

Zambia: The right to health and international trade agreements

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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. This work was conducted as part of an internship for an LLM in Human Rights, specialising in Reproductive and Sexual Health and Rights at the University of Free State Law Faculty funded by the Ford Foundation.

Executive summary

This work was carried out under EQUINET, SEATINI and the Health and Human Rights programme at the University of Cape Town, as coordinator of the Health Rights theme work for EQUINET. This work was conducted as part of an internship for an LLM in Human Rights, at the University of Free State Law Faculty funded by the Ford Foundation. It aims to investigate, analyse and raise awareness on the major implications of WTO agreements on the delivery of health services to the poor and vulnerable thereby affecting the realisation of the right to health in Zambia.

One of the much vaunted benefits of globalisation is that innovations of science and technology can be more readily available and shared by the citizens of the world. Proponents of globalisation further argue that significant gains in the advancement of treatment of diseases would be available to people in the furthest regions (Feachem, 2001). However, as recent experience has shown, availability does not mean accessibility - especially in the case of life-saving drugs and affordable health services in developing countries. This has affected the realisation of the right to health in a big way, especially for the poor and vulnerable in less developed regions of the world.

The right to health, widely documented in international human rights instruments, implicates mostly access to medication and affordable health services. It impresses upon governments the obligation to take steps to progressively realise that right. Basic aspects involve governments endeavouring to provide citizens with reasonable access to drinking water, adequate sanitation, basic levels of food and shelter. It also encourages states to provide universal access to medical care in emergencies and to affordable, essential medicines. It includes freedoms and entitlements. Like other human rights, it has a particular preoccupation with the disadvantaged, vulnerable, and those living in poverty.

The duty to respect human rights means that the state is responsible for ensuring the enjoyment of rights relevant to the concerned service. In the case of health services, the state has an obligation to prevent third parties from compromising equal, affordable and physical access to sufficient, affordable and acceptable health services. Privatisation, then, **must not** force the state to abdicate its responsibility to respect, protect, fulfil and promote human rights. The state has the duty to ensure that ownership of the delivery system - public or private - does not compromise accessibility, availability, quality and acceptability of basic services. Most importantly, privatisation must not result in denial of access to vulnerable and poor people to socio-economic rights.

This report undertakes an analysis of the relevant provisions of the World Trade Organisation (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPs) and the General Agreement of Trade in Services (GATS) agreements with respect to the provision and accessibility of health services. The globalisation of production and marketing of drugs and health services is impacting heavily on developing countries. Consequently, the patent system works very well in industrialised countries where the burden of health care (on both governments and individuals) is relatively low and ensures the continuing development of new drugs. But in poor countries, where the burden of health care is very high, the patent system has failed to provide an adequate response to many prevalent diseases and has restricted access to cheaper drugs. Coupled with the pressure of liberalising and privatising health services under the GATS agreement, this will lead to the collapse of health delivery systems of most developing countries.

1. Introduction

"It is my aspiration that health will finally be seen not as a blessing to be wished for; but as a human right to be fought for."

United Nations Secretary General, Kofi Annan

The Republic of Zambia gained independence from the United Kingdom in 1964. After nearly two decades of one party rule, 1991 saw the introduction of a multiparty democracy and the Movement for Multi-party Democracy (MMD), led by Frederick Chiluba, came to power. According to DFID (2006) Zambia is one of Africa's poorest countries – with about 7 million of the 10 million population living below the national poverty line of less than \$0.93 a day, and very low health indicators including:

- one in six children dies before their fifth birthday;
- maternal mortality went up from 649 per 100,000 during 1996-2000 to 729 per 100,000 during 2001-2;
- life expectancy of 39.01 years (World Health Report, 2005);
- 16% adult HIV infection rates; and
- child hunger (24% child malnutrition from 1996-2000 to 28% during 2001-2).

These indicators paint a rather gloomy picture of the Zambian health services sector. However, overall poverty levels have improved from 73% in 1998 to 68% in 2004.

Zambia's health services sector is composed of both public and private service providers, but is dominated by the public sector. There was a large expansion of health facilities during the first decade of independence (1964-1974) (DFID, 2006). The government built many hospitals and health centres. Health services were provided free and funded wholly from the government budget. The private sector was discouraged until about the late 1980s. Since 1991, there has been a big reform effort to re-organise and liberalise the sector. Major changes have taken place. These include the decentralisation of health services from large hospitals to district hospitals (Lake, 2000) and the introduction of a referral system. The government's role is restricted to policy formulation, mobilisation of resources, making rules and regulations and the co-ordination of international co-operation.

The commitment of the Zambian government to realising public health for its people cannot be doubted. Public health, defined by the World Health Organization (WHO) as 'all organized measures, whether public or private, to prevent disease, promote health, and prolong life among the population as a whole' seems to be at the heart of government's health policy (ibid). This definition of public health shows how the right to health and other rights are linked, as shall be shown later on in this work. Universal health is an international objective and is one of the pillars of sustainable economic development (WHO WSSD, 2006).

Many factors come into play in providing quality healthcare to meet a population's needs. Qualified staff, essential medicines and medical supplies, and well-equipped facilities must be available, and service must be sufficiently funded to ensure fair access, whether provided through affordably priced state insurance or services delivered by the public sector (United Nations Committee on Economic, Social and Cultural Rights, 2000). The availability of these factors is affected by macroeconomic factors such as economic liberalisation and freer trade, as will be discussed later in this paper.

As a sign of commitment to fulfilling the right to health, the Zambian government has ratified various international human rights instruments which enshrine the right to

health.¹ The discussion about Zambia's commitments on the internationally recognised right to health shall be discussed later on in this work. The fulfilment of these commitments is however under threat due to a number of factors at play in the international arena.

Despite the expansion of the health sector and the commitment by the government to improve the health sector, Zambia's domestic health services sector is still underdeveloped. This is mainly because of the inherited dominance of the public health services sector over the private health services sector. There is need to build its domestic capacity so that it can improve on its quality and efficiency. The World Trade Organisation (WTO, 2000) argues that one way of doing this, is to bring about competition through participation in international trade in health services. It further argues that this will also enable the other modes in the export of health services to develop.

Zambia¹, as a WTO member, is a signatory to various trade instruments including:

- Trade Related Aspects of Intellectual Property Rights (TRIPs) (WTO, 1994)
- General Agreement on Trade in Services (GATS) (WTO, 1994).

These agreements are the subject of this study.

It has been argued (Balakrishnan, 2005) that the proliferation of trade agreements is putting pressure on governments to liberalise many services, including a number of services in the healthcare sector. In Africa and around the world, the state's capacity to maintain public health programs and regulate the sector could be undermined by the multilateral agreement negotiations in progress in the WTO (Balakrishnan, 2005). It is therefore important to assess the impacts these negotiations may have on the access to and provision of healthcare services, especially for poor populations, which may be the most heavily affected by freer trade (Sinclair, 2000). This work seeks to answer the question whether the operation of trade agreements restricts the kind of initiatives a country like Zambia can take to protect and promote human rights particularly the right to health.

2. Review of Zambia's GATS commitments

Under GATS, the Zambian government has committed itself to liberalise:

- business services
- construction and related engineering services
- health and related social services
- tourism and travel related services.

This study will particularly focus on the health and related services sector. Zambia has fully liberalised its health sector under GATS. Just like Malawi, it has made its market more attractive for foreign service suppliers by not placing any national treatment or market access limitations (EQUINET and SEATINI, 2002).

GATS proponents have argued that opening up of services will bring many advantages to the developing world, chief among them being the much needed investment as well as improvements in service delivery (Sinclair, 2000). This in turn will bring development to the developing world and help to eradicate poverty. However, these assertions have also been heavily challenged as elaborated below.

¹ Zambia acceded to the International Covenant on Economic Social and Cultural Rights (ICESR) on 10/04/1984, ICCPR on 10/04/1984, and ratified the CERD on 4 February 1972, CEDAW on 21 June 1985, the Convention on the Rights of the Child on 6 December 1991. It also ratified the African Charter on 10 January 1984.

Whether Zambia will, by opening up its health service sector, glean any of the alleged advantages, remains to be seen.

Liberalisation of basic services like health services has been heavily criticised by human rights activists (Balakrishnan, 2005). It has been argued, for instance, that current negotiations on GATS threaten to erode the ability of the Zambia government to implement measures for the equitable provision of essential services such as health, water, sanitation to all its citizens. The implementation of such measures is a central requirement of states under their human rights treaty commitments.

Mandated negotiations may also threaten governments' capacity to regulate services in the public interest. Any consideration of the potential impact of the GATS should address the power imbalances between countries in the negotiation process, and the existing pressure towards privatisation of the public sector under the policy prescriptions of international multinationals.

The rights of poor and vulnerable populations to the highest attainable standard of health, and other rights like the right to food and education which implicate on the right to health may be put in jeopardy insofar as:

- the human rights obligations of private corporations are not, as yet, legally enforceable in all circumstances, as the home countries of those corporations are hesitant to adopt extra-territorial legislation to that effect; and
- as the host States may find it legally or practically impossible to impose strict obligations on foreign corporations (Brock, 2001).

While, services 'provided in the exercise of governmental authority' (Article 1:3 (b)) are excluded from GATS, these are defined very narrowly as 'any services which is supplied neither in commercial basis nor in competition with one or more service suppliers' (Article 1:3(c))². In the case of Zambia where the public provision of health services exists together with private sector provision it means that public health services are covered by GATS. Zambia also introduced user fees during its International Monetary Fund mandated Structural Adjustment Programme; therefore health service provision is now treated as a commercial commodity instead of basic entitlement. The introduction of user fees itself has proved to be problematic: 'the largest impact of user fees has been to create a new tier structure for health care provisions. Private health care for the rich and better educated in the society and the public for the poorer and less educated' (Ayah, 1997). This state of affairs already existed in Zambia before the introduction of GATS and is likely to be further fuelled by trade liberalisation. Zambia has since April 2006 scrapped user fees in the rural areas, a move that has been hailed by health activists (Moszynski, 2006). User fees however remain effective in the urban areas which mean nothing much change in terms of GATS coverage.

By fully liberalising its health service sector the government of Zambia might not be able to continue subsidising the health sector. If it continues to do so, it will be in violation of the National Treatment clause which states that public health service providers and private health service providers should be afforded the same treatment (WTO, 1994).³ Therefore, if the public health sector receives a subsidy, private service providers must receive the same subsidy. This is a case of using public funds to finance private profits. Zambia, as a least developing country (LDC) can hardly afford this luxury and it would also be a clear abuse of public funds. So GATS 'proves

² Note that if either condition is met, then GATS applies.

³ The *National treatment* clause requires governments give foreign services and service providers the best treatment given to like domestic services and service suppliers, both in law and in fact.

to be more intrusive to legitimate domestic regulation and may potentially be more destructive of democratic governance' (Sinclair, 2000).

3. Review of Zambia's TRIPs commitments

The TRIPs Agreement brings intellectual property rights under one common set of international rules and establishes the minimum levels of protection that all governments within the WTO must give to the intellectual property of fellow members. The TRIPs agreement can only be enforced by the laws of individual countries; it is not an automatic universal law.

The TRIPs Agreement mandates universal pharmaceutical patent protection by all WTO Members, whether developed or developing, with the exception of LDCs. As an LDC, Zambia is not required to have TRIPs-compliant patent legislation in place until 2016, but it already provides patent protections through its Patent Act.

Article 65(5) of TRIPs states:

A Member availing itself of a transitional period ... shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66 (1) addresses specifically the situation of LDCs:

In view of the special needs and requirements of least-developed country members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such members shall not be required to apply the provisions of this Agreement other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65.

It appears that by virtue of Article 66, LDCs escape the transitional period requirements set out under Article 65, including the requirement that laws, regulations or practice, not be changed in a way that would make the country less TRIPs compliant during that period. Therefore, a country such as Zambia could take steps to suspend the operation of its current patent laws until 2016 when it will be required to become TRIPs compliant (as suggested by Baker, 2004). Suspending the operation of its patent laws would allow Zambia, simply on the basis of notification and without granting a compulsory license, to import generic drugs from a country like India - which produce reasonably priced generic drugs under TRIPs. Where pharmaceutical patents have already been granted in Zambia, such action could be problematic and could open the government to claims from patent holders. In such cases, it would likely be more practical for Zambia to issue a compulsory licence for import of the patented pharmaceutical. The suspension of Zambian patent laws could, however, be beneficial in the future, for drugs not yet patented in Zambia, and this could reduce the administrative burden involved in importing generic pharmaceuticals, since compulsory licenses would not need to be issued.

In order to import generic pharmaceuticals from a country like India for example, Zambia would first have to notify the TRIPs Council of the type and amount of drugs to be imported. This requirement poses a hurdle in the process of importing drugs hence directly affecting the population's right to access to drugs.

As an LDC however, Zambia does not have to show that it lacks the manufacturing capacity to produce the drug domestically. If Zambia has suspended the operation of its patent laws, or if no patent has been granted for the pharmaceutical in question,

no further notification need be made. If a patent has been granted for the pharmaceutical in question in Zambia, Zambia must notify the TRIPS council that it either has, or that it intends to, issue a compulsory licence for the import of this pharmaceutical.

Even if Zambia fulfils all of these requirements, India must still grant a compulsory licence to manufacture the drugs for export to Zambia. Under TRIPS, and under the Indian Patent Act No 15 (2002), adequate remuneration must be paid to the patent holder in India prior to the export of the pharmaceuticals to Zambia (Carroll, 2005).

The Doha Agreement (2001) and the Agreement on the Implementation of Paragraph 6 (2003) were drafted in order to respond to the strict limitations on export under compulsory licences in TRIPS. Article 31(f) of TRIPS provides that compulsory licences must be predominantly for the supply of the domestic market of the authorising Member. If an authorising Member issues a compulsory licence predominantly for the supply of its own market, there is nothing in TRIPS to prevent it from exporting a non-predominant share of the pharmaceuticals produced under licence.

Therefore, if the Zambian market for a particular pharmaceutical is not being supplied or developed, and if a country such as India were to grant a domestic compulsory licence for the production of that pharmaceutical, the non-predominant portion of the drugs produced under that licence could be exported to Zambia. Again, in this situation, if the pharmaceutical is patented in Zambia, Zambia would have to have incorporate the doctrine of exhaustion into its legislation so that importation would not violate the inventor's patent rights in Zambia.

Under Article 31(k) of TRIPs, a country can bypass the voluntary licensing requirements and the requirement that production be primarily for the domestic market "where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases." In the very rare circumstance that a country issues a compulsory licence to combat anti-competitive conduct, Zambia could import unlimited quantities of the pharmaceutical in question (to the extent that it was available) from a manufacturing country under this provision.

Another possibility exists for the importation of generic pharmaceuticals. Article 30 of TRIPS states that:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

The Doha Declaration (2001) is a strong political statement that can make it easier for developing countries to adopt necessary measures to ensure access to health care without the fear of being dragged into a legal battle. The Declaration is also a Ministerial decision with legal effects on member states and on the WTO bodies, particularly the Dispute Settlement Body and the Council for TRIPS. It states the purpose of the TRIPS Agreement in the area of public health, interprets the TRIPS Agreement with regard to some important aspects, instructs the Council for TRIPS to take action, and decides on the implementation of the transitional provisions for LDCs.

A "declaration" has no specific legal status in the framework of WTO law (Correa, 2002); it is not strictly an authoritative interpretation in terms of Article IX.2 of the Marrakesh Agreement Establishing the WTO (1994). However, given the content and mode of approval of the Doha Declaration, it can be argued that it has the same effects as an authoritative interpretation. In particular, in providing an agreed understanding on certain aspects of the TRIPS Agreement in paragraph 5, members have created a binding precedent for future panels and Appellate Body reports. Developing countries like Zambia should consider (with relevant technical assistance provided) reviewing their legislation in order to ensure that the flexibilities, as clarified in the Declaration, as well as other flexibilities allowed by the TRIPS Agreement, are incorporated in national laws and effectively used to address public health concerns.

4. Are Zambian laws conforming, conflicting or consistent with GATS and TRIPS?

Zambia has Patent Legislation dating from 1958. The legislation is not entirely TRIPS compliant, but it does:

- provide for patent protection for sixteen years
- give patent holders the right to make, use and sell the invention.⁴

As a LDC member of the WTO, Zambia is not required to become TRIPS compliant until 2016.

The Zambian Patent Act (1958) incorporates African Regional Industrial Property Organization (ARIPO) patents in Section 10A (1982). A patent granted by ARIPO, that has not been objected to by the Registrar under section 3 (6) of the Harare Protocol is valid, and is treated as if it had been granted under the Zambian Patent Act. The Harare Protocol allows ARIPO to receive and process patents on behalf of member states⁵. A single patent application can be filed with ARIPO designating any or all member states in which the applicant seeks patent protection. ARIPO then examines the application to determine patentability (i.e. the invention is new, non-obvious and useful). Once this determination has been made, copies of the application are sent to each designated member state, who have six months to inform ARIPO that if the patent is granted it will not have effect in that country. ARIPO provides patent protection for twenty years, and in this regard, it is TRIPS compliant. The Zambian Act, so far as it incorporates ARIPO provisions, can also be said to be partly TRIPS compliant. The Zambian Patents Act also provides for compulsory licensing - a feature also incorporated into the TRIPS Agreement. In that regard, it can also be said to be TRIPS compliant. The effects of this provision will be discussed later.

In 1995, the National Health Service Act was enacted to facilitate health sector reforms in Zambia. It called for a significant change in the role and structure of the Ministry of Health and for the establishment of an autonomous health service delivery system. This massive reform process involved the establishment of Central Board of Health (CBoH) in 1996 which acts as a technical unit responsible for the delivery and implementation of health reforms and the development of the primary health care (PHC) program - an important component of the health care delivery system.

⁴ While the Zambian Patent Legislation only provides for patent protection for a period of 16 years, section 3(10) of the Harare Protocol provides patent protection for a period of twenty years.

⁵ ARIPO Member States are: Botswana, The Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

The vision of the health reforms in Zambia is to “provide equity of access to cost-effective, quality health care as close to the family as possible” (CBoH, 2001). The mission of the health sector is to significantly increase life expectancy in Zambia by creating environments and encouraging life styles that support health. The financing of the basic health care package is a priority to try to reduce both morbidity and mortality rates and contribute to poverty reduction (Ministry of Financing and National Planning, 2002). While, this legislation on its own is very progressive and could go a long way in facilitating the realisation of the right to health for Zambia nationals, the extent to which its vision conforms with Zambia’s commitments under TRIPs and GATS is extremely questionable.

The Medical Aid Societies and Nursing Homes (Dissolution and Prohibition) Act of 1975 banned the establishment and operation of private hospitals in Zambia. However, with the moves to permit greater market activity in the late 1980s, this act was amended in 1990 to permit the operation of licensed private hospitals. To be approved, all private hospitals must provide a minimum level of facilities, including:

- emergency and casualty services
- operating theatre facilities
- laundry facilities
- kitchen and catering facilities
- ambulance service
- laboratory and blood bank services
- mortuary and incinerator services
- pharmacy.

These requirements are rather high in Zambia’s context, and probably act as a significant barrier to market entry. Foreign investors might find it easier to finance these requirements, but the condition that private facilities are mainly Zambian-owned will tend to deter them. Thus, there are only two private hospitals in Lusaka Zambia (Berman, 1995). In this regard, the provisions of this act do not conform with GATS which encourages the removal of any barriers for non-Zambian nationals or companies wanting to trade in services with Zambia. It is also important to note at this point that there has not been increased investment in the health sector since the liberalisation of the sector in 1995 (ibid). This can be attributed to several factors, including the fact that Zambia’s economy is too weak to sustain a private sector that would attract foreign investment, and trade liberalisation has not assisted much.

5. What does the right to health mean for Zambia in light of international and regional human rights law?

International human rights law offers standards for evaluating government conduct and mechanisms for establishing some degree of accountability in terms of their human rights commitments. For example, state parties to human rights instruments have reporting obligations to different human rights committees like the ICESCR Committee. Legal arguments support the primacy of International Human Rights Law over all other legal norms, trade agreements included. Under international human rights law, states have the obligation of non-retrogression, i.e. they may not remove, weaken or withdraw from legislation and programs, which implement their human rights obligations. It is essential that investment and trade agreements contain no provisions impeding the capacity of the state to respect, protect, ensure or fulfill human rights in accordance with their obligations under international and domestic human rights law.

From a human rights perspective, all national and international rules, including economic liberalisation agreements which include WTO agreements, derive their democratic legitimacy from protecting human dignity and inalienable human rights which today constitutionally restrain all national and international rule-making power. The right to health forms part of international law.⁶ According to its international human rights commitments, the Zambian Government has a duty to respect, protect and realise the right to health (United Nations Committee on Economic, Social and Cultural Rights, 2000). These commitments involve progressively realising the right to health and abiding by immediate minimum obligations, including access to essential drugs and affordable and accessible health services.

As a state party to the International Covenant on Economic, Social and Cultural Rights (ICESCR) and other international and regional human rights instruments (e.g. Article 16 of the African Charter on Human and People's rights (OAU, 1981)), Zambia has committed itself to respect, protect and realise the right to health. This commitment includes not only the obligation to progressively realise the right to health but also immediate obligations, including minimum core ones. The UN Committee on Economic, Social and Cultural Rights, which monitors the ICESCR, established in its General Comment 14 (paragraph 43) that those minimum core obligations include access to essential drugs and basic health care, as well as the obligation:

- to fulfil contains obligations to facilitate access to and provide health care services and conditions necessary for health;
- to respect requires states to refrain from interfering directly or indirectly with the enjoyment of the right to health;
- to protect requires states to take measures that prevent third parties from interfering with the right which Article 12 of the ICESCR guarantees (third parties in this instance include pharmaceutical companies whose prohibitive prices may make the realisation of the right to health for the poor and the vulnerable a distant goal); and
- to fulfil requires states to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realisation of the right to health.

However, the Constitution of Zambia does not enshrine the right to health in its Bill of Rights. Economic, social and cultural rights under which the right to health belongs do appear in the Zambian Constitution, amended in 1996, under part IX on the Directive Principles of State Policy and the Duties of a Citizen, Article 111:

The Directive Principles of State Policy set out in this Part shall not be justiciable and shall not thereby, by themselves, despite being referred to as rights in certain instances, be legally enforceable in any court, tribunal or administrative institution or entity.

This means Zambian citizens cannot go to a law court and sue the government on the grounds that their right to health, for example, has been denied.

Article 112 lists the Directives of State Policy, which include, inter alia:

- the creation of an economic environment encouraging individual initiative and self reliance among the people;
- the creation of conditions under which all citizens shall be able to secure adequate means of livelihood and opportunity to obtain employment;

⁶ This right is enshrined in the Universal Declaration of Human Rights, The International Covenant on Economic, Social and Cultural Rights Art 12, Convention on the rights of the Child Art 24 as well as African Charter on Human and Peoples' Rights Art 16.

- the provision of clean and safe water, adequate medical and health facilities and decent shelter for all persons;
- the provision of a clean and healthy environment for all;
- the recognition of the right of every person to fair labour practices and to a safe, healthy environment.

These articles suggest that the current Zambian legal system fails to adequately provide for economic, social and cultural rights to be justiciable rights. The constraints of the legal system hampers their full realisation of these rights as victims cannot obtain redress and compensation in case of rights' violations.

The Zambian Constitution's limits with respect to economic, social and cultural rights as human rights, in spite of the fact that their violation triggers the state's responsibility, is particularly worrying given the prevalent socio-economic context. Despite its position in the domestic legal system of Zambia, health is recognised internationally as a human right as evidenced by its incorporation into various international human rights instruments, treaties and declarations, foremost of which is the 1948 Universal Declaration of Human Rights (UDHR), Article 25:

Everyone has the right to a standard of living adequate for the health, and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in the circumstances beyond his control.

The recognition and application of the principle of health as a human right are significant in many respects:

- It signifies awareness of the relationship and interdependence of health with the other human rights such as civil and political, economic, cultural and social rights (World Conference on Human Rights, 1993). As asserted by Mann (1997), founder and former chairperson of the Joint United Nations Programme on HIV/AIDS (UNAIDS), the promotion and protection of human rights is fundamentally linked to the promotion and protection of the right to health since all forms of human rights violations have consequences on the health of the individuals. The right to health is an embodiment of two basic human rights - the right to life and the right to human dignity, which is the essence of human development.
- The link between health and human rights indicates the centrality of the right to health in the attainment of the development. To promote human life and dignity, the right to health must be held in highest regard by society. Since realising human dignity is the ultimate goal of development, health should be an essential component of any development program - GATS and TRIPs included.

For LDCs like Zambia, these principles are critical. Healthy and productive people are crucial to attaining development, while a healthy population is an important indicator of development. Thus, the right to health is both a goal of and a means to development (Simbulan, 1999). It is important therefore for the Zambian government to realise that developmental programmes on their own, at the expense of the population's access to health services and essential drugs, will not yield much. Thus, the realisation of the right to health has implications for development for the Zambian society at large.

Access to essential and affordable drugs is an integral part of the right to health. This right can come under threat in a regime where trade agreements operate. TRIPs, for instance, has been branded as a perversion of the concept of patents which were

designed to defend scientific merit not to restrict benefits accruing from scientific discoveries in the pursuit of profit (Human Rights Commission, 2003).

As the UN Committee on Economic Social and Cultural Rights (2000) explains:

The right to health contains both freedoms and entitlements. The freedoms include the right to control one's health and body including sexual and reproductive freedom and the right to be free from interference such as the right to be free from torture, non-consensual medical treatment and experimentation. By contrast, the entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

As already alluded to, all sectors of Zambian society feel the magnitude and impact of AIDS. About 1.2 million Zambians are living with HIV/AIDS and over 0.2 million of these need treatment now (IRIN PlusNews, 13 February 2006). Regrettably, most of them do not have access to drugs needed to treat disease or alleviate suffering. In 2003, WHO/UNAIDS estimated that Zambia's total treatment need was 140 000 people, and the WHO "3 by 5" treatment target was calculated as 70 000 people (based on 50% of estimated need). In 2004, WHO/UNAIDS estimated that Zambia's treatment need had risen to 149 000 people. As of September 2004, an estimated 13,636 people were accessing antiretroviral therapy (ART) in Zambia (13,555 through the public sector and 81 at a designated MTCT-Plus site). At the end of 2004, the CBoH reported that 15,328 Zambians were receiving ART, mostly through the public sector (UN and WHO, 2004).

The difference between the people needing treatment and those on treatment is high; therefore many people die for want of treatment. The major barrier to the needed treatments is high prices of drugs - a direct result of strong intellectual property protection. Article 30(f) of the TRIPS Agreement, for instance, limits compulsory licensing predominantly to supplying domestic market. Zambia lacks production capacity so that such compulsory licensing provisions confer not much benefit, but further act as barriers to essential drugs (Carroll, 2005).

The protection of patents offered by the TRIPs agreement unarguably results in excessive prices for essential drugs putting them beyond the reach of the poor majority in Zambia. The resultant excessive pricing of essential drugs is directly responsible for the premature, predictable and avoidable death of people living with HIV/AIDS (UN and WHO, 2004) – including the estimated 89,000 Zambian's that die of AIDS every year. Unless this is remedied, access to health care products necessary to protect and improve the health and lives of people living with HIV/AIDS, will remain a dream unrealised. By limiting access to drugs, the TRIPs Agreement protective provisions undermine the scientific gains which have made AIDS a medically manageable disease today.

In General Comment 14 (UN ESCRC, 2000) clarified that the state's responsibility include among other things 'ensuring that the privatisation of the health sector does not constitute a threat to the availability, accessibility, acceptability, and quality of health facilities'. Thus controlling the marketing of medicines explicitly addressed 'the failure to regulate the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others' (UN and WHO, 2004).

The pre-eminence of human rights over trade agreements cannot be over-emphasised. Article 103 of the United Charter confirms the pre-eminence of human rights obligations: 'In the event of a conflict between the obligations of the Members of the United Nations under the present Charter and their obligations under any other

international agreement, their obligations under the present Charter shall prevail.’ The United Nations Charter provides for civil and political rights as well as social, economic and cultural rights under which the right to health falls. It is critical therefore for any trade regime to facilitate development and human wellbeing if it has to attain any moral or political legitimacy. The Zambian government owes a higher duty to fulfilling its human rights obligations to its people especially the poor and vulnerable particularly the right to health.

In a nutshell, the right to health implies that the government of Zambia should be able to provide medical treatment to its people when they are sick and that they should be able to access essential drugs to treat ailments. The right to health implies that the government of Zambia have not only moral or humanitarian obligation responsibilities to undertake such measures to ensure access to essential medications and affordable health services, but also have legal obligations. When a legal obligation is not met the result is a violation (Yamin, 2003).

6. Are trade agreements and national laws promoting, inhibiting or neutral in realising the right to health?

As already discussed in this paper, the health status of most Zambians is very poor and the Zambian government still faces many challenges in trying to realise the right to health for its people. The major barriers to the realising the right to health include:

- poor economic performance
- poverty
- economic liberalisation due to International Monetary Fund and World Bank policies
- lack of adequate health facilities and personnel.

The operations of GATS and TRIPs in Zambia do not warrant an outcry as they have not yet had a major impact on the Zambian health delivery system. This work, however, demonstrates the potential that GATS and TRIPs have to impact negatively on the Zambian population’s access to health services. The Zambian legal system does not adequately establish a framework for the provision of affordable health services to the most vulnerable members of its population. No laws have been enacted to specially cushion the poorest members of the Zambian community from adverse effects of economic liberalisation and trade agreements.

The Zambian Constitution does not enshrine the right to the highest attainable standard of health, hence the people of Zambia have no recourse in the Zambian courts in the event of a breach. They cannot even challenge the government’s decision to enter into trade agreements on the basis that these agreements may undermine the people’s access to affordable medicines and health services. Further, Zambian health legislation does not provide for:

- the enjoyment of the highest attainable standard of physical and mental health;
- the creation of conditions that would ensure medical service and medical attention for all in the event of sickness.

The right to the highest attainable standard of physical and mental health (UN Committee on Economic, Social and Cultural Rights, 2000) is a fundamental human right, indispensable for the exercise of other human rights. Minimum core obligations under the right to health include to:

- (a) ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalised groups;
- (b) ensure access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone;

- (c) ensure access to basic shelter, housing and sanitation and an adequate supply of safe and potable water;
- (d) provide essential drugs, as defined under the *WHO Action Programme on Essential Drugs*; and
- (e) ensure equitable distribution of all health facilities, goods and services.

It is argued in this work that the major problem posed by GATS in the realisation of the right to health is the fact that it overrides any domestic law viewed as presenting barriers to trade. Global business interests have managed through GATS to impose binding, global and irreversible rules on services. In other countries, multinational corporations have shown a strong interest in reducing the cost of complying with the regulations they face in different countries (Sinclair, 2000). They do this at the expense of the right of locals to a life with dignity, particularly with regards to access to basic services like health care.

Sinclair (2000) argues that the major problem with GATS is that 'it practically covers all governments' measures', including laws, regulations and even unwritten practice. No government measure "affecting trade in services" - whatever its aim - is in principle beyond GATS scrutiny' (ibid). It is clear therefore that GATS affect democracy, taking away the people's right to govern themselves by threatening them with sanctions whenever they enact a law that goes against the aims of GATS.

It appears then, any laws Zambia may wish to enact to ensure universal access to services for its vulnerable population will not have much effect in progressively realising the right to health for its people since it will be under threat from GATS - especially in relation to health care delivery. Thus GATS (in conjunction with any law) can inhibit the progressive realisation of the right to health, since the principles represented by GATS violate any steps a country may take to progressively realise the right to health by restricting government actions affecting services through legally enforceable constraints backed up by trade sanctions (Chapman, 2002).

As the *Zambian Ministry of Trade* (2003) noted during ongoing GATS negotiations:

Zambia is currently undergoing a revision of its Investment Act and submissions are being received from the public on what they feel should go into the Act. In this regard, we have encountered a number of hitches as most of the submissions if accepted, will contradict our schedule of [GATS] commitments in its current form. For example, some of the submissions border on joint venture conditions for foreign investment and setting aside of certain sub sectors for locals ... Zambia is currently very cautious in its approach to the GATS negotiations considering the hitches we are facing in attaining our developmental objectives through the adoption of other policies and regulations.

This illustrates the dilemma GATS present to developing countries between improving the lives of their people and fulfilling their obligations in the global village.

Problems of access to health care and essential medicines are familiar in many parts of the developing world, Zambia included, arising from cost-recovery programmes based on user fees imposed as loan conditions by the World Bank and IMF. GATS takes this process one stage further through the commodification of health services for trade on international markets. Hilary (2001) argues that the increased involvement of foreign companies in the health sector of developing countries threatens to create more problems than it solves because GATS undermines a country's ability to regulate its health services: restricting domestic regulation in order to remove 'unnecessary' trade barriers threatens to drive down regulatory standards rather than raising them to provide the best possible guarantee of public health.

The problems presented by TRIPs on the realisation of the right to health for developing countries are well documented. The TRIPs Agreement in many developing countries, including Zambia, places a serious obstacle to the fulfilment of obligations under international human rights law, particularly those obligations contained in CESCR. Chapman (2002) argues that for intellectual property to qualify as universal human rights, widely accepted, its regime and implementation must be consistent with other internationally recognised human rights. The Committee on ESCR (2001) has noted that 'any intellectual property regime that makes it more difficult for a state party to comply with its core obligations in relation to health, food, education, or any other rights set out in the Covenant is inconsistent with the legally binding obligations of the state party'. Similarly, the UN High Commissioner for Human Rights (2001) has expressed concerns about the negative implication of strict patent rights on access to medications and enjoyment of the right to health.

The main public health implication of TRIPs is that it leads to higher drug prices. Patent protection increases the likelihood that prices for the patented product will be higher, especially in developing world where competition is limited. Price is an important determinant in access to drugs - a critical component of the right to health (Velasquez and Boulet, 1999).

Despite an argument presented in favour of TRIPs that patent protection is necessary for research and development, free trade policies and agreements are not addressing the obvious market failure to develop and market affordable drugs for diseases prevalent in the developing world like TB, Malaria and HIV/AIDS. In Zambia for instance, Malaria is the number one killer, accounting for 50,000 deaths a year, or 47% of all deaths in the country (Irin News Webspecials – Malaria). Drug companies have traditionally been reluctant to develop drugs for neglected diseases because the patients are too poor to pay for them, so there is no financial incentive for drug development (Trouiller et al, 2001).

The TRIPS Agreement however, allows for some flexibility, compulsory licensing, parallel importation and early working exception while incorporating the agreement into domestic legislation, not many countries of the developing world have been able to take advantage of these flexibilities. But on a positive note, the Zambian Patent Act includes compulsory licensing provisions:

- Under Article 37, after three years from the date the patent was granted, or four years after the application, whichever is longest a person who can show that he has been unable to obtain a voluntary licence on reasonable terms can apply to the Registrar for a compulsory licence on the basis that the reasonable requirements of the public for the invention are not being or will not be satisfied.
- Section 40 sets out provisions for the use of a patented invention by the government for the service of the state.
- Section 41 is probably the most useful section with respect to the import of generic pharmaceuticals. Under this section, the Minister can declare a "period of emergency", during which the government or a person authorised by the Minister has the power to make, use, exercise and vend the invention "for any purpose which appears to the Minister necessary or expedient". Possible purposes include "the maintenance of supplies and services essential to the life of the community" and "securing a sufficiency of supplies and services essential to the well-being of the community." (s. 40(2))

In September of 2004, the Zambian government declared a five-year HIV/AIDS emergency, opening the possibility to override patent protection of ART (Ntomba, 2004). The Zambian government has already granted a compulsory licence for the

manufacture of a triple dose combination by Pharco Ltd, a company incorporated in Zambia (Ministry of Commerce, Trade and Industry, 2004).

In some other cases, where some of these countries have indicated their willingness to invoke the exceptions (e.g. South Africa and Brazil), they have often faced serious opposition from developed countries that benefit mainly from the patentability on drugs. A strict patent regime, as suggested by TRIPs, is an impediment to access to HIV/AIDS treatment and a threat to the rights to health and life guaranteed under international and regional human rights instruments. Yamin (2003) notes:

The duty on the part of a state party to provide access to life-saving or life-sustaining medications would not only clearly seem to fall within the expanded notions of obligations deriving from the right to life, but has also explicitly challenged international human rights bodies to draw together conceptually the rights of life and health.

At the Doha WTO Ministerial Meeting (2001), it was resolved that the TRIPs Agreement 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, promote access to medicines for all'. Today, in some developing countries, efforts have been made to provide ART to people living with HIV/AIDS, but this is just for few people. With the exception of Brazil (where ART is available free for virtually all the infected people), countries are only meeting the needs of a minimal percentage of infected persons. In Zambia, for instance the number of people needing treatment exceeds by far the number of people receiving ART (Irin PlusNews, 13 February 2006).

In conclusion, it is imperative that Zambia, as a LDC with a majority of its population living beyond the Poverty Datum Line, provide reasonably priced health services and drugs. This report recommends that domestic national trade and intellectual property protection regulations must respect and abide by international human rights law. The human rights obligations of Zambia cannot be subordinated in the formulation of trade agreements or intellectual property regimes (UN Committee on Economic, Social and Cultural Rights, 2001b).

While GATS do not technically require withdrawal of the state from the provision of essential services, the logic of liberalisation of trade in services does not favour equitable provision of those services - especially health. While governments are elected to provide oversight to service provision, the legal requirements of the GATS continue to threaten effective state involvement in this regard. As negotiations under GATS continue, the Zambian government should apply caution and consult various stakeholders before committing any further sectors which may affect the enjoyment of human rights.

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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

EQUINET is governed by a steering committee involving institutions and individuals co-ordinating theme, country or process work in EQUINET:
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