Pharmaceutical Pricing: Assessing the Impact of Factors Influencing HIV/AIDS and AIDS Related Medicine Prices in Zimbabwe

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A Thesis Submitted to the University of Cape Town in Partial-Fulfilment of the Requirements for the Award of the Degree of Master of Commerce in Economics

University of Cape Town
Faculty of Commerce
(2002)

Declaration

I declare that this is my own original work apart from the assistance I got from my supervisor. This work has not been presented and will not be presented to any other university for any other degree.

Student Name: _____

Signature: _____

This dissertation has been submitted for examination with my approval as the University of Cape Town Supervisor.

Supervisor: _____

Signature: _____

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Acronyms

AIDS: Acquired Immuno-Deficiency Syndrome

ARIPO: African Regional Intellectual Property Organisation

EDLIZ: Essential Drug List and Treatment Guidelines for Zimbabwe

DDA: Dangerous Drugs Act

GDP: Gross Domestic Product

GNI: Gross National Income

HIV: Human Immuno-Deficiency Virus

IPR: Intellectual Property Rights

MASCA: Medicines and Allied Substance Control Act

MCAZ: Medicines Control Authority of Zimbabwe

MNCs: Multi-National Companies

R&D: Research and Development

TRIPs: Trade Related Aspects of Intellectual Property Rights

WHO: World health Organisation

WIPO: World International Property Organisation

WTO: World Trade Organisation

US $: United States Dollar

ZW $: Zimbabwean Dollar

Acknowledgements

Firstly and for most, I would like to thank the almighty God for giving me the ability, courage and strength to write this Thesis. Many thanks go to my supervisor Clas Rehnberg for his guidance and contributions through out the course of my thesis. I would also like to give thanks to the Swedish International Development Agency for sponsoring my Masters programme and my Thesis.

I would like to thank Mrs Hove, Mrs Chipwere (MCZA), Mr C. Chitemere (Varichem), Mr Chindove (CAPS), Mr E. Sackey (ARIPO), Mr G. Sibanda (ARIPO) Mrs Wilson (Ministry of Health), for allowing me to use their resources during my fieldwork and for allowing me to interview them.

My family played a major role in giving me the encouragement and support during difficult times thank you for believing in me. Many thanks go to my brother Mukayi for being there when I needed you most; you offered me a shoulder to cry on in difficult times. God bless your soul. I would also like to thank my brothers, Tee-Dee, Allen (Jangwa), Simba, my nephew Taku, my sisters Hazel and Penelope, my brother-in-law Chris and my sisters-in-law Charmaine and Ruvimbo for being my biggest supporters.

Special thanks go to my classmates for keeping the momentum going, may all your wishes be fulfilled. To Rufaro, thank you for the role you have played in my life up to this point. God bless you.

I dedicate this Thesis to the two most important people in my life who made me what I am today,

To My Parents

Mr Dickson Endaimberi Mutsago and Mrs Dilly Ndakaiteyi Mutsago

May God bless you; you are the best thing that ever happened in my life, thank you.

Thank you all once again

Abstract

HIV/AIDS death and mortality rates have proven to be one of the largest threats to the economies of many developing countries, in particular Zimbabwe. Twenty five percent of the adult population in Zimbabwe is HIV positive and it is estimated that at least 2000 people die every week of the disease. Consequently, there is an urgent need to find means and ways of reducing the number of premature deaths due to AIDS.

Access to affordable drugs will have great impact on reducing these premature deaths in the country. However high AIDS and opportunistic infections drug prices have rendered these medicines unaffordable and inaccessible to the vast majority of the population infected with the virus. Moreover the majority of the population has to meet most of its drug cost through out of pocket payments. Furthermore, high antiretroviral drugs prices have resulted in their exclusion from the essential drug list; hence they cannot be made available in the public sector through public procurement. The costs of these medicines are beyond the financial means of the government, which has a very limited budget for the health sector. It is important however to note that these prices are international prices and are not set specifically for Zimbabwe.

It is important to note that pharmaceutical prices are a function of both international agreements (for example patents) and domestic factors in the pharmaceutical market. The main aim of the study is to analyse influences of supply side and demand side factors (patents, parallel importation, duties, taxes, mark ups, exchanges rates and competitive tendering) on the final end user prices. Furthermore, it will briefly assess the implication of the final end user prices obtained from the study on access to affordable antiretroviral drugs in Zimbabwe.

Both quantitative and qualitative methods were used to obtain data from various key informants, pharmacies, wholesalers and manufactures. The analysis of quantitative data was done using Excel and Stata software packages and a descriptive analysis method was used to interpret the data.

The main findings from the study are that, patented antiretroviral and opportunistic infections drugs are more expensive compared to their generic equivalents or therapeutic generic equivalents. Lack of competition because of few therapeutic alternatives has led to a monopoly market for the few generics that are available. Nonetheless, this is not to say drugs should not be patented, patents are necessary since they promote and encourage investment in R&D and innovation of newer drugs. Thus, there is need to strike a balance between the commercial interest of multinationals and public health needs of developing countries. Further more it is evident that taxes, duties and mark-ups can even double manufacturer's prices, however,

there are both positive and negative implications associated with both polices, those that target taxes and those that target mark-ups as means of trying to curb escalating prices. Competitive tendering has contributed enormously to lower drug prices in the public sector; this is because of high volumes purchased by the government, which consequently lead to high demand. The government also has high bargaining power. However, at present, competitive tendering has minimal impact on prices of the patented drugs since these are hardly procured by the government as a result of their exclusion from the essential list.

Two sensitivity analyses are carried out, the first sensitive analysis assesses the sensitivity of final end user prices to a different exchange rate and the second analysis assesses the sensitivity of end user prices to the implementation of parallel importation. It is evident that prices of antiretrovirals could fall substantially if one assumed an official exchange rate as opposed to the black market rate that is currently prevailing in the country. Furthermore, the second sensitivity analysis further reinforces earlier findings that generic competition as a result of parallel importation of generics could lead to a significant reduction in drug prices even in the presence of parallel market rates.

Additionally, antiretroviral drugs in Zimbabwe were found to be more expensive than in USA, Brazil, India and Uganda, for which comparable data is available. Thus, AIDS drugs are far from being equity priced. The expected relationship between the income level of a country and the prices of drugs is not obvious in this study. It was also found that the costs of year's triple therapy is out of the reach of average individuals in the country who have to work an equivalent of up to 15 years to purchase a year's triple therapy. Furthermore, the costs of providing antiretroviral drugs would far exceed the current health budget if the government were to provide such drugs to all those who need treatment. Antiretroviral drugs are out of the reach of both the government and the vast majority of the population. Only the elite members of the society can afford to purchase them in the private sector.

The paper concludes by suggesting key policy recommendations that the government, with the help of the international community could adopt to try and curb escalating prices of vital drugs. However, the policies should not be implemented in isolation. There is need to implement mutually supportive strategies.

1 CHAPTER ONE: INTRODUCTION

1.1 Background and Overview

Evidence from recently published literature has shown that, at least 21 million people have died of AIDS since the start of the pandemic 20 years ago. At least 36 million people are living with HIV/AIDS, and more than 25 million people leave in sub-Saharan Africa.[1] The projections have also shown that the number of AIDS deaths can be anticipated to escalate in the next 10 years to more than double the number of deaths due to all other causes if there is lack of or no treatment for the disease.[2] Almost all the cases of HIV/AIDS are prevalent in communities that are already weakened by severe poverty, presence of other diseases and lack of education.[3] The developing world has experienced at least 95% of all AIDS deaths to date, and at least 2.5 million people die each year from the disease. The availability and affordability of antiretroviral drugs in the developed world has drastically reduced the mortality rates as a result of AIDS, for example Antiretroviral drugs have decreased the AIDS-related mortality rate in the USA by 75% in the short run.[4] However the same cannot be said about the developing world where treatment for opportunistic infections such as Cryptococcosis and Candidiasis and antiretroviral therapy may be beyond the financial means of many public health systems and most individuals.[5] In developing countries, less than 10% of the people with HIV have access to antiretroviral therapy.[6]

Several interrelated factors determine access to essential drugs, including drugs to treat HIV/AIDS and opportunistic infections. Among them are appropriate use of medicines, affordability (medicine prices), supply management, economic issues (e.g. sustainable financing), rational drug selection, legislation and regulation, manufacturing and distribution (this includes reliable systems to ensure medicine procurement, distribution and use), cultural factors and research and development (R&D) decisions. A number of World Health Organisation (WHO) member states have expressed the opinion that, unaffordability (hence high drug prices) is a chief contributing factor to lack of access to drugs. The market price of these drugs is often high; as a result, they are not affordable, and thus non-existent for the great majority of developing countries' population in need. Evidence from the literature also supports the notion that, although prices are

[1] Dorrington, et. Al, (2001)
[2] Ibid
[3] Panos Institute (2000)
[4] Perez-Cassas, (2000), Perez-Cassas et al. (2001), and UNAIDS (1998)
[5] Ibid
[6] UNICEF and UNAIDS Secretariat, (2001)

not the only reason why people do not get access to affordable medicines, it is a major barrier in many developing countries.[7]

Medicine prices are important to look at since drugs have certain characteristics that if access is improved more people are able to improve their health status. Additionally the importance of assessing the impact of supply and demand side factors on overall medicine prices hinges upon the fact that medicines constitute a large proportion of medical expenses in most developing countries both for households and for the health budget compared to other inputs like machinery. Although labour is an input factor that also constitutes a large proportion of the health budget, it is often not tradable.

Data from poverty assessments from the developing world show that, exorbitant medicine prices is one of the main factors causing poor individuals to either avoid seeking treatment or to cut their treatment short.[8] In Kampala, Uganda, three quarters of the population surveyed had reduced their spending on meals in order to buy medicines. High drug costs contribute indirectly to drug resistance, because of the high costs, poor people usually do not finish the course, and this results in strains not killed off by the medication, thereby developing resistance.[9] On the other hand inability to finish the course as a result of high costs of drugs is not the only reason leading to resistance. Over consumption of drugs could also lead to resistance. Additionally, especially with respect to the HIV virus, it has been found that the virus develops its own resistance mechanism to certain drugs.[10]

The problem of high drug costs can further be illustrated by looking at the treatment of pneumonia, one of the opportunistic infections associated with AIDS, which claims over three million lives each year. In Zambia, it costs about US$8–$10 to treat a single episode of the illness, provided that drugs are available. In this country, almost 60% of the population lives on monthly incomes of less than US$18 a month; this is equivalent to the cost of a minimum food basket. It is clear that "families living on the very margins of existence would have to cut their food spending by one-half to treat a single case".[11]High AIDS medicine prices in poor countries have preordained poor people who suffer from AIDS to premature deaths.[12]

One may argue that no prices are low enough to ensure access in the absence of adequate financing and delivery systems or in the presence of compromised financing and delivery systems as to make the

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[7] Perez-Cassas, (2000)
[8] Oxfam (2001)
[9] Oxfam (2001)
[10] Naik (2002)
[11] Oxfam (2001) pp. 16
[12] Perez-Cassas (2000)

attainment of the health goals promised by such drugs unlikely.[13] Efficient financing and delivery mechanisms are essential since even with low prices, the majority of the population may still not be able to access and afford drugs if proper financing and delivery mechanisms are absent. Yet prices still remain an important part of affordability. Prices are also important in ensuring access to essential medicines especially for countries with limited resources. Medicine prices remain a "locus of contestation" as they have for nearly 50 years.[14] Drug prices have a reflective influence on other factors as well. Many system-wide policy choices are impacted on by the costs of obtaining medicines. For example, the decision as to whether AIDS-related drug care should be provided in the public sector or not. The Panos institute advocates that; " the main reason why antiretroviral drugs are not widely available in the developing world is the price of the drugs themselves".[15] Inclusion of certain drugs on the essential list to a great extent depends on the prices of drugs themselves since most governments primarily consider the price of the drugs before making a decision on whether to include the drug on the list or not.[16]

The final end user drug price is a function of number of factors of which most of them originate from local influences. These include, presence/absence of price regulation, import duties and tariffs, local taxes, wholesale and retail mark-ups, public medicine procurement polices, degree of competition, value of the domestic currency, R&D costs, production costs, size of the market,[17] and drug financing mechanisms. Yet, one of the most important major factor influencing final end user prices is the final price set by the industry for newer drugs for both the public and private health sector.[18] More specifically newer drugs are proprietary (still new and under patent) as opposed to generics that are sold at prices closer to the cost of production. Since HIV/AIDS is quite recent and topical in medical history, most of the drugs manufactured especially to treat HIV/AIDS and related infections, are proprietary and therefore still patented in many countries. The degree of monopoly enjoyed by these on-patent drugs allow researched based companies to charge high monopoly prices, which render the treatment of AIDS and related illnesses less affordable than that of other diseases.

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[13] Gray (2001)
[14] Gray (2001)
[15] Panos Institute (2002)
[16] Gray (2001)
[17] Investment in terms of research and development is positively related to the price of the drug, i.e. high research and development and production costs would be reflected in higher prices for the medicine than otherwise would be if such costs were lower. If the size of the market is big, prices tend to be relatively lower than in smaller markets since manufacturers would be trying to maintain a certain level of profit in these smaller markets. A detailed discussion is however beyond the scope of this paper.
[18] Perez-Cassas et al. (2001)

The price implications of the Trade-Related Intellectual Property Rights agreement (TRIPs) are at the heart of the debate. This agreement concerns itself with property rights protection and obligations (patent protection). TRIPs requires patent protection for all products and processes, with a minimum duration of 20 years from the original date of filing the application, without any special concern for pharmaceuticals.[19] However filing is not the same as approval. It may take about 3-4 years from the date of filing before the product is approved and launched onto the market. Additionally if a patent is granted it does not follow that the product will be approved, some patented products actually never make it onto the market. Nonetheless, the time granted for patent protection could considerably hinder the introduction of new generic drugs, depending on the way in which the national legislation is designed and implemented. These exclusive marketing rights coffered to multinational drug companies may allow them to command the highest possible prices, and thereby catering only for the countries' elites.[20] This could leave such drugs out of the reach of the vast majority of people living in developing countries. Evidence from research undertaken has also shown that there is no relation between prices and public health needs or buying power of households/ individuals in most developing counties.[21]

On the other hand, patents are viewed as essential mechanisms of appropriating economic returns on innovation. Patents are a necessary incentive to encourage companies in less developed and industrialised countries to channel R&D resources towards certain neglected diseases. However, patents are not always sufficient to achieve this.[22] It is also argued that technological transfer and foreign direct investment can be increased by facilitating access to technologies that patent holders may not be otherwise willing to transfer in the absence of intellectual property rights (IPR) protection. Additionally potential foreign investors may take into consideration IPR protection when making their decisions as to where to locate production facilities.[23]

Nonetheless, the high cost of antiretroviral drugs not only keeps patients from getting treatment but also dispirit health ministries from improving the quality of patient care through use of newer and better medicines.[24] Although prices of antiretroviral drugs have been falling on average, they have not however fallen enough to reach millions of people in the developing world who need them. Therefore, the question of whether a drug is under patent protection or not is of significant importance in determining the final price and consequently it is important for drug procurement.

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[19] WHO (2000)
[20] Pérez-Casas, (2000)
[21] Ibid
[22] Kettler and Collins (2001)
[23] South Centre (2001)
[24] Boulet, Perriens and Renaud-Théry (2000)

In the light of the above, this paper will outline and discuss the most important supply side and demand side factors influencing pharmaceutical prices in Zimbabwe. The paper also seeks to establish and assess how these factors impact on the final consumer prices of antiretroviral and opportunistic infections drugs in Zimbabwe. The paper will also present how HIV/AIDS medicine prices in Zimbabwe compare with international prices. Furthermore the paper will briefly discuss how the final end user prices of drugs affect affordability of essential HIV/AIDS drugs, based on the health budget of the country and the average income of most individuals. On the other hand, medicine prices should not be the only focus of attention. Developing health systems and financing drug purchases should also be taken into account since they are also fundamental pieces of the "access jigsaw".[25] This paper however mainly focuses on prices but at the same time is aware that price is not the only issue. Finally the paper offers some suggestions and recommendations for policy makers in order to assist them make informed decisions.

1.2 Problem Statement

AIDS is the largest single threat to health in Zimbabwe. It has reduced life expectancy from 65 years before the epidemic struck to 37.13 years, it has created some 800,000 orphans, it kills 700 a week, and it wreaks havoc within the Zimbabwean economy. These figures are alarming but true. The number of AIDS deaths is disturbing and the social and economic impact is going to be devastating if something is not done. The existing problem lies in finding means and ways of reducing the number of people dying of AIDS and the number of AIDS cases. Prevention is always better than cure and should be any country's number one priority. On the other hand, people who are already infected do not really benefit from preventive methods. Lack of access to affordable medicines is an issue of growing concern since it is one of the main reasons rendering the reduction in the number of people dying of the disease impossible. The WHO considers equitable access to health care a basic human right. It is argued that it is the poor who are most affected by this disease and die quickly from it. It is clear that the poor cannot afford the expensive medicines. Once a person is infected, access to reasonably priced medicines eventually becomes the bottom line to long-term survival. It follows that high prices for drugs imply an inequitable and unequal access to life saving medicines. Keeping an AIDS patient alive for a year in Zimbabwe costs up to US $15 000, which is 24 times the average annual income in Zimbabwe.[26] Hence, medicine prices and economic access (affordability) to HIV/AIDS and opportunistic infections medicines is a major cause for concern.

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[25] Thomas (2001)
[26] Viriri (1998)

1.3 Rationale For the Study

Zimbabwe has one of the highest AIDS/HIV prevalence rates in Africa and one of the highest in the world. One in every four adults is infected with HIV (25%). It is projected that 1.6 million of Zimbabwe's population of 12.5 million is living with HIV. In 1997, approximately 2,000 people acquired new HIV infection every week and 15% of new AIDS cases were among children under five years of age. The rising number of orphans is changing the social structure of the country.[27]

Households spent about ZW $23 million related to AIDS deaths in 1999. It is estimated that by 2005, 60% of Zimbabwe's health budget will be required for AIDS treatment alone. The cost of a triple therapy cocktail is unaffordable to the majority of the people of this country where the monthly wage averages around 20-55 US dollars.[28]High unemployment rates coupled with low wage rates relative to other countries has resulted in low average income in many sectors of the economy that the majority of the population are engaged in. There is little research that has been done in developing countries to assess the impact of factors affecting drug pricing on the final consumer price and consequently on access to affordable drugs. Empirical evidence is necessary since one is able to identify problem areas for which intervention should be targeted at. There is need to identify those variables which are contributing to high drug prices, specific to Zimbabwe. Without this knowledge, interventions could be targeted at wrong areas leading to a waste of scarce resources.

Premature deaths as a result of AIDS can be prevented if the right treatment is available and can be economically accessed by those who need it the most. Although drug pricing is not the only obstacle to access, it is apparent that it plays a central role in many poor countries. The above discussion establishes the need to carry out an investigation on how supply side and demand side factors impact on HIV/AIDS and AIDS related drug prices and consequently how the final consumer prices impact on access to affordable HIV/AIDS drugs in Zimbabwe. This study will then provide information that will facilitate policy makers in decision and policy making. Additionally, the study will also contribute to the already existing body of literature pertaining to medicine pricing. The study will also help identify the gap that exists between what the ministry of health hopes to achieve with regard to access to affordable medicines and what is happening in practice.

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27 UNAIDS and U.S. Agency for International Development (1999)
28 Agence France-Presse (2001)

1.4 Aims and objectives

1.4.1 Aim

To establish and study the fundamental factors that influence the prices of medicines and assess the extent to which they impact on HIV/AIDS and opportunistic infections end user medicine prices and to briefly assess the implication of final consumer prices on access to affordable HIV/AIDS drugs in Zimbabwe.

1.4.2 Specific Objectives

1. To map out and summarise how the pharmaceutical sector in Zimbabwe functions and to review the current national pharmaceutical legislation, and assess how the TRIPs agreement is implemented into the law system.
2. To identify and quantify the most important drugs for HIV/AIDS and opportunistic infections that are registered and marketed in Zimbabwe and review the patent status of these drugs (i.e. defining the scope of patentibility of these drugs).
3. To conduct an analysis of factors affecting drug pricing in order to study, accurately assess and document how these elements (generic competition, drug patenting, exchange rates, mark-ups, duties, taxes and competitive tendering, parallel importation) have influenced the prices of HIV/AIDS and opportunistic infections drugs in Zimbabwe.
4. To compare prices of HIV/AIDS drugs in Zimbabwe with international prices and briefly assess and discuss the implications of final consumer prices on access to affordable drugs used to treat HIV/AIDS.
5. To identify and recommend appropriate policy recommendations for intervention to ensure regular access to affordable HIV/AIDS and AIDS related drugs.

1.5 Structure of the Dissertation

The remainder of paper is arranged as follows:

- Chapter two gives an overview of the country context in terms of the demographic pattern, health sector and the economy as well as the background to the AIDS crisis in Zimbabwe and other developing countries.

- Chapter three presents a detailed review of the literature that has been written in relation to the topic at hand. Specifically it will look at the global pharmaceutical industry, the market for drugs, the economic theory on price regulation, and the background to the trade related aspects of intellectual property rights. The chapter also presents a brief look at competitive tendering, medicine mark-ups, duties and taxes. Finally chapter three outlines the conceptual approach to medicine pricing.

- Chapter four provides and outlines the methodology used during data collection and to analyse the data. Furthermore, the type of data collected is also presented. The chapter summarises the data collection instruments, identifies the variables, data source and data collection procedures. The chapter also identifies data and research problems as well as biases and limitations associated with the study.

- An overview of the pharmaceutical industry in Zimbabwe is presented in chapter five.

- Chapter six deals with the analysis of results and discussion of key findings. The analysis of results is presented descriptively and analytically and this is followed by a discussion of key research findings.

- Chapter seven draws some conclusions from the study and offers some recommendations for policy makers.

2 CHAPTER 2: COUNTRY CONTEXT

2.1 Introduction

This section will mainly focus on the background to the country. It will mainly discuss the demographic pattern of the country, the economy, and the health sector. A brief discussion of the background to the AIDS crisis in Zimbabwe and other developing countries is also given.

2.2 Background of the Country

Zimbabwe is a developing, low-income and landlocked country situated in southern Africa. It is bordered by South Africa, Botswana, Zambia, and Mozambique and it has a total area of 390,580 sq km. The country is characterised by recurrent droughts but floods and severe storms are rare.[29]

2.2.1 Demography

The total population is estimated to be 12,806,143 and it has a population annual growth rate of about 2% (2000 est.). About 58% percent of the population is between the age of 15 and 64 and 32% of the population lives in the urban areas and 68% resides in rural areas. It has a birth rate of 24.68 births/1000 population and a death rate of 23.22 deaths/1000 population and has a life expectancy of 37.13 years (2001 est.) These estimates unambiguously take into account the effects of excess mortality due to AIDS. This can result in lower life expectancy, higher infant mortality rates and death rates, lower population growth rates, and changes in the distribution of population by age and sex than would otherwise be expected. It is also estimated that 85% of the population is literate.[30]

2.2.2 Economy

The country's economy is agricultural based; tobacco is the key cash crop and corn is the chief source of food. Other products include cotton, sorghum, peanuts, wheat, sugarcane, soybeans, and coffee. There are abundant tea plantations in the country and dairy farming is important in the high veld. Forests in the South-East of Zimbabwe yield precious hardwoods, including teak and mahogany. Zimbabwe is endowed with a

[29] World fact book (2001)
[30] World fact book (2001)

wide selection of mineral resources, including gold, nickel, asbestos, tin, iron, chromate, copper, and coal. Its industrial products include iron and steel, cement, foodstuffs, machinery, textiles, and consumer goods. A hydroelectric station at Kariba Dam on the Zambezi River generates most of its electric power. The country has good roads, railway networks and domestic and international air services. The country's major trading partners are South Africa and the United Kingdom. Zimbabwe is a member of the Southern African Development Community.[31]

The country has a GDP of US $7.4 billion (2000 est.), a GDP annual growth rate of –4,9% (2000 est.), a GNI of US $5.9 billion and a GNI per capita of US $480 (2000 est.). The GDP breaks down as follows: agriculture (18.3%), industry (35.3%), and services (46.4%). The GDP growth rate was 10.6% in 1996 and –0.7% in 1999. The GDP was US $8.6 billion in 1996 and US $5.5 billion in 1999.[32] This shows that the GDP growth rate has been declining over the years and it has recently been negative. Sixty percent of the population lives below the poverty line. The country has a labour force of 5.5 million and an unemployment rate of about 50%. Badly needed support from the IMF suffers delays in part because of the country's failure to meet budgetary goals. Inflation rose from an annual rate of 32% in 1998 to 59% in 1999, 60% in 2000, 103% in 2001 and 122.5% to date. This implies that prices of all commodities are skyrocketing at the moment in the country.[33]

The country currently faces a severe shortage of foreign currency, which has led to ongoing shortages of liquid fuels and a scramble for funds to import materials and spares, as well as the decline or even failure of businesses that depend on imports. Since the government is reluctant to adjust exchange rates to more realistic levels, an unofficial market for foreign currency has developed where foreign currency is bought at rates that about four times the official rates. This has increased inflation, which is floating at around 120%. Worse still, energy costs have spiralled much faster than overall inflation and are now a key worry for the country.[34]

The country faces a wide variety of economic problems as it struggles to consolidate earlier moves to develop a market-oriented economy. Excessive government deficits and AIDS are steadily weakening the economy.[35]

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[31] The Columbia Electronic Encyclopaedia (2000)
[32] These figures are at current prices, World fact book (2001) and world development indicators database (2002)
[33] World fact book (2001) and world development indicators database (2002)
[34] Country Spotlight (2001)
[35] World fact book (2001)

2.2.3 Health sector

AIDS, Malaria and Tuberculosis account for many of the deaths. Notwithstanding the magnitude of the AIDS epidemic, few people see themselves to be at risk. Denial and stigma encourage discrimination and weaken prevention efforts. Lack of strong government leadership has hampered HIV prevention efforts in the past.[36]

Zimbabwe's struggling health system is supposed to have free health care for the poorer people, but it is short of expertise and staff. After independence in 1980, the country inherited a health system that was prejudiced towards the ruling colonial minority since the early 20th century. Nonetheless the government then embarked on a programme of free primary health care for all in an effort to correct the historical imbalances. The policy saw substantial investments in the health sector, the construction of new health centres, clinics, hospitals and hiring of more staff.[37]

At the turn of the decade, the government realised that performance in the health sector was deteriorating due to declining fiscal provisions. To date the Ministry of Health has been experiencing a decline in its real financial allocation from the central government. On the other hand, the demand and need for health services have been increasing. The major problems facing the health sector are:

a) The centralised public health administration which is not responsive to local demands and expectations,
b) Dwindling of fiscal resources, and
c) Loss of core personnel to the private sector and neighbouring countries.[38]

In an effort to recover some costs the government has re-introduced user fees, which are collected by district hospitals. The district hospitals retain 50% of the user fees for hospital management but primary healthcare for example immunization (mainly at baby clinics) is free. An important development was the introduction of a compulsory Social Health Insurance in 1998 for those employed in the formal sector only. This does not cover medicines, and it is a form of co-payment insurance. A small proportion of the population is covered by private insurance where they make private contributions and in some cases the employer also contributes a certain amount. Most insurance companies do cover drugs as well. However,

[36] U.S. Agency for International Development (1999)
[37] Kindersley (2000) and Chirove (1999)
[38] Chirove (1999)

the majority of the population (which is involved in the informal sector and the unemployed) has to rely on out of pocket payments for consultation, treatment and drugs.[39]

Poor drug financing implies that the consumers may have to bear all the costs of financing drugs. In many developing countries, financial resources are not sufficient enough for the governments to subsidise a reasonable amount for drugs. Moreover many donors have cut or discontinued their funding to Zimbabwe for political reasons and this has put further constraints on the already limited health sector budget.[40] Hence, very few drugs for AIDS related illnesses are subsidised in Zimbabwe. In addition the shortage of foreign currency and depreciation of many African countries' currencies implies that the costs of importing drugs has increased. Developing countries produce less than 10% of total drug output and moreover, many local producers import almost 90% of their raw materials.[41]

It is the policy of government to treat all patients, and this is the policy that is currently working. The government is also encouraging people to join private medical aid societies, which have different schemes and different levels. This would enable individuals to afford at least one medical aid scheme with a certain amount of cover. However the government can never really afford to treat everyone in the country.[42]

Healthcare financing is both private and public, yet the government is by far responsible for the vast majority of the population. This is because the majority of the population is around 15 years of age, and do not earn any income. Additionally, there is a small percentage of people who work relative to the whole population. All civil servants belong to a public service medical aid.[43] Private health insurance plays an important role in financing the health care needs of a small section of the society. In July 1995, 23 private health insurance schemes covered 750,000 Zimbabweans and their dependents. This represents less than 7% of the population. Employer-based and industry-based programs account for the smallest percentage of beneficiaries, and the programs have recently been declining in number because of viability problems. Membership is around 260,000, and all the members are employed in the formal sector. Hence, only about 17 percent of all those in formal employment, (excluding agricultural and domestic services), are covered by employer-based schemes. In 1994 individual direct spending accounted for 31% of the total health spending in the private sector. This accounted for the largest single category of expenditure. Health insurance

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[39] Chirove (1999)
[40] Ibid
[41] WHO (2000)
[42] Ibid
[43] Ibid

accounted for 11.8%. The above reflects an inequitable distribution of resources in favour of the well-off members of the population.[44]

Anyone who earns under ZW $500 is entitled to free health care, however, this still needs to be revised. The burden of disease has increased so have the costs of running a hospital. There is a social dimension fund that comes under labour and social welfare, where people tend to apply for help, though this is usually very much under funded since the demand surpasses what they can offer.[45]

Health care in Zimbabwe is supplied by government institutions, private not-for-profit institutions (missions, NGOs), mining and industrial companies, private for-profit institutions, (general practitioners, private hospitals and clinics) and traditional medical practitioners (including faith healers and traditional midwives). However, the public sector is still by far the most dominant player. [46] The government has built 1200 clinics, and there are 55 district hospitals and 4 teaching hospitals and a special psychiatric hospital. The local governments (municipalities) have their own clinics and people in urban areas use these.[47]

The ministry of health has a national drug policy, which contains guidelines for selection, procurement, distribution, managing and rational use of drugs. The policy aims to improve and sustain, within the available resources, the health of the majority of the population of Zimbabwe by treating, curing, reducing or preventing diseases and conditions through the use of safe, effective, good quality and affordable drugs. The government's aim is to have at least 90% drug availability for all essential drugs at primary healthcare levels at all times.[48] The ministry of health conducts drug surveys, and the last survey was done in September/October 2001. This survey established that there was a drug availability of 69,2%; nonetheless, the government would like 100% drug availability for the vital drugs.[49] However, they have never reached 100% availability but in the past years they managed to reach about 95% vital drug availability.[50]

There is a generic procurement policy that encourages all pharmacies in public hospitals and clinics to buy, dispense and prescribe generic drugs as opposed to branded medicines. The Ministry of Health has its own Essential Drugs list for Zimbabwe (EDLIZ), which was first published in 1994. The drugs are put into the

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[44] Ministry of Health and Child Welfare
[45] Ibid
[46] Ibid
[47] Wilson (2002)
[48] The Zimbabwe national drug policy (1995)
[49] Drugs are grouped into three categories, vital, essential and necessary drugs
[50] Wilson (2002)

following categories; C level (clinic level) B level (district level) A level (provincial level) and S level is the teaching level. Each institution orders drugs according to drugs that fall under its category.[51]

The government has a tendering policy system, where NatPharm (which was 100% government owned but has recently been privatised), tenders for drugs on behalf of the government for the whole country. Government Hospitals order their drugs through NatPharm [52]. Hospitals also have little funds of their own, and can buy through informal tenders up to a value of ZW $5.5 million. NatPharm does not pay import duties on drugs they import. Mission hospitals also order from the government and may also get donations, but the government is not too keen on drug donations, they would prefer donations in form of money and use it to tender for drugs. Mission hospitals also get a budget from the government but they are under funded.[53]

The Zimbabwean health budget

Year	Health budget (ZW $)	Health Budget (US $)	As a % Of the total government budget
2001	12 billion	218 million	4.36%
2002	22 billion	400 million	5.21%

The table above shows the allocation of the health budget between 2001 and 2002. It is clear that the budget allocated to the health sector increased by about US $ 182 million. This is quite a substantial amount in normal terms, yet the real increase is much lower than the above figure if we take into account the high rates of inflation currently being experienced in the country. The ministry of health argues that this is not enough, they need a budget of about ZW $35 billion to meet all the necessary basic health needs of the country's population. The domestic health allocation per person was US $9.21[54] in 1999 and US $15.44 in 2000. The national health expenditure as a percentage of GDP was 7.8% in 1999.[55]

Over and above, it is clear that the health sector in Zimbabwe suffers from a shortage of financial resources. Only a small percentage of the population is covered by health insurance. It follows that treatment expenses have to be borne by households and individuals through out of pocket payments.

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[51] Wilson (2002)
[52] This is the government buyer for drugs for all government hospitals and some mission hospitals.
[53] Ibid
[54] This was 2,2% of the GDP
[55] Report of the secretary for Health and Child Welfare (2000)

2.3 Background to the AIDS crisis in Zimbabwe and Other Developing Countries

Zimbabwe is among the poorest countries in the world. Studies have found HIV prevalence rates of 70% to 86% among high-risk groups. By 1998 an estimated 750,000 children had lost one or both parents to AIDS, with projections of nearly one million AIDS orphans by 2005. [56] As a result of HIV/AIDS, the crude death rate in Zimbabwe will be more than 200% higher in 2005 than it was in 1990. BUCEN estimates that in 1997, 28% of pregnant women attending Harare urban antenatal clinics and 46% attending Beitbridge rural district clinics tested positive for HIV. Seven out of ten AIDS cases occur among Zimbabweans during the most productive years of their lives, between the ages of 20 to 49. About 70,000 Zimbabweans were expected to die from AIDS-related diseases in 1999; this is twice as many as in 1998.[57] On average, it costs an individual about ZW $40,000 (725 US dollars) a month for a single therapy of drugs to fight the disease.[58]

UNAIDS has estimated that there were 3 million deaths due to AIDS in 2000, (which is the highest global total since the beginning of the epidemic) and there were 5.3 million newly infected individuals. Overall it is estimated that 36.1 million individuals are living with HIV or AIDS.[59] The vast majority of these are in Africa and South and South-East Asia. Recent studies have shown that 70% of the people living with HIV or AIDS (25.3 million) and of new infections of HIV (3.8 million) are in Sub-Saharan Africa. About 15 % of the people living with HIV or AIDS (5.8 million) and of new infections of HIV (780,000) are in South and South-East Asia. In eight countries in Africa (including Botswana, South Africa and Zimbabwe), 15% or more of the adult population is living with HIV or AIDS. [60]This speedy rise in adult deaths has resulted in an exceptional number of orphans: 13.2 million worldwide and 12.1 million of them are in Sub-Saharan Africa alone. In some African countries, one in every 10 children is an orphan. Furthermore, while infection rates are declining in the developed world, they are constant or rising in most developing countries.[61]

Evidence from studies recently undertaken has shown that AIDS destroys human capital, weakens institutions, and aggravates deeper and wider poverty in society. There is also an increasing body of evidence which shows that, to a great extent, AIDS causes poverty, and that some aspects of being poor can increase the risk of exposure and susceptibility to the disease.[62] The disease can worsen income distribution and has overwhelming effects on households. It has reduced agricultural productivity by about

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[56] UNAIDS and U.S. Agency for International Development (1999)
[57] Ibid
[58] Ibid
[59] World Bank Group (2001)
[60] Ibid
[61] Ibid
[62] Adeyi, Hecht and Soucat (2001)

50% in Zambia.[63] AIDS is also likely to increase poverty through the rise in the number of children who lose one or both parents. Current studies have shown that orphans have significantly lower enrolment rates and are more likely to be malnourished than non-orphans. Escaping poverty (for orphans) would be made even more difficult in the absence of good schooling and adequate nutrition.[64]

Remarkable social and economic effects are evident on families and the economy as a result of illnesses and deaths caused by HIV/AIDS. Many households will exhaust their resources caring for the sick and dying, coping with funeral expenses, and compensating for lost labour and income. In urban areas especially, traditional and social care support mechanisms are breaking down at a very fast rate. Families are now hesitant to support members of their extended families since they are also battling to meet their own needs and obligations. Food security is being endangered by AIDS-related decline in the labour force and rural household savings. Households are forced to plant less labour-intensive crops, resulting in a 61% loss in rural production. A study by The Zimbabwe Farmers Union (ZFU) showed that the death of a breadwinner due to AIDS has a much greater impact on crop production in small-scale farming and communal areas than does a non-AIDS death.[65]

At national level, a diminished skilled labour pool as a result of the disease affects economic prosperity, foreign investment, and sustainable development. Seven out of ten AIDS cases occur among those in the most productive stage of their lives, between the ages of 20 to 49. The costs of training new workers, lost productivity, and absenteeism due to HIV/AIDS are taking their toll on many industries in developing countries.[66] According to the World Bank, HIV/AIDS ranks second among all diseases in loss of productive years in Sub-Saharan Africa. A study on a major transport company with 11,500 workers in Zimbabwe found that more than 3,400 employees were HIV-positive in 1996, with 64 AIDS-related deaths. The company's total HIV/AIDS costs were 20% of the company's profits. Health care costs accounted for half the loss in profits.[67]

HIV/AIDS costs threaten to devastate many health sectors in Africa and other developing countries that face severe budget cutbacks. As a result, they are overloaded and understaffed. In Zimbabwe it was projected that by 2005, 60% of the budget of the Ministry of Health and Child Welfare will be required for AIDS treatment alone, excluding antiretroviral therapy. Insurers are trying to protect their businesses from such

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[63] Adeyi, Hecht and Soucat (2001)
[64] World Bank Group (2001)

[65] U.S. Agency for International Development (1999)
[66] Ibid
[67] Ibid

losses by charging high premiums or refusing policies to HIV positive clients. For example Life insurance premiums in Zimbabwe quadrupled in two years because of HIV/AIDS.[68]

Thirty-eight countries have seen a life expectancy decline since 1990 and most of these countries are hard hit by the AIDS pandemic. 12 countries lost more than five years.[69] Table 1 below shows the life expectancy of five African countries before and after the epidemic. It is evident that all these countries have lost quite a substantial amount of years due to AIDS. Zimbabwe has the highest number of years lost equal to 26 years. Of the Five countries, South Africa has the least number of years lost due to the epidemic.

Table 1: Cuts in African life expectancies due to AIDS

Country	Life expectancy before the epidemic	Life expectancy after the epidemic	Lost years
Zimbabwe	65	39	26
Botswana	62	40	22
South Africa	65	56	9
Uganda	54	43	11
Zambia	56	37	20

Source: US census Bureau, "World Population Profile: 1998."

The high AIDS rates in Africa require an urgent, workable and sustainable intervention if the number of people dying is to be reduced. Access to low priced drugs is an indispensable step to solving the problem. Nevertheless, even with low medicine prices, substantially expanding access to essential medicines will require additional domestic and international financing for the purchase of essential drugs as well as for building effective health and supply systems. This is necessary because when drug prices fall and many low priced essential drugs are already available, there is still no guarantee that poor communities can afford them. This is particularly true for HIV/AIDS drugs. Even with costs coming down to US $500 per patient per year, it is still well beyond the reach of many developing countries whose total health expenditure is less than US $10 to US $20 per person per year. In addition, a course of antibiotics can be purchased for the equivalent of two to three hours wage and a year's treatment for HIV infection cost the equivalent of four to six months' salary in industrialised countries. However, in the developing world a course of antibiotics for pneumonia may cost one month's wage and if a year's treatment of HIV were purchased, it would use up about 30 years' income. Thus, considerable amounts of external financing are required in these cases.[70]

[68] Ibid
[69] U.S. Agency for International Development (1999)
[70] WTO (2001), and Myhr (2000)

With personal incomes frequently less than $2 a day, there is considerable agreement that half of the world's population is too poor to pay for many of the drugs they need from their own resources even at the lowest possible prices. Organised and sustainable health care financing is required for domestic public health and social security budgets where national resources are inadequate, and this needs to be reinforced by international assistance.[71]

Given the above evidence, it is true that the health and AIDS crisis in Africa cannot be ignored. Something needs to be done and it has to be done soon. Ignoring this outcry would only increase the mortality rates in developing countries thereby negatively impacting on production in all sectors of the economy as noted above. This would worsen the already weakened and struggling economies. We cannot keep a blind eye on those already infected because without them, their children would endure even worse suffering. This is because of the correlation between poverty and HIV. As noted earlier, increasing evidence has led to a wide belief that AIDS causes poverty, and moreover some aspects of being poor can enhance the risk and susceptibility to the disease. The children of infected parents cannot be left to fend for themselves, enrolment rates will drop and these children will still live in poverty and history will just repeat itself. In countries like Brazil where there are no restrictive patent laws[72], generic production of HIV drugs is taking place. The result has been that the country's mortality rate has fallen by about 50%.[73] High costs of antiretroviral drugs not only keep patients from getting treatment but also discourage health ministries from improving the quality of patient care through use of newer and better medicines.[74]

Economic access entails affordability. None the less, if the annual average income in Zimbabwe and other developing countries is barely enough to purchase a monthly supply of triple therapy, then the problem at hand is even greater than meets the eye. There is need to put an effective mechanism in place to make newer drugs affordable to developing countries. Access is sensitive to prices because most people in developing countries pay for medicines from their own pockets and a significantly large portion of the budget is spent on medicines by state health services. Moreover price is related to the presence of monopoly or market exclusivity in the drug markets.[75] In the presence of intense financial pressures facing developing counties' health systems, high medicine prices are without a doubt a significant aspect that needs to be

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[71] Ibid
[72] However such countries may have strong local working requirements.
[73] Chequer et.al (2000)
[74] Oxfam (2001)
[75] Oxfam (2001)

addressed.[76] This suggests that a reduction in drug prices of essential AIDS medication is a key step towards bringing the AIDS mortality rate down in most Sub-Saharan countries.

On the other hand, it has been shown that developing countries' governments can do far more to make medicines available at more affordable prices. Most governments spend far less on public health compared to their military budgets. Additionally tertiary level services used by better off groups absorb a large proportion of the health budget while primary health care is under funded.[77] Therefore there is need for the reduction in medicines prices to be accompanied by huge efforts by developing countries' governments with regard to enhancing and managing public sector finances as well as developing their health systems if positive results are to be realised. Thus, the pricing problem can only be tackled if policy makers become aware of the main factors that result in such high prices. Only when such knowledge is available can one come up with policies that can dampen the influences of such factors on prices.

[76] Thomas (2001)
[77] Oxfam (2001)

3 CHAPTER 3: LITERATURE REVIEW

3.1 Introduction

This chapter reviews the literature that has been written in relation to the topic at hand. Specifically it will look at the global pharmaceutical industry, the market for drugs, the economic theory on price regulation, and the background to the TRIPs. It also provides a brief look at competitive tendering, mark-ups duties and taxes. Finally it outlines a conceptual approach to medicine pricing.

3.2 The Global Pharmaceutical Industry

Medicines are exceptional goods and also the only input in health care (apart from equipment) that is a physical good that is traded internationally. The production of Pharmaceuticals requires extensive technological input and consequently a somewhat high level of industrialization, but on the other hand they are very essential.[78] New drugs require an even higher order of technological degree for their production. In practice, very few commodities are both essential and command high technical input. As a result, the medicine industry has a distinctive type of social responsibility. The essential nature of drugs makes a solution to reducing their costs rather urgent. On the other hand, the costs of high knowledge input necessary for their conception and production also needs to be covered.[79]

The pharmaceutical industry is dominated by a small number of extremely powerful transitional corporations. Recent years have seen major acquisitions and mergers. The pharmaceutical industry differs from a 'textbook' monopoly market in that no single firm dominates the market. On the other hand, there is evidence of substantial concentration within therapeutic sub-markets. In addition, best-seller drugs in these categories may account for large percentages of the sales volumes. There is also evidence of large intra-firm trade since many of the manufacturers of raw materials are located in countries of origin of the major firms. This results in "transfer pricing" (where prices are inflated to achieve optimal profits for the global level) practices for local subsidiaries.[80]

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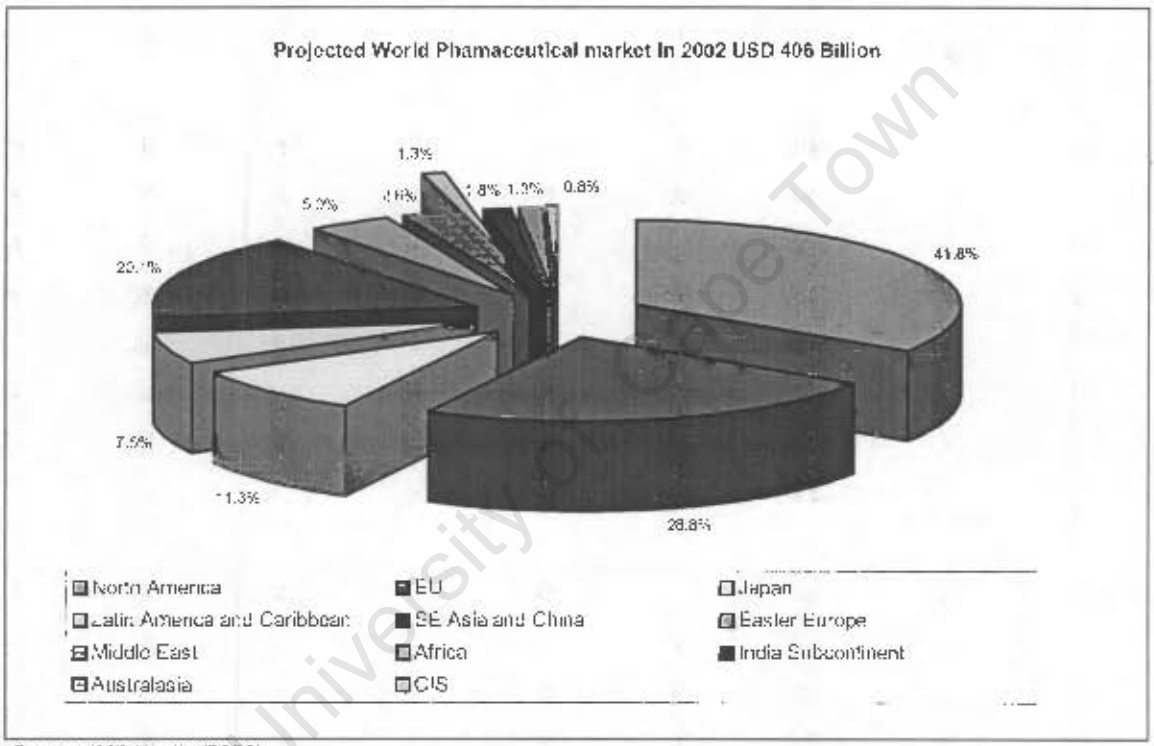
[78] Thomas (2001)
[79] Ibid
[80] Gray (2001) and Sarmiento (1995)

The global pharmaceutical industry is largely located in the industrialised North. The global sales in 2002 are expected to be $406 billion. These sales are mainly in industrialised regions.[81] Figure 1 below shows the projected global pharmaceutical market for 2002. It is clear that North America accounts for 41.8% of the whole market followed by European Union countries with, 28,8% and SE Asia and china with 20,1% of the market. However notwithstanding the fact that the sub-Saharan Africa countries have a high numerical prevalence and disease burden, they account for only 1.3% of the multi-billion pharmaceutical market. Thus, these countries are only a very small part of the global pharmaceutical market.

Figure 1: Projected World Pharmaceutical Market in 2002



Source: IMS Health (2006)
http://www.ims-global.com/insight/report/global/report.htm

In essence, developing countries have the highest burden of disease compared to developed countries. Yet over the last 20 years, the share of developing countries in the world's pharmaceutical consumption has actually dropped from a quarter to 20%. In other words 75% of the world's population is only consuming about 20% of the world's drugs and 25% is consuming about 80% of the world's drugs in terms of value (expenditure), however, the number of actual drugs consumed is probably more than suggested by these figures.[82]

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[81] Gray (2001)
[82] Quick cit. in Briscoe (2001)

An analysis of the world's top 75 medicines reveals that, after the USA, Britain's pharmaceutical companies' market share is easily more than all its European competitors combined. The US economy spends 2.3% of its GDP on medicines alone followed by France, which spends about 2% of its GDP on medicines. The top five pharmaceutical manufacturers are shown in table 2 below, this table also summarises the world's market share for each company.

Table 2: Leading Pharmaceutical corporations in 2000

	Country	Sales £	Growth* %	Share of world market** %
Pfizer	USA	15,286	13	7.3
GlaxoSmithKline	UK	14,533	13	6.9
Merck & Co	USA	10,875	18	5.2
AstraZeneca	UK	9,423	11	4.5
Bristol-Myers Squibb	USA	8,758	12	4.2

Source: IMS World Review (2001), OECD, Office for National Statistics

Pfizer has 7.3% of the world's market share followed by GlaxoSmithKline with 6.9%. The top ten leading Pharmaceutical companies have 45.7% of the world's market share and the top 20 have 64% of the world's market share. Of the leading top 20 companies, all but one are in Europe and USA.

In 2001 it was estimated that, research-based pharmaceutical companies invested US $30.5 billion in R&D. This represents an 18.7% increase over expenditures in 2000 and more than triple the investment in 1990. In 2000, both U.S.-owned and foreign-owned companies spent US $23.6 billion on R&D within the United States. U.S.-owned firms abroad conducted an additional US $6.8 billion in R&D. Over the past three decades, the amount of sales allocated to R&D has increased from 11.4% in 1970 to 17.4% in 1999. In 2001, it was estimated to be 18.5%. In the US pharmaceutical manufacturers invest a higher percentage of sales revenue in R&D than virtually any industry, including high-tech industries such as electronics, aerospace, computers, and automobiles.[33]

It is difficult to determine exactly how much R&D is devoted to specific diseases due to the nature of the R&D process and of diseases. A product may be under investigation to treat several conditions or diseases such as HIV/AIDS or malaria, which require numerous treatments within numerous therapeutic areas.

[33] Pharmaceutical industry profile (2001)

Nonetheless, about US $4.1 billion will be spent on products acting on parasitic and infectious diseases, including anti-viral and antibiotic compounds.[84]

From the above, it is evident that the US spends more on R&D than any other country. Moreover it has the highest market share than any other country. The U.S. also has three of leading top five pharmaceutical companies in the world. This concentration could also be as a result of mergers and acquisitions between companies, with the headquarters located in the US. It is important to note that of the leading top twenty manufacturing companies there is no African owned manufacturing pharmaceutical company and there is only one company in Asia (Japan). This means that most of the production and research and development takes place in the US and Europe. In addition all African manufacturers that are domestically owned only specialise in generic production. In other words they depend on innovations of the big companies in the North and West. This is so because of the large amounts of capital investments that are required in the manufacturing of branded drugs, which is definitely out of the reach of many, if not all domestically owned manufacturing companies in Africa.

3.3 The Market for Drugs and Health Care

People demand medicines because they want to be healthy. This desire to remain healthy has led to a continuous growth in the demand for health care and medicines. The demand for drugs has increased dramatically over the past years 40 years as a result of changes in the age structure, increasing real incomes and improvements in medical technology. A market for medicines has two groups: the buyers and the sellers who interact with each other.[85]

The basis for any discussion of markets is the theory of perfect competition. The theory assumes that there are many buyers and sellers in the market who should be left to transact their businesses without government interference. Additionally, information is freely available and complete and consumers act rationally to maximise their satisfaction. There are also no barriers to entry and hence the forces of demand and supply will only be the most efficient ways of allocating resources through prices, since prices are assumed to reflect the preference of consumers.[86] Consequently, goods are allocated where they are needed and valued the most. However as shall be demonstrated below, these conditions barely apply in the market for health care and medicines.

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[84] Ibid
[85] Green (2001)
[86] Lipsey and Courant (1996)

The drug market is characterised by market imperfections. There are four main types of market failure in the drug market which are drawn from those in the broader health market:

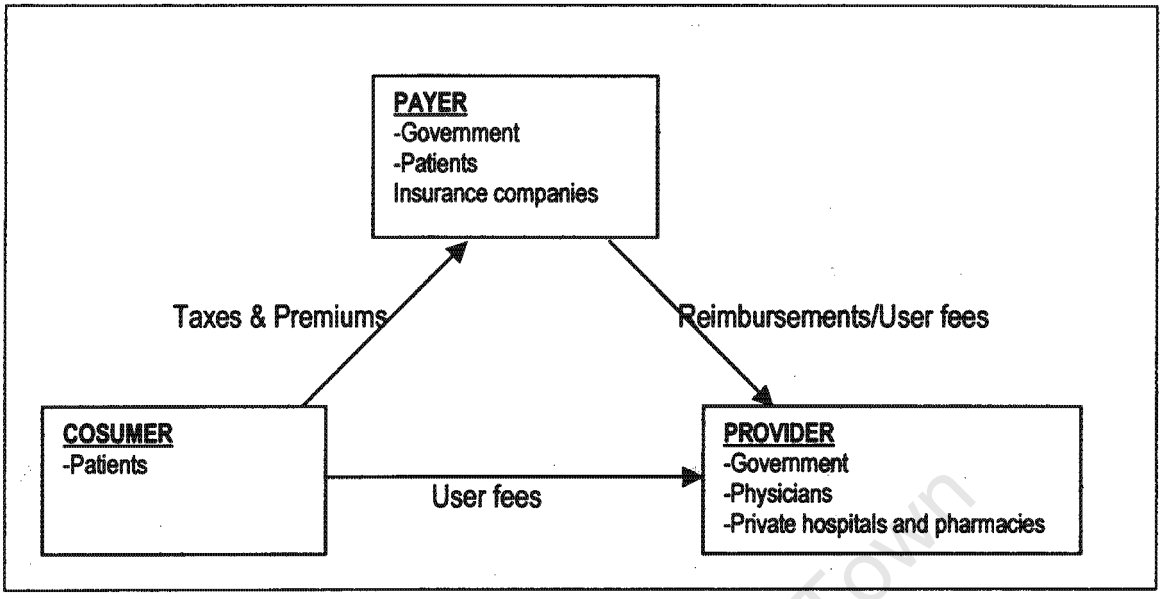
a) Poor and asymmetric access to information
b) Failure of competition
c) Homogenous goods
d) Externalities[87]

Hence, there is need to highlight these imperfections in order to identify and evaluate the role of the state in rectifying such imperfections.

Medicines are not ordinary goods of trade and are far from being homogenous. The demand and supply characteristics of drugs do not follow the classic market principles like other ordinary goods.[88] When you go and purchase a CD for example, you know exactly what you want; you really do not need a shop assistant to tell you what you should buy. Conversely in the market for drugs you may need a doctor/pharmacist to diagnose you and tell you what type of medicine to take to cure your illness. A three-tiered demand structure exists. This is so because the prescribers (physicians and others) are in most cases the actual demanders and the patients are the consumers and the health care system is in most cases the payer (this is both in the public and private sector). Consumers generally do not choose or pay (if they have private insurance) for the medicines they take. This is especially true for developed countries.[89] Even in developing countries (where consumers meet their drug costs through out of pocket payments) it is in most cases the doctors or nurses who prescribe (except in some case where consumers buy "over the counter" medicines). In countries such as the US where the burden of buying health insurance is passed on to individuals, it is still the doctors who decide on the appropriate treatment and insurance companies pay for the costs of drugs.[90]

[87] The World Bank Group (2002)
[88] Velasquez, Madrid, Quick (1998)
[89] Bloom And Van Reenen (1998)
[90] Bloom And Van Reenen (1998)

Figure 2: Agency in the allocation of health care and financial flows



As illustrated in figure 2 above, the payers for drugs or health care are; insurance companies, patients and the government in form of reimbursements and out of pocket payments (user fees) to health care providers. In addition the patient is also the consumer but also pays taxes (e.g. income tax) to the government and premiums to health insurance companies. The government could also act as the provider in the public sector. Physicians, private pharmacies and hospitals are also providers of health care. However, in most developing countries like Zimbabwe, the insurance companies only serve a few privileged individuals. Most patients meet their drug and other treatment costs through out of pocket payments. Limited government financial resources have further exacerbated the problem.

More often than not, competition among suppliers is often limited especially where patented products are concerned. Patenting of pharmaceutical products prevents other firms from producing the same products for a number of years. This creates monopoly, resulting in high prices for medicines. Barriers to entry exist. Medical professionals, pharmaceutical products, pharmacies and hospitals have to be registered and licensed.[91] Such regulations restrict entry into the market and lowers competition. Exit is also not free in the sense that when students qualify as doctors, there is a lock-in effect. There is a substantial amount of resources invested in order to qualify; this restricts them to the health care industry. Their skills are not transferable to other sector with great ease. [92] On the other hand although other sectors do experience lock in effects they may not have other characteristics noted above that encourage market failure. Moreover, in

[91] Normand (1991)
[92] McIntyre (1997)

hospitals and in the production of pharmaceuticals, there are huge economies of scale present. Their existence can result in the creation of monopolies or oligopolies. This can allow such firms to set prices above the perfectly competitive price.[93]

Medicines also have both positive and negative spill over effects (externalities). Externalities occur when the consumption or non-consumption of a good affects the welfare of parties not directly involved in the transaction.[94] Such spill over effects occur for example, if one person purchases a vaccine for whopping cough, he confers benefits to himself. On the other hand, other people also benefit because they are now protected against catching whooping cough from that particular purchaser. The free market misses such spill over effects. Under-provision of vaccinations would occur in a free market and consequently this would impose a cost upon society. In the presence of externalities, the market price does not accurately contain all the information about the benefits and costs of a market transaction.[95]

Incomplete information exists in this market because information known to the prescribers and consumers is unbalanced and selective. Information is not equally shared between buyers and sellers, instead the seller (physician), has far more information than the purchaser (patient). The separation of buyers and sellers is undermined by the presence of information asymmetry. Most medical information can not be easily understood by patients because it is technically complex and worse still many illnesses do not repeat themselves, thus gaining such information is very costly.[96] Additionally, a mistaken or wrong choice carries greater costs and is less reversible than in other cases, at worst, wrong decisions can lead to death. Patients lack the necessary expertise to diagnose their illnesses or to tell whether the prescribed treatment is necessary or appropriate. They may also not be in a position to make rational decisions.[97] In this case, health care or medicines can be viewed as merit goods; they will be under-consumed if left to individual discretion to consume them. More often than not, treatment is difficult to postpone and thus it becomes virtually impossible to shop around. In any case it is not easy to choose between different doctors' opinions. Consequently patients rely on doctors to act in their best interest, doctors make decisions regarding consumption of health care on the patients' behalf. On the other hand, doctors may have their own interests; this creates the possibility of doctors exploiting patients by advising more treatment to be purchased than is

[93] Culyer (1983) and Maynard (1986)
[94] Lipsey and Courant (1996)
[95] Green (2001)
[96] Ibid
[97] For example, the mentally ill and those who are unconscious may not realise their need for treatment.

necessary.[98] This demonstrates the notation of supply-induced demand in the market for medicines and health care.[99]

In summary, the preceding discussion reflects on the major imperfections that are present in the market for medicines and health care. There is an unresolved debate with regard to the implications of market failures in this market and with respect to the role of the state. The true social costs and benefits are often not reflected by market forces of demand and supply, hence social objectives such as equity cannot be met in the presence such market imperfections. The factors given above coupled with the inability of the industry to develop and provide needed drugs for most tropical diseases in developing countries has resulted in market failure.[100] The existence of market failure does present a case that justifies and warrants government intervention through policymaking, pharmaceutical regulation and legislation, financing and provision in order to correct market failures and to meet health objectives.[101]

On the other hand government's attempt to introduce changes in order to correct market failure may introduce further distortions. Government failure is when intervention results in outcomes that depart from the efficiency or distributional goals by which markets are judged to fail.[102] The government could be incompetent and seeks to serve the interest of strong interest groups (both internal and external), for example, the interests of big businesses like the pharmaceutical sector and the interests of politicians and the bureaucracy. It can be argued that the government may lack the necessary information to implement and make policies. There is no guarantee that if the market fails due to lack of information the government would not suffer from the same problem.

Government intervention could result in unpredictable or perverse outcomes. For example direct drug price controls could reduce the supply of necessary medicines. Furthermore, how does one define public interest, the state could end up pursuing the interests of strong interest groups. It is also true that every policy has winners and losers and it becomes very difficult to choose who should win and who should lose.[103] Implementation failures may also occur as a result of public sector inefficiencies. Individuals may also seek to influence the state in order to transfer welfare to themselves. Consequently lobby groups will invest resources to influence the form, structure and incidence of regulations, licensing laws and tariffs in the drug

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[98] Green (2001), Mills and Gilson (1998), Le Grand and Robison (1984)
[99] Gray (2001)
[100] Market failure occurs when the outcomes of the market are not pareto efficient, i.e. it is still possible to reallocate resources and make at least someone better off without making anyone worse off.
[101] Ibid
[102] Ajam (2000)
[103] Ibid

market.[104] This effort by individuals to maximise their utility could result in social waste and dead weight loss to society.

In conclusion market failure is a necessary but not sufficient condition for government intervention. Government failure also exists. It follows that there is need to arrange incentives to improve government performance, for example by defining objectives or by allowing the private sector to provide health care and medicines if they are financed or subsidised by the government. It is important therefore to evaluate government failures equally against market failures and assess the role of the market and the government against these failures.

3.4 Economic Theory on Price Regulation

Controlling the price of drugs is a major issue on the policy agenda of most modern governments. The reasons are clear. On the one hand, modern states are generally assumed to have a duty to provide at least a minimum level of healthcare services for their citizens. The costs of these healthcare services appear to be inexorably rising.

In the previous section it was noted that market failure warrants government intervention. Market failure rationales for price regulation are:

a) Monopoly Markets
b) Natural Monopolies
c) Externalities
d) Public/merit Goods[105]
e) Oligopolies

Monopoly markets, externalities, oligopolies and merit goods are the most common rationales for regulation in the drug market. In the drug market, monopoly can arise as a result of patents, which allows firms to enjoy monopoly power for twenty years before generic substitutes can be manufactured. In addition, since doctors are likely to have only a limited concern for expenditure control and generally do not have comprehensive information on drug prices they are somewhat insensitive to price changes.[106] Since

[104] Ajam (2000)
[105] Merit goods are goods that are deemed especially important and public goods are goods that have characteristics that if they provide benefits to anyone, they can (at little or no additional costs) provide benefits to a large group of people.
[106] Bloom and Van Reenen (1998)

monopolists set higher prices for consumers who are more price insensitive, it follows that, in the absence of price regulation pharmaceutical firms will most likely charge inflated prices that are above their marginal costs for their on-patent drugs, and can restrict output at the same time.[107]

Another reason could be due to the absence of many competitors in the market for drugs. The industry could be dominated by large few concentrated firms or multi-nationals which gives rise to oligopolies. [108] On the other hand oligopolies or monopolies can enjoy large economies of scale, this allows such producers to move to lower new short run average cost curves. This will enable them to produce more cheaply and the marginal cost curve can shift down and to the right. If it shifts far enough the producer could end up producing the perfect competitive output and charging a price close or equal to marginal cost. However this can only be realised if the economies of scale are large enough to influence the cost of production.[109]

Economic theory tells us that the presence of monopolies or oligopolies results in dead weight loss to society, it leads to socially excessive expenditure in the absence of price regulation. Therefore, it is argued that the introduction of price regulation in the market for drugs would reduce any deadweight loss that may occur. There are different forms of price regulation both direct and indirect. However the goal of any form of price regulation is to compel firms to charge prices that are equal or close to their marginal costs of production. This new price would be below the monopoly price, and consequently the firms would increase their drug output production. In this instance there will be more users since the price that consumers pay for drugs may fall. Additionally, price regulation leads to lower introductory prices for new drugs; this increases the welfare of consumers by increasing their consumer surplus and reducing the size of the dead weight loss.[110] This is likely to benefit consumers in poorer countries who have to meet their drug expenses through out of pocket payments.

On the other hand, evidence has shown that there are certain costs associated with price regulation.[111] Firstly, it is argued that significant price cuts might damage the welfare of patients as much as the drug firms in the long run. Pharmaceutical firms will only embark on R&D into the next generation of drugs if they expect to earn a profitable return on their efforts.[112] Global prices may be particularly sensitive to change in prices in a particular country especially if its market share is large relative to other countries. For instance, any severe price cuts in the UK could provide a cue for retaliatory price-cutting by regulators in other

[107] Bloom And Van Reenen (1998)
[108] Ibid
[109] Griffiths and Wall (2000)
[110] Clark (1993)
[111] Anis and Wen (1998)
[112] Bloom and Reenen (1998)

countries. Also, UK prices could actually feed directly into the prices of many other European countries. This is because the UK price is a key element in other countries' reference pricing schemes. This creates an additional means for UK prices to influence global prices[113]. The impact of one country's regulation on firms based in another country is increasingly expanding because of the indirect effects from the regulatory use of international price comparison. Many countries like Canada and Italy use foreign prices to set limits on their domestic prices.[114] Danzon argues that the overall impact of price comparisons is to force prices to converge on the lowest price in the comparison group countries.[115] It follows that dramatic reductions in UK prices of pharmaceuticals for example would negatively impact on the long run success of the UK pharmaceutical industry through their effect on international prices.

Furthermore, Danzon argues that this convergence of price does not benefit consumers because of high R&D costs, which causes drug firms to be vulnerable to aggressive price regulations. This is so because in the long run, investments in R&D and discovery of new innovative drugs would decline. This would have adverse effects on the supply of drugs for consumers worldwide. If prices become uniform across countries, then all consumers will be worse off in the long run than under policies which permit price differentials based on willingness to pay.[116]

Stringent price regulation also tends to weaken competition between therapeutic substitutes and competition from generics and over-the-counter medicines that succeed as cheaper alternatives in countries that allow freer pricing of branded drugs. By and large, the result is that the net difference in the price of drug therapy to consumers, between closely regulated countries (for example France and Italy) and those that allow freer pricing (such as Germany (until 1993) and the United States) is not as great as has been disputed in studies that contrast only the prices of leading, branded, originator drugs. [117]

In addition to the above, evidence from studies done in the US have shown that generic competition operates as a more effective control on prices in less regulated regimes. This is predominantly in the US, which have both more price competition and more generic competition between competitors than do regulated regimes.[118] Furthermore, as price controls often go from being price ceilings to price floors, they

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[113] Bloom And Van Reenen (1998)
[114] Danzon (1998)
[115] Ibid
[116] Ibid
[117] Ibid
[118] Danzon and Chao (1999)

can result in higher prices in the medium to long run, in contrast to allowing competitive pricing in the post patent period.[119]

To sum up, in theory, direct price regulation may look attractive in the sense that consumer surplus could be increased. However, in cases where there are large economies of scale, direct price regulation may not be warranted since marginal cost pricing can be achieved depending on the extent of the economies of scale. In addition, direct price controls may not always result in increase in welfare in the long run. In countries which use foreign prices to set limits on their local prices, prices may converge on the lowest price in comparison country. This could adversely affect the long run success of the industry. This is so because drug firms in parent countries with huge foreign market shares may lack the motivation to invest in R&D if there is a fall in profits due to a reduction in prices in foreign markets. Indirect methods like generic competition have however showed more positive results. Thus policy makers should also pay attention to factors that have effect on the entire vector of pharmaceutical prices and not only those subjects specific to regulation.[120] On the other hand, complementary polices could be put in place to counteract the costs of price regulation so that net gains that benefit the society can be realized.

3.5 Background to the Trade-related Aspects of Intellectual Property Rights (TRIPs) Agreement

The 1994 Uruguay round negotiations resulted in the formation of the World Trade organisation (WTO). The organisation had 132 members in 1997. All members are expected to abide by its rules and where necessary, the national legislations of these countries are to be harmonised with these rules. There are certain treaties on trade in goods and services annexed to the WTO convention of which one of them is the TRIPs agreement. This agreement established certain minimum standards in the field of intellectual property. In addition public health should be considered when implementing this agreement.[121]

The provisions of the WTO agreement on TRIPs are extending patents rights around the world. Advocates of the TRIPs agreement believe that patents and other intellectual property rights are important and indispensable in the promotion of R&D as well as stimulating innovation. On the other hand, critics of the agreement have expressed concern about the impact of TRIPs on the availability and prices of drugs. They argue that scant evidence exist that shows that the introduction of TRIPs has promoted transfer of R&D or

[119] WHO (2000)
[120] Danzon (1998)
[121] WHO (1999)

innovation from the developed world to the developing countries. In other words, more often than not evidence seems to show that TRIPs mostly benefits the already developed world. Thus, evidence from proponents and critics of TRIPs has sparked a heated debate as to whether the benefits of TRIPs out weigh its costs.

3.5.1 Protection of International Property Rights Before TRIPs

Many states did not issue patents for pharmaceuticals on their territories before the Uruguay round, hence the inventors had no rights over their inventions in those particular countries. The absence of global minimum level of patent protection gave these governments substantial flexibility to decide upon the coverage and legal framework for patents, in harmony with their national interests.[122] However, at international level, World Intellectual Property Organisation (WIPO) managed the regulation and protection of intellectual property. The WIPO conventions especially the Paris convention only imposed general rules, for example rules on national treatment, which required equivalent treatment for foreigners and nationals. Furthermore these conventions did not apply to states that had not endorsed them.[123]

Before the Uruguay round, about 50 countries did not grant patent protection for pharmaceutical products and some only granted process patents. This allowed them to manufacture products patented elsewhere by alternative processes. This mainly included many of the developing countries such as India and Egypt.[124] Availability of cheaper substitutes limited the effective monopoly enjoyed by originator companies and brought prices down dramatically. Ironically, most of the developed countries managed to improve their pharmaceutical industries using these measures. For example Switzerland only introduced patents when her pharmaceutical industry had reached a certain degree of development. On the other hand, in 1994, 123 countries including the poor African nations signed the TRIPs agreement.[125] Given the above, it follows that the TRIPs agreement was to bring a significant change in the drug industry since it stipulates that patents are to be granted in all fields of technology without exclusion.[126]

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[122] Oxfam (2001)
[123] WHO (1999)
[124] Oxfam (2001)
[125] Oxfam (2001)
[126] WHO (2000)

3.5.2 Interpretation of the TRIPs Agreement

The agreement seeks to "strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations."[127]The Agreement makes the granting of patents obligatory. It requires all member states to give longer market exclusivity to all drugs with patents filed after 1995.[128] The objective of the TRIPs agreement is to encourage inventive activity and foreign direct investment as well as technology transfer and activities associated with the commercialisation or marketing of an invention. It was felt that these effects would mainly be realised in developing countries.[129]

A patent is a title granted by the state in a specific country that gives exclusive rights over the manufacturing and use of an invention to the owner of this invention in that country, in exchange of the disclosure of the invention to the public.[130] Its social function is to stimulate innovation.[131] A patent is national and applications for patents must be filed in every country where protection is desired for a particular invention.[132] This affects the pricing of drugs and consequently access to medicines. The patent of a new drug is expected to last for 20 years before other cheaper generic drugs can be produced. It is clear that patent protection will allow research-based firms to enjoy monopoly power, thereby creating monopolies, which result in higher prices for consumers.

3.5.3 Relationship Between Intellectual Property Rights (IPR) Protection, R&D and Innovation

Proponents of strong IPR in particular patent protection presume a link between strong patent protection and R&D and innovation in the pharmaceutical industry.[133] The industry is viewed as an exceptional textbook case "where patents are considered an important mechanism of appropriability of economic outcomes of innovation." [134] Intellectual property protection is believed to give incentives to inventors and creators since they expect to receive some future benefits from their innovations. This encourages new inventions, for example new drugs, whose development costs are in most cases very high, hence private

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[127] WTO (2001), 1
[128] Oxfam (2001)
[129] Boulet, Perriens and Renaud-Théry (2000) and WHO (2001)
[130] Ibid
[131] Oxfam (2001)
[132] Boulet, Perriens and Renaud-Théry (2000) and WHO (2001)
[133] Kettler and Collins (2001)
[134] Lacetera and Orsenigo (2001), 6

rights will also result in social benefits.[135] It is argued that in the absence of such protection they will be under investment in research by profit-making firms as opposed to social optimum outcome.[136]

It is clear that the message proponents are trying to send home is that in the absence of patent protection they will be no R&D. This is because pharmaceutical R&D is characterised by high R&D sunk cost of about $300 600 million for each new product.[137] This accounts for more than 30% of the total costs of developing, producing and marketing the product. Additionally production of pharmaceuticals has a low marginal cost; once the products exist they are relatively easy to produce. This facilitates the production of generics at costs way below the costs of producing the patented product. Consequently in the absence of patent protection generic manufacturers can always enter the market and bid down prices to marginal cost. Since marginal cost cannot cover the fixed costs of R&D, then R&D is likely to fall, resulting in a reduction in number of new products launched onto the market by research based industries.[138]

Generally, although patent laws tend to benefit innovators they are not enough on their own to encourage innovation in settings where innovation capabilities are very low or absent altogether. This is supported by a study done by Lacetera and Orsengio of the interplay between policy regimes and technological regimes In US and Europe. Consequently innovation is likely to be sustained and promoted by high degrees of appropriability in high innovative and competitive settings as opposed to environments where little or no innovation takes place. Incentives to innovate are magnified by patents but they are not created where competencies to innovate are lacking. If competence is minimal in developing countries, it implies that IPR will not have the expected effect of improving developing countries' abilities to undertake R&D and innovation to a global standard.[139]

3.5.4 Expected Impact of the TRIPs Agreement

There are many cited advantages of patent protection, which among others include increase in R&D, increase in access to medicines in domestic markets from foreign markets, decrease in inefficient local production and decrease in domestic monopoly.[140] Nevertheless, depending on the environment in which a country exists, these benefits may or may not be realised. Most developing countries were unenthusiastic about signing this agreement because they recognised that there was high concentration of drug production

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[135] WTO (2001)
[136] Lacetera and Orsenigo (2001)
[137] Kettler (2002)
[138] Kettler and Collins (2001)
[139] Lacetera and Orsenigo (2001)
[140] WHO (1998)

in developed countries and innovation was almost entirely undertaken in these countries. During the time of negotiations, about 96% of worldwide R&D was done in developed countries and only 4% in all fields of science and technology was done in developing countries.[141]

Evidence from recent studies has shown that if patents are introduced in a monopolistic market, they sustain monopolistic prices and greater loss is realised if they are introduced in an already competitive markets. This is especially true for many developing countries. Patented drugs by definition have no close substitutes, hence, demand may tend to be less sensitive to prices due to lack of alternative treatment of equivalent quality and effectiveness.[142] After a patent has expired its price is suppose to drop because generic drugs are suppose to appear. However, the ability of local companies to produce manufactured copies depends on the number of domestic companies. In many developing countries, where the number of such companies is small, there would only be competition among trans-national companies. Moreover local companies heavily depend on external sources for raw materials; consequently, only 10% of the total production value comes from local companies. This leads to a creation of monopoly by trans-national companies. Even before the signing of the agreement, economic studies done by the World Bank showed that patent protection for medicines in developing countries would result in, increase in medicines prices, increase in royalty and profit payments overseas and would lead to a larger market infiltration by foreign firms.[143]

A study done by Watal and Borell found that, although patents promoted local availability of new drugs, they resulted in higher prices for these drugs on the whole. In this study, market exclusivity increased average prices by 32%, and firms doubled the average prices when patents were available.[144] TRIPs will delay the introduction and production of legal generic medicines by ten years or more in those countries that formerly restricted patenting of medicines. Medicines prices would be up to three or more times higher than they would otherwise be, during this period. These prolonged high prices would lead to a reduction in access to essential medicines and consequently unnecessary death and suffering.[145]

Evidence from several case studies does not support the notion that the introduction of TRIPs compliant standards of IPR would encourage transfer of technology, encourage foreign direct investment, strengthen R&D and innovation and ensure early introduction of new medicines. If evidence on transfer of technology

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[141] WHO (1998)
[142] O'Neill (1998)
[143] O'Neill (1998) and UNAIDS (1998)
[144] Watal and Borell (2001)
[145] Oxfam (2001)

from industrialised countries to developed countries is limited, it follows that the knowledge gap between the south and the west may increase if this transfer does not materialise.[146] This is so because innovation and R&D will only take place in developed countries and not transferred to the developing countries. This would lead to an increase in technological know-how in industrialised countries and none in developing countries. Also, the bargaining power would be biased towards the producers of knowledge who are in the developed world. This weak bargaining power in negotiating prices with monopoly suppliers would have strong effects on distribution especially with respect to patents effect on the prices of medicines.[147] Moreover the introduction of new medicines would be delayed thereby creating an impression of denying people the right to new drugs. Furthermore a shift in the market share from generics to branded products would be evident.[148]

Drug firms in the developed world are concerned with focusing R&D efforts on problems that have lucrative markets; for example impotence and obesity rather than widespread tropical diseases that have smaller markets. Little R&D has been undertaken in countries that have widespread tropical diseases. Hence, when markets are small, there is little R&D in medicines that treat tropical diseases. Consequently, there would be little technological transfer. Thus, the above evidence does not support the notion that significant technological transfer would occur.

It is also argued that domestic manufacturing would be crippled because the production of new medicines in developing countries is done through reverse engineering. It is only possible where patent law protects the process and not the product, since the patented product can be produced using an alternative process. Process and product patents would also result in extension of monopoly protection through minor changes to existing medicines where the product patent has expired[149]

Thus requiring countries to enforce patents may result in companies charging exorbitant prices that the poor cannot afford. Although the price of drugs alone does not determine who gets access to health care, it was noted that the health expenditure of the world's poor is largely devoted to buying drugs, often through private outlets. So the price of essential drugs matters to poor people and to poor countries.[150] For many developing countries the implementation of TRIPs necessitates resources and capabilities in excess of those already in existence.

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[146] WHO (2000)
[147] World Bank (1998)
[148] WHO (2000)
[149] Oh (2001)
[150] UNAIDS (1998)

3.5.5 Provisions/limitations of the TRIPs Agreement

Essential drugs are more similar to public goods and access to them is a human right. The TRIPs agreement goes some way in realising this by allowing some safeguards to protect public health.[151] Patent rights are subject to certain limitations as a result of certain provisions contained in the TRIPs agreement which developing countries can make use of in order to buy or produce drugs at more affordable prices. These limitations are to be effected through national legislation. However, it will be shown that even in the presence of such provisions there are certain obstacles that may render these provisions ineffective. These exemptions should not unreasonably conflict with the exploitation of the patent and should not prejudice the legitimate interest of the patent owner. The provisions include, the bola provision, compulsory licensing and parallel importation.

3.5.5.1 Compulsory Licensing

The government grants compulsory licenses without the consent of the patent holder. The license should be predominantly for the supply of the domestic market but some exports are still possible. Compulsory licensees generally compensate the patent holder through payment of remuneration. The license keeps the patent holder in check by reminding him/her that in case of abuse of rights or non-availability of the product, a third party can be allowed to use the invention, this prevents misuse of patent rights.[152] The grounds for issuing such a license include public health reasons, emergency situations, epidemics, public non-commercial use and to remedy anti-competitive practices. Such licenses serve as an important mechanism to encourage competition and increase the affordability of drugs, without depriving the patent holder of reasonable compensation. This can increase the number of generic producers in the market[153].

The presence or absence of generic competition in the market is a key determinant of pricing levels. Generic drug manufacturers play an important role in bringing competition to pharmaceutical markets and improving production efficiency, which would reduce prices further. A price comparison for HIV/AIDS medicines demonstrates that MNCs sell their medicines at higher prices than those of generic producers. For example, the US price of 3TC (Lamivudine) marketed by Glaxo is US $3,271 (per patient per year) whilst Indian generic manufacturers, Cipla Ltd. and Hetero Drugs Limited, offer their generic versions at US $190 and US $98, respectively per patient per year. In the case of Zerit (Stavudine), the US price offered by

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[151] Oxfam (2001)
[152] WHO (2000)
[153] WHO (2000)

Bristol-Myers Squibb is US $3.589 (per patient per year) as compared to US $70 and US $47 for the generic versions by Cipla and Hetero.[154] This point is further illustrated by Cipla's recent offer for a year's supply of a combination of these three anti-AIDS medicines for US $350-600, in contrast to US $10-15 thousand offered for the branded medicines for a year's supply.

Therefore presence generic competition will result in the lowering of prices of medicines. For example, generic companies in Thailand market Fluconazole[155] for US $0.29 and in India for US $0.64. This contrast with market prices for brand-name drugs, which are US $10.50 in Kenya, US $27 in Guatemala and (until recently) US $8.25 in South Africa.[156]

The Brazilian case offers another example. When the Brazilian government began generic production of AIDS drugs, the prices of comparable branded products dropped by 79%. The Brazilian government has been able to offer universal free treatment as a result of domestic production of AIDS drugs, making its AIDS programme one of the most successful. The AIDS death rate has been halved; this has enabled the country to save US $472 million from averted hospitalisations.[157]

On the other hand, compulsory licensing may not be adequate in making drugs affordable. The major limitation is that in practice, a country needs to have a pharmaceutical industry, which is sophisticated enough in order to produce the medicines concerned. It should be in a position to achieve economies of scale so as to bring the price down to affordable levels. Many of the developing countries fail on both accounts.[158] Hence, few developing countries are able to make use of compulsory licences to facilitate domestic generic production of patented drugs.[159]

The solution might be to import from a generic manufacturers in countries with strong pharmaceutical sectors, but this is unlikely to be viable unless a compulsory license has also been issued in the exporting country. Even if it has been granted, the TRIPs agreement states that compulsory licensing can only be issued only if production is 'predominantly' for domestic needs, so the exporting country may breach the rules if it decides to export. The manner in which the TRIPs agreement is drafted further limits the scope for state action.[160] Compulsory licenses can only be granted if the proposed user has made efforts to obtain a

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[154] Kavaljit, (2001)
[155] These prices are for 1 unit (50mg)
[156] Oxfam, (2001)
[157] MSF, (2001)
[158] Oxfam (2001)
[159] Balasubramaniam, (2001)
[160] Oxfam (2001)

license from the patentee on commercial grounds, and the patent holder is compensated. In addition, there should be a limit to the scope and duration of compulsory licenses. Moreover, no clear criteria exist for determining the public-health grounds that may limit the rights of patent holders. The threat of trade sanctions by dominant industrialised countries further cripples the position of developing countries' governments.[161]

3.5.5.2 Bolar Provision

A Bolar provision allows interested generic manufacturers to start the production of test-batches of the patented drugs (the "early working" of patented drugs) before the patent actually expires. This would reduce the delay of generics to enter the market after the expiration of the patent, and in so doing enhancing competition. Generic drugs can also be made available more rapidly.[162] On the other, hand developing countries are facing pressure from the USA to prohibit "early working" in their patent laws. The US government is also demanding that company data submitted to regulatory authorities on the testing and effectiveness of new drugs be protected. This rule would result in further restrictions of legitimate generic competition.[163]

3.5.5.3 Parallel Importation

This refers to the importation of medicines into a country from a third country without the authorisation of the patent holder, where the patent holder has marketed the product. This is usually done if the price the patent holder is charging, in the country concerned, is much higher than the price in the third country. This is only allowed if the option is included in the national legislation. The principle of exhaustion of rights is the underlying notion of parallel imports. The principle hinges on the assertion that; where the patent holder has been rewarded through the first sale or distribution of the product, they no longer have the right to control the use or resale of the product.[164]

Since the pharmaceutical industry generally sets prices differently throughout the world for the same medicines, it follows that parallel imports are of paramount importance for public health interests. Parallel importation of a patented medicine will facilitate more patients in the importing country to get access to

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161 Oxfam (2001)
162 Oxfam (2001) and Pérez-Casas (2000)
163 Oxfam (2001)
164 Correa (2000b)

drugs. The patent owner would still receive remuneration for patented invention in the country where the product is first sold.[165]

It important however to note that parallel importation has been used elsewhere (e.g. Philippines), hence this mechanism is not really governed by the TRIPs agreement. Therefore, to some extent its use hinges upon national practice.

Multinational pharmaceutical companies that may seek to establish uniform global prices at the highest possible level may discourage implementation of parallel importation. They would then charge a single price worldwide consequently leading to an increase in the price that may otherwise be charged in low-income countries.[166] To a certain extent, the evidence above "holds water". However there is also some available evidence that shows that in many developing countries, the prices of the same medicines are much higher than in developed countries anyway. For example, the retail prices of 10 out of 13 commonly used drugs, for which comparable data is available, are higher in Tanzania, which has an annual per capita GNP of US $120, than in Canada with a per capita GNP of US $19.380. The average prices of drugs surveyed in South Africa are higher than in any of the 8 Western European countries for which data is presented.[167] Implementation is also crippled by the absence of information on market prices for pharmaceutical products.[168]

In summary, although the TRIPs agreement has certain safeguards in place that developing countries can use to protect public health, they are very difficult for developing countries to implement. Most of them are not yet incorporated into their national legislation. Only a few countries have strong pharmaceutical sectors to make use of such safeguards through domestic production. Some developed countries (especially the US) are known to use political pressure and threat of trade sanctions to compel countries to endorse laws that are based on a highly restrictive interpretation of the agreement.[169] Additionally, most developing countries believe that the TRIPs agreement will put them at a disadvantage. They trust that they risk being pushed to the margin and cosmetic drugs will have preference at the expense of drugs for tropical diseases, this puts profits before people. The price of technological transfer becomes high, this blocks poor countries from the vibrant knowledge sector since multinationals are likely to dominate the global market. Therein lies

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165 Oh (2001)
166 Health Action International (1998)
167 Health Action International (1998)
168 Oxfam (2001)
169 Oxfam (2001)

the need to review the TRIPs agreement and drug pricing so that their negative effects on drug affordability and access to health can be rectified.

3.5.6 Country Experiences

TRIPs principles only became enforceable recently, thus not that many studies have been undertaken to determine its impact so far. Nevertheless, in countries such as Chile, Columbia, Thailand and some other Andean countries, evidence has shown that foreign direct investment has not improved expect through acquisition of domestic companies by foreign companies. No new investments have been undertaken.[170] Additionally, most formulation plants have closed since foreign companies have decided not to produce locally but rather to import. They are no longer working the patent in these countries granting the right. Trade deficits increased because of replacement of local production by direct importation. Because of the acquisitions, there has been no clear technological transfer to local companies. In addition, technological transfer was never substantial in this industry because licence agreements means that the active ingredient is provided by the patent holder, but the patent holder does not provide the technological know-how for producing the active ingredient. The licensee will just be formulating. In Italy, the prices of medicines increased by almost 200% and it became a net importer of medicines and experienced severe trade deficits. Tendency to import drugs relative to local production was evident in most of the countries where studies were undertaken, indicating that the patent law benefited foreign rather than local companies.[171]

3.6 Mark-ups, Taxes, Duties and Exchange Rates

Distributional costs also influence the price of drugs. These costs include costs of packaging, transport costs as well as import duties. Import duties are important in many developing countries where many countries are still trying to protect their industries (infant industries) from outside competition. Therefore, tariffs for drugs from outside tend to be very high and consequently the prices of imported drugs are also high. Transport costs are a very significant factor in countries where petrol costs are skyrocketing; consequently these costs are transferred to the consumer through high mark-ups on drugs.

Exchange rate variations play a significant role in supporting retail price differences across markets. This is especially true in countries with massive shortage of foreign currency (e.g. Zimbabwe) and together with the depreciation of many African countries' currencies; the costs of importing drugs have increased. A shortage

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[170] WHO (2000)
[171] WHO (2000)

of foreign currency results in creation of black markets where currency is traded at higher than official rates. This implies that manufacturers and wholesalers have to source for their own foreign currency at unofficial rates in order to buy raw materials and drugs. Consequently, this would be fed into the final prices charged at the retail level. Depreciating currencies also have the same effect in that they make imports relatively more expensive than before the currency depreciated. This would increase the prices of most raw materials and other essentials, for example fuel. This would result in an increase in prices of all other local products including drugs as a result of increasing operating and input costs of most firms.[172] Developing countries import almost 90% of their raw materials.[173] This has resulted in high mark ups for drugs.

Sales tax on drug contributes to the final price charged by the percentage of the tax rate. In developing countries, pharmacies also charge a fixed dispensing fee for all the drugs sold. For example in Zimbabwe there is a fixed dispensing fee of ZW $100 per pack.

3.7 Competitive Tendering

Competitive tendering is a demand side intervention perceived to be one of best ways to acquire drugs of good quality at low prices.[174] The state gives contracts to suppliers for the exclusive right to supply a fixed volume of the drugs at a fixed price for a stipulated period of time. Competitive bidding by both local and foreign suppliers ensures that the government gets the lowest possible prices for drugs. The government is also able to command large discounts due to bulk purchasing. On the other hand, manufacturers who fail to get contracts may cease trading or leave the market as a result. This could reduce competition and thus increase prices. This is usually true in countries with comprehensive national health services. However, this unlikely in countries where the private sector plays a central role since suppliers can still supply the private sector. In cases where competitive tendering poses such problems, the government can opt to have more than one contract running concurrently but for different quantities of the drug.[175]

3.8 Conceptual Approach to Medicine Pricing

Pharmaceutical pricing is not only determined by forces of supply and demand in the market place of buyers and sellers like under the ideal perfect competition scenario. On the contrary, different buyers and sellers have varying degrees of bargaining and negotiating power, which in the end can skew prices of medicines in

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[172] This is known as imported inflation resulting in cost-push inflation.
[173] WHO (2000)
[174] UNICEF (2001)
[175] Country doctor (2002)

favour of that side with the highest negotiating power.[176] Economic theory and research has come up with a conceptual approach to understanding price influences in the drug market. The basic approach has been price discrimination and monopoly and these two to some extent offer some insight into understanding the players in the drug market and consequently influences of medicine pricing.

3.8.1 Price Discrimination

This concept assumes that sellers have the ability of segmenting the market into two groups, and can distinguish them by their responsiveness to price: those who are sensitive to price changes and those who are less sensitive. Sellers can then charge different prices in different markets. However, this model breaks down in the presence of many sellers since consumers can shop around for prices.[177] Yet, if multinationals were to come together and agree on a single price in those markets that are more responsive to prices there could be progress towards price discrimination. Additionally mechanisms can be put in place to prevent spillovers back into the country of origin where consumers are less sensitive to price changes.

3.8.2 Monopoly

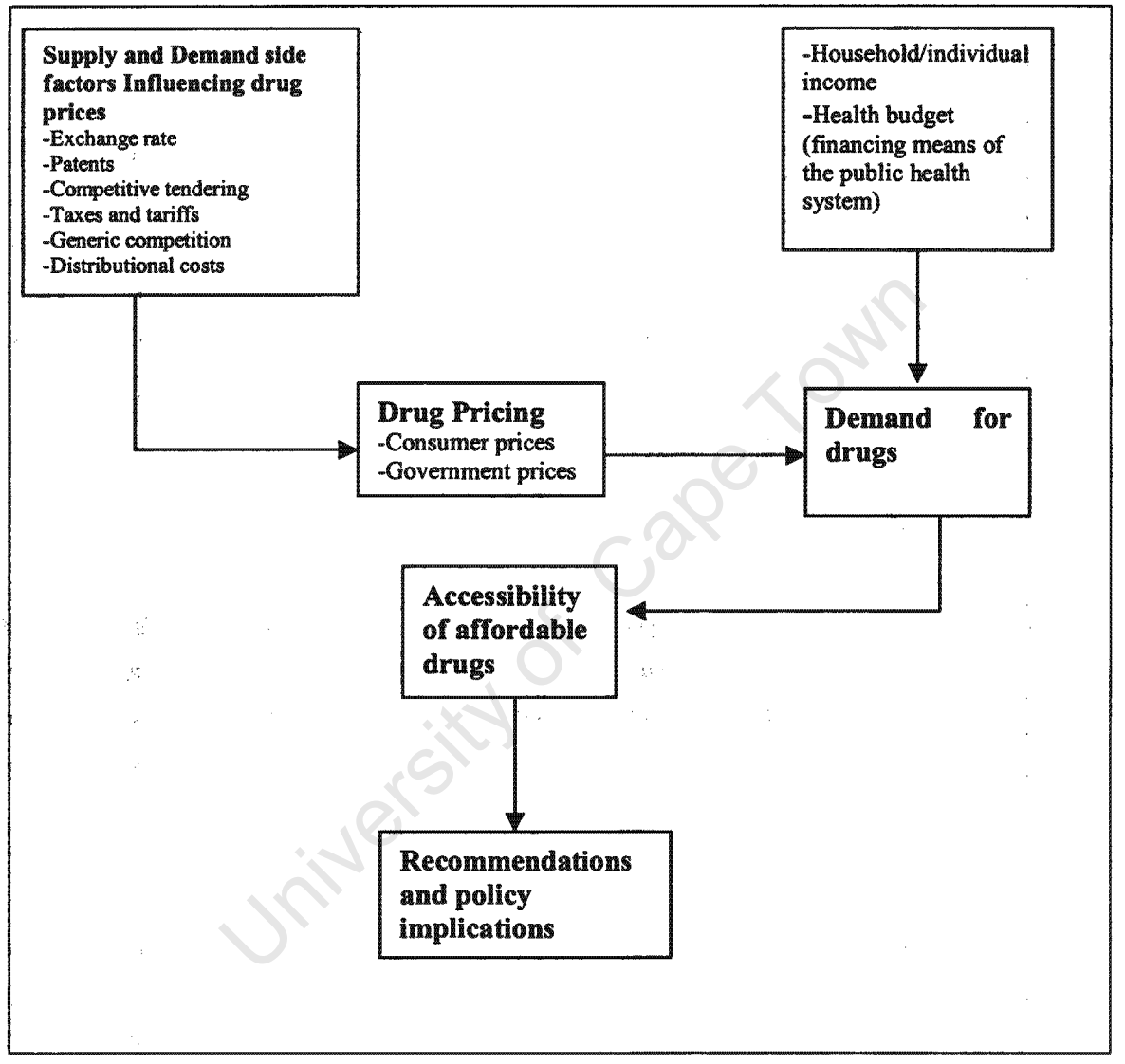
Monopoly is an extreme case where there is only one seller and many buyers. Due to lack of competition the monopolist is able to charge a price above marginal cost and restricts output. This results in supernormal profits. On the other hand this model can be modified if we relax the assumption of a single seller. In the market for drugs there are relatively few large sellers who can form a market structure called an oligopoly. These firms have significant influence over the price in the market. They charge the highest possible price consistent with their profit motive.[178]

The above conceptual approach to price determination can be modified to allow other factors that influence drug prices to come in. Additionally it has become common knowledge in economics that increase in prices would imply that people would tend to demand less of the drug. This does not however imply that the good has become unimportant in one's life. It is because it is now out of their reach or beyond their means and vice versa if the price of the good falls. The final price is therefore determined by supply side and demand side factors together with the degree of negotiating power of all the players in the market. The conceptual

[176] Cantor (1998)
[177] Ibid
[178] Lipsey and Courant, 55 (1996)

framework below puts into perspective how these factors influence prices and consequently affordable access to drugs.

Figure 3: Conceptual Framework



The above framework brings the following to light, patents, generic competition, competitive tendering, distributional costs, taxes, tariffs and exchange rates affect the pricing of drugs either directly or indirectly. Furthermore, each company takes into consideration the price of the patent-protected competition into consideration before establishing its "launch price". Thus, new drugs for which loose substitutes exist are usually priced lower than they would otherwise be in the absence of competition. This profit maximisation strategy is simply recognising the oligopoly market structure as opposed to monopoly. However, if the drug

is a pioneer drug then the manufacturer can enjoy monopoly status and can price its drug accordingly. But this status is enjoyed subject to oligopolistic competition from new substitutes.[179]

The presence of large buyers also puts constraints on the prices that manufacturers can charge. This is achieved through competitive tendering by government stores, which purchases large quantities through tendering and sourcing for the best price possible. Generic producers, as noted earlier, price their products lower than those already in the market and as more and more generics come in the price of generics will drop even further. Although generic entry does not necessarily lead to a fall in prices of pioneer drugs, it leads to a lower weighted average price of medicines in the market.[180] Distributional costs, taxes and tariffs influence the price in that they increase the price by percentage of the tax/tariff levied or by the percentage mark-up. Exchange rates influences the final price of medicines in that if the exchange rate depreciates imported drugs and raw materials become more expensive. The price of locally produced drugs will also increase because of the increase in the costs of obtaining raw materials and vice-versa if the exchange rate appreciates. The same results are also expected in the presence of unofficial market exchange rates. In such cases, firms will have to source for foreign currency (to buy raw materials and import drugs) at exchange rates way above the prevailing official market rates. This usually occurs in the presence of foreign currency shortages (foreign currency crisis) in a particular country.

Affordability of medicines by both the consumers and the government is a function of the final price charged to the government and the consumers, the financial resources devoted to purchasing medicines by the government and the income of households/individuals. The final price charged to both the consumers and the government, individual/household income and the financial resources available to purchase medicines determine how much consumers/government would demand. The final amount of medicines demanded to some extent reflects how much consumers/government can afford to purchase. Affordability is one of the most important factors that determine degree of access to affordable drugs. Only by considering how the above factors interact and influence each other can one draw policy implications, recommendations and identify gaps and areas that may require further investigations and research.

[179] Cantor (1998), Boston consulting group (1993), Schweitzer and Comanor (1996)
[180] Cantor (1998)

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MUTSAGO, ALITHER R

PHARMACEUTICAL PRICING: ASSESSING THE IMPACT OF FACTORS INCLUENCING HIV/AIDS AND AIDS RELATED MEDICINE PRICES IN ZIMBAB

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4 CHAPTER 4: METHODOLOGY AND DATA

4.1 Introduction

This chapter outlines a detailed description of the methodology used to conduct the study at both data collection and data analysis levels. The chapter will first look at the data collection instruments used during the field survey to collect data from different sources. The chapter will then give a detailed overview of the variables used, the data sources and the data collection procedures used in this study. A brief look at the method used to analyse the data will also be outlined. Finally the section identifies some research problems associated with the study and it also outlines some biases and limitations that should be taken into account when conducting such a study.

The study was carried out in Harare the capital city of Zimbabwe. The data collection was done during 4-5 weeks in February and March 2002. The method was described in a written instruction; this instruction also included the necessary information on the drugs and what data to collect. Information on drugs and their prices and information on duties, taxes and mark-ups were collected from nine pharmacies, the main referral hospital, five wholesalers and five manufacturers. Interviews were also carried out with key informants from the ministry of health, African Regional International Property Office (ARIPO), Patents Office, Medicines Control Authority of Zimbabwe (MCAZ) and manufacturing companies.

4.2 The Study Population

The study population comprised of all pharmaceutical manufacturers, wholesalers and pharmacies in the capital city of Zimbabwe. The population also included all key informants from manufacturing companies, the Ministry of Health, MCAZ, ARIPO and the Patents Office. Additionally, the population also comprised of all drugs that are registered in Zimbabwe that are used to treat HIV/AIDS and AIDS related illnesses.

4.3 Data Collection Instruments

The data collection instruments that were used comprised of the following:

a) Structured survey forms

These were spread sheets used to collect quantitative information on prices, mark-ups, dosage forms, strengths and unit packs for different drugs.

b) Semi-Structured questions

These questions were used in conducting structured qualitative (audio recorded) in-depth interviews with key informants. The semi-structured questions acted as interview guides, and they ensured that all key questions were covered and that interviews were kept on track. The questions covered specific issues in areas of interest. Furthermore, these semi-structured questions were complemented by follow up questions for clarity where necessary.

c) Documents

Certain documents with relevant information for the study were obtained. This included, the patents act, the medicine and allied control act, the drug register, the drug legislation/regulation guidelines, EDLIZ, the drug policy, the health strategy and the patents amendment bill. Additionally data on drug prices and dosage forms from comparison countries were obtained from other studies.

4.4 Identification of Variables, Sampling Procedures, Data Source and Data Collection Procedures

A basket of 35 different drugs in total were selected of which 13 of them are antiretroviral drugs and 22 of them are used to treat opportunistic infections. The selection was made based on essentiality and availability of drugs that treat HIV/AIDS/opportunistic infections and their patent status. Firstly, a drug register was obtained from MCAZ to determine which drugs are registered and approved to marketed in Zimbabwe. This was also complemented with information from EDLIZ. The EDLIZ made it possible to identify essential generic drugs used for opportunistic infections. Unfortunately no antiretroviral drugs appear on this list as yet. A list of the antiretroviral drugs that are registered in Zimbabwe was obtained from

the drug register. With the help of doctors and pharmacists, a drug checklist of the most important drugs that are used to treat HIV/AIDS/opportunistic infections and their patent status in Zimbabwe was drawn up as shown in table 3 and 4 below. This served as a guide when colleting data on prices, taxes, duties and mark-ups. All the drugs in table 3 and 4 are prescribed widely in both developing and developed countries.

Table 3: Drugs used in the treatment of opportunistic infections and their patent status

Drug	Patent status	Drug	Patent status
Acyclovir (30*200mg)	generic	Fluconazole (14*50mg)	patented
Cotrimoxazole (1000*480mg)	generic	Itraconazole (15*100mg)	patented
Indomethacin (1000*25mg)	generic	Vtamin B-complex (100*50mg)	generic
Ketoconazole (100*200mg)	generic	Prednisolone (1000* 5mg)	generic
Metronidazole (1000*200mg)	generic	Codeine phosphate (100*30mg)	generic
Miconazole (varg. Cream 40g)	generic	Azithromycin (3*500mg)	patented
Miconazole (oral gel 40g)	generic	Azithromycin (6*250mg)	patented
Miconazole (cream 20g)	generic	Amitriptyline (1000*25mg)	generic
Amoxycillin (1000*250mg)	generic	klacid (10*250mg)	patented
Nystatin (15)	generic	Doxorubicin (iv -3*150mg)	patented
Nystatin (oral suspension 30ml)	generic	Amphotericin B (vial)	Off-patent

Source: table a, appendix, average drug prices survey in Zimbabwe

Table 4: Drugs used in the treatment of HIV/AIDS and their patent status

Drug	Patent status	Drug	Patent status
3tc (oral sln. 240ml)	Patented	Viracept (270*250mg)	Patented
Epivir, 3tc (60*150mg)	Patented	Videx (60*100mg)	Patented
Retrovir (100*100mg)	Patented	Zerit (60*30mg/40mg)	Patented
Retrovir (syrup 200ml)	Patented	Crixivan (180*400mg)	Patented
Combivir (60*450)	Patented	Viramune (60*200mg)	Patented
Hivid (100)	Patented	Hydrea (100*500mg)	Patented
Invarise (270*200mg)	Patented		

Source: table b, appendix, average drug prices survey in Zimbabwe

Prices were collected from pharmacies, wholesalers, manufacturing companies and one central hospital in Harare. A list of all registered premises was obtained from the MCAZ. From this list, only manufacturers wholesalers and pharmacies in the capital city Harare were selected. Five major manufacturers were purposefully selected for interviews. Five wholesales were selected based on whether they sold at least some antiretroviral drugs, and among the five, was government stores (Natpharm), which represents the public sector. The selection of pharmacies was based first on those that sold at least more than two antiretroviral drugs. This scaled down the pharmacies to 30. However, of the thirty pharmacies only nine were willing to give out information on drugs they sold, mark-ups, taxes and prices. For each drug, the price, the dosage form, the strength, the unit pack and the mark-up were recorded using a spreadsheet. In

addition, the information above was also obtained from the major referral hospital in the country (Parerenyatwa). Information on mark-ups, discounts received, exchange rates, official duties and taxes was also collected from manufacturers, wholesalers, the department of central statistics and the central bank. This information would be used to estimate the final price paid by patients in the private and public sector. All prices were listed in local currency and then converted to US dollars using the average exchange rate for March 2002.

Information on patent status was obtained from the Patents Office and from ARIPO, and this was complemented with information from documents that were electronically accessed from the Internet. The drug patenting guidelines were obtained from ARIPO and from the patents act.

It is important to note that there is no formal/direct price regulation for drugs in Zimbabwe, hence, there are no formal price regulation laws. However there are certain policies in place that indirectly control such prices. These polices include the tendering system and control of import duties on essential drugs and raw materials used in the production of these drugs. In addition to the above, since there is a problem of parallel market exchange rates in Zimbabwe (This was sited as one of the contributors to high drug prices in Zimbabwe), NatPharm gets all its foreign currency at official market rates. Furthermore, the drug policy encourages all government hospitals to prescribe/sell generics rather than branded products. This information was collected from the ministry of health, where documents on the national drug policy were obtained. This information was also acquired through recorded interviews with the chief pharmacists at the ministry of health and from the procurement manager of NatPharm.

A recorded interview was conducted with the director of MCAZ to obtain information regarding the implementation of the TRIPs agreement into the law system. This interview was guided by structured questions and the director was also given a chance to contribute some of his own views with regard to the TRIPs agreement. An attempt was made to try and find out what the MCAZ perceived were the likely impact of the agreement. A report on the proposed patents amendment bill, the amendment bill and the medicines allied substance control act was also obtained.

Since the TRIPs agreement is yet to be implemented, only the likely impacts of the provisions/safeguards such as parallel importation, Bolar provision and compulsory licensing, can be estimated based on other studies and experiences from other countries. These documents were obtained from ARIPO and MCAZ. Information on negotiated procurement and generic competition was obtained through structured interviews with the procurement manager of NatPharm, directors from the manufacturing companies and wholesalers

and the chief pharmacist from Ministry of Health. Documents on national drug policy, guidelines for drug donations and the national health strategy for Zimbabwe were obtained form the Ministry of Health. In addition data on exchange rates, and data on income and expenditure survey were also obtained.

Information on background of health sector, AIDS policies and the pharmaceutical industry was obtained through structured tape-recorded interviews with the director of the MCAZ, the marketing directors five manufacturing companies. Interviews were also conducted with key informant form the national AIDS control programme in order to obtain information on the national AIDS policy in Zimbabwe. Documents on the national health profile were also obtained from the Ministry of Health.

Data cleaning occurred through out the collection process by reviewing the data collected in order to check for inconsistencies, errors and omissions in recording responses. Such issues were corrected immediately.

4.5 Analysis of Data

Data analysis was done using Stata and Excel computer software. Results were presented in form of simple tables and graphs and a quantitative descriptive analysis was conducted to establish the relationship between prices and other variables in question. Example of outputs from these tables includes average prices for all drugs and average prices for dual therapy in different countries. Graphs were also used to compare prices between countries and between the public and the private sector, etc. Further more a detailed analysis was conducted to establish the relationship between patents and prices, impact of competitive tendering on prices, contribution of taxes, duties and mark-ups to the final consumer prices and how generic competition influences the prices of drugs. Finally, two sensitivity analyses were conducted, firstly to show how black market rates could have contributed to high drug prices. Secondly a sensitivity analysis assuming parallel importation was also undertaken to show that prices of antiretroviral drugs would fall substantially in the presence parallel importation. A brief assessment of the effect of final end user prices on access to affordable drugs was done and presented as part of the discussion of results.

4.6 Data problems

Like with most survey studies, certain research problems were encountered. It is also important to highlight the likely biases and limitations to the study at hand. These limitations should be taken into account when drawing conclusions and interpreting results.

4.5.1 Research Problems

During data collection, it was evident that not all key informants were well conversant with the TRIPs agreement. Consequently, some did not understand how it would affect their day-to-day running of the business in the pharmaceutical industry and how it would impact on public health systems in the country. This made it difficult to get information on how the TRIPs agreement would be implemented into the law system. With regard to prices of drugs, out of the thirty pharmacies that were sampled only ten pharmacies were willing to give information with regard to prices and mark-ups and information on dosage forms and strength, this reduced the sample size drastically. Information on change in prices overtime could not be obtained readily because prices of drugs changed every time new stock was received and fluctuated depending on the exchange rate (either the official or the unofficial rate) that prevailed when the drugs were purchased. Consequently, one may find that the same drug in a particular retail outlet from different suppliers has different prices. In addition, most companies only got computerised recently; hence, such data was not captured on an on going basis.

4.5.2 Biases and Limitations

A recent article by Danzon and Kim found that cross-national study results are highly sensitive to methodological choices. Comparing prices between countries is inherently difficult because of problems encountered when comparing official exchange rates, parallel market exchange rates and real currency values. Sample selection, unit of measurement for price and volume and the relative weight given to consumption patterns in the countries being compared contribute to the sensitivity of results.[181] Also differences in pharmaceutical distribution channels (private versus public sector, retail versus wholesale) and different strengths and pharmaceutical dosages as well as price fluctuations over time make comparisons between countries and between the private and public sector difficult.

[181] Danzon and Kim (1998)

A selection bias is created especially when price comparisons are done for few-selected top selling drugs that are patented, since certain drugs available in one country may not be available in another.[182] Moreover, when drugs that have been approved and marketed in two countries for example, become accepted therapy in one country but not in the comparator country, huge disparities in market share, and consequently prices, for similar medicines may result.[183]

Dosage form, strength or pack size may differ across countries. This compels researchers to impute prices for missing product strengths or dosage forms based on per unit prices. This can lead to biased price comparisons if unit prices are by and large lower for large package sizes.[184] This applies to both domestic comparisons and cross-country comparisons. Different utilisation rates between countries under comparison create a bias in price comparisons because price levels vary with volume. Prices for drugs that are not frequently prescribed are usually higher. This implies, for example that a popular drug in the US may appear more expensive in other countries, consequently this results in an upward bias in medicine prices in the comparator country.[185]

Another source of bias could come from currency conversions. For example in this study when the price data was collected there was the problem of parallel market rates. Some drugs were imported at black market exchange rates, which were about 5.5 times higher than official exchange rates. However, not all drugs were purchased with foreign currency obtained at this rate. If a wholesaler is lucky they can source currency at a lower rate or even at the official rate. This problem could be solved to some extent by taking the average price. On the other hand an upward bias in prices could still be present and this would pose some problems when doing cross-country comparisons.

Lack of uniformity in cooperate pricing policies across different markets makes comparison between prices for patented drugs and generic equivalents difficult. Additionally, the national legislation and the terms on which the TRIPs agreement is implemented could also have an important bearing on the price outcomes.[186]

In short, methodological problems can make meaningful comparisons difficult since different methods produce different results. Thus, it is important that future research should test the robustness of results to

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[182] One could end up with a very small sample of few selected drugs that are available in both countries.
[183] Department of Health & Human Services (2000)
[184] Ibid
[185] Ibid
[186] Ibid

alternative assumptions with respect to types of drug products compared, their relative importance with regard to domestic consumption, and how they are priced by making use of sensitivity analyses.[187]

4.7 Ethics

In collecting the data certain ethics were taken into consideration. Certain interviewees asked not to be quoted; this will be taken into consideration in this paper. Furthermore, care was taken to make sure that information that was confidential from certain institutions and organisation was not revealed to other parties. During the interviews, participants /respondents were first informed about the purpose of the interview and they were give the opportunity to refuse or make available the information and data required from them.

[187] Ibid

5 Chapter 5: The Pharmaceutical Industry in Zimbabwe

5.1 Introduction

This chapter provides an overview of the pharmaceutical industry in Zimbabwe. It focuses on how the industry operates, the key players and reviews the drug distribution system and procurement. It will also look at how the TRIPs agreement is implemented into the law system. Finally, the chapter discusses the price regulation system in Zimbabwe and the likely impact of the TRIPs agreement on the industry as perceived by the key players.

5.2 Background of the Sector

The Zimbabwean pharmaceutical industry is solely a generic manufacturing industry, in other words it, is a derivative market of research-based companies. Its success therefore depends on the success of foreign multinational companies. If the multinationals do not come up with super blockbuster drugs, then it means that the local industry will not have any drugs to copy and manufacture. The industry relies on imminent patent expiry in order to come up with new generic versions of branded drugs. Thus, there are no locally manufactured drugs that are patented.[188]

In previous years, Pfizer and Glaxo Smith Kline were the only two multi-national companies in Zimbabwe. At the moment however there are no multinational companies in Zimbabwe. They all disinvested as a result of the economic recession that is currently being experienced in the country. The country has been going though an economic recession for the past four years. However, most multinationals have local agents that import from multinationals based in other countries for example South Africa, Denmark, Germany, India, Switzerland and Canada.[189] CAPS and Varichem are two of the major local pharmaceutical manufacturers and they are both registered with the South African Medicines Control Council (MCC), which has some of the most stringent quality requirements in pharmaceutical manufacturing. This in itself shows that the industry is keeping up with international quality standards in terms of pharmaceutical production.

The manufacturers in the industry as a whole try to protect themselves from competition from other competitors. They are generally not too keen on giving out information with regard to profits, sales volumes, market share and consumption patterns to the public. Such strict polices make it difficult for the department

[188] Pharmaceutical Manufacturers (2002)
[189] Ibid

of central statistics to publish data with regard to the above. As a result data on profits, sales volumes, market share and pharmaceutical consumption patterns in Zimbabwe is very scarce if any is available to the public. The rival firms have felt that giving away such information is not a competitive strategy since one will be making available information to other rival companies that they could use to outlast the firm that has made its information public.[190]

The prices of the local manufacturers for drugs differ depending on whether they are selling to the private or public sector. This is as a result of the tendering procurement method used by NatPharm. When NatPharm goes to tender, it asks for large volumes of medicines and it ask as many manufacturers as possible to give them the best quotation for the medicines. It follows that, the prices that NatPharm receives for drugs for onward distribution to government hospitals, mission hospitals and council hospitals are in most cases a third of the prices that manufacturers charge to the private sector. This is because of the economies of scale involved when manufacturing large volumes of medicines/drugs for one customer.[191] Manufacturers tend to view this as a project in its own right, and hence they totally isolate the project from their everyday business. They have a profit motive when producing for the private sector, however, when they produce for tender, they will be looking at capacity utilization in the factory. In most cases, they would have not budgeted for these volumes; therefore they will not be trying to recover all their expenses. Thus, these prices will tend to be much lower than the prices charged in the private sector. Most companies view tenders as a way of mopping up excess capacity in the firm.[192]

The total consumption of pharmaceuticals was estimated to be US $50 million in 2000, however because of escalating inflation and rise in costs of pharmaceutical products this has probably shrunk to about US $45-40 million. The local industry does not only produce for the domestic market but also for export purposes. Varichem's estimated turnover for this year is about a billion ZW dollars and last years turnover was ZW $ 550 billion. Its market share is quite substantial and their export volume is about 15%-20% of their turnover. CAPS' market share is about 30%-35% in therapeutic areas where it is actively competing in terms of pharmaceutical products. However, if one takes the total consumption including therapeutic areas where they are not competitive, its market share comes down to about 15%-13%. CAPS' export contribution to the turnover is about 20%-30% of their annual turnover. Their major exporter is South Africa and it accounts for 40% of their exports. Other major export markets for the industry include Botswana, Zambia, Malawi, Namibia, Lesotho, Swaziland, Mauritius and Uganda.[193]

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[190] Ibid
[191] Pharmaceutical Manufacturers (2002)
[192] Ibid
[193] Ibid

Contrary to the general view that few if any of the African countries have industries with the capacity to produce generic antiretroviral drugs, the local manufacturers argue that they have enough capacity to produce their own generics to meet local demand. Some of the manufacturers already have started batch production; they are only waiting to find means and ways to circumvent the issues surrounding patent formulation laws. However countries like India are able to produce generic antiretroviral drugs because they do not have to respect patents on formulation until 2005.[194]

5.2.1 The key Players

There are eight local active pharmaceutical manufacturers in the country. These form an association called the Pharmaceutical Manufacturers Association of Zimbabwe. The prime objective of this association is to look out for the interests of the pharmaceutical manufacturers in terms of how they relate with the authorities with regard to licensing and registration of products and relationship with other key players in the industry. It also acts as a lobby group with regards to issues where the manufacturers need a collective voice. It represents the industry's interests to the MCAZ. It is also self-regulating as to what sort of conduct it expects from its members.[195]

There is only one pharmaceutical company listed on the stock exchange. This means that the state/government, individual shareholders, banks and foreign companies can buy stock. Datlabs and other manufacturers are not listed hence they are independently owned. Additionally, foreign-based companies or local companies own most of the wholesalers. There are relatively few manufacturers in the industry, in other words they operate more or less like an oligopoly. The manufacturers association facilitates this since they can lobby to sell within stipulated prices. However, this market structure is difficult to sustain since local manufacturers also face intense competition from foreign manufacturers.

About 60% of pharmaceuticals consumed in the country are manufactured locally and about 40% is imported. There are also drug importers who import finished products, which in most cases are innovator brands that are still under patent. The drug importers are agents for multi-national companies like Pfizer, Glaxo-Wellcome and Roche. They belong to an association called Ethical Drug Association. There are also a number of local wholesalers. They buy from local and foreign manufacturers and most of them are

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[194] Ibid
[195] Pharmaceutical Manufacturers (2002)

representatives of outside companies. NatPharm is also a major key player a wholesaler for the government. NatPharm also imports medicines on tender from foreign organizations.

On the retail side there are about 220 retail pharmacy outlets in both the urban and rural areas, which sell prescription medicines, and over the counter drugs to the private public. They all belong to the Retail Pharmacy Association of Zimbabwe. Local supermarkets also play a role in that they also sell over the counter medicines. In the public sector, individuals interface with dispensaries at government and mission hospitals. Any new drug that has to be sold has to be registered, licensed and approved by the MCAZ.[196] The approval system will be discussed later below.

5.2.2 The Distribution Chain System

The national drug policy in Zimbabwe aims at ensuring safe, cost effective and efficient distribution of drugs and other medical supplies to the entire country. In addition, it aims to guarantee that drugs are available and accessible to all those who need them at all time. It is the responsibility of the ministry of health to ensure the provision and maintenance of adequate, efficient and appropriate transportation, communication and personnel required for drug distribution at all levels of health care.[197]

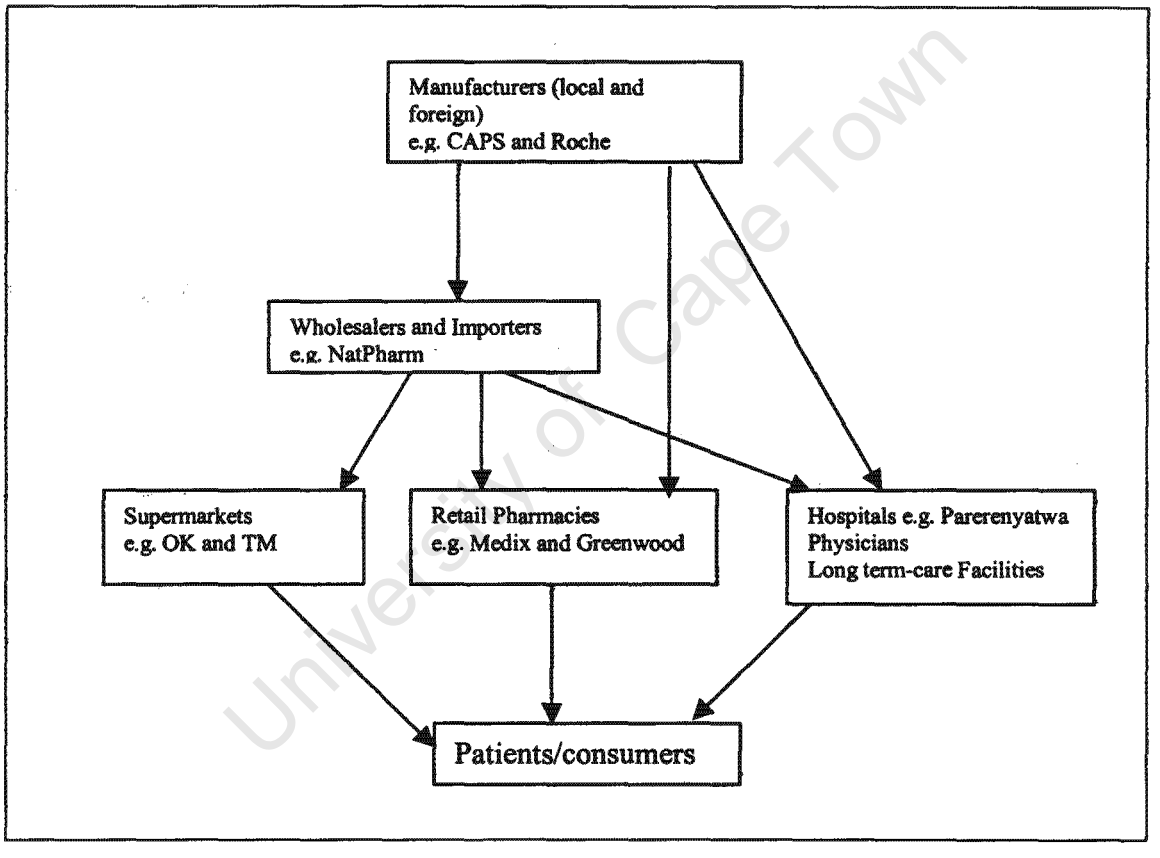
Drug provision to patients involves complex, system of drug distribution which consists of various players such as pharmaceutical manufacturers, wholesalers, retailers, third-party administrators, pharmacy benefit management companies, managed care organizations, and other providers of health care. All the players take part in the pricing of drugs as either purchasers or providers. The distribution chain in the country is illustrated in figure 4 below.

Pharmaceutical manufacturers tend to attract enormous attention because they are perceived as the most profitable link in the distribution chain. Since manufacturers in Zimbabwe are generic producers, they price their products as any other commodity trying to gain market share through lower prices.[198]Drug wholesalers function as 'middlemen' between the drug manufacturers and the retail pharmacies. The wholesalers provide a very useful purpose to independent and chain pharmacies as they purchase in very large amounts and then distributes in small portions. Pharmacies are relieved from the burden of dealing with each

[196] Pharmaceutical Manufacturers (2002)
[197] Ministry of Health and Child Welfare (1995)
[198] O'Neill (1998)

individual manufacturer for every purchase.[199] While there are still a number of wholesalers in operation, the top five wholesalers account for a substantial share of the entire wholesale drug market. This intense purchasing allows these few wholesalers to have influence over drug pricing in the distribution chain.[200] In addition there are also independent importers who play a similar role as the wholesalers. The only difference is that the act as agencies of multi-national firms and import drugs from outside the country for local distribution. Importers have to be registered with MCAZ and all the drugs they import also have to be registered with MCAZ.

Figure 4: Channels of Distribution for Drugs



Independent and chain pharmacies and supermarkets characterize the retail level in the distribution chain. Due to recent economic hardships in the country, the number of pharmacies has shrunk a bit. Chain pharmacies are able to command volume discounts from manufacturers/wholesalers and to contract directly

[199] Smith (1975)
[200] O'Neill (1998)

with managed care organizations for exclusive distribution rights because of their ability to move large market shares of drug products. [201]

Government hospitals, municipality clinics and mission hospitals in most cases buy their drugs from NatPharm. However, they can in some instances source their own drugs from either private wholesalers or directly from manufacturers if need be. Physicians, private pharmacies and private hospitals also buy from private wholesalers or directly from manufacturers. Hospitals, physicians and pharmacies then distribute these drugs to the final consumers (patients). In addition it is important to note that the number of key players within the distribution chain increases as one moves down the distribution chain, i.e. there are fewer manufacturers compared to wholesalers and retail outlets.

5.2.3 Public Sector Drug Procurement

NatPharm under takes public procurement. Drug availability has recently become a major problem due to financial constraints and foreign currency constraints. However the procurement process does not only involve NatPharm but other departments, clients and other agencies. Collaboration of these players is required if effective and efficient procurement is to be realized. The whole procurement process rests on policies that seek to create and support the public commitment to essential drug supply. The system seeks to deliver the correct drugs to patients who need them. There is need for a viable organisational structure, adequate financing and good management for the procurement process to function effectively.[202]

Figure 5 below summarizes the procurement cycle in the public sector. The Public sector uses the tendering system as a method of procurement to obtain drugs and medical supplies. The procurement cycle is truly a cycle because each major function builds on the previous function and leads logically to the next. The amount of medicines required for the whole country in the public sector is estimated in quantification stage. This quantification follows from rational selection based on real experience with drug use and health needs. There is need to review the prevalent health problems, identify treatment choices, identify the drugs and dosage forms relevant to pattern of prevalent diseases[203] and deciding which medicines are to be dispensed at each level of health care.[204]

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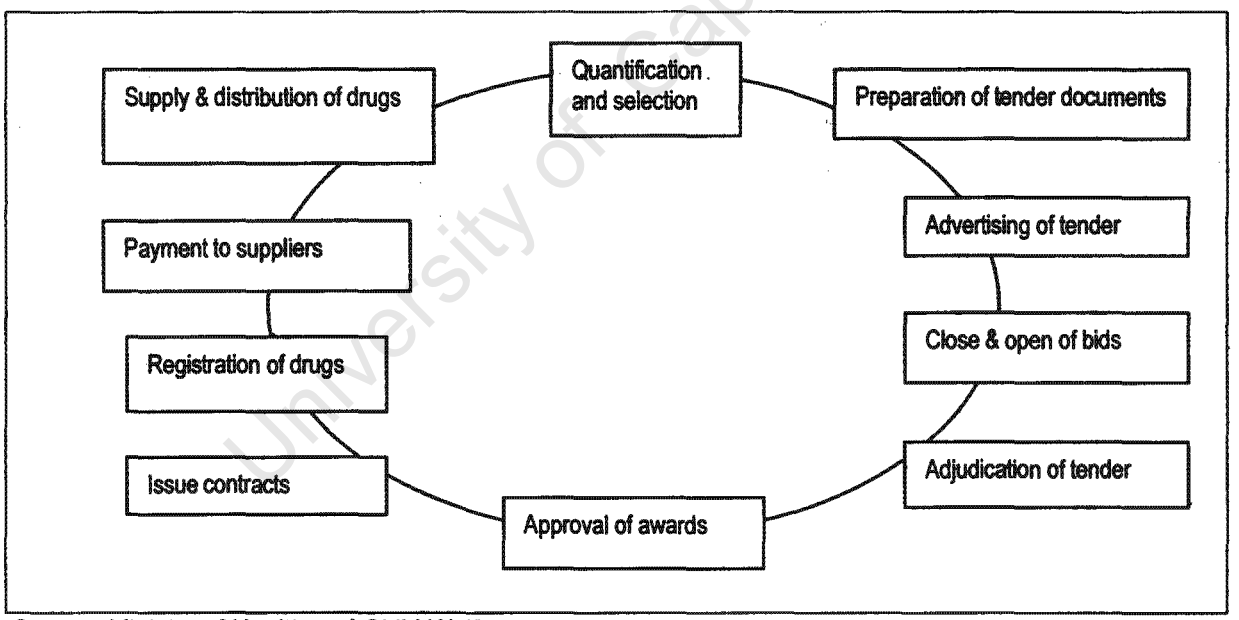
[201] Ibid
[202] World Bank Group (2002)
[203] The drugs chosen should be of proven adequate quality, and should be safe and effective.
[204] Ibid and Ministry of Health and Child Welfare

The committee will then meet to prepare and draft the tender documents and specifies the terms and conditions for the tender. The tender is then advertised in newspapers and journals to ensure that it reaches all potential bidders. Bids are then opened and closed at NatPharm and the tender board assesses the tenders. The awards are then approved and the contracts are issued to the organizations, which win the bids. The drugs are then registered if they have not already been registered and suppliers are then paid up. The drugs are then supplied and distributed to NatPharm, which will be responsible for distributing the medicines to various government hospitals, council clinics, mission hospitals and army hospitals.[205] The goal is to maintain a sustainable supply of drugs to all facilities and at the same time ensuring that resources are being utilised in the most cost effective way.[206]

In Zimbabwe, only drugs that are registered or authorized by the drug regulatory authority are procured for use in the public and private sectors. However, non-registered drugs for specific use can be procured by arrangement when deemed necessary.

Figure 5: Public Sector Procurement Cycle



Source: Ministry of Health and Child Welfare

[205] Ministry of Health and child welfare
[206] World Bank Group (2002)

Priority in procurement is given to drugs in the EDLIZ in accordance with the VEN[207] classification and to drugs used in other national programmes. Procurement is by generic name not brand name. Public procurement is done using any one of these methods: pre-qualification of suppliers, open worldwide general tenders and negotiated procurement or direct procurement (only in special circumstance). First preference is however given to domestic manufacturers (with regard to tenders) depending on costs, quality, performance and reliability of supplies. Public sector dispensing is by generic name only and the MCAZ enforces regulations on dispensing issues. All drug donations regardless of the source are handled through NatPharm according to all the requirements applying to normal procurement procedures. Donations are normally accepted only for drugs included in the EDLIZ.[208]

5.2.4 Medicine Legislation and Approval System

Early control of medicines around the 12th century was concerned with correct identity and freedom from adulteration or impurity. Many of these medicines were from crude vegetable drugs and fraud by substitution, adulteration or even falsifying weight by wetting material was not uncommon. Consequently, there was need to control medicines. Control of medicines is done through acts of parliament. Nevertheless, acts do not have in them a lot of detail but they empower the ministers to introduce rules and regulations, which are the nuts and bolts of legislation. In Zimbabwe, the legalisation was introduced in 1969, and the control of medicines in Zimbabwe is provided for under the Medicines and Allied Substances Control Act (MASCA) and its regulations and the Dangerous Drugs Act (DDA) and its regulations.[209]

The MASCA provides for:

- Establishment of the medicines regulatory authority and the medicines control authority
- Registration of drugs
- Licensing and control of premises and persons handling medicines
- Control of clinical trials
- Procedures for handling prohibited drugs and
- General provisions.[210]

The DDA provides for control of:

- Production

[207] V stands for vital, E for essential and N for necessary.
[208] Ministry of Health and Child Welfare, (1995)
[209] Kuwana (2001)
[210] Ibid

- Importation and exportation
- Possession and sale and
- Distribution and use

of dangerous drugs that are mostly narcotics and liable to abuse.[211]

The government is also acceded to three international drug conventions namely

- Single conventions on narcotic drugs, 1961
- The convention of Psychotropic substances, 1971 and
- United Nations convention against illicit traffic in narcotic drugs and Psychotropic substance 1988

These guarantee that substances under this control are kept in legal channels and to establish use for legitimate purposes.[212]

The MCAZ is comprised of 8-12 members and is the regulatory authority responsible for the approval, licensing and registration of drugs in Zimbabwe. They receive and review applications for registration and the approval process takes between 3 to 5 months for most drugs before they can be approved to be sold on the market. The criteria used in the approval process include, ensuring that drugs are safe and are of acceptable quality and that they offer effective treatment. In addition, approval is also based on availability, being in the public interest, and also the drug has to be registered in the country of origin. It costs a firm about US $800 to register each drug and in addition, the firm has to pay an annual fee of about US $1000 for each item registered. If for example, a firm in the UK registers a certain drug, then wholesalers are not allowed to buy this drug from any other manufacturer besides the one in the UK even if it is the same manufacturer in a different country. This in itself automatically makes parallel importation difficult.[213] Only drugs that are registered with the MCAZ are permitted to be imported, manufactured, wholesaled, retailed, prescribed, dispensed and supplied. The MCAZ has procedures and polices for sampling, testing and registration of drugs. Furthermore the MCAZ gives priority on the basis of need and inclusion in the EDLIZ.[214]

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[211] Ibid
[212] Ibid
[213] MCAZ (2002)
[214] Ministry of Health and Child Welfare (1995)

5.3 Implementation of the TRIPS Agreement into the Law System

The agreement has not yet been implemented in Zimbabwe because the Ministry of Health has not yet finished amending its legislation; hence it has not been made law yet. Zimbabwe has always been observing patent laws. However, this does not imply that the country became TRIPs compliant at independence. The country only chose to be TRIPs compliant ahead of the schedule. Nonetheless since the country has always been observing patents, changes within the legislation would mainly focus on the TRIPs provisions by incorporating these into the law system. As soon as the bill goes through parliament, the country will be TRIPs compliant. There are three provisions that are going to be included in the national legislation namely, the Bolar provision, compulsory licensing and parallel importation.

5.3.1 Review of the Proposed Patents Amendment Bill

The amendment of the Patents act (chapter 26:03) arises from the need to make certain that the legislation in Zimbabwe is TRIPs compliant. In addition there is need to make sure that suitable provisions are provided for, which will cater for the availability of medicines. However, the bill had not passed in parliament therefore was it was still open to comments.

5.3.1.1 Compulsory Licensing and Parallel Importation

Article 31 of the TRIPs agreement allows member countries to grand compulsory licenses on grounds deemed necessary by the member country. This provision allows the government to license one of its agencies the right to use a patent without consent of the patent holder. However, provision should be made to compensate the patent holder. The new section 31 empowers the Registrar of patents to grant compulsory licenses. This facilitates judicial matters to be solved on an administrative basis rather than through a cumbersome judicial tribunal process. The new section 31(9) provides for remuneration for compensation to the patent holder to be determined as a percentage of net sales. This should take into account the average royal rates usually paid in the sector or branch, product specific R&D costs and domestic market share of the total world market.[215]

Any person can apply for:

a. A licence under the patent

[215] Mandaza (2001)

b. An entry to be made in the register to the effect that licences under the patent is to be available as a right or
c. Where applicant is the state department, for the grant of any agency specified in the application,

at any time after the expiration of 3 years from the date of grant of a patent on grounds where:

- The patented invention is capable of being commercially worked in Zimbabwe, that is not being worked to the fullest extent or
- Demand for the product is not being met or being met to a substantial extent through importation
- The invention can be worked in Zimbabwe but is being prevented by the importation of the product,
- A national emergency exist or for public health reasons or if it is in the public interest (e.g. security reasons)

Furthermore, compulsory licences shall be issued predominantly for the supply of the domestic market except in cases of anti-competitive practices in which case such a restriction shall not apply.[216]

Section 34 allows the use of patented inventions without the consent of the patent holder by the state, this will enable medicines to be imported or offered for sale without the permission of the patent holder. Importation of patented products that have been put on the market in another country is allowed without the consent of the patentee if the cost of importing is cheaper than purchasing from the patentee. The period of emergency for which compulsory licences can be granted or parallel importation can be effected, includes any period when an emergency or disaster threatens the life or well being of a community or any period when Zimbabwe is engaged in any war.[217]

5.3.1.2 Bolar Provision

The early working of patents for rapid generic production to promote generic competition is provided for in the new section 36A. This proposed provision would allow the experimental development of medicines that are under patent by any person. Test batches of the patented product can be produced six months before the patent expires but they cannot be put on the market until the patent expires. However the bill does not provide for stock pilling of medicines whose patents are about to expire.[218]

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[216] Ibid
[217] Ibid
[218] Ibid

5.4 Perceived Impact of the Agreement by Key Players

Most people in the industry are not well conversant with the TRIPs agreement; the ministry of health has failed to involve all the key players that should have been involved when implementing the agreement into the national legislation. The government went on to sign agreement without consulting with all the relevant key players in the industry. For example the government did not take into consideration that the local pharmaceutical industry is not as developed as that of industrialized countries.[219]

India has until 2005 to start implementing patents on formulation, this has given the country enough time to develop its industry and equip it with the necessary tools needed to implement the TRIPs agreement into their law system. In addition, they managed to create a market for themselves by not respecting patents on formulations, hence they were able to reverse engineer the process and work out another process, but in the end they ended up with the same raw material. Thus, they ended up with a market for their raw materials. After mastering the above, only did they manage to come up with their own chemical entities.[220]

Therefore key players in the industry argue that the government should not have gone ahead to sign the agreement yet as yet. As a result the country has suffered a lot in terms of not having drugs that are cheaper and accessible. The country could have benefited a lot in terms of formulations if they had not gone ahead to sign the agreement straight away. They would be able to produce third generation generics for drugs still under patents like India and Egypt, which did not sign the agreement.[221] However, this view is not consistent with the fact that Zimbabwe has always observed patents; therefore it is not clear how it would have benefited in terms of formulations if it had not signed the agreement. Nevertheless, it is perceived that the local industry could benefit from making use of compulsory licensing, parallel importation and the Bolar provision.[222]

The ethical drug association who are the importers are up in arm with regard to parallel importation. They perceive that parallel importation will negatively impact on their operations; this is because most multinationals have representing agents in Zimbabwe, and they pay for drug registration and retention fees and other expenses. They argue that it would be unfair then for someone who does not pay for all these costs to bring in these drugs from another source where they are cheaper.[223]

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[219] Pharmaceutical Manufacturers (2002)
[220] Ibid
[221] Ibid
[222] Ministry of Health and Child Welfare, (1995)
[223] Pharmaceutical Manufacturers (2002)

In terms of foreign direct investment, it was felt that the country is not really going to see much because at the moment, foreign companies are not interested in investing in the country. In terms of technological transfer, it was felt that there is likely to be transfer of the active ingredient and not necessarily technological transfer per ser. The response of multinational companies has been to continue to maintain control in industrialised countries and only primarily involved in opening local distribution centres responsible for distributing the medicines in developing countries.[224] In addition, at the moment the political and economic situation in the country does not offer a favourable environment for any foreign direct investment.

On the other hand most of the key players were very optimistic about the impact of the TRIPs provisions such as Bolar provision, compulsory licensing and Parallel importation. The government is going to effectively make use of these provisions, which are likely to increase access to vital medicines through reduction in prices and increase in availability in the country.

5.5 Price Regulation in Zimbabwe

There is no formal/direct price control in Zimbabwe. Price control introduction has proved to be quite a challenge in the country because the most of the raw materials and packing materials are imported and also 40% of the medicines consumed domestically are imported. Consequently, different manufacturers will have different manufacturing costs hence it is not so easy to have one price for a particular drug. It was also pointed out there is lack of expertise within the regulatory authority to introduce price regulations. There has been a discussion underway however to put formal/direct price controls on the so-called essential medicines or medicines used for chronic conditions. Nonetheless, there are certain informal/indirect tools that are in place to try and regulate the prices of medicines. Still, their effect on prices of drugs is not as profound as with direct price regulation of putting floors or ceilings on prices.

5.5.1 The Tendering System

As noted earlier, public procurement is done through the tendering system. NatPharm puts to tender any drugs they wish to purchase. This means that number of firms will have to compete with each other to give the best quote to the government. Economic theory tells us that competition on its own prevents manufacturers from charging huge prices for their products. This enables NatPharm to get the best prices for their medicines. In addition they get discounts on their medicines because they purchase large volumes

[224] Pharmaceutical Manufacturers (2002)

of medicines, which results in high demand. This enables them to negotiate favourable prices with suppliers because of high demand. On the other hand, since the government encourages generic procurement, drugs that are still under patent are less likely to be procured. Hence, their prices are less likely to be controlled through competitive tendering, for example, the government does not purchase antiretroviral drugs yet because there are no cheaper generics available for sale in Zimbabwe.

5.5.2 Essential Drug Policy and Generic Prescribing

Generic drugs are as a rule preferred by insurance programs and other third-party payers since they are cheaper than branded drugs. There are exceptions to this rule, however, for example when a large purchaser negotiates a favourable price for a brand name drug, it may turn out to be less expensive than the generic alternative. The essential drug policy encourages physicians and medical practitioners to prescribe generic drugs, which appear on the essential drug policy. This ensures that the majority of the population can have access to cheaper medication. In addition it is also cheaper for the government to purchase generics. It follows that this policy to some extent ensures that the poor can buy cheaper drugs.

5.5.3 Drug Donation

Donations of drugs that appear on the essential list imply that NatPharm only puts handling charges on drugs that are donated. Therefore, the prices that are paid by consumers at hospitals for drugs that have been donated will be below the market price for the drugs. However, drug donations cannot be relied on since they are not frequent. There is no guarantee for Zimbabwe that donations will be maintained, and also the donor incurs costs, rather than being revenue neutral or making a profit. Therefore, donor companies may fail to sustain donations on a large scale, where several products are involved.[225] Additionally most donor-funded projects have been suspended in the country because of the current political situation. Moreover, the guidelines for drug donations to the country have very strict specifications, which may prevent donations of certain drugs that do not appear on the essential list.[226] This implies that organisations that wish to donate drugs that are not generics or that are still under patent may find it difficult to do so. It becomes complicated then for patented drug prices to be controlled through drug donations. In addition, drugs of a different dosage forms, strength and formulation from the ones commonly used in Zimbabwe are

[225] Thomas (2001)
[226] All donated drugs should appear on the EDLIZ

frequently not favoured. This is because the members of staff at different hospitals have been trained to use certain formulations and dosage forms and therefore cannot constantly change their treatment guidelines.[227]

5.5.4 Import Duties and Mark-Ups

The government has of late been trying hard to bring down the amount charged for duties on all medicines. If a drug is considered essential or if it is used to treat chronic illnesses, then a zero percent import duty is levied. Also the raw materials used in the production of such drugs have zero percent import duty. The government has also removed all import duties on all antiretroviral drugs. This has been done to try and curb the costs of these drugs to the final consumer. In addition, the Pharmacist society of Zimbabwe has agreed that all pharmacies that sell antiretroviral drugs should put a flat mark-up of 10%. However not all pharmacies are actually observing this rule.

5.5.5 Drug Financing

Financing of pharmaceuticals is fundamental because drugs save lives and improve health; hence drug financing should ensure access to essential drugs for all segments of the population. Drugs are also costly, in developing countries, they commonly represent from 25% to 50% of the total public and private health expenditures. Drug availability and effectiveness are key factors in maintaining public interest and contribution in health related activities.[228] Common drug financing options used in the country include public financing, private and public health insurance, not-for-profit donations and out of pocket payments. An option that is likely to have profound effect on drug prices is public financing where an allocation is made from the health budget to purchase drugs. The funds are then used by NatPharm to purchase drugs that are much cheaper. Private and public health insurance will have effect if insurance companies encourage their members to purchase generics, this would boost the demand for generics resulting in increase in demand and reduction in prices for generics.

The above discussion has revealed that although formal/direct price regulation is non-existent in Zimbabwe, there are certain tools that can be employed by the government to try and indirectly control prices there by curbing the costs of drugs. On the other hand it is evident that most of these tools used cannot really control the prices of those drugs that are patented and those that are not included on the essential list. Additionally, the pharmaceutical sector is exposed to external factors for example fluctuations in exchange rates. This is

[227] Ministry of Health and child Welfare (1996)
[228] Drug financing in developing countries

because about 90% of the raw materials and 40% of the drugs including all HIV drugs are imported. The industry is also more vulnerable to economic shocks because prices of most pharmaceuticals are internationally determined because of importation, but in other health care services prices are to a large extent domestically determined.

6 CHAPTER 6: RESULTS ANALYSIS AND DISCUSSION

6.1 Introduction

This section analyses the data and results and provides a discussion of the key findings. It mainly assesses the impact of supply side factors and demand side factors, which are patents, retail and wholesale mark-ups, duties, taxes and competitive tendering on prices. Two sensitivity analyses are also conducted to illustrate that the results are not insensitive to changes in exchange rates and the presence of parallel importation. Finally this section will briefly discuss the impact of final end user prices on access to affordable AIDS drugs in the country.

6.2 Patents and Prices

This subsection will look at the relationship between patents and prices. As noted earlier, evidence has shown that patents allow multinationals to enjoy monopoly power since they do not face any competition, thereby charging higher prices and restricting output. This would result in higher prices than otherwise would be if such prices were competitively determined in the presence of generic competition. It will be shown that generic drugs are cheaper than patented drugs because generic manufacturers do not bear all the costs of R&D. Thus, they are able to price their drugs equal to marginal cost and still able to make a profit. An important indicator of the price effect of market monopoly is the difference between the price of patented drugs in markets that respect strong patent laws, and the price of generic equivalents produced in countries where there is no patent protection[229]. The presence of generic competition would eventually force the prices of patented drugs down since generic manufacturers are able to introduce their drugs at very low prices because of low production costs associated with the production of generics. Therefore, if the prices of patented drugs do not fall as a result of generic competition then the patent holders will not be able to sell as much since consumers can always switch to cheaper generics. Table 5 and 6 below computes the average prices of selected generic patented drugs.

[229] Oxfam (2001)

Table 5: Average prices for opportunistic infections generic drugs in Zimbabwe

Opportunistic Infections Drugs (generics)	average price (Pvt.)	lowest	highest	ratio of lowest to highest	No. of pharmacies	Median
Cotrimoxazole (1000*480mg)	$ 62.38	$ 28.91	$ 80.75	1:2.79	8	$ 64.76
Indomethacin (1000*25mg)	$ 105.37	$ 80.93	$ 177.40	1:2.19	7	$ 92.15
Ketoconazole (100*200mg)	$ 89.48	$ 111.73	$ 124.64	1:1.12	7	$115.13
Metronidazole (1000*200mg)	$ 89.48	$ 60.38	$ 102.73	1:1.70	6	$ 96.97
Miconazole (oral gel 40g)	$ 29.81	$ 28.05	$ 32.62	1:1.16	5	$ 29.09
Amoxycillin (1000*250mg)	$ 309.85	$ 259.09	$ 388.15	1:1.50	6	$301.82
Nystatin (oral suspension 30ml)	$ 37.06	$ 27.93	$ 48.18	1:1.73	5	$ 39.15
Fluconazole (14*50mg)	$ 350.98	$ 313.64	$ 376.82	1:1.20	6	$363.40
Vtamin B-complex (100*50mg)	$ 9.75	$ 10.95	$ 14.09	1:1.29	4	$ 11.85
Predinisolone (1000* 5mg)	$ 118.64	$ 84.09	$ 145.60	1:1.73	7	$120.00
Codeine phosphate (100*30mg)	$ 80.46	$ 23.64	$ 134.18	1:5.68	6	$ 79.31
Amitriptyline (1000*25mg)	$ 123.09	$ 104.18	$ 167.25	1:1.61	5	$107.82
Amphotericin B (vial)	$ 121.82	$ 109.09	$ 134.55	1:1.23	2	$121.82
Acyclovir (30*200mg)	$ 33.59	$ 27.73	$ 39.45	1:1.42	2	$ 33.59

Source: Table a, average drug prices survey in Zimbabwe (appendix)

Table 6: Average prices for opportunistic infections patented drugs in Zimbabwe

Opportunistic Infections Drugs (patented)	average price (Pvt.)	lowest	highest	ratio of lowest to highest	No. of pharmacies	Median
Clacid (10*250mg)	$ 130.47	$ 108.27	$ 155.18	1:1.43	6	$124.83
Fluconazole (14*50mg)	$ 350.98	$ 313.64	$ 376.82	1:1.20	6	$363.40
Azithromycin (3*500mg)	$ 159.88	$ 116.35	$ 278.62	1:2.39	4	$122.27
Itraconazole (15*100mg)	$ 316.44	$ 304.33	$ 331.36	1:1.09	3	$313.64

Source: Table a, average drug price survey in Zimbabwe (appendix)

Tables a and b, (see appendix) give the average retail prices in US dollars of different units of 35 dosage forms of 35 most commonly used drugs in the treatment of HIV/AIDS and related illnesses. The tables also give the highest and lowest prices for nine pharmacies in the private sector and the ratio between lowest and highest price for each drug. Tables 3 and 4 above shows a few selected drugs from Table a in the appendix. Table 1 shows the data for generic drugs and Table 2 shows the drugs that are still under patent that are used to treat opportunistic infections. It is clear from table b in the appendix that there is no systematic pattern indicating that the average prices are way above the median, thus it is least likely that there are extreme values that are pushing the averages up.

A closer look at the results above reveals that pharmacies sell their drugs at different prices in Zimbabwe. The variation in retail prices for generics ranges from 1:1,12 to 1: 5,68 and the retail price for patented drugs

varies from 1:1,09 to 1:1,29. The retail prices of both generics and patented drugs do not vary widely[230], however, the retail prices of generics show a much wider difference in the range of retail prices relative to the retail prices of the patented drugs. This is because patented drugs face no generic competition. These results indicate that, in Zimbabwe, the patented drugs enjoy monopoly[231] and there is very little price difference among pharmacies.

Generic drugs are not under patent therefore they compete among themselves and also compete with the originators' branded drugs. However, if we take the 'rule of five" into consideration,[232] it is clear this rule does not hold in Zimbabwe. This is because most of these generic drugs do not really face that much competition because there are less than five therapeutic alternatives[233] for each opportunistic infection.[234] This could be the reason why the range in retail prices among generic drugs does not vary as widely.[235] Zimbabwe like other developing countries has not put into the market some of the cheaper generic equivalents available in the world market. Although generics are not patented, to some extent, a monopoly market for these drugs exists. There are actors in the pharmaceutical industry that are making monopoly profits from generic drugs as result of limited competition among generics.

Table 7: Average prices for HIV/AIDS patented drugs in Zimbabwe

Anitretrovirals	US$(pvt)	lowest	highest	ratio of lowest to highest	N	Median
Epivir, 3tc (60*150mg)	$1,041.08	$ 918.18	$1,272.15	1:1.39	3	$ 932.91
Retrovir (100*100mg)	$ 503.38	$ 247.93	$ 694.78	1:2.80	3	$ 435.73
Combivir (60*450)	$1,110.90	$ 752.73	$1,655.11	1:2.20	5	$ 972.40
Invarise (270*200mg)	$1,106.60	$ 721.51	$1,757.13	1:2.44	3	$ 1,490.76
Videx (60*100mg)	$ 190.86	$ 149.84	$ 256.93	1:1.71	9	$ 210.25
Zerit (60*30mg/40mg)	$ 81.89	$ 63.82	$ 95.02	1:1.49	7	$ 83.15
Crixivan (180*400mg)	$ 507.58	$ 424.51	$ 827.15	1:1.95	8	$ 483.93
Viramune (60*200mg)	$ 394.62	$ 335.45	$ 517.18	1:1.54	5	$ 377.27
Hydrea (100*500mg)	$ 157.17	$ 160.69	$ 195.55	1:1.22	3	$ 164.55

Source: Table a, average drug prices survey in Zimbabwe (appendix)

[230] This is relative to other findings from other studies undertaken, for example, by Bala and Sagoo. They found that in OECD the range of ratios for generic drugs varied from 1:2 to 1:11, 5 and in developing countries that do not observe patents, the range for patented products varied from 1:1.2 to 1:4. Bala and Sagoo (2000)

[231] Zimbabwe has always observed process and product patents

[232] This argument is based on the idea that prices tend towards their lowest achievable when there are five or more competing products. This is because long-term experience with pharmaceutical pricing has showed that lowest prices are generally achieved only when there are five therapeutic alternatives or five competing producers. WHO-WTO secretariat (2001) and Ministry of Health and child Welfare

[233] See table 8 and the discussion that follows

[234] See footnote 230

Table 7 shows the average prices of antiretroviral drugs and the ratios between the lowest and highest price for each drug. The above results support earlier findings that patented drugs enjoy monopoly power in Zimbabwe hence the retail price range only varies from 1:1,22 to 1:2,8, which is relatively not a huge variation compared to the one found in the study done by Bala and Sagoo.[236] Results from patented antiretroviral drugs marketed in Zimbabwe also support the above findings that there is little variation in prices among pharmacies because of absence of generic competition.

6.2.1 Price Comparison of Patented VS Generic Drugs

This subsection will look at the price difference between patented drugs and generics within the same therapeutic class.

Table 8: Patented vs. generic drug prices of equivalent therapeutic classes in Zimbabwe

Patented drugs	Price	Generic drugs	Price	ratio
Fluconazole (100*50mg)	$2,507.00	Ketoconazole (100*200mg)	$ 89.48	1:28
Azithromycin (100*500mg)	$5,329.33	Metronidazole (100*200mg)	$ 8.95	1:595
Klacid (100*250mg)	$1,304.70	Metronidazole (100*200mg)	$ 8.95	1:146
Doxorubicin (iv -3*150mg)	$1,680.71	Amoxycillin (100*250mg)	$ 30.96	1:54
		Cotrimoxazole (100*480mg)	$ 6.24	1:269
Itraconazole (100*100mg)	$2,109.60	Amphotericin B (vial)	$ 121.82	1:17
Fluconazole (100*50mg)	$2,507.00			1:21

Source: Table a, average drug prices survey in Zimbabwe (appendix)

Table 8 above shows a comparison of retail prices in US dollars of 100 units of 12 drugs of equivalent units (5 patented drugs, 6 generics and 1 off-patent drug) that are used to treat opportunistic infections. This comparison is done for drugs, which are within the same therapeutic class for which comparable data are available. For example, Fluconazole is an antifangal drug used to treat:

- Prophylaxis or Cryptococcal Meningitis
- Oropharyngeal and Vaginal Candidiasis (not responding topical therapy)
- Oesophageal and systematic Candidiasis
- Treatment and maintenance of Coccidiodomycosis.

[236] See footnote 230 above

It falls in the same therapeutic class as Ketoconazole since Ketoconazole is used to treat oesophageal and resistant Oropharyngeal Candidiasis.[237] It is evident that Fluconazole, which is still under patent is 28 times more expensive than Ketoconazole.

Azithromycin and Metronidazole are used to treat mycobacterium Avium infections and Chalamydium infections for example genital Chalamydia and Gonorrhoea infections and Klacid is used to treat Mycobacterium Avium complex infections in AIDS patients. From the table it clear that Metronidazole is 595 times less expensive than Azithromycin and 146 times less expensive than Klacid.

Doxorubicin is used to treat Kaposi Sarcoma and AIDS related Lymphoma. Amoxycillin and Cotrimoxazole are used to treat HIV related respiratory conditions of which pulmonary Kaposi Sarcoma is one of them, this puts these three in the same therapeutic class as Doxorubicin. Doxorubicin is 54 times more expensive than Amoxycillin and 269 times more expensive than Cotrimoxazole. Amphotericin B (vial) is an old drug that is not patented anymore but it faces little generic competition because it is difficult to manufacture. It is used in HIV/AIDS to treat Cryptococcal Meningitis, Histoplasmosis and Coccidiodomycosis, Aspergillosis. [238] Itraconazole is used to treat resistant oral and Oesophageal Candidiasis, maintenance of Cryptococcosis, and in the treatment of Histoplasmosis. Given what Fluconazole is used to treat, it follows Fuconazole and Amphotericin B fall in the same therapeutic class and Itraconazole and Amphotericin B are in the same class. However, since Amphotericin B is off patent and faces some competition, it 17 times cheaper than Itraconazole and 21 times cheaper than Fluconazole

The above results support the notion that, patented drugs are more expensive than generic drugs. On the other hand drugs that are not patented anymore tend to be less expensive than those, which are still under patent even if they face little competition. This further evidence to support the idea that patents (where they are observed) lead to higher prices because of the monopoly power they enjoy.[239]

Figure 6 below compares the prices of six patented HIV drugs that are sold in Zimbabwe to prices of six generic equivalents (in US dollars, of equivalent units) that are sold in India for which comparable data is available. The drug prices are for a month's supply. The graph illustrates, that there is a stark contrast between the prices of patented products in Zimbabwe and the price of the non-patented equivalents in India. It is evident that the prices in Zimbabwe for patented drugs are way above the prices of their generic equivalents produced in India.

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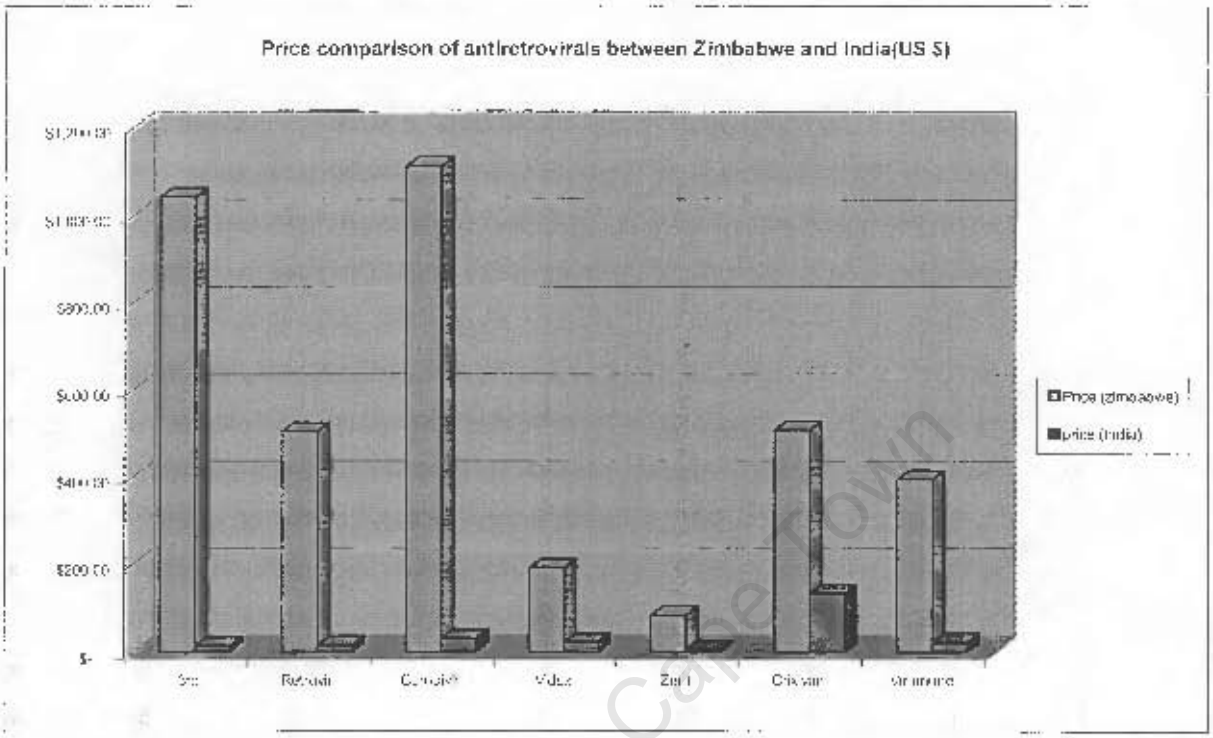
[237] EDLIZ (2000) and UNICEF, UNAIDS Secretariat (2001)
[238] UNICEFand UNAIDS Secretariat (2001)
[239] Bala and Sagoo (2000)

Figure 6: Price comparison of antiretroviral drugs between Zimbabwe and India



Source: Table c (appendix,. average drug prices survey in Zimbabwe and http://www.cipladoc.com/publications/aidswatch/aidsupdate.html#newprices and Perez-Casas (2002). HIV/AIDS Medicines Pricing Report

The prices of patented antiretroviral drugs are from 4 times up to 80 times more expensive than their generic equivalents in India. For example the drug 3TC sells for about $1,041.08 in Zimbabwe compared to its generic equivalent Lamivir, which only sells for about $13.07 in India for a month's supply. The same generic drug could cost less if it was produced locally or imported from India as revealed by the graph above. A month's supply of Zidovir costs about $14.28 compared to its patented equivalent Retrovir, which costs about 35 times more ($503.38). The only drug that does not show a huge price difference is Crixivan, which costs about 4 times more ($507.58) than its generic equivalent Indivan, which costs about $131.73 in India. Combivir costs approximately $1.110.90 in Zimbabwe whereas its generic (Duovir) costs only $30.50 in India. Viramune is nearly 18 times more expensive than its generic equivalent Nevimune, the price of Zerit is about 15 times higher than that of Stavudine and Dinex is 15 times cheaper than the generic equivalent Videx respectively.

However, the above results need to be interpreted with caution because of the data problems encountered during data collection. Firstly because of a small sample size, they were fewer data points used to compute average prices/. Hence the above results may not be representative of the whole population. In addition in some cases pack sizes and strength for some drugs were different across pharmacies. Hence some prices were imputed based on the per unit pack which could lead to biased price comparisons.

Nonetheless, the above results support and confirm conclusions reached in studies by Bala and Sagoo (2000) and Myhr (2000) that patented drugs tend to be more expensive than their generic equivalents. This is so because their manufacturers do not face any competition, hence they act as monopolies. This enables them to set higher prices and at the same time restrict output. The prices of generics in India show that product competition through availability of generics will result in lower prices, since generics are priced at lower prices than their patented counterparts. India has not started observing patent laws yet, therefore they benefit from generic competition through generic manufacturing using reverse engineering. On the other hand it is important to understand the economics of patents. Patents are there to reward research based companies for undertaking R&D. Complete removal of patents could result in under investment in R&D and innovation, thus resulting in the reduction in number of newer drugs introduced onto the market. This calls for a balance to be struck between the need to promote R&D and the need to promote competition that results in competitive prices for drugs. Additionally, it is important to note that prices in Zimbabwe are not country specific; these are most likely international prices set in the international drug market. Yet, these are the prices consumers in Zimbabwe are faced with.

It is argued that, India and Brazil are two of the few developing countries with pharmaceutical industries capable of producing generics through reverse engineering. However, evidence from interviews carried out in Zimbabwe with marketing managers of manufacturing companies showed that the expertise and technological know-how to produce generics is available. This further supports the idea that if local manufacturers in Zimbabwe were allowed to produce generics, then the prices of antiretroviral drugs would fall substantially. Studies done in India and Brazil have shown that the prices of generics are between 50%-70% less than brand name drugs. Between 1996 and 2000, Brazil substantially increased its large-scale production of antiretroviral drugs. By 2000, there were 11 local producers. During this period, the average price fell by up to 73% for domestically produced drugs and prices had come down by 82% within five years. [240] In the same country, recent offers from generic producers have sparked a price war for antiretroviral drugs and this has caused the price of a year's triple therapy to fall from $10,000 to $350 in a single year.

[240] WHO-WTO secretariat (2001)

Drug patenting in Zimbabwe has substantial impact on prices as evidenced above, consequently it impacts on affordability. Not only are prices too high for average individuals, but also such high prices put huge strain on the country's financial resources since these drugs have to be purchased in US dollars. Such exorbitant prices makes it impossible for the government to finance such highly priced drugs and make them available in public hospitals. This is because they consume a substantial amount of the health budget. This is one of the reasons why antiretroviral drugs and some important drugs that are used to treat opportunistic infections are unavailable in the public sector. However, although low availability of drugs in not unexpected in the public sector, total absence of AIDS drugs and related illnesses should be unacceptable because poor people rely on the public sector to get their drugs since this is where some of their drug costs are at least covered.[241]

In short, it is clear that monopoly markets are bound to thrive in the absence of competition. The absence of competition will allow multinational companies to keep up high prices for as long as the patent is still valid. Monopoly prices can be reduced through competition, and this will make drugs cheaper especially in developing countries. Introduction of generics in Zimbabwean will force multinationals to decrease their prices in order to compete with local manufacturers. On the other hand, IPR protection is necessary to encourage R&D and innovations. However, since Africa only constitutes 1.3% of the total global sales. Hence, the introduction of generics in these countries would surely not significantly harm the profits of multinationals as long as there is a mechanism in place to prevent spillovers into industrialized countries in disease cases such as HIV/AIDS where there are global markets. Another argument against the introduction of generics is that, if generics were allowed in developing countries, then multinationals would not invest in R&D for medicines needed to treat tropical diseases such as Malaria.[242] However, compensating research-based companies through payments of royalties and issuing compulsory licenses could go some way in resolving this issue. Therefore, there is need to strike a balance between the need to encourage R&D using IPR and efforts by governments of developing countries to minimise the negative impact of patents on prices of essential medicines. It will be in the best interest of public health to have low priced antiretroviral drugs in Zimbabwe because price is a critical factor when choosing drugs for the essential drug list. One of the main reasons why there are no antiretroviral drugs on the essential drug list is because of their exceptionally high prices.[243]

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[241] Myhr (2000)
[242] Bala and Sagoo (2000)
[243] Bala and Sagoo (2000)

6.3 Duties, Mark-ups and Taxes

This sub-section seeks to assess the contribution of import duties, mark-ups and taxes to the final retail price of pharmaceuticals used in the treatment of HIV/AIDS and related illnesses. Import duties, mark-ups and taxes are likely to contribute substantially to the costs of drugs especially in a country like Zimbabwe where there is no formal/direct price control on drugs. Distribution margins including retail mark-ups are important since they frequently account for as much as half of the consumer price[244], margin structures also provides dispensing incentives.[245] Import duties increase the prices of imported drugs directly by levying a tax on them. In addition the resulting costs of importing drugs also allows domestic producers to charge higher prices for their outputs than if there were no import tariffs.[246]

The retail mark-ups for patented antiretroviral drugs varied between 10% and 25% and the retail mark-ups for opportunistic infections medicines varied between 40% and 50%. Because of these disparities in mark-ups used by different pharmacies and wholesalers, average mark-ups were used. Unlike other African countries, for example Kenya and Uganda, Zimbabwe charges import duties on all drugs for acute illnesses. However, there are no import duties for all medicines used to treat chronic illness and for HIV drugs. Table 9 below shows the percentage contribution of all taxes, duties and mark-ups to the final price from the manufacturer up to the retail pharmacies.

Table 9 Official duties, taxes, mark-ups etc

	Antiretroviral (patented)	Opportunistic infections drugs (patented & generics)
Import duty	0%	10%
Sales tax	15%	15%
Wholesale mark-up	20%	30%
Retail mark-up	15.6%	45%
Dispensing fee	$ 1 .82	$ 1 .82

Source: average drug prices survey in Zimbabwe (2002)

As shown in table 9 above, there are no import duties charged on all antiretroviral drugs, on the other hand, since most drugs for opportunistic infections are used to treat acute illness, they attract 10% duty on cost if the drugs are imported. Therefore, when wholesalers put their mark-up, they first add the amount of the duty levied to the costs price and then mark-up their opportunistic infections drugs by about 30%. However, the

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[244] According to WHO, import duties, taxes, wholesale and retail mark-ups, both formal and informal, can double the price of a drug between the manufacturer and the consumer.
[245] WHO (1998)
[246] Woodward (2001)

average wholesale and retail mark-ups on antiretroviral drugs are slightly lower (20% and 15.6%) compare to the average wholesale and retail mark-ups on opportunistic infections drugs (30% and 45%). All drugs that are locally produced do escape the 10% import duty levied. In addition to the mark-up retailers have to add a 15 percent sales tax on all drugs plus a $1.82 US dollar equivalent dispensing fee.

The results above reveal that, duties, mark-ups and taxes contribute approximately 51% to the final price of antiretroviral drugs and about 100% to the final price of opportunistic infections medicines. This is quite a substantial amount. This also confirms earlier findings of a study done by WHO[247] that local taxes, distributional costs and mark-ups at wholesale and retail level can double the price between the manufacturer and the consumer. In some developing countries, studies have found retail and wholesale mark-ups of up to 150%-200%.[248]

Table 10: Official duties, taxes, mark-ups etc for patented and generic drugs in three East African countries

	Kenya	Tanzania	Uganda
Import duty	0 %	10 %	0 %
Port charges	8 %	1 %	
Clearance and freight	1 %	2 %	
Pre shipment inspection	2.75 %	1.2 %	8 %
Import licence			
Pharmacy Board fee		2 %	
VAT			
Total tariffs and taxes	11.75 %	16.2 %	8 %
Wholesale mark-up	15 %	not fixed	not fixed
Retail mark-up	20 %	not fixed	not fixed
Grand total	46.75 %	N/A	N/A

Source: Myhr (2000) Price survey East Africa

Table 10 above shows results of a study done in East Africa by Myhr (2000). From table 10 it is evident that the total percentage of all taxes duties and mark-ups for Kenya comes to about 46% for all drugs.[249] A comparison of these results with those in table 9 reveals that the total contribution of distributional costs, taxes and tariffs to final price is quite substantial in Zimbabwe compared to that of Kenya. The reason could be that in Kenya all drugs are exempted from sales tax/VAT. In addition, they have fixed wholesale and retail mark-ups of 15% and 20% respectively for all dugs,[250] unlike in Zimbabwe where different institutions put different mark-ups and are free to set profit levels they want. Such high mark-ups and taxes can make it

[247] WHO (2001)
[248] IFPMA (2000)
[249] Myhr (2000)
[250] Ibid

difficult to carry out cross-country comparisons with high precision. This could be one the reasons why some studies that have been done show that prices in low and middle income countries tend to be higher than those in high income countries because of some unregulated mark-ups in some developing countries like Zimbabwe. The above results also show that pharmacies and wholesalers in Zimbabwe have high mark-ups on drugs for opportunistic infections than on antiretroviral drugs since all but a few drugs for opportunistic infections are generic copies and hence tend to be cheaper, therefore they tend to attract a higher mark-up than the more expensive antiretroviral drugs.[251]

It is also evident that progressive mark-ups are still the norm in Zimbabwe. On the other hand, many industrialised countries have long abandoned progressive mark-ups for dispensing. These have been replaced by digressive mark-ups and dispensing fees that offer little incentive to dispense expensive drugs.[252]

In summary, the methodology used for this analysis is a simple one, however, the results seem to suggest that retail mark-ups both at wholesale and retail level contribute the most to the final price compared to taxes and duties. It may be suggested that even if they contribute the most reducing them will act as disincentive to wholesalers and retailers to invest more resources into their business. Thus reducing import duties and taxes looks more attractive.[253] However, it should be noted that any potential benefits associated with taxes and import reductions will be at least partly offset by related losses in government revenue. Some of the revenue from taxes and duties that accrue to the government are used for health-promoting expenditures.[254] Consequently, the overall effect on public finances of a reduction in duties and taxes on drugs will be zero especially where they are purchased by the public sector, and negative where they are purchased privately. A reduction in resources available for recurrent spending seriously constrains health services and related activities, and hence, it will have a significant adverse effect on health.[255] Therefore, a further investigation should be conducted to evaluate the costs and benefits of reducing taxes or mark-ups and estimate which one of the two would have a lesser negative impact on the overall welfare of the public. This should take into consideration the associated impact on utilisation and government revenue losses due to reduction in taxes and duties as well as the reduction in investment by retailers and wholesalers as a result of reducing mark-ups.

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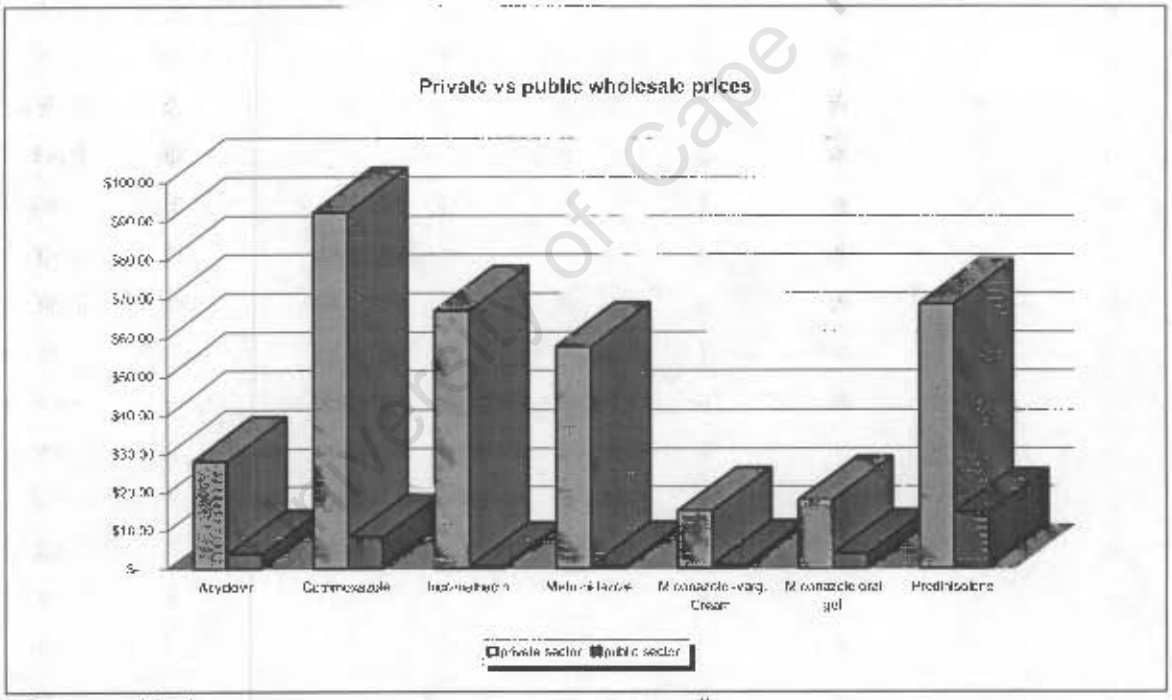
[251] Myhr (2000)
[252] Ibid
[253] For example the Indian government has now cut taxes on some drugs for HIV/AIDS and this has lead to a further reduction in AIDS drugs.
[254] Woodward (2001)
[255] Ibid

6.4 Competitive Tendering and Bulk Purchasing

As noted earlier, competitive tendering plays an important role in the public sector in Zimbabwe. NatPharm buys most of these drugs on tender and they also buy in bulk, hence they get substantial discounts on medicines they purchase. Such negotiations that result in substantial discounts enable government hospitals to make drugs publicly available for less. In this section it will be shown that competitive tendering results in lower prices for drugs in the public sector than in the private sector. However, it should be noted that in most cases government stores buys drugs that are on the essential list, consequently, this excludes anti-HIV drugs. The impact of competitive tendering can be estimated at wholesale level by comparing the prices of private wholesalers to those of government medical stores or at retail level by comparing the prices of private pharmacies to those of the main referral central hospital.

Figure 7: Private VS Public Wholesale Prices



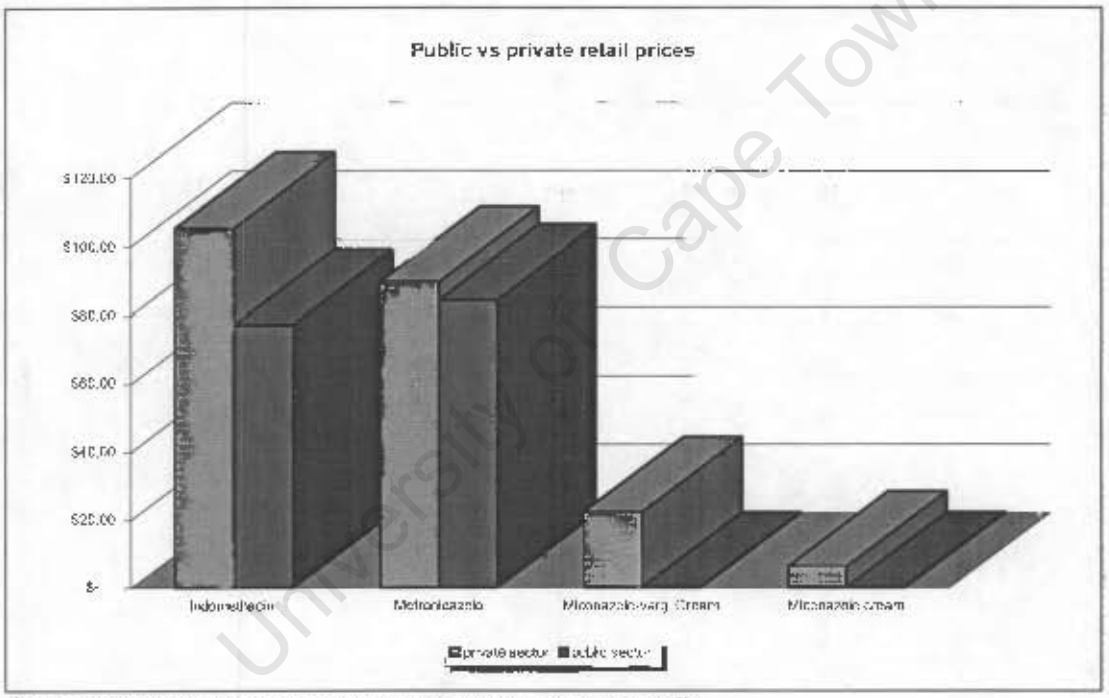
Source: table 1e, average drug prices survey in Zimbabwe appendix

Figure 7 above compares the average prices of 7 drugs available both in private and public sector wholesales for which comparable data is available. From the graph it is clear that all the drugs under comparison are cheaper in the public sector than in the private sector. Acyclovir is about 631% cheaper in the public sector than in the private sector. A thousand Indomethacine tablets cost about $ 0.67 in the public sector and about $ 66.91 in the private sector which makes it $66.33 more expensive in the private sector.

Metronidazole is 81 times cheaper; Miconazole oral gel and Prednisolone are 4 times cheaper in the public sector than in the private sector. Cotrimoxazole tablets are 1034% more expensive in the private sector than in the public sector.

Figure 8 below compares the prices of drugs in the public and private sector that were also available at retail level during the period the data was collected. The figure reveals that, at retail level, the same drugs for which comparable data is available are less expensive in the public sector than in the private sector. However, the price difference although still substantial it is not as enormous as the price difference at wholesale level.[256]

Figure 8: Public VS Private Retail Prices



Source: table 1e, average drug prices survey in Zimbabwe appendix

Nonetheless, it is evident that Indomethacine is about 37% more expensive in the private sector than in the public sector and Metronidazole cost about 1.06 times more in the private sector than public sector.

[256] A possible explanation could be that at the time the data was collected, NatPharm could have just received some drugs in form of donations, which it had not yet distributed to the central hospital and the hospital pharmacy was still selling old stock.

Miconazole varginal cream cost approximately $ 0.13 in the public sector and about $22.26 in the private sector, which makes it $22.13 times less expensive in the public sector than in the private sector.

The above results reveal the importance of competitive tendering in the public sector in Zimbabwe. NatPharm receives discounts through bulk purchasing, which reduces its cost prices substantially. In addition competitive tendering ensures that NatPharm gets the best competitive price for all drugs it puts to tender. Moreover the public sector also receives some drug donations from several international organisations; hence, they only have to put a handling charge on these drugs when selling them. All this contributes to the lower prices charged in the public sector compared to the private sector. These findings suggest that that if Zimbabwe were allowed to issue compulsory licenses or make use of parallel importation, antiretroviral drugs could be obtained at much cheaper price than in the private sector. This would be as a result of the tendering system, which ensures that the public sector is able to receive the lowest prices possible. As noted earlier the poor depend so much on the public sector, for this reason, if drugs could be obtained cheaply, less strain would be put on the public sector's financial resources. Antiretroviral drugs would be made available in the public sector since the government would be able to purchase them cheaply through the tendering system from both local and foreign manufacturers for example, Cipla in India. Cheaper drugs for the poor would imply increase in access, and as a result, there will be an improvement in the health status of the vast majority of the population suffering from AIDS.

On the other hand, as noted earlier, one should also be aware of government failure. The government is not immune to failures. Therefore there is need to evaluate potential failures associated with government public sector provisions and rectify these were possible before putting all the responsibility in the hands of the government. Sometimes a near Pareto optimum outcome could be achieved by combining both public sector and private sector provision.

6.5 Comparing Prices of Antiretroviral Drugs In Zimbabwe With International Prices

The objective of this section is to compare the prices of antiretroviral drugs in Zimbabwe with international prices. The aim is to compare how prices in Zimbabwe fare compared to other countries. This section will show that although the prices of identical drugs varies between the countries under comparison, there is no clear correlation between the per capita gross national income and prices of drugs charged in Zimbabwe. It will also be shown that anti-HIV drugs prices are on average higher in Zimbabwe than in the United States. The HIV drugs and drugs used to treat some of the opportunistic infections in Zimbabwe are less affordable

because the prices are too high. Such high prices are mainly as a result of the presence of patents, lack of generic competition, the black market exchange rates, high mark-ups and taxes/tariffs.

Table 11: Cross-country comparison of HIV Drug prices

	Zimbabwe	India	USA	Brazil	Uganda	Ratio between lowest & highest
Per Capita GNI	$ 460.00	$ 450.00	$ 34,100.00	$ 3,580.00	$ 300.00	
Epivir, 3tc (60*150mg)	$ 1,041.08	$ 13.07	$ 259.80	$ 18.00	$ 96.00	1:80
Retrovir (100*100mg)	$ 503.38	$ 14.28	$ 91.00	$ 10.00	$ 70.00	1:50
Combivir (60*450)	$ 1,110.90	$ 30.50	$ 423.60	$ 42.00	$ 222.00	1:36
Videx (60*100mg)	$ 190.86	$ 21.79	$ 109.20	$ 30.00	$ 78.00	1:9
Zerit (60*40mg)	$ 81.89	$ 5.45	$ 291.00	$ 18.00	$ 186.00	1:34
viracept (270*250mg)	$ 2,162.81		$ 583.20	$ 367.20		1:6
Viramune (60*200mg)	$ 394.62	$ 21.79	$ 255.00	$ 78.00	$ 282.00	1:18

Source: Drug prices survey in Zimbabwe, Pérez-Casas (2000), *HIV/AIDS Medicines Pricing Report Setting and* http://www.cipladoc.com/publications/aidswatch/aidsupdate.htm#newprices

Table 11 presents the results for each country and for each drug. It summaries the average prices of seven anti-retroviral drugs of the given strength and quantity for which comparable data is available in five different countries together with their respective per capita gross national income. One would expect the prices of drugs to be higher in the USA than any other country since it is a high income industrialised countries and the rest are middle income and low-income countries. However the table above shows that all drugs except Zerit are more expensive in Zimbabwe than in the USA and all the other three countries under comparison. USA has gross national income of $34 100, which is about 74 times higher than that of Zimbabwe. The ratio of price differences between Zimbabwe and USA ranges between 1:1,5 to 1:5,5. Which implies that HIV drugs in Zimbabwe are between 55% and 403% more expensive than those in the USA. The price difference in drugs between Zimbabwe and Uganda could be as result that Uganda has been receiving generic versions from countries like India and Brazil after it declared a state of emergency for AIDS. Brazil has lower drug prices as a result of the availability of generic versions. Locally produced HIV drugs in Brazil are sold at a fraction of their global prices.[257] A generic form of Zidovudine is about 50 times cheaper in Brazil than in Zimbabwe. The cheapest drug in Brazil (3tc) is about 5684% more expensive in Zimbabwe than in Brazil.

There is now adequate clinical data to provide evidence that combination therapy with 2 or 3 drugs is far superior to mono therapy and that triple therapy can contain viral reproduction by up to 2 years. None of the

[257] Sam (2000)

approved antiretroviral agents can eradicate the infection, but if given in combination they can suppress viral replication, improve immunologic status, delay infectious complications and prolong life.[258]

Table 12: Price comparisons of Combination Therapies in five countries

Treatment	Daily dose	Year's supply (365)	Zimbabwe	India	USA	Brazil	Uganda
Combivir (450)	2	730	$ 13,516	$ 371	$ 5,154	$ 511	$ 2,701
Triple therapy combination							
Retrovir (100mg)	6	2190	$ 11,023.96		$ 1,992.90	$ 219.00	
Epivir, 3tc (150mg)	2	730	$ 12,666.46		$ 3,160.90	$ 219.00	
viracept (250mg)	9	3285	$ 26,314.20		$ 7,095.60	$4,467.60	
Total	17	6205	$ 50,004.62		$12,249.40	$4,905.60	
Videx (100mg)	4	1460	$ 4,644.27	$530.26	$ 2,657.20	$ 730.00	$ 1,898.00
Zerit (40mg)	2	730	$ 996.31	$ 66.28	$ 3,540.50	$ 219.00	$ 2,263.00
Viramune (200mg)	2	730	$ 4,801.19	$265.13	$ 3,102.50	$ 949.00	$ 3,431.00
Total	8	2920	$ 10,441.77	$861.67	$ 9,300.20	$1,898.00	$ 7,592.00

Source: drug price survey in Zimbabwe, Pérez-Casas (2000), *HIV/AIDS Medicines Pricing Report and http://www.cipladoc.com/publications/aidswatch/aidsupdate.htm#newprices*

Table 12 above shows one example of a dual therapy (Combivir) and two examples of triple therapies and their average prices for a year's supply in five countries for which comparable data is available. All the combination therapies are more expensive in Zimbabwe than in the other four countries under comparison.

In Brazil and India, where Combivir is produced locally as a generic, the total yearly cost of a dual therapy combination is US $371 in India and US $511 in Brazil. In Zimbabwe where no generics are available, the total cost is about US$13,516 per year, which is 36 times more expensive in Zimbabwe than in India, and 26 times less expensive in Brazil. The second triple therapy is 12 times more expensive in Zimbabwe than in India where generics are available, and 1.12 times less expensive in the USA than in Zimbabwe and 1.4 times cheaper in Uganda (where proprietary brands are sold) than in Zimbabwe.

The above analysis reveals that, of all the drugs surveyed, the retail prices[259] are higher in Zimbabwe than in USA, Brazil, India and Uganda, of which Brazil and USA are much more developed and more affluent than Zimbabwe. Brazil has a GNI per capita of US $3 580, which is about 8 times more than that of Zimbabwe. This supports evidence from other studies, which shows that variation in prices between industrialized countries and developing countries are especially marked, yet not in the pattern of lower prices for lower-income countries that maybe expected.[260] This is also supported by findings from a study

[258] Aids watch (2000)
[259] Expect for Zerit which is more expensive in the USA
[260] Oxfam (2001)

done in ten African countries that clearly showed that pricing policies of multinational companies were the major variable. This study went on to show that it is wrong to assume that these firms automatically charge lower prices in developing countries. Rather prices are often higher in developing countries because of the strategy of targeting sales at local elites – a low volume, high price market. In addition, developed countries with national health systems are better able to negotiate reduced prices with research-based firms compared to developing countries.[261] Also, it has been shown that Lamivudine is marketed by Glaxo in developed countries at prices 20 per cent lower on average than in Africa. Prices for branded versions of Lamivudine are higher in Mozambique, "where over half of the population lives below the poverty line and 14% of the population has the HIV virus", than in the USA.[262]

Zimbabwe is among one of the poorest countries in the world and it has recently been going through a recession. However, its average drug prices are higher than one of the richest nations in the world, USA. The above results do not support what one would expect, higher prices in USA and Brazil than in Zimbabwe. Moreover, in the case of the USA and other high-income countries, the costs of health services and medication are meet by prepaid private insurance or public health insurance. In Zimbabwe most people meet their treatment costs including the medicine expenses through out of pocket payments. In sub-Saharan Africa, about two-thirds of the total spending on drugs is made by households. This is a reflection of the inadequacy of public health investment and the inability of poor people to afford private health insurance.[263]

6.6 Implications of High End User Drug Prices on Access to Affordable Antiretroviral Drugs

Drug affordability is among other things a function of household/individual income[264] and/or share of the health budget devoted to purchasing medicines and the cost of medicines. About 50-90% of pharmaceutical expenses are met through out of pocket purchases and medicine expenses account for a large portion of out of pocket health expenses at individual or household level.[265] Richer households are far less sensitive than poorer households to price changes because the same expense will represent a larger share of poorer households' income. Moreover, for poorer households, spending their income on medicines may divert resources from other necessities, such as food and education. As a result, the main focus should be on

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[261] Oxfam (2001)
[262] Oxfam (2001) pp. 28
[263] Oxfam (2001)
[264] In this case average wages are use as a proxy for household/individual income
[265] Oxfam (2001), WHO (1998), Myhr (2000)

minimising drug prices to ensure affordability. There is no clear correlation between prices of medicines and per capita gross national income or purchasing power parities in developing countries. On the other hand, in developed countries, high insurance coverage, which includes some parts of cost of drugs, helps ensure affordability.[266]

Findings from the results analysis section have has shown that patents, generic competition, competitive tendering/bulk purchasing import duties, taxes and mark-ups could profound impact on prices of medicines in Zimbabwe. Economic theory tells us that increase in price for a commodity would mean a reduction in demand and quantity demanded because consumers will be unable to afford the commodity at such a high prices. It follows that high drug prices can prevent access to drugs. In addition such high drug prices could also imply that the government of Zimbabwe cannot put such drugs on the essential list although the drugs may be essential. The government could also be prevented from financing such drugs because they would consume a large portion of the health budget.

The results in table 12 above reveal that, for Combivir, it would cost the government of Zimbabwe about 14 million US dollars and about 10,5 million US dollars for the cheapest triple therapy of the two to treat a thousand people every year if it were provided. The cheapest triple therapy (to treat a thousand patience) would consume 2.6% of the health budget, which is US $400 million for 2002. It is estimated that 96 thousand people are dying every year of the disease and about 1,5 million people are infected in Zimbabwe.[267] However, not all the infected individuals need treatment since some of them die. From these statistics, it can be estimated that about 6.4% of those infected die every year, therefore, about 94.6% (1,404 000 million) of those infected need treatment every year. This means that it would cost the government about US $15 billion to provide the cheapest triple therapy treatment for these people. This amount surpasses the current annual health budget by far.

Essentially, it costs the Brazilian public health system the same amount to treat 1,000 HIV/AIDS patients per year, as it would the Zimbabwean government to treat approximately 182 HIV/AIDS patients per year if the government tried to provide antiretroviral drugs. It would costs the India government the same amount to treat 1000 HIV patients per year as it would the Zimbabwean government to treat only 83 patients per year.[268]

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[266] Ibid
[267] Associated Press (2002)
[268] These costs exclude the costs of diagnostics and other expenses.

The agricultural sector in Zimbabwe is characterised by low skilled workers who earn an average income of about US $55 a month, and the majority of the people in the country live in the rural areas and rely on the agriculture sector for survival. They do not really have formal employment; hence their income is dependent on how well crops do in that particular year. The average income in the manufacturing industry is about US $181 a month.[269] It follows that the yearly average income for a farm worker is about US $660 and that of a manufacturing worker is about US $2172. It is clear that this amount is barely enough to buy a cocktail of a year's triple therapy, which costs about US $10,442. Farm workers would need to work an equivalent of about 15,8 years if they were to purchase a year's triple therapy and manufacturing workers would need to work an equivalent of about 4,8 years if there were to purchase a year's triple therapy. This assumes that they save all their income without purchasing other necessities like food, rent and electricity and payment of other bills. However, evidence from developed countries for example Canada, shows that a year's triple therapy treatment for HIV infections costs an equivalent of four to six month's salary and a greater part of the costs of drugs is reimbursed.[270]

In summary the above, results and findings have shown that HIV drugs are more expensive in Zimbabwe than in the other four countries under comparison. The costs of HIV drugs are definitely out of the reach of the Zimbabwean health system, with a year's triple therapy costs of treating those who require treatment far exceeding the annual health budget for the country. Average workers in Zimbabwe can only dream of ever affording to buy mono-therapies of antiretroviral drugs, let alone combination therapies. Prices are exceptionally high in Zimbabwe and this is negatively impacting on affordability of AIDS drugs. Some of the price differences could be attributed to parallel market exchange rates in Zimbabwe. Yet, it is still clear in the sensitivity analysis in section 6.7 below, that prices in India are still way below those in Zimbabwe. Additionally, price comparisons between developing countries with different patent regimes show akin results. A study done by Lanjouw shows that prices in Pakistan, which respects product patents for pharmaceuticals, are 3 to 14 times higher than in India, which will not grant patents until 2005. While Pakistan is comparatively richer than India, the income difference is too small to account for the price differentials. [271]

On the other hand, the Brazilian and India government were able to provide antiretroviral drugs to more than 80,000 citizens by the end of 1999, which led to a more than 50% drop in AIDS-related mortality between 1996 and 1999. This is as a result of the availability of cheaper generic drugs.[272] In 1997, there were

[269] Income and expenditure surveys (2001)
[270] Myhr (2000)
[271] Ianjouw (1999) and Oxfam (2001)
[272] Brazilian Department of Health (Unpublished data)

580,000 people living with HIV/AIDS in Brazil.[273] Nonetheless, if Brazil provided patented treatments to HIV/AIDS sufferers, the costs would consume the entire nation's drug budget. Notwithstanding US pressure, Brazil continues to manufacture generic equivalents at one-fifth of the costs of the US products, and it is making them widely available. This has reduced mortality rates by 50% since 1996.[274] The availability of cheaper generic versions has enabled the Government of Brazil to save at least US $472 million on hospitalisations and treatment for opportunistic infections between 1997 and 1999.[275]

Consequently, besides the high social costs of not providing antiretroviral drugs, there are real financial costs for the government when antiretroviral drugs are not available at affordable levels. It could be more costly for a government not to provide antiretroviral drugs than to provide them, because of the high costs involved in caring for AIDS patients.[276] If people in Zimbabwe continue to be denied access to antiretroviral drugs because of such high prohibiting drug prices, which makes antiretroviral drugs unaffordable to the majority of the population in Zimbabwe, then HIV/AIDS will continue to condemn AIDS infected individuals to premature deaths.

6.7 Sensitivity Analysis Assuming a Different Exchange Rate

A sensitivity analysis assuming a different exchange rate is fraught with the following problem, it is difficult to track whether the wholesalers actually bought drugs using foreign currency obtained at black market rates or whether they were able to source foreign currency somehow at the official rates. If some of the drugs were purchased with foreign currency obtained at the official rate then the calculations used would underestimate the prices given in column five.

[273] Human development report (2000)
[274] UNAIDS (2002a)
[275] Brazilian Department of Health (Unpublished data)
[276] Myhr (2000)

Table 13: Cost of Combination therapies (exchange rate sensitivity analysis)

Treatment	Daily dose	Year's supply (365)	Zimbabwe (black market rate)	Zimbabwe (Offical rate)	India	USA
Combivir (450)	2	730	$ 13,515.95	$ 2,477.92	$ 371.13	$5,153.80
triple therapy combination						
Videx (100mg)	4	1460	$ 4,644.27	$ 851.45	$ 530.26	$2,657.20
Zerit (40mg)	2	730	$ 996.31	$ 182.66	$ 66.28	$3,540.50
Viramune (200mg)	2	730	$ 4,801.19	$ 880.22	$ 265.13	$3,102.50
Total	8	2920	$ 10,441.77	$ 1,914.32	$ 861.67	$9,300.20

Source:, average drug prices survey in Zimbabwe, Pérez-Casas (2000) *HIV/AIDS Medicines Pricing Report and http://www.cipladoc.com/publications/aidswatch/aidsupdate.htm#newprices*

Table 13 above shows the estimated average retail prices of a dual therapy and triple therapy combinations for Zimbabwe assuming both the black market exchange rate (which most of the imported drugs in the private sector are bought at by wholesalers) and the official exchange rate,[277] and the prices for India and USA for which comparable data is available. The results reveal that, if one assumes an official exchange rate, the price of a dual therapy and triple therapy is about 5.45 times less compared to the black market rate price which most of the imported antiretroviral drugs are purchased at by wholesalers. It is also evident that, at the official rate the prices in Zimbabwe would be about 4.9 times less than those in the USA and only about 2.4 times higher than those in India. This shows that consumers could save quite substantial amount if the official exchange rate were to prevail in the country.

Although the above results are not 100% reliable the black market rate in Zimbabwe has a huge impact on the current prevailing drug prices in Zimbabwe. The black market exchange rate implies that imported drugs become more expensive than otherwise if an official exchange rate prevailed. This is later translated into higher domestic prices, in other words imported inflation is the end result. However, as noted earlier these results should be interpreted with caution taking into account that it is difficult to tell whether the final prices reflect the effect of the black market exchange rate or not. There is need for further investigation with regard to exchange rates, which is beyond the scope of this dissertation.

The local industry's key players argue that multinationals should try and assess those local firms who have the capacity to produce antiretroviral drugs and give them voluntary licenses without having to be approached first. This would greatly reduce the costs of antiretroviral drugs because of local generic manufacturing. Wholesalers require 100% foreign currency to import fully finished products. However, if there is local production they will be some local component. It follows that the availability of such drugs

[277] Official rate is US $1:ZW $55 An black market rate is US $1:ZW $300

would improve if compulsory licences were issued because the government/wholesalers would not require 100% foreign currency to purchase locally produced generics. Foreign currency would only be needed to import raw materials rather than the whole finished product of which foreign costs would be built in. Certain production costs (e.g. labour costs) in developed countries are much more expensive than domestic equivalents. The Zimbabwean government has agreed to make available foreign at official market rates to manufacturers who win tender bids in order to buy raw materials for drugs that would be sold in the public sector. However when producing for the private sector or buying for the private sector wholesalers and manufacturers have to go out and source for foreign currency at black market rates. The production of cheaper generics would act as an incentive for the government to finance antiretroviral drugs and include them on the essential list. Accordingly, foreign currency would be made available to local manufacturers to buy the raw materials at official rates. This would further reduce the prices of drugs by a substantial amount.[278]

6.8 Sensitivity Analysis Assuming Parallel Importation (Public And Private Sector)

Parallel importation is based on the principle of exhaustion of rights; it allows cross border trade in a patented product or its generics without the manufacturer's permission. This is only possible when parallel importation has been implemented into a country's national law. Parallel imports allow countries to import brand name products or their generic equivalents from countries where the patent holder or licensee sells them at a lower price.[279] Parallel importation is not yet allowed since the bill has not yet become law. Therefore the impact of parallel importation can only be estimated by means of a sensitivity analysis, assuming that parallel importation was allowed from India. It is important to note that these results are only estimates and caution should be taken when interpreting them.

Table 14 below shows the prices of two combination therapies in Zimbabwe, India and USA. There are three different prices shown for Zimbabwe. The first price column shows the final average price in the public sector assuming parallel importation from India using the official rate. An official exchange rate is used here because Natpharm gets its foreign currency at the official rate from the government when they import drugs. The second column shows the price in the public sector assuming a black market exchange rate since private wholesalers have to source for their own foreign currency at unofficial rates. The third price column shows the prevailing average prices in the private sector. In addition, the final prices assuming parallel importation were estimated as follows:

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[278] Pharmaceutical Manufacturers (2002)
[279] Pérez-Casas (2000)

Firstly the prices of antiretroviral drugs offered in the public sector in India were taken as given in the table. Secondly, all the taxes, and mark-ups at wholesale and retail level plus the dispensing fees as per table 9 above were added on to the prices. Import duties were not added since all antiretroviral drugs are exempted from import duties.

Table 14: Sensitivity analysis assuming parallel importation in Zimbabwe

Treatment	Daily dose	Year's supply (365)	Final retail prices in the public sector (Zimbabwe)	Final retail prices in the private sector (Zimbabwe)	Prices without parallel importation (Zimbabwe)	India	USA
Combivir (450)	2	730	$ 592.06	$ 3,231.23	$13,515.95	$ 371.13	$ 5,153.80
Triple therapy combination							
Videx (100mg)	4	1460	$ 845.91	$ 4,615.88	$ 4,644.27	$ 530.26	$ 2,657.20
Zerit (40mg)	2	730	$ 105.74	$ 578.58	$ 996.31	$ 66.26	$ 3,540.50
Viramune (200mg)	2	730	$ 422.96	$ 2,308.85	$ 4,801.19	$ 265.13	$ 3,102.50
Total	8	2920	$ 1,374.61	$ 7,499.67	$10,441.77	$ 861.67	$ 9,300.20

Source: average drug prices survey in Zimbabwe, Pérez-Casas (2000) *HIV/AIDS Medicines Pricing Report and http://www.cipladoc.com/publications/aidswatch/aidsupdate.htm#newprices*

It is evident from the table above that Combivir would be 23 times cheaper in the public sector and about 4 times less expensive in the private sector than the current prevailing price. The triple therapy combination is estimated to be 659% less expensive in the private sector and 39% cheaper in the private sector compared to the current prevailing price of $10 442. A cross-country comparison shows that, with a parallel importation, Zimbabwe could actually achieve prices that are about 6.8 times lower in the public sector and 28% lower in the private sector than those offered in the USA. With parallel importation the prices in the public sector for triple therapy are only 1.5 times higher in the public sector and 8.7 times more in private sector than in India. However, there are 12 times more expensive in the private sector without parallel importation.

These results reveal that consumers could buy drugs that are approximately 10.5 times less expensive in the public sector and 3.3 times less expensive in the private sector than the current prevailing prices in the private sector. Parallel importation from India could reduce the costs of drugs from $10, 442 to $1,375 per patient per year if these drugs were made available in public sector and to about $7, 500 per patient per year in the private sector. On the other hand, even with parallel a farm worker will still have to work an equivalent of about 2 years in order to afford the triple therapy in the public sector and a manufacturing worker would have to work an equivalent of about 6 months to be able to afford the therapy if it were purchased.

These findings show that parallel importation will go a long way in reducing the costs of drugs in both the public and the private sector. However, even with parallel importation, the prices will still not be low enough for average workers in the country. Nonetheless parallel importation will at least give incentive to the government to include these drugs on the essential list. This in its self would make a difference since government stores would be able to procure these drugs through competitive tendering. The government can offer tender bids to countries like Thailand, India and Brazil that are currently producing these generic drugs. These manufacturers would have to actively compete for the bids, which could result in further reduction in prices. Moreover, the government would get substantial discount as a result of bulk procurement.

Even so, the implication of the above for the government is that, there is need for substantial, sustainable and adequate financing for medicines. This would enable the government to subsidise drugs procured through parallel importation to average consumers since they will still not be able to afford them if there is no financing mechanism in place to help subsidise the drugs. There is need to review the health budget and reallocate financial resources. The government should then seek to obtain voluntary licences so that local or foreign generic producers can supply life saving drugs as this would help bring prices down. In instances where voluntary licenses cannot be obtained then compulsory licenses could be issued. Furthermore international organisations should actively support the country's efforts to improve access to affordable life saving drugs.[280]

[280] Pérez-Casas (2000)

7 Chapter seven: Conclusion and Recommendations

7.1 Introduction

This study aimed at establishing the impact of key supply side and demand side factors on final end user prices of drugs that are used to treat AIDS/HIV and related opportunistic infections. Further more the study aimed at establishing the implications of the final consumer prices of antiretroviral drugs on access to affordable life saving medicines for the majority of the population in Zimbabwe. This section will give a summary and overview of the key research findings. The key findings are presented in relation to the objectives outlined in chapter one. The most important policy recommendations that arise are summarised. Furthermore areas that need further research, investigations and undertakings of analysis are identified.

7.2 Summary of Key Findings

1. **Map out and summarise how the pharmaceutical sector in Zimbabwe functions and operates and to review the current national pharmaceutical legislation and assess how the TRIPs agreement is implemented into the law system.**

Chapter 5 reviews how the pharmaceutical sector in Zimbabwe functions and operates. It is evident that the pharmaceutical industry in Zimbabwe is solely a generic manufacturing industry and therefore relies on imminent patent expiry for the production of new generic drugs. The local industry supplies about 60% of local consumption and 40% is meet through importation. The total annual consumption is estimated to be between US$45-50 million. There are about seven local manufacturers and several private pharmacies and wholesalers. There is also a government wholesale, Natpharm, which procures all drugs for all government medical institutions and some mission hospitals. The procurement of medicines in the country is guided by the national drug policy. The policy aims to ensure that only safe, effective and cheap drugs procured and are accessed by those who need them.

All medical premises have to be registered with the MCAZ. The MCAZ is the regulatory authority responsible for approval, licensing and registration of drugs. Medicines can only be approved if they meet the safety, quality and effectiveness standards of the board. Furthermore only drugs that are registered can be imported, manufactured and marketed in the country.

Even prior to signing the TRIPs agreement, the country had always been observing all patent laws. However, the patents bill is still being revised in order to make it TRIPs compliant. The amendment will make sure that all the necessary and suitable provisions are provided for to ensure that all the life saving drugs are available to those who need them. The main provisions to be included are parallel importation, compulsory licensing and the 'Bolar provision'. However, the government has failed to involve all the key players in implementing the bill and some key players are still in the dark with regard to the impact of TRIPs on public health. It was felt that the industry could have benefited more if the government had not rushed into signing the agreement. There are also certain lobby groups that are against parallel importation on grounds that it would be unfair, since the importing companies who will parallel import need not incur registration and retention fee costs. On the whole it was felt that if the TRIPs provisions are used effectively, they could increase access to affordable drugs, there by improving the health status of the majority of the population.

There is no formal or direct price regulation in the country. Nevertheless, the government has certain polices and indirect methods in place to try and curb the escalating drug prices. This mainly includes the drug tendering system used in the procurement of medicines for the public sector. Furthermore the essential drug policy, generic prescribing, drug donation, control of duties and mark ups and employment of certain drug financing mechanisms are some of the tools that the government employs to control the prices of medicines. Yet, it is evident that it is difficult to employ these tools to control the prices of patented medicines since none of the antiretroviral drugs appear on the EDLIZ.

2. **Identify and quantify the most important drugs used to treat HIV/AIDS and related opportunistic infections that are registered and marketed in Zimbabwe and review the patent status of these drugs.**

With regard to the above, at least 22 Dosage forms in total were identified for the treatment of opportunistic infections. Furthermore, 13 dosage forms of antiretroviral drugs were identified. These drugs are registered with MCAZ and are marketed and distributed in Zimbabwe. These medicines were available both at wholesale and retail level during the time the data was collected. The results of the findings are summarised in table 3 and 4.

Table 3 gives a summary of the most commonly used drugs used to treat of HIV/AIDS related illnesses. It is evident that most of the drugs used in the country to treat opportunistic infections are generics. At least

fifteen of the drugs are generics, Amphotericin B is branded but it is now off patent and Itraconazole, Fluconazole, Klacid and Doxorubicin are still patented.

Table 4 provides the most commonly used drugs to treat HIV/AIDS in Zimbabwe. It is clear that all the antiretroviral drugs that are registered and marketed in Zimbabwe are still patented. Additionally, there are no generic antiretroviral drugs marketed in the country because the country observes strong patent laws. Therefore, generic importation of antiretroviral drugs was not permitted at the time this research was undertaken. Accordingly, this in itself would have a great impact on end user prices in the country.

3. **Conduct an analysis of the main factors affecting drug pricing in Zimbabwe in order to accurately assess and document how these elements (generic competition, drug patenting, exchange rates, parallel importation, mark-ups, duties, taxes and competitive tendering) have influenced the end user prices of AIDS and related opportunistic infections drugs in Zimbabwe.**

Chapter 6 presents an analysis of the results and discussion of the impact of generic competition, drug patenting, duties, taxes, mark-ups and competitive tendering. In addition two sensitivity analyses are conducted, the first one estimates how black market exchange rates may have influenced the results and findings. A sensitivity analysis of the potential impact of the presence parallel importation on prices is also assessed.

The impact of patents on drug prices is assessed using price comparisons. The analysis showed that retail prices for generics and patented drugs do not vary widely. Nevertheless, the retail prices of generics show a much wider variation in the range of retail prices relative to retail prices of the patented brand drugs for both antiretroviral and opportunistic infections drugs. Additionally, there are less than five therapeutic alternatives for most generic drugs, which could explain the relatively smaller variation in retail prices of generic drugs in contrast to variations found in other studies. It follows that patented drugs enjoy monopoly power and there is very little price difference among pharmacies. To some extent, there are also monopoly markets for generic drugs in Zimbabwe because of fewer therapeutic alternatives for opportunistic infections drugs.

The results present further evidence that support earlier findings (from other studies) that patented drugs tend to be more expensive than generic drugs. Moreover patents (where they are observed) lead to higher prices because of the degree monopoly they enjoy. Off patented drugs are less expensive than thosethat are still under patent even though maybe they are faced with little competition.

A comparison between patented antiretroviral drugs in Zimbabwe and their generic equivalent sold in India reveals that generics are up to 80 times cheaper in India relative to their patented equivalents in Zimbabwe. Drug patenting in Zimbabwe has substantial impact on prices. Monopoly markets are bound to thrive in the absence of competition. Lack of generic competition will allow multinational companies to keep up high prices for as long as possible. As a guiding principle, multinationals seem to set an upper limit (in fixing prices) according to what the market can bear. If the international community continues to prioritise patent law protection over public health then the people in Zimbabwe will continue to die of the disease in large numbers.

On the other hand drug patenting is not always a bad thing. Patents are necessary since they encourage research-based companies to invest in R&D and innovations of newer drugs. Research based companies need to be rewarded for undertaking R&D since R&D requires enormous investment and involves risk. Absence of IPR protection, in particular patent protection, can lead to under investment in R&D of newer drugs. It would also be unfair to allow generic producers to make profits from generic production of on-patent drugs at the expense of research-based companies this is because generic manufacturers do not really engage in much R&D, which involve enormous risk and requires huge capital investments. The fact that generic manufacturers do not cover all the R&D costs allows them to price their drugs equal to marginal cost and still make a profit. Therefore there is need to strike a balance, generic manufacturers can compensate multinational companies through payments of royalties. Indeed multinationals should realise that developing countries constitute a small percentage of total global sales. Therefore, if generic production of patented drugs were to be allowed coupled with royalty payments, then the profits of research based companies are less likely to be hurt significantly as long as there is a mechanism in place to prevent spillovers of these generics back into industrialised countries.

It follows that there is need to balance commercial interest of patentees and the development needs of poorer countries like Zimbabwe. The results from the price comparison have shown that availability of generics result in lower prices for generic antiretroviral drugs. Consequently presence of generic copies in Zimbabwe could see the prices of antiretroviral drugs falling substantially.

Duties, mark-ups and taxes contribute around 51% to the final price of antiretroviral drugs and about 100% to the final price opportunistic infection medicines. The presence of duties, taxes and mark-ups at wholesale and retail level could even double the price between manufacturers and consumers. The total contribution of distributional costs, taxes and tariffs to final price is quite substantial in Zimbabwe compared to that of

Kenya. In Zimbabwe, institutions put different mark-ups and are free to set profit levels they want. Such high mark-ups and taxes can make it difficult to carry out cross-country comparisons with high precision.

Additionally, there are certain trade offs associated with policies that aim to reduce prices through reduction in taxes and those that aim to curb drug prices by regulating mark-ups at wholesale and retail level. Hence, the government should evaluate associated impact on utilisation and government revenue losses through reduction in taxes and tariffs against under-investment by retailers and wholesalers as a result of reductions in mark-ups and dispensing fees.

The impact of competitive tendering is shown by comparing the prices of selected generics for HIV/AIDS related illnesses in the private sector to those in the public sector. It was shown that the prices in the public sector could be up to 1034% cheaper than those in the private sector at wholesale level and up to 172 times less expensive in the public sector than in the private sector at retail level. The analysis reveals the importance of competitive tendering in the country. Competitive tendering ensures that the government gets the best price for their drugs. Hence, in the presence of parallel importation and compulsory licenses, lower prices for antiretroviral drugs can also be achieved in the public sector through competitive tendering. This would put less strain on the already scarce financial resources in the health sector. However, positive results to the benefit of the whole population at large can only materialise if there are policies in place to rectify government failure. Public provision in the presence of government failure could result in less optimal outcomes. Therefore a Pareto improvement outcome could sometimes be achieved by combining both public and private provision.

Although both sensitivity analyses that were conducted are not without their faults, there were able to show that the results that were obtained earlier are not insensitive to a different exchange rate and the presence of parallel importation. A sensitivity analysis assuming an official exchange rate showed that the prices of combination therapies are 5.45 times less compared prices of drugs imported at the prevailing black market rate. It is also evident that at the official rate the prices in Zimbabwe are assumed to be 4.9 times less than those in the USA and about only 2.4 times higher than those in India. Consequently consumers in Zimbabwe could be paying up to 445% more for combination therapies under the prevailing black market rate relative to the official market rate.

However, these results should be interpreted with caution, nonetheless they are consistent with economic theory, the presence of an unofficial exchange rate implies expensive imports, which can be translated into higher domestic prices. The implication of this is that in the presence of parallel market exchange rates,

prices can be lowered through generic local production since only raw materials will be imported instead of importing the whole finished product. This is so because 100% foreign currency would not be required to purchase locally produced generics. Foreign currency will only be required for raw materials. Moreover foreign currency would be made available at official market rates to manufacturers who win tenders, in order to buy raw materials for drugs that would be sold in the public sector.

In the presence of parallel importation of legal generics of on-patent drugs, the results estimate prices of 659% less in the public sector and a 39% reduction in prices in the private sector for a year's triple therapy than the current prices. A cross-country comparison illustrates that prices of about 6.8 times lower in the public sector and 28% lower in the private sector than those offered in the USA are possible with parallel importation. The price of a triple therapy will only be approximately 1.5 times higher in the public sector and about 8.7 times higher in the private sector than in India. The results estimate a possible 10.5 fold reduction in price from the current private sector price for the public sector and 3.3 fold reduction in price in private sector for triple therapy. More importantly, although the presence of parallel importation will not result in total affordability, reduction in prices as a result of parallel importation will at least give incentive to the government to include these drugs on the essential list. Consequently, the drugs can be procured through tendering. On the other hand, this can only be achieved if government is able to provide substantial, sustainable and adequate financing for medicines.

4. **To compare prices of HIV/AIDS drugs in Zimbabwe with international prices and briefly assess and discuss the implications of the final consumer prices on access to affordable drugs used to treat HIV/AIDS.**

Chapter 6 also compares the prices of antiretroviral drugs in Zimbabwe with international prices for which comparable data is available and briefly looks at the implication of the final end users prices in Zimbabwe on access to affordable drugs. Of the drugs surveyed the retail prices of all antiretroviral drugs[281] were higher in Zimbabwe than in USA, Brazil, India and Uganda. This is besides the fact that Brazil and USA are much more developed and more affluent than Zimbabwe. The expected pattern of lower prices for lower-income countries is not evident here. This supports the idea that multinational companies target sales at local elites in developing countries and set their prices according to what the market can bear. As a result, these drugs are out of the reach of the majority of the population considering that they meet their drug costs through out-of-pocket payments. In contrast, for most individuals in the USA, costs of health services and medication are meet by prepaid private insurance or public health insurance.

[281] Expect for zerit which is more expensive in the USA

About 1,404 000 million HIV/AIDS patience need treatment every year and it would cost the Zimbabwean government about US $15 billion to provide the cheapest triple therapy treatment for these people. This amount is in excess of the current annual health budget. Essentially it costs the Brazilian public health system the same amount to treat 1,000 HIV/AIDS patients per year, as it would cost the Zimbabwean government to treat approximately 182 HIV/AIDS patients per year if the government tried to provide antiretroviral drugs. It would cost an average farm worker an equivalent of 15,8 years' salary and an equivalent of 4.8 years' salary for an average manufacturing worker if they were to purchase a year's triple therapy. This is in stark contrast with developed countries where a year's treatment for HIV infections costs an equivalent of four to six month's salary and a greater part of the costs of drugs is reimbursed. Additionally, as a result of the availability of cheaper generics, the Brazilian and Indian government were able to provide antiretroviral drugs to more than 80,000 citizens by the end of 1999 and this led to a more than 50% drop in AIDS-related mortality between 1996 and 1999.

In summary, this study has shown that patents, competitive tendering, availability of generics, taxes, duties, mark-ups, exchange rates and parallel importation have substantially impact on the prices of AIDS and related opportunistic infections drugs in Zimbabwe. Competitive tendering and availability of generics through parallel importation or local production could result in the reduction of drug prices by a substantial amount. This could pave way for the availability of affordable HIV/AIDS and related illnesses. On the other hand absence of generic competition (as a resulted of patents), high taxes, duties and mark-ups and unofficial market exchange rates have contributed substantially to high drug prices in the country. Thus, these drugs are out of the reach of the majority of the population and the government of Zimbabwe. Price should not be an obstacle to preventing affordable access to medicines. Excessive prices make it unfeasible for the government to finance such drugs since it would consume a considerable amount of the health budget. Exorbitant on-patent drug prices have also led to their exclusion from the essential list. Unaffordable medicines mean that public health cannot be protected, and the implications of failure to protect public health are devastating. On the other hand, the government should also act accordingly to try and come up with ways and means to improve on their financing mechanisms of the health system in the country.

7.3 Policy Recommendations in The Context of Key Findings

There are effective medicines that exist to treat AIDS/HIV and related illnesses that are responsible for the high mortality and morbidity rates in Zimbabwe. However, these medicines are out of the reach of the government and the majority of the population. This is as a result of many interrelated factors, of which high drug prices play a critical role as evidenced in this study. Efforts to alleviate the disease will be fruitless if there are no policies in place to counter act escalating drug prices. This thesis will offer some policy recommendations that arise from the study in order to help policy makers make informed decisions.

Patents are one way to encourage innovation for newer drugs and hence offer benefits to society. On the other hand they contribute substantially to high drug prices that are currently causing significant delays in provision of cheaper medication to treat AIDS/HIV and related illnesses. Thus a balance should be struck between commercial interest of the patent holders and the public good. Since the government is already signatory to the TRIPs agreement it should try at all cost to make its legislation TRIPs compliant. This would allow the government to declare a state of emergency so as to make use of compulsory licensing and parallel importation. As noted earlier, these two provisions would allow the flow of cheaper generics into the country instead of expensive on-patent drugs.

On the other hand for the benefits of the above provisions to be realised there are certain standards that the government should meet, otherwise evoking the provision would result in a mere waste of resources. There is need to prepare the health system for the implementation of such provisions.

Firstly, there is need to put an AIDS drug policy in place that would serve as a guiding principle. This policy is necessary in order to equip the health system with the necessary tools required for the successful implementation of the provisions. Among other things the AIDS policy should state clearly the specific combination therapies and other drugs that the government would import or issue compulsory licences for. It should also clearly state the manufacturers who are to produce these drugs locally if compulsory licences are to be issued. The choice of manufacturers should be based on the capability and expertise to produce and adequately meet local demand. The policy should also document the countries where the government would parallel import from and decide on how much to import and on how much to produced locally. The government also needs to document the prescribers, i.e. whether the drugs would be prescribed at all public hospitals or at specific hospitals. The staff at different hospitals also needs to be trained in order to familiarise themselves with the dosage forms and related prescribing methods. The financing mechanism should also be decided upon, i.e. decide on whether there is need to raise more revenue or to review and

reallocate the state budget in order to allocate more resources to the health sector. The policy should also include any potential donors. The policy should document the means and ways of distributing the drugs to the rural communities and other hospitals in remote areas.

Secondly, there is need to deal with current economic issues that may hinder the smooth running of such polices. For example the absence of foreign currency could act as an obstacle to importing cheaper drugs or produce them locally to meet local demand. The government should strive to coordinate its policies and come up with a holistic approach to solving the current economic crisis. This indicates the impact of the macro economic situation on the health sector.

It is wrong however to assume that such provisions alone will solve the problem of affordability. Medicines may still be unaffordable, but if the implementation of the provisions is well coordinated, it would act as a key element in encouraging domestic financing and competitive tendering. This would further facilitate and improve access to affordable drugs, and hence, provide a sustainable way to obtain cheaper drugs.

The government should also consider reviewing the budget so that more financial resources are allocated to health and diverted from other sectors such as defence. The present government should abstain from prioritising the needs of a few elites at the expense of the majority of the populations. The government should come up with new means and ways of mobilising financial resources so as to improve the financing system of the health sector. Such efforts should also be accompanied by support from international and local NGOs. In short, there is need for political commitment by the state, it should prioritise the needs of the people rather than continue to pursue polices that are self-serving at the expense of the majority of the population.

The country should also follow other countries like Uganda that have embarked on an accelerative access initiative policy. Yet, this initiative can only work in the presence of an AIDS drug policy. Furthermore the state should try and initiate regional bulk purchasing. For instance, negotiating with other members of the SADC countries so that they can to come together and parallel import from generic manufacturers in bulk. This bulk purchasing would result in substantial discounts from manufacturers since bulk purchasing or regional procurement creates high volume and high demand. This would help further curb the prices of antiretroviral and AIDS drugs not only in Zimbabwe but in other affected SADC countries This would increase rather than restrict the number of patients to be treated in the region as a whole. On the other hand external finance would be required to facilitate and encourage the purchase of drugs.

It was shown earlier that taxes and mark-ups do contribute substantially to the end user prices. However it was also noted that there are trade offs associated with targeting both mark-ups and taxes. These trade offs call for the government to come up with polices that encourage or act as incentives for pharmacies and wholesalers to reduce their mark-ups, for instance offering pharmacies and wholesales subsidies that are financed through taxes, so as to curb escalating drug prices. Also, the pharmacies and wholesalers should try and reach an agreement and set fixed mark-ups for expensive drugs like antiretroviral drugs that are vital for the survival of HIV patients.

The government should continue to make use of the tendering system even in the presence of parallel importation or compulsory licensing for the procurement of antiretroviral drugs. The tendering system would ensure that the government gets even lower prices on top of the reduction in prices resulting from the implementation of the provisions. However, there is need to make sure that the tendering system is not fraught with government failure for example corruption and red tape that may hinder the smooth running of the system. This could be done by constantly monitoring the system to ensure that government failure is minimised. It is important to ensure that essential antiretroviral drugs are included on the essential list so that they can be procured through the tendering system.

The issue of direct price controls should also be looked at, however price controls require enormous information and evaluation of the side effects of such controls. These should be weighed against the benefits of price controls. Furthermore lack of expertise to actually initiate price controls should be addressed by offering the necessary training to authorities responsible and by seeking advise from other countries that implement such controls.

Moreover, since there is no cure for aids and the prices of drugs are souring, traditional medicines are increasingly becoming important in the treatment of HIV related diseases in Zimbabwe. There are many approved traditional preparations on the market in Zimbabwe, so the prices of these preparations should have a profound effect on the treatment of AIDS and opportunistic infections. Hence, the government should try and work hand in hand with Zimbabwe Traditional Healers Association (ZINATHA) by allowing them to test their medicines in labs and help them prescribe their medicines in correct dosage forms. The international community should also come into play by providing funding so as to encourage R&D into traditional medicines.

Developed countries should work hand in hand with the country. They should refrain from threatening developing countries with trade sanctions if they make use of the provisions. For example the US has been

known to use threats at developing countries that have tried to make use of these provisions.[282] There is also need to review the restrictions that come with the provisions; for instance, compulsory licensing should only be predominantly for local production. This implies that generic manufacturers in countries like Brazil and India can only export smaller amounts to Zimbabwe. Moreover these countries are in constant fear of trade sanctions from developed countries. Therefore the TRIPs should be amended so as to allow exports to certain developing countries in real need (like Zimbabwe) that have high AIDS rates. Slow response to the crisis at hand would continue if impediments associated with the provisions are not dealt with.

Technological transfer is also necessary if the country is to issue compulsory licenses. Newer drugs cannot be produced efficiently using outdated technology. Therefore, the state should initiate technological transfer by sending delegates to countries like India for training and also invest in new machinery needed to produce the drugs. This would encourage and facilitate the production of quality generics.

Price discrimination is a potential policy that multinational companies could consider introducing that may result in lower prices compared to the profit maximising price strategies that most multinational companies use. Multinationals could sell their drugs at a lower price in poorer countries with high price elasticises relative to high-income countries. Price discrimination has potential in the presence of mechanisms that prevent flow backs of drugs into high-income countries. However price discrimination has to be systematic and should only be allowed so as to benefit poorer countries.

Finally there is need for an international database that shows different prices in different countries. This is because drug price information is very scant universally, thus it should be collect and made accessible to developing countries. This would reinforce the effectiveness of parallel importation since the database would enable the government of Zimbabwe to make informed decisions as to where they should parallel import. It could also help them decided as to whether it is cheaper for them to manufacture locally or to parallel import from other countries.

To sum up, the above policies should not be implemented in isolation because no one policy would solve the problem of high drug prices if implemented in isolation. There is need for a holistic approach that is comprehensive where mutually supportive strategies are implemented concurrently.

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[282] Oxfam (2001)

7.4 Suggested Recommendations for Future Research

It is evident that the results and key findings were affected by the timing of the research. The research was conducted at a time when the country was experiencing an economic recession and going through an economic crisis. The same study should be undertaken in future when the economic crisis has passed. It would be interesting to compare the results and evaluate how much the crisis influenced the above results and findings. Furthermore, it is too early to assess the impact of the TRIPs agreement in particular the effect of employing the provisions on drug prices. Therefore, future studies should try and assess whether the potential positive impacts on prices as a result of making use of the provisions would actually materialise.

There also is need to develop economic models for predicting or determining the effects of international agreements like TRIPs on pharmaceutical prices. Economic models should also be developed to test for robustness of results. The results from this study combined with results from economic models to be developed in future could be used to develop and test hypothesises in more advanced studies. There is need to carry out price surveys in Zimbabwe so that researchers can have access to reliable data on pharmaceutical prices and utilisation rates.

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9 Appendices

9.1 Appendix 1: Drug Price Survey

Table a: Opportunistic infections Drugs

	Medix, A	Medix, P	Greenwood	Avondale	9 Plaza	Borrowdale	Pastol	shamrock	QV	lowest	highest	ratio of lowest to highest	Median
Mark-up	25%	25%	10%		10%	10%	20%	15%	10%				
Acyclovir (30*200mg)							$27.73	$39.45		$27.73	$39.45	1.42	$ 33.59
Cotrimoxazole (1000*480mg)	$80.75	$28.91	$78.25		$78.93	$49.55	$66.80	$53.16	$62.73	$28.91	$80.75	2.79	$ 64.76
Indomethacin (1000*25mg)	$177.40	$92.15			$103.36	$86.40	$80.93	$109.16	$88.18	$80.93	$177.40	2.19	$ 92.15
Ketaconazole (100*200mg)	$124.24	$113.09			$115.13	$111.73	$111.73	$124.64	$123.25	$111.73	$124.64	1.12	$ 115.13
Metronidazole (1000*200mg)		$94.85			$102.73	$60.38	$99.18	$80.65	$99.09	$80.38	$102.73	1.70	$ 96.97
Miconazole (varg. Cream 40g)					$20.25		$23.20	$23.64	$21.82	$20.25	$23.64	1.17	$ 22.51
Miconazole (oral gel 40g)	$32.62				$28.36		$28.05	$30.91	$29.09	$28.05	$32.62	1.16	$ 29.09
Miconazole (cream 20g)		$8.75			$3.38	$3.96	$6.22	$7.64	$7.27	$3.38	$8.75	2.59	$ 6.75
Amoxycillin (1000*250mg)				$388.15	$327.27	$262.84	$259.09	$276.36	$381.82	$259.09	$388.15	1.50	$ 301.82
Nystatin (15)		$21.53			$20.38		$20.38	$19.71		$19.71	$21.53	1.09	$ 20.38
Nystatin (oral suspension 30ml)					$27.93	$39.15	$41.22	$28.84	$48.18	$27.93	$48.18	1.73	$ 39.15
Fluconazole (14*50mg)	$376.82		$351.80		$375.00		$375.00	$313.64	$313.64	$313.64	$376.82	1.20	$ 363.40
Sporanox (15*100mg)						$331.36		$304.33	$313.64	$304.33	$331.36	1.09	$ 313.64
Vtamin B-complex (100*50mg)			$12.44			$10.95	$14.09		$11.27	$10.95	$14.09	1.29	$ 11.85
Predinisolone (1000* 5mg)		$145.60	$109.16		$120.29	$118.47	$84.09	$132.87	$120.00	$84.09	$145.60	1.73	$ 120.00
Codiane phosphate (100*30mg)	$134.18	$104.07	$46.35		$54.55		$119.96	$23.64		$23.64	$134.18	5.68	$ 79.31
Zithromax (3*500mg)	$278.62		$116.35			$122.73		$121.82		$116.35	$278.62	2.39	$ 122.27
Zithromax (6*250mg)		$49.24			$27.13					$27.13	$49.24	1.82	$ 38.18
amitripline (1000*25mg)			$167.25		$107.82	$107.65	$128.53	$104.18		$104.18	$167.25	1.61	$ 107.82
Ciacid (10*250mg)	$151.53	$155.18	$108.27			$124.20		$125.45	$118.18	$108.27	$155.18	1.43	$ 124.83
Doxorubicin (iv -3*150mg)			$1,680.71							$1,680.71	$1,680.71	1.00	$1,680.71
amphotericin B (vial)								$134.55	$109.09	$109.09	$134.55	1.23	$ 121.82

Table b: Antiretroviral Drugs

Drug	Medlx, A	Medlx, P	Greenwood	Avondale	Plaza	Borrowdale	Pastol	shamrock	QV	lowest	highest	ratio of lowest to highest	median
3tc (oral sln. 240ml)				$260.91						$260.91	$260.91	1.0	260.9
Epivir, 3tc (60*150mg)				$918.18	$932.91		$1,272.15			$918.18	$1,272.15	1.4	932.9
Retrovir (100*100mg)			$435.73	$694.78				$415.84		$415.84	$694.78	1.7	435.7
Retrovir (syrup 200ml)		$435.73		$260.91						$260.91	$435.73	1.7	348.3
Combivir (60*450)				$752.73	$945.45	$972.40		$1,365.45	$1,655.11	$752.73	$1,655.11	2.2	972.4
Hivid (100)							$999.58			$999.58	$999.58	1.0	999.6
Invarise (270*200mg)					$1,490.76		$1,757.13		$721.51	$721.51	$1,757.13	2.4	1490.8
Viracept (270*250mg)				$2,483.64	$545.45	$2,599.80	$3,545.16	$1,640.00		$545.45	$3,545.16	6.5	2483.6
Videx (60*100mg)	$210.25	$210.25	$210.25	$168.18	$163.64	$149.84	$214.15	$256.93	$184.98	$149.84	$256.93	1.7	210.3
Zerit (60*30mg/40mg)	$89.40	$83.15	$83.15	$63.82	$71.96			$95.02	$89.16	$63.82	$95.02	1.5	83.1
Crixivan (180*400mg)	$494.95	$570.62	$570.62	$472.91	$443.53	$424.51		$443.98	$827.15	$424.51	$827.15	1.9	483.9
Viramune (60*200mg)				$377.27	$410.18	$335.45		$517.18	$372.64	$335.45	$517.18	1.5	377.3
Hydrea (100*500mg)					$195.55			$160.69	$164.55	$160.69	$195.55	1.2	164.5

Table c: Zimbabwe VS India

drug	India (generic equivalents)	Price (Zimbabwe)	Price (India)	Ratio of lowest to highest
3tc	Lamivir	$ 1,041.08	$ 13.07	80
Retrovir	Zidovir	$ 503.38	$ 14.28	35
Combivir	Duovir	$ 1,110.90	$ 30.50	36
Videx	Dinex	$ 190.86	$ 21.79	9
Zerit	Stavudine	$ 81.89	$ 5.45	15
Crixivan	Indivan	$ 507.58	$ 131.73	4
Viramune	Nevimune	$ 394.62	$ 21.79	18

Source for prices in India: http://www.cipladoc.com/publications/aidswatch/aidsupdate.htm#newprices

Table d: Cross Country comparisons

	USA	Brazil	Uganda
Epivir, 3tc (1*150mg)	4.33	0.3	1.6
Retrovir (1*100mg)	0.91	0.1	0.7
Combivir (1*450)	7.06	0.7	3.7
Videx (1*100mg)	1.82	0.5	1.3
Zerit (1*30mg/40mg)	4.85	0.3	3.1
viracept (1*250mg)	2.16	1.36	
Viramune (1*200mg)	4.25	1.3	4.7

Source: Carmen Pérez-Casas (2000) HIV/AIDS medicines pricing report.
Setting objectives: is there a political will? And

The above table shows the price of 1 capsule. These were the base prices used for calculating the prices of combination therapies.

Table e: Private VS Public sector Prices

Wholesale level			
drug	private sector	public sector	ratio
Acyclovir	$ 28.18	$ 3.85	631%
Cotrimoxazole	$ 92.39	$ 8.15	1034%
Indomethacin	$ 66.91	$ 0.67	9846%
Metronidazole	$ 57.62	$ 0.71	8026%
Miconazole -varg. Cream	$ 14.98	$ 1.02	1371%
Miconazole oral gel	$ 17.82	$ 3.80	369%
Prednisolone	$ 68.64	$ 14.64	369%
Retail level			
Drug	private sector	public sector	ratio
Indomethacin	$ 105.37	$ 77.16	37%
Metronidazole	$ 89.48	$ 84.25	6%
Miconazole-varg. Cream	$ 22.26	$ 0.13	17143%
Miconazole cream	$ 6.23	$ 0.18	3325%
Prednisolone	$ 118.64	$ 134.36	13%

Source: drug price surveys in Zimbabwe

9.5 Appendix 2: Structured questions for the key informants at the ministry of health

- Can u give any details of government negotiated voluntary licences with local and international companies?

- If yes

.5 Company	Drug

- Could describe the current measures or policies that are currently in place to promote generic competition?

- What is the country's position with regard to the accelerative initiative programme?

- What schemes exist for bilateral negotiations and bulk purchasing, in order to negotiate for low prices both at international, regional and local level?

- List the name of the countries and the manufactures

- Which pharmaceutical manufacturers are supplying these drugs to Zimbabwe at a discount or donating them?

Manufacturer	Drug

Capturing market structure and degree of competition

Branded name	Therapeutic alternatives	Locally produced (company)	Imported (company)

- What structures are currently in place within the legislation with regard to parallel importation?

- Comments: If there are no drugs that are being imported estimate the amount that the drug would have cost, if the government had bought these drugs where there are cheaper.

- Can you outline and elaborate any negotiations for meaningful price reductions that are already in place?

- Is there policy in place to ensure that the poor get these drugs at a cheaper price than the rich, and how does this policy work?

- Which of the drugs on the indicator are available both in the public sector and in the private sector? Record the price difference of these drugs both at wholesale and retail level?

Drug	Price in the public sector	Price in the private sector

- What is the current situation with regard to private insurance or social health insurance coverage of antiretroviral and opportunistic infections drugs?

- What is the main source of drug financing?

Social health insurance _____
Government funded _____
Out-of-pocket _____
Private health insurance_____

Comments:

1..1 Access to drugs

Data to be collected	Sources	Comments
DHS (household income, age, sex,)	DHS	
Aids cases and aids mortality	NAC	
Treatment rates	Ministry of health	

- No of aids cases to be treated

- How many cases have been treated/not treated

- Present access level

- The health sector
- Per capita heath spending
- Annual health budget as a percentage of the total health budget
- What are the national health priorities, and what polices are currently in place to help achieve them.
- What percentage of the health budget goes to the financing of drugs in general?
- What policy is in place with regard to the provision of antiretroviral drugs
- What percentage of the population has access to health insurance?
- Could you comment on external assistance by donors and donor-funded projects, and are these donations sustainable and what conditions do they come with.
- NB: All the questions above were supplemented by follow up questions to clarify certain issues.

9.5 Appendix 3: Structured Questions Informants at MCAZ for Key

- Has Zimbabwe already started implementing the TRIPS agreement?
- Yes_____ No_____
- If yes when was it first implemented? _____
- If no when will it be implemented? _____
- What provisions of the TRIPS agreement that are incorporated into the national legislation?
- What national priorities and policies does the proposed implementation take into account?
- What are the policy instruments that are outside the intellectual property rights that are used to address issues of access and prices of drugs, e.g. price or reimbursement controls.
- What are the TRIPS safeguards that are provided for under the agreement that the government has/will adopted/adopt and How are these safeguards being utilised or how will they be utilised?
- If no Compulsory licences have been issued, what are the main reasons for not issuing such licences?
- What are the grounds for issuing compulsory licences that are allowed by Zimbabwe's national legislation. (Tick the appropriate ones and add any additional below)
    - Public health reasons
    - Emergency situations
    - To remedy anti-competitive practices
    - To protect the environment
    - Public non-commercial use
- Can u describe in detail the current policy situation with regard to parallel importation of medicines? (Use follow up questions for elaborations)
- **Patent Laws**
- When was the Patent Law introduced in Zimbabwe?

- Does the Patent law provide for process patent or product patent or both? Describe in detail the scope of patentability

- Describe and outline in detail the current measures that the pharmaceutical regulatory authorities have put in place to monitor supply and prices of drugs?

- Does the patent law make provisions for parallel importation, Bolar-type provision and compulsory licence?

Patent status of drugs from the indicator list

Company	Drug	Patent status	Patent expiry

Comments

Document review

Data to be collected	Sources of data	Comments
Pharmaceutical price regulation laws (guidelines)	Medicines control authority of Zimbabwe.	Document review, NB: price controls with regard to antiretroviral and opportunistic infection drugs
Implementation of the TRIPS agreement into the law system (guidelines)	Same as above	Document review of established data
Drug patenting guidelines (laws and legislations)	Same as above	Review the guidelines to drug patenting
-Indicator list of antiretroviral drugs and opportunistic infection drugs that are registered and marketed in Zimbabwe -Obtain a list of these drugs that appear on the essential drug list	-National register for drugs-Drug control authority of Zimbabwe -Natpharm	Need to identify the most important drugs and draw up an indicator list. -Review the essential drug list and identify the antiretroviral and opportunistic infection drugs that appear on the list.

NB: All the questions above were supplemented by follow up questions to clarify certain issues.

9.5 Appendix 4: Structured questions for the key informants at Manufacturing Companies

- Could you give a brief introduction with regard to your company and the type of industry your operating in?
- What is the pharmaceutical consumption per capita?
- Could you provide information with regard to your sales volumes and production volume?
- What is your total market share for the domestic industry?
- What percentage of your total annual sales is from exports?
- Which countries are you currently exporting to?
- Briefly explain your interpretation of the TRIPs agreement
- How do you see the agreement affecting your day to day running of the business?
- What do you thing are the potential impacts of the agreement on foreign direct investment, transfer of technology, research and development for the local industry
- How are you going to make use of the TRIPs safeguards?
- Do you for see the introduction of new generics being slowed down by the agreement?

9.5 Appendix 5: Some background information on antiretroviral drugs

Source : *http://www.cipladoc.com/publications/aidswatch/aidsupdate.htm#newprices*

Classification of antiretroviral drugs

Nucleoside reverse transcriptase inhibitors (NRTIs)	Non-nucleoside reverse transcriptase inhibitors (NNRTIs)	Protease inhibitors (PIs)
Zidovudine	Nevirapine	Indinavir
Stavudine	Efavirenz	Nelfinavir
Lamivudine	Delavirdine	Ritonavir
Didanosine		Saquinavir
Zalcitabine		Amprenavir
Abacavir		Lopinavir

Triple drug antiretroviral combinations

- Lamivudine + Stavudine + Nevirapine (TRIOMUNE-30/40)
- Zidovudine + Lamivudine + Nevirapine (DUOVIR-N)
- Lamivudine + Stavudine (LAMIVIR-S 30/40) + Efavirenz (EFAVIR)
- Zidovudine + Lamivudine (DUOVIR) + Efavirenz (EFAVIR)
- Lamivudine + Stavudine (LAMIVIR-S 30/40) + Indinavir (INDIVAN)
- Zidovudine + Lamivudine (DUOVIR) + Indinavir (INDIVAN)
- Didanosine (DINEX) + Stavudine (STAVIR-40) + Nevirapine (NEVIMUNE)
- Didanosine (DINEX) + Stavudine (STAVIR-40) + Efavirenz (EFAVIR)
- Didanosine (DINEX) + Stavudine (STAVIR-40) + Indinavir (INDIVAN)

How long should the HIV-infected patient continue taking antiretrovirals?

It is important to appreciate that antiretroviral therapy should be continued indefinitely. This is because therapy is suppressive and not curative. The patient should be started on antiretrovirals only if he is committed to lifelong therapy.

Why can't HIV infection be eradicated?

HIV infects various cells and body compartments including the CNS, testes, etc. The virus remains latent in certain cells such as the long-lived resting memory CD4 cells. Antiretroviral therapy is not effective against these cells as they are not actively multiplying. Hence eradication of HIV is presently not considered to be a realistic goal.

Combination Therapy in HIV-infected Patients

With the explosion in the number of HIV-infected individuals and those with full blown AIDS, the management of HIV infections is of critical importance to every physician. New approaches to monitoring and treating patients have improved management. These include a better understanding of the replication kinetics of HIV throughout the disease process, the development of quantitative viral assays that help to predict the progression of the disease and the availability of new antiretroviral agents. Most importantly, there is now sufficient clinical data to prove that combination therapy with 3 drugs is far superior to mono or dual therapy and can suppress viral replication up to 2 years

Rationale of Combination Therapy

Currently, 11 antiretroviral agents are approved by various health authorities worldwide. None of these agents can eradicate the infection but given in combination they can suppress viral replication, improve immunologic status, delay infectious complications and prolong life. The high viral turnover rate and the error prone nature of the RNA virus replication make it mandatory for potent combinations to be used, and an approach that does not maximally suppress viral replication can lead to resistance and treatment failure Recent studies have shown that there are reservoirs of HIV such as the resting memory CD4 cells, cells in the brain etc., which harbour the virus for prolonged periods and make viral eradication difficult. Different drugs can target different cellular reservoirs and cells in different stages of activation. For example, zidovudine is more effective in replicating peripheral blood mononuclear cells, while lamivuudine, usually used in combination, is more effective in resting cells.

Reasons for Combination Therapy

1. Potent inhibition of viral replication
2. Prevention of emergence of resistant strains.
3. Sustained clinical improvement
4. Target different cellular reservoirs o H IV
5. Target cells in different stages of activation

Selection of Initial Antiretroviral Regimens

There is no single combination that is best for all patients. A regimen is usually chosen which is expected to durably reduce the plasma HIV RNA below the lowest limit of detection (as measured by sensitive assays) thereby preventing the development of resistance and providing sustained clinical benefit. Several clinical trials have examined various combinations. In addition to the above, the choice also depends on the following factors:

1. Tolerability profiles
2. Past clinical history e.g. history of peripheral neuropathy or pancreatitis.
3. Potential of a given agent or regimen to limit future therapeutic options or activity due to selection of cross-resistant or multi-drug resistant mutants.
4. Pharmacokinetic and metabolic interactions e.g. liver enzyme system, inductor or inhibitor, intracellular interactions etc.
5. Activity in different cell lines.
6. Convenience of administration.
7. Administration of antiretroviral therapy in the past.

Most combinations recommended include a combination of two nucleoside reverse transcriptase inhibitors (NRTIs) with a protease inhibitor (PI) or non-nucleoside reverse transcriptase inhibitor (NNRTI). Others include 2PIs plus 1 or 2NRTIs, 1 PI and 1 NNRTI with or without 2 NRTIs and 3 NRTIs.

These regimens result in virologic success rates from 60% to 90% as judged by reduction of plasma HIV RNA to less than 500 copies/ml at 24 weeks or beyond. It is difficult to say if one combination is superior to another. The combination of zidovudine, lamivudine and indinavir (Figs. 1 & 2) is synergistic and has been shown to significantly reduce plasma viral load for up to 1 year and is superior to dual therapy. If zidovudine is not suitable then stavudine with lamivudine (or didanosine) and a PI or NNRTI is a good option. Saquinavir or nelfinavir may be useful for initial regimens since neither causes cross-resistance that would preclude subsequent use of other PIs.