increased the technological capabilities of the firms, allowing for further upgrading (Haakonsson, 2009a). SADC firms must be aware of these pitfalls, and need to ensure that transfers come with the necessary skills development to facilitate the learning of new production methods. Strong mutually beneficial linkages may be key to ensuring firms are willing to share knowledge and production secrets rather than merely transferring low-level technology.

Haakonsson (2009a) also identifies process upgrading in the pharmaceutical industry of Uganda. Improving economies of scale is a key strategy in a market where there is high demand for low-value products. This occurs through process upgrading as firms introduce more efficient equipment, often second hand from developing country suppliers. Again, the strength of the individual firm's relationship with firms who can provide machinery is crucial and therefore larger firms with stronger upstream vertical linkages have an advantage over smaller firms with weak linkages (Haakonsson, 2009a). Finally, product upgrading to higher value pharmaceuticals remains limited due to the characteristics of the market. The increase of in-house production in Uganda is not in new products but rather replaces the import of the same basic products. Product upgrading therefore takes the form of improved quality and packaging materials. Haakonsson (2009a) argues that product upgrading could be encouraged through partnerships between government and donors and the private domestic firms to develop new treatment programmes and health projects. Development through both trade and health may potentially benefit the pharmaceutical industry and could be a viable option for SADC nations. The contribution of skills training and financing for developing nations' firms may be another way in which SADC countries can upgrade.

The second case Haakonsson (2009c) evaluates from an upgrading perspective is the Indian pharmaceutical industry. Haakonsson (2009c) identifies three different types of relations within the industry between suppliers and buyers (MNCs) which have implications for upgrading. All exist within a captive governance structure (explained in Chapter 2). These relationships are based on historical factors and product types and are complex, have high codifiability and low capabilities. This case is relevant as it provides ways in which pharmaceutical companies in developing nations can upgrade their operations to capture more value-added. Many Indian pharmaceutical companies operate as contract manufacturers (suppliers) for global MNCs and

their relationship is based on reliability of quality and timing as well as the ability to produce almost all intermediates from APIs to packaging material and finished formulations (Haakonsson, 2009c). The PMPA discussed in Chapter 3 stresses the same characteristics for the development of the African pharmaceutical industry which makes the Indian case important for Africa's growth path (AU, 2007). SADC nations could bypass the high start-up costs associated with large pharmaceutical buyers and rather position themselves as suppliers or contract manufacturers which would allow for further upgrading to OEM.

According to Haakonsson (2009c) the Indian industry includes short-term relations involving assembly or renting a plant by buyers, exclusive relations within a long-term relationship and specialised relations for niche products. These relationships are led by the MNCs or buyers who outsource production, among other activities, to suppliers within these three relationships. Suppliers who enter short-term relations with buyers focus on the production of basic generics which are easy to codify. MNCs often rent the production facility, chosen based on their high production standards and reliable service with respect to quality and timing, while they supply the materials and supervise quality control (Haakonsson, 2009c). As moving into upstream activities allows for more reliable sourcing of intermediates this results in functional upgrading rather than functional downgrading for supplier firms. However, due to the captive governance structure and the suppliers having little bargaining power, they often compete on price which may lead to a 'race to the bottom' type situation. First tier suppliers in short-term relations are exposed to upgrading through 'learning by exporting' but they also face high risks, as noted above (Haakonsson, 2009c). Product upgrading in this relationship involves upgrading product portfolios to enter high-value export markets. This means that facilities have international approval for each product produced, enabling suppliers to attract orders. Functional upgrading for short-term suppliers involves entering new functions in the value chain such as manufacturing APIs and entering new production processes (assembly OEM/ODM) and offering 'package solutions' (Haakonsson, 2009c).

Exclusivity is the nature of long-term relations which are based on trust. MNCs aid in installing and upgrading production facilities to their process and production specifications for high-value branded and often patented products (Haakonsson, 2009c). The investment made by the MNC and business secrets provide the supplier with some security while it enters higher value activities through process and product upgrading. Process upgrading involves technology and knowledge transfers while product upgrading includes moving into patented and branded products. Shifting

suppliers is costly and Indian companies have been attracted to this form of relationship through direct investment from MNCs and the draw of a long-term relationship and secure market (Haakonsson, 2009c). However, suppliers often discard producing their own products and risk their independence by becoming dependent upon one or a few buyers. This results in the captive form of governance and a functional downgrade from producing their own brands (OBM) to producing only for a buyer (OEM). The entrance of other firms into the gap created by the supplier discontinuing its own brands makes it difficult to ever regain market share in the future. One path this relationship may take in the future is the development of a hierarchy through vertical integration or the suppliers breaking away and establishing specialised supplier firms (Haakonsson, 2009c).

The third relationship is specialised relations. Sectors within the pharmaceutical industry such as dental and eye-care products require specialised knowledge and facilities. The difference between long-term relations and specialised relations is that the latter have upgraded through functional specialisation which has enabled them to retain some independence (Haakonsson, 2009c). They also require less monitoring by buyers due to having stronger capabilities than short-term relations. In order to maintain their position, these suppliers need constant upgrading in products and processes as well as investment and international approval. Firms who have the capabilities to specialise but not the necessary requirements to market their products globally enter these relationships and this is a long-term solution for many companies. As suppliers constantly upgrade their capabilities governance styles may shift from captive to modular. Specialised firms however still produce what their buyers demand but upgrade through functional specialisation. This involves perceived downgrading when suppliers abandon their brands but is actually upgrading through 'learning by exporting' while copying product design and technology from their buyers. Haakonsson (2009c) therefore suggests that specialised relations have the best opportunities for functional upgrading. These include either using functional upgrading to become global contract manufacturers or by expanding activities into international marketing of their own brands through ODM and OBM. In general, for the specialised suppliers to upgrade functionally, they would have to develop new products or market their own brands. However, this contains risks and costs which are not viable in this industry.

These cases provide lessons for the development of a regional pharmaceutical manufacturing industry in SADC and therefore the fostering of development integration. The Ugandan case study,

along with the Industry expert (2017: interview), provides a starting point, formulation, for countries who have yet to enter the pharmaceutical manufacturing industry. Zimbabwe has achieved this step and can now either upgrading through 'learning through importing' or 'learning by exporting' as contract manufacturers or suppliers for MNCs. Both options require strong linkages to be built with global information and production networks, including buyers and suppliers, to facilitate knowledge and technology transfers. For countries that seek to upgrade through linkages with production networks, care should be taken to avoid relationships that are one-sided. Relationships should beneficial to both parties and nations such as Zimbabwe should not be used as markets for cheap imports which will negatively affect local manufacturers. This tradeoff between health and industrial policy discussed in Section 5.3.3.

Firms in both Zimbabwe and South Africa could follow the lead of India and position themselves as contract suppliers for MNCs producing intermediates such as APIs, packaging and formulations. This relationship is characterised by a captive governance structure and firms may have to downgrade from OBM to OEM. Advantages of this relationship include a secure market for suppliers product through supply agreements, buyers providing financing for operations and expansions and the ability to 'learn by exporting' through knowledge and technology transfers. These suppliers, and pharmaceutical manufacturers in general, can upgrade through achieving compliance with standards such as WHO GMP standards. This allows access to often more lucrative markets and the ability to sell products with higher margins.

The gap in the SADC pharmaceutical industry is the production of APIs and established MNCs such as Aspen and Adcock Ingram in South Africa may, just as American MNCs have done in India, provide opportunities for setting up contract suppliers in SADC. If African SADC governments can provide the right incentives to attract investment in API production in their countries, this may be a way for countries to upgrade from formulation manufacturing to API production as the market for APIs expands in South Africa in the future. This is discussed further in Section 5.3.3.

5.3 Productive Sector Policy versus Traditional Industrial Policy

As identified in Section 5.2, there are a number of prospects for upgrading in the pharmaceutical industry context. Government policy has an important role to play in order to achieve this upgrading. In order for sectors, economies and countries to embrace and benefit fully from GVCs,

and upgrading within GVCs, it has been argued that there needs to be a shift from traditional to GVC-based industrial policy (Kaplinsky and Morris, 2015). Traditional industrial policy focused on building domestic value-added in strategically chosen sectors in order to compete eventually with MNCs in foreign markets. Policy therefore prioritised exports and the production of final goods (Milberg, Jiang and Gereffi, 2014; Kaplinsky and Morris, 2015). The specialisation in core activities and production of components rather than final goods within chains led by MNCs requires a change in the thrust of industrial policy. According to Kaplinsky and Morris (2015) a key issue that needs to be addressed is the move from narrow 'industrial policy' to broader 'productive sector policy'. This is because coherent industrial policy applies to agriculture, resources, services and manufacturing, not just industry, and needs to take the linkages between these sectors into account. Therefore, this research adopts the term 'productive sector policy' in recognition of this broader conception of industrial policy. Section 5.3.1 provides background to the shift from traditional policy towards productive sector policy within GVCs in order to build a coherent argument which can provide recommendations in later subsections for policies to develop the pharmaceutical manufacturing industry in the SADC region.

5.3.1 Productive Sector Policy in a Global Value Chain Framework

Developing country governments constantly seek the best productive sector strategies to promote development and gain significant benefits from participating in GVCs. The questions governments need to answer successfully is not whether to participate in the global economy, but rather, how (Kaplinsky and Morris, 2015). Productive sector policy in GVCs differs from traditional industrial policy. Under GVCs there is emphasis on firms rather than states, and governments need to adjust their industrial policy frameworks to the GVC context (Milberg *et al*., 2014). Both the advancements in communications and transport and the advances in production technology and standards leading to the rise of GVCs have had large impacts on government productive sector policies. Governments aim to maximise the value that is captured in an economy to increase welfare standards such as a better quality of life as well as increasing productivity, advancing technologies and a developed economy (Low and Tijaja, 2013).

According to Dalle, Fossati and Lavopa (2013) organisations such as the WTO, OECD and UNCTAD have made numerous valuable contributions to the literature on GVCs. However, these groupings often claim that trade liberalisation is the best strategy for developing countries to adopt

in the face of GVCs. This is a short-sighted approach, however, as even these organisations acknowledge (albeit to a limited extent) that merely integrating into GVCs will not lead to economic development. As noted in Chapter 2 with reference to the smile curve, links at the beginning of the value chain such as R&D, design and production of advanced components, and at the end of the chain such as marketing and distribution, often provide larger shares of value-added than links in the middle of a chain such as assembly. Dalle *et al*. (2013) find that the middle, low-value, labour-intensive stages mainly occur in developing countries while the beginning and end stages which are knowledge intensive are found in developed countries. Neo-Schumpeterian authors such as Gereffi and Kaplinsky who have focused on GVCs identify occupying the knowledge intensive rungs at the beginning and end of the ladder, such as R&D, design, marketing and distribution, as key and place emphasis on sustained growth in income levels through upgrading. This split into high-value and low-value levels in GVCs creates a new division of labour as a result of falling barriers to entry into the manufacturing industry, which was originally located in developed countries, but which is now mainly carried out in countries which provide low cost manufacturing such as China and India (Dalle *et al.,* 2013). As the majority of value remains in areas away from production, lead firms tend to outsource and offshore non-core processes, a phenomenon which has been wide spread in the pharmaceutical manufacturing industry. Active productive sector policy that takes account of the GVC context is required to facilitate upgrading by developing country firms, in order to avoid firms being stuck in low value-added segments of the chain.

According to Gereffi and Sturgeon (2013) and Milberg *et al*. (2014) productive sector policy in the past focused on key domestic industries either behind protectionist walls through import-substituting industrialisation (ISI) or by increasing market access through export promotion using export-oriented industrialisation (EOI). A major difference between traditional and GVC-oriented policy is vertical specialisation, defined as the import content of exports (Milberg *et al*., 2014). Vertical specialisation is high in GVCs and more so when they span many borders which leads to an increase in the trade of intermediate products. Milberg *et al*. (2014) refer to vertically specialised industrialisation (VSI) which is the process by which firms and economies upgrade their positions in a chain in order to capture more value-added which in turn leads to economic upgrading and development. VSI focuses less on the national economy and more on linkages to value chain actors. While ISI focused on building national capabilities and EOI on final goods, in

an era of GVCs VSI requires policy that focuses on regulating links, such as trade, FDI and exchange rates, to the global economy (Milberg, 2013). As the focus in VSI is using intermediates to upgrade in a value chain, countries must seek ways first to attract a steady supply of intermediates and then build domestic capacity to produce intermediates first through foreign firms and then by domestic firms (Milberg *et al.*, 2014). As VSI relies extensively on ties to GVCs already set up in developing nations, as opposed to EOI which focused on exports to developed nations, trade has shifted globally from North-South to South-South trade (Milberg *et al*., 2014). Along with this, many emerging economies are turning their focus inward and developing or joining RVCs while focusing on production for domestic markets. VSI, arguably more so than EOI and ISI, provides countries the opportunity to promote policies aimed at upgrading regional and domestic markets. This is important for the SADC context.

Gereffi and Sturgeon (2013) and Milberg *et al.* (2014) argue that there can be no return to these policies of ISI and EOI in the era of GVCs and countries must rather focus on moving to higher value niches in GVCs through upgrading. Government productive sector policies must place emphasis on providing national companies the correct incentives and conditions to foster upgrading from low value to higher value links in the chains in order to generate higher returns. It is important to note that upgrading in value chains does not happen automatically and varies depending on the country and industry and requires some sort of government intervention (Dalle *et al.*, 2013). According to Milberg *et al.* (2014) focus should be placed on obtaining greater value using intermediate inputs in a chain. Converting to locally manufactured as opposed to imported intermediates is an efficient upgrading method. Therefore, according to these neo-Schumpeterian authors protectionism which may sometimes be counterproductive, may also be necessary in some cases to support the development of local production.

Any productive sector strategy in the GVC era focusing on increasing domestic capacity should place emphasis on the relationship between global and local members of production networks and take into account the interests, pressures and power of lead firms while accepting the role of foreign NGOs in local value chains (Gereffi and Sturgeon, 2013; Milberg *et al.*, 2014). There is a tendency by lead firms in a chain to make their suppliers compete with each other which makes upgrading national firms difficult. This is because it limits the government's influence over these lead firms and they cannot successfully implement local procurement policies while there is a lesser chance of building links with local suppliers. Gereffi and Sturgeon (2013) identify that some countries are

looking inwards and focusing on regional production networks developed through regional industrial policy. South Africa is one of the countries that is beginning to implement this value chain-oriented policy as the country emphasises regional integration as one of the bases for industrial upgrading. The regional focus is on key sectors of relevance to the South African economy such as mining, agro-processing and, importantly for this study, pharmaceuticals (Davies, 2011; DTI, 2017a). South Africa's strategy focuses on upgrading through increasing the value of exports from the region with the additional processing of raw materials, shifting production away from China and towards Africa. The focus on upgrading in value chains to foster economic development has forced South Africa to identify ways in which the region can keep more of the profits from its rich resources at home than it is currently able to. The intention is not only to retain a larger profit share in Africa, but also to ensure better skills development and higher wages.

The regional-based aspect of South Africa's industrial policy sees the development of the region as providing upgrading opportunities for each country individually. Development and growth of the region creating a larger regional entity can improve access to and processing of more raw materials and minerals, increase productivity and processing capacity and provide a larger market, all of which is aimed at promoting upgrading (Milberg *et al.*, 2014). However, it is yet to be understood how the value will be more evenly spread across economies to avoid the likelihood that South Africa would retain the higher value segments of regional value chains. If higher value processes remain concentrated in South Africa, problems related to the unequal distribution of the benefits of integration will remain, and development integration would not be achieved.

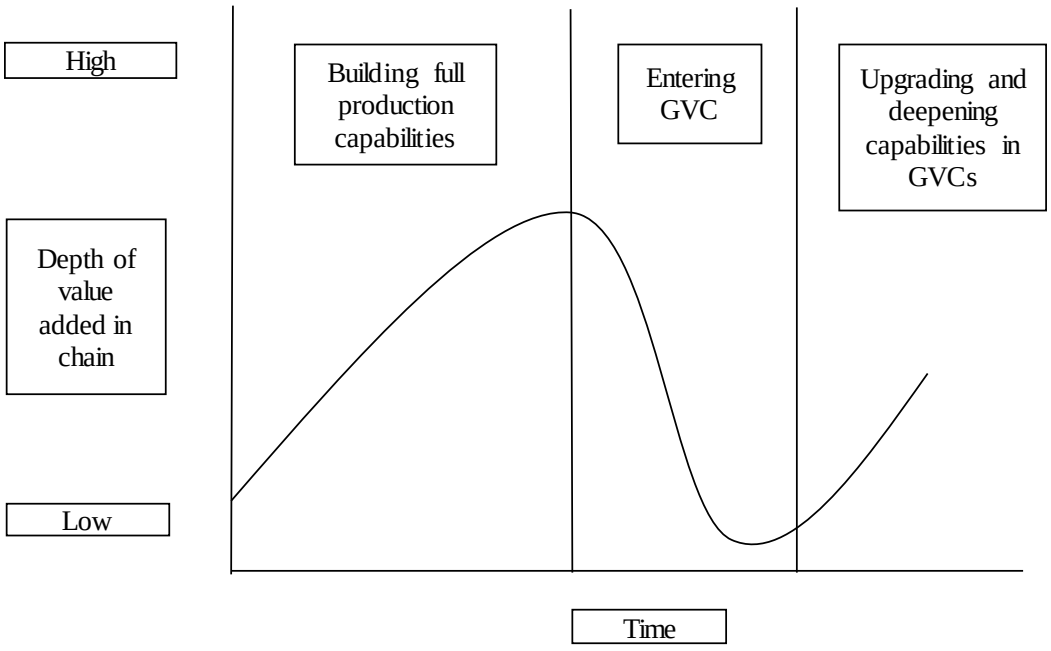
Upgrading in GVCs tends to favour large countries over small countries due to a number of advantages they possess. However, the increasing potential of RVCs is arguably providing smaller countries with the opportunity to take advantage of low costs and close proximity to large markets to build export capacities in specialised GVC niches in the context of regional production. The pharmaceutical industry could provide African countries the opportunity to enter some of these niches, such as manufacturing APIs, and a growing region will provide a larger market for locally manufactured products. An example of how smaller countries can harness the advantages of RVCs is Nicaragua which previously bought textiles from China but is now seeking supplies from firms in Honduras and Guatemala (Gereffi and Sturgeon, 2013).

5.3.2 Productive Sector Policy in Vertically Specialised versus Additive Value Chains

Each of the two value chain typologies distinguished by Kaplinsky and Morris (2015), and introduced in Chapter 3, namely vertically specialised and additive value chains require different corporate strategies and different forms of policy support. This section focuses on policy recommendations for vertically specialised value chains. The pharmaceutical sector falls mainly into this type of value chain. For the sake of comprehensiveness, and due to the slight overlap of the industry between the two typologies, policies designed to support additive value chains are also explored, although in somewhat less detail.

Vertically specialised chains have evolved out of the practice of outsourcing non-core capabilities (to focus on core capabilities) as opposed to the traditional practice of deepening value-added. The focus has therefore shifted from sectors to capabilities, and firms specialise in areas containing rents that they can successfully exploit. This outsourcing leads to a thinning of value and therefore policy in these chains is referred to as 'thinning out' (Kaplinsky and Morris, 2015).

Figure 7: ‘Thinning out’ Value-Added in the Chain.



Source: Kaplinsky and Morris (2015: 12).

Figure 7 explains how entering a GVC and outsourcing all non-core components leads to the thinning of value within a firm. This is indicated by the steep fall in the curve once it crosses the ‘entering GVC’ section. The figure also highlights that over time upgrading and deepening capabilities allows firms to increase their share of value-added.

Critical to this study is the point highlighted by Kaplinsky and Morris (2015) that some vertically specialised GVC participants may not start with established domestic oriented industries that require thinning out but rather may begin as global suppliers. The Indian pharmaceutical manufacturing industry is one such example of this as it began producing medicines for MNCs which were then distributed globally. It then upgraded functionally into OEM and further into ODM and OBM. These firms are initially given very limited space in the value chain and rather than thinning out, reorienting production from domestic to foreign markets, there is an agenda of thinning in whereby firms begin participating in foreign markets as global suppliers (Kaplinsky and Morris, 2015).

Due to the offshoring of outsourced activities, policy in vertically specialised GVCs revolves around trade policy. Creation of a conducive environment for trade is the key goal through the

reduction of impediments to trade such as the removal of tariff and non-tariff barriers, for example, 'at the border' bureaucracy, as well as introducing export and other incentives (Kaplinsky and Morris, 2015). This trade policy needs to be accompanied by trade infrastructure which functions efficiently, including airports, rail, roads and ports, as well as effective access to the internet.

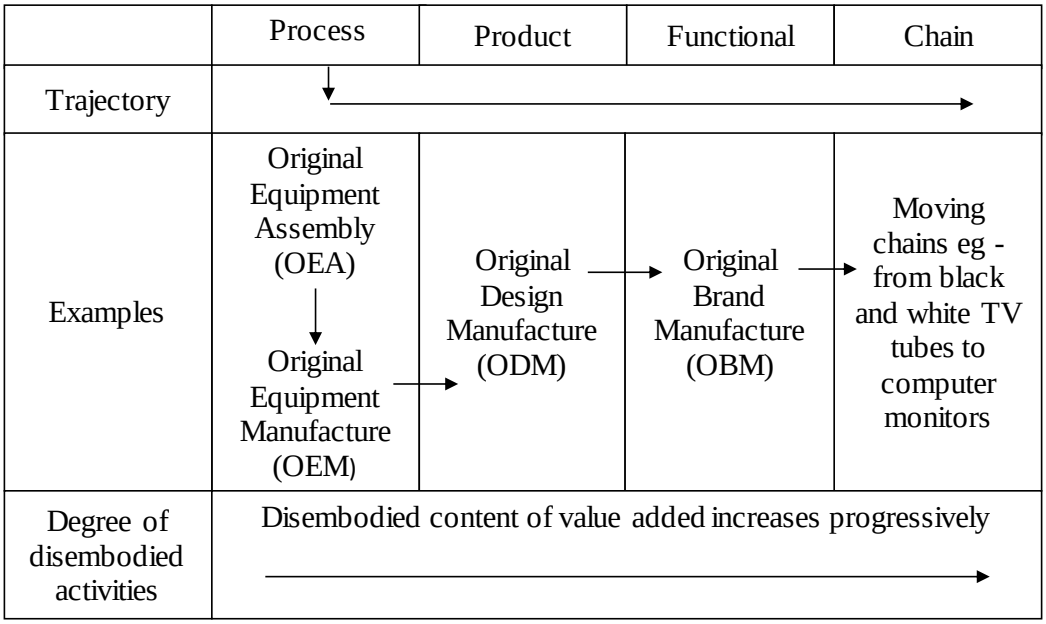
MNCs provide entry into global markets for some economies and policy in vertical specialised chains may include the setting up of Export Processing Zones (EPZs) providing incentives to foreign investors to invest in domestic production. These might include tax holidays, subsidised accommodation and freedom from domestic labour laws among others (Morris, 2016). According to Kaplinsky and Morris (2015) some policies introduced in other economies form part of vertically specialised GVC policy. This includes agreements such as the African Growth and Employment Act (AGOA) which is designed in part to foster growth in vertically specialised GVCs in exporting economies.

Trade policy mainly focuses on the early development of vertically specialised chains. However, once established, follow-on policies allow for the deepening of firms in the value rich links in the chain (Kaplinsky and Morris, 2015). At the firm level this is achieved through upgrading, which is considerably enhanced through government support, at a firm, cluster and sector level. Government support takes the form of human resource development, financial incentives promoting R&D and innovation and strengthening the National Systems of Innovation (NSI) relevant to the sector (Kaplinsky and Morris, 2015).

As identified in Section 2.5, upgrading includes process, product, functional and chain upgrading (Humphrey and Schmitz, 2002: 1020). Kaplinsky and Morris (2015) find that while a linear movement from process through to chain upgrading is not certain, Asian economies which have successfully implemented vertically specialised GVCs often exhibit this trait. Entry into the chain is often through assembly, following the procedures set out by lead firms, and early upgrading involves process improvement. Efficiency is a major focus until eventually capabilities increase to a level that allows the move from assembly to manufacturing. Manufacturing allows firms greater independence to produce or source local components. Further capability improvements could lead to product upgrading and the ability to design its own products and eventually functional upgrading through acquiring or building an own brand. In the Asian economies, once firms have mastered the capabilities in a specific chain, they may move into a

new chain. This growth path reveals an increasing knowledge intensity and share of outsourced activities as firms move up the chain (Kaplinsky and Morris, 2015).

Figure 8: The Upgrading Trajectory.



Source: Kaplinsky and Morris (2015: 13).

Figure 8 features the value chain trajectory often followed by vertically specialised Asian economies and recommended for the pharmaceutical manufacturing industry. This includes the movement from original equipment assembly (OEA) and OEM within process upgrading through ODM in product and OBM in functional upgrading, and finally, chain upgrading.

In contrast to vertically specialised chains, productive sector policy in additive value chains focuses on 'thickening' and therefore deepening value-added (Morris, 2016). This is done by building linkages in the sector backwards, forwards and horizontally to distribute capacity, income and employment and evenly spread the gains from globalisation (Morris, 2016). While this mostly occurs in the resource sector, linkages are important in many manufacturing sectors including the pharmaceutical manufacturing industry. Linkages include supplier linkages and, most importantly, service linkages such as transport, logistics and ICT (Cattaneo, 2009). As is discussed in Section

5.3.3, policy to foster these linkages is important as they are crucial to the functioning of value chains.

Another important aspect of additive chains from a lead firm perspective is CSR. Pressure from government and civil society to promote developmental spin offs from industry has led to some MNCs embracing supplier development under CSR programmes. This is beneficial as it provides the lead firm with better quality suppliers while meeting the needs of civil society (Kaplinsky and Morris, 2015). Traceability, being able to trace a final product back through the value chain to its origins, falls under CSR and lead firms can differentiate their product if they develop the capabilities of all actors along the supply chain. Policy to require some form of CSR within value chains may therefore have developmental benefits for all along the chain.

5.3.3 Productive Sector Policy in the Pharmaceutical Industry

This section provides a range of policy recommendations and suggestions for the pharmaceutical manufacturing industry in the SADC region, drawing on the lessons from the theory and GVC framework above. These policies are designed with the view of developing the industry in each country through the building of pharmaceutical manufacturing RVCs in SADC to foster development integration leading to improved health access and coverage in SADC. Policy recommendations emanate from the analysis in this thesis, policy documents released by organisations such as the AU and SADC as well as the South African DTI and a range of experts writing in their personal capacity. Many of the policy proposals suggested previously have been aimed at South Africa due to the country's relatively large pharmaceutical sector and its position as the dominant economy within SADC. These proposals are drawn upon and are useful in providing new recommendations for other SADC nations.

Both the DTI's National Industrial Policy Framework (NIPF) and its implementation plan, the IPAP, include the pharmaceutical industry among the 'lead sectors' targeted for economic intervention (Naude and Luiz, 2013). According to the DTI (2017b) there are a number of policy tools available to governments to use to foster development in the industry and which, along with theoretical policy suggestions by authors using the GVC framework, form the backbone of the policy recommendations in this chapter. These tools include public procurement, industrial financing, incentives and export support, developmental trade policy, Special Economic Zones (SEZs), cluster development and regional integration. The DTIs productive sector policy for

pharmaceuticals includes the building of investor confidence through the use of public procurement, boosting exports and a reasonable approach to pricing along with growing domestic capacity through technology transfers, incentives for investment, tariff protection and an expedited approval process and moving away from simple manufacturing and towards R&D and new pharmaceutical technologies (DTI, 2017b). This policy trajectory echoes the policy issues that pharmaceutical manufacturers in South Africa are lobbying government to implement.

According to the Industry expert (2017: interview) there are six key policy issues that South African pharmaceutical manufacturers are engaging government with at present and significant headway has been made on each. The first is an expedited registration for companies that are manufacturing locally. This is a reasonably fiscal neutral way to reward local investment and it is done at the expense of companies that import medicines. The second policy consideration is that of defensive tariffs. These are key for products that countries aim to increase production of and promote from both a domestic consumption and export consumption point of view. However, as noted below, these tariffs must be used with caution within the framework of setting up pharmaceutical RVCs and must not be introduced at a level that hinders the development of these RVCs. The use of tariffs would also need to comply with existing WTO (and other international trade agreement) obligations. Thirdly, a tailored or customised incentive scheme that rewards incremental volume manufacturing provides companies with the motivation to expand production. The fourth policy issue is strengthening public procurement. In line with the incremental volume incentive, manufacturers are also targeting an incremental export volume incentive from government. Lastly, and an issue dealt with in DTI (2017a), it is important to have certainty and predictability around the regulatory and business environment, including single exit pricing and other regulations (Industry expert, 2017: interview).

A source of concern for resource constrained governments is the trade-off between providing access to high quality, low priced medicines for all versus the promotion of a domestic pharmaceutical manufacturing industry (Kaplan and Laing, 2005). This creates tension between health and productive sector policies which need to work together in a cohesive manner in order to find solutions to developing the local pharmaceutical industry while maintaining the ability to provide full access to medicines (Kaplan and Laing, 2005). Numerous DTI documents recognise this relationship as key to the health and pharmaceutical sector and it is an important recommendation made in this thesis. Ngozwana (2015) argues that there is a lack of a clear vision

for the South African pharmaceutical industry while the DTI (2017a) and DTI (2017b) identify the lack of cohesion and coordination between the DTI, Department of Health and National Treasury as a major stumbling block to the development of the industry in South Africa and beyond.

According to Mackintosh, Mugwagwa, Banda and Tunguhole (2017) African countries now strongly agree that there may be significant developmental synergies from expanding the manufacturing of pharmaceuticals and the improvement of quality and coverage of healthcare, especially in low income countries (AU, 2007). Therefore, Ngozwana (2015) suggests that a framework for policy alignment around South Africa's core documents which are the National Development Plan 2030, IPAP, the Department of Science and Technology's Bio-Economy Strategy and National Department of Health's Strategic Plan is created to ensure the development of the industry is beneficial from a health, economic and social perspective. According to Mackintosh *et al.* (2017) the development of a 'local health' policy that identifies both existing industrial capabilities and local health priorities and then constructs synergies and linkages on the ground between health systems and industrial developments will enable the local pharmaceutical industry to support the strengthening of the health system. Ngozwana (2015) argues that a National Vision and Strategy for the sector must also be developed.

From a GVC perspective, and according to Milberg (2013), VSI requires policy that focuses on regulating links, such as trade, FDI and exchange rate links, to the global economy. Therefore, policy needs to focus on the regulation and development of service links important to pharmaceutical manufacturing, such as logistics and distribution. According to Cattaneo (2009) the service linkages that facilitate production sharing are crucial for the development of regional trade. For example, improving the efficiency of transport between countries and streamlining border crossings will promote trade and enable the development of RVCs. Therefore Cattaneo (2009) suggests the development of a coherent agenda for the services sector in Southern Africa and the identification of the best framework for regional cooperation in services due to the importance of services in supporting manufacturing production and trade in a value chain context.

According to Milberg *et al.* (2014) the use of intermediates within value chains requires policy that will encourage first the attraction of a steady supply of pharmaceutical intermediates and then domestic production. In order to attract intermediates, such as APIs, into the pharmaceutical industry in SADC countries a conducive trade environment must be created through reducing regional non-tariff trade barriers and transport costs, as well as providing export incentives and

removing bureaucracy at the borders (Mutambara, 2009; Kaplinsky and Morris, 2015). The removal of barriers to trade will assist with the smooth flow of pharmaceuticals, whether it be intermediates or final products, between SADC nations within a RVC structure. In order to achieve development integration, it is essential that this trade policy is implemented along with trade infrastructure that is efficient and includes airports, rail, roads and ports, as well as effective access to the internet. Infrastructure development should aim not only to link each country to the global economy but should also provide efficient and reliable access between all members of SADC.

Milberg *et al.* (2014) argue that countries and regions should then shift towards the local production of intermediates. Prioritising local production is a major goal of the DTI (2017b). In order to attract foreign investment into production of intermediates, countries and regions must offer a conducive investment environment (DTI, 2017a). According to Kaplinsky and Morris (2015) Asian countries used EPZs (similar to SEZs but aimed at manufacturing for export) as one method to attract investment by MNCs and therefore stimulating the local production of intermediates. EPZs and SEZs have laws, such as tax exemption laws and labour laws for example, that benefit investment (Kaplinsky and Morris, 2015). Milberg *et al.* (2014) argue that once domestic firms have built the necessary capabilities, the production of intermediates should be transferred to local companies as converting to locally manufactured (as opposed to imported) intermediates is an efficient upgrading method and fosters local production. In order to give these companies an advantage, governments may need to use some form of protectionism such as defensive tariffs. These should however be used sparingly in the RVC framework so not to act as an impediment to trade between SADC nations.

A further policy tool of the DTI (2017b) is regional integration. As discussed in Chapter 3, the traditional market integration approach involving a linear progression from a FTA to a customs union, common market and beyond is an inadequate regional integration strategy for developing countries at highly unequal levels of development. Development integration has instead been proposed for the SADC region, and the development of RVCs in sectors such as pharmaceuticals is a key aspect of this strategy. In order to set up pharmaceutical RVCs within SADC there must be cohesion between the respective government authorities in all countries to create an active and efficient strategy for the pharmaceutical manufacturing industry in SADC. There must also be policy which promotes technology and skills transfer from South Africa to other member states to assist with the development of the industry within each country. Developmental trade policy, as

noted above, is another key policy that may foster RVCs. South Africa must also, while not neglecting its own sector, assist with the setting up of learning and skills training centres in SADC nations. It is important that each nation identifies the pharmaceutical industry as a key sector and prioritises pharmaceutical RVCs in a development integration context. While each country will likely need to start at the bottom with formulation (Industry expert, 2017: interview), care should be taken so that firms in each country have the opportunity to upgrade to higher value activities within the chain. Within the development integration framework, there should be an equitable balance of the benefits of integration achieved through coordinated industrial policy, infrastructure development and, where necessary, compensatory and corrective measures particularly orientated towards least developed regions (Davies, 1996).

5.4 Conclusion

This chapter focused on upgrading and productive sector policy within the pharmaceutical industry, with lessons for the SADC region. The discussion on upgrading draws attention to the experiences of India and Uganda where upgrading occurred through 'learning by exporting' and 'learning by importing' respectively. An important link between upgrading and industrial policy or, as it is referred to here, productive sector policy is highlighted in the upgrading section. This link is important as in order for upgrading to occur within a country or sector the correct policy to foster this upgrading must be designed and actively implemented. Before providing recommendations on productive sector policy for the pharmaceutical industry an analysis of policy within vertically specialised and additive chains was carried out. Lastly, and most importantly, policy recommendations for the pharmaceutical manufacturing industry were provided in Section 5.3.3. These recommendations drew on the value chain analysis in earlier sections and chapters of the thesis, as well as the DTI's (2017b) policy tools which include public procurement, industrial financing, incentives and export support, developmental trade policy, Special Economic Zones (SEZs), cluster development and regional integration, as well as a key industry expert interview. It was argued that appropriate policies supporting the introduction and growth of pharmaceutical manufacturing RVCs in SADC would facilitate development integration in the region, with benefits for both health and production sectors, as well as regional trade.

CHAPTER 6: CONCLUSION

The high disease burden of countries in SADC and erratic supply of medicines calls for the strengthening of pharmaceutical production to ensure a steady supply of high quality medicines within the region. At the same time, the failure of numerous formal regional integration arrangements throughout Africa, often leading to polarised rather than balanced development, demands a different approach to regional integration. This thesis argues that a solution may be found through the development of pharmaceutical manufacturing RVCs within SADC and the use of these and other RVCs as a tool for development integration within informal integration arrangements. The study employs a value chain framework for the analysis and discusses development integration options, drawing on the East Asian experience with RVCs and on case studies involving India in the case of the pharmaceutical industry.

Due to the critical importance of having a steady supply of high quality medicines and the emphasis placed on growing the pharmaceutical industry by SADC (2015) and the DTI (2017a), this thesis focuses on the pharmaceutical manufacturing industry in SADC. It uses the GVC framework to understand and analyse the dynamic nature of the global and SADC pharmaceutical manufacturing industry with a focus on South Africa and Zimbabwe. It argues that development integration outside of formal integration arrangements is a credible option for fostering regional integration, especially in regions that have countries of unequal sizes and at different levels of development. Pharmaceutical manufacturing RVCs are identified as an important tool, alongside other RVCs, that SADC nations can use to foster balanced economic growth through development integration. Suitable productive sector policy, discussed in Chapter 5, is required to grow and develop pharmaceutical manufacturing RVCs. Critical for SADC is fostering service links to facilitate production sharing through an agenda for the service sector to ensure high costs and inefficiencies do not affect the advantages of regional production sharing.

Chapter 2 of the thesis first developed the theoretical framework for the analysis. It outlined the different value chain typologies before providing an overview of important theoretical aspects of value chains such as governance and upgrading. Other theoretical aspects included in Chapter 2 were the rise of GVCs and the importance of end markets and standards in value chain analysis. Further, the smile curve, an important theoretical tool that identifies the shift of value added away from manufacturing and towards links at the beginning and end of the chain, such as R&D and

marketing, is discussed in this chapter. Characterising the pharmaceutical manufacturing chain in SADC in terms of the typologies discussed in this chapter, along with its governance structure and upgrading opportunities, provided a basis for considering upgrading prospects and policy for the sector.

Chapter 3 of the thesis developed the theoretical framework further by considering the relationship between GVCs and RVCs. It concluded that RVCs could be used beneficially as a pathway or stepping stone to participation in GVCs. It also explored the link between RVCs and regional integration. Alternative models of integration were discussed and it was found that in regions where there are unequal levels of development, a development integration approach that takes into account trade integration, infrastructure development and industrial development would be beneficial. Furthermore, it was suggested that RVCs could be used as an effective tool to achieve development integration, provided the right productive sector policies were put in place. Case study analysis found that while East Asian RVCs developed outside of formal integration arrangements due to low natural barriers to trade, it was important to develop strong and effective regional cooperation. Since SADC does not enjoy these low natural barriers, a development integration approach that prioritises the removal of non-tariff barriers such as high transport costs is arguably able to achieve more than a purely market integration approach. Development integration focuses on overcoming the problems of integrating countries at unequal levels of development through building infrastructure and the development of effective industrial policy to facilitate the emergence of RVCs and growth in fragmented trade.

The discussion in Chapter 4 turned towards a value chain analysis of the pharmaceutical industry. The sector profile on South Africa highlighted the import dependence problem as well as the ways in which the country is seeking to solve it through increasing local manufacturing. A major lesson from the Zimbabwe sector trade profile is how developed the manufacturing industry was before the economic troubles that started in the early 2000s. While pharmaceutical exports from Zimbabwe are low and relatively insignificant, the existing and previous pharmaceutical base indicate the potential for the pharmaceutical manufacturing industry in Zimbabwe to contribute to the development of RVCs in this sector, subject to the implementation of an appropriate policy framework.

The thesis attempts to provide an in-depth framework outlining what is needed in order to develop the pharmaceutical industry from the lowest level of entry into the value chain and how

to use pharmaceutical manufacturing RVCs to foster development integration. In this vein Chapter 5 first discussed upgrading, using case studies on Uganda and India, in the pharmaceutical manufacturing industry and found that each country upgraded through different means, Uganda through 'learning by importing,' and India, 'learning by exporting'. These cases are relevant for SADC countries and provide a link between upgrading and productive sector policy. Before providing policy recommendations for the pharmaceutical industry an analysis of policy within vertically specialised and additive chains was carried out.

Chapter 5 concluded with productive sector policy recommendations, identified from both the value chain analysis in this thesis and sources such as policy documents and other authors, that governments and regulatory authorities should implement. These include providing investment and incremental production and export volume incentives; strengthening public procurement; certainty and predictability around the regulatory and business environment; the removal of non-tariff barriers within SADC and the use of defensive tariffs to grow the regional manufacturing industry. Importantly, a coherent regional policy agenda for the industry with input from all countries and both private and public actors should be developed and actively implemented creating synergies and linkages on the ground between health systems and industrial development. A major concern of potential manufacturers in South Africa is a slow approval and registration process. Expediting this process in all SADC nations would encourage investment into the industry.

Policies recommended from the GVC analysis in this thesis include regulating and developing service links to the global economy. A coherent agenda for services, including FDI, transport, logistics and exchange rate links, is crucial to facilitate production sharing and regional trade of pharmaceutical products within SADC. For example, improving the efficiency of transport between countries and streamlining border crossings will promote trade and enable the development of RVCs. The removal of non-tariff barriers is important from a developmental trade perspective in order to attract a steady supply of intermediates, such as APIs, which are needed to promote manufacturing, and final products within a RVC structure. In line with development integration, trade policy that promotes efficient trade infrastructure should be implemented including airports, rail, roads and ports, as well as effective access to the internet. A conducive trade and investment environment, which includes EPZs and investment incentives among others, should be fostered within SADC and once the industry has upgraded sufficiently governments

should promote the local manufacture of intermediates to reduce the import dependence in the industry.

There is scope for further research to produce a more in-depth numerical analysis of the industry in SADC with more detailed production and employment figures that will provide a clearer picture of the current status of the industry and explain trends such as rising imports into Zimbabwe. Better data that is accessible at a reasonable cost to academic and NGO researchers would go a long way to facilitate further research in this important field.

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