Protecting access to Anti-Retroviral Therapy (ART) under trade and market policies: The Zimbawean case

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Through institutions in the region, EQUINET has been involved since 2000 in a range of capacity building activities, from formal modular training in masters courses, specific skills courses, student grants and mentoring. The capacity building activities in EQUINET are integrated within the existing areas of work of the network or build cross cutting skills demanded across themes by institutions in the network. The papers and reports produced in these training activities are products that are used to support or target mentoring. This report has been produced within one of these capacity and skills building activities and is disseminated in this context.

Executive summary

This audit was done after a regional training workshop on “Protecting Health in Trade Agreements” held in Harare Zimbabwe in August 2005 within an EQUINET programme with Centre for Health Policy, South Africa and SEATINI and TARSC, Zimbabwe.

The audit aims to present to government, policy makers, technocrats and other stakeholders in the health sector and civil society specific aspects of how trade agreements such as General Agreement on Trade in Services (GATS) and Trade Related Aspects of Intellectual Property (TRIPS) are impacting on, or are likely to impact on health systems and the exercise of national health policy.

It specifically examines access to ART in Zimbabwe and how Zimbabwe can protect rights of access to Anti-Retroviral Therapy (ART) under such international trade and market policies. The paper explores:

- What are the national health policy objectives on access to medicines?
- How will trade agreements affect access to medicines?
- How will these effects relate to national policy objectives?
- What reforms are currently taking place on access to medicines?
- How do these reforms relate to the national policy objectives?
- Where are the reforms coming from and why?
- What options exist to promote national policy objectives for access to medicines?

In addressing the issues the paper sought to identify where policy on access to medicines is generated, the actors/institutions involved in access to medicines, their position on national policy and trade pressures, and their policy influence. The study used the evidence to suggest measures to protect national policy objectives on access to Anti-Retroviral Therapy (ART) in trade agreements and in reforms.

The audit highlighted various strengths and weaknesses in the current legal and institutional arrangements for ART, particularly in relation to national policy goals and needs outlined. As a result of its health profile we suggest that Zimbabwe prioritise measures to ensure access to healthcare and apply patent rules in ways that protect public health. Public health, particularly pharmaceuticals, should receive special attention in implementing the TRIPS Agreement at a national level.

The TRIPS Agreement has left room for flexibility at the national level that we suggest government exploit, particularly in terms of:

- existing legislation on parallel importation of pharmaceuticals;
- ensuring equitable use of available resources to promote coverage and access to essential medicines; and
- choosing approaches to compulsory licensing that provide incentives for the production and export of essential medicines.

There is also a clear need for all stakeholders, including trade and health ministry officials, parliamentarians, civil society and the public, to be sensitised about the links between trade and health, to ensure that as a country we do not sign away our right to health in the pursuance of economic gain in the global market.

1. Background

This study was implemented after a regional workshop, “Protecting Health in Trade Agreements” held in Harare Zimbabwe in August 2005 within an EQUINET programme with Centre for Health Policy, South Africa and SEATINI and TARSC, Zimbabwe. The main objective of the workshop was to build capacities in state, legislative and civil society institutions to know, understand, analyze and promote public sector equity–oriented health systems within Trade and investment policies and agreements.

The stakeholder meeting pointed the group in the direction of the country level audit focus on access to ARVs under World Trade Organization (WTO) Trade agreements. The study was proposed as a follow up to the training to test and use the knowledge gained with mentorship from CHP and SEATINI. The study was carried out with generous support from SIDA Sweden and IDRC Canada through the Centre for Health Policy and SEATINI in EQUINET.

The audit aims to present to government, policy makers, technocrats and other stakeholders in the health sector and civil society specific aspects of how trade agreements such as General Agreement on Trade in Services (GATS) and Trade Related Aspects of Intellectual Property (TRIPS) are impacting on, or are likely to impact on health systems and the exercise of national health policy.

This audit specifically examines access to Anti-Retroviral Therapy (ART) in Zimbabwe and how Zimbabwe can protect rights of access to ART under such international trade and market policies. The study looked at how the health system would perform if market orientated reforms were implemented fully under the World Trade Organisation (WTO) and international agreements.

The focus of the paper is on:

- What are the national health policy objectives on access to medicines?
- How will trade agreements affect access to medicines?
- How will these effects relate to national policy objectives?
- What reforms are currently taking place on access to medicines?
- How do these reforms relate to the national policy objectives?
- Where are the reforms coming from and why?
- What options exist to promote national policy objectives for access to medicines?

In addressing the issues the paper sought to identify where policy on access to medicines is generated; and the actors/ institutions involved in access to medicines, their position on national policy and on trade pressures and their policy influence.

The study used the evidence to suggest measures to protect national policy objectives on access to ART in trade agreements and in reforms. It also attempted to proffer suggestions for: policy development on the actors most likely to promote measures protecting national policy objectives; and the proper policy processes to adopt in order to ensure rights of access to essential medicines.

2. Methods

A desk-based study was conducted to establish the ambit of government HIV/AIDS policy, government initiatives on ART access, and the impact of trade agreements on access to health care, including limitations imposed on the policy space and ability to regulate the health sector and ensure equitable access to health care particularly ART.

Interviews or/and focus group discussions (FGDs) were conducted with key persons and other staff in different institutions considered to be major stakeholders in the health sector, especially in areas concerning health care and ART delivery. A steering committee, set up to assist in producing this paper, formed the core of the focal group discussions on issues included in the study. Committee members were drawn from:

- Community Working Group on Health (CWGH)
- National Pharmaceutical Company (NPC)
- Zimbabwe Association of Church-Related Hospitals
- Parliament of Zimbabwe – Portfolio Committee on Health
- Institute of Development Studies, University of Zimbabwe (IDS)
- Medicines Control Authority of Zimbabwe.

Stakeholder interviews were drawn from:

- Ministry of Health and Child Welfare (MoHCW)
- Ministry of Industry and International Trade (MoIIT)
- National AIDS Council (NAC)
- Medicines Control Authority of Zimbabwe
- Health Professions Authority
- Parliament of Zimbabwe – Portfolio Committee on Health.

3. General country context

3.1 Economic trends

At independence in 1980, Zimbabwe inherited a dual economy, characterised by uneven development with relatively well-developed urban areas surrounded by poor communal areas. Under the colonial regime, black people were denied equal education and employment opportunities, and salaries for the same job differed with race. These policies introduced great inequalities and also perpetuated poverty among blacks.

After independence, influenced by the government's socialist ideology (led by the Zimbabwe African National Union – Patriotic Front (ZANU-PF) party), efforts were made to reverse the imprint of colonialism. One of the major challenges was redressing past inequalities by adopting welfarist policies. With a major objective of "growth with equity", accent was on education, health, rehabilitation of the war raged infrastructure, removing discriminatory laws, promoting the advancement of women, and the resettlement of the landless people. The government adopted redistributive policies, such as a minimum wage policy, expansion of access to education and healthcare, and land redistribution and resettlement, including heavy subsidies in agriculture, health and industry.

Post-independence, the government vigorously embarked upon a "command economy" characterised by heavy subsidies in agriculture, health and industry. Substantial

progress was achieved during the 1980s and tremendous strides were made in the social development sector. In the health sector in the first decade of independence hospitals and clinics were built - particularly in the rural areas, staff were trained and equipment was procured. Government adopted an essential drugs policy and expanded the prescription of generic drugs under this policy, thereby increasing access to medicines, particularly those required for priority public health conditions.

However, against a backdrop of a growing budget deficit and the threat of a stagnating economy, the government was forced to abandon its interventionist and redistributive policies, in favour of an orthodox Structural Adjustment Program (SAP), prescribed by the World Bank and International Monetary Fund (IMF). The SAP sought a fundamental shift from state intervention in the economy to one largely driven by market forces. In 1991, the government adopted the Economic Structural Adjustment Programme (ESAP). ESAP recommendations called for increased budget allocations to industry and reduced the per capita funding on education and health. The key policy elements incorporated in ESAP covered five principal categories of reforms:

- fiscal and monetary policy reforms, including budgetary and monetary stabilisation measures, the liberalisation and deregulation of banking and finance;
- trade liberalisation, including the abolition of quantitative controls and the reduction and harmonisation of tariffs and duties;
- deregulation of prices, wages, interest rates and exchange rates;
- public sector restructuring, entailing downsizing of the civil service and reorganisation and commercialisation of parastatals; and
- a social safety net in the form of Social Development Fund (SDF) for those vulnerable to the adverse effects of structural adjustment (Allen, 1999).

From 1993 to 1995, the country took considerable steps towards financial sector deregulation and trade liberalisation. However by 1997, the budget deficit remained high at 12,6% of the Gross Domestic Product (GDP). The GDP per capita began to fall and economic growth was slow. As exports dived, so did foreign currency reserves compared to the foreign debt. The net effects of these polices was a skyrocketing cost of living indicated by rising inflation, declining real wages, job losses leading to unprecedented levels of poverty and desperation. *Table 1* shows the declining trend in social and health indicators in Zimbabwe covering the period of ESAP and beyond.

Table 1: Trend of selected social and health indicators (1988-2003)

Social/ health Indicator	1988	1990	1995	2000	2002	2003
Population (millions)	9.2	9.7	11.5	11.6	11.6	11.87
Population growth rate %	3.1	2.5	-	2.5	1.1	-
HIV prevalence (15-49 years)	-	16.5	25.1	33.7	33.7	-
Life expectance at birth (years)	-	61	55	43	43	43
% Undernourished children under 5	-	12.7	16.9	13	-	-
Under five mortality rate (deaths per 1000)	-	59.9	76.9	102.1	-	-
Maternal Mortality rate (deaths per 1000)	-	283	350	695	-	-

Source: Ministry of Finance and Economic Development, 2003 cited in Poverty Reduction Forum 2003: 9.

The far-reaching recommendations of ESAP aimed to make the state an ‘umpire’ and limited its role as a service provider, in line with the concept of stewardship espoused by

the World Bank and IMF, with the state under pressure to 'steer and not row'. Regarding the health system, this means the government's role is facilitating and steering health care provision and financing in a context of public-private mix (Waddee et al, 2005).
In 1997, the government replaced ESAP with a home-grown reform program - the Zimbabwe Programme for Economic and Social Transformation (ZIMPREST) - which aimed to correct the shortcomings of ESAP, including the low growth rate, high budget deficit, declining tax revenues and increasing inflation. While the fundamental thrust of controls remains the pillar of the strategy, ZIMPREST placed great emphasis on social development. It envisaged a comprehensive restructuring of government to achieve an efficient delivery of key services and better facilitate economic empowerment, private sector development and job creation. Many of the policies outlined in ZIMPREST were designed to tackle poverty directly through, for example, land reform, indigenisation, direct poverty alleviation, fostering small-scale enterprises and a national AIDS strategy.

Subsequently, in 2001 the government adopted the Millennium Economic Recovery Program (MERP) to steer the country towards restoring economic stability by removing the fundamental causes of inflation, restoring macro-economic stability, creating an environment conducive to low interest rates, stabilising incomes and reducing the poverty of the masses. The major objectives of the programme were to:

- consolidate fiscal adjustment policies;
- accelerate and complete the public enterprise reforms;
- stabilise prices at lower levels;
- lower interests rates;
- stabilise the value of the Zimbabwe dollar and resolve the foreign currency crisis;
- deepen financial sector reforms;
- stimulate the growth of productive sectors and build confidence;
- protect vulnerable social groups; and
- establish implementation, accountability and monitoring institutions.

Given the lack of resources to implement these programs, coupled with the withdrawal of World Bank, IMF and other donor support, these programs did not achieve the desired results. In a bid to address these issues, the government introduced other economic policies and programmes such as the 2003 twelve-month stabilisation measures program, the National Economic Revival Program (NERP), while continuing to consider options for long-term economic recovery.

However, none of these programmes improved the country's economic situation. Zimbabwe is categorised as a developing country. However, its economic performance has deteriorated since the launch of ESAP in 1990, marked by a slowdown of economic growth. Zimbabwe's economy has been unstable in the past five years, with negative growth, a growing budget deficit, inability to service external debt, hyperinflation and high levels of unemployment. For example, from 1988 to 2003, CPI increased from 7% to 525.8% and real GDP growth rate fell from, 7.5% to -13.9% (see *Table 2*).

Table 2: Trend in economic indicators (1988-2003)

Economic indicator	1988	1990	1995	2000	2002	2003
Real GDP Growth rate %	7.5	7.0	0.2	-8.2	-14.5	-13.9
Per Capita Real GDP Growth	4.3	3.7	-1.3	-7.7	-14.7	-14.1
CPI Inflation (annual average)%	7.0	12.4	22.6	55.9	133.2	525.8
Net Foreign Direct Investment (US$ million)	-	-12	98	16	23	5
Domestic Debt (Z$ billion)	4.8	6.7	24.5	162.1	357.0	589.0
External payment arrears (US$ million)	-	-	290	471.1	1,460.0	1,682.0
Export growth (%)	17.0	15.2	14.4	-1.0	-11.8	-3.9

Source: Ministry of Finance and Economic Development, 2003 cited in Poverty Reduction Forum 2003: 9.

3.2 International trade policy context

Zimbabwe is a WTO member, and a member of other regional bodies and trade arrangements, including the African Union (AU), Southern African Development Community (SADC), the Common Market for East and Southern Africa (COMESA), and the Africa, Caribbean and Pacific group of countries (ACP) under the Cotonou Agreement with the European Union. In addition to the multilateral trading system, membership in regional trade groupings adds complexity to the goal of creating trade sensitive health policy.

Zimbabwe's major trading partners are southern African and other COMESA countries - particularly South Africa, the European Union and the United States of America. In the past year, Zimbabwe's top ten trading partners were South Africa, United Kingdom, China, Mozambique, Zambia, Germany and the United States of America. Japan, China and other Southeast Asian countries are also emerging as growing trade partners in line with the government's "look east" policy which encourages the diversification of export markets away from the traditional western countries such as the EU and USA.

Zimbabwe regulates international trade through the Ministry of Industry and International Trade. The process of negotiating international bilateral or multilateral trade agreements is spearheaded by the Department of International Trade. The ministry does undertakes relevant research, and national and inter-ministerial consultation, and chairs an inter-ministerial committee. Any negotiating position arrived at must be approved by Cabinet. International agreements may be signed by the president (as head of State), the relevant Minister, Permanent Secretary or any other designated official. Sectoral agreements, e.g. those covering health, education or defence, are signed by relevant ministry officials (Minister, Permanent Secretary or any other designated officials). In general, multilateral and bilateral agreements are signed by the foreign minister or head of state.

FGDs carried out for this audit revealed a public perception that policy makers (government ministries) do not consult widely enough before they undertake trade negotiations. The general public is not privy to deliberations of relevant cabinet and ministerial committees. A general need to widen the scope of public consultation and strengthen the quality of public participation was felt. A simple way to do this would be to give detailed notification of the issues to be discussed to enable meaningful preparation and participation

Parliament's role in relation to international agreements is at the stage of ratification. Before they can be part of Zimbabwean law, international agreements must be ratified by Parliament. Before ratification, agreements have to be scrutinised by the relevant Portfolio Committee. Stakeholder interviews reveal that in practice, there may be little attention to detail, little or no debate, or consultation at constituency level, prior to ratification, perhaps indicating limited understanding of the content of the agreements. This means that agreements can eventually get ratified by parliament with little understanding of the ramifications. Even Parliamentarians are, at times, not fully aware of the policy implications of these agreements.

The role of Parliament thus appears to be passive: MPs are not actively involved in the consultations; after ratification they simply play an oversight role of shadowing the particular ministry/department. Addressing any shortcomings is a mammoth task as it is difficult to renegotiate international agreements and in some instances the damage will already have been done.

3.3 Domestic legal context

During preparation of legislation and regulations, a consultative process enables the public to input into the law making process. This consultation is essential as it gives government an initial indication of whether the law will achieve its intended purpose. Parliamentary Committees afford the public a platform to influence laws. Once a bill is published in the Gazette it is referred to the relevant Portfolio Committee, which examines expenditure, administration and policy of government departments. Among other things, they consider and deal with all bills, statutory instruments, and all international treaties, conventions and agreements negotiated and entered into.

Members of the public are allowed to attend meetings of parliamentary committees. However, when the committee is deliberating no members of the public may be present. Parliamentary portfolio committees consult with the public primarily by inviting experts to give evidence. Further parliamentary debates are made available to the public. There is thus some room available for private persons or groups to influence trade and health policy and legislation. This provides an opportunity for civil society to influence how international trade agreements affect areas of health, such as access to ART, in particular and health in general. However, the complexity of trade and health policy can produce challenges, such as which portfolio committee is ultimately responsible for addressing the adverse impacts of trade policy on health.

In Zimbabwe there is also a constitutional provision for private sponsorship of the passage of laws in the country at various levels of government, provided the originator of a Bill sponsors it. However, the cost of the whole process from research to drafting through to consultation and lobbying is largely prohibitive. Attempts to sponsor private bills have been made, for instance, on the land question, but have not reached fruition. Private persons may also directly petition Parliament, through the Speaker, to promote laws or other issues. A member may present a petition to Parliament. If the petition falls within the terms of reference of the Parliamentary Legal Committee and the member presenting it supports this, a petition is sent to the Committee for examination. However, in practice this procedure is infrequently and ineffectively used as petitions may never get past the Speaker's desk.

Private persons may lobby government ministries or departments to promulgate new legislation or amendments to existing legislation. A successful lobby would result in a law being drafted and submitted to Parliament through the relevant Minister, then taken forward through the parliamentary process by the government Ministry. This is the most effective and most widely used process. The level of buy-in by government is such that once the Bill is passed it is largely impossible to tell that a private person or group originated it.

In summary, therefore the public is brought into policy and legal reforms by:

- consultation with relevant government ministries or departments;
- private sponsorship of legislation; and
- Parliamentary Portfolio Committee meetings.

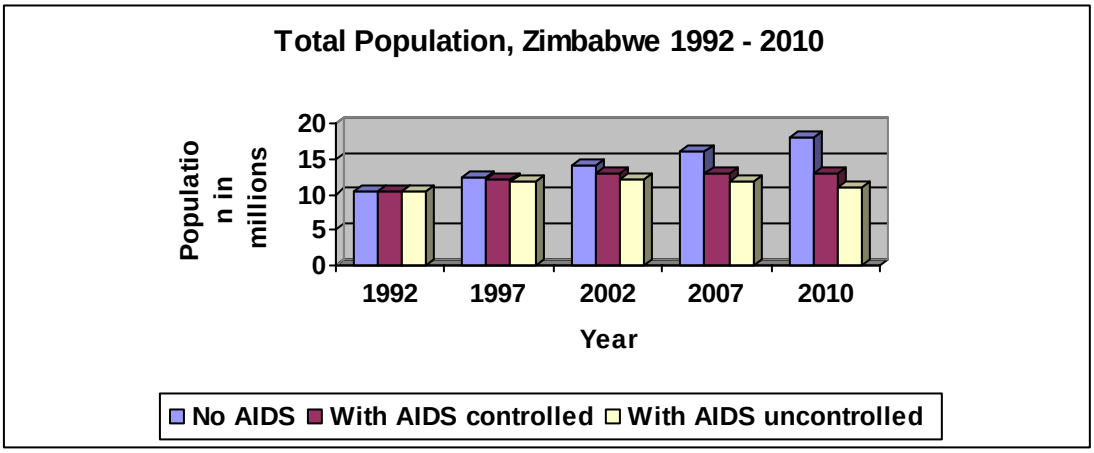
3.4 The HIV and AIDS epidemic

Any analysis of the health system in Zimbabwe is undertaken against the backdrop of the HIV/AIDS epidemic and the key concern of ensuring HIV prevention, management of care, and access to ART and other essential medicines.

The first HIV/AIDS case in Zimbabwe was reported in 1985. Since then the problem of HIV/AIDS has grown at an alarming rate. By the end of 2002, UNAIDS estimated that 2.3 million people had been infected and the adult prevalence rate was 34%. According to the MoHCW AIDS Programme, by 2003 an estimated 600 000 people would have full blown AIDS out of a total 2,1-2,3 million persons infected with HIV. In 2002, an estimated one third of the adult population (33.7%) aged between 15 and 49 years was living with HIV/AIDS (USAID, 2002). By 2000, the estimated number of deaths due to AIDS was more than 2000 death per week while the estimated total number of children orphaned by AIDS was 900 000. The number of children orphaned was expected to rise to 35% of all children by 2010 (UNAIDS, 2000).

A study on costing AIDS-related hospitalisations showed that 50-60% of the hospital inpatients suffering from HIV related illness (Hansen et al, 2000 cited in Chimbari MJ, 2003). With about 300 000 people needing ARVs, more resources are required to import or locally manufacture ARVs and other essential medicines if most of the population is to have access to them.

Figure 1: Effect of HIV/AIDS on total population



Source: Matinhure, 2003.

Zimbabwe is experiencing one of the world's most severe HIV/AIDS crises. It is a humanitarian and development crisis of epic proportions. If a turnaround is to be achieved, it is imperative for access to ART to be systematic, effective and equitable.

In 2003, WHO and UNAIDS estimated Zimbabwe's total treatment need to be 290 000; the WHO "3 by 5" treatment target was calculated at 145 000 (50% of estimated need). In 2004, WHO and UNAIDS estimated that Zimbabwe's total treatment need had risen to 295 000 people. The government declared a national treatment target of 55 000 people by the end of 2005. As of June 2004, an estimated 6000 people were receiving ART, mostly from private practitioners and largely via their own means. In November 2004, 8000 people were reported to be receiving ART, of which about 760 people were being catered for by operations research projects such as Development of Antiretroviral Therapy in Africa and the Zimbabwe AIDS Prevention Programme. Both are concentrated in urban areas. A rural faith-based organisation also provides some treatment in Mutoko. As at March 2005, a reported total of 12,000 people were receiving ART, and by May 2005, 15,000 people were receiving ART in Zimbabwe (WHO, 2005).

3.5 Millennium Development Goals

Zimbabwe's Millennium Development Goals (Ministry of Finance and Economic Development, 2004) also reflect some key health polices. Three of the eight goals are health related, namely to reduce infant mortality, improve maternal health and to combat HIV and AIDS, Malaria and other diseases. One of the challenges acknowledged is improving access to essential drugs:

"One of the major challenges beyond prevention is making HIV and AIDS drugs available at affordable cost as well as establishing an adequate and responsive drug distribution system. Of key importance is the provision of antiretroviral drugs and essential drugs for the treatment of opportunistic infections. The current shortage of foreign currency stands as a limiting factor in the area of drug procurement."

Source: Government of Zimbabwe, 2004: 47.

Other challenges include inadequate resources to combat the epidemic - the health sector is experiencing a significant reduction in its budget in real terms, while at the same time undergoing human resource depletion due to HIV/AIDS related deaths and the brain drain. The brain drain phenomenon is largely induced by a decline in real wages and generally unattractive conditions of service. The challenge is to revamp the health delivery system by availing the sector of more resources and continuously improving working conditions (Ministry of Finance and Economic Development, 2004: 4).

An estimated real GDP growth rate of at least a 4-5%, combined with global partnership resources is needed to achieve the total resources required to reach Zimbabwe's MDG 2015 poverty reduction goal. The estimated resources required are US$600 million (excluding ARVs) and US$2.2 billion (including ARVs) (Ministry of Finance and Economic Development, 2004).

4. Health systems context

4.1 Structure and organisation of the health care system

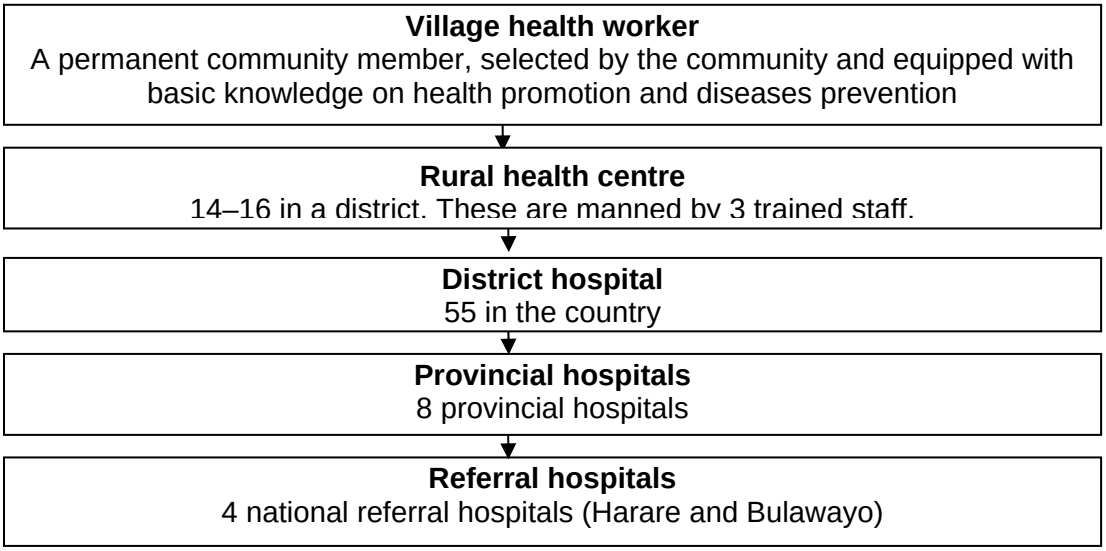
The health system of any country includes all actors, institutions, and resources that undertake health actions whose primary intent is to improve health (Wadee et al, 2005). The Zimbabwean system is predominantly state-centred. The state is the major health care purchaser and provider, funded primarily by taxation. Individuals play a minimum role as purchasers through out of pocket payments and private insurance schemes.

Health care providers in Zimbabwe include:

- The *public sector*: primarily constituents of the MoHCW and Local Authorities (Urban and Rural District Councils), the Uniformed Forces (Defence, Prison Services and Police), and the Ministry of Public Service, Labour and Social Welfare, which provides Occupational Health Services.
- *Private medical sector*: the private-for-profit includes private hospitals, maternity homes, general practitioners, traditional health practitioners and industrial clinics.
- *Not-for-profit private sector*: health care facilities and services provided by church missions, and other faith based organisations (FBOs), and non-governmental organisations (NGOs).

In Zimbabwe the care of HIV/AIDS in the public sector is primarily integrated into the primary health care delivery system shown in *Figure 2*.

Figure 2: Structure of the Zimbabwean Primary Health Care system



The public-private mix in the provision of health care services

The burden of provision of health care in Zimbabwe has historically been shouldered by both the government (central and local) and the private sector. Before 1980 most private sector provision was done by churches and other FBOs, which set up mission clinics and hospitals, mostly in the rural areas. Some companies, which employed a substantial number of people, also set up hospitals to provide for their staff and their families. These include mining companies and farming estates and plantations (e.g. Hwange Colliery,

Triangle Limited) which are essentially integrated into the public system, deferring to government policy. Another type of health care facility is the industrial clinic set up by companies to treat their employees. These are usually manned by a nurse and sometimes a covering doctor supervises nursing staff and/or visits periodically to attend patients. However, these workplace facilities do not provide ART.

Table 3: Selected registered health institutions at 30 September 2004

Type of health institution	Number*
Medical practitioners	1000
Nurse practitioners	170
Government clinics	550
Industrial clinics	200
Mission clinics	40
Private clinics	50
Rural District Council clinics	300
Urban Municipal clinics	80
Hospitals	500
Maternity homes	20
Medical laboratories	85
Nursing homes	20
Operating theatres	10
Pharmacies	300
Psychological practices	30

*Statistics provided by the Health Professions Authority (2004).

The public-private mix in the financing of health care services

The increased liberalisation of the health system, which began in the 1990s, hot on the heels of ESAP, produced a corresponding increase in private sector health care provision, including companies, NGOs, FBOs and medical aid societies. In particular, the role of medical aid societies has expanded, with a number venturing into acquisition of health care facilities, such as consulting rooms, clinics, hospitals, medical laboratories and pharmacies, to provide services to their members and the rest of the public. A few have also taken the initiative to import ARVs for their members. Some companies have also begun to do the same for their staff and their spouses. The weakening of the state under economic reforms severely undermined its ability to deal with national challenges such as those relating to HIV/AIDS. Thus, the national response to the epidemic so far, though not sufficient, is commendable given the context.

Health indicators improved greatly between 1980 and 1990 as healthcare resource allocation targeted previously disadvantaged groups, namely the rural areas and the urban poor. However, 1990 saw a peak then general decline in the fiscal spending on health, dropping below pre-independence levels after 1995/6, occasioned by the ESAP focus shift.

Table 4: Health expenditure (1980-1996)

Fiscal year spending	Real expenditure as percentage % of GDP and government expenditure		Real per capita
	GDP	Government expenditure	
1980/1	2.0	5.3	35.62
1985/6	2.5	5.3	39.48
1990/1	3.0	6.2	57.72
1995/6	2.2	4.2	35.86

Source: Piotti et al (1998).

4.2 Key national policies on health and access to ART

Zimbabwe National Drug Policy (ZNDP)

The MoHCW's Zimbabwe National Drug Policy (ZNDP) (1995) is currently in place. It aims to ensure that the selection of medicines to be included in the Essential Drugs List of Zimbabwe (EDLIZ)(2000) is based on the World Health Organisation (WHO) concept of essential drugs that a model list of about 250 drugs could serve about 90% of the most common health conditions of the country. The main elements of the ZNDP are:

- rational essential drug selection
- quantification of needs
- sustainable financing
- procurement
- quality assurance.

The main objective of the ZNDP is:

> *[T]o 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 essential pharmaceutical products (*MoHCW, 1995*).*

Generic medicine use is promoted in both the public and private sectors and is an important cornerstone of drug policy. Specifically generics are promoted in relation to prescribing, procurement and regulation.

The Zimbabwe Essential Drugs Action Programme (2004) by the National Drug and Therapeutics Policy Advisory Committee (NDTPAC) - a multidisciplinary committee which includes experts from the private and public sectors and advises the MoHCW on issues relating to access to medicines – spearheaded EDLIZ. In drug regulation, priority attention is given on the basis of need and inclusion in EDLIZ. The policy stipulates that drug procurement in the public sector will be by generic name and priority in procurement will be given to drugs in EDLIZ. The policy also seeks to ensure rational prescribing and dispensing is carried out at all levels of the health care system in both the private and public sectors

EDLIZ provides an essential drugs list and treatment guidelines for the most common health conditions in the country. Selection of drugs included on the list is based on efficacy, safety, quality and cost. The following criteria are used for selection:

- relevance to prevalent diseases
- proven efficacy and safety

- adequate scientific data in a variety of setting
- adequate quality
- favourable cost-benefit ratio
- desirable pharmacokinetics
- possibilities for local manufacture
- availability as single ingredient items.

The MoHCW is of the view that drugs in EDLIZ are chosen to meet the healthcare needs of most of the population and therefore should always be available and accessible at a price that the patient and the nation can afford. Through EDLIZ, the MoHCW also encourages generic purchasing and prescribing due to considerations relating to clarity, quality and price. Zimbabwe has a well-understood policy, which requires that all prescribing should be in the generic name, and the dispenser can make generic substitutions (unless bioavailability is an issue in which case the health professional providing the script should indicate this).

Over the years EDLIZ has evolved from the first publication in 1985 to the fourth edition in 2000. This recent edition (currently under review) has incorporated a comprehensive list of medicines and standard treatment guidelines for the most common health conditions in Zimbabwe. This was followed in December 2003 with the publication of "Guidelines for Anti-Retroviral Therapy in Zimbabwe" following a policy decision by government to introduce ARVs in the care and management of HIV/AIDS.

EDLIZ deals with HIV related disease ranging from respiratory conditions to Kaposi sarcoma. It also deals with drug reactions, palliative care in HIV and ARVs. However when the current edition of EDLIZ was produced (2000), ARVs were very expensive and not available in the public sector. Thus the only mention of them is that only doctors who have been suitably trained and are experienced in their use should prescribe ARVs.

The policy makers recognised the need to monitor the implementation of the ZNDP components through active monitoring and evaluation. This has been done through regular Medicines Survey at the national level co-coordinated by the Department of Pharmacy Services in the MoHCW. National surveys have been undertaken on a regular basis initially in the public sector since the inception of the essential drugs action programme in the 1980s and from 1993 in the private sector. With the ongoing health sector reform, a key strategic component is partnership with the private sector. Hence the need to survey the private sector was recognized in 1993. The recent survey was conducted in 2004 and incorporated new indicators to assess access to ARVs.

National policy responses to HIV/AIDS

In response to the HIV/AIDS pandemic, the Zimbabwe government developed and adopted several policies, most of which were largely silent about ART. This may have been essentially due to limited knowledge and the view at the time that ART was out of the reach in terms of price. In 1987, with financial and technical assistance from WHO, the government established a National AIDS Control Programme (NACP) within the MoHCW, responsible for playing the leading role in combating the epidemic. It undertook a one-year Short Term Plan (STP), which sought to implement prevention programs. Realising that one year was not enough time for planning and implementing responses, the first five-year Medium Term Plan (MTP1) was put in place. This sought to facilitate planning, coordination, implementation and monitoring of AIDS/STD prevention and control activities at all levels (Chimbari, 2003).

In 1999, the government adopted a comprehensive policy to promote and guide present and future responses to AIDS. The policy focus was:

management of the national response to HIV/AIDS;

human rights issues including:confidentiality, mandatory testing, discrimination, partner notification; surveillance and notification, children and young people; wilful transmission of HIV; commercial sex work; prisoners and compulsory testing and segregation;

public health issues such as: sexually transmitted infections (STIs); blood transfusion condoms/ barrier methods; pregnancy and HIV; breastfeeding;

care for people living with HIV/AIDS including: medical and nursing care; community home-based care; counselling and psychological support; voluntary counselling and testing; informed consent to HIV testing; referral and discharge system for people living with HIV/AIDS; burn-out among care providers;

gender issues including sexual health and gender violence;

information and education about HIV/AIDS/STIs; and

HIV/AIDS research.

In developing the National Policy on HIV/AIDS, it was recognised that the policy needed to encompass a wide range of concerns in the broad areas of healthcare, home care, counselling, research, information and legal and human rights in general. Government recognised that a strong and unified response was necessary to effectively combat the far-reaching socioeconomic impact of HIV/AIDS. To reach policy positions on these issues, the National AIDS Coordination Programme established a highly consultative process. It initiated a multi-sectoral response through NAC, a statutory body set up by the National AIDS Council of Zimbabwe Act [Chapter 15:14] (2001), by government ministries/departments, the private sector, NGOs, the churches, communities, community based organisations (CBOs) including support groups, the media and international collaborating partners.

Access to ARVs: HIV/AIDS initiatives

In relation to treatment access, Zimbabwe's need was clearly established by relatively high levels of HIV infection (WHO, 2005). The national HIV/AIDS policy has not yet clearly articulated ART as a strategy and needs revision to take this on. Work to revise the National AIDS Policy, co-ordinated by the NAC, is underway and considerable progress has been made. The country already has an ART initiative in place.

HIV testing is provided in the context of voluntary testing and counselling, diagnostic testing (preventing mother-to-child transmission (PMTCT), opportunistic infections and ART, and blood safety). Rapid tests are most frequently used, and other tests are used for quality assurance. There is no mandatory HIV testing.

Zimbabwe has a comprehensive response to HIV, especially for care and treatment, which includes: treatment for opportunistic infections, community and home-based care and support for ART.

ART guidelines have been developed and disseminated. Zimbabwe follows WHO-recommended ART treatment guidelines. The first-line regimen is stavudine+lamivudine +nevirapine. The average cost is about US$222 per person per year. There are two local manufacturers of generic ARVs. All first-line and alternative generic drugs for ART have been registered with the Medicines Control Authority of Zimbabwe (WHO, 2005)

In 2002, the government declared HIV/AIDS and the lack of ART to be an emergency. It intends to provide access to treatment to everyone in need. However, because of resource constraints, a phased approach has been adopted for ART scale-up. PMTCT services are delivered at 174 sites throughout the country. Laboratory support is available, with two laboratories (Harare and Mpilo) capable of performing CD4 counts. Most hospitals can already carry out rapid HIV tests, and full blood counts and chemistry. However, additional laboratory support (especially with regard to equipment and reagents) is still required (WHO, 2005).

The Zimbabwe government coordinates through the MoHCW AIDS and TB Unit, in conjunction with various partners, a programme to make opportunistic infection services available to people living with HIV/AIDS. These services are integrated into the existing health system and range from counselling, testing, and management of opportunistic infections, even in the absence of ARVs. These services are free for those patients who cannot afford to pay. Free treatment is also facilitated through the Social Dimensions Fund, which issued coupons for free treatment to deserving individuals. Those who can afford to pay, contribute towards the cost of treatment and drugs. This is heavily subsidized by government as patients are asked to pay $50 000 (US$2) per month (Opportunistic Infections Clinic, Parirenyatwa Hospital, Harare) compared to Z$700 000 to Z$1 300 000 charged in the private sector, according to a random survey of prices in retail pharmacies in Harare (August 2005). (In 2005 Z$30 000 was about US$1v.)

The rationale is that ARVs can then be introduced and integrated into the system at the district hospital level where there are adequate facilities to initiate a patient on ARVs. Other institutions, like the rural health centre can then follow up on the patient once treatment has been initiated. ARVs are currently available at 47 facilities.

ARV supplies presently procured through two local companies, one manufacturing and the other imports generics, primarily from India. However, distribution is set to be taken over by the National Pharmaceutical Company (Natpharm) a wholly-government owned company, which operates as a registered wholesale dealer in terms of the Medicines and Allied Substances Control Act. It procures all public sector medicine requirements.

However, because of Natpharm's comparative advantage in terms of acquiring lower prices through the tendering process, where there is excess stock of essential medicines, Natpharm offers these to other registered wholesalers to try to pass on the lower prices to consumers in the private sector. Other registered wholesalers import medicines to supply the private sector including retail pharmacies. Individual institutions in the public sector may also buy or import medicines in their own right. This however is usually done where Natpharm has no stocks or where the medicine is unregistered and special authorisation has been obtained from the MCAZ.

The use of WHO clinical staging (2005b) is encouraged so that no testing is necessarily required before initiating a patient on ART. However, baseline testing is encouraged. The government is currently equipping its institutions with machinery such as CD4 machines, with a first target of one at each provincial hospital. This points to the

investment in capacity required to provide ART; unless drug prices are reduced, the ability to invest in support infrastructure and resources is severely undermined as ARVs are the major cost driver. There are also efforts underway to ensure that laboratories in these institutions have equipment and reagents.

Like other areas of the health system, this is hard hit by manpower constraints at every level, affecting the capacity to develop and expand the programme. To counteract the effects of movement of health personnel, particularly doctors and nurses, new cadres have been introduced to enable the medical staff to concentrate on providing medical services. These include Primary Care counsellors and Primary Care nurses.

4.3 General overview of health legislation and regulation

Regulatory authorities in the health sector control:

- market entry and exit
- competitive practices
- market organisation
- remuneration standards or quality
- safety.

In Zimbabwe both professionals and service provision are legally regulated. Legislation regulating professionals includes:

- Health Professions Act [Chapter 27:19] (2001b)
- Veterinary Surgeons Act (Chapter 27:15] (2001)
- Natural Therapists Act [Chapter 27:09] (1989)
- Psychological Practices Act [Chapter 27:11] (1992)
- Traditional Medical Practitioners Act [Chapter 27:14] (2002)

The professional councils, set up in terms of the relevant statute, manage professional registrations. The relationship between the government, professionals and the registration body is usually one of mutual cooperation. Professionals operate in an environment regulated by government statute and policy. In some instances, even the board members of the council are appointed by the relevant minister.

Legislation regulating service provision includes:

- Medicines and Allied Substances Control Act [Chapter 15:03] (2001c)
- Health Professions Act [Chapter27:19] (2001b)
- Medical Services Act [Chapter 15:13] (2002b)
- Competition Act [Chapter 14:28] (1996)

Other legislation and regulations relating to the health sector include:

- Public Health Act [Chapter 15:09] (1998)
- Mental Health Act [Chapter15:06] (1996)
- Animal Health Act [Chapter 19:01] (1999b)
- Food and Food Standards Act [Chapter 15:04] (1996b)
- Hazardous Substances and Articles Act [Chapter 15:05] (2001d)

The dimensions of service delivery that these laws regulate primarily cover safety and quality. Various standards setting bodies have been created nationally for health services. Standards are set for various aspects relating to provision of health services, particularly ART (see *Table 5*).

Table 5: Standard setting bodies and area of regulation

Standard setting body	Area regulated
MoHCW	Treatment guidelines for HIV/AIDS care in public and private sector.
Health Professions Authority	Standards of all facilities providing health related services.
Medicines Control Authority of Zimbabwe	Quality, safety efficacy of all medicines, including ARVs. Compliance of pharmaceutical premises and persons.
Various professional councils	Professional services provided by the different health professionals.

At an international level, standards may be set by bodies such as WHO or SADC (particularly where there are initiatives towards harmonisation of legislation and processes between member states, in various aspects). However, for these standards to be applicable at the national level in Zimbabwe, they must be formally incorporated into the relevant laws or the guidelines applied by national standard setting bodies.

Competencies to make law or regulation

In Zimbabwe once any law is enacted, a Minister is assigned responsibility for its administration. Legislation usually enables the Minister to make subsidiary regulations, as may be specified. This is to ensure policy implementation in accordance with the Act, and to regulate specific aspects of practical application. These regulations usually take the form of subsidiary legislation, namely statutory instruments.

The Minister responsible for the administration of the Act therefore has the power to make regulations. Relevant stakeholders are usually consulted. In some instances, the consultation process may be stipulated to some extent by the legislation. In practice, the relevant government department or statutory body will advocate the promulgation of regulation and prepare the draft statutory instrument for the Minister's approval. Some enactments may delegate the power to make regulations to a statutory body. Where this is done, it is normally provided that regulations are made in consultation with the relevant Minister. His approval must therefore be obtained before enactment.

Medicines regulation is done through the Medicines and Allied Substances Act [Chapter 15:03] and the Dangerous Drugs Act [15:02] (2001c) and the Regulations passed pursuant to these Acts. The Medicines Control Authority (MCAZ) is a statutory body, responsible for:

- registration of medicines and allied substances such as condoms;
- control of market access and advertising;
- approval of clinical trial involving the use of medicines;
- licensing of pharmaceutical premises and persons handling medicines;
- inspection of premises for compliance;
- post-market medicines and allied substances surveillance to ensure quality is maintained;
- medicines and allied substances analysis on registration and post market surveillance; and
- regulating all aspects of manufacturing, wholesaling, retailing, dispensing and handling of medicines.

Table 6: Institutions and persons licensed by MCAZ

Institution/person	Number
Licensed pharmaceutical premises	
Pharmaceutical manufacturers	17
Pharmaceutical wholesale dealers	120
Retail pharmacies	254
Hospital pharmacies	17
Industrial clinics	214
Veterinary medicines general dealers	
Dispensing medical practices	99
Dispensing veterinary practices	11
Licensed Persons	
Pharmacists	485
Medical practitioners	306
Veterinary surgeons	109
Pharmacy technicians	140
Nurses	300
Sales representatives	323

Source: MCAZ, 2005.

5. Specific aspects relating to the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) and health systems

Changes in international trade and intellectual property (IP) protection considerably affect pharmaceutical markets, with major implications for access to medicines by the poor.

5.1 Intellectual property rights in Zimbabwe

As a member of the WTO, Zimbabwe has commitments in terms of the TRIPS Agreement (1994). Zimbabwe is also a signatory to various other international agreements relating to intellectual property rights (IPRs), which include:

- Paris Convention for the Protection of Industrial Property (1885)
- Berne Convention for the protection of Literary and Artistic Works (1886)
- Patent Co-operation Treaty (1970)
- WIPO Copyright Treaty (1996)
- Agreement on the creation of an African Industrial Property Organization (1976).

The TRIPS agreement imposes a minimum standard of protection of IPRs, including patents. As a WTO member and a TRIPS signatory, Zimbabwe must ensure its intellectual property legislation complies with the TRIPS agreement.

The main piece of legislation governing IPR issues relating to medicines is the Patents Act [Chapter 26:03] (1994), including drug patenting, compulsory licensing and parallel

importation, while the registration of medicines is governed by the Medicines and Allied Substances Control Act [Chapter 15:03] (2001c). The minimum rights conferred by a patent under the Patent Act are that the patent owner/holder has full power during the term of the patent to make, use, exercise and vend the invention as he deems fit, and to prevent unauthorised persons from using the patented process and making, using and selling the patented product. The patent holder shall have and enjoy the whole profit and advantage accruing because of the invention during the term of the patent.

Patent law in Zimbabwe grants protection to any invention relating to products or processes in all fields of technology, except for: diagnostic, therapeutic or surgical methods for the treatment of human beings; and patents sought for plants and animals, other than microbiological organisms, and essentially biological processes for the production of plant or animals, other than microbiological processes. The Patents Act (1994) also attempts to provide a framework for implementing TRIPS flexibilities to address drug access issues, particularly local production and importation.

Government use

The Patents Act [Section 34] (1994) provides for the use of a patented product or process for service of the State. Any state department or any person authorised by the Minister of Justice may make use of any patented invention.

State use during emergency

Section 35 of the Patents Act (1994) makes special provision for state use in an emergency. It provides that during any period of emergency the State or any person authorised by the State may make, use, exercise or vend any patented invention for any purpose which to the Minister appears necessary or expedient for the maintenance of supplies and services essential to the well-being of the community, among other things. On 27 May 2002, Zimbabwe declared a period of emergency in accordance with this section. This was to enable the State or any person authorised by it to make or use any patented drug, including any ARVs and to import any generic drug used in the treatment of persons suffering from HIV/AIDS or related conditions. Three Zimbabwean companies were granted license to manufacture or import generic alternative ARVs under these two provisions, which has made ARVs more available in the public and private sectors. The drug price has also become significantly cheaper than other imported brand drugs. This is particularly important against the backdrop of current economic problems, especially the shortage of foreign currency, which has contributed to hyperinflation and created a scenario where most people cannot afford medicines. The declaration of an emergency is also significant as it enable government use orders and compulsory licenses to be granted without having to first attempt to obtain a voluntary license.

Compulsory licensing

The Patents Act (1994) also provides for compulsory licensing. A compulsory licence may be granted in case of abuse or insufficient use of patent rights [Section 31]. Any person interested in a patent who can show that he has been unable to obtain a voluntary licence may apply to the Registrar of Patents for a compulsory licence on the ground that the reasonable requirements of the public with respect to the invention have not been satisfied or will not be satisfied. This provision relates to private actors. Under the Act, government cannot issue a compulsory license of its own accord. There must be an applicant who has failed to secure a voluntary license, who wishes to commercially work a patented product, which the patent owner has failed or neglected to work.

Parallel importation

Parallel imports are goods produced genuinely under protection of a trademark or patent placed into circulation in one market, and then imported into a second market without authorisation of the local owner of the intellectual property. For example, where company A has patented a drug, which it makes under patent in the Brazil and the United Kingdom, but sells at a lower price in the United Kingdom. If a second company buys the drug in the United Kingdom and imports into Brazil at a price that is lower than company A's price that would be a parallel import.

The legal principle applicable here is "exhaustion of rights": once company A has sold its product in a country, its patent is exhausted and it no longer has any rights over what happens to that product. According to the theory of exhaustion of IPRs, the exclusive right of the patent holder to import the protected product is exhausted, and thus ends, when the product is first launched on the market. When a state or group of states applies this principle of exhaustion of rights within a given territory, parallel importation is authorised to all residents in the state in question. In a state that does not recognise this principle, however, only the registered patent holder has the right to import the protected product. Specific legal provision allowing for parallel imports would be necessary in order to benefit from the principle of international exhaustion of rights.

Legal provisions allowing for parallel imports have been enacted into law in Zimbabwe through the Patents Amendment Act of 2002 (Section 24A):

> *A patented product which has been put on the market in another country by a patentee may be imported into Zimbabwe, without the consent of the patentee, if the cost of importing such product is less than the cost of purchasing from the patentee.*

This is a general provision relating to inventions in all fields of technology. However, unlike South Africa, Zimbabwe does not have specific legislation dealing with parallel importation of medicines. The South African Medicines and Related Substance Control Act (1965) provides in section 15C that:

> *The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the Public, and in particular may –*
> *notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts with regard to any medicine which has been put onto the market by the owner of the medicine, or with his or her consent;*
> *prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;*
> *prescribe the registration procedure for, as well as the use of, medicine referred to in paragraph (b).*

As Article 6 of TRIPS states that exhaustion of rights is not subject to the dispute settlement mechanism of the WTO, the broader provision in Patents Act (1994) section

24a should be adequate to cover pharmaceuticals under TRIPS, but problems may be encountered at national level.

These provisions do not take into consideration the way the pharmaceutical industry operates (e.g. the granting of sole agency) or the registration process which is a prerequisite for obtaining authorisation to put a medicine on the market. For example, an attempt to do a parallel import of a pharmaceutical product registered in both Zimbabwe and Zambia might result in an importer falling foul of the Medicines and Allied Substances Control Act (2001c) because the packaging used for the Zambian market differs from the packaging authorised for Zimbabwe when the product was registered. There is therefore need to separately and specifically provide for the parallel importation of pharmaceuticals.

Early working/ Bolar provision

The early working or manufacturing of a patented product such as a drug is permitted in specific circumstances. An 'early working' or 'Bolar' provision persons other than the holder of a patent to work on a patented drug, using the patent specifications in order to produce a generic version of the drug. This limited production includes actually manufacturing the drug, in sufficient quantities for testing, clinical trials and any applications for registration of the drug that the generic manufacturer may be required to make to enable him to market the generic product. The generic manufacturer is also then able to manufacture batches of the drug for release onto the market on the day after the patent expires. Such provisions are necessary and allowable because of the length of time that generally needed for the generic manufacturer to develop his product and get it registered, which in some instances can be as much as ten years. Therefore, to ensure availability of medicines, the rights of the patent holder to exclusively manufacture and market his product are limited in the public interest.

The Patents Act (1994) provides that test batches of a patented product may be produced without the consent of the patentee six months before the expiry of the patent. They may not be put on the market before the expiry of the patent. Further, once test batches have been produced, the term of the patent may not be extended.

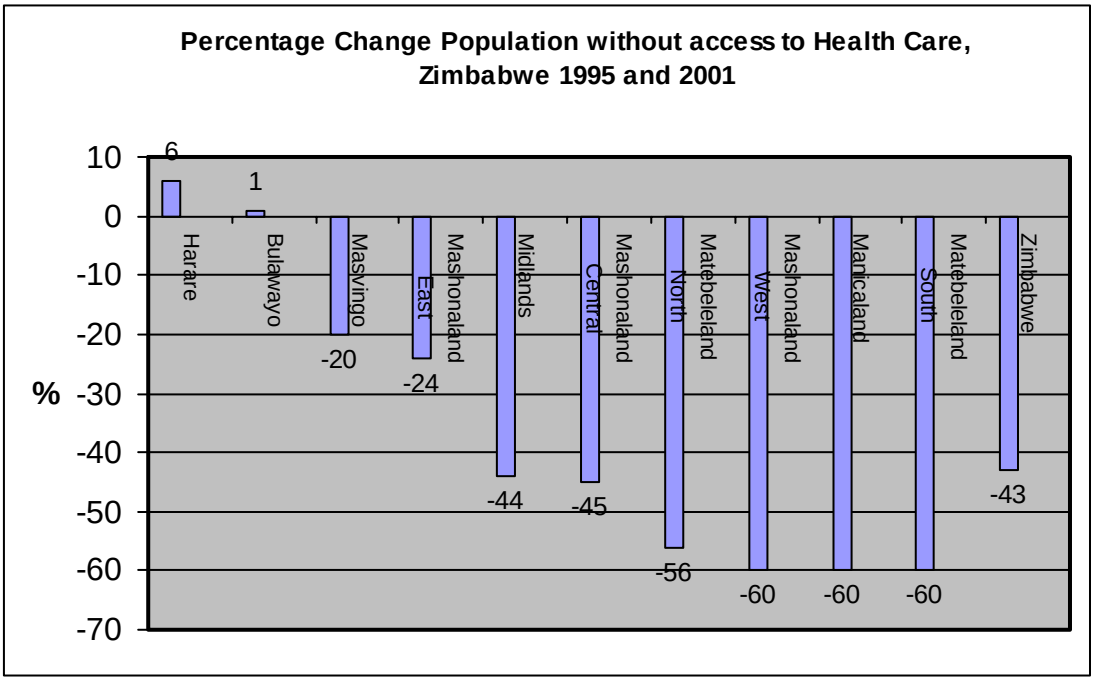
This provision enables the early working of pharmaceutical patents to acquire generic medicine registration. Once registration is complete, a manufacturer may produce and stockpile, awaiting the expiration of the patent, unless a compulsory licence is obtained. Zimbabwean manufacturers have used this provision to enable them to manufacture generic versions of patented ARVs for research and registration.

The audit findings suggest there is need to critically examine legislation pertaining to patents and the regulation of medicines in Zimbabwe to ensure it fully exploits TRIPS flexibilities and ensures a legal framework which facilitates access to medicines, particularly ART in Zimbabwe. It is important to ensure that they adequately provide for necessary conditions for public/ private production and procurement of generic ARVs.

Cost of drugs and access to health care

The issue of access to health care is critical, particularly under the HIV/AIDS epidemic environment. *Figure 3* shows a general trend of reduced access to healthcare in Zimbabwe, which translates to reduced ART access.

Figure 3: Percentage change of population without access to health care



Source: Malaba, 2003.

The trend in the provincial analysis indicates that only two out of the ten provinces recorded improved access to health care. Between 1995 and 2001 the percentage of the population without access to health care increased by 43%. The cost of drugs is a key determinant of access, particularly in Zimbabwe and in light of the current economic challenges. The Essential Medicines Survey in Zimbabwe (2004) carried out under the Health Sector Support Programme by the MoHCW and the European Commission revealed an average household expenditure on medicines per month of Z$81,500 (UD$16). Of the 98% of people diagnosed in a public health centre or hospital, 21% did not purchase all drugs prescribed, 7% due to insufficient funds and 89% unavailability of drugs. These findings suggest that the issue of access to medicines remains a real challenge in Zimbabwe, despite various enabling policies and measures.

5.2 Areas of concern in protecting health under IP trade regimes

Enhanced IP protection affects access to medicine in both producing and importing countries by stimulating changes in the market and industry structure. While patent protection may stimulate investment in research and development for new medicines, it also limits price competition on new medicines by generic manufactures. To address concerns over unmet public health needs and to expand access to medicines for all, in November 2001 WTO members adopted the Doha Declaration on the TRIPS Agreement and Public Health. This was to clarify TRIPS-compliant flexibilities for accessing medicines. Subsequently, through the Decision of the 30 August 2003, WTO members agreed on a mechanism for supplying needed new medicines to non-producing countries that lacked sufficient capacity to produce such products domestically.

Use of TRIPS flexibilities
TRIPS flexibilities theoretically enable countries with public health needs and insufficient manufacturing capacity to import lower-cost products from other countries. In developing country governments, awareness of public health threats, and the political will to act are often low. Experience in implementing TRIPS and its flexibilities is limited and requires effective co-operation between different government departments including health, trade and industry, that may have limited experience in developing common policy. In Zimbabwe, such co-operation is ongoing and some ground is being gained. Capacity building is also ongoing.

On 27 May 2002, Zimbabwe declared a period of emergency in view of the rapid spread of HIV/AIDS. This period was later extended to five years. The declaration of an emergency facilitated granting compulsory licenses for the manufacture and importation of patented drugs for the treatment of HIV/AIDS related illness, including ARVs.

Impact of stronger patent protection in producer countries
Of concern is how the implementation of TRIPS compliant patent laws in countries that have traditionally produced generic drugs will play out in the future. The compliance by India and China in 2005 with the provisions of the TRIPS agreement means their laws now provide for the protection of products and manufacturing processes. This is an issue of concern because large scale manufacturing of generics by these countries has played a major role in creating downward pressure on the price of medicines globally.

Some uncertainty has been created about the patent status of drugs patented under the “mailbox” procedure. (Countries such as India had to accept patent applications from 1995 onwards pending review when its laws became TRIPS compliant, i.e. 2005. These mailbox applications would be reviewed retroactively.) A lot of newer ARVs fall into this category. For the same reasons the patent status of active pharmaceutical ingredients is therefore also of concern, as Zimbabwe is a net-importer of pharmaceutical raw materials. Furthermore, with time and as newer products are produced, the supply of those new products would be limited under the acceptable exceptions under TRIPS.

Production and supply could continue under a system of compulsory licenses issued by both importing and exporting countries. Zimbabwe would be able to import as it does not have sufficient manufacturing capacity for its own needs. However, sufficient incentives need to be put in place for companies to manufacture specific products. Currently, in Zimbabwe, companies granted government use orders are unable to meet the countries ARV demand. It is my view that those that are manufacturing may face a number of challenges in trying to export their products. For example, resistance may be met in markets in the region where ARV procurement is donor funded as donors may specify procurement sources or conditions that manufacturers must meet. Further, generic manufacturers may not be able to meet the demand for drugs, as they would have to be producing predominantly for their domestic market.

Countries like India now face a constraint on the share of locally produced drugs they are permitted to export. Reductions on this will limit the supply of cheaper drugs from India to countries like Zimbabwe that do not have domestic production capacities

6. Conclusion and recommendations

This audit has highlighted various strengths and weaknesses in the current legal and institutional arrangements for ART, particularly in relation to national policy goals and needs outlined in this study. Because of its health profile, we suggest that Zimbabwe prioritise measures to ensure access to healthcare, and apply patent rules in ways that protect public health. Public health, particularly pharmaceuticals should be singled out as needing special attention in the national implementation of the TRIPS Agreement.

The TRIPS Agreement has left room for flexibility at the national level. It is imperative that the government resist any pressures that seek to impede the use of available flexibilities, as this runs counter to the spirit and purpose of TRIPS. This includes signing bilateral agreements containing provisions, which can be described as TRIPS plus. In setting up laws and regulations to implement TRIPS and other international trade agreements, the government should be ever mindful of the public health needs of the country. The link between trade and health should never be overlooked, as government negotiates, signs, ratifies and implements international or bilateral trade agreements.

Existing legislation also needs to be reviewed to ensure that it fully utilises available flexibilities. For example, specific legislative provisions could be strengthened dealing with parallel importation of pharmaceuticals.

The situation on the ground needs to be monitored to ensure that beyond the legal framework, access to foreign currency and other factors that hinder ART access are dealt with in an equitable manner, and that available resources are distributed in ways that provide greatest coverage and access.

In considering various approaches to the issue of compulsory licensing, the government may be mindful of choosing an approach that provides adequate incentives for the production and export of essential medicines.

There is also a clear need for the sensitisation of all stakeholders, including trade and health ministry officials, parliamentarians, civil society and the public to the links between trade and health to ensure that as a country we do not sign away our right to health in the pursuance of economic gain in the global market.

Government could put in place or improve measures for consultation with civil society and with the public. It is necessary to broaden the base for consultation, to ensure it is more representative and qualitative.

Finally, there is a lot of scope for further study in this area in view of the ongoing discussions on the amendment of the TRIPS Agreement relating to countries without adequate manufacturing capacities of pharmaceuticals.

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Equity in health *implies addressing differences in health status that are unnecessary, avoidable and unfair. In southern Africa, these typically relate to disparities across racial groups, rural/urban status, socio-economic status, gender, age and geographical region. EQUINET is primarily concerned with equity motivated interventions that seek to allocate resources preferentially to those with the worst health status (vertical equity). EQUINET seeks to understand and influence the redistribution of social and economic resources for equity oriented interventions, EQUINET also seeks to understand and inform the power and ability people (and social groups) have to make choices over health inputs and their capacity to use these choices towards health.*

EQUINET implements work in a number of areas identified as central to health equity in the region:

- Public health impacts of macroeconomic and trade policies
- Poverty, deprivation and health equity and household resources for health
- Health rights as a driving force for health equity
- Health financing and integration of deprivation into health resource allocation
- Public-private mix and subsidies in health systems
- Distribution and migration of health personnel
- Equity oriented health systems responses to HIV/AIDS and treatment access
- Governance and participation in health systems
- Monitoring health equity and supporting evidence led policy

This report is produced under a training programme as part of a skills building exercise. It does not reflect the views of EQUINET and is not a formal EQUINET discussion or policy paper.

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