

# **Implications of the GATS and TRIPS agreements for the Right to Health in Malawi**

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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 a Masters in Law, focusing on Reproductive and Sexual Health 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. The work was conducted as part of an internship for a Masters in Law, focusing on Reproductive and Sexual Health 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 Malawi.

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 access - especially in the case of life-saving drugs and affordable health services in developing countries. This has significantly affected the realisation of the right to health, 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 and 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

Malawi, a former British colony, gained independence in 1964. It has a population of 1,301,396 (CIA World Fact book, 2006 estimate). For 30 years, it was ruled under a dictatorship, until elections ushered in a multi-party democracy in 1994. A new Constitution (by Act No 7 of 1995), which became completely effective in 1995, legally marked the political transition.<sup>1</sup> The Constitution prescribes two sets of fundamental principles designed to guide the interpretation of other Constitutional provisions and inform subsequent legislation, policy initiatives and executive action. The first set of principles is constitutional and the second governs national policy.

With respect to health, the principles affecting national policy impose an obligation on government to promote the health and welfare of the people by enacting laws and policies that facilitate the provision of adequate, internationally acceptable health care.<sup>2</sup> Malawi, however, remains one of the poorest countries in the world, with:

- a per capita GNP of US\$210;
- 60% of the people earn less than US\$60 per annum;
- only 11% of the population living in major urban areas.

Malawi is a landlocked country and has a narrow economic base with no significant mineral resources and high costs of external trade. Consequently, it is heavily dependent on donor support (CIA, 2006). Despite some improvements made to the health care delivery system, the health status of the population remains relatively poor, due to:

- lack of financial and human resources;
- reduced donor support;
- increased demand for health services;
- the resurgence of diseases such as TB and malaria; and
- the escalation of the AIDS pandemic.

Malawi has a limited pharmaceutical manufacturing base and thus depends significantly on imports from foreign-based manufacturers (ibid). This is partly because of the chronic under-funding of the health sector. Health expenditure as a percentage of GNP in Malawi is among the lowest in Sub-Saharan Africa (Ministry of Health and Population, 1999b). Ayodele (2004) reports that throughout Malawi, there are less than 35 hospitals and one doctor for every 32,000 patients. Other health care personnel simply do not exist. The lack of good roads prevents the delivery of medicines in rural areas, clinics are few, and there are inadequate storage and refrigeration facilities once the drugs are delivered. Its health indicators are amongst the lowest in the world (see *Table 1.1*)

**Table 1.1: Health indicators for 2004 by country**

	<b>Kenya</b>	<b>Malawi</b>	<b>Zambia</b>	<b>Cuba</b>	<b>Britain</b>
Life expectancy at birth (years)	48	40.2	39.7	78	79
Maternal mortality rate (per 100,000 live births)	1,000	1,800	750	33	13
Under 5 mortality rate (per 1,000 live births)	120	175	182	7	6
Infant mortality rate (per 1,000 live births)	79	110	102	6.8	5

Source: UNICEF, 2004.

<sup>1</sup> It initially operated provisionally for one year effective from 18 May 1994.

<sup>2</sup> Section 13(c) of the Constitution.

Despite the gloomy picture, the government has taken steps to show that it is committed to improving the health status of its people. Malawi is a signatory to the Universal Declaration on Human Rights and has ratified among many other international conventions:

- the International Covenant on Economic, Social and Cultural Rights;
- the African Charter on Human and People's Rights; and
- the Convention on the rights of the Child.

All of these articulate Malawi's obligations and enshrine the right of Malawians to attain the highest standard of physical and mental health.

However, Malawi is also a member of the World Trade Organization (WTO) and bound by WTO agreements it entered into, including the General Agreement on Trade in Services (GATS) and the Trade Related Intellectual Property Rights (TRIPs). WHO and the WTO Secretariat (2002) argue that: "A liberal international trade regime, subject to reasonably stable and predictable conditions, improves the climate for investment, production and employment creation, and therefore contributes to economic growth and development. Generally, the health status of a country is affected positively by such growth."

This paper analyses the impact of specific trade agreements on the capacity of Malawi to realise the right to health. It argues that macroeconomic policies, especially unfair trade regulations enforced by the WTO favouring private capital and transnational corporations rather than people, potentially restrict the kind of initiatives countries can take to protect and promote human rights and, in this instance, the right to health (Chapman, 2002: 861). This paper aims to establish, using human rights lens, whether there is compatibility between:

- economic globalisation; and
- the fulfilment of human rights and governments' social responsibilities for the well-being of their citizens.

In practice, free trade has not been a guarantee of national development. It is therefore important to assess the impacts these negotiations may have on the access to and provision of healthcare services, especially for the poor populations, which may be the most heavily effected by freer trade.

As Chapman (2002: 866) states: 'In a situation of potential or actual conflict, where one of obligations is tied to effective enforcement mechanisms and sanctions (trade agreements) and the other is not (human rights instruments) it is easy to anticipate the outcome. And this situation, of course frames the current human rights concerns regarding the implications of TRIPS Agreement.' Where there is a conflict, enforcement of trade agreements weigh heavily against realising human rights.

## **2. Malawi's GATS commitments**

Malawi is one of the less developed countries (LDCs) which has signed GATS and has specifically committed itself to liberalise:

- business
- construction/engineering
- health and social
- banking
- tourism and travel.

Malawi has fully liberalised its health sector by indicating 'none' in the schedules for market access and national treatment for professional services. In essence then, Malawi does not place any restrictions on foreign suppliers in the domestic market

(EQUINET and SEATINI, 2003) and has committed itself to provide market access to other WTO member countries without any restrictions.

GATS broad definition of services has been widely criticised, as such broad definition presents problems from a human rights perspective since some sectors under GATS - like education and health services - have a human rights dimension. This may lead to increasing tension between international human rights law and international trade law (Balakrishnan, 2004). The agreement fails to differentiate between services that fall under its auspices and ones that fall under government authority and therefore not subject to GATS. For instance, governments under the international law regime, have a duty to provide free primary education and primary health care to its citizens. Under GATS, these rights are under threat.

Articles 1(3) (b) and (c) of GATS sets out a legal exemption:

*(b) "services" includes any service in any sector except services supplied in the exercise of governmental authority;*

*(c) "a service supplied in the exercise of governmental authority" means any service which is supplied neither on a commercial basis, nor in competition with one or more services.*

Many (e.g. Muroyi, 2001; Balakrishnan, 2004) have criticised this exclusion provision for being very narrow, despite WTO's claims that this exemption covers social security schemes and other public services such as health or education, provided under non-market conditions. The reference to non-market conditions is material to an understanding of the implications of GATS to developing countries like Malawi.

Because of the International Monetary Fund's (IMF) Structural Adjustment Programmes, Malawi introduced user fees for its health services; this can be construed as being run on a commercial basis and not in the exercise of governmental authority. Alternatively, the existence of two health systems, one that is free (in the public health sector) and one which charges high fees (the private sector), may lead to the inapplicability of the exclusionary rule in GATS since health will be provided "in competition with one or more service providers" and not "in the exercise of governmental authority". It is clear therefore that the exclusionary rule in GATS is inadequate to protect the health sector in Malawi from international trade pressures. The other effect of this is that the general obligations of GATS Article II, Most Favoured Nation (MFN)<sup>3</sup> and transparency in regulations (GATS Article III) will be applicable to the service concerned, even in the absence of any specific market access or national treatment commitments thereon.

The WTO claims that the 'right to regulate' is protected under GATS. Yet this depends on governments knowing how and when to make exceptions and impose limitations when committing sectors to liberalisation. This requires an unrealistic level of foresight and capacity which LDCs like Malawi do not possess. Furthermore, the purpose of the current GATS negotiations, according to Article XIX is to remove any scheduled government exceptions and limitations on commitments, through "progressive liberalization of services". The agreement is meant to reassure potential foreign investors that the regulatory climate will not change, which is why it is so difficult for countries to reverse decisions.

GATS article XIX (1) creates an internal dynamic among members to provide increased sectoral liberalisation commitments by requiring 'progressively higher levels of liberalization'. It will not be easy for Malawi to backtrack from the

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<sup>3</sup> The MFN clause obliges each member to accord 'immediately and unconditionally' to the service suppliers and service of any other member treatment no less favorable than that it accords to like service suppliers of any other country.

commitments made under GATS, although the WTO does not clearly state that withdrawal of commitments is a stringent and difficult procedure. Modifying or backtracking on the commitment, should a country wish to make its services regulatory regime more strict, can only be done:

- (a) three years after entry into force of those commitments; and
- (b) after negotiating to provide to its trading partners compensatory adjustments of liberalised commitments in other sectors (GATS Article XXI (1) and (2)).

The WTO Secretariat informed Zambia, which is undergoing a process of revising its Investment Act and is under pressure from the public to retract commitments under GATS, that “no country has for gone through the renegotiation process and it would be a complex issue for Zambia to go through’ (EQUINET and SEATINI, 2003). The same sentiments raised about Zambia apply equally to Malawi, illustrating the complexity of Malawi’s commitments under GATS.

### **3. Review of Malawi's TRIPs commitments**

TRIPs essentially protect intellectual property rights and lay down minimum standards of protection to which all countries must adhere. It covers the following areas of intellectual property:

- patents
- copyrights and related rights
- trademarks
- geographical indications
- industrial designs
- layout-designs, of integrated circuits
- trade secrets.

This paper specifically focuses on patents and how the mechanisms in patent law increase or inhibit access to medicines in Malawi, thereby affecting the realisation of the right to health.

Under TRIPs Malawi committed itself:

- to recognise patents for inventions in all fields with limited exceptions;
- not to discriminate with respect to the availability of patent rights;
- to grant patents for at least twenty years from the date of application;
- to limit the scope of exceptions to patent rights;
- to grant compulsory licenses only under certain conditions; and
- to effectively enforce patent rights.

As an LDC, Malawi has until 2016 to make legislation TRIPs compliant. But even though it does not have to implement the TRIPS Agreement yet, it has to comply on the basis of bilateral agreements. It is also likely that countries like Malawi will be affected by the TRIPs compliance of other countries that produce key generic pharmaceuticals, such as India. This means that Malawi cannot set TRIPs matters aside simply because the LDCs do not have to comply yet.

According to Correa (2000), in light of the high costs of research and development (R&D), TRIPs promote and stimulate health related R&D. Patent protection may influence foreign investment, technology transfer and research, especially joint research programmes and research to address local needs for developing countries. Patent protection also provides for government-sanctioned, limited-term monopolies as an incentive and reward for useful inventions. However, all these advantages have been criticised for being "theoretical", while in practice TRIPs application has

resulted in higher prices for drugs thereby restricting access for the poor and the marginalised (UN Human Rights High Commission, 2001).

Conforming to TRIPs by protecting pharmaceutical processes and products, poses special challenges for developing nations like Malawi. The way legislative reform is made to conform to the provisions of the agreement may have a significant impact on health policies particularly on people's access to essential drugs (Correa, 2000).

The TRIPs agreement and Doha Public Health Declaration (2001) affirms that "the TRIPs Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPs Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health, and, in particular, to promote access to medicines for all."

Malawi is therefore under obligation to make patent laws TRIPs compliant, so as to use general exceptions under WTO agreements to protect human rights when the implementation of trade agreements threatens human rights. However, many commercial and political disincentives continue to:

- limit the practical availability and utility of flexibilities such as compulsory licensing and parallel importation; and
- hamper the ability of poorer countries to ensure that TRIPs outcomes are consistent with their human rights obligations.

Further, the crisis of lack of drug development for neglected diseases (such as malaria, HIV and other infectious diseases mainly affecting developing country populations) demonstrates the limitations of the market-based justification for stringent intellectual property laws as an incentive for innovation.

#### **4. Are Malawi's laws conforming to or conflicting with GATS and TRIPs?**

The task of improving health services in Malawi, explained in government policies and laws enacted in parliament seems daunting. The government's overall policy goal in the health sector is to ensure that all Malawians remain in good health. According to the National Health Plan (1999-2004) (Ayodele, 2004) a number of policy measures and strategies have been formulated to achieve this goal, including:

- expanding the range and quality of health services focused on maternal health and children under the age of five years;
- increasing access to basic health care facilities and services;
- increasing, retaining and improving the quality of trained human resource and distributing them efficiently and equitably;
- providing quality health care services in all health facilities;
- strengthening, expanding and integrating relevant health services;
- strengthening collaboration and partnerships amongst the health sector; and
- increasing the availability and allocation of overall resources to the health sector.

Providing basic health care to the entire population, regardless of their socio-economic status, is at the heart of the Malawi health policy. While these aspirations are noble, their conformity with GATS and TRIPs is not very clear. For instance, its inspiration to retain and improve trained human resources can be easily frustrated by GATS which advocate for the movement of professionals among countries.



As an LDC and pursuant to TRIPs Article 66.1, Malawi is due to comply with the TRIPs general provisions by 1 January 2006<sup>4</sup>. However, Malawi has flexibility under recent WTO decisions (Paragraph 7, Doha Declaration, 2001) to reverse its legislation and delay the granting of pharmaceutical product patents until 2016. Regardless of these potential flexibilities, the discussion here focuses on the existing binding provisions of the Patents Act (1992), which are far from compliant with the provisions of TRIPs. The study focuses on issues relevant to access to medicines and notes where provisions of Malawian law vary from the standards provided for under TRIPs and, in particular, where it fails to take advantage of TRIPs flexibilities.

The Malawi Patent Act (1992) Section 29 grants protection on the first-to-file principle for sixteen years (with a possibility for extension) and renewal fees payable from the fourth year. This is not consistent with TRIPs which provides a twenty year patent protection period. Biological materials and biotechnology processes are not patentable in Malawian law, in conflict with TRIPs provisions. However, led by the Malawi Ministry of Justice, a process is underway to reform the Malawi Patent Act (1992) to incorporate articles required by the TRIPs Agreement<sup>5</sup>.

Malawi's patent legislation does not take advantage of key flexibilities available under TRIPs, the subsequent Doha Declaration (2001) or the Paragraph 6 Implementation Agreement<sup>6</sup>, although it does have some potential flexibilities built in. In fact, in relation to access to medicines, Malawi's entire patent regime can be described as TRIPs-plus because it prematurely provides patent protections for medicines.

It remains critical for Malawi to amend its national law to take advantage of the Paragraph 6 Implementation Agreement. Even though as an LDC, it is automatically eligible to use the agreement to import medicines, the agreement imposes obligations regarding notifications and issuing compulsory licences for import. To the extent that Malawi intends to source newer medicines from countries like India that must become TRIPs-compliant in 2005, those countries will ordinarily need to issue Paragraph 6 Implementation Agreement compulsory licence for export, but can only do so if Malawi likewise abides by the Agreement. Admittedly, non-predominant quantities might be imported via orthodox compulsory licences granted in India and unlimited quantities might be imported via competition-based licences, but the major route of future importation may well be pursuant to Paragraph 6 Implementation Agreement provisions.

The Constitution of Malawi does not enshrine the right to health as does, for example, the Constitution of the Republic of South Africa (1996) Section 27. However, it does enshrine the right to life which has implications for the right to health if interpreted widely. Recently, domestic courts across the globe have supported the assertion that a denial of the right to health may implicate on the right to life. For example, the Indian Supreme Court held that denial of the right to emergency medical care is a violation of the right to life guaranteed by the Indian Constitution (*Pachim Banga Khet Majoor Samity v State of West Bengal*, 1996).

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<sup>4</sup> Malawi has not requested any extension of the general grace period for the implementation of its TRIPs obligations i.e. that beyond pharmaceutical product patents, pursuant to Article 66.1 of TRIPs.

<sup>5</sup> For example, pharmaceuticals could be excluded from patentability until 2016 pursuant to paragraph 7 of the Doha Declaration.

<sup>6</sup> Under Article 66 governing transitional periods, Malawi is not obliged to implement any of the provisions of TRIPs, except for Articles 3 and 4, prior to 2006. However, its premature and thus TRIPs-plus patenting scheme is a result of Malawi's colonial legacy rather than of any bilateral or multilateral trade agreements or pressure.

The Constitution of Malawi provides that the state must actively promote the welfare and development of the people of Malawi by progressively adopting and implementing policies and legislation aimed at, inter alia:

- obtaining gender equality (by addressing such issues as non-discrimination, domestic violence and reproductive health);
- achieving adequate nutrition for all to promote good health and self-sufficiency;
- promoting adequate health care, commensurate with the health needs of Malawian society and international standards of health care;
- managing the environment responsibly to:
  - prevent environmental degradation;
  - provide healthy living and working conditions;
  - fully recognize the rights of future generations by means of environmental protection and the sustainable development of natural resources; and
  - conserve and enhance biological diversity;
- supporting the disabled through greater access to public places, fair opportunities in employment and the fullest possible participation in all spheres of society;
- encouraging and promoting the full development of children as healthy, productive and responsible members of society;
- recognising and protecting the family as a fundamental and vital social unit; and
- supporting the elderly through the provision of community services and encouraging their participation in community life.

The Malawi Constitution, Article 14 on the *Application of the Principles of National Policy*, provides that the principles of national policy "shall be directory in nature, but the courts shall be entitled to have regard to them in interpreting and applying any of the provisions of this Constitution or any law or in determining the validity of decisions of the Executive and in the interpretation of this Constitution". That is, the Malawian Constitution gives aggrieved citizens access to recourse through the courts of law, thereby making economic, social and cultural rights justiciable which is a good sign for the realisation of the right to health.

The Constitution also provides for:

- the right to personal liberty
- the inviolability of human dignity
- equality before the law
- children's rights
- women's rights.

All these rights implicate the right to health as provided in various international instruments and various human rights committees' general comments and recommendations. The Constitution also provides for the establishment, powers and composition of a Human Rights Commission, tasked with promoting the population's rights protected by the constitution and international human instruments to which Malawi is party. It is clear from the constitutional provisions that the government aims to promote adequate health care, commensurate with the health needs of Malawian society and international standards of health care.

However, fulfilling these aspirations can remain just a pipe dream considering the hindrances that international trade agreements present: by signing the TRIPS agreement, the government of Malawi bound itself to some provisions in the agreement which may affect the enjoyment of the right to health, in particular, through reducing access to pharmaceuticals and increasing their costs. This makes it difficult for the poor - the majority of the Malawian population - to access essential drugs. If Malawi is to be bound to its human rights obligations and follow the human rights approach, which focuses mainly on the rights of the most disadvantaged and marginalised, then it will be in conflict with its obligations under the trade agreements.

This is because drugs play a significant social role and are an integral part of the realisation of a fundamental human right - the right to health – and are thus classified as essential goods (Munot and Tyson, 2000).

Malawi has enacted competition legislation in the form of the Competition and Fair Trading Act 43 of 1998. Unfortunately this law's applicability to patents is rather unclear and according to Section 3 (d) of the act, is definitely not applicable to use, assignment, or licensing agreements. Given that such agreements are important features of patent rights in many countries and given the prevalence of abusive licensing, the wisdom of this exclusion is questionable. However, to the extent that the act provides remedies for other patent abuses, it may still be a valuable public policy tool for accessing medicines, especially if remedies include issuing compulsory licences that permit access to registration data and some degree of technology transfer. In that regard, this law may be considered TRIPs compliant.

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

This section clarifies the meaning of the right to health in Malawi in light of international and regional human rights obligations. It seeks to answer the question: 'What are the obligations of the Malawian government towards realising their population's internationally recognised right to health?'

The Malawian Constitution does not enshrine the right to health in the Bill of Rights, but rather it is included as a directive principle, to be used as interpretative guides and basic principles of administrative review, and not legally enforceable.

The right to the highest attainable standard of health, enshrined in many international and regional human rights instruments, is central to the protection and promotion of human rights. The Charter of the UN urges state parties to respect rights to a higher standard of living and solutions to international health problems (United Nations, 1945). Article 25(1) of the Universal Declaration of Human Rights (1948) provides that 'everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services'.

Although the Universal Declaration is not a treaty, it has been widely accepted as an authoritative document on human rights. The core provision of the right to health in international instruments is set out in Article 12 of the International Covenant on Economic, Social and Cultural Rights (1966) which recognises "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health". Article 12 (2) further provides for the steps parties to the covenant must take to realise this right, including those "necessary for the prevention, treatment and control of epidemic, endemic, occupational, and other diseases" and "the creation of conditions which would assure to all medical attention in the event of sickness".

This provision is wide and all-embracing, placing obligations on state parties to take active steps towards realising the contents of the provision. Similarly, the Preamble to the Constitution of the WHO (1949) gives a detailed and comprehensive explanation of the nature of the right to health and a definition of health:

*Health is a state of complete physical, mental and social well-being, not merely the absence of disease or infirmity. The enjoyment of the highest attainable standard of health is one of the fundamental rights of all human beings without distinction as to race, colour, and religion.*

The right to health is also enshrined in various international instruments<sup>7</sup> and regional human rights instruments. For example, the African Charter on Human and Peoples' Rights whose Article 16 (OAU, 1981) provides for every individual to enjoy: "the best attainable state of physical and mental health" and mandates state parties to take "the necessary measures to protect the health of their people".

Malawi is a party to all these agreements and therefore has obligations under these human rights provisions. Under international law, state parties to international human rights instruments are assigned the primary responsibility of assuring implementation and assuming three obligations:

- to respect
- to protect
- to fulfil (UN Committee on Economic, Social and Cultural Rights, 2000).

A states' first duty towards their citizens is to respect the right to health by refraining from adopting laws or measures that directly infringe upon people's health. States also have an obligation to adopt measures to protect the population from effects of policies imposed upon states by pharmaceutical companies, third party states and international organisations such as the WTO.

As a party to the International Covenant on Economic, Social and Cultural Rights (ICESCR) (1966) and human rights instruments, Malawi has made an undertaking 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 General Comment 14 (paragraph 43) that those minimum core obligations include access to essential drugs.

General Comment 14 (UN, 2000) sets four standards by which to evaluate the attainment of the various dimensions of the right to health: availability, accessibility, quality and acceptability. The committee further defines accessibility as:

- physical accessibility: "health facilities goods and services must be within safe physical reach for all sections of the population especially vulnerable or marginalized groups";
- economic accessibility: "health facilities, goods and services must be affordable for all"; and
- information accessibility: includes the right to seek, receive and impart information and ideas concerning health issues.

General Comment 3 (1992) also outlines Malawi's core obligations regarding the right to health, including to:

- ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalised groups;
- ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water;
- ensure for everyone access to the minimum essential food which is sufficient, nutritionally adequate and safe and to ensure their freedom from hunger;
- provide essential drugs, as from time to time defined by WHO's Action Programme on Essential Drugs;
- ensure equitable distribution of all health facilities, goods and services; and

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<sup>7</sup> The Convention on the Rights of the Child Article 24, The International Covenant on the Elimination of All forms of Discrimination Against Women of 1979 Article 12, The International Convention on the Elimination of All forms of Racial Discrimination of 1965.

- adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population.

These obligations are of paramount importance. Just as Malawi is bound by its GATS and TRIPs commitments, it is also obliged by International Human Rights law to fulfil concrete commitments made under various human rights instruments. Legal arguments however support the supremacy of International Human Rights Law over all other legal norms. The pre-eminence stems from Articles 55 and 103 of the United Nations Charter (1945) and the interpretation thereof in the Universal Declaration of Human Rights: 'In the event of a conflict between the obligations of members of the United Nations under the present charter and their obligations under any other international agreement, their obligation under the present charter shall prevail'.

The Doha Declaration (2001) supports this position and affirms that TRIPs "does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO member's right to protect public health and in particular to promote access to medicines for all".

The human rights community has been concerned about the detrimental impacts of drug patents and other intellectual property restrictions on access to affordable medicines and treatments. As noted above, the provisions of essential drugs, equitable distribution of all health facilities, goods and services, and measures to prevent, treat and control epidemic and endemic diseases are considered core human rights obligations for all countries, rich or poor.

In practice, human rights are interrelated and interdependent, since a violation of one is frequently a violation of another. In the Vienna Declaration and Programme of Action of 1993, it is reaffirmed that all human rights are universal, interdependent interrelated and indivisible. As such, the right to health implies that fundamental principles of human rights such as dignity, non-discrimination, participation and justice are relevant to issues of health care (Leary, 1994). Indeed, the conventions that express these rights, as well as national constitutions, are themselves interrelated and may be permeable.

The right to health has been closely linked with the right to life - the most basic of all rights (UN Human Rights Commission, 1982). For instance, the ICCPR committee in General comment 6 (1966) gives a wider definition of the right to life and defined the state's role in protecting human life to include obligations to: reduce infant mortality, increase life expectancy and eliminate malnutrition and endemics. The right to health is indivisibly linked to the inherent dignity of the human person and is therefore indispensable for the fulfilment of other human rights.

Trade agreements can, in most cases implicate, the principle of non-discrimination as far as it relates to the right to health, because the impacts of trade agreements differ in how they affect people of different economic and social standing within the population. While negotiating trade agreements, states must therefore pay attention to their potential impact on vulnerable populations. It is important to gauge not only the intentions, but also the results, of certain policies. For example, if the effect of a policy is to disproportionately impoverish women, the indigenous or other groups, this is discrimination, even if this was not the intention of the policy. The principle of non-discrimination regarding the right to health for a particular country cannot be separated from the now widely preferred notion of *substantive* over *formal* equality.

On a regional level, Article 4 of the African Charter on Human and People's Rights (1981) provides for everyone's right "to respect for life and integrity of his person". Interpreting this right the African Commission on Human and People's Rights found the government of Nigeria responsible for violating Article 4 because, among other things, pollution and environmental degradation attributable to government had risen "to a level humanly unacceptable and has made living in Ogoniland a nightmare" (Social and Economic Rights Action Centre v Nigeria, 2001). Yamin (2003: 333) argues that "the language of 'humanly unacceptable' and the notion of holding the government responsible for allowing oil exploitation to turn life into a nightmare suggests that given appropriate case, similar reasoning could be applied in the realm of access to medications and to the government's obligation with respect to the conduct of pharmaceutical companies." This argument can be further used to derive the right to health from the right to life enshrined in the Malawi constitution<sup>8</sup>, as according to *Morales v Guatemala* (2001) the arbitrary deprivation of life is not limited to the act of homicide but rather extends to the deprivation of the right to live with dignity.

## 6. The effect of trade agreements and national laws in realising the right to health

Any country seeking to provide adequate health care for its citizens should revisit its intellectual property laws in the light of the current global developments, particularly:

- the extent to which the government's legislative and policy programme has furthered access to essential medicines; and
- taken advantage of TRIPs flexibilities.

Like any democracy, the aspirations of Malawian people as enshrined in their constitution, legislation and government policies are directed towards ensuring a good life for all. As international trade agreements, concluded by governments on behalf of citizens, have implications for ordinary people at national level, they can impair the effectiveness of national legal instruments in realising these aspirations. This section analyses the implications of trade agreements in conjunction with national laws in realising the right to health for Malawians.

Section 211 of the Malawian Constitution provides that:

*...any international agreement entered into after the commencement of the Constitution shall form part of the law of the Republic if so provided by or under an Act of Parliament.*

This means that Malawi does not recognise the self-execution of international agreements and thus any obligations are only domestically enforceable to the extent that they are recognised by national legislation. It is the responsibility of parliament to ensure that any international agreement Malawi enters into is translated into national law. This is evidenced by the fact that although Malawi is a signatory to the WTO, its legislation has not been amended to reflect its WTO commitments.

Malawian Patent law is not TRIPs compliant. As a LDC, Malawi has until 2016 to make its legislation TRIPs compliant with regards to medicines. This study:

- focuses on issues of relevance to access to medicines;

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<sup>8</sup> Constitution of the Republic of Malawi Section IV article 16 provides that: "Every person has the right to life and no person shall be arbitrarily deprived of his or her life: Provided that the execution of the death sentence imposed by a competent court on a person in respect of a criminal offence under the laws of Malawi of which he or she has been convicted shall not be regarded as arbitrary deprivation of his or her right to life."

- notes where provisions of Malawian legislation vary from TRIPs standards; and
- shows where Malawian legislation fails to take advantage of key TRIPs flexibilities, the Doha Declaration (2001) or Paragraph 6 Implementation Agreement.

In relation to access to medicines, Malawi's entire patent regime is TRIPs-plus as it prematurely provides patent protections for medicines.

TRIPs pose formidable obstacles to the progressive realisation of the human right to health and the right to life, particularly in terms of access to medicines. By protecting, or indeed mandating, monopoly rights for at least twenty years, and stifling competition from lower-cost producers, TRIPs enable drug prices to be set high and to stay high. Yet the UN Commission on Human Rights (2002) in one of its resolutions, states that: 'Access to medication in the context of HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest status of physical and mental health.'

The International Covenant on Social, Economic and Cultural Rights (1966) Article 2(1) provides for:

- the progressive realisation of the right to health; and
- minimum core obligations for every state towards realising the right to health.

The state has an obligation to devote the maximum available resources toward progressively realising the right to health, while international trade agreements such as GATS and TRIPs effectively undermine the state's ability to fulfil its obligation, rather than facilitate its fulfilment.

Some sections of the Malawian Patent law have a bearing on access to medication thereby impacting on the country's potential to realise the right to health. Two elements of Section 18, "Refusal of application in certain cases" are of potential relevance to the question of access to medicines:

- Subsection 18.1(b) provides that the Registrar of Patents may refuse an application if "the use of the invention in respect of which the application is made would be contrary to law or morality". However, TRIPs Article 27.2 allows for exclusion of inventions from patentability on the grounds of 'human health', 'public order' or 'morality', but not "merely because the exploitation is prohibited by their law". Therefore, in its current form, subsection 18.1(b) may violate TRIPs Article 27.2, unless the challenged patentability and exploitation of the product is specifically linked to 'human health', 'public order' or 'morality'.
- Section 18.1(c) potentially impacts several intellectual property rights strategies commonly employed by the major brand name pharmaceutical companies to extend the life of their patents beyond the TRIPs-mandated 20 year term. For example, Section 30 *Extension of patent* provides for the extension of patent terms beyond the sixteen years provided for in Section 29. But this violates the provisions of TRIPs Article 33, which requires that the term of a patent "shall not end before the expiration of a period of twenty years counted from the filing date". However, Section 30 also exceeds the TRIPs requirements as they do not require any extension of patents beyond their basic term. Section 30 ultimately affects access to medicines because extending the life of pharmaceutical patents prevents early entry of cheaper generic equivalents.

In Malawi, the Central Medical Stores procures drugs and medical supplies required by public hospitals, then supplies them directly to public health facilities and centres. Section 21 of the Public Procurement Act No 8 of 2003) is of particular relevance to the issue of access to essential medicines. It stipulates that "procurement entities shall plan procurement with a view to achieving maximum value for public

expenditures.”<sup>9</sup> This provision, in other words, requires public officers to be prudent in their use of public funds and seek the most favourable market price. In the case of medicines procurement, achieving the maximum value might mean procuring generics instead of more expensive proprietary brands. But this provision not consistent with Malawi’s TRIPs commitments which, in effect, do not promote the use of generic drugs, casting into doubt the law’s usefulness in enhancing access to affordable medication.

The Malawian Constitution does not provide for the right to health but rather includes it as a directive principle, which means this right is not an entitlement and not justiciable. This position makes it difficult for citizens to make a claim to the state in the event of a violation. Malawians cannot take their government to task on the basis of their constitution for violation of their right to health.

GATS is one of many factors and instruments encouraging greater mobility of professionals. Although the agreement focuses on temporary movement of the labour force, it may lead to and facilitate permanent migration as well. The implications of increased mobility of nurses and doctors are particularly relevant to developing countries. In Malawi for instance, the patient doctor ratio is very low - currently pegged at one doctor per 32,000 patients (Ayodele, 2004). It will be a major challenge to improve health systems if large numbers of well-qualified professionals and graduates are attracted to positions in other countries.

The education of health professionals is relatively expensive, and in LDCs like Malawi, there is a lack of skilled personnel. For instance WHO (2004) estimates that there are a total of 3,094 nurses and 134 doctors in Malawi, which is rather low for a country with a total population of about 12,6 million. It is unlikely that the export of an educated health workforce is desirable for LDCs. Given the problem of "brain drain" of skilled workers from many countries, the value of remittances back is minor in compared to the loss of potential earnings. The brain drain of skilled workers is an issue in the context of the GATS. Malawi, one of the countries hardest hit by the HIV/AIDS pandemic, has a nursing staff deficit of 52.9 per cent (UN, 2005).

Many commentators have raised the possibility that GATS will threaten public funding of public health. This is because GATS raises the question of the capacity and role of government with respect to providing access to basic health care. For instance, if health is seen as a public function, can private providers or foreign providers help fulfil this public function, and if so, be eligible for the same subsidies? The concern is that public funding directed, for example, to public health institutions providing clinical primary health care, would be interpreted as an unfair subsidy by a private health service provider. There is concern that this might lead to a situation where public subsidies must be made available to private providers or, to a situation where public funding is decreased (Knight, 2002).

The benefits put forward for more liberalised trade in health services are based on the assumption that this would improve effectiveness in service provision. However, in the case of health systems, more commercialised systems tend to be more costly and less equitable. The focus on health care as an industry may easily lure attention away from the fundamental functions of a health system. The primary purpose of health services is to provide quality care for the sick, and preventive and promotive services to help people to become and stay healthy (Koivusalo, 2003).

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<sup>9</sup> This requirement is similar to the Global Funds lowest cost-pricing requirement. This means that grant recipients will be obliged to procure the lowest cost medicines that meet other standards concerning quality and legality (Baker, 2003: 50).



Therefore TRIPs and GATS Agreements do not, in any way, help Malawians realise the right to health, especially the poor who cannot afford private health care services. This goes against the provisions of the Alma Ata Declaration (WHO, 1978) which Malawi is party to, which provides for the provision of Primary Health Care to all the people without discrimination. Any laws or policies that would restrict access to medication by increasing prices are not compatible with this goal.

## 7. Conclusion

The implications for realising the right to health in Malawi in relation to commitments under the international trade agreements should serve as an example to other African states especially the least developed ones. In light of the implications of GATS and TRIPs for realising the right to health, the following recommendations are made:

- A sound regulatory framework for public and private service providers should precede or accompany liberalisation. Developing states should realise that macroeconomic trade policies, particularly unfair trade terms imposed on them by the WTO, have substantially increased poverty and inequality between and within countries. Government delegates must be armed with relevant information when they go to trade negotiations.
- Since health care delivery is a fundamental human right under international human rights law, states must retain their “policy space” and not make far-ranging commitments on services affecting health that they cannot go back on.
- States must assess the domestic and international implications of service liberalisation before making commitments. They should undertake social and human rights impact assessments and consult with civil society to make informed commitments under GATS and TRIPs. As Machedze (2003) says: "There are dangers in signing agreements and/or entering into negotiations without adequately consulting the various stakeholders. TRIPs and GATS have far reaching implications for the health and food security of African countries."

The importance of the right to health in international law cannot be over-emphasised: numerous international human rights treaties – many of which have been widely ratified - recognise this right. It is critical that developing countries be vigilant in matters concerning commitments they make on behalf of their people which have human rights implications. More particularly, the state, in conforming with its obligations to its citizens, should:

- guarantee access to food and water, which are important determinants in realising the right to health;
- not undertake frantic privatisation, encouraged by international financial and commercial institutions, in diverse sectors such as water, agriculture, health. Privatisation in Malawi, which predates GATS, has contributed to the disintegration of the health service delivery system. As Hong (2000) argues: ‘The World Bank and IMF through SAPs, have successfully:
  - destroyed domestic economies, disintegrated societies;
  - enhanced the integration of countries into the global free market;
  - increased the dependence of indebted countries on the North for their survival;
  - empowered the role of the Trans National Corporations in controlling their economies;
  - facilitated the spread of corruption; and
  - increased poverty and hunger and a deterioration in health in these societies.’

WHO should appoint a commission to report on obstacles to access to drugs, including trade rules and TRIPs, and to explore alternative arrangements, which place access to drugs as an entitlement to be guaranteed by the state and supported

by the United Nations. TRIPs serves to strengthen the hand of giant pharmaceutical companies, resulting in excessively high prices, and this does not serve the interest of the world's poor, most of whom are resident in the developing world, nor does it promote and protect of the public health of developing nations.

Despite primarily serving the interest of the industrialised nations Articles 30 and 31 of TRIPs do offer limited benefits to developing countries through the provisions for exceptions to the rules, and the mechanism for compulsory licensing in the case of abuse of patents. These mechanisms are the only possible means to facilitate greater access to life saving drugs, but they are not easy to implement. Therefore the main challenge facing the developing world in relation to the TRIPs remains: the need to ensure that accessibility to life saving medication does not become casualty of intellectual property rights protection remains the world's greatest challenge.

It makes economic sense for developing countries to invest in the health of their people because as the World Bank (1993) concludes: "Improved health contributes to economic growth in four ways:

- it reduces production losses caused by worker illnesses;
- it permits the use of natural resources that had been totally or nearly inaccessible because of disease;
- it increases the enrolment of children in school and makes them better able to learn; and
- it frees for alternative uses resources that would otherwise have to be spent on treating illness.

Developing countries should therefore be concerned with placing importance on health issues because, among other things, it makes economic sense."

Paragraph 4 of General Comment 14 on the right to health reminds us that the right to health embraces a wider range of socio-economic factors that promote conditions in which people can lead a healthy life. This extends to the underlying determinants of health, such as food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions and a healthy environment. The Declaration of Alma Ata in 1978 explicitly recognised structural inequalities and macroeconomic factors as determinants of poverty and therefore of population health status, and called for a New International Economic Order. At the turn of the century, twenty years more evidence of the negative health effects of free market neoliberalism is available (Hong, 2000). In terms of GATS and TRIPs, and options for developing countries, caution is the operative word. This caution should extend to services that are important to the determinants of health, such as water and sewage treatment. Before entering into any into trade agreements that have potential to force changes in government policy, governments have an obligation to consult with the public and to take measures to protect the right to health in general and access to medication in particular (Joseph, 2003).

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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
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- 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

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