

Protecting rights of access to essential medicines under trade and market policies: The Tanzania case study

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

Executive Summary

This study examined and analysed how, through the General Agreement on Trade in Services (GATS) and the Trade Related Intellectual Property Rights Agreement (TRIPS), national policy options that support equity in health are threatened. More specifically the study examines how we can we protect rights of access to essential medicines under trade and market policies.

The report was produced under a programme of the Regional network for Equity in Health in East and Southern Africa (EQUINET) with Centre for Health Policy South Africa, SEATINI Zimbabwe and TARSC. The audit was implemented following an EQUINET training workshop on trade and health held in Tanzania in 2005.

A qualitative methodology was used with desk review of relevant literature. Additional information was collected through key informant interviews in the health sector including the Ministry for Health, Tanzania Food and Drug Authority, the Business Registrations and Licensing Agency (BRELA), Medical Stores Department (MSD), pharmaceutical companies, pharmacists and other medical practitioners.

The report outlines that the noble objectives of equitable accesses to health care services generally and specifically to essential medicines, which were implicit in the Tanzania's Ujamaa policy, were jeopardised by the economic crisis that befell the country in the late 1970s and early 1980s. The prescribed strategies by Breton Woods Institutions to address the economic crisis included a wide range of economic and social reforms. They included introduction of cost sharing in the public health care facilities and liberalisation of health care provision to allow the private sector, which hitherto was restricted. Besides increasing the degree of inequality in access to essential medicines, the adoption of the health sector reforms, which were not participatory in their formulation process, increased the difficulty of access among poor people and other marginalised groups of people, i.e. expectant mothers, children, the elderly and people living with HIV/AIDS. The report explores the flexibilities in the World Trade Organisation's (WTO's) General Agreements on Trade in Services (GATS) and Trade Related Intellectual Property Rights (TRIPS), so that Tanzania's equity objectives in access to essential medicines could be safeguarded, even within the increased integration in the global economy.

We conclude that equitable development, which goes hand-in-hand with equitable access to essential medicines, is a choice. If countries like Tanzania choose to develop and share the benefits of development equitably, then equitable access to essential medicines can be achieved. Tanzania's long upheld equity objectives need to be safeguarded even as the world becomes increasingly integrated. This is important to achieve the health related millennium development goals (MDGs).

Inequity in access to essential medicines that has progressively been apparent in the country following the reforms in the health sector could be reversed by introduction of equity safeguarding regulation in the sector. The fact that under GATS countries have the possibilities of choosing to make commitments only in some sectors, and to set the limits as required to deal with various policy concerns, makes it possible for countries like Tanzania to maintain its long upheld equity objectives in all spheres of life including equitable access to essential medicines.

1. Introduction

The objective of this study is to examine and analyse how, through the General Agreement on Trade in Services (GATS) and the Trade Related Intellectual Property Rights (TRIPS) agreements, national policy options that support equity in health are threatened. More specifically, the study examines how we can protect rights of access to essential medicines under trade and market policies.

The report was produced under a programme of the Regional network for Equity in Health in East and Southern Africa (EQUINET) with Centre for Health Policy South Africa, SEATINI Zimbabwe and Training and Research Support Centre (TARSC). This programme aims to build capacities in state, legislative and civil society institutions to know, understand, analyse and promote public sector equity oriented health systems within trade and investment policies and agreements. The audit was implemented following an EQUINET training workshop on trade and health held in Tanzania in 2005.

The methodological approach employed to achieve the study objectives is qualitative in nature and constituted mainly of an intensive desk review of the literature, i.e. documents on health policy, health reforms, GATS and TRIPS agreements, various reports and papers related to health and GATS and intellectual property rights in Tanzania. Additional information was collected through key informant interviews in the health sector including the Ministry for Health (MoH), Tanzania Food and Drug Authority, the Business Registrations and Licensing Agency (BRELA), Medical Stores Department (MSD), pharmaceutical companies, pharmacists and other medical practitioners.

2. The Tanzanian health system

The United Republic of Tanzania, with an area of 940,00km², is divided administratively into 26 regions and 131 districts (*note that new districts have recently been formed, this will increase number of districts in the country*). The total population is about 34.5 million, 980 000 of whom are from Zanzibar (National Bureau of Statistics, 2002).

Communicable diseases are the major cause of morbidity and mortality in Tanzania. Health facility based data compiled in the Health Statistics Abstract (2002a) shows that the leading 5 killer diseases among the population aged 5 years and above were malaria (22%), clinical AIDS (17%), tuberculosis (9%), pneumonia (6.5%) and anemia (5.5%). Life expectancy at birth stands at 51 years and the infant and child mortality rate (per 1000 live births) is 153. Total fertility rate is currently 6.3 while the annual population growth rate is 2.9 percent. The literacy rate stands at 70%. By 2004, Tanzania had a total of 217 hospitals, 434 health centres and 4 408 dispensaries. The doctor-patient ratio stands at 1:25 000 (National Bureau of Statistics, 2005).

Tanzania has a fairly well-developed health care delivery system. By 2001, Tanzania had a total of 4 990 health facilities of which 3 060 (61%) were government owned through the ministries of Health and Regional Administration and Local Government and 1 930 other facilities owned by non-governmental organizations, parastatal organizations, voluntary agencies, faith based organizations and the private-for-profit sector. About 70% of the population is within a distance of 5km of health facility and 90% within 10 km. Health services are organised at three levels: tertiary, secondary and primary with six (6) tertiary hospitals in the country. The secondary level consists of regional hospitals, which provide both basic and specialized services. The primary level

consists of dispensaries, health centres and district hospitals. At the regional level, the Regional Medical Officer (RMO) is the overall in-charge of all health services within the region, while at the district level health services are provided and managed by the local government under the supervision of Council Health Management Team (CHMT) headed by the District Medical Officer (DMO). Other members of the CHMT include the District Executive Director (DED) district pharmacist, district nursing officer, district health officer, district health secretary, district laboratory technician, district education officer. Members of the CHMT may co-opt other members from the district council as it deems fit, depending on specific needs of the district.

During the Ujamaa (Socialism) era, the government was the major financier of health services with a strong emphasis on Primary Health Care (PHC) services. The emphasis on PHC led to massive expansion of health services in rural areas. Due to the economic recession of 1970s and 80s, the health system experienced inadequate resource allocation leading to the deterioration of health services. The government responded by introducing a reform process which included other financing options such as community health funds (CHF), user fees and national health insurance fund (NHIF). However, the government continues to be the major financier of health services with support and contributions of other players such as the local government, voluntary agencies, religious organizations, executive agencies, communities, private organizations and development partners (Ministry of Health, 2002b).

2.1. National health policy objectives on access to medicines

Access to essential medicines has been one of the implicit policy objectives in the health sector since independence. It is indeed one of the important aspects of the Tanzania National Drug Policy (1993). The national drug policy in Tanzania is a dynamic reflection of the National Health Policy since it attempts to operationalise the general policy statements enshrined in the health policy document. The overall objective of the National Drug Policy (1993) is to provide free and comprehensive basic health services to all Tanzanians at affordable costs. This is in line with the constitution of Tanzania, which provides for the right of every individual to life and enjoyment of good living standards. The overall objective of the drug policy seeks to contribute to the attainment of the right to life by ensuring free and comprehensive health services to all Tanzanians. This is intended to be achieved through making available to all Tanzanians at all times the essential pharmaceutical products which are of quality, proven effectiveness and acceptable safety, at a price that the individual and the community can afford.

Preventive and promotive healthcare is emphasized, as opposed to curative care. The policy seeks to ensure the availability and accessibility of essential drugs and basic health services near to the people. In this regard, the government is encouraging private sector participation in the provision of healthcare and particularly in ensuring access to essential drugs. Private pharmacies and drug shops were established following the trade liberalisation, which has gone hand in hand with health and trade reforms that began in the 1980s. For goods such as drugs/medicines, trade liberalisation may mean reducing tariffs and reducing regulation or a reduction in the role of the state and an increase in the role of the market. In Tanzania the liberalisation of drug sector has ushered in a mushrooming of private drug outlets and local manufacturing companies.

Liberalisation of trade in drugs followed the structural adjustment programmes (SAPs) introduced in the 1980s. This put into play companies dealing in importation and supply

of drugs manufactured abroad. It is important to note that apart from regulating international controls such as border control measures, GATS is also concerned with internal/domestic regulation of services and service supply and this may affect the way locally manufactured drugs and related health products are traded. As pointed out by Hilary (2001), GATS places more emphasis on the trade significance of health services and not the social function of health services. It appears that the social function advocated by national governments may be in sharp contrast with the spirit of GATS.

The drug policy aims at developing and supporting the national pharmaceutical industries with a view to increase local production, thus encouraging self reliance (MoH, 2000). In this regard the government seeks to ensure the availability of drugs/medicines for the population by avoiding the higher costs of importing drugs, which could interfere with the policy aim of achieving universal access to medicines. Following bilateral agreements with countries, ARVs will now be imported. In 2003, the government of Tanzania through MoH entered into agreement with foreign manufacturing companies to help ensure anti retroviral drugs (ARVs) become available to more people in need. The move aimed at increasing access by reducing prices of ARVs from Tanzania shillings (TShs) 80,000 to TShs 35,000 (US\$71 to US\$31) per dose (Mtanzania, 2003:1).

Some options that can be applied to curtail costs and improve access to drugs are encouraging local production of drugs and developing an essential drugs list. Local production of drugs, particularly those drugs for major diseases of public health importance such as AIDS, malaria, and tuberculosis, will help ensure drug availability and thus make easier the process of drug selection, procurement, distribution and quality assurance. Local production of drugs is a locally supported move as it is one way of developing domestic industrial capacity and providing employment opportunities. Rights groups and consumer association are likely to support such a policy move. However, encouraging local production of drugs may not be in the interests of multinational pharmaceutical industries as they are far less concerned with issues of equity in access to essential medicines and it is perceived as a threat to their own industries abroad. Therefore in terms of policy making and implementation the promotion of local production of drugs will be low politics issue since it will receive the support of most Tanzanians as individuals as well as human rights and consumer associations. Furthermore, this move has little public involvement as it involves bureaucrats at the central governmental level.

The concept of essential drugs underlies the selection of drugs in that those drugs of utmost public health importance are given first priority. One of the criteria of essential drug selection is cost and price. Drugs will be selected and distributed as generics, and the number of drugs in the market will be restricted to two brand name products for each drug on the national drug list. This may not be the case today since there may be more than two brand names for a generic drug on essential drug list. For instance, there are more than two brand names for anti-malarial drugs currently in use in Tanzania.

3. Effect of trade agreements on access to medicines

The World Health Organization (WHO) estimates that currently one third of the world's population lacks access to essential drugs. In the world's poorest countries like Tanzania, this figure rises to over 50% (WHO/WTO, 2000). The World Health Organization defines essential drugs as those that appear on WHO's model list of

essential drugs which satisfy the health care needs of the majority of the population, should be affordable, and represent the best balance of quality, safety and cost for a given health setting.

In Tanzania the previous practice was to have a uniform list of essential drugs being distributed monthly from the central medical stores to all health facilities across the country. This practice was later found to be inappropriate since the same types of drugs were distributed regardless of the health problems existing at a particular locality. In the practical sense, this may lead to waste of resources as those drugs that were not needed in a certain place were dumped. The MoH has now introduced the so-called 'indent system' whereby health facilities through local authorities request drugs according to the disease profile of a particular district. In this way, only those drugs needed for existing health problems are supplied. The list of essential drugs is the same across the country but each district authority has a mandate to procure drugs based on the most important health problems in a district.

Access to medicines, among other things, depends on four critical elements: affordable prices, rational selection and use, sustainable financing and reliable supply systems. However, in health and trade discussions, the focus is usually on drug prices (WTO/WHO, 2002). Drug prices are seen to be more of a threat to equity in access and countries need to take measures to address this issue in order to make drug prices more affordable. WHO estimated that in most developing countries, 25 to 65% of total health expenditures is for pharmaceuticals, while government health budgets are too low to purchase enough medicines and poor people cannot afford to buy them on their own (WHO, 2000). The per capita public health expenditure in Tanzania stood at less than US\$10 by the year 2001 (MoH, 2002b). In the context of access to medicines this means that a minimal range of drugs is available, given the low level of affordability - especially branded drugs, those for which no or few generics are available and those not in a country's essential drug list.

3.1. GATS and access to drugs

The GATS is one of the WTO tools to regulate the international trade in the services sector. A country may enter into full or specific agreement with WTO depending on how it is classified on the basis of economic development. The GATS is a complex agreement because it regulates a very difficult area, trade in services and when fully implemented, governments will have no or little restrictions on trade in services. GATS will remove Tanzanian government authority to regulate the health sector in terms of movement of human resources for health as well as the number and distribution of health care facilities. A country under full GATS commitments will have health related implications with regard to four areas namely; market access, national treatment, general exception and domestic regulation. These are discussed below.

In terms of *market access*, Tanzania can not limit the number of health facilities in a particular location, say in a certain district or region of the country. This may have negative implications for those areas that are already historically marginalised in terms of access to health services. For example, Dar es Salaam, Arusha and Kilimanjaro regions generally have relatively better and many health facilities (of various levels) than other regions of Tanzania. These regions are also doing better economically with various local and international investment projects. For instance, the Dar es Salaam region has 26 hospitals, six of which are government owned, one is parastatal owned and 19 are

privately owned. Ruvuma region in the south of the country has nine hospitals, of which, three are government owned and six are owned by voluntary/faith based organizations (MoH, 2002a).

Therefore, under GATS, if the country enters into a WTO agreement little that can be done to address uneven distribution (particularly the rural-urban dichotomies) of health facilities. The state might have minimal or little role in regulating this phenomenon. For historical reasons, some areas (e.g. in southern Tanzania) are relatively marginalised in most socio-economic development issues including health. This is a high politics issue since it requires government mobilisation of a lot of financial and human resources. And it affects different actors who shape the provision of health services such as doctors and nurses who may try to resist the reallocation to areas they consider less privileged.

Health is related and affected by other factors which may affect (either positively or negatively) equity in access to health services. A region with poor roads and communication infrastructure will be negatively affected compared to a place where communication infrastructure is better. In other words, it might difficult to tackle the structural inequalities that exist within the health system. Therefore even if the government succeeds in improving access to drugs, it might still be constrained in its ability to improve access to service through legislation or improving physical access to services by improving infrastructure such as roads and allocating health workers to the “marginalised” areas in the country.

Any service provided by both the government and private sector is likely to be included in the GATS, and also included are those services provided by government on commercial basis. The Tanzanian government has a central medical store known as Medical Stores Department (MSD) which supplies drugs to government and mission (faith-based) hospitals all over the country. Under full GATS commitments, and regardless of what the concept “commercial” means, such companies may fall under trade obligations pertaining to drug supply within the country since GATS is not limited to the national level only, but also the local and regional level within a particular country. In terms of policy analysis, this is a high politics affair since it is technically complex and administratively taxing. The MSD may be enjoying “preferential treatment” which it may not be ready to relinquish. The costs of implementing this policy action are concentrated in the government; similarly the benefits are not clearly seen to be dispersed to most of the population in need of essential drugs.

GATS provide for equal or same treatment to foreign service providers operating in a particular country. This means that a service provider from a foreign firm will be accorded the same treatment as a Tanzanian service provider or formally equal. For example, if a domestic health insurance company such as National Health Insurance Fund (NHIF) is given preferential treatment by the government, the same treatment should be given to a foreign insurance company operating in Tanzania. This could mean that local companies need to be more equipped to compete with big multinational companies dealing in drug and related health services. Local experts in trade, business law and health should also be dynamic and creative in dealing with trade disputes at the local level and in providing proper interpretation of the legal and health implications of GATS to the peoples of Tanzania.

There are exceptional cases whereby a government can take measures deemed necessary to protect human health. However, the government must build a case to

demonstrate that such a measure is “necessary”. A necessary measure applied in one country will differ from that applied in another. Under GATS commitments, the government must ensure that such measures do not restrict trade, as that will be against GATS principles.

The GATS has four different modes of service delivery:

- consumption of services abroad
- cross-border supply of services
- presence of natural persons
- commercial presence.

A country like Tanzania may enter into specific commitments for each of these modes of service provision. Regardless of the modalities of commitments, there are rights and obligations. The general obligations apply to all countries and all services, including health services and drug supply services.

On the other hand, a member state may make specific commitments which refer to specific sectors open for foreign trade (as listed in a schedule of commitments). But these are to be negotiated at the WTO. With the low negotiating power of developing countries, it is unlikely that many of these countries will be able to reach “bottom up” agreements with WTO in order to safeguard public health interests. We have less potential to export health products to other countries and are more likely to lose human resources because health workers may freely migrate within and beyond the country to look for greener pastures in other more developed countries. In terms of policy options, this could mean staff shortages, increasing workload on remaining staff and changes in training/human resources policies to reflect such realities. Poor working conditions coupled with meager salaries may push health workers away from the public sector to the private-for-profit sector or into other health-related occupations.

In other words, the establishment of health facilities by foreign companies could also create an internal brain drain since it is likely that the private establishments (for profit as well as non-profit, especially those NGOs that offer competitive salaries and conditions of employment) will recruit those working in the public sector. These and other possible implications (such as increased workload on public sector health staff, low salaries, low staff morale and lack of motivation) may require a review of policies to cater for the changes that can have serious consequences in terms of equity in access to health services and particularly in access to essential medicines.

3.2. Effects of trade agreements on national policy objectives

Under GATS agreements a country is supposed to treat foreign services and service suppliers in no less favorable terms than those given to domestic ones. The national drug policy emphasises the need to support local pharmaceutical industries in order to meet the goal of self reliance in drug/medicines supply in the country. With the full commitments to GATS this objective might be compromised as it goes contrary to principles of protecting foreign services providers/suppliers in the same way or sometimes even favoring foreign companies. It is worth noting that under national treatment any attempt to foster local production is potentially under threat under the existing interpretations of GATS.

Recently, a trade row developed between Tanzanian business people and their Kenyan counterparts over the unilateral decision by Kenyan government to remove tariffs on imported drugs without consulting other East African countries. The Tanzanian business people were reported to be planning to sue Kenya over its decision to suspend the customs union common external tariffs (CET) of 10% on pharmaceutical products imported into Kenya (The East African, 2005). This Kenyan decision was reported to mean that more and possibly cheaper drugs from multinational pharmaceutical companies would be imported into Kenya, jeopardizing the survival of local pharmaceutical companies in Tanzania. This highlights the difficulty of adopting a regional approach versus a country-level strategy. For Kenya accessing cheaper drugs immediately has disadvantages for local production regionally, unless specific measures are put in place to deal with this.

The ideal would be to have a regional approach to access to medicines. This is not simple, however, as within regions some countries are at a more advanced stage of local production than others.

Those countries with greater capacity and at more advanced stages of development appear to be better placed to take on the challenges posed under respective GATS and TRIPS agreements. It will be interesting to see how such trade rows are treated under GATS and TRIPS and how they could impact on access to medicines. In terms of access, this could create availability of drugs and possibly lower drug prices thus making them more affordable to more people. Under GATS, a country cannot limit the number of suppliers and therefore Tanzania may explicitly state in its investment and trade policies that foreign suppliers of health services including drugs, are welcome to operate in the country. As noted above the trade offs between immediate, lower cost access and longer term domestic production then need to be assessed and managed.

3.3. TRIPS and access to essential medicines in Tanzania

Tanzania is a member of WTO and therefore to the TRIPS Agreement. As a least developed country (LDC), Tanzania is given until 2006 to be TRIPS compliant (WIPO, 1997). Tanzania and other LDCs has sought an extension of the transitional period up to January 2013. According to the Doha Declaration (WTO, 2001) compliance in the field of pharmaceuticals has been extended to 2016.

The category of industrial property which is relevant to pharmaceuticals is the industrial property that is administered in Tanzania by the Business Registrations and Licensing Agency (BRELA) with the following legislations: Patent Act. No. 1 of 1987; Trade and Service Marks Act of 1986; and the United Kingdoms Design Ordinance Cap. 219 of 1936. The Ministry of Industry and Trade is responsible for WTO and TRIPS Agreement issues. Currently, BRELA is reviewing legislation to have a single Act dealing with industrial property, which will be TRIPS compliant and include patents, trade and service marks, and industrial design.

The current Patent Act No. 7 of 1987 (URT, 1987) provides for pharmaceutical patenting. Section 7 (2) (d) excludes patenting of methods for treatment of human or animal body by surgery or therapy and diagnostic methods, but not products for use in these methods. In this case, with reference to medicines, the patent act is TRIPS-Plus. The proposed new Industrial Property Act will exclude patenting of pharmaceuticals till 2016. As far as access to medicines, the Patent Act provides only one provision of

compulsory license for products of vital importance. Section 54 gives the Minister power to direct that patented inventions concerning certain kind of products or processes be declared of vital important to public health, so a compulsory license may be granted.

The Patent Act does not include the flexibilities offered by the TRIPS Agreement for access to essential medicines such as parallel importation. This legislation has not provided many options for access to medicines, but since it is being reviewed, it will be very important for the new legislation to take on board the flexibilities offered by TRIPS, the Doha Declaration and the WTO General Council Decision of August 2003 (WTO, 2003). The Ministry of Industry and Trade has started some initiatives to see how Tanzania should be prepared to deal with the TRIPS Agreement. In a February 2005 workshop on “WTO Agreement on trade related intellectual property rights with emphasis on public health and other aspects”, it discussed the challenges Tanzania will face to ensure access to essential medicines.

The current drugs procurement system in Tanzania did not involve issues of intellectual property as many of the registered drugs by the TDFA are generic. The problem arises for new drugs, which will be patented in those developing countries which were the suppliers of the generic drugs. This importation will involve issues of intellectual property and hence the need to use safeguards provided by the TRIPS Agreement, which must be included in the new industrial property legislation. So it is very important for the MoH to be aware of these challenges. The MoH should be aware of the intellectual property system under the TRIPS Agreement and its options offered for health care so that it could take advantages to ensure access to medicines. Hence, close collaboration between the MoH and the Ministry for Industry and Trade, and between BRELA and TFDA is needed.

Therefore, in reviewing the National Health Policy, it is important to incorporate intellectual property issues, clearly stating the options offered by the TRIPS Agreement to ensure access to essential medicines. The Industry and Trade Policy should also incorporate health care issues, especially those to be affected by the TRIPS Agreement on pharmaceuticals.

4. Policy making on access to medicines and their implications on national policy objectives

Drug policy is made by the MoH, through its various organs under the coordination of the chief medical officer. The chief medical officer is the chairperson of the Pharmacy Board. The Pharmacy Board is the organ responsible for general oversight of the ethical and professional aspects of pharmacy practice in Tanzania (Interview with Pharmacist-university lecturer, July 2005). However the views of the pharmacist were in more limited in scope to the experiences I got from another health systems expert from Muhimbili University College of Health Sciences. It was revealed that policy formulation and health legislation is normally done at the central level of the ministry.

There are two ways by which any health related policies (including drug policy) are made. Policy can be made as a result of:

- Public outcry over a health issue, highlighted by civil society organisations, NGOs, the MoH through the minister responsible, or from research findings on that particular

issue. For instance, the government of Tanzania has decided, based on public outcry and research evidence, to change from sulfadoxin pyremethinine (SP) as a first line malaria drug to the new combination therapy known as coartem.

- Policy review whereby an existing policy is reviewed to incorporate new development as time goes by. This may be done when the experts find that the existing policy is not in line with current realities and developments. For example, the National Drug Policy (1993) is now being reviewed at the ministerial level to incorporate changes since its introduction. There is no organised way in which the civil society or the general community can influence the development of national drug policy as described earlier in the policy making process.

When the draft policy document is in place, the next step is to discuss it at the Ministry of health (MoH) where the inputs of directors of different departments are considered. For instance, if it is a drug policy the directorate of planning should reflect on financial and human resource implications of implementing a particular policy, looking at questions such as:

- *“To what extent will the change from using SP to Coartem as first line malaria drug affect budgetary allocation in drugs?”*
- *“What will it mean in terms of allocations to other drugs?”*

The director of preventive services may also reflect on the human resource implications of introducing ARVs in health facilities in Tanzania.

After discussion by MoH directors, the draft document is sent back to the policy and planning division where different experts work on directors' comments or suggestions. The policy and planning department is normally staffed with people with knowledge of health economics and human resources; their role is to assist in policy implementation, particularly by determining human resource implications of implementing any policy.

The draft policy document is then moved to a higher level, i.e. the secretariat. The secretariat (an inter-ministerial body) is formed by experts from all ministries. The aim of this forum is to get a broader picture of the policy and how it relates to policies in other ministries/departments, so as to avoid conflicts in implementing a new policy in relation to other already existing policies. Ideally, at this stage the Ministry of Trade and Industry, which is responsible for overseeing issues of trade (and therefore TRIPS and GATS), should be aware of the contents of the policy and how it could be affected by such agreements (Interview with health systems expert, August 2005).

Having discussed the policy document and revised it to meet the needs of different ministries, the policy document is sent to the Inter-ministerial Technical Committee (IMTC) formed by permanent secretaries of all ministries for decision making. With the advice of the Attorney General, the policy document will be presented to the cabinet for final decision, and if approved it is sent back to the MoH, or in some cases it may be sent back to the Ministry of Health for further corrections or to provide any necessary legal backing. Thereafter it is sent to the parliament and finally to the president to assent (Interview with Health systems expert, 2005).

The process of policy making presented above means that there is minimal involvement of most people in articulating their interests in a policy. It is only when there is a vibrant and well organised civil society in a country, that the interests of the majority and particularly the poor members of society are voiced by civil society and this input is reflected in policies that affect human health. As far as drug policy amendments going

on in Tanzania, it is still not clear to what extent peoples representatives have been involved in this process and whether the revised version will be shielded from the possible effects on access to medicines when Tanzania fully commits itself to TRIPS and GATS!

The vision of the National Health Policy is to improve the health and wellbeing of all Tanzanians with a focus on those at risk, and to encourage the health system to be responsive to the needs of the people (MoH, 2002b). This policy vision may not be easily achieved/ realised under GATS environment. To achieve the goal of better health for all, the health system will be affected by other sectors which support health. For instance, GATS covers many sectors including water and sanitation, which are important in ensuring people's wellbeing, and are increasingly being privatised across Tanzania. There must be regulatory mechanisms to ensure that the private and business interests of water and sanitation service providers do not compromise the public health interests of the government as stated in its policy documents. A recent experience of termination of contract with a UK-based water and sanitation company in Dar es Salaam after the company failed to deliver should be a lesson in future contracts between government and foreign firms dealing in trade in services (WDM, 2005).

On the other hand, it is increasingly reported that the private sector has experienced a number of problems with quality, price and distribution of private health services. This has led to a growing focus on the role of government in regulation (Kumaranayake et al, 2000). The critical role of the government in regulation and in facilitating the overall management of the diverse health sector is therefore coming under renewed focus as there are agreements and trade liberalisation policies which have reduced the role of state on many of the services sector. The authors are of the view that regulating the services sector is different from regulating goods and may require different techniques.

Tanzania has had difficulties for instance regulating the private pharmaceutical sector. There is evidence of malpractices among the private retail drug sellers particularly in terms of quality of drugs, dispensing practice and drug pricing. Despite the development of the Tanzania Food and Drugs Authority (TFDA) in 2003 to regulating the drug sector, there is still more to be done to monitor the operations of private retail drug sector. This is important as private retail drug sellers are closer to most of the population, and normally the first care seeking site for people who may not be able to go through health facilities for diagnosis.

Like any other policy, the health and drug policy making process involves competing interests of the state, private sector, academia, civil society and other stakeholders (Gardner, 1992). Various schools of thought have proposed how the policy making process can be participatory, by accommodating the interests of a wide range of stakeholders. For instance, the pluralist (Gardner, 1992) perspective on health policy sees interest groups competing with each other to achieve their desired outcomes. In addition, this perspective recognises that since the power resources of these groups vary, no single group is able to act autonomously. The pluralist view is closely associated with the notion of participatory democracy (Gardner, 1992). One would expect this perspective to apply to all countries, like Tanzania, that claim to be governed under (liberal) democratic principles. The author points out that the Marxist and Elite perspectives on health policy contend that power is normally in the hands of few. However, the source of power is ultimately in the economic system and specifically emanating from those who own the means of production. From a Marxist analysis of the

capitalist system health is a commodity to be bought and sold like any other goods. This view is one of the cornerstones of GATS and TRIPS as far as trade is concerned.

4.1. Regulatory mechanisms for quality, safety and effectiveness of medicines

The government has established the TFDA as a regulatory body for quality, safety and effectiveness of food, drugs, herbal drugs, cosmetics and medical equipment. It was established by Act No 1 of 2003 –The Tanzania Food and Cosmetics Act which repealed the Pharmaceutical and Poisons Act No. 9 of 1978 and the Food (Quality Control) Act No 10 of 1978.

This body registers all drugs which comply with the rules and regulations of the Act. These are the only drugs and medical resources which can be procured by MSD or any other private dealer. Unless the drug or medical supply or equipment is registered by the TFDA, it cannot be imported or used in the country. Before TFDA was established, the Pharmacy Board registered drugs. The TDFDA obtained bigger mandate to include food and herbal medicines. The statistics of the Pharmacy Board on drug registration and application for 1997-2002 are as shown in *Table 1* below:

Table 1: Cumulative status of drug registration applications and approvals between January 1997 and December 2002

Year	Human drugs						Products registered
	Applications			Evaluations			
	Generics	Vaccines and new Drugs	Total	Generics	Vaccines and new Drugs	Total	
1997	246	7	253	246	7	253	
1998	438	21	459	438	21	459	
1999	536	6	542	536	5	541	436
2000	1,075	40	1,115	1,075	22	1096	972
2001	567	41	606	567	28	541	503
2002	556	72	628	556	50	408	300
Total	3,416	187	3,603	3,416	187	3,603	2211

Source: Pharmacy Board Annual Report, 2002.

The table shows that most drugs registered by the TFDA are generics and there is only few applications for new drugs. In the registration of the drugs the issue of intellectual property is not considered.

4.2. Health sector reforms and equity in access to essential medicines in Tanzania

Efforts to reform the health sector in Tanzania date back to the 1960s when Tanzania adopted the Arusha declaration in 1967. The health sector objective of the Arusha declaration was to ensure equity in access to PHC services by all people in the country. The Germans introduced the conventional health care services in Tanzania along coastal areas during the 1880s colonial period. The health care system was urban

based and intended mainly to serve the interest of the colonialists. This health care system, later extended to other regions during the British rule, did not cater for the health care needs of all the people in the country, especially those in the rural areas.

The objective of socialism in the United Republic of Tanzania was to build a society in which all members:

- have equal rights and equal opportunities;
- can live in peace with their neighbors without suffering or imposing injustice, being exploited, or exploiting; and
- have a gradually increasing basic level of material welfare before any individual lives in luxury. (Nyerere, 1968: 340).

Equity is a fundamental principal attached to Tanzania's heritage from its past.

The health sector reforms following the Arusha declaration therefore aimed to address the discriminatory urban-based health care system inherited from the colonialists after independence as stated in *The second five year development plan* (1969). This plan stresses equitable distribution and access to social services, with targets set at one health centre for every 50,000 people and one dispensary for every 10,000 people. The government of Tanzania therefore embarked on free health care strategy to all people and banned the provision of health care services by the private sector in 1977. This was to ensure an equitable access to health care for all people in the country without discrimination, in line with the Alma Ata declaration of 1978 of 'Health for All' by 2000.

However, due to the economic crises, which faced many developing countries in the 1980s, the health care system could not meet the health care needs of Tanzania's people. Hospitals faced shortages of medicine and clinical equipment and unmotivated medical staff. Access to publicly-provided health care services including medicine, depended on the ability to pay a bribe (Malyamkono, 1990) to the public health workers. This situation revealed a defeat of the noble national objective of ensuring equitable access to health care service by all people in the country and points to the infiltration of commercialisation into the health system.

5. The origins of the current health care reforms

The reforms mainly originated from the World Bank and International Monetary Fund (IMF) SAPs, introduced in the mid 1980s. The SAPs called for reduction of government expenditure as a strategy to address the fiscal imbalances, balance of payment crisis and other economic instabilities developing countries were experiencing.

Following the worsening government budget constraints, mounting debt and growing shortages of goods and services in the economy, Tanzania had to succumb to the mounting pressure from the multilateral and bilateral organisations to adopt SAPs. The SAPs demanded a reduced state role in the economy, privatisation of publicly owned facilities, liberalisation of the economy, introduction of user fees, charges on state provided goods and services, and removal of all forms of subsidies. Tanzania, which hitherto had a long-standing commitment to the social sector and basic services for the population dating back from the Arusha declaration in the 1967, started to redefine its roles in the provision of public social services. In the health sector, the government turned its focus and allocation of public financial resources from curative to preventive health care services (The PHC Strategy (1992); the Social Sector Strategy (1995); the

Strategic Health Plan: 1995-1998, (1995c)). This entailed the elimination of public provision of free curative health care services to the Tanzanian people.

Generally, these Tanzanian health sector reforms were aimed at achieving efficiency, improving healthcare quality, preserving or promoting equity, and generation of new resources for health care. This was to be achieved through reducing government predominance in both the provision and funding of health care to a complementary health care delivery and financing mix between the public and private (for profit and not-for profit) sectors. The National Health Policy (1990) document - the first in the country - stressed reduction of infant and maternal mortality through provision of an adequate and equitable health service available and accessible to all people. Primary Health Care (PHC) is the cornerstone of the policy which stresses community involvement and decentralisation of the implementation to regions and districts. The structure of health services remained unchanged from village health posts via dispensary, health centers to district hospitals, regional and referral hospitals (MoH, 1990).

In 1993 the MoH reviewed the health sector and identified a number of problem areas, such as inadequate public spending leading to deteriorating health facilities, shortage of drugs, low morale of health workers and organisational problems especially at district level. These findings led to suggestions to develop the Health Care Reform Program.

The process of developing the Health Sector Reform Program started by the World Bank sending a "Health Sector Reform Project Identification Mission" to Tanzania in 1995 (MoH, 1995a). The mission recommended three components of the reform project i.e. public health, health insurance and health services management. Three working groups were therefore constituted to carry out preparatory activities including studies and workshops for identifying and developing the project interventions. The supervision of the project was under the Multisectoral Project Coordination Committee with support from a technical committee. Workshops were undertaken for each component aimed at quality control and consensus building.

The resulting Health Care Reform Program (1995b) has six main components:

- (i) Communication systems
- (ii) Organisational management
- (iii) Effective health care services
- (iv) Sustainable health financing
- (v) Drugs, supply and logistics
- (vi) Human resources management.

As far as access to essential medicine is concerned, the objectives of the reform are to:

- ensure the availability of quality drugs, medical supplies and essential equipment for reasonable price at all facilities;
- pilot and expand the intent system;
- completely liberalise drug procurement, storage and distribution, and to gradually phase-out of the kit system; and
- re-organise the transport and logistics system at the district and regional levels.

These objectives are good but lack a mechanism of guaranteeing equity in access to essential medicines, especially among the poorest, vulnerable and those people living in the rural areas. With respect to sustainable health financing, the reform program seeks to:

- re-program the national budget to finance costs effective clinical and public health packages and increase national health budget to at least 14%; and
- develop and expand alternative cost-effective and sustainable health care financing, e.g. cost sharing, group (medical) insurance, community health fund.

Table 2: Historical perspective of the health sector reforms in Tanzania

Year	Sectoral initiative	Motive for the decision	Origin of the reforms and level of public involvement in decision making
1888	Introduction of health services in Tanzania (then Tangayika)	Provision of basic health services to the population using uniform population based standards for infrastructure and staff	Decision made at the discretion of the Germans with no involvement of the target group or indigenous population
1916 – 1922	Re-construction of the civil medical practice after the 1st World War		Decision made at the discretion of the British with no involvement of the target group or indigenous population
1967	Introduction of PHC services delivery systems in the rural areas	Meeting the 1967 Arusha Declaration for elimination of all forms of exploitation and achieving equality in access to social services including health services.	TANU ruling party decision with little specific involvement of the target population at community level
1972	Increasing autonomy to regions and districts in articulating their own development issues; Decision-making through political party mechanisms including on health care	Decentralization Act which contributed to the establishment of numerous health care facilities throughout the country and thus making health services accessible to all Tanzanians	Decision by the central government under the mandate of the one ruling party (TANU) political system of the time and thus through this system
1977	Private medical practice for profit banned. Universal Free Medical Services for all Tanzanians declared	Ensuring equitable access to health care services by all citizens without discrimination; Ensuring that citizens are not exploited by profit seeking motives of private health care providers	Decision by the central government under the mandate of a one ruling party (TANU) political system at that time
1982	Increased autonomy to local governments in articulating their own development issues and decision making	Local government	Decision by the central government under the mandate of a one ruling party (TANU) political system at that time
1991	Private practice (regulation amendment) to re-introduce private for profit medical practice in the country	Aimed at efficiency in public resource utilization in the provision of health care services and diversification of health care providers	Decision by central government in response to SAPs conditionalities from the Breton Woods Institutions i.e. World Bank (WB) and International Monetary Fund (IMF)
1996	Health Sector Reforms Program	Reducing the burden of providing health care services from government and enhancing government role of facilitating other actors in the provision of health care services in order to increase access to health care services by all.	Central government with support from WB IDA, local governments, other donors, NGOs and private providers. Ordinary Tanzanians involved in the reform process through acceptance of the policy (URT 1996:11)

The approach of the Health Sector Reform Program had three fundamental problems:

- It relied on the World Bank International Development Association mission to identify health sector reform priorities, which led to departure from the health sector policy objectives of ensuring equity in access to health sector services, mainly due to:
 - lack of 'local' knowledge on the part of the IDA members, inadequate participation of beneficiaries in health sector reform priority identification or the representation of the health sector problems, which the health sector reform program set out to address had little basis in local realities (Green, 2003: 125); and.
 - programmes are often claimed as the initiatives of recipient governments, particularly at national level; the planning process only starts in earnest once governments have agreed in principal, outright rejection almost never happens (Green 2003:128).
- Working groups did not have a wide representation of stakeholders (see *Table 3*). Most group members were from the MoH. In addition to that, the local counterparts are often ill-equipped to dialogue on policy issues, undertake studies and skillfully assess policy options. Therefore the capability of the working group to come up with sound recommendations, inline with Tanzania's long -held vision of ensuring equitable access by all people to health services can be questioned.
- Experiences from "Workshopping in Tanzania's development culture" show that stakeholder workshops are not necessarily participatory although they are concerned with participation, creating bottlenecks as pointed out by Green (2003:134-135):
 - To influence workshop outcomes, participants must have the authority to influence and skills to manipulate discussion and its representation. Unfortunately, stakeholder workshops in Tanzania's development culture assume a particular institutional form and are conducted in a fairly standard ways, according to professional expectations of the development facilitators (who specialise in their operation) and "professional participants" (employed in professional capacities in development agencies and the public sector, whose work in maintaining aid-dependent administrations involves participation in workshops) (Green 2003:132).
 - Even when representatives of beneficiary groups are present in a workshops, they are likely to be fewer than the professional groups and, given the etiquette of hierarchy and power in Tanzania, are less likely to speak critically before those representing themselves as government.
 - The tight organisational structure of facilitation and construction of workshops as a site for managing outputs ensure that workshops produce highly limited visions.

Table 3: Health Sector Reform Program working groups and representation

Working group	No. of members	Institutional and sectoral representation
Public health	6	5 MoH 1 National AIDS Control Program
Health care financing	4	3 MoH 1 Prime Ministers office
Health services management	3	3 MoH
Total	13	11 MoH 2 Other ministries and government agencies

Source: Health Sector Reform Project (1995b).

The end result of this process was a Health Sector Reform Program which constituted:

- legalisation of private medical practice;
- liberalisation of the wholesale and retail trade in pharmaceuticals, which hitherto was under the monopoly of the National Pharmaceutical Company (NAPCO);
- deregulation of health insurance and introduction of user fees for health services at public hospitals;
- measures taken by the government to increase the pool of financial resources for financing public health care services, including:
 - private finance through patient cost-sharing or user fees/charges; and
 - health care financing through non-budgetary sources such as voluntary insurance.

User fees and/or charges in the health sector have often been promoted as a way of rationalising the use of care, mobilising local additional sources within the health sector, encouraging community participation, and thereby making the delivery of health services more efficient, equitable and financially sustainable (Sepehri et al, 2001:184).

These reforms brought rapid changes in the country's health sector. The number of private health care services providers, and wholesale and retail pharmaceutical shops increased rapidly throughout the country. This increased the availability of health care services and the availability of drugs and other medical supplies, as both domestic production and imports of pharmaceuticals increased. However, all these major changes have not yet ensured an equitable access to essential medicine by all people.

This is contrary to 2002 National Health Care Policy objectives on access to medicines, which are to:

- ensure availability of essential pharmaceuticals of quality, efficacious, acceptable safety, at affordable price;
- make pharmaceutical products available (the policy aims at rationalising the use of drugs through better information, prescription and compliance}.
- promote production of pharmaceutical by developing and supporting the National Pharmaceutical Industries with a view to increase local production; and
- use the potential of traditional medicines of acceptable safety side-by-side with allopathic medicine, when such treatment is acceptable to the individual.

Monitoring the effect of these changes will be important. There are now some studies that provide evidence that the introduction of user fees in the public health care facilities and the liberalisation of health care services in the country have reduced the ability of poor people to access these services (Msambichaka et al, 2003). This needs to be further explored.

6. Conclusions

The Tanzania long upheld equity objectives in the country's development strategies need to be safeguarded even as the world becomes increasingly integrated. Besides, achieving health related MDGs, these equity objectives affect efficiency and equity in access to essential medicines in a country. Inequitable access to essential medicines could also jeopardise the realisation of wider health policy goals. The paper argues that inequity in access to essential medicines has emerged in the country following the reforms in the health sector, and traces some of the policies that have weakened equity. We argue that these outcomes could be reversed by introduction of equity safeguarding

regulation in the sector. As countries have the possibility, under GATS, of choosing to make commitments only in some sectors and to set the limits as required to deal with various policy concerns, it is possible for countries like Tanzania to maintain long upheld equity objectives in the health sector through these options. Further the country can fully exploit the flexibilities in TRIPS and ensure that bilateral or other trade agreements do not narrow these flexibilities.

The current Patent Act has provided patenting for pharmaceuticals. In this case, regarding medicines, the patent act is TRIPS-Plus. The proposed new Industrial Property Act will exclude patenting of pharmaceuticals till 2016. As far as access to medicines is concerned, the Patent Act has only one provision of compulsory license for products of vital importance. So the Patent Act does not include other flexibilities offered by TRIPS for access to essential medicines such as parallel importation. We argue that it will be very important for the new legislation to use the flexibilities offered by TRIPS.

Issues of intellectual property are not involved in the current drugs procurement system in Tanzania. Many drugs registered by the TDFA are generic. The problem will be for the new drugs which will be patented in those developing countries, which were the suppliers of the generic drugs. This will necessitate the use of safeguards provided in the TRIPS agreement. To use these safeguards, they must be included in the new industrial property legislation. It is therefore important that intellectual property issues should be incorporated in the National Health Policy and that the Industry and Trade Policy should also incorporated health care issues especially those to be affected by TRIPS on pharmaceuticals.

It is therefore recommended that countries like Tanzania introduce and maintain regulations in the health sector that ensures both equity and efficiency in the delivery of health care services and access to essential medicines. The formulation of policies and regulations related to the health sector should be done in a consultative manner while ensuring a broader participation of local stakeholders including civil society organisations at each level of the process. Development is a choice - if countries like Tanzania choose public policies that develop and share the benefits of development equitably, equitable access to essential medicines is more likely to be achieved.

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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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