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DISSERTATION

The impact of production techniques on the competitiveness of the pharmaceutical manufacturing firms in Zimbabwe

A Dissertation submitted in Partial Fulfilment of the Requirements for the Master Degree in Business Administration

By

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Dedication

This dissertation is dedicated to my wife, Glory and family for their ever enduring patience, love and great moral support. And to all my friends and fellow pharmacists, thank you for thus far the Lord has brought us.

Declaration

I, Mandimika Brian Paidamoyo, hereby declare that this research is a result of my own investigation and study, except to the extent pointed out in the Acknowledgements, References and by comments indicated in the body of the report and that it has not been submitted in part or in full for any other degree to any other University.

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Student signature Date

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Supervisor signature Date

Acknowledgements

I would like to acknowledge all those who assisted me in conducting this research. Firstly I would like to acknowledge the guidance throughout the research from my supervisor Dr G Muponda. To all my friends and production pharmacists (managers) PMA members and Mr L Chapanga I greatly appreciate your help. My heartfelt appreciation goes to all pharmacy respondents, who took their time to assist me. May God bless you all in your endeavours.

Abstract

The purpose of the study was to assess the effect of current production techniques on the competitiveness of pharmaceutical firms and pharmaceutical products in Zimbabwe and suggest ways in which these can be improved in order to enhance efficiency and competiveness.The study was motivated by the considerable decline (of thirty-three percent) in contribution to GDP from pharmaceutical manufacturing. Local manufacturers have been producing only forty-seven percent of the local demand for medicine supply both by volume and value. Low production from local manufacturers has resulted in the growth in pharmaceutical imports and the country is slowly becoming a net importer of pharmaceutical products despite having local manufacturers.Previous studies established that the local manufactures were facing operational challenges that resulted in low capacity utilization in production while evidence on what actual factors that had an impact on production in Zimbabwe remained scarce.

An action studywas conducted on the pharmaceutical manufacturers in Harare. Interview guides were used to collect data from twenty-two participants. The study adopted a qualitative approach and content analysis was used to analyse data to come up with the current production techniques and competitive strategies that the local manufacturers were currently using in production. Operational challenges that the manufacturers were facing were also noted.

The study established that local manufacturers falling short on adopting international production techniques and hence lack WHO prequalification. The Zimbabwean pharmaceutical manufacturing companies are plagued with numerous challenges that are threatening their survival. Utilities, high overheads, inadequate capital and old equipment have been pointed out with great emphasis, with old equipment being identified as the major challenge. There were no clear pricing strategies as local manufacturers were focusing more on survival strategies, given the current economic conditions. The study also established that the industry is highly affected with unfavourable policies that included duty on raw materials while imported finished products were duty free.

The study recommended that prohibitive legislations be removed and emphasized the need tocompel donors to procure from locally manufacturing companies. Manufacturers were recommended to obtain WHO prequalification, implement a visible and effective competitive strategy and retool the industry for growth and competitiveness of the industry.

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ABBREVIATIONS AND ACRONYMS

IMF	International Monetary Fund
GDP	Gross Domestic Product
UNIDO	United Nations
CAPS	Central Africa Pharmaceutical Society
CZI	Confederation of Zimbabwe Industries
TB	Tuberculosis
HIV	Human Immunodeficiency Syndrome
AIDS	Acquired Immunodeficiency Syndrome
MCAZ	Medicines Control Authority of Zimbabwe
NATPHARM	National Pharmaceuticals
OTC	Over-The-Counter medicines
PP	Prescription Preparation drugs
HR	Household Remedies
API	Active Pharmaceutical Ingredient
MASCA	Medicines and Allied Substances Control Act
FPP	Finished Pharmaceutical Products
ICH	International Conference on Harmonization
CTD	Common Technical Document
GMP	Good Manufacturing Practices
ARV	Anti-Retroviral
R & D	Research and Development
QC	Quality Control
FDA	Food and Drug Administration
WHO	World Health Organisation
cGMP	current Good Manufacturing Practices
QA	Quality Assurance
TPS	Toyota Production
JIT	Just-In-Time
NDDS	Novel Drug Delivery Systems
OECD	Organisation for Economic Co-operation and Development

PMA	Pharmaceutical Manufacturers Association
SADC	Southern Africa Development Community
ZESA	Zimbabwe Electricity Supply Authority
ORS	Oral Rehydration Salts
VAT	Value Added Tax
UK	United Kingdom
GMO	Genetically Modified Organisms
AMA	Agricultural Marketing Authority
ZIMRA	Zimbabwe Revenue Authority
SPB	State Procurement Board
PAYE	Pay As You Earn
ZIMASSET	Zimbabwe Agenda for Sustainable Socio-Economic Transformation

CHAPTER ONE
INTRODUCTION TO THE STUDY

1. Introduction

The Zimbabwean pharmaceutical sector experienced a number of challenges during the period between 2001 and 2008 mainly as a result of the hyperinflationary environment in the economy (Musundire, 2012). This resulted in liquidity challenges which made it difficult for the pharmaceutical entities to embark on essential capital projects that provide the capacity for growth and increased productivity. In 2009, the economy however showed signs of recovery throughdollarization that brought a more stable environment for companies to operate in (IMF, 2011).Bogetic (2000b) noted that dollarization implies that the national economic agents use a foreign currency as legal tender instead of their local currency. In most cases, the US dollar is used for economic transactions when the local currency is legally and officially abandoned as means of payment, unit of account and store of value.

It would have seemed automatic that the introduction of the multicurrency system would boost investor confidence and industrial productivity simultaneously, but that was not the case. In recent times, the economy has actually been struggling due to a huge trade deficit, and closing down of industries in a deflationary economic environment. The table below shows the growth trends of the pharmaceutical sector and its contribution to GDP.

Table 1:1 Pharmaceuticals contribution to annual GDP growth rates

Year	2009	2010	2011	2012	2013
GDP % p.a.	5.40%	10.60%	9.60%	4.40%	3.40%
Pharmaceutical Manufacturing Contribution	17.00%	4.00%	14.40%	4.85%	3.20%

Source: Zimbabwe Economic Review (2013)

The figures in the table indicate that GDP improved from the year 2009 to 2010 where it peaked at 10.6%, then taking a steep decline to 3.4% in 2013. Ultimately, the figures show that economic activities shrunk by eleven percent over the five year period, whilst the pharmaceutical sector contribution to GDP growth declined by thirty-three percent. This implies that the role and significance of pharmaceutical manufacturing in the GDP declined, a sign that domestic productivity was decreasing with time. The Zimbabwe Economic Review (2013) went on to

highlight thatfactors which include weak aggregate demand, low disposable income and poor financial services sector could have contributed to this weak performance.

Musundire (2012) cited that some of the manufacturing companies are currently specializing in importing and repackaging of finished medicines rather than production. This could be an indication that the pharmaceutical industry could be facing production challenges which dollarization alone could not eradicate. As noted by UNIDO (2010), local manufacturers are producing 47% of local demand leaving the rest slowly being flooded with imported medicines from neighbouring South Africa, Zambia, and even as far as from India. It has been noted that local manufacturers are facing production challenges and are operating at below 60% capacity utilization (Musundire, 2012). In addition, the recent closures and workers going for months without salaries at CAPS holding, a local pharmaceutical manufacturer, are some of the signs of the distressed industry.

In his inaugural speech on 22 August 2013, President Mugabe noted that the country is fast turning into one huge warehouse, a dumping ground for all manner of imports. The country is slowly becoming a net importer of finished goods and a net exporter of raw material (CZI Manufacturing Survey Report, 2013). This comes in the backdrop of Zimbabwe being ranked as highly uncompetitive, ranking 170 out of 189 countries in 2013 according to the World Bank report (Zimbabwe economic review, 2013).

1.1 Study Background

Most governments in developing countries have the mammoth task of ensuring the population's access to quality and essential drugs at affordable prices among other prime challenges (UNIDO, 2010). In recent years however, considerable progress has been made in these endeavours, through the support of The Global Fund for example, to fight Aids, Tuberculosis and Malaria, inthe supply of essential medicines inorder to combat the three pandemic diseases of HIV/AIDS, malaria and TB (Mbendi, 2009).

The Global Fund, apartnership between the private sector, developed countries, civil society, developing countries, and affected communities was established in 2002. Its main objective is to function as an innovative financing mechanism seeking to rapidly raise and facilitate the disbursing of funds for programs that help in reducing the impact of malaria, HIV/AIDS and

tuberculosis that are prevalent in low- and middle-income countries (Poore, 2004).Despite this, there is still asubstantial gap that exists between the type and volumes of the very drugs required onthe one hand and those that can be afforded by the poor segment of the population on theother.UNIDO (2010) noted that one option available to countries like Zimbabwe in addressing this demand-supply gap includes the stimulation of domestic production of essential generic medicines.

The process of pharmaceutical manufacturing requires capital injection for machinery and raw materials and usual requires government intervention through funds in situations where there are no foreign investors. Favourable government policies that normally protect local manufacturing companies also play a big role in pharmaceutical manufacturing (Poore, 2004). With foreign investors reluctant to invest in the country's manufacturing industry, the government of Zimbabwe has not been aiding local manufacturers through capital injection for recapitalisation of the industry in working capital and or machinery, and as well as implementation of favourable policies which include protection from cheap imports (WEF, 2012).

Protection can be achieved through higher taxation on imported medicines (Musundire, 2012). In 2013, only 10% was allocated to health policy implementation. The Ministry of Finance in its 2013 budget presentation noted that most pharmaceutical companies' equipment and machinery were antiquated and thus required massive investments in terms of re-tooling and new technology. These would be achieved through partnership with friendly foreign investors. This is because some of the larger investment requirements cannot simply be wholly underwritten domestically (Zimbabwe economic review, 2013). Prior to that, the IMF (2011) had highlighted the need to increase government expenditure on education and health after Zimbabwe's Health Minister, Henry Madzorera, invited Indian pharmaceutical manufacturers who supply generic medicines to the country.

These manufacturers were urged to set up local manufacturing plants as a way of aiding growth of the local pharmaceutical sector. The main goal was that of the health ministry to expand the production capacity of the local pharmaceutical sector through collaborations with foreign Indian companies. In the pharmaceutical industry, such boosting in terms of production is greatly required through investments in new technologies, modern plant and equipment, industrial protection and as well as human skills development.

1.2 Structure of Zimbabwe's pharmaceutical industry

The structure of the Zimbabwean pharmaceutical industry can be analyzed using the following:

- the industry overview;
- the regulatory environment and
- the competitive environment

1.2.1 The industry overview

The Zimbabwean pharmaceutical industry consists of a few manufacturers (total of nine manufacturers) according to the Register of Licensed Pharmaceutical Manufacturing Premises released by the Medicines Control Authority of Zimbabwe (MCAZ). Of these nine manufacturers, four are serious generic manufacturers whereas the rest are largely focusing on trading and have narrow product portfolios. The four companies account for ninety percent of the pharmaceutical manufacturing in the country. The pharmaceutical industry is categorised on the basis of pharmaceutical form and therapeutic application. The industry is made up of the private and public sectors. The public sector involves the government aiding on the procurement and distribution of medicines through NATPHARM (National Pharmaceuticals) which is under the Ministry of Health. On the private sector, various pharmaceutical manufacturers among them Varichem, CAPS, Plus five, manufacture and distribute to private wholesalers and retail pharmacies. The local manufacturing industry is a key partner in the delivery of health to the national population. The pharmaceutical industry offers direct employment of Zimbabweans in addition to support of both downstream and upstream industries. The upstream success has been on the establishment and support of a fairly vibrant primary packaging manufacturing industry. The downstream side sees local manufacturers supporting a number of retail pharmacies and pharmaceutical wholesalers locally.

The main products of the pharmaceutical industry are medicines which are classified into three main categories. Firstly, there are prescription preparation drugs (PP) which should be dispensed to a patient with a valid doctor's prescription. Secondly, there are the over-the-counter medicines (OTC) which are accessible to all even without a prescription and thirdly, the household remedies (HR) which are available even in supermarkets.

The PP and OTC preparations are strictly available in pharmacies and dispensing doctor's premises.Currently, no local manufacturing company is carrying out primary manufacturing of

bulk drugs. Primary manufacturing is the manufacturing of the Active Pharmaceutical Ingredient (API) (Maloney and Segal, 2007). The anti-infective, cardiovascular and analgesic segments make up the majority of the country's retail formulations market. Secondary manufacturing then involves the mixing of the primary product (API) and the various exipients of additives to produce medicines like tablets and capsules that can be taken by the patient.

In Zimbabwe, pharmaceutical distribution occurs through pharmacies, authorised dispensing doctors and authorised wholesalers. In addition, some companies have their own private distribution systems. Local pharmaceutical sales occur through public and private channels (Mbendi, 2009) and some medicines. The table below shows the trend in revenue generation from pharmaceutical sales and export performance over the past five year period.

Table 1:1 Zimbabwean pharmaceutical sales and export performance

	2009	**2010**	**2011**	**2012**	**2013**	**2014**
Pharmaceutical sales (US$ bn)	0.14	0.14	0.18	0.20	0.23	0.25
Pharmaceutical sales (US$ bn) % change year on year	33.0	4.2	27.8	12.1	10.9	10.4
Pharmaceutical sales, % of GDP	2.22	1.91	2.43	2.66	2.86	2.96
Pharmaceutical exports (US$mn)	1.87	2.91	3.49	3.75	4.06	4.42
Pharmaceutical imports (US$mn)	75.03	78.18	99.90	112.50	125.01	138.25
Pharmaceutical trade balance (US$mn)	-73.16	-75.27	-96.41	-108.75	-120.95	-133.83

Source: Business Monitor International (2013)

The figures in the table imply that sales contribution to GDP remained constant at below three percent whilst exports where characterised by a sluggish growth. Pharmaceutical imports however registered a thirteen percent growth in value over the same period. This growth in imports is due to the fact that local demand of medicines that is not satisfied by local production is being catered for by pharmaceutical imports, thus making the country a net importer in the long run. Local manufacturers have been able to supply only forty-seven percent by item of Zimbabwe's essential medicine requirements (UNIDO, 2010). On average ten percent of output

is exported, with the rest being consumed locally. Exports are being shipped to destinations which include South Africa, Namibia, Lesotho, Botswana, Swaziland, and the Caribbean (Mbendi, 2009).

1.2.2 The regulatory environment

The pharmaceutical industry in Zimbabwe is regulated by the Medicines and Allied Substances Control Act (MASCA) andthe Dangerous Drugs Act, together with their corresponding regulations.MASCA is an Act to institute a Medicines Control Authority of Zimbabwe andto bestow on such Authority with respect to the registration of medicines. Medicines to be sold in Zimbabwe should be registered as stipulatedin the regulations. The MCAZ keeps a register of all medicines pending full registration which is availableat a fee in both electronic and hard formats.The Authority also develops and publishes guidelines on various topicscovered by the Act in addition to the MASCA. The MCAZ is currently working on the process of Guidelineson Submission of Documentation for Registration of Multisource FinishedPharmaceutical Products (FPPs). This would capture the latest developments in generic manufacturingpre-approval best practice. These guidelines will ensure that structure and format ofthe local product dossier will obey the rulesof the International Conference on Harmonization (ICH) andCommon Technical Document (CTD). The MCAZ also enforces Good Manufacturing Practices (GMP) which is worldwide standards in the production of medicines that are of high acceptable quality, efficacy and safety.

1.2.3 The competitive environment

The local industry is faced with a lot of competition from other external generic manufacturers, mainly from India. From the African region, competition is mainly limited to two South African companies namely Aspen andAdcock Ingram (Mbendi, 2009).The threat of new entries is relatively low due to compliance and high set up costs for new projects. Moreover, price based competition further reduces industrial attractiveness and the existing number of manufacturers, against a background of the economic crisis further reduces the number of new entrants. The power of suppliers is considerably high. This is because of the fact that drug master files required in the production of a consistent Active Pharmaceutical Ingredient (API) for both generic and innovator drugs have a high global demand. There is a high tendency for innovator and generic

drug manufacturers to buy up all API's being produced from Drug Master Files facilities to hedge against future competition. In some instances, the API supplier plays a dual role by producing an API and manufacturing simultaneously thereby creating a significant cost advantage over local manufacturers. The result is the creation of economies of scale coupled with the non-existence of tariffs on exported finished pharmaceutical medicines, in addition to export incentives that will further lower the final export product prices.

The power of buyers, who include private wholesalers, government and retail pharmacies, is relatively high as these are price sensitive. Therapeutically equivalent substitutes are readily available, giving these buyers a wider choice of products to choose from. The threat of substitutes is high given the high number of generic substitutes readily available. Rivalry in the industry is intense with local manufacturers facing stiff completion on market share from external exporters and foreign manufacturers who have local distributorship rights

1.3 The main pharmaceutical manufacturers

The intense competitive force thus shapes the generic pharmaceutical industry in Zimbabwe and is composed of the following main manufacturers:

1.3.1 CAPS (Pvt) Ltd

CAPS Holdings was founded in the year 1952 as a small pharmaceutical manufacturing and wholesale business. In 1958, the company decided to cease general wholesaling operations thus focusing on the manufacture and marketing of pharmaceutical preparations. The manufacturing company became the second pharmaceutical company in Zimbabwe to manufacture Anti-Retroviral (ARV's) locally. It completed a new facility in order to meet increasing GMP requirements which was temporarily shut down by the MCAZ in December 2009 and re-opened in mid-March 2010. This is because the MCAZ had not sanctioned the full operation of the new facility. There is generally a perception that the company has a strong product portfolio which is however getting old and heavily commoditized. There has also been a decrease in export activity despite the fact that during its early days the company used to derive at least twenty percent of its turnover from exports. By then, the product portfolio was still young and thus prone to less

competition. In addition, new product introductions have also been minimal (UNIDO, 2010). Currently the company is facing operational challenges (Musundire, 2012).

1.3.2 Datlabs (Pvt) Ltd

Datlabs is a one hundred percent subsidiary of Pharmalabs Jersey Limited located in the Channel Islands. It was established in Bulawayo in the early 1950s. The manufacturing company has well established links with the Adcock Ingram Group through various technology agreements. A strong portfolio of consumer health care products gives the company advantage on the local market. The company does not have its own Research and Development (R & D) facilities and thus benefits from dossiers from its technical partner in South Africa. Regulatory differences in manufacturing requirements between the two countries strongly present a disadvantage to Datlabs in its business development and manufacturing activities. Technology transfer issues also present a huge compliance hindrance with respect to the first mover advantage (UNIDO, 2010).

1.3.3 Plus Five Pharmaceuticals

Plus Five Pharmaceuticals Private Limited is a local generic pharmaceutical company in Zimbabwe. It was established in August 1996. The company embarked on a plant refurbishment project in 2009 to upgrade to GMP standards. The second phase of the upgrade was due in 2010 for utilities and the construction of a Quality Control (QC) laboratory. Again, Plus Five Pharmaceuticals does not have an independent R & D facility. Furthermore, the company does not have a fully Good Manufacturing Practice (GMP) compliant QC laboratory and microbiology activities are outsourced (UNIDO, 2010).

1.3.4 Varichem

Varichem Pharmaceuticals was established in 1985 as the first private pharmaceutical company in Zimbabwe. It was one of the leading pioneers in the manufacturing of generic antiretrovirals in the whole of Africa. The company introduced its first generic ARV in October 2003. The last quarter of 2010 saw the company becoming the first local pharmaceutical company that obtained a WHO prequalification status for its two ARVs. It was the fastest growing pharmaceutical manufacturing company until late 2006 when this development lost momentum with its product pipeline and subsequent new approvals significantly declining. In 2006 the company embarked

on upgrading of its premises so as to meet international GMP standards, including WHO prequalification project requirements with the assistance of UNDP. Varichem boasts of the strongest R & D amongst local generic manufacturers although the R & D facility needs to be upgraded to meet GMP requirements. Additional equipment and machinery is however required, especially on the manufacturing side. In addition, the company's current production equipment is more on the analytical side of development (UNIDO, 2010).

The table below is a summary of companies together the attributes of the main manufacturers that have a bearing on production of pharmaceutical products in Zimbabwe

Table 1:1 generic pharmaceutical manufacturers

company	Facility manufacturing licensing	Average age of equipment	Capital needed for additional equipment	Capacity utilization (2009)
CAPS	Approved, MCAZ, Namibia NMRC, Botswana DRU	n.a.	n.a.	20-30%
Datlabs	Approved, MCAZ, Namibia	16.5+ years (Range: 1 yr to 30+ years)	US$ 1.5 million	32%
Plus five	Approved, MCAZ	8.25 years (Range: 0.5 to 20 years)	US$ 1.5 million	17.5%
Varichem	Approved, MCAZ, MCC, Namibia NMRC, Botswana DRU	9.6 years (Range: 2 to 30+ years)	US$ 1.0 million	30-60%

Source: UNIDO (2010)

From the table above table, the figures indicate that capacity utilisation is very low and needs to be increased by boosting production. Good Manufacturing Practices (GMP) inspections are carried to ensure that facilities and manufacturing procedures meet the manufacturing standards accepted internationally. All manufacturers have a full approval of the Medicines Control Authority of Zimbabwe (MCAZ), with some even having external approvals from other countries like Botswana, but lack international approvals. International approvals, for example

from Food and Drug Administration (FDA) increase credibility to local premisesand ensure that products are easily accepted on the international markets. The capital needed for additional equipment is high which shows that the industry requires capital investment against a backdrop of liquidity crisis that the country is going through (Zimbabwe Economic Review, 2013).

1.4 Statement of the Problem

There has been a considerable decline (of thirty-three percent) in contribution to GDP from pharmaceutical manufacturing. Local manufacturers have been producing only forty-seven percent of the local demand for medicine supply both by volume and value. Low production from local manufacturers has resulted in the growth in pharmaceutical imports and the country is slowly becoming a net importer of pharmaceutical products despite having local manufacturers. Local manufacturers are plagued with very low capacity utilization of below sixty percent over the past four years to as low as twenty percent. In addition, some local manufacturers have resorted to repackaging and trading on finished imported medicines rather than production, an indication that the pharmaceutical industry could be facing production and competitive challenges which dollarization alone could not eradicate (Musundire, 2012).

1.5 Purpose of the study

The purpose of the study was to assess the effect of current production techniques on the competitiveness of pharmaceutical firms and pharmaceutical products in Zimbabwe and suggest ways in which these can be improved in order to enhance efficiency and competiveness.

1.6 Proposition

The proposition behind the study was that the productivity of the firms is constrained by inefficient production techniques andcompetitive strategies.

1.7 Objectivesof the study

The study had four objectives, which were:

1. To assess current production techniques used by local pharmaceutical manufacturers
2. To determine the current competitiveness of pharmaceutical products on the local and international market

3. Toassess theoperational factors leading to low capacity utilisation and hindering manufacturing of pharmaceutical products in Zimbabwe
4. To recommendways in which the manufacturing processes can be improved so as to meet world class standards and increase production and competitiveness of Zimbabwean pharmaceutical firms

1.8 Research Questions

The study was based on the following study questions:

1. What are the current production techniques used by local pharmaceutical manufacturers?
2. How do the current competitive strategies being implemented by local pharmaceutical manufacturers affect production of pharmaceuticals for the local and international markets?
3. Which operational factors are resulting in the low capacity utilization and hindering manufacturing of pharmaceutical products in Zimbabwe?
4. What issues need to be addressed in order to improve the manufacturing processes to increase production and competitiveness of local firms?

1.9 Justification of study

The study contributes knowledge on factors inhibiting the performance of the pharmaceutical sector in Zimbabweand makes recommendations on the measures that need to be taken to enhance the contribution of the sector to the growth of the country's GDP and improvement in the balance of payments.

This study will assist in exploring the true production and competitive advantages which the country can exploit to improve the country's pharmaceutical sector. It will also help determine sensitivity of the pharmaceutical products to the global market forces with a view of crafting policies and structures to insulate the pharmaceutical sector from unfavourable developments as well as increasing export revenues over time. In addition, the study willhelp the pharmaceutical production management and other policy makers to make informed decisions and improve quality of locally produced pharmaceutical products.

1.10 Chapter Summary

The role of pharmaceutical production contribution to GDP has declined over the period of the previous five years. Although there has been theoretical understanding of what needs to be done to boost local production, little practical issues have been implemented. The local pharmaceutical industry is lacking innovation in an economic constrained environment. Capacity utilization and ultimately production is very low and companies are opting to trade in finished imported medicines. The country is slowly becoming a net importer of pharmaceutical products despite having local manufacturers. Whilst there has been significant research on production in other economies like India and South Africa, limited research has attempted to study factors affecting productionand competitiveness in developing countries like Zimbabwe.

The rest of the study will consist of four chapters. Chapter two focuses on literature review and analysis of relevant previous studies, and then chapter three elaborates the methodology used in collecting data. Chapter four focuses on data analysis and discussion of the revealed findings. Chapter five will conclude the study and give recommendations.

CHAPTER TWO
LITERATURE REVIEW

2. Introduction

This chapter reviews literature on productivity in pharmaceutical manufacturing in relation to thecompetitive strategies and factors affecting it. The main purpose of this chapter is to get a deeper understanding of the factors affecting productivity as prescribed by theory relating them to common practice then looking specifically at these factors in other economic sectors worldwide. Thus research gaps will be identified and appropriate research theme will be developed.

The first section of the chapter presents the aspect of pharmaceutical productivity, and then a discussion on the factors affecting productivity focusing on theories and empirical studies, particularly looking at their inter-correlations and how productivity interacts with these factors. After a discussion of these factors the chapter will then look at the impact of various government policies on pharmaceutical productivity and the competitive strategies that are mainly used in pharmaceutical production and distribution of products from manufacturing companies. An analysis of the different methods being implemented internationally will then follow. Finally the chapter gives a summary of the identified literature gaps.

2.1 Pharmaceutical production

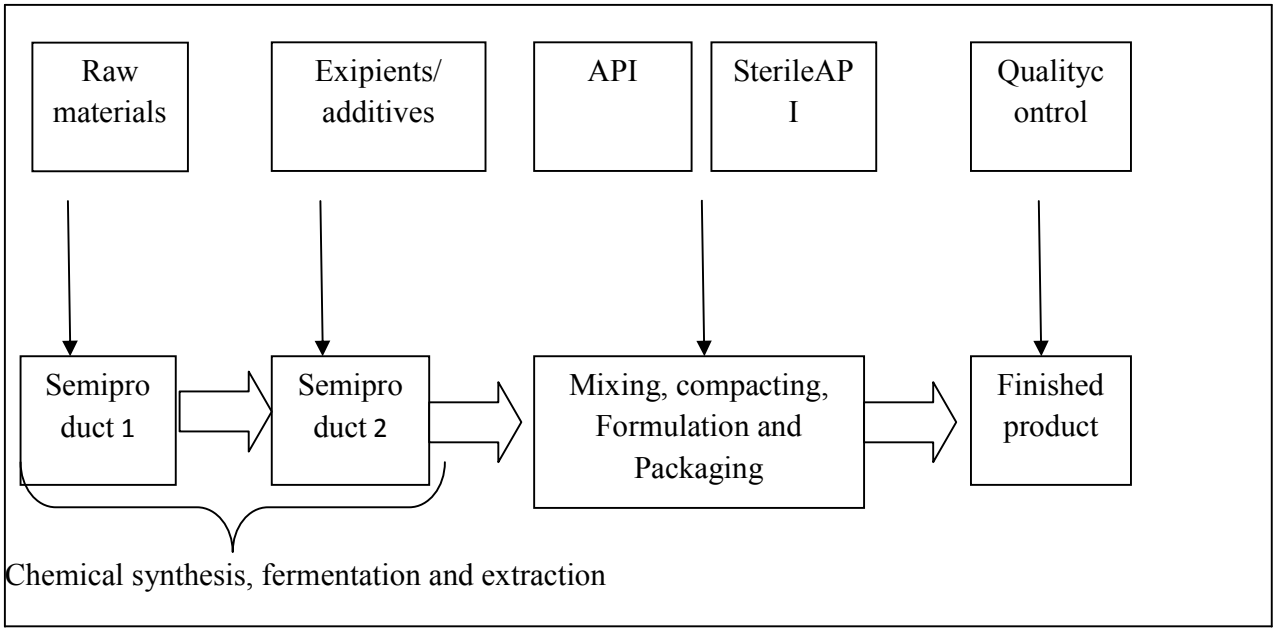
Pharmaceutical production refers to the process of mixing of an Active Pharmaceutical Ingredient (API) with various exipients to come up with medicines and drugs that would satisfy customer's quantitative and qualitative medical needs (Shekunov and York, 2000). These medical products should also be environmentally safe, meet functional requirements and as well as having minimum waste generation. Furthermore, the product must ensure optimum consumption of all resources that are required for manufacturing (Mbendi, 2009). Pharmaceutical production can be described using the following stages of production:

- primary production;
- secondary production and
- tertiary production

Shekunov and York, (2000) noted that medical drugs are rarely administered in their pure chemical substances alone and thus are given as formulated preparations or medicines. These

vary from relatively simple solutions to the complex drug delivery systems through the use of appropriate additives in the formulations. Manufacturing requires technical and financial resources such that no country is self sufficient as far as pharmaceutical production is concerned. Even those countries that have more pharmaceutical exports than imports still rely on imported Active Pharmaceutical Ingredient (API) (World Bank, 2005). The process pharmaceutical production is outlined below

Figure 2:1the pharmaceutical manufacturing process



Source: Source: Kaplan and Laing (2005)

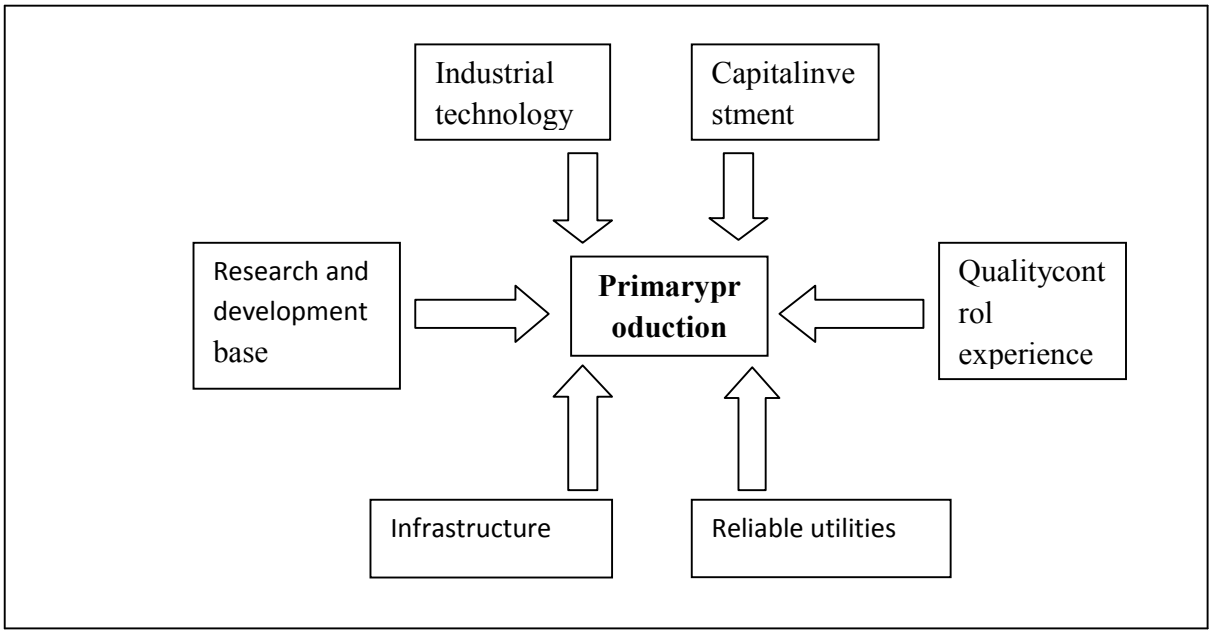
The figure above shows the various stages of production in which raw materials are converted into semi products which are further processed through mixing, compacting and formulation to produce the final product. Highly mechanised equipment will be used at each production stage and these enhance production efficiency and facilitate economies of scale.The exipients or additives will provide varied and specialized pharmaceutical functions. It is the formulation additives that will solubilise, suspend, thicken, modify dissolution, improve the compressibility and flavour the drug substances to form various preparations. The primary objective of dosage form design is mainly focused on achieving a predictable therapeutic response to a drug that is included in a formulation which is capable of large scale pharmaceutical manufacture with reproducible product quality.

Multinational companies have substantial abilities in primary and secondary production activities and have used this ability to globalize their manufacturing operations (UNIDO, 2010). There are three distinctive types of production that are primary, secondary and tertiary.

2.1.1 Primary production

Primary production involves the processing of raw materials to produce an active pharmaceutical ingredient (API) used in pharmaceutical formulations. Primary manufacturing involves biological or chemical processes that require various skills, knowledge and technology in appropriate facilities. Process development, capital equipment and quality assurance systems, makes the manufacture of active ingredients the most expensive pharmaceutical aspect. Sophisticated products require modern skills, industrial technology and infrastructure that is normally absent in low to medium income countries.Mohammed (2009) identified the factors that affect primary production which can be summarized as below

Figure 2:1 factors affecting primary production



Source: Mohammed (2009)

2.1.2 Secondary production

Secondary manufacturing deals with the production of finished dosage forms such as capsules from raw materials from both local and imported sources. This type of production is less technically demanding than primary manufacturing, but should be completed to precise specifications. Main factors of this stage include high speed precision equipment for mass production and meeting international GMP standards.

2.1.3 Tertiary production

This stage of production involves packaging and labelling of finished products into bulk packs for wholesalers and small packets for individual usage. There is need to maintain the initial quality of product that has been incorporated from the primary and secondary stages. Tertiary production is also important in job creation and addressing of local specifications for certain preparations in terms of labelling and packaging (Mohammed, 2009).

Although most countries are part of the global pharmaceutical market, very few are self sufficient. This is because raw materials are produced and traded in the same way that commodities are produced. This makes these raw materials the basis of the industry backbone. Countries, even the largest, are bound to acquire some raw materials at some point in their manufacturing activities which makes the whole process a matter of competitive advantage rather than imaginary independence. Pharmaceutical production standards entitled Good Manufacturing Practices have been adopted by the World Health Organisation (WHO) and the pharmaceutical industry as quality requirements aimed at consistent production and meeting product specifications (UNIDO, 2010). Countries often go the extra mile of ensuring quality through higher manufacturing standards due to the fact that obtaining an export market demands extensive compliance with international good manufacturing practises.

2.2 Concept of productivity in pharmaceutical production

The term ‘productivity’ was coined back in 1776 denoting the efficiency with which a product is produced by the resources utilizing the available resources like power, time and money to achieve the higher production of products (goods and services) at the lowest cost (Sontakey 2000).

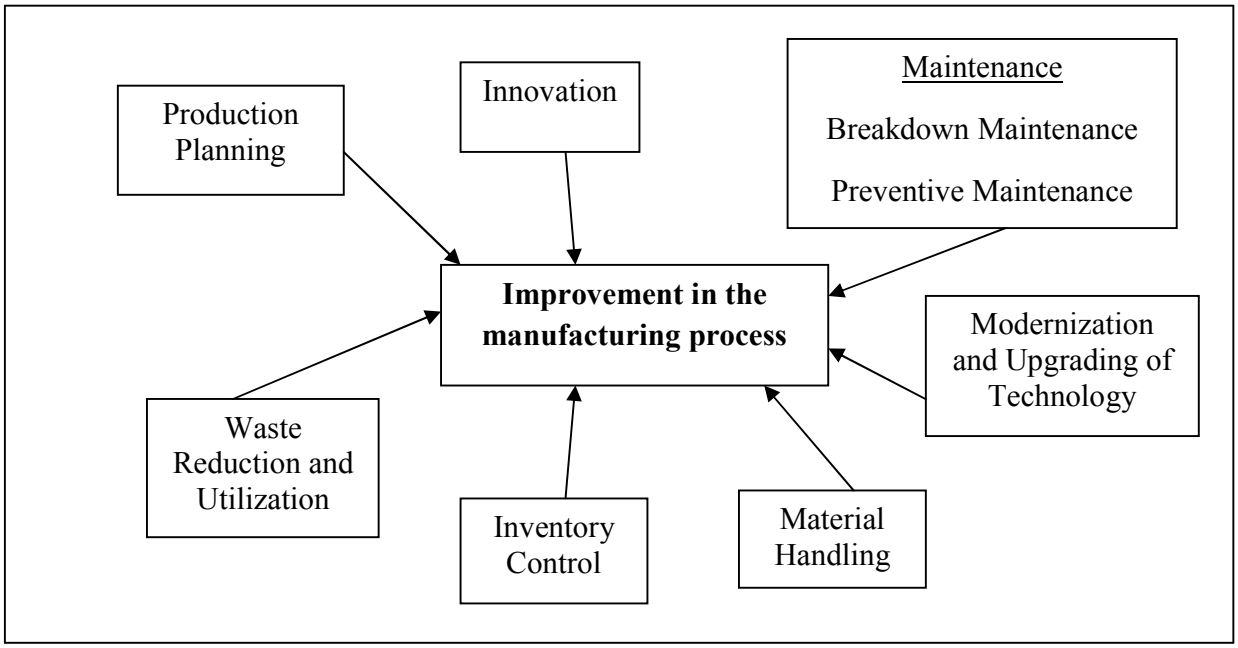
Pharmaceutical production is basically evolving from a historical art form to one that is now based on science, engineering and technology. Heskett (2003) highlighted that when this

knowledge is effectively used in evaluating manufacturing processes, it can substantially improve the efficiency and productivity of the whole manufacturing processes. The term productivity denotes the ability to do things better today than they were done yesterday and continuously. Patil and Prakash (2011) went on to add that productivity is the ultimate key to success and sustainable growth in every sector of economic activity. Superior productivity benefits every individual irrespective of works, the result being national prosperity (Vaughan, 2010).

2.3 Improvement in theproduction process

Efficiencyand effectiveness of manufacturing is of paramount importance in the smoothand economical running of the entire productionsystem. If the productionprocess is poorly organized, wastage of time, constant disruptions may result in poor quality of products which is accompanied with the escalation of costs (Patil and Prakash, 2011). The figure below points out issues that need tobe considered as far as improving themanufacturing process is concerned.

Figure 2:1 Factors in the improvement of the manufacturing process



Source: Patil and Prakash (2011)

Figure 2.3 shows the various factors that influence the manufacturing process in the pharmaceutical industry. Production planning satisfies requirements of the marketing department

through provision of quantities and products on demand at the highest level of manufacturing efficiency (Kaplan and Laing, 2005). After formulation, the production planning should be strictly and constantly followed for the effectiveness of the actual manufacturing performance.Mbendi (2009) went on to add that machine maintenance is of paramount importance since it provides a means of plant and equipment maintenancethereby enhancing the manufacturing process.

In Breakdown Maintenance, the equipment is repaired when it breaks down such that there is urgency to restore the running conditions of the machine. As a result, the machine might not receive adequate maintenance. Preventive Maintenance involves constant inspection of the machine condition and carrying out preventive action so as to reduce the chances of breakdown.Waste Reduction and Utilization should be practised by all individuals through optimum efficient resource consumption and preventing wastage of material (Maloney and Segal, 2007).

Material handling should be focused on increased output and the subsequent cost reduction through the use of personnel protective equipments in the handling of hazardous materials. Principles on material handling must be followed with respect to time & distance of each movement. In possible situations, gravity should be used since it provides a cheap source of motive force (WHO, 2010).Inventory control determines the quantity of resources that are kept in stockat any particular moment. The main aim of inventory control is to ensure that adequate inventory is available for production and prevent overstocking.World Bank (2005) went on to note that modernization and upgrading of technologyleads to increasedproduction efficiency and elimination of waste. Innovation as aprocess of creates new and improved drug product with superior quality and low production costs.

Since the 1980's, local governments and international organisations had been promoting the idea the manufacturing capacity in developing countries with the aim of increasing medicine quality, creating new jobs. Furthermore local production was believed to enhance the countries' efficiency in pharmaceutical supplies and acquiring foreign currency through exports World Bank (2005). This was later disputed by WHO (2010), in its report suggesting that even with the

enthusiasm on the role of pharmaceutical manufacturing, technological requirements and economies of scale requirements where hampering this idea of local production.

Patil and Prakash (2011) suggested that improvement in productivity will result in increased income, reduction in running operational costs, efficient use of resources and increase in market share for the organisation. Manufacturing plants need to be operated at peak performance in order to maintain their profit margins and productivity. Equipment utilization can be improved thus reducing changeovers. Automation andreview of all personnel policies ensures that the manufacturing plant operates with an optimum number of personnel. Staff should be trained in Good Manufacturing Practices and as well as Internal Quality Audits requirements. This ensures that drugs will be manufactured to appropriate GMP quality standards (WHO, 2010).

2.4 Production techniques in pharmaceutical manufacturing

The role of current Good Manufacturing Practices (cGMP) in the pharmaceutical industry has resulted in its world over usage. Boppanaand George (2011) analysed and gave a critique of the link that exists between current Good Manufacturing Practices and Lean Manufacturing. They went on to refer to a definition by the World Health Organization (WHO) (2010) that defined cGMP as theQuality Assurance that ensures products are produced consistently in a controlledprocess tomeet the quality standards appropriate for their intended usage as required by the customer.Pharmaceutical production is embedded with stringent quality and standard measures due to its delicate materials involved that affect human health and lives as a whole. These standard measures in manufacturing have been necessitated by thecGMPs issues which by nature are regulatory (UNIDO, 2010).

Apart from meeting regulatory requirements, manufacturersneed to engage in self imposed performance and improvement strategies which include LeanManufacturing.As noted by Greene and O'Rourke (2006), the pharmaceutical industry was laggingbehind as far as the implementation of lean principles in favour of cGMPs is concerned. The comparison shows that cGMPs focuses on production as a means to manufacture safe and effectiveproducts for the patient while lean manufacturing is focused on production as a locus forimprovement and value creation from the patient's view. The study led to the conclusion that in a pharmaceutical manufacturing environment, both cGMP and leanmanufacturing practices must be equal

partners. Both should be embedded in the culture of themanufacturing organization and thus must be reflected in the company's business strategies.

In pharmaceutical manufacturing, quality standards are very stringent as good manufacturing practices focuses mainly on the manufacturing of safe and quality products (Greene and O'Rourke, 2006). Manufacturing industries around the world are being affected profoundly by emerging technologies resulting in a significant increase in competition in local, regional and global markets. Berry (2008) summarized the cGMP regulations for finished pharmaceuticals to be the minimum good manufacturing methods to be practised in the facilities and controls that are used for the manufacturing, processing and packing as well as holding of a drug in such a way to ensure that such drug does meet the safety requirements.

2.5 GMP role in enhancing production techniques

GMP enforces the notion that the pharmaceutical production process requires a full definition before being started with allthe necessary facilities having been provided. Lund (1994) noted that in real practice, personnel should be well trained,approved standard proceduresfollowed and recommended storage and transport facilities being made available or an efficient production process.The production techniques applied in Good Manufacturing Practices (GMP) are summarized below

2.5.1 Quality management

Authorized manufacturersshould produce medicinal products at the same time ensuring their intended use, compliance with the GMP requirements thusprotecting the patients from the risk due to inadequate safety and poor efficacy. To achieve this objective, there is need for senior management and staff commitment and participation in conjunction with the manufacturers' distributors and suppliers (EudraLex, 2012). Quality managementin the pharmaceutical industry is focused on the aspect of management operations determining and implementingthe quality policywhich dictates the overall direction of an organization with respect toquality production (WHOTRS 961, 2011).

2.5.2 Quality Control (QC)

Stubbs (2008) noted that Quality Control is concerned with the sampling of products, specific tests, documentation and the subsequent release procedures that ensurenecessary and relevant product tests are conducted such that materials are only released foruse, sale or supply whentheir absolute quality has been confirmed to besatisfactory. Quality control should not only be limited to laboratory operations, but should be involved in various operations involving product quality (Miller, 2008). QC in its full strength will also focus on duties that include establishing, validating and implementing of all QC measures involved in the evaluation maintenance, andstorage of the reference standards for medicinal substances. Furthermore, it ensures correct labelling of drug containers to ascertain the monitoring and stability of the important active pharmaceutical ingredients (APIs). Theseoperations must be carried out in with respect to written procedures and recorded where necessary (WHOTRS 961, 2011).

2.5.3 Sanitation and hygiene

High sanitation and hygiene levels must be observed in every discipline of themanufacturing process of medicinal products. The concept of sanitation and hygiene involves aspects such as personnel, equipment and apparatus, products used in cleaning and disinfecting, and as well as anything that has the potential of becoming a source of product contamination (WHO, 2010). All potential contamination sources must be eliminated by means of an integratedand comprehensive process of good sanitation and hygiene. It should also be ensured that the premises to be used in the manufacturing process and storage of the drug product be maintained in a confirmed clean andsanitary condition as suggested by Greene and O'Rourke (2006).

2.5.4 Personnel, training and personal hygiene

Sharp (2005) proposed that it is the ultimate quality of the personnel that has a ripple effect on the quality of the product that they produce. This is because of the fact that establishing a satisfactory quality assurance systemand correct manufacturing and control of pharmaceutical products greatly depends on people carrying out the process. It is for this reason that sufficient qualified personnel should be made available to execute all theprocedures for which the manufacturer is entirely responsible for (Berry, 2008). Responsibilities have to be clearly defined and comprehended by the personnel involved and written down as job descriptions (WHOTRS

961, 2011). All personnel should be made aware of the vital principles of GMP affecting themand thereby made to receive training and as well as hygienic instructions that is expected of them (Sharp, 2005). High levels of knowledge and experience allows the effective monitoring and control of all GMP processes in a pharmaceutical manufacturing facility.

2.5.5 Documentation

Proper documentation is an important aspect of the Quality Assurance system and thus should exist for allthe processes of GMP. WHO (2010) suggested that documentation is aimed at definingthe specific procedures involved in the control and manufacture of all materials andmethods. It ensures that all the authorized personnel involved in manufacturing have the expertise, knowledge and access to allthe information required in deciding whether to release medicine for sale. The personnel should also ensure the compiling of documented evidence and records that will permit investigation if anything goes wrong in the manufacturing process. Documentation also ensures the accessibility of manufacturing data that is needed forprocess validation, review and product statistical analysis (WHOTRS 961, 2011).

In Good Manufacturing Practices, the drug should possess the identity and strength, quality and purity properties that it purports or is said to possess. This was also further echoed by Eatock et al (2009) who added that thecGMP covers other aspects of the manufacturing process which include a specificmanufacturing process, validation of critical manufacturing steps and suitable transport, premises and storage. This has lead to a number of federal regulations world over that relate to cGMP which can lead to criminal penalties if not diligently followed. Furthermore, selling of products in US markets requires approval from the FDA, which makes the whole aspect of international inspection and approval very significant for exporting countries (Greene and O'Rourke' 2006). Moreover, the WHO (2010) presented the concepts of quality assurance (QA), GMP, and quality control (QC) as important interrelated aspects of quality management.

Their fundamental importance to the manufacturing and control of pharmaceutical products goes beyond ensuring adequate confidence that a manufactured drug product will satisfy the given requirements for quality. Further, the report articulates that quality is not only tested in a finished drug product, but is built right into it from the start. This is achievable through several ways which include production facility control, starting materials, stages of production, product testing methods, identity of materials through adequate labelling and the controlling of storage, etc (Berry, 2008).

Stubbs (2008) further emphasized the importance of the compliance regulations of Food and Drug and Administration's (FDA's) initiative which has the ultimate business goals of boosting efficiency and reducing costs.To achieve product and process quality in pharmaceutical manufacturing plants, Miller (2008) recommends a holistic and approach in incorporating the basic lean manufacturing principles and practices. This will assist in the elimination waste products both from within the firm and across the overall value chain (Sua´rez-Barraza and Ramis-Pujol, 2010).

2.6 Lean manufacturing as a production technique

Pharmaceutical manufacturing companies have come to the recognition that it is the consistent and disciplined application of the lean manufacturing strategies that can lead to business excellence through the emphasis on waste elimination and vital process streamlining (Mejabi, 2003; Taj, 2008). The same sentiments were echoed by Rahman et al (2010) who identified Lean Manufacturing as a vehicle aimed at attaining World Class production statusthrough the extensive elimination of all kinds of waste. Lean manufacturing paradigm is based on the record fundamental goals of Toyota Production System (TPS), which were aimed at continuously minimizing waste and subsequently maximize flow (Vinodh et al, 2010).

Womack et al (2007) further notedthat the concept of lean manufacturing is mainly based on Just-In-Time (JIT) principles introducedto describe the philosophy and practices of the TPS. Seth and Gupta (2005) went on to note that Westernautomobile manufacturers who had applied the concept in mass production benefited from thereduction of lead times consequently improving in flexibility (Womack et al, 2007). It was thus establishedbeyond doubt by Womack et al (2007) that the companies that had mastered lean manufacturingpractices had substantial cost and quality advantages compared to those that were still practicingtraditional mass production.Waste consumes resources but does not add any value to the product.

The seven most common wastes according to TPS are: transport; unnecessary inventory; overproduction; waiting; inappropriate processing; waste of motion and defects (Ohno, 1988). This was later endorsed by the study of Hobbs (2004). In this theory, work cells are arranged to

facilitate one-piece flow production with the close arrangement of people, machines as per the processing sequence (Dolcemascolo, 2008; Satoglu et al, 2010).

In the same vein, Ohno (1988) emphasized on the fact that any humanactivity absorbing resources but at the same time creating no value deserves to beeliminated. This goes hand in hand with the principles behind lean that are basically the integrated set of activities that aredesigned to achieve maximum production coupled by the use of minimum inventories of raw material as well as work-in-progressand finished goods(Womack et al, 2007). It is these lean principles that have beenapplied extensively to different manufacturing and operations environments yielding higher productivity in pharmaceutical manufacturing.

2.7 Challenges in pharmaceutical production

The history of entrepreneurship was developed by Marshall (1890); who initially identified the necessity of entrepreneurship in production. He concluded that there are four production factors which are: capital; land; labour and organization. Of the four, organization becomes the coordinating factor. This is because it brings the other factors into interaction. Marshall went on to assert that entrepreneurship is the driving force behind organization. Later on Knight (1921) defined entrepreneurship as the ability to deal with uncertainty, differentiating risk, which can be calculated from uncertainty which cannot. Schumpeter (1934) went on to define an entrepreneur as the undertaker of change and economic development whilst and entrepreneurship to be the undertaking of new business ideas and combinations. In the same vein, Srivastava and Gnyawali (2011) proposedthe notion that socio-economic conditions and government policies have an important role in enterprise propensity. They went on to suggest that factors that include support from government agencies are responsible for the creation of enterprise culture which allows manufacturing firms to take reasonable risk, at the same time seeking profits.

Business environment of a manufacturing entity consist of both the internal and external factors affecting the performance of the organization.Patil and Prakash (2011) suggested that the factors that affect pharmaceutical productivity can be classified into two categories which are the internal and external factors. External Factorsare factors from outside the organisation and Internal Factors are from within. The internal factors are further classified into Static Factors and Dynamic Factors. Static factors are usually difficult to change.

High productivity in a manufacturing entity mainly depends on internal factors whereas efficiency of the organization at large is based on the overall efficiency of each individual internal factor. Delmar and Wiklund (2008) went on to note that the business environment has a considerable impact on business performance. In addition, Smith (2007) went on to define business environment as all factors, both internal and external, that influence the continued existence of the entity. Beck (2006) went on to note that for organizations to achieve their business objectives there is need to strengthen both their internal and external business environment.

The external environment is made up of the initial conditions facing entrepreneurs in every economy (Aldrich and Kenworthy, 1999). These environmental conditions play a significant role in resource-based theory in relation to an organisation's performance. Inthe behavioural based approach, issues which includemotivation, personality and attitudes of the entrepreneur all dependent on the business environment (Gartner, 1985). The resource-based theory suggests that the firm's resources form the basis for achieving success (Lerner and Almor, 2002). Hardly imitational and rare tangible and intangible resources are valuable (Barney, 1991) and can be productive on their own.The firm's capabilities are based on resources which form the driving force behindthe competitive advantage to execute a certain task or activity. These factors can be analysed as below:

2.7.1 Research and Development (R&D) and Patenting

Barney (2002) proposed that a firm's competitive advantage is mainly centred on its innovative strategy. In the same vein, Lund (1994) had previously stated that the innovative strategy helps in the development of superior new products and technologies with well-defined competitive advantage especially in the knowledge intensive disciplines such as the pharmaceutical industry. This industry requires firms to be continuously innovative through development and marketing of new products, product attributes and pharmaceutical drug delivery systems, using cutting-edge technological advances to achieve growth and survival national and global levels.

A study on Indian D&P industry showed that low R&D intensity was attributable to the fact that Indian leading pharmaceutical manufacturers focused on the generic production drugs through non-infringing processes until 2005 (Miller 2008). This was also supported by Musundire (2012) who suggested that generic drugs required low levels of capital investment as compared to the

process of developing, testing, production and marketing of the new novel and drug delivery systems (Miller, 2008; Mejabi, 2003,). Business environment induced changes saw the firms starting to invest more resources towards R&D processes as part of an inevitable strategic shift. Large sized, shifted their focus on Novel Drug Delivery Systems (NDDS) as well as expanding their manufacturing plant or facilities through importation of technologically advanced capital goods. These firms generated patents in order to acquire knowledge stock as their future bargaining leverage in pharmaceutical production (WHO, 2010).

In a study in South Africa, it was found out that pharmaceutical growth could be achieved through manufacture of generic antibiotics and over the counter drugs whose patents are expiring soon, yet their demand was on the rise (UNIDO, 2003). In addition, growth was also achieved through a number of mergers and take-overs, because of the need for the industry to restructure in order to meet competitive challenges. In that setting Multinational pharmaceutical companies were found continue to dominate the industry (Mbendi*,* 2009*)*.

The locally produced medicines were mostly generic, and the majority of the production facilities were privately owned; accounting for a small proportion of national requirements (WHO, 2005).Research showed that there is limited local production of generic active ingredients, however drug formulation and last step synthesis was found to be common among the local subsidiaries of multinational drug companies (Mbendi, 2009). A World Bank (2005) study showed that locally owned South African manufacturers obtained thirty-nine percent of active ingredients, ninety-seven percent of packing materials and forty-nine percent of exipients locally. On the contrary, local subsidiaries of multinational drug companies at the same time secured one and half percent of active ingredients, thirty six percent of packing materials and twenty percent of exipients locally. The externally sourced inputs mainly came from India and China (Kaplan and Laing, 2005; Maloney and Segal, 2007). In addition, the study showed the potential for growth through technological transfer facilitated by mergers with foreign investors.

2.7.2 Human and physical infrastructure

The pharmaceutical sector is believed to have a highly trained labour pool and produces high quality drugs which are competitive even on the export market. Some of the companies even boast of modern production methods (UNIDO, 2010). Rodriguez and Rodrik (2000) reported that productivity in the manufacturing sector has been believed to be undermined by lack of new

investments, macroeconomic instability, leaving companies to operate with old and obsolete equipment, some of which was commissioned as far back as 1950s. Such a situation could only promote un-competitiveness on both the domestic and export markets.

The global pharmaceutical industry since the 1990s has been experiencing a shift in industry dynamics stemming from both a shrinking drug pipeline and rising drug development, and production costs. Consequently, most companies have found themselves consolidating their production and manufacturing activities through mergers and acquisitions. This has created "centres of excellence" in a few countries which are characterized by large, low-cost units that are logistically well-placed areas that are attractive to service major markets. Major global pharmaceutical manufacturers like India and China been positively affected by this trend (Maloney and Segal, 2007).

Olcay and Laing (2005) suggested that low income countries have a primary constraint of the ability to possess and retain skilled workers especially engineers and scientists. The issue of quality assurance, meeting GMP standards and regulatory compliance are considered as key especially in fixed dose combinations where technical expertise is important. In the same vein, Stevens and Linfield (2010) added that functional utilities play a significant role in pharmaceutical manufacturing. Utilities that include electricity, gas, water and a sound road network usually form the basis of production. A good road network ensures transportation of raw material and labour to the facilities and at the same time finished good away from the same facilities. In addition, if raw materials and spare parts are not available locally, they have to be imported from countries that have vibrant pharmaceutical industries (UNIDO, 2003).

2.7.3 Regulatory and legal provisions

Pharmaceutical regulation prohibits dangerous and unproven manufacturing of medicines at the same time promoting the availability of quality, safe and effective medicines (WHO, 2007). Long processes of registration and corruption can sometimes limit the manufacturer's interest in producing the same product. An increasing motion now exists in establishing GMP concept and as well as enforcing it due to globalisation of the pharmaceutical sector. Olcay and Laing (2005) in the same vein noted that standards enforcement is therefore carried out through inspections of manufacturing facilities by local authorities. This ensures export business especially if the home authority is considered credible by the international market. This adherence to GMP comes as a challenge to many developing countries as it increases the operating cost of a manufacturing

company. Consequently, the manufacturers tend to relax in their adherence if the local authorities are weak in enforcing GMP. When these GMP standards are poor, the product faces scrutiny on the international market resulting in exports from that country being rejected by the international market (UNIDO, 2010).

2.7.4 Economic incentives and disincentives

Mohammed (2009) suggested that raw materials for pharmaceutical manufacturing as well as the Drug Master Files are traded internationally as competitive commodities. Rapid and reliable access to information and foreign exchange is of paramount importance for any producer. Preferential tax treatment as well as local production incentives may facilitate reduction in production costs through measures such as tax abatement, assisted capitalisation and direct subsidies (UNIDO, 2003). This is however in contrast to the fact that the incentives that are used to boost exports from the local manufacturers do not positively affect pharmaceutical production from a developing country since this is dependent on external demand of that particular country's medical product.

2.7.5 Duties and import controls

Mohammed (2009) identified that differential taxation in pharmaceutical raw material and finished products tend to have a significant impact on local production. If the priority is to creation of a level as far as competition is concerned, then there should be equal treatment of raw materials and finished goods as far as tax considerations are involved. This is because higher taxation on production raw materials and packaging materials normally results in retarded local industrial production and development. In the efforts to reduce this challenges, the Organisation for Economic Co-operation and Development (OECD) countries resolved in reaching a consensus to abandon tariffs on a specified list of active pharmaceutical raw materials to facilitate trade between the countries (Stevens and Linfield, 2010).

2.8 Market strategy and competitiveness

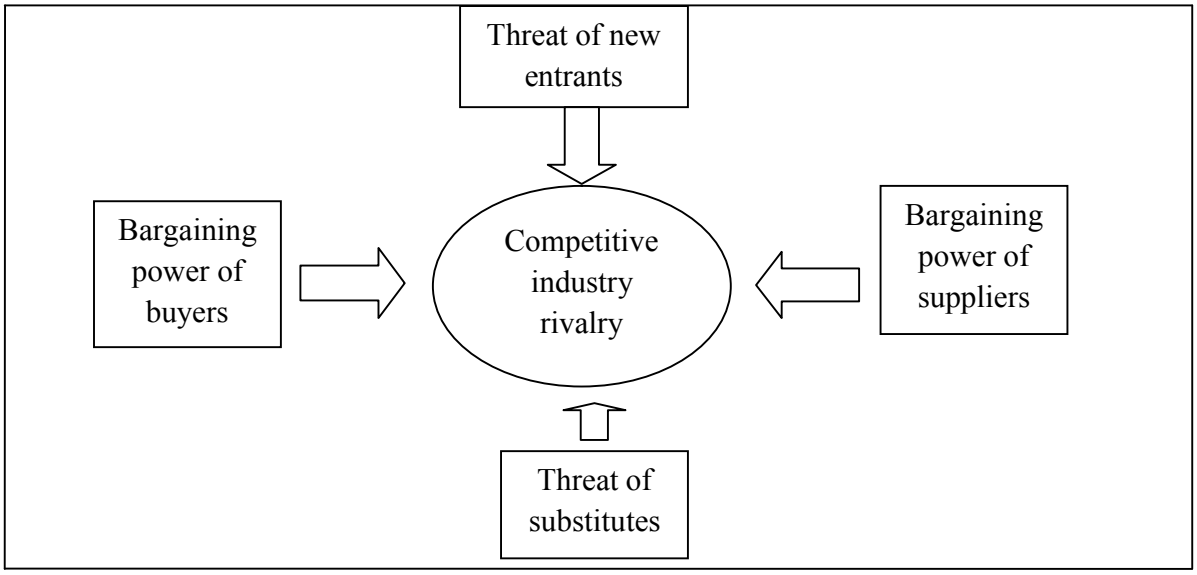
The competitive strategies implemented by an organisation are mainly based on consumer demand in order to win customers and gain market competitiveness. This requires the manufacturer to select a proper competitive strategy that is in line with consumer demand. The principle of economics states that the consumer's demand is depends on the consumer's capacity to pay and desire to purchase (Barney, 2002).Thus the focus of having a competitive strategy lies in the desire to stimulate motivation as far as consumer's purchasing behaviour is concerned.

The motivation to purchase by a consumer is based on two factors: the value of the product and selling price of the same product. The product value includes the useful value, after-service facilities and product quality. For consumer's purchase motivation to occur, the value of the product as perceived by the consumer should be higher than the product selling price such that the higher the difference the higher is the product demand. There are two competitive strategies as identified by Porter and Teisberg (2006) namely cost leadership and product differentiation.

2.8.1 Cost leadership strategy

The objective of the cost leadership strategy is clearly based on the overall industry cost leadership as far as product cost is concerned (Akan*et al*, 2006). Acquiring cost leadershiprequires aggressive building of efficient scale facilities coupled with vigorous cost reductions gained through experience. Cost control is brought about by tight overhead cost control, and minimizing cost that include sales force and advertising. Low product costs relative to a competitor forms the basis on which cost leadership strategy may be used generate superior profitability over competitors. As suggested by Porter and Teisberg (2006) a low-costposition is meant to give a manufacturer some defence against competitor rivalry since a lower cost meansthat the manufacturer still earns a good return after its rivals have used their profits through competitiverivalry and mitigation of possible market forces summarized in figure 2.5 below that affect any industry.

Figure 2:1 Market forces affecting an industry



Source: Porter and Teisberg, 2006

Manufacturers' low-cost position forms protection against powerful buyers since buyers can only use their power to bring prices down to price level being offered by the next most efficient rival manufacturer (Barney, 2002). Against powerful suppliers, low cost provides a more flexible margin that can upset increases in input. The cost advantage and scale economies then will provide substantial barrier to entryplacing the manufacturer in a competitive position relative to its industry competitors. Barney & Hesterley (2006) went on to identify main sources of cost advantages that include size differences coupled with economies of scale, experience, access to productive inputs, technological advantages and policy choices. Thestudy went on to state that a valuable cost leadership strategy can be used in the creation of a sustainable competitive advantage if the strategy is rare and as well as costly to imitate.

2.8.2 Differentiation strategy

Grant (2005) proposed that differentiation strategy is focused on creation of a product or service that is perceived by the entire industry as being rare and unique. This can be achieved through various methods that include, brand image, technology, and dealer network. To implement differentiation, a manufacturer may directly focus on product attributes, or focus on its relationship and its customers through product customisation or focus on the linkage between firms including viable distribution channels and service support. Barney & Hesterley (2006) in the same vein mentioned that product differentiation by a manufacturer is an expression of the level of creativity within the company. This creativity is only limited by the existing opportunities and potential opportunities that can be created in a specific industry and ability of the manufacturers to explore ways of exploiting the available opportunities.

Porter and Teisberg (2006) stated that a differentiation strategy can be used to generate superior profitability by providing insulation from competitive rivalry through customer brand loyalty and the resulting low sensitivity to prices. Margins can be increased thus avoiding the need for a low-cost position in the industry. Higher margins yielded from differentiation deals with supplier power whilst mitigating the power of buyers since there are no comparable alternatives which result in subdued price sensitivity.

In addition to reduction in the five threats, differentiation can be used by a manufacturer to create value and thus enabling a manufacturer to charge a premium price greater than the normal extra cost that is incurred by the process of product differentiation. Barney & Hesterley (2006) went on to add that rarity of a unique differentiation strategy is based on the individual firms' ability to create and finding new avenues as far as differentiation of their products is concerned. Creative manufacturers are innovative enough to differentiate themselves from their potential competitors. As competitors try to imitate the manufacturers' last differentiation move the innovation of the manufacturer allows them to be working on the new move thus maintaining the manufacturers' position one step ahead of potential competition (Lumpkin et al, 2002).

Creation of an effective brand cognisance facilitates better product pricing with the overall marketing mix resulting in dynamic modelling that depends on feedback from the consumer that can be used in improving a product in the long run as well as facilitating launches of an upgraded product.

2.9 Existence of foreign markets for market expansion

As noted by WHO (2007), the size of population and its distribution that determines aggregate demand of medicines in any economy. Difficult economic environment may result in low disposable income and government expenditure on health demands even if health aspirations are relatively in that economy. This comes in the backdrop of developing countries' economies that cannot absorb all the medical output from their domestic production even if this production is to scale (Stevens and Linfield, 2010). Therefore the manufacturer in this situation may need to consider export markets where there are sophisticated market networks and compulsory quality standards, the Good Manufacturing Practises (GMP). Establishing barriers to import through high taxes on finished good and embargoes on imports may help local manufacturers initially in the short term, but will result in high prices for the final consumer due to monopoly and make the local manufacturers uncompetitive internationally as far as prices are concerned (Mohammed, 2009).

The pharmaceutical manufacturing industry faces strict global regulation and is comprised of highly competitive companies. In this global market, Research and Development (R&D)

activities have a significant role as far as product development is concerned, a discipline that is important to companies involved in the export of pharmaceutical products. On a study on the Swedish industry, the export market share of pharmaceuticalsdecreased from four point six percent in 1997 to three point seven percent in 2003 as compared to the total exports in the Organization for Economic Co-operation and Development countries (OECD, 2007). The other major exportingcountries as far as pharmaceutical products are concerned in the world are summarized in table 2.1 below:

Table 2:1 Major global pharmaceutical exporting countries

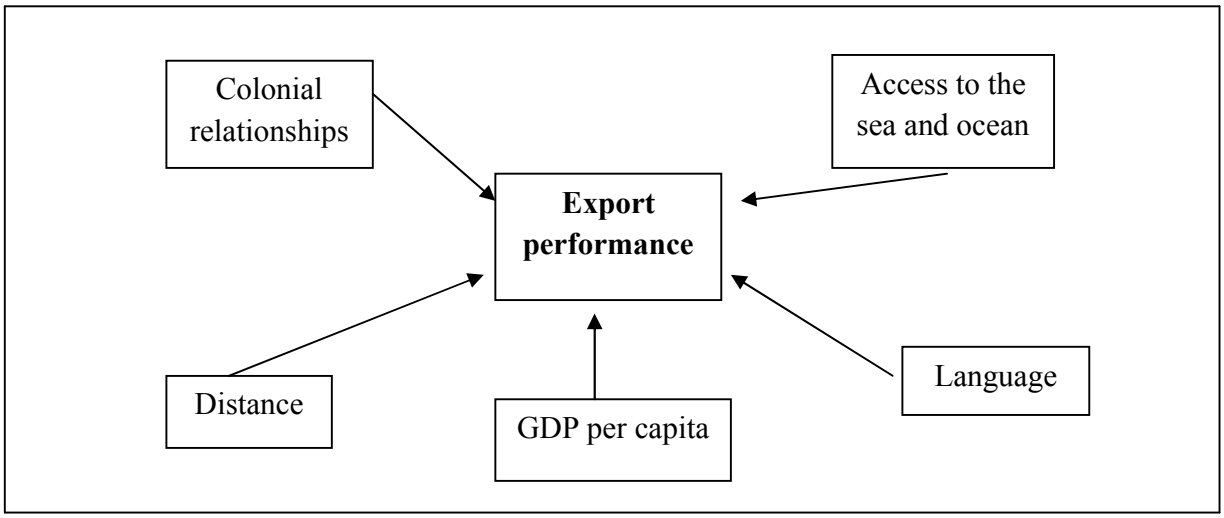
Country	**Exports to global markets**
Belgium	14.3%
Germany	12.5%
UK	10.7%

Source: OECD, Statistics (2007)

Hallak (2006) estimated pharmaceutical trade flows involving 60 different importing and exporting countries in 1995 and confirmed the notion that rich countries traded with other rich countries with respect to economic performance. Distance was found to be having a negative influence on trade whilst a common border, common colonial relationships and a common language encouraged pharmaceutical trade as a result trade cost reduction. Andersson (2007) went on to analyse the factors that affected Swedish pharmaceutical exports to 150 foreign countries and had the same findings with previous studies. The total export from a country increased with GDP and at the same time decreased with distance as expected. The study also confirmed that a country without borders to the sea and ocean reduced trade because of higher transport costs as compared to shipping costs.

It is therefore important to identify the various factors affecting pharmaceutical exports for a country to continue being amajor exporter of pharmaceutical products (World Bank, 2005). These factors can be summarized in figure 2.5

Figure 2:1 Factors affecting pharmaceutical export performance



Source: Hallak (2006)

Figure 2.7 summarises the factors that Andersson (2007) proposed to be affecting export performance of pharmaceuticals. In his analysis of trade flows between countries, the study showed that manufacturing countries with equivalent GDP per capita tradedmore with each as compared to othercountries with richer or poorer economies than the country that is exporting. In addition, distance was also found to have a much significant role. This is because foreign buyers may not beaware of such market opportunities from distant countries. Several historic authors, Sinai (1970) andTesar (1975) suggested that a country usually start exporting to the countries of physiological proximity and then expanding their products markets to countries that are physiological furthest. Johansson andWestin (1994a) went on to examined how the affinities and barriers influences trade flows. They concluded that countries with similar pharmaceutical affinities traded more together.

In another study, Johansson and Westin (1994b) analyzed the attributes that affected Sweden's pharmaceutical exports for the 1970 to 1987 period. The results concluded that distance played an important factor in export performance. Furthermore Hacker and Johansson (2001) language and common border also played a part in export performance of a country. The trade flows were found not to be symmetric despite the strong affinities between the countries meaningtrade levels were not equal in both directions.

The study from Hacker and Johansson (2001) was later on echoed by Hacker and Einarsson (2003) after they carried out a study on 19 Europeancountries for the 1993 to 1996 period. The study findings were in line with both studies and theory previously. Pharmaceutical exports were found to decrease with distance and at the same time increasing with other variables that include common border, population distribution and GDP per capita.

2.10 Identified gap in the body of literature

Although there are previous extensive studies on factors that have a negative influence to affecting pharmaceutical productivity and export performance on pharmaceutical products, little has been done on factors that actually promote manufacturing and export performance Patil and Prakash (2011). Even landlocked countries have been involved in export trading despite distance being a barrier in export marketing as shown by studies before Hallak (2006) which shows that there are other factors that actually promote export performance of a country despite it having a number of factors against it. Whilst most studies on pharmaceutical production and export performance have been done in developed and advanced economies, very little attention has been given for developing economies like Zimbabwe where Good Manufacturing Practices and regulations have been noted to be poorly adhered to (UNIDO, 2010). Very little attention has been paid to production factors specific to the pharmaceutical sector such that the factors have rather been generalized across the whole industry divide in developing countries, in this particular case, the Zimbabwean industry.

2.11 Identified study theme

Figure 2:1 manufacturing techniques in Good Manufacturing Practice

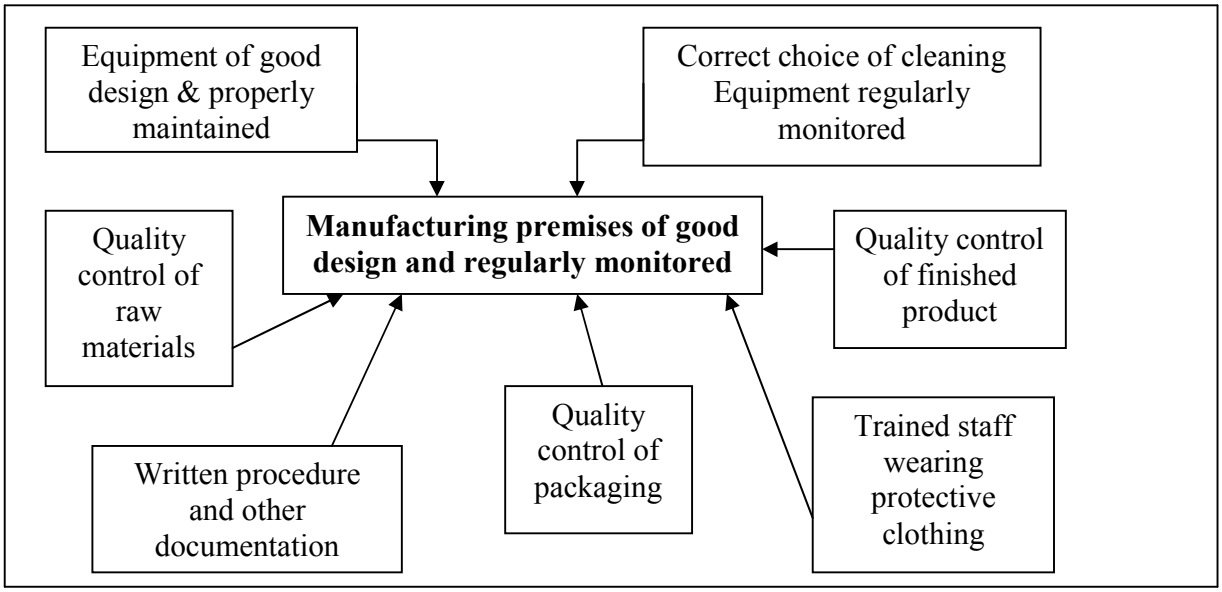
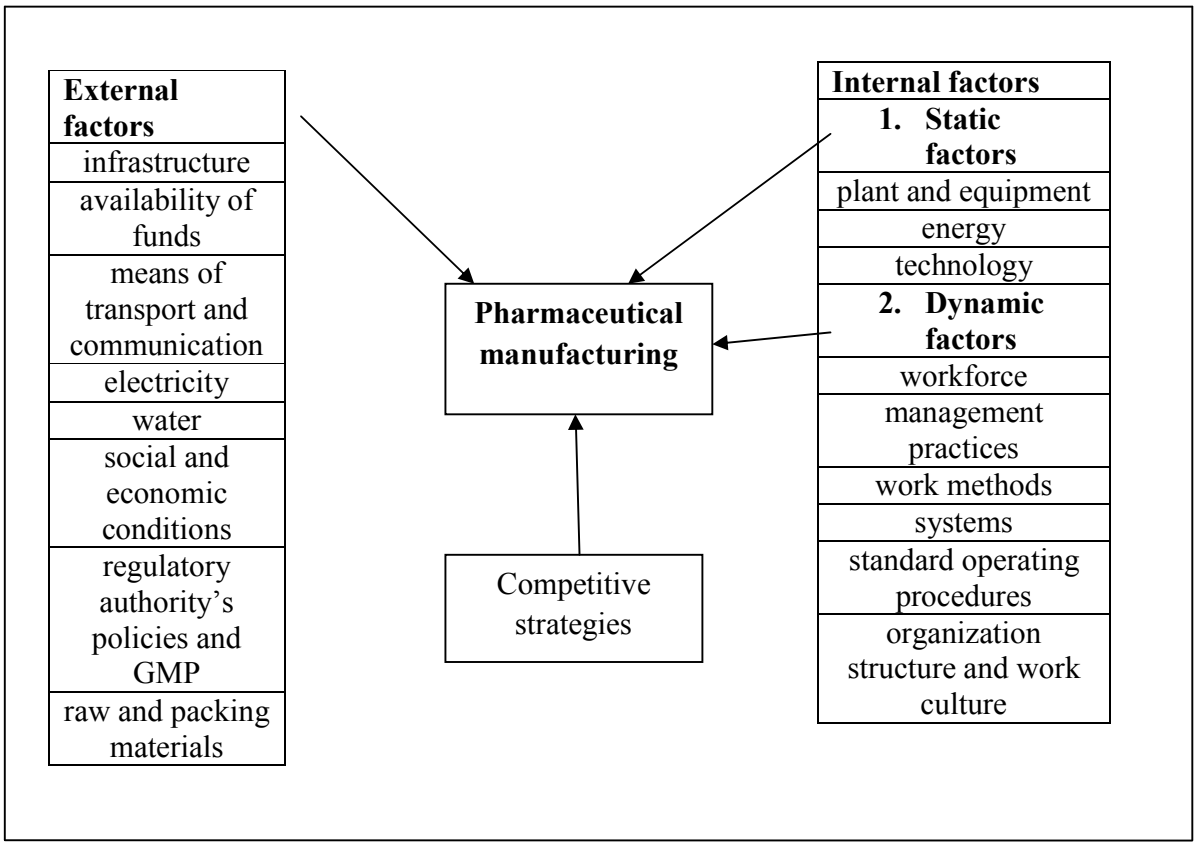


Figure 2.6 shows how the various manufacturing techniques of GMP are related and can be used to improve pharmaceutical productivity

Figure 2:2 Operational challenges in pharmaceutical manufacturing



2.12 Chapter summary

This chapter reviewed theoretical factors that are involved in influencing pharmaceutical manufacturing techniques and the effect of competitive strategy on pharmaceutical products. The literature has highlighted that Good Manufacturing Practises and regulations are important in pharmaceutical manufacturing making it a key regulation for success and performance of any pharmaceutical manufacturing business. This is because GMP regulations, when followed will determine customer satisfaction, product safety, efficacyand acceptance of the pharmaceutical products on the international market. Various factors have been identified in theory, but have been limited to those factors that have been negatively affecting the production and export of pharmaceutical products. This study focuses on literature in a critical area considering that Zimbabwe is coming from a decade of economic meltdown and still needs to provide medical products to its citizens and industrial studies will be useful in policy making.

CHAPTER THREE
RESEARCH METHODOLOGY

3. Introduction

Saunders et al (2009) noted that research requires a systematic and well planned approach to finding answers to study problems. This chapter discusses the methodology and method which were used for data collection for this study. It elaborates how the study population, the study methods and the study instrument were determined. The methodology sought to conduct the study in a manner that addresses the study questions on pharmaceutical manufacturing techniques and factors that affect the effectiveness of implemented competitive strategiesof pharmaceutical medicines in Zimbabwe.Furthermore, the chapter will discuss the study approach, data collection techniques and data analysis.

3.1 Study approach

There are two approaches to a research design: quantitative and qualitative methods. The quantitative method follows the positivist paradigm whilst qualitative aligns to the naturalistic paradigm. The quantitative approach is objective and deductive. In this case the deductive reasoning means that the approach starts with a general theory, followed by hypothesis which narrows down the general theory. Data is collected which is used to test the hypothesis. Finally, the theory is either confirmed or disconfirmed. In contrast, qualitative approach is naturalistic and inductive (Saunders, 2009). The inductive approach starts with specific observations, detects patterns and regularities, discusses propositions and develops general conclusions. The qualitative approach has depth since it allows the generation of a narrative report and direct quotations from research participants, but lacks width, whilst the quantitative approach has width but lacks depth.

Saunders et al. (2009) suggested that no study design is superior or inferior to another. They argued that what is of paramount importance is ensuring that the adopted design allow the study to address all the study questions and objectives. Consequently, such choice of study design will be guided by the study questions and objectives as well as considering the philosophical approach, amount of time and any other important resources available. The qualitative approach

has gained increased credibility in the past despite the quantitative approach being considered as more rigorous (Greene, 2007). Both are suitable methodologies in studies that contribute to the body of knowledge of which the selection of a particular methodology depends on research questions that stem from the study problem and purpose.

This study was based on the qualitative approach since it is based on social science that involves perceptions, views and emotions. The justification of a qualitative paradigm is based on the fact that the study focused on a relatively small sample of the informants with the required data such that new theories can be developed using subjective data. A location that is natural was used acquire an in-depth understanding of the pharmaceutical production techniques and competitive strategies as explained by the personnel that are responsible for controlling, maintaining and implementing the production process and strategies on a day to day basis. The study was cross sectional in nature and was based on the action research strategy of the qualitative paradigm. An action research is justifiable for the study because it generates new data which is analysed together with actions taken to transform the situation and is suitable for small scale studies were there is need to understand, evaluate and change the way a process has been operated (Saunders et al, 2009). As a result, probing and thorough engagement with the study respondents was required (Saunders, 2012).

3.2 Study design

A study design is defined as the plan of how study questions are going to be answered and as well as specifying the sources from which data will be collected. It also takes into consideration the possible constraints that are involved in data collection (Saunders et al, 2009). Thus, the objective of a study design is to define the way that the study will unfold so as to answer the study questions and at the same time ensuring validity of findings. Khothari (2004) went on to add that a study design, as a structure of the study, presents how the study parts work in synchronisation thereby addressing the study questions.

The study commenced by assessing the production techniques of the firms with particular reference to how the production process was being run and the production techniques adopted. This includedassessment on the current GMP with respect to world standardsand identifying the individual authorised to monitor the process in the manufacturing phase, the availability and use standard operating manual, documentation of the processes, personnel hygiene and protection,

cleaning and plant maintenance. The study then analysed the competitive strategies with respect the main pricing strategies that are cost leadership and product differentiation. The marketing mix of product, price, promotion and place was also used to assess how it affects the production output and product attributes influencing the adoption of various competitive strategies by local manufacturers. Finally, the study made an assessment on the impact of both production techniques and competitive strategies of the firms on the local market through assessing the feedback obtained from a selected number of retail and hospital pharmacies who are involvedordering, stocking and final distribution of local pharmaceutical products to the final consumer (patient) taking the medical products.

3.3 Study population

The study gathered data from three populations. Thefirst population was made up of **five** pharmaceutical manufacturing companies basedin Harare which were Graniteside Chemicals, Gulf pharmaceuticals, Pharmanova, Varichem and CAPS pharmaceuticals. The manufacturing companies manufacture human medical products. These products are classified into over the counter (OTC) medicines, prescription (PP) medicines and home remedies (HR).From these companies, **two respondents** were chosen from each pharmaceutical manufacturing company so that information can be corroborated from each company. From each company, one production manager and one operations manager were chosen for interviews.

This made the total number of interviews to be done on **ten managers**, a number that ensures saturation on data collected. The purpose of selecting these managers was to assess the production techniques and competitive strategies that they were implementing in their different companies, and the challenges they faced in doing so. These respondents were chosen on the basis of their knowledge and involvement in the control, supervision and operation of the overall pharmaceutical manufacturing process.

This was motivated by an understanding that the subject of discussion will be best dealt with in its natural set up in which practitioners would be able to air their views, experiences, and understanding of the production techniques and factors that the study sought to study as an exploratory study. Such non probability sampling method is justifiable in exploratory stages of study and is normally used in business practice (Powell and Renner, 2003).

The participants were asked on the current production techniques, challenges that they faced in the operation of the production process, factors affecting competitiveness of their products and as well as issues to do with compliance to international manufacturing standards that are based on Good Manufacturing Practices (GMP).

The second set of participants was made up of **ten** pharmaceutical clients that were identified by the managers to be the two largest consumers of their pharmaceutical products with respect to value and frequency of business transactions in terms of ordering and stocking of products that the consumer had with the specified manufacturer. These clients were made up of retail and hospital pharmacies in the private and public sectors of the health delivery system in the country based in Harare.

The third set of participants consisted of **two**key informants from the Pharmaceutical Manufacturers Association (PMA), which is the pharmaceutical governing body in Zimbabwe. The two informants interviewed were the chairman and a non executive board member. This was achieved through in depth interviews for the purpose of following up to what was said in the managers' interviews and well as giving an insight into the issues concerning the regulation of the pharmaceutical industry. Respondents and key informants were notified of the interviews and appointments set. In addition, prior authorisation was obtained from the relevant authorities before the interviews were conducted.

3.4 Data collection and analysis

3.4.1 Data collection

The data collection technique adopted by the study was based on interviews which used a semi structured interviewer-administered guide as the data collection tool. This type of data collection instrument is justifiable for a qualitative study because it allows the non verbal gestures and body languages to be noted thus enhancing response quality. Face to face interviews also have a high response rate as suggested by Patton (2002). Three different interview guides were developed for the three different sets of participants based on study questions and purpose.

The responses from the participants were tape recorded for validity and reliability purposes and facial expressions, gestures and other body languages in responding noted down as well. The interviewsundertaken with managers from each of the pharmaceutical companies, and key informants lasted forty-five minutes each and were conducted in the managers' offices on a face to face basis whilst interviews with the customers/consumers of the manufacturers' products lasted for thirty minutes each.

An interviewer-administered guide was used to gather answers on the study questions in order to meet the study objectives. The interviews on managers representing manufacturing companiesensuredthat respondents answer questions on the production techniques, operational challenges and strategies associated with pharmaceutical production in Zimbabwe.The interview guide provided direction into the discussion while allowing in-depth intensive insights and clarifications from the respondents through the use of follow up questions. The questions on the guide provided guidance to all the respondents in a uniform way. The desire was to probe and acquiredeeper understanding of the interviewees' positions, knowledge, experiences and views thus making it imperative to adopt an interview guide as a data collection tool during the study (Saunders et al, 2009).

The pharmaceutical manufacturers' interview guide was made up of four main sections. The first part of the study guide gatheredbrief demographic information on the pharmaceutical companies to ensure that the data gathered is contextualized. The next section, section B focused on the current operation of the pharmaceutical process with respect to Good Manufacturing Practices (GMP). Section C focused on questions to do with operational factors affecting the local pharmaceutical production process. Finally, section D focused on the competitive strategies implemented by pharmaceutical manufacturing companies in the Zimbabwean pharmaceutical industry.A copy of the interview guide is attached in the appendices section of the study.

Towards the end of each interview, managers from the respective companies were asked to disclose two of their big customers whom they trade with. A total number of **ten** pharmaceutical clients were identified and were interviewed to assess the impact of pharmaceutical manufacturers' products and competitive strategies using a semi structured interviewer

administered guide to collect data. The information was used to assess the effect of the manufacturers' product attributes and competitive strategies aimed at making the local pharmaceutical products preferred on the local market. The last interviews were then conducted on **two** key informants from the PMA. These informants were interviewed mainly on legal issues affecting the pharmaceutical industry as well as soliciting the informants for possible solutions to resolve the challenges that the pharmaceutical sector was facing.

3.4.2 Data Analysis

The qualitative analysis was based on meanings expressed through words, non standardisation classified into categories and the use of conceptualisation. The recorded interviews were transcribed and content analysis was carried out through the systematic examination of field notes (text). This was followed by identifying and grouping themes and coding, classifying and developing categories until no new categories could be identified.

The next step was then to review all the interviews so as to come up with areas of similarities and differences.To complete the process, the first step was to read for content in which emergent themes are developed and topics that need further exploration noted (Glaser and Strauss, 1999). In this case, the quality of the data was noted in terms of rich and deep response, detail of the descriptions and contextual detail thereby developing a system of identifying problems in the data (audit trail) and identifying patterns and relationships between themes. This was followed by Data reduction which is a process of distilling the data in order to bring out the essential concepts and relationships in the concepts studied. Data reduction assisted in petting the overall sense of the data and distinguishing between primary and secondary themes as well as separation of the essential from non essential data.

This was then followed by data coding which involved classifying data under different codes which conforms to identify themes (Saunders et al, 2012). The codes were recorded, defined and necessary revisions and changes made in order to ensure uniformity and consistency. Unitizing of data was then carried out in which chunks of data were attached to the codes and examining the evidence that supports each sub-theme. This was then followed by Data Categorization in which groups of associated codes were grouped into categories, this facilitated the ability to explain and predict concepts in the data. In this process the coded items or sub categories became

explanatory descriptions of the categories. The relationships between categories was also analyzed and presented through network diagrams and hierarchies (Strauss and Corbin, 1998). Data interpretation was then carried out to identify the core meaning of data at all stages, searching for core meanings of thoughts, feelings sand behaviours. Explanation on how study questions were answered were also given and as well as the meaning of findings beyond the study context.

3.5 Validity and reliability

The term ‘reliability’ has been once a concept used in quantitative study evaluation and is now used in other research paradigms. If testing determines information elicitation, then quality becomes the important test of a qualitative study.

A good qualitative study helps in understanding a confusing situation when reliability is used to generate an understanding of current practises (Eisner, 1991). Stenbacka (2001) went on and noted that the idea of reliability is misleading in qualitative research whilst Patton (2001) in contrast states that validity and reliability concepts in designing a study, analysing results and as well as in judging the quality of any qualitative study. Healy and Perry (2000) went on to say that the study quality should be judged with respect to its own paradigm's terms. In qualitative paradigms there is use of rather different terms that include Credibility, Consistency, Dependability and Applicabilitywhich determine quality in qualitative study.Healy and Perry (2000) further emphasize that the inquiry auditcan be one measure that enhances the dependability of qualitative study. In this case both the process and the product of the studyare examined for consistency. In the same vein, Seale (1999) endorsed the idea of dependability with reliability in a qualitative study.

The term ‘validity’ is defined by a number of terms in qualitative studies and is not a universal concept, but a contingent construct based on the processes and intentions of particular study methodology (Winter, 2000). Creswell & Miller (2000) in the same vein went on to suggest that the validity of a study is ultimately affected by the perceptions of the researcher on study validity their choice of paradigm assumption and have often named them more appropriate terms that include rigor and trustworthiness (Davies & Dodd, 2002). Stenbacka (2001) noted that

discovering of truth through the measuring of reliability and validity is being replaced by the concept of trustworthiness in qualitative studies which is mainly focused on establishing confidence as far as study findings are concerned.

The study ensured thatreliability and validity of data collected was achieved by ensuring that the study steps were verified through examination of raw data, data reduction products and as well as process notes as recommended by Campbell (1996). In addition to this, reliability and truth value in the qualitative study was enhanced through the cross examination for trustworthiness in all respondents by the selection of production and operation managers from each company so that the data can be corroborated. In addition, human experience discovery as they were perceived by the respondents enhanced the reliability of the qualitative study. These managers were trusted to have the information of the companies since they are involved in the day to day operation of the systems as supported by Seale (1999), who stated that trustworthiness of a study lies at the heart of issues discussed as validity and reliability.

3.6 Reflexivity

Qualitative studies involve perceptions, views and emotions that normally require the researcher to be very objective, neutral and refrained from bias. The study was carried out in a way that was meant to reduce interviewer bias and the use of interviewer perceptions, expectations and beliefs. Interviewer bias was minimised through the use of voice recorded interviews to capture only what the respondents actually said. There was no tempering on the data in terms of additions or omission of vital information. The study was carried out in a free environment without any intimidation or prejudice of the respondents and with consent on recordings. The respondents were assured of anonymity and that the study will not bring them and their companies in disrepute. The researcher ensured that the interview did not contain offending statements or questions allowing respondents stick to the purpose of the study and not stray into personal feelings, use of hate language and political issues.

3.7 Values and Ethics

Cooper and Schindler (2008) identified ethics to be the norms of behaviour that direct moral choices about conduct and relationships. In this study, ethics that relate to study design, access to data and its collection, processing and storage of data was duly observed in a moral way. Therefore, the study aimed at avoiding the subjection of respondents and their companies to

disrepute or deception. In ensuring this, the respondents' names were not mentioned. Interviewee consent was sought and relevant authorities notified before the study was conducted in addition to full disclosure of the study purpose.

3.8 Methodological Limitation

There are study limitations that the researcher acknowledges as far as data collection is concerned. Firstly, the use of a cross-sectional method in the study meant that a snapshot of manufacturing events was captured. This meant those events before and those after the study were not recorded. Respondents interviewed were busy people and thus gave only limited time for the interviews. This could have limited the information that they could have given during the interviews. Interviews also are prone to interviewer bias that could affect quality of data captured. This limitation was reduced through tape recording of the interviews.

3.9 Chapter Summary

This chapter outlined the mixed method approach adopted in data collection for the study. It also outlined how the data was reduced, coded and processed in coming up with study findings. The chapter also introduced the interview guide that will be used in the study, its structure and as well as how it was administered. Ethics and morals were also guaranteed to respondents and disclosure of the study purpose. The next chapter focuses on the presentation of data and findings that the study came up with.

CHAPTER FOUR
FINDINGS AND DISCUSSIONS

4. Introduction

The chapter will present the study results and as well as a discussion on the findings. The findings will be presented in a narrative sequence and verbatim quotations provided where appropriate. The study findings sought to address the following study questions;

1. What are the current production techniques used by local pharmaceutical manufacturers?
2. How do the current competitive strategies being implemented by local pharmaceutical manufacturers affect production of pharmaceuticals for the local and international markets?
3. Which operational factors are resulting in the low capacity utilization and hindering manufacturing of pharmaceutical products in Zimbabwe?

The above study questions will be addressed sequentially with the discussions being made together with the study findings and key findings pointed out before a summary given at the end of the chapter.

4.1 Participant distribution categories

A total of twenty-two participants had interviews successfully conducted on them thus allowing the study to gather sufficient and saturated information for data analysis. These participants are outlined below

Table 4:1 Participant distribution analysis

Types of participant	Number of interviewed participants
Pharmaceutical clients	10
Pharmaceutical company managers	10
Pharmaceutical Manufacturers Association (PMA)	2

Participants from the pharmaceutical clients (hospital and retail pharmacies) were mainly pharmacists and stock controllers who were responsible for buying and stocking of

pharmaceutical products. These customer participants highlighted that they consider mainly price, quality and delivery options when ordering from a specific manufacturer. Discounts and credit facilities also have an effect on most of these customers. The pharmacies were located in and around the Harare Central Business District. The percentages of local products within the organisations' stock ranged from twenty to forty percent and the rest being imported generic substitutes and brands.

4.2 Current production techniques used by local pharmaceutical manufacturers.

The current production techniques by local manufacturers after data analysis brought about the following codes as presented in Appendix A

Manufacturing and testing procedures

The interviewed pharmaceutical company managers all alluded to the fact that their manufacturing and testing procedures agreed with the regulatory requirements of the Medicines Control Authority of Zimbabwe and have managed to keep the qualified personnel, who are mainly production pharmacists, in their key production line ranks. This has been successfully achieved despite the loss of qualified personnel the nation has faced over the past few years

Documenting procedures

Most of these participants said that they had documented procedures for the personnel responsible for plant inspections, GMP deficiencies, production failures and of associated actions that usually occur due to complaints or results in recalls as one respondent P4 said,

> "*….SOPs exists- Deviations, Change control, OOS/OOT, CAPA, Management review of quality system, etc...*"

It seems when talking of documentation, the organisations keep their records basically in hard copies for convenient referencing. Soft copies are also kept on computers and are mostly used for sharing and backup in case the hard copy is lost or is not readily available. The interviewer had a chance to see the cabinets at one location where one manager P7 proudly outlined that;

> *"...we have a Good documentation policy- which details the dos and don'ts. QA manager approves all quality documents. We currently have hybrid –paper*

&electronics recording systems. With the paper records being the main documentation record system…."

One visibly vivid manager P3 had this to say:

"... Training on production techniques covers new employees and regular basis for all personnel. There is a training officer whose daily functions are running and coordinating training activities…"

This, according to the managers, has ensured that the quality of the pharmaceutical products produced does not fall below required standards thus guaranteeing their products' continued competition on the local market.

Equipment cleaning and production environment

Only one manufacturer was found to be WHO prequalified pharmaceutical manufacturer meaning that their manufacturing facility was inspected and approved by WHO to manufacture drugs of high quality with respect to international standards, and thus can be marketed on the international markets The other manufacturers noted that there are documented quality management systems in place and one respondent P10 who promised to produce a sample if requested said,

". . . We comply with GMPs as per WHO guidelines, we are not certified to a quality standard such as ISO 9000, and it is our belief that GMP compliance is sufficient for our manufacturing processes and purpose..."

There was a general consensus in the pharmaceutical production industry that each type of equipment, no matter how small it is must be cleaned, stored, and, where appropriate, sanitized or sterilized to standardized requirements to prevent contamination or carry-over of a material that would alter the quality of the intermediate pharmaceutical products like said by one manager P5,

"....there are cleaning SOPs for each equipment, walls & floors which details cleaning agents, sanitizing agent , quality of water to be used for final rinse and storage as well as action on using a piece of equipment that has not been used for some days. There is cleaning validation studies done to measure the effectiveness

of cleaning. All machine surfaces that come in contact with product are stainless steel which is not reactive and ease to clean…."

This also included the cleaning of room walls, floors and general working environment as recommended by GMP guidelines. One manager P6 who became specific on the matter said,

"...cross contamination prevented through procedures, work flow, cleaning personnel training, HVAC system continuous floors (no joints), smooth and coved walls, etc..."

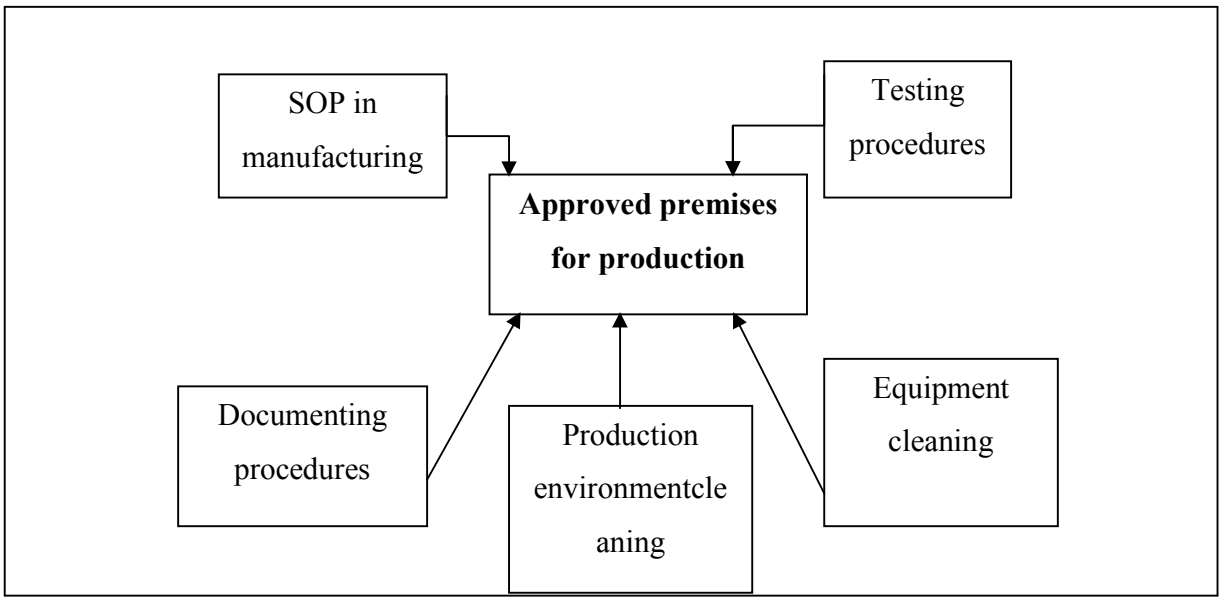
All local manufacturers do not manufacture APIs, but rely on imported API from China, India and UK where they are patented and the companies there have better and advanced technologies and skills for R&D activities for new medical products. Most local manufacturers have multiple product manufacturing facilities and therefore do not dedicate the equipment they have to a certain specific product. One manager P4, from a WHO prequalified manufacturing pointed out that the company does have separate facilities dedicated for penicillin products because of the need to prevent cross contamination of other products by penicillin dust which has a high incidence of causing penicillin allergies in patients taking medicines exposed to penicillin dust, he went on to say that;

"...we do not manufacture APIs. We have a multi-product manufacturing facility so no dedication of equipment to a product. However we have in addition a separate facility dedicated for penicillin based products…"

Key findings on production techniques

The key findings as far as production techniques that are being used in the Zimbabwean pharmaceutical industry can be summarized in figure 4.1. These key findings are based on the codes in appendix A

Figure 4:1 Production techniques in the Zimbabwean pharmaceutical industry



Source: study findings

The above production techniques are in line with international standards, but fall short of the full recommendations that qualifies a manufacturer to obtain WHO prequalification. In comparison to the study theme in chapter 2, these techniques fall short of the recommended techniques in Good Manufacturing Practices and thus will reduce the recognition of local pharmaceutical products on the international market.

4.3 Strategies being used by pharmaceutical manufacturers

The Zimbabwean pharmaceutical manufacturing industry despite facing viability problems due a number of challenges highlighted latter on in this document has been managing to thrive by being able to use a number of survival strategies. Managers of the pharmaceutical manufacturers highlighted that the government does not impose price controls on locally produced medical products. This leaves the manufacturer with liberty to choose a suitable pricing strategy on pricing their products. If the price is reasonable, the manufacturer achieves competitiveness, and if it is too high, they compete themselves out of business if customers become price sensitive, thereby preferring a cheaper imported substitute.

Manufacturers used mixed production strategies to adapt to the current economic situation

The managers interviewed from the local pharmaceutical manufacturers converged on the cost leadership strategy as the strategy that their respective companies were following. This however

was in contradiction with what was said by the customers interviewed. The bulk of pharmacies' customer respondents think that more of these manufacturers are struggling with adopting this specific strategy, but are adopting a survival strategy in which the strategies are mixed in order to adapt to the current economic situation. This was because the prices of the local products were considered high as compared to the competitor products on the market. One client P16 said;

> *"…there is no clear strategy that the manufacturers are using. It seems like they are in a survival mode because the product price is high and yet the quality of the product is just adequate to meet regulatory requirements…."*

The low cost pricing technique is said to be in use but not very popular since it compromises on quality and therefore is not favoured. This was said to work in some products considering that some sections of customers are more sensitive on the price than the quality.

Manufacturing firms strive to maintain a good relationship with the pharmacies

A greater number of the interviewed pharmacists customers agree that the manufacturing firms strive to maintain a good relationship with the pharmacies by providing facilities such as discounts when large quantities are purchased, promotional materials such as t-shirts and caps which the pharmacies usually distribute among staff or their regular customers as noted by client P12;

> *"… The manufacturers hold product launches workshops when they have a new product or want to provide promotional information for an already existing product on the market. They invite their clients where they explain to them the product specifications and use. They also take the opportunity to issue out promotional material such as fliers, t-shirts, pens and hats…"*

In terms of product distribution, the manufacturers mentioned that they had delivery vehicles that deliver ordered products to their customer's destinations. One proud and confident manager P9 specifically said the following;

> *"...We do have internal distribution trucks to distribute products to our customers mainly in Harare and Bulawayo and so we have control on delivery except when*

we hire commercial delivery trucks for the rest of the country. We have performance standard times for deliveries..."

On Time delivery of ordered goods

The delivery facility and its effectiveness were later on echoed by the customers who applauded the local manufacturers for on time deliveries. The customers are happy with the service and have not been facing problems in getting the items that they would have ordered. One customer P13 went on to say;

"...we receive only the goods that we would have ordered in good conditions, without omissions and breakages and there have been no mistakes for a long time..."

Looking beyond the borders for markets

Manufacturing industry managers and PMA members alluded to the fact the local market was now saturated with pharmaceutical products and manufacturers were turning to the international market, mainly the SADC region. One PMA member said the lack of WHO prequalification for most manufacturers has resulted in their products having poor recognition on the international market. Currently only one manufacturer is WHO prequalified, but has been facing numerous challenges from import restrictions in desired destinations and high prices emanating from high production costs.

The imposition of non-tariff barriers by South Africa on drug imports from Zimbabwe is a major setback on drug exports from Zimbabwe to South Africa. All drug exports into South Africa, from Zimbabwe, have to be air-lifted to OR International Airport in Johannesburg and cannot be transported by road through the Beit-Bridge/Musina Board Post because it is not a designated entry for drugs into South Africa. This is highly considered as an uneven competitive advantage since drug imports from South Africa into Zimbabwe are allowed entry by road freight through the same border post by Zimbabwean authorities. One manager P7 went on to elaborate that;

"...the air-freight cost ranges from $2-$10/kg depending on weight and volume of shipment while road freight is much cheaper at below $0.50/kg. South African companies, by design or lack of it, enjoy an unfair trade advantage over

Zimbabwean companies exporting into that country. Zimbabwean drug exports into countries landlocked by South Africa like Swaziland and Lesotho are equally affected and will need to be air-freighted. Tender business in these countries, which constitute more than 70% of the market, it is virtually impossible to compete on account of the low margins which are wiped out by the air-freight costs…."

Another manager P9 added that;

"...For exports we engage commercial transporters by road to Namibia, Botswana, Swaziland, Mozambique, Zambia & Malawi. For exports destined for RSA, we use air transport as this is the only mode permitted for medicines by RSA authorities. This makes our products costly in that market and is really some form of non-tariff barrier by SADC member. The main sea port we use is Durban then to Harare by road. Previously we used to use railways as well, but these days NRZ is in reality non-functional but is cheaper..."

Key findings on competitive strategies

Local pharmaceutical manufacturers do not have a specific pricing strategy because of the prevailing harsh economic conditions. Local manufacturers are more concerned about survival more than anything else. Efforts are being made to gain customer loyalty and market share but these measures are being faced by stiff competition from imported products that still have low prices because they are duty free. On the international markets, there has been very low activity because of strict regulations and protection on the intended destination markets thus making the difficult for local manufacturers to export their products.

4.4 Manufacturing challenges and their impact on capacity utilization

Inadequate capital for new and existing projects and strategies

Managers alluded to the fact that the credit squeeze has resulted in them not being able to pursue capital projects. This was worsened by the fact that most of their raw materials suppliers, especially from China are demanding cash upfront because of the liquidity risk that the country is currently facing. In addition, the local banks have reduced lending to the local manufacturers

because of the problem of non-performing loans which has resulted in some local banks being liquidated. This coupled with stiff competition has really resulted in constrained cash flows.

Old and obsolete equipment

When asked to rank these main challenges, all managers agreed to the fact that old equipment was one of their biggest challenges. This was because the old equipment is prone to numerous breakdowns and has limited number of unit per batch of product. Most of the equipment still requires manual intervention unlike the new technology equipment that is fully automatic. One manager P10 sadly outlined the following;

> *"... The equipment that we use is obsolete and falls way behind with world technological advancements. One machine still does 40000 capsule units as compared to 200000 capsules per hour done by the latest machine..."*

Even if they manage to purchase equipment, it is usually imported since it's more expensive to buy from local dealers. In the case of any faults, there is no local expertise; the service technician will have to be flown into the country. One manager P4 said:

> *"... However at times the challenge is when there are equipment breakdowns that may not be attended to quickly as the suppliers will have to fly to Zimbabwe. Issues of Visa applications as well will further compound the delays further..."*

These delays lead to increased downtimes which will likely affect business and availability of products on the market.

Utilities (water and power outages)

The unfavourable trend in the availability of electricity has had a negative bearing on the production industry in the form of increased production costs and downtimes. One manager P5 confirmed this by saying the following

> *"...ZESA has been erratic and have relied on generators to run the factory, more when the production areas have to maintain positive air pressure at all times. Fuel cost is becomes an issue where the generator we have is sized to supply*

enough electricity for the whole factory by consuming 110liters of diesel per hour…."

Most respondents also highlighted that the municipal water level of purity is well below the expected standard. This meant that they needed to invest in purifying the water as stated by one manager P3:

'…municipal water needs to be processed (thru deionization and reverse osmosis) to make it meet pharmaceutical specifications. The quality of the municipal feed water is important as well it's the pressure, the level of purity is very low. We have had problems of low pressure of feed water, and results in negatively impact on our manufacturing..."

This was said to be difficult in the harsh economic environment in which the companies are already struggling to keep prices low while the cost of production continues to increase.

High overhead costs

All managers agreed to the fact power outages have resulted in an increase in production costs. Fuel costs and maintenance of heavy duty generators has a high impact on production costs. In some cases were the production process is suspended because of power outages, the companies have idle workers who still need wages despite not producing any products. Frequent breakdowns of the old equipment also increase overheard costs when an outside consultant, usually from the country of origin of the machine, will be required to attend to the broken down machine.

Low capacity utilisation

Due to a number of factors highlighted earlier that include the unavailability of capital to fund the acquisition of modern equipment with higher throughput, high costs of importing raw materials and high overheads, coupled with low product demand and preference of imported drugs ahead of locally produced ones among other issues have, according to the managers, led to companies not fully utilising their capacity. The other emerging issue at this point is the fact that the industry's customers (the pharmacies) prefer a one-stop-shop where they will get a wide range of products and equipment for their businesses which most manufacturers cannot provide. A concerned manager P2 had this to say:

"...reduced local demand and stiff competition from low priced imports especially from India, has resulted in our company cutting down on production. Currently there are no government purchases (tenders) which are usually high volumes compared to the private sector. This is worsened by the fact that some of the major clients are not settling debts on medicines supplied..."

The government which as stated by the manager does not procure locally and this has led to reduced production quantities since the government used to buy in large quantities.

Customs duties on imported raw materials

As per government policy to make drugs available for the local people and avoid a complete collapse of the health industry during the period of economic depression, zero taxes were put on all imported medicines meaning that finished pharmaceutical products that are imported into Zimbabwe are not charged duty or VAT. The same was not done on packaging materials, raw materials and machinery imported by local manufacturing companies to produce the same products locally. This, according to one manager from a local firm resulted in the final price of a locally manufactured product being higher compared to the imported competitor substitute. A visibly disturbed interviewed manager P1 said,

"...raw materials of agricultural origin imported into the country for local production require import permits and GMO certification. However import permits or GMO certification is not requested of imported drugs containing the same ingredients. This increases the cost of raw materials by as much as 20% before consideration of other costs drivers ..."

The imported raw materials attract customs duties ranging from 5 to 40% while finished products are exempted. A number of import permits are required for raw materials like starch and gelatine and these include Agricultural Marketing Authority (AMA) registration fee of $1,000; Ministry of Agriculture plant quarantine $30 per permit; National Biotechnology Authority Permit $350. The total time required to get all these permits is one week. Import permits are not requested for finished drugs containing the same raw materials in their formulation. Therefore, this increases the cost of raw materials and packaging and has a direct effect on the market price of the end product. However, the finished products when imported will be charged zero duties and enjoys

better preference on the market than locally produced products because of lower prices. One manager P6 went on to outline the following;

> *"...there is list of materials (API, exipients and packaging) proposed by PMA and approved by ZIMRA for materials that should be zero rated for duty. But each manufacturer must open a bonded warehouse first that must meet ZIMRA specifications and get their approval. All materials must be received into the bonded warehouse and you apply to ZIMRA for the quantity of material you require to use at a time and this does not pay duty..."*

This is rather a complicated process as some materials are used in other industries such as food or cosmetics where duty has to be paid. So far no PMA member has benefited from this duty benefit as they are still in the process of setting up bonded warehouses. Specialised machinery does not pay duty but VAT (15%) is paid. Laboratory and other equipment attract a duty of 5% and Vat of 15%.

A practical mathematical example on the effect of duty on the final price was given by one enthusiastic manager using a simple bottle of 1000 tablets of Cotrimoxazole 480mg Tablets; a commonly used drug for general infections and prophylaxis in AIDS cases.

Table 4:1 Cost comparison using cotrimoxazole tablets 1000's

	Description	Quantity	Cost of Raw Material	Customs Duty	VAT	Total Incremental Costs	LOCALLY PRODUCED	IMPORTED PRODUCT
1	Sulphamethoxazole	400g	$4.40	$0.220	$0.693	$0.913	**$5.31**	**$4.40**
2	Trimethoprim	80g	$1.92	$0.096	$0.302	$0.398	**$2.32**	**$1.92**
3	Gelatine	20g	$0.23	$0.012	$0.036	$0.048	**$0.28**	**$0.23**
4	Starch	50g	$0.07	$0.001	$0.010	$0.011	**$0.08**	**$0.07**
5	Magnesium Stearate	2g	$0.01	$0.000	$0.001	$0.001	**$0.01**	**$0.01**
6	Closure	1	$0.13	$0.020	$0.022	$0.042	**$0.17**	**$0.13**
8	Container	1	$0.30	$0.045	$0.052	$0.097	**$0.40**	**$0.30**
9	Label	1	$0.05	$0.020	$0.011	$0.031	**$0.08**	**$0.05**
10	Leaflet	1	$0.01	$0.004	$0.002	$0.006	**$0.02**	**$0.01**
TOTAL			$7.11	$0.418	$1.129	$1.547	**$8.66**	**$7.11**

Source: Pharmaceutical production files

Awarding of Tenders

There is a strong feeling among managers of local pharmaceutical manufacturing companies that local pharmaceutical manufacturing companies should enjoy a price preference of at least 30% on all public tenders managed by the State Procurement Board (SPB). This sentiment was also echoed by members of the pharmaceutical manufacturers association (PMA) of Zimbabwe. SPB tenders account for more than 60% of the industry's revenues and capacity utilisation. Access to this market is therefore critical for the turnaround of the industry. Currently the situation is that, in terms of State Procurement Board (SPB) regulations (SI170 of 2002 Cap 22.14) all local companies enjoy a 10% price preference on public tenders. The current setup does not discriminate between a manufacturer, importer or trader. This means foreign companies through their locally registered agencies, distributors or importers enjoy the same 10% discount as local manufacturing companies. This policy does not therefore support local pharmaceutical production. It achieves the exact opposite. One manager P10 was quoted as saying;

> *".....we believe there should be an additional pricing advantage extended to local manufacturing companies as is the case in most countries including South Africa. This is because of the overwhelming economic benefits accruing from local production. Economic benefits include among others employment, economic (GDP) growth, economic and scientific development, exports and contribution to government revenues through PAYE, income tax and VAT among various taxes levied on the company, its employees and suppliers. The multiplier effect of such contribution to the economy is huge…."*

The managers went on to applaud the indigenization and empowerment laws that prescribe that government should procure at least 50% of its requirements from local companies, but this directive was being hardly followed currently.

Existence of cheap counterfeit drugs on the market

The participants from the manufacturers and pharmaceutical manufacturers association bemoaned the existence of cheap, substandard and counterfeit drugs imported or smuggled into the country. The pharmaceutical manufacturing industry has been identified as a key strategic

sector not only in the Medicines Policy but also in the Industrial Development Policy as indicated in the Zimbabwe Economic Review (2013) and most importantly in ZIMASSET.

Drug registration with Medicines Control Authority of Zimbabwe (MCAZ)

The critical success factors for the growth of industry include product range and the time it takes to get registration approval of a new drug application. As highlighted in the interviews done with the managers and pharmaceutical manufacturers' association, the local industry is currently suffering from very low product registrations relative to foreign suppliers. One manager P4 pointed that;

> *"…in the past 18 months to the end of 2014, out of 56 approvals by the MCAZ only six were from local manufacturing companies. Such anomalies have seen the share of essential drugs manufactured by the local industry fall from 80% to 46% in the past 2 decades…"*

This current rate of drug approval by the local medicines authority is outlined in the table 4.2 below

Table 4:2 drug approval time frames for the MCAZ

	Application Fees for a Locally Produced Drug	**Application Fees for an imported drug**	**Actual Average Being Taken to approve new drug application**
Normal Application	$900.00	$2,500	12-18 months
Fast Track	$4,000	$4,000	3-6 months

Source: Pharmaceutical product registration files

One participant P22 actually explained that;

> *"….registration fees lower for a local manufacturing company are lower than foreign company. However it takes 12 to 18 months for the drugs to get registration approval. Fast track applications receive priority evaluation over normal applications. This is motivated more by a revenue collection point of view*

on account of the high fees. Companies are therefore forced to opt for the fast track process which local companies are finding prohibitively expensive…"

This finding actually means that new products are taking long to be registered for the local market unless the whole process is fast tracked. This comes as a burden for the local manufacturers who have capital constraints unlike the competitor product suppliers who have a bigger financial muscle to fund the fast track process. Resultantly more imported products will be on the registered product list as compared to the local products. Introduction of favourable regulatory policies can resuscitate and support the sustainable growth and development of the domestic pharmaceutical manufacturing industry.

The development of the local industry can be enhanced if drug registration applications submitted by local manufacturing companies are approved within 3 months from date of submission. In addition, protection can be achieved by restricting competitive from an external supplier to be registered once a product is locally registered. In any case regulatory capacity is intertwined with the level of pharmaceutical manufacturing in the country. Critical success factors for the growth of this industry include product range and the time it takes to get registration approval of a new drug application.

Drug donations

One of the PMA members raised a point about their concern on drug donations and the effects it has on the local pharmaceuticals industry since donors prefer to procure their requirements from foreign suppliers in most cases favouring companies from the donating country. One key informant P4 interviewed was specific on the issue highlighting that;

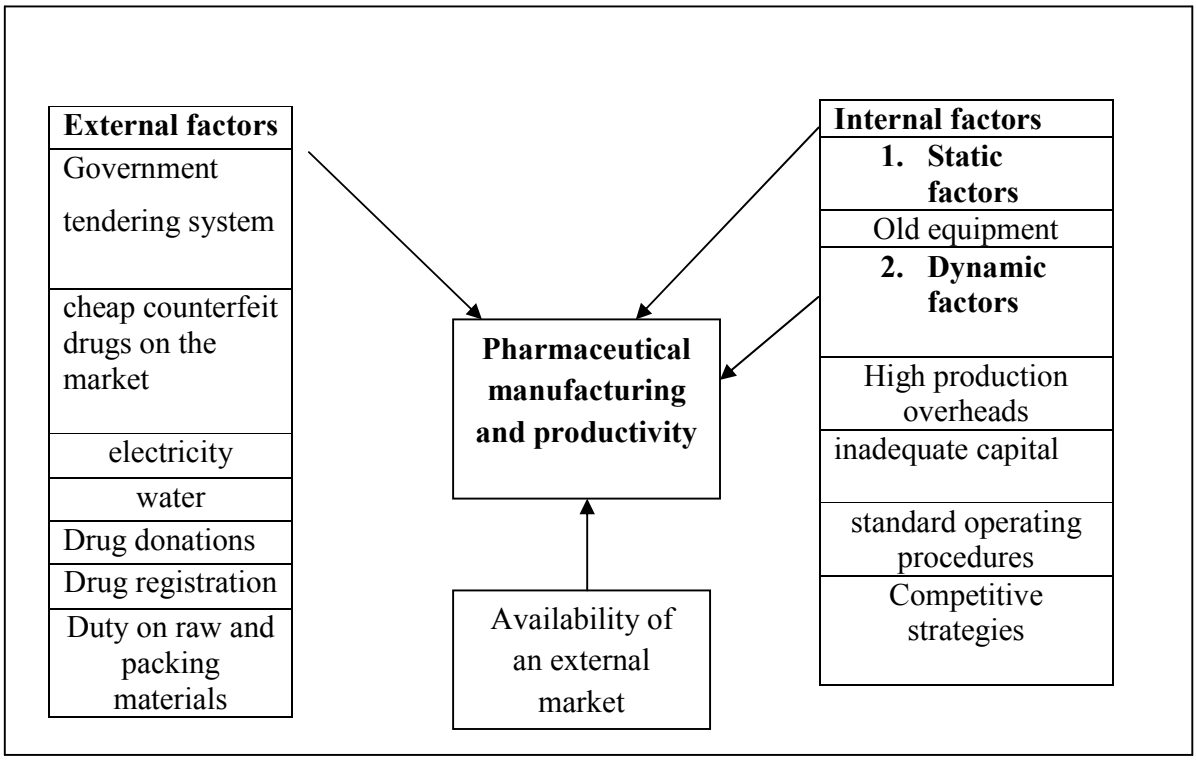
"…For example the country has the capacity to supply IV Fluids (Drips) but 2 of such facilities at Datlabs and CAPS are lying idle. During the cholera outbreak IV fluids were air-freighted into the country by humanitarian organisations instead of being procured from local companies. Some of the donated drugs are of poor quality posing national health risk but also because of donor pressure the country is forced to allow unregistered drugs into the country or to fast track registration of such drugs..."

If the responsible authorities compel donors to procure from local manufacturing companies, it will bring a twofold benefit to the local government and the local people in the sense that the donors will fulfil their humanitarian objectives and at the same time sustaining the country's capacity to meet its drug requirements when the donations eventually end**.**

Key findings on operational challenges

The key findings with respect to challenges that the local manufacturing companies are facing can be summarized in the figure 4.2 below

Figure 4:1 Operational challenges in the Zimbabwean pharmaceutical industry



Source: study findings

The factors that are affecting pharmaceutical productivity in Zimbabwe are generally in line with factors that affect pharmaceutical companies on the international level as outlined in chapter 2. However, the factors that are affecting the Zimbabwean industry are mostly biased towards policies, demand and capital constraint. If favourable policies are implemented, then there will

be support for the local manufacturing companies. Capital injection would result in replacement of the obsolete equipment that is expensive to run in production.

4.5 Discussion of the key findings of the study

In the production processes, the organisations do have training plans for new personnel and refresher courses for all personnel supporting the evidence noted by Sharp (2005) that this ensures that products of high quality can be produced. High product quality means that the medical product possesses efficacy and safety requirements thus are value for money for the final consumer as noted by Stubbs (2008). This however does not resonate with the clients who were complaining of poor product quality. The manufacturers thus cannot compromise on product quality, otherwise the local market would prefer imported substitute, a situation detrimental to local manufacturers' business.

WHO prequalified has been found to be a necessity for manufacturing companies. This is because the prequalification guarantees international recognition of local manufacturers' products as noted by WHOTRS 961 (2011). Currently only one manufacture is WHO prequalified which makes it difficult for local products to gain on international market due to poor recognition. This finding was in line to the study by Kaplan and Laing (2005) that lack of WHO prequalification will result in poor international recognition of pharmaceutical products. Dedication of equipment was suggested by Olcay and Laing (2005) to be of importance in production. This is because separate facilities dedicated for a certain product are needed to prevent cross contamination of other products, for example, penicillin dust which has a high incidence of causing penicillin allergies in patients taking medicines exposed to penicillin dust.

In terms of documentation, the organisations keep their records basically in hard copies for convenient referencing a finding that is line with WHO (2010) suggestions. In comparison of the production techniques adopted by the local manufacturers, it can be seen that the Zimbabwean pharmaceutical industry is still trailing behind international standards. There is need for improvement as far as adoption of Good Manufacturing Practises is concerned in order for local companies to have their products recognised on the international market. This has resulted in only one local manufacturer being endorsed with a WHO prequalification status.

Barney (2002) noted that the competitive strategies implemented by an organisation are mainly based on consumer demand. These strategies are mainly designed in order to win customers' loyalty and gain market competitiveness. This requires the manufacturer to select a proper competitive strategy that is in line with consumer demand. From the findings, local manufacturers do not have a specific pricing strategy. In actual fact it is not clear which strategy is being used in the manufacturer from the customers' perspective. This is because there is need for survival in a harsh economic environment. This finding is in line with the study by Barney and Hesterley (2006) who suggested that in a distressed economy, pharmaceutical manufacturers usually produce products that will just meet the consumer quality expectations and having a low price. Concurrently, the desire to achieve a low price will inevitably compromise the product quality. The issue of high product cost when trying to adopt a cost leadership strategy can be attributed to high cost of production (UNIDO, 2012).

Manufacturing challenges being faced by local pharmaceutical companies have been worsened by the economic meltdown that the country went through prior to dollarization and as well as the current liquidity crunch which has dented the recapitalisation of the entire industry. These challenges were found mostly to be based on unfavourable policies and financial constraints.Local production costs tend to be high due to labour costs not linked to productivity and working capital constraints as suppliers of raw materials demand payment upfront (prepayment) due to country risk as previously suggested by the World Economic Forum (2012). The low capacity utilisation was mainly because of low market demand from the local consumers such that the manufacturers had to cut on their production quantities to avoid losses through producing excess or incurring storage costs on the excess quantities, a scenario that was also revealed by a World Health Organization Regional Committee for Africa (2005) study. This is worsened by the fact that the local demand is highly unpredictable and inconsistent as found earlier on by Kaplan and Laing (2005).

The fact that imported products are not charged duty whilst raw materials are charged has a direct impact on the final price of the locally produced products as noted by Olcay and Laing

(2005).Using the example of Cotrimoxazole 480mg Tablets the incremental costs to a local company is 21.75% before other considerations as shown in table 4.3

Table 4:1 Percentage increase in cost price

Locally Produced	$8.66
Imported	$7.11
Increase	**$1.55**
% Increase	**21.75%**

This means that management of chronic conditions like HIV and AIDS using locally produced cotrimoxazole becomes relatively expensive for a number of patients thereby dampening the effort of the Global Fund in the fighting of AIDS as noted by Poore (2004). It also means that the patient taking this drug would end up preferring the imported product over the locally produced one because of price differences given the fact that consumers are highly price sensitive because of low disposable incomes. A study by Maloney and Segal (2007) actually showed that as long as a local product is 30.8% less expensive compared to the price of an imported product the country will benefit economically.

The pharmaceutical industry, which is trying to recover from an economic recession, is currently exposed without any form of protection, to compete against foreign companies that not only enjoying export subsidies and other incentives, but also operate in favourable economic environments in their country of origins. In Ghana which now has more than 30 pharmaceutical manufacturing companies and still growing had less than 5 companies twenty years ago. This was only after they banned importation of 44 drugs that were commonly produced by local companies. The same impact has been felt in Nigeria where the number of companies has increased from 25 to more than 250 in the same space of time.

In addition, North African countries such as Morocco, Algeria and Tunisia prohibit the importation of any locally produced drug. As a result investors including multinational companies have set up pharmaceutical manufacturing plants in these countries to take advantage of the protection they will get from imports. For example Sinof a French multinational company is in the process of setting up a $100 million manufacturing plant in Algeria. These countries

manufacture more than 90% of their essential drugs requirements and have some of the most viable pharmaceutical industries on the continentas previously suggested by the World Bank (2005).

The challenges in the pharmaceutical industry highlighted in this study are not all but the ones this study could bring out under the conditions of limitations highlighted earlier on in this study document. Some of these findings agree with previous studies that where outlined in the study theme in chapter 2

4.6 Chapter summary

The chapter outlined the current production techniques that local manufacturers located in Harare are using with respect to meeting regulatory requirements and international standards. The manufacturers are meeting these requirements in their manufacturing processes using the Good Manufacturing Practice recommendations despite facing numerous operational challenges. Use of obsolete machinery has been identified as the biggest challenge that the manufacturers are facing and has been responsible for high overhead costs. Subdued demand for the medical product on the local market has resulted in manufacturers cutting on their production quantities and has forced them to shift their focus to the SADC market. Tight market regulation, lack of WHO prequalification and high tariffs has dampened their effort in exporting their products and thus they have limited activity on international markets. The current competitive strategies being implemented by local pharmaceutical manufacturers have also been assessed. From the customers' point of view, it seems like the customers believe that the manufacturers are not using a specific strategy, but are in the survival mode despite the manufacturers claiming that they are adopting the cost leadership. Chapter five will conclude the study and give recommendations.

CHAPTER FIVE
CONCLUSIONS AND RECOMMENDATIONS

5. Introduction

This chapter will outline the study conclusion and recommendations that were drawn from the analysis of study findings presented in chapter four. Study limitations and suggested areas of further research will also be given in this chapter. The first section of this chapter will give a summary of the main conclusions. This will be the followed by a discussion of the research objectives and validation of the study proposition. It should be noted at this point that only the study findings have been analysed basing on the researchers' analytic views and interpretation. The study findings are of paramount importance to policy makers within the government and pharmaceutical regulatory body and most importantly production management that is responsible for planning, organising and controlling of the pharmaceutical production process and competitive strategies. In closing, the chapter will give possible suggestions aimed at stimulating further studies on the area.

5.1 Purpose of the study

The purpose of the study was to assess the current production techniques and competitiveness of strategies implemented by pharmaceutical manufacturing companies in Zimbabwe. The study contributes knowledge on factors inhibiting the performance of the pharmaceutical sector in Zimbabwe. I addition, the study explores the true production and competitive advantages that the pharmaceutical sector can exploit to enhance the contribution of the sector to the growth of the country's GDP, improvement in the balance of payments and consistent supply of quality, efficacious and safe medicines to the nation.Production managers and other policy makers will also be helpedin making informed decisions aimed at improving quality of locally produced pharmaceutical products and as well as reviewing these strategies where there is need to do so.

5.2 Summary of Main Conclusions

The study conclusions include the verification of the success level in achieving the study objectives and conclusion being guided by the study findings and study questions. The following main conclusions were drawn from the study:

5.2.1 Current production techniques used by local pharmaceutical manufacturers

Adoption of Good Manufacturing Practices by manufacturers can be seen as an effort to gain international recognition, a finding in line with a study by Mbendi (2009) andechoed by UNIDO (2012). Literature recommends that Good Manufacturing Practices should be followed in order for a manufacturing company to produce medical products of high quality, safety and efficacy that can be recognised on the international market (WHO, 2010). The study established that manufacturers are abiding by these regulations in terms of techniques that include documentation, cleaning of equipment and retaining qualified and trained personnel in critical areas of production. The local manufacturers are struggling to maintain these good practices in the face of numerous challenges that are threatening the survival of the industry as a whole.

5.2.2 Effect of competitiveness strategies on pharmaceutical products on the local and international market

Porter and Teisberg (2006) found in a study that for a company to succeed, it should embark on a specific competitive strategy for it to gain market share and loyalty. From the study, the manufacturers were found to have no specific strategy as perceived by the customers. This could be because the current hostile economic condition has forced manufacturers to focus on survival strategies resulting in loss of customer loyalty. An effective competitive strategy is the key to gaining market share and customer loyalty.

Zimbabwean local manufacturers have been struggling to achieve and maintain the cost leadership strategy that they claim to be using. From the customers' view, there is no clear cut strategy that the manufacturers are using. Rather they are in a survival mode due to the current economic hardships and subdued demand. The local products are highly uncompetitive and are still more expensive with rather low quality in some cases than the imported substitutes. This has resulted in local customers stocking twenty to forty percent of the local products. This means that the country is importing medical products when it has local manufacturers with a potential to supply the whole market if correct strategies and policies are implemented. In addition, little activity has been recorded on the international market due to tariffs, registration restrictions, and local preference policies among others in the targeted destinations resulting in exports of less than four percent by local manufacturers.

5.2.3 Impact of manufacturing challenges on pharmaceutical production and capacityutilisation

Chaudhary (2005) and later on Joseph (2011) strongly emphasised the need for a large enough market for high capacity utilization by manufacturing companies. In addition, technology advancements in equipment and effective utilities were found to have an impact on pharmaceutical production.

The study findings show that the Zimbabwean pharmaceutical manufacturing companies are plagued with numerous challenges that are threatening their survival. Utilities, high overheads, inadequate capital and old equipment have been pointed out with great emphasis, with old equipment being identified as the major challenge. Obsolete equipment is highly inefficient and results in increased overhead costs incurred through frequent breakdowns and maintenance. This is in line with Greene and O'Rourke (2006) findings that obsolete machinery is highly inefficient and is responsible for raw material wastages and overhead costs.

5.3 Proposition confirmation

The study was based on the proposition that the productivity of the firms is constrained by inefficient production techniques and competitive strategies. From the study findings, the proposition is accepted. Use of obsolete equipment and failure to implement a successful strategy is greatly affecting the productivity of the local pharmaceutical industry. The study added to the body of knowledge the revealing that the Zimbabwean pharmaceutical industry production techniques and competitive strategies tends to differ from other industries because of the economic hardships the country went through and is still recovering from. The industry is rather being affected more by policy issues and liquidity constraints that have restrained capital projects that are necessary to retool the industry and replace obsolete machinery in production.

5.4 Recommendations

5.4.1 Remove or modify prohibitive legislations

The Government of Zimbabwe can level the playing field by regulating duties and taxes charged on raw materials and packaging imported by licensed pharmaceutical manufacturing companies for local production of medicines. These should be zero rated, just like imported medicines. The government can also waiver import permit requirements for imported pharmaceutical raw

material which unnecessarily increases cost of raw materials and locally produced drugs since there is no such requirement for imported drugs containing the same materials.

5.4.2 Protective legislation of the industry against counterfeits

In order to save and resuscitate local pharmaceutical manufacturing companies, the Government of Zimbabwe should come up with measures to protect the industry from cheap, substandard and counterfeit drugs imported or smuggled into the country. This will give the industry time and space to recover and gain global competitiveness.

It is against this background that the Government should put in place import bans on a selected list of drugs commonly produced by local companies to promote the local pharmaceutical industry.

5.4.3 Compel donors to procure from local manufacturing companies

It is the researcher's considered view that the responsible authorities should compel donors to procure from local manufacturing companies. This will bring a twofold benefit to the local government and the local people in the sense that the donors will fulfil their humanitarian objectives and at the same time sustaining the country's capacity to meet its drug requirements when the donations eventually end.

5.4.4 Obtain WHO prequalification, implement a visible and effective competitive strategy and retool the industry

Local manufacturers should replace old equipment with new technologically advanced machinery for increased efficiency and reduced overhead costs. It is also important to adopt and stick to an effective and sustainable strategy that is visible to their customers for continued loyalty and market share.

5.5 Study limitations

The study had time limitations since it was conducted over six months thus shortening the time frame for the study. This limitation resulted in the study having geographical limitations since it was conducted on pharmaceutical manufacturers in Harare which could have introduced some limitation as far as generalisation of findings on the entire Zimbabwean pharmaceutical industry was concerned.

5.6 Area for further study

A number of factors have been identified as the cause of low productivity and low capacity utilization. It is the researcher's recommendation that these identified factors need to be assessed individually on their impact on productivity and determined the extent to which each and every factor impacts on pharmaceutical productivity on the Zimbabwean pharmaceutical industry.

6. Appendix A: Codes from study findings

category	Product codes	Emerging themes
local product attributes	***Pricing***	Prices for locally produced products are higher than those of imported products for a product manufactured with the same ingredients.
	Product Quality	manufacturers say products are of high quality, pharmacists say the products are of poor quality
		products are not value for money
	Product distribution	Distribution is done on time as requested.
		purchased goods are usually delivered
	Packaging	inserts are difficult to remove, especially for tablets
		bottles a sometimes leak for liquid products
		packaging is not very appealing, most manufacturers try to keep costs low and use cheap low quality packaging material
Production techniques	***Manufacturing and testing procedures***	manufacturing and testing procedures are being followed and are in line with the regulatory requirements of the Medicines Control Authority of Zimbabwe
		Manufacturers have managed to keep the qualified personnel, who are mainly production pharmacists, in their key production line ranks.
	Documenting procedures	most of the organisations say they document procedures for the personnel responsible for plant inspections, GMP deficiencies, production failures and of associated actions
		The organisations keep their records basically in hard copies for convenient referencing. Soft copies are also kept on computers and are mostly used for sharing and backup in case the hard copy is lost or is not readily available
		pharmaceutical products produced does not fall below required standards

	Equipment cleaning and production environment	each type of equipment, no matter how small it is must be cleaned, stored, and, where appropriate, sanitized or sterilized to standardized requirements to prevent contamination or carry-over of a material that would alter the quality of the intermediate pharmaceutical products
		there are cleaning SOPs for each equipment, walls & floors which details cleaning agents, sanitizing agent , quality of water to be used for final rinse and storage as well as action on using a piece of equipment that has not been used for some days
		local manufacturers do not manufacture APIs, but rely on imported API from China, India and UK where they are patented and the companies there have better and advanced technologies and skills for R&D activities for new medical products
Strategies being used by pharmaceutical manufacturers	***Production Strategy***	No clear production strategy is being used.
		Manufacturers used mixed production strategies to adapt to the current economic situation. Manufacturers are struggling with adopting a specific production strategy, but are adopting a survival strategy in which the strategies are mixed in order to adapt to the current economic situation. This was because the prices of the local products were considered high as compared to the competitor products on the market
	Relationship with Clients	Manufacturing firms strive to maintain a good relationship with the pharmacies. The manufacturing firms strive to maintain a good relationship with the pharmacies by providing facilities such as discounts for when large quantities are purchased, promotional materials such as t-shirts and caps which the pharmacies usually distribute among staff or their regular customers
	Delivery of ordered goods in	On time delivery of ordered goods.

	time	Pharmacies say they get ordered goods on time.
		wrong products and breakages are sometimes the problem
	Widening the Market	Looking beyond the borders for markets
		The local market is flooded
Manufacturing challenges and their impact on capacity utilization	***Old and obsolete equipment***	old equipment is prone to numerous breakdowns
		limited number of unit per batch of product
		Still using manually operated equipment.
		No local supply for modern technology equipment
	Utilities (water and power outages)	Level of purity of the water is lower than expected. Requires expensive further purification
		unfavourable trends in the availability of electricity, generators require fuel and service therefore added production costs
		increased downtimes leads to product unavailability on the market, affects customer confidence
	Low capacity utilisation	industry's customers prefer a one-stop-shop where they will get a wide range of products and equipment for their businesses which most companies cannot provide
		High operational costs and high prices against low priced imports, less demand from the local market, low sales.
	Customs duties on imported raw materials	No taxes were put on all imported medicines meaning that finished pharmaceutical products that are imported into Zimbabwe are not charged duty or VAT
		VAT and other taxes charged on raw materials imported by local manufacturers including laboratory equipment.
		Leads to market prices of the locally produced goods products being higher than those of imported substitutes.

		Raw materials like starch and gelatine require authorisation permits from Agricultural Marketing Authority (AMA), Ministry of Agriculture; National Biotechnology Authority. The total time required to get all these permits is at least one week
		The prices of locally produced goods are about 20% higher than the same imported alternatives
	Existence of cheap counterfeit drugs on the market	The existence of cheap, substandard and counterfeit drugs imported or smuggled into the country affects the locally produced products' performance on the market.
		The industry exposed without any form of protection, to compete against foreign companies that not only enjoy export subsidies and other incentives, but also operate in favourable economic environments in their country of origins.
	Drug registration with Medicines Control Authority of Zimbabwe	the local industry is currently suffering from very low product registrations relative to foreign suppliers
		New products are taking long to be registered for the local market, more imported products will be on the registered product list as compared to the local products
	Drug donations	donors prefer to procure their requirements from foreign suppliers in most cases favours companies from the donating country
		donors need to procure from local manufacturing companies

7. Appendix B: Interview guide for participants

INTERVIEW GUIDE

University of Zimbabwe

Graduate School of Management

My name is Brian P Mandimika, a postgraduate student with the university of Zimbabwe, who is currently doing a dissertation study. My study is on **the impact of production techniques on the competitiveness of the pharmaceutical manufacturing firms in Zimbabwe.** The study will be based on the following study questions:

1. What are the current production techniques used by local pharmaceutical manufacturers?
2. How do the current competitive strategies being implemented by local pharmaceutical manufacturers affect production of pharmaceuticals for the local and international markets?
3. Which operational factors are resulting in the low capacity utilization and hindering manufacturing of pharmaceutical products in Zimbabwe
4. What issues need to be addressed in order to improve the manufacturing processes to increase production and competitiveness of local firms?

The study will collect data using interviews with the **production manager** and **legal** or **QA** or **R&D mangers** at your firm. These interviews will be 30 minutes long and will be carried out on a one on one basis using a semi structured interview guide. Tape recordings will be done for Individuals who are comfortable with being tape recorded for reliability and validity reasons as required by the university. Data collected will be handled ethically and sensitive company information will not be included in the interviews. The interviewee will remain anonymous and company information will not be used outside the study purpose.

1. **Section A: Company Profile**

   a. Company name.....

   b. Company Size

   No of Employees: ☐ <100 ☐ 100-500 ☐ 500-1000

   >1000 ☐

   c. Number of current product lines

   .....

   d. What type of production is the company involved in?

   Primary ☐ secondary ☐ tertiary ☐

2. **Section B: assessment of production techniques using Good Manufacturing Practices (GMP) standards**

   Is the organisation compliant with good manufacturing techniques in production?

   .....

   .....

   .....

   .....

   Can you describe the current production techniques that your company has in place in terms of pharmaceutical production?

   .....

   .....

   .....

   .....

   .....

Are these techniques in accordance with international standards?

.....

.....

.....

.....

What challenges are you facing in adopting these production techniques?

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.....

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.....

Anyother comments on GMP implementation and challenges

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.....

.....

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Has the company ever gone through a product recalls in the last five years, if so, what was the cause of the recall(s)?

.....

.....

.....

.....

3. Section C: The Main Operational Challenges in Pharmaceutical production

What are the main challenges that you face with drug manufacturing?

.....

.....

.....

.....

.....

In terms of capacity utilisation where are you as a company? …..%

What factors do you think are resulting in the capacity utilisation mentioned above?

.....

.....

.....

Can you describe the cost and reliability of water, power, manufacturing equipment supply and transport services

.....

.....

.....

.....

Are there barriers to imported products (degree of protection)?

.....

.....

.....

How do the following factors affect your production and competitiveness of your pharmaceutical products?

•Market size

……

…….....

.....

•Pharmaceutical products Demand

……

…….....

•Medicine Supply by other private wholesalers

……

…….....

•Medicine Prices

……

…….....

•Competitors for other multinational suppliers

……

…….....

Does the organisation have R&D department? If yes is it fully operational and what challenges are they facing?

.....

.....

.....

.....

4. Section D: Local competitive strategies and Export performance of products

In what state are most of your exported products?

Raw materials ☐ Semi Processed ☐ Finished ☐

In percentage terms;

Raw materials ….....% Semi Processed….....% Finished….....%

What percentage of your products are you currently exporting .....%

If below 100% what is it that you need most in order to boost your exports?

……

……

…….....

.....

Export Destination:

South Africa ☐ Europe Zone ☐ BRICS ☐ USA ☐

Other.....

What challenges have you been facing in making your products attractive on the international market?

.....

.....

.....

.....

.....

There are two competitive strategies that can be used for products. These are cost leadership and differentiation. Of the two, which one is the company using, if any?

.....

For the above named strategy, give reasons for its adoption

.....

.....

.....

.....

.....

.....

In your own view, is the above strategy yielding the intended results for your company?

.....

.....

.....

.....

.....

Is the mentioned strategy sustainable in the long run considering the current economic conditions? Give reasons.

.....

.....

.....

.....

Can you identify two of your biggest local purchasers of your products?

.....

.....

PHARMACIES INTERVIEW GUIDE

Location of pharmacy.....

Who is responsible for ordering of pharmaceutical products? .....

Percentage of local products in stock.....

What factors do you consider when ordering pharmaceutical products?

.....

.....

.....

Describe the quality, promotion, price and distribution of local products by local manufacturers.

.....

.....

.....

What problems are you having with local manufacturers' products?

.....

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There are two main competitive strategies that can be used by local manufacturers; these are product differentiation and low cost pricing. Which one do you think they are using? .....

Give reasons for the above

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In your own opinion, is the above strategy suitable for the local products and market conditions?

KEY INFORMANT INTERVIEW GUIDE

I. Government Role and Incentives:

Which incentives are being offered by the Government to promote pharmaceutical production and exports?

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What else can the government do to improve pharmaceutical production and hence the competitiveness of local products?

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II. Government Conditions:

Were there any performance commitments or agreements signed or agreed upon by the pharmaceutical industry and the government?

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In what way are the conditions put in place above impact the productivity of the pharmaceutical manufacturing companies in Zimbabwe?

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III. Investment and industrial development environment

How strong is the country's financial sector in supporting pharmaceutical industry and what are the requirements to access such financial support?

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IV. Industry regulation

Is the status of laws on pharmaceutical registration favourable for new pharmaceutical products and what challenges are being faced in new registrations by your members?

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Does the regulatory agency have systems and capacity to assure product quality through GMPs and enforcement of standards, what challenges are being faced?

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