

BONELA



Botswana Network on Ethics, Law and HIV/AIDS

Botswana's ARV Treatment Programme:

Past Lessons and Future Outlook



13 August 2005

Maharaja Conference Centre

Gaborone

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Hivos

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Executive Summary

Botswana's antiretroviral (ARV) treatment programme has received international acclaim for its ambition and accomplishments in serving the country's large HIV-positive population. While the Botswana Network on Ethics, Law and HIV/AIDS (BONELA) joins in the praise, we also believe it is time to step back and reflect on the programme's past and present in order to advance its future. Taking a closer look at MASA, the public programme that provides ARVs to Botswana, is a key part of enabling its expansion without neglecting the rights and needs of Botswana's broader population.

Aimed at informing policy makers, civil society, and other stakeholders, a seminar hosted by BONELA in Gaborone intensified the spotlight on matters crucial to securing the programme's long-term success. The objective of the August 2005 workshop was to promote among policy makers ways to improve the efficiency of procurement and equity in the distribution of HIV treatment drugs. The process engaged policy makers to communicate how decisions are made at different ends of government bureaucracy and how to foster better understanding of those policies by non-government stakeholders with a view of discussing options for increased sustainability.

Of fundamental importance are issues surrounding medical safety, trade and intellectual property law, equity, and the programme's cost. Under these headings, speakers and participants discussed and debated the future of the ARV programme, delving into the particulars of procuring a safe supply of drugs, generating revenue for the programme, and the selection of individuals eligible to undergo treatment.

Medical Safety

Many agree that, in the future, Botswana will have to start using generics to sustain the growth and stability of MASA. Dr. Diana Dickinson, a member of the Botswana chapter of the Southern Africa HIV Clinicians Society examined the advantages and disadvantages of including generic drugs in the ARV programme. In particular, she reviewed the international controls available to ensure the safety of generics. These will be important issues for consideration as Botswana looks to the future of the treatment programme and will have to begin developing the processes to deal with the complexities presented by generics.

Trade and Intellectual Property Law

To ensure access to a sustainable supply of affordable medicines, it is important to understand the international and domestic legal environment in which the production of drugs operates. Jonathan Berger, who heads the Law and Treatment Access Unit of the AIDS Law Project (South Africa), recommended reforming Botswana's Industrial Property Act, which governs intellectual property and patents in the country. Developing an appropriate patent law could improve Botswana's ability to negotiate for lower prices of the drugs used in MASA.

Equity

Although people have a right to equality, the reality is that access to HIV/AIDS treatment is not equal. Clear and fair rules for who receives ARVs—in the present and the future—need to be created. Mark Heywood, the director of AIDS Law Project urged policy makers to consider the distribution of HIV care and treatment between, for example, women and men, adults and children, urban and rural dwellers, and for marginalised groups such as gay men and commercial sex workers. A balancing act between HIV/AIDS treatment and other forms of health care and support is also important.

The gap between need and supply of ARVs in Botswana is wide. To maintain and expand such an ambitious ARV programme in the future will require increased revenue. UNDP economist Sennye Obuseng suggested raising taxes in a strategic way to sustain MASA.

Cost

MASA is incurring significant expenses for the government of Botswana. It costs roughly US\$1 million to treat 1000 patients, about half of which is spent on drugs. Since the programme was launched in 2001, the prices of drugs have somewhat fallen but the cost of the programme is still significant. Segolame Ramotlhwa, MASA's operations manager, advocated looking for new ways to achieve a more affordable approach.

The BONELA-hosted workshop provided a forum for insight and exchange of ideas on the future of Botswana's ARV programme. It is important that civil society and government in this country start taking the steps now to develop the mechanisms necessary to sustain a safe and accessible HIV/AIDS treatment programme.



Seminar Programme

The Botswana Network on Ethics, Law and HIV/AIDS (BONELA)

'Botswana's ARV Treatment Programme: Past Lessons and Future Outlook'
Saturday, 13 August 2005, Maharaja Conference Center

Programme

08:30 – 09:00	Breakfast Tea	
	Master of Ceremonies	Dr. Banu Khan Private Practitioner
08:45 - 09:00	Opening Remarks	Gloria Jacques Vice-Secretary, BONELA
09:00 – 09:15	Medical Safety	Dr. Diana Dickinson Southern Africa HIV Clinicians Society (Botswana)
09:15 – 10:00	Medical Safety Q&A	
10:00 – 10:15	International Trade and Intellectual Property Law	Johnathan Berger Head of Law and Treatment Access Unit, AIDS Law Project
10:15 – 11:00	International Trade and Intellectual Property Law Q&A	
11:00-11:30	Equity	Mark Heywood Director, AIDS Law Project Sennye Obuseng Economist, UNDP
11:30– 12:15	Equity Q&A	
12:15 – 12:25	Way Forward	Christine Stegling Director, BONELA
12:25 – 12:35	Closing Remarks	Dr. Kwame Ampomah Resident Representative, UNAIDS
12:35	Lunch	

I. Medical Safety

Generics: Why Not?

Based on presentation by Dr. Diana Dickinson

Southern Africa HIV Clinicians Society (Botswana chapter) and private practitioner

I. The Botswana Roll Out

The Botswana programme to roll out ARVs has been quite successful. The prices are reasonable, and indeed, a considerable part of the drug supply is provided free of charge. At present, the use of brand-name drugs is viable but, in the future, Botswana may need to explore other options.

Ironically, it would be unacceptable if the rate of people living with HIV decreases in the near future. This would indicate that people who have contracted the virus are dying, which should not occur if the population has access to effective ARV treatment. Because of this, Botswana should be proud to have the highest HIV rate for the next 30 years or, at least, the country's prevalence rate should not drop dramatically. The rates of people living with HIV in Uganda decreased because the number of deaths increased.

II. Generic Drugs

In general, the big advantage of employing generic drugs in an ARV programme is that they are likely to cost less than brand-name medications. It should be noted, however, that they are not always cheaper; there have been instances such as with the drug, abacavir, when generics are actually more expensive. For this reason, it is important to always ensure careful and discriminate selection when choosing what drugs to buy.

Generics offer another advantage in their pioneering of fixed-dosed combination (FDC) pills and capsules. FDCs—which contain a set ratio of various anti-HIV drugs—are designed to reduce the number of pills the patient is required to take. In reducing the pill burden, patients should increase the level to which they adhere to their drug regimen.

Generics also generate competition among drug manufacturers, which should help to ensure that shortages of drugs do not occur.

The big disadvantage of generics is that some players in the drug market produce “sugar pills” and attempt to sell them as actual drugs.

Fixed-dose combinations have a downside as well. Despite being easier to take, it decreases the ability to change the dosage of a particular drug in combination therapy.

III. Brand-Name Drugs

Among its advantages, brand-name drugs normally have reliable bioavailability, which refers to the percentage of a dose of medication that is absorbed by the body. Brand-name pharmaceutical companies provide considerable training, information, and support, which is

extremely valuable for building infrastructure. These companies also conduct a great deal of research, which is important in the long term.

Brand-name companies have responded to activism, particularly the Treatment Action Campaign, the South Africa-based movement aimed at increasing access to HIV treatment. As a result, many countries are now receiving drugs free of charge or at greatly reduced prices.

Brand names offer another benefit because there is increased flexibility in dose levels in administering combination ARV therapy. The pills are also much smaller and easier for patients to take. On the other hand, due to the smaller scale production by brand-name companies, they do not produce FDCs because countries have not agreed on the best ratio of drugs in combination to be providing patients. Clearly, this is a drawback since FDCs would likely increase patient adherence levels.

In addition, the prices of brand-name drugs may not necessarily stay low because medications are sold essentially on a seller's market. For example, problems with procuring drugs have surfaced, which compromises the entire treatment programme. Botswana's supply of the antiretroviral 3TC ran out on one occasion, as has Ritonavir. On another occasion, the country's supply of Efavirenz ran dangerously low. Because it does not have to pay for these drugs, Botswana may be reducing the incentives for donor companies to produce a steady supply. Using generics could act as a good back-up supply, which would at the same time increase competition on the market to ensure steady and cheap supplies from brand-name manufacturers.

IV. Controls to Ensure the Safety of Generics

World Health Organization Pre-Qualification List and National Drug Regulatory Units

The World Health Organization (WHO) list is intended to ensure the quality of the medicines available on the world market. The pre-qualification list, however, does not replace drug regulatory units (DRUs); it is meant only to complement them. The WHO maintains an ongoing monitoring system to review how the drugs are made. The ongoing element of the system is critical to make sure that quality does not dip at any point in time. Assessments are made to be in line with the highest international standards rather than lower "third-world" standards.

Drugs are selected for inclusion on the list after a review of a full dossier provided by the company that includes information about quality, safety, efficacy, and stability. This last criterion is especially important in Botswana due to extreme temperatures during the summer months. Good manufacturing practices are verified as is the bioavailability of the drug (checked at high technology sites using samples from all over the world at different times).

The monitoring system works with DRUs of most countries, particularly the ones where generics are being produced. The entire process must be transparent and trustworthy, otherwise, the results are of no value.

The WHO monitoring system employs the same assessment mechanisms used by the United States' Food & Drug Administration (FDA) and its European counterpart. This means that fixed-dose combinations are evaluated against their brand-name equivalents and assessed separately to ensure safety and efficacy as well as toxicity levels remain within appropriate and advertised ranges.

How Are Drugs Rejected

Most companies employ contract research organisations (CROs) to conduct bioequivalence tests and to produce dossiers. Most companies withdraw drugs from the assessment process as a result of discrepancies shown between the information provided to regulatory bodies and the actual data about the drug itself. When drugs have been thrown out of the selection process, it is the data that is being rejected, not the drugs per se. Caution should be taken before arriving at a conclusion about such a drug. It may be the case that the drugs are of sub-standard quality, but it is also possible that the drugs are safe and that the problem lies with the research and improper documentation conducted by the CROs. In general, the work of CROs should be taken warily. Over time, specific firms may earn a satisfactory level of trust and credibility. The WHO should be tracking those CROs that are reputable and those that are not.

Generic Efficacy

Studies on generic efficacy first emerged and were presented at the 2002 International AIDS Conference in Barcelona. The studies have shown and continue to show similar efficacy between brand-name and generic drugs. At least one study indicated that the concentration level of active ingredients in certain generics *in vivo* were higher than those found in brand-name drugs. This may not necessarily always be positive since higher levels could lead to toxicity problems.

V. Investigations

The viability of programmes depends on testing viral loads and CD4 counts. However, investigations are one of the most expensive aspects of a treatment programme. This may mean that finding cheaper methods of conducting rigorous testing requires slightly more priority than the generics issue. Malawi has been assessing an US\$7 experimental test that appears to result in fairly decent levels of sensitivity and specificity. The test, however, suffers from disadvantages such as being technically challenging and requiring a considerable amount of blood to conduct. Other options include dry blood spots, which are also proving themselves viable for testing viral loads and can be dispatched to testing sites via post.

VI. Evolving Knowledge

HIV treatment is on the cutting edge of medical science. It requires interested parties to be extremely pro-active about keeping up with new information. Excessive red tape poses a serious threat to being able to react properly to new information. It may also be necessary to frequently change guidelines. Training should include methods for keeping up with new information. For example, more recent MASHI studies undertaken in Botswana have shown that the single-dose Nevirapine therapy to combat mother-to-child-transmission should be stopped immediately. The research shows that this therapy has no effect on the transmission of HIV to babies and in fact can compromise future treatment options.

More private-public collaboration is needed. Currently, private labs can offer 24-hour turnaround time for testing viral load and CD4 levels. Generally, publicly-funded facilities take longer to make results available. There should therefore be increased transfer of skills to and training of more people to conduct this work. This would help, for example, pharmacy technicians who are presently extremely overworked. In addition, there are clearly not enough doctors to reach approximately 300,000 patients. In order to improve the capacity of health facilities, nurses should be trained to deal with cases of patients using generics and doctors employed to deal with complications.

Discussion

Based on selected questions and comments from workshop participants

Responses based on comments by Dr. Diana Dickinson unless otherwise noted

1. *It appears that Botswana is under strict directions from the United States and the President's Emergency Plan for AIDS Relief (PEPFAR) to supply HIV/AIDS patients in Botswana only with branded drugs even though it is evident that generic drugs can be acquired at a lower price. Is this because generics are not as effective or that the manufacturing pharmaceuticals of brand-name drugs are based in the United States?*

Response:

Generics are not currently being used because they are not yet needed. Thus, there is no need to change the policy. It does not, however, appear that the government will exclude generics on the basis that they are generics.

Response (from Ministry of Health):

The Botswana government adheres to a policy that includes the use of brand-name drugs in all government hospitals. The government also purchases numerous generic drugs for treatment of certain illnesses but generic ARVs have not yet been made part of this practice. However, this policy does not restrict pharmacists in anyway since there are pharmacists who sell generic drugs over the counter. The government is currently using brand-name drugs because they are cost-effective and non-toxic; it is not because Botswana is under any international restrictions. The government of Botswana cannot introduce generic drugs at the moment because the adequate infrastructure is not yet in place to maintain their use. Botswana does not have the capacity to conduct tests on these drugs. Whenever drugs are introduced, several medical issues, such as bioavailability and safety, must be considered.

2. *Most large pharmaceutical companies contend that there is a lack of financial resources to fund research on drugs. To what extent has this issue been established? It is critical that Botswana undertakes research on the effectiveness of brand-name drugs and generics; however, funding is and will always be a restriction in carrying out such research.*

Response:

In regards to funding and research, it is critical to not cut back. This is why brand-names remain incredibly important. These pharmaceutical companies carry on this research at levels other companies and organisations do not. There is no replacing this research.

3. *Would it not be logical for patients enrolled in the ARV program to air their views on the use and effectiveness of ARVs?*

Response:

Of course, people living with HIV/AIDS should be involved in the decision-making process. Patients should know that there is usually no difference in toxicity between generics and brand-names, but generics are often easier to use because they come in one-pill, fixed-dose combinations. What the patient prefers, however, is still extremely important.

4. *There is concern about the ethical issues involved in having a type of drug being recommended for use. At the moment, nothing has been established on the differences in terms of effectiveness between generic drugs and brand-name drugs in patients. However, the advantage of using generics is that they are easy to adhere to since patients take only one pill a day, unlike the brand-name treatment which is a combination treatment. As a medical practitioner, I do not have a problem with the types of drugs being used because brand-name drugs are effective as is. However, there should be worry about people taking other forms of drugs rumoured to be working better than ARVs—practitioners should recognize the need for treatment literacy among people enrolled in the ARV programme.*

II. Trade and Intellectual Property Law

Ensuring access to a sustainable supply of affordable medicines

Based on presentation by Jonathan Berger

Head of Law and Treatment Access Unit, AIDS Law Project (South Africa)

The context provided by international law

Sources of international law

International law provides an important context within which the issue of access to medicines is to be addressed. Numerous sources of international human rights and trade law exist. While only some of these laws may be directly enforced by a domestic court, most (if not all) are relevant for the development and interpretation of domestic laws that deal with access to medicines, whether directly or indirectly. In Botswana, the Industrial Property Act (1996) regulates the granting and enforcement of patents, thereby having a significant impact on access to medicines.

In considering the obligations that arise in terms of international trade law, one should take note that it does not sit in isolation from other bodies of law in the full landscape of international law. For example, it must—at minimum—be interpreted in accordance with various obligations that arise under international human rights law. Many even argue that human rights law should—and indeed does—take precedence over trade law.

In regards to HIV/AIDS, the Revised Guideline 6 of the UNAIDS International Guidelines on HIV/AIDS and Human Rights is one of the more relevant documents of international human rights law, even if it is not directly enforceable. It seeks to ensure that HIV/AIDS-related goods and services are accessible—in other words, available and affordable.

Regional human rights documents

In addition to international law, regional agreements are another source of non-domestic law that should be used in guiding the response to HIV/AIDS. The Abuja Declaration on HIV/AIDS, Tuberculosis and Other Infectious Diseases sets out a number of obligations that African governments themselves have undertaken regarding the provision of relevant health care services. One of the important and most forceful obligations from this declaration is to “take all necessary measures to ensure availability of resources and their efficient and effective use.”

International trade law and the TRIPS agreement

With the establishment of the World Trade Organisation (WTO) in 1995, member states adopted the Agreement on Trade-related Aspects of Intellectual Property Rights, also known as TRIPS. TRIPS obliges all WTO members to legislate certain minimum standards of intellectual property (IP) protection for all types of technologies. However, there was much dispute regarding the nature of these obligations and, in particular, the steps that countries could take to ensure access to a sustainable supply of affordable medicines.

Adopted at the 2001 WTO ministerial meeting in Doha, Qatar, the *Declaration on the TRIPS Agreement and Public Health* (Doha Declaration) states that TRIPS “can and should be interpreted and implemented in a manner...to promote access to medicines for all.” Rather

than creating any new law, the Doha Declaration merely provides clarity on what some of the murky language in TRIPS actually means.

One of the more pressing issues that emerged from the Doha Declaration was known as the “Paragraph 6 problem.” Aside from the steps that countries are permitted to take in terms of TRIPS to ensure access, paragraph 6 of the declaration recognises that for countries with limited or no domestic pharmaceutical manufacturing capacity, such steps may be insufficient. Recognising that TRIPS itself limits the production of generic medicines produced under compulsory licence for export (including to countries with limited manufacturing capacities), paragraph 6 concerns the need to relax strict rules regarding exports.

An interim “solution” to the problem was adopted by the WTO on 30 August 2003, allowing generics to be produced largely or solely for export to countries with limited or no domestic manufacturing capacity. But the interim “solution” adopted is overly complex containing possibly unworkable rules. It has yet to be used by any country, even though a few manufacturing countries (such as India and Canada) have amended their laws to allow exports for this purpose. It is hoped that the permanent amendment to TRIPS will get rid of some of the many technical barriers to access that the interim August 30 agreement brought into force.

Options available under international law for ensuring access to affordable medicines

Developing an appropriate patent law

Various issues should be considered while attempting to develop a patent law to ensure a sustainable supply of affordable medicines:

- fully incorporate the flexibilities available in TRIPS;
- ensure that the law allows governments to intervene in appropriate circumstances, so that they are able to meet their human rights obligations;
- limit unnecessary litigation by establishing clear, reliable and predictable rules (an example from Malaysia: laws required a manufacturer to pay “reasonable royalties” for producing on-patent drugs; the state has been caught up in years of expensive court proceedings aimed at determining what constitutes a “reasonable royalty” in the circumstances);
- regional and international implications of domestic action (or inaction) should be taken into account

While it is important to empower the state to act, it is equally important that domestic legislation similarly empowers non-state actors. In some cases, the state may be facing international political pressure to refrain from taking action against the abuse of rights in a patent, such as excessive pricing that limits access. While it may have the legal authority to intervene, politics may deter a government from acting. It is therefore important for countries to enact laws that allow third parties—that is, civil society organisations and generic manufacturers—to take action on their own. Botswana’s Industrial Property Act, for example, contains broad provisions for government use but only weak provisions for third parties. Currently, when the Botswana government fails to act, third parties have limited options available.

Options for ensuring access

There are two broad ways in which domestic laws may facilitate access: first, by limiting the scope of what can be patented; and second, by legislating various mechanisms that allow for the early market entry of generic competition.

Regarding the first, countries such as Botswana should not grant patents where TRIPS does not require the granting of patents, such as for new uses of old products. For example, the antiretroviral drug AZT was developed in the 1960s as an anticancer drug, but it is on patent in a number of countries because of its new use in fighting HIV. Under international law, there is no reason for Botswana to grant a patent for AZT.

New forms of known substances also should not be given patent protection. For example, both AZT and 3TC, another antiretroviral, are protected by patents. Combivir, the branded version of the product that combines AZT and 3TC into a single pill, is protected by patents that will exist well beyond the life of those granted for the two separate drugs.

While it is important to restrict the scope of patentability, the use of mechanisms to ensure market entry is the most effective way to ensure access to a sustainable supply of affordable medicines. The Doha Declaration, which deals with two of the key mechanisms (compulsory licensing and parallel importation), provides clear guidance to countries on what they can and cannot do. It should serve as a guide to countries such as Botswana when amending their IP laws to ensure access.

Critique of Botswana's Industrial Property Act, 1996

Botswana is not unique amongst former British colonies and protectorates that inherited laws protecting various forms of IP in excess of what TRIPS requires. Of concern, however, is that Botswana's Industrial Property Act (which contains provisions beyond TRIPS requirements) was adopted in 1996, more than 30 years after independence. The country's existing legislation requires substantial amendment if it is to sustain an accessible and affordable supply of medication for HIV/AIDS therapy in Botswana.

What should be removed?

Patent infringement includes such acts as importing generic versions of patented products without the patent holder's approval, even if such products are registered in the country. Criminal sanctions for patent infringement are dealt with in section 76(6) of the Industrial Property Act. Patent infringement can result in penalties ranging from stiff fines to imprisonment for between six months and two years, or both. Criminal sanctions are not required by TRIPS. Most countries simply allow for the patent holder to sue through a civil lawsuit, with the state taking no active role on patent enforcement.

The law is not only limited to penalising patent infringement, but also contains a provision for prior restraint. This means the patent holder can also take legal action "against any person...who performs any act which makes it likely that infringement will occur" (Section 25(1)), such as a generic company that begins preparing a dossier for drug registration before patent expires. Once again, TRIPS does not require such a heavy-handed provision that places so much power in the control of the patent holder.

Provisions (Section 31) dealing with an initial moratorium on the grant of compulsory licences unnecessarily limit access and should also be removed.

What should be amended?

The law entitles the government to grant licences on patented products for broad range of uses (Section 30). This is the most access-friendly provision of the statute, but could be even further strengthened by:

- expressly defining anti-competitive conduct; and
- by removing the limits on exports of products produced under licence for public, non-commercial uses and/or to remedy anti-competitive conduct.

This is expressly permitted by TRIPS.

Section 31 deals with compulsory licensing, which is an authorisation (granted by a government or a court or some other legal forum) to use an invention that is protected by patent without the consent of the patent holder. A voluntary licence, on the other hand, is express authority that is voluntarily granted by the patent holder. The two are linked. For example, the threat of a government issuing (or a non-state actor seeking the grant of) a compulsory licence may be used to ensure that patent holders stop abusing their rights or grant voluntary licences. For example, the government of Brazil has used the threat of issuing licences to negotiate lower prices for drugs.

This lesson can be applied to Botswana, which does not necessarily have to invoke compulsory licenses to obtain less expensive drugs to treat HIV/AIDS patients. What is important is to ensure that domestic law takes full advantage of the flexibilities and public health safeguards recognised by TRIPS, the Doha Declaration and the August 30 agreement, so that threats of compulsory licensing are credible. A compulsory licensing provision that is beyond the scope of TRIPS and is difficult to use is unlikely to get patent holders to grant licences where they have been unwilling to do so previously.

What else is missing?

There are three issues that are not considered by Botswana's Industrial Property Act:

- the exclusion of unlawful patents;
- patent revocation in cases where the grant of a compulsory licence has not been sufficient; and
- a "Bolar exemption," which would allow for generic drug registration even before a patent expires.

All three, which should be included in a revised statute if Botswana is serious about ensuring access to a sustainable supply of affordable medicines, are clearly permitted by TRIPS.

Discussion

Based on selected questions and comments from workshop participants

Response based on comments by Jonathan Berger

1. *These laws seem to mostly apply to domestic patents. If the patents are not granted in Botswana, are they still applicable?*

Response

TRIPS does not automatically create patents domestically. Although Botswana has membership in the WTO, it does not mean that patents in other countries automatically apply in Botswana. It does mean that Botswana has to grant certain minimum levels of patent protection (as set out in TRIPS) if and when sought in Botswana. However, if a patent has been granted by a body such as the African Regional Intellectual Property Organization (ARIPO) of which Botswana is a member, then the patent automatically applies in Botswana unless the registrar of patents deems otherwise.

III. Equity

Equity in Access to HIV Care and Treatment Service

Based on presentation by Mark Heywood

Director, AIDS Law Project (South Africa)

In Africa, Botswana is leading in terms of the number of people with access to HIV/AIDS treatment. But it remains a question how Botswana will ensure that this number will continue to increase and that people will stay on treatment. It is, therefore, crucial to talk about access to HIV care and the issue of equity in access to health care services.

Equity is a term that is much abused and often confused with equality. When defining equality, reference should be made to the Universal Declaration of Human Rights which says that all human beings were born equal in dignity and rights. But the reality is that access to health care, for instance, varies based on wealth or the lack thereof, race, profession (e.g., sex workers tend to have less access) and geography (e.g., remote-areas dwellers versus urban dwellers).

Equity is different from equality in that it recognizes even though people should have equal rights, we are not equal. Equity recognizes the wish to pursue a policy that provides equal opportunity for access. The current policy in Botswana premises itself on equal access, but for example, as noted in the latest edition of the BONELA newsletter, there is not equal access for groups such as refugees. In order to recognize equity, it is necessary to have a plan of equity.

Equity can be applied to a number of relevant issues, including:

How to make sure that the provision of ARVs is an equitable process? Is there an equitable system for deciding who receives ARVs and who does not?

Is there equity between HIV care services and ARVs? Is there equity between ARVs and other health care services? Is there equity between those who need HIV services and those who have other health service needs? HIV may be an emergency, but other health needs still exist.

Is there equity between the investment in MASA and other social programmes (e.g., education)? It may be useful to see the linkage—that is, the absence or weakness of social programmes may increase the risk of HIV infection.

According to a recent presentation by Professor Jibril of Princess Marina Hospital in Gaborone, approximately 40 percent of the number of people needing ARV treatment three years ago are now receiving treatment. In 2002, roughly 100,000 people needed antiretrovirals. Today, approximately 40,000 people are on this treatment.

Concern for equity raises a number of questions. Who is being treated? Who is not? Who is next? Why? Is there an equitable distribution between men and women? Do children get equal access? Do prisoners? Do gay men? Do sex workers? Is there a plan that says the policy is based on equity?

Does Botswana have a plan, for example, that says treatment will not be delayed in Francistown and Gaborone because it can be done now, but over time it will commit to bringing services to more remote rural areas? A policy that recognizes inequity attempts to distribute medicines on an equitable basis.

Concepts of public health are important to consider. For example, if sex workers are not treated, what are the consequences for infection of others? As Botswana tries to work out such a policy, what are the considerations and criteria?

It may be beneficial to consider:

- Botswana is a democracy that subscribes to international human rights treaties. Many of these treaties have provisions relevant for the implementation of treatment plans.
- Ethical guidelines demand that we must do good—or, at the least do no harm—and that actions must be premised on social justice. For example, ignoring sustainability with respect to ARVs would be doing harm.

Two years ago, a meeting within the UNAIDS organisation was held to look at equity within the context of Three by Five, the initiative attempting to get anti-retroviral treatment to 3 million people by 2005. But within programs such as these, it is important to have the meaningful involvement of civil society and to act in a manner that is transparent, consultative, and communicative.

There are many false ultimatums that policy makers are faced with, for example, to have to choose between treatment or prevention and so forth. These false dichotomies need to be discarded. In South Africa, the number of in-patients increases by 100,000 per year due to cases of HIV infections. It is important to note that HIV—and not ARV treatment—causes this increase. Brazil introduced ARV treatment in 1996 and within a few years had seen a drop in both deaths and in-hospital admissions for a variety of infections.

A balance needs to be struck among the various interventions. Achieving equity is not only about the sustainability of the drug supply. For example, as pointed out in Dr. Jibril's presentation, insufficient thought had been given to the human resources required for routine testing of HIV. It has also been reported that people who start programs such as prevention of mother-to-child transmission are more likely to come from those who test in voluntary counselling and testing sites than through routine testing sites. An equitable approach requires attention to all of these issues.

The experience from South Africa shows that issues around income support are also a concern. Now that people receiving ARV treatment are getting better, the government is withdrawing their entitlements to disability benefits under the pretext that they are healthy now. The bigger picture for treatment—including the goal of maintaining patient adherence—includes links to other social services such as education. If you fall foul on any of these, the prospects for access are diminished.

Access, Equity and the Future of Botswana's ARV programme

Based on presentation by Sennyee Obuseng

Economist, United Nations Development Programme

In much of the developed world, HIV/AIDS mortality rates have declined. Access to medicines has improved, nutrition has improved, and better systems have been developed for disease management. In the developing world, HIV/AIDS mortality is rising. Access to care is poor and poverty results in poor nutrition. Botswana is not managing the disease as well as it could. In this context, a number of equity issues arise.

Access is fundamental for equitable care and treatment. Do members of society have a fair chance of getting HIV/AIDS-related health services when they need them? Not likely, for the following reasons:

- **Cost:** ARVs are relatively new. There is a high knowledge content, and thus, there is a premium to pay. For many people in the developing world, these drugs are not accessible without external support.
- **Access:** Physical access is also an issue. The geographic presence of a publicly-funded system does not on its own guarantee access.
- **Capacity:** It is an important factor whether or not the health system, public or private, has the capacity to deliver. In Botswana, this has a tendency to be restricted to major centres.

There is an imbalance between need and the supply capacity. The sheer pressure of need mediates against access. At the household level, there is no capacity to speak of. The population's level of income is a severe bottleneck on capacity. This aspect of equity impacts on the national economy. The distribution of the burden and of services causes a shock to the development process and to the government budget.

The biggest constraint is the absolute lack of resources. Without adequate resources, it is difficult to deliver even a basic package of health services. The erosion of capacity has been due to mobility, death, and brain drain, for example, resulting in Botswana's loss of its health care workers. There needs to be a programme of expansion that considers coverage and access.

It is important to remember that, despite the desire for universal access, it is simply not possible now and in the foreseeable future. Thus, the question is: what is the best way to expand resources? One obvious answer is that the state needs to raise additional revenue. Thus, decisions have to be made on how to distribute the burden for providing revenue to the state. Some people have suggested raising the taxes with the broadest base, for example, value-added tax (VAT). This is the one tax with a base wide enough that substantial revenue generation could occur with minimal burden and very small increases. It could be a way to mobilise resources without imposing too heavy a burden on society.

Botswana is receiving substantial external support for the national ARV programme. Botswana needs to mobilise the requisite capacity to sustain other programmes as well. The country will need to look more at public/private partnerships. One caveat is that it is almost inevitable that this will involve a lowering of standards.

It is unfortunate that issues of intellectual property rights and research are driven by the North even as the disease burden is heavier in the world's south.

Discussion

Based on selected questions and comments from workshop participants

Responses provided by presenters as noted

1. *The government has tried hard to develop health facilities treating other conditions covering appropriate geographic areas. ARVs, in particular, are where difficulties arise though there are now 32 infectious disease care clinics. With ARVs, there are additional concerns. When you get inside the clinic, you are told to wait two or three months without preparation or counselling. This information, which would help ensure that medication is taken in a proper manner, needs to be disseminated in a better manner. The particular facility I go to provided me with counselling for 45 to 50 minutes. It is not enough. People require ongoing support. My organisation, which works with people living with HIV/AIDS, does not have the resource capacity to bring this information to potential patients. How can we access that if it is that way?*

Response (Mark Heywood):

Distribution and availing of services is key because our governments will not have that capacity. There has to be pressure on all of us, everyone in this society needs to come together. How are we going to do this?

2. *Some people have chosen to use alternative medicine on their own or in combination with ARVs. For example, people in Selebi-Phikwe are using the alternative medicine canova (which reportedly helps to boost the immune system but is not a replacement for ARVs even though some are rejecting ARV treatment as a result). What happens in a situation where one has to explain confidentiality and most patients are illiterate or semi-literate? Many of these people believe that doctor knows best. Where does autonomy come in?*

Response (Mark Heywood):

Equity should not be pursued at the cost of autonomy. Part of the problem is access since people were not coming for testing. Routine testing is meant to diminish inequity between those who know their status and those who do not. But, if people do not properly understand, they may not be able to deal with it. Pre-test counselling remains very important. This, however, does not mean that we do not have to change the way we do testing. Let us not lose sight of these issues simply because of the controversy over canova.

These 100,000 people cannot just be treated as beings that we need to get pills into. Treatment education and literacy is important. People need to make their own decisions, especially if those decisions mean taking drugs every day for the rest of their lives. People who really value their lives are not going to make the wrong decisions.

3. *I think routine testing for HIV is the answer. Many people do not know their status. Counselling after testing is needed; it is absolutely critical as is the right support. With*

respect to taxation, people are already having a hard time with the devaluation of the Botswana Pula. More taxes will mean an increased financial burden for some. For the first time in 19 years in Botswana, I am seeing people who can't afford to eat. If we do use tax to subsidise, we need to tax high- not low-income people.

Response (Sennye Obuseng):

The tax debate is one that will be avoided—for now. There is a real demand on government to step up revenue mobilisation efforts. Maybe the government can use existing taxes more efficiently. Taxes other than VAT do more harm to the poor, even though it may look like VAT increases their burden disproportionately. Botswana lacks capacity but it is also not using what it has as much as it could.

4. *The issues discussed at this seminar are all very relevant if we are looking at mobilising civil engagement with other stakeholders. The seminar is discussing information without the necessary backing and support of facts and evidence. These issues have been discussed many times, but hard data is needed in order to make policy changes and recommendations. General discussion will not help make recommendations to move forward, but there is hard evidence out there to let us make the specific recommendations that matter. Today, civil society was well-represented at the seminar, but not the government. The government representatives originally listed on the programme are not present.*

Response (Christine Stegling, BONELA):

With regard to the changes made to the programme, BONELA is equally frustrated since it was originally planned with knowledgeable representatives from government. Until two days ago, government representatives were scheduled to address 1) safety issues with generic drugs and 2) negotiations in drug prices. The seminar was also supposed to provide a forum to help the Ministries of Health and Finance coordinate information and logistics regarding the government's process of drug procurement. BONELA has been working on these issues for the past one and a half years and this seminar was an attempt to bring together the work. Why so many ministries decided to pull out at the last minute is not clear.

5. *The seminar has been looking at addressing HIV in the context of the public health sector. The main thing to accept and acknowledge is the complexity of the issue. Individuals have many options out there. The seminar also needs to acknowledge that the government is very clear: "There is a long way to go." Government needs to engage the private sector. There need to be changes of a substantive nature. It is important to address these so that there are no misconceptions*
6. *While broadening the base for taxation is valuable, VAT is an impediment. For patients who have to pay 10 % VAT for health services, the VAT becomes an obstacle to adhering to their treatment plan because it increases the cost. Botswana needs to try to exempt health care from VAT. The country needs to look at the way it finances the health care system. P2 for health services in the public sector from everyone is not sustainable. There needs to be a system of cost sharing or a system where the poor pay less.*

IV. The Cost of the MASA Programme

Cost Analysis of MASA

**Based on presentation by Segolame Ramothlwa
Operations Manager, MASA**

Within the public sector, females make up 60 to 65 percent of the total patients enrolled in MASA. Approximately 10 percent of the total participants are children. As part of the national development plan for the country, the goal is to enrol everyone who is eligible.

About half of the total cost of the ARV programme is spent on drugs. Approximately 40 percent is accounted for by human resources and laboratory tests while the remaining 10 percent is expended on Information, Education and Communication materials, infrastructure, and so forth. Over time, the costs of drugs, human resources and lab testing are expected to increase as more patients enrol. As a percentage of total cost, infrastructure should decrease since this is a one-time expenditure.

The total cost to treat 1000 patients for one year tallies to US\$1 million. In the 2009 National Development Plan, the projected expenditure on ARVs was 3 to 3.5 billion Pula. MASA hopes that the price of drugs will continue to go down.

The program was launched in 2001. The cost of first-line drugs has decreased by 65 percent since that time while second-line drug prices have decreased by 72 percent. Lab tests have decreased in cost by 60 percent overall. In particular, the cost of CD4 tests has seen the greatest reduction with a 70-percent decrease.

At some point, generic ARVs need to be seriously considered as an option. Botswana needs to be cognizant of a number of things and there are a number of steps, however, before government will arrive at the conclusion to purchase and distribute generic ARVs.

The situation in Brazil, which uses generics, is in no way comparable to the situation in Botswana. The HIV prevalence rate in Brazil is less than one percent. More than one third of Botswana's productive population is HIV-positive. If something should go wrong, the consequences in Botswana would not be comparable to those in Brazil. There are many technical issues that need to be addressed, including boosting Botswana's limited registration capacity. There needs to be standards in labs to monitor quality.

Botswana's programme is quite expensive and MASA wants to explore ways to achieve a more affordable approach. Generics are generally used in countries with greater regulatory authorities and capabilities.

Discussion

**Based on selected questions and comments from workshop participants
Responses provided by presenters and participants as noted**

1. *In Botswana, there is a lack of male enrolment—only 35 percent of those on the programme. The same issue is a concern in South Africa.*
2. *What happens if something goes wrong with a drug trial? For example what happened with thalidomide trial, who is liable? Is it the government? Is it the trial? Who is responsible with a multinational trial?*

Response (Mark Heywood):

The company involved in the trial could be liable for claims up to 15 years after the trial takes place. Successful claims against the company can be the result if it can be established that it did not follow the proper procedure or against the government if they were negligent in approving the trial.

Some of the generics coming out of India may be of low or unproven quality, but there are manufacturers in Asia and Africa (including Aspen in South Africa) who produce drugs of the highest quality and are being registered by the South African Medicines Control Council. There needs to be a system where registration in one country is considered a sufficient guarantee of quality to use in another country. There needs to be recognition that experiences like that of the thalidomide trial helped to establish the standards that we use now.

3. *Approximately one third of people who are HIV-positive are classified as having AIDS. People are still not coming forward to test. Routine testing is a way to increase the number of people testing.*
4. *How is it possible to pay for the high costs of treating all the people in Botswana needing ARVs?*

Response (Jonathan Lewis, UNICEF):

It is necessary to remember that the cost of inaction would be two to three times higher than the cost of using brand-name drugs.

5. *Economies of scale should be taken into consideration. The prices of drugs cannot always be calculated in a straightforward way. The notion of equity is to get into those least serviced areas.*

Way Forward

**Based on remarks by Christine Stegling
Director, BONELA**

Dr. Moeti, who represents the Ministry of Health, helped provide insight into government views. There is clearly a need for critical debate and analysis on these issues. The questions raised at this seminar are being asked by BONELA for very much the same reason that activist movements attempting to increase access to treatment are asking those questions. The answers, however, are not entirely clear.

Many have asserted that generics are not needed right now in Botswana. However, even now the figures of the amount of drugs required have not yet been made clear, and everyone seems to agree that generics will be needed in the future. This is a good opportunity to try to understand what needs to be done now in preparation for the time when generics will be necessary.

The quality of generics is often questioned while brand-name drugs are not often placed under scrutiny. However, there have been examples of brand-name drugs being pulled from markets for proving to be unsafe. Thus, the need for safety mechanisms is similar for both brand-name and generic drugs.

Many of the recommendation on developing an effective patent law brought up in Jonathan Berger's presentation, "Ensuring access to a sustainable supply of affordable medicines," can be brought to the Legislative Review team for consideration.

To conclude, civil society needs to continue to find ways to make things easier for government and to help increase capacity in order to make the MASA programme sustainable.



APPENDIX I: List of Participants

Duncan Thela	(AFA Botswana)
Boitumelo Makunga	(Attorney General's Chambers)
Monica Tabengwa	(Auwah, Khan & Partners)
Maame Auuah	(Auwah, Khan & Partners; BONELA Board member)
Renaeraber Kelefhile	(Botswana Federation of Secondary School Teachers)
Annie Lungu	(Botswana Family Welfare Association)
Daniel Motsatsing	(Botswana Network of AIDS Service Organisations)
Werani Chirambo	(BONELA)
Kristi Kenyon	(BONELA)
Milikani Ndaba	(BONELA)
Nthabiseng Nkwe	(BONELA)
Vanisree Ramanathan	(BONELA)
James Sams	(BONELA)
Christine Stegling	(BONELA)
Botho Tlhobogang	(Botswana Gazette)
Patrick Chengeta	(Botswana Federation of Trade Unions)
Annie Mathew	(Botswana Christian AIDS Intervention Programme)
David Ngele	(Botswana Network of People with AIDS)
Kebapetse Kebapetse	(Botswana Press Agency)
Amouglang Makgabenyana	(Botswana Press Agency)
E. Lowenthal	(Botswana Baylor Children's Clinic)
Moronawa Phala	(ECHO)
Mogakulodi Boikanto	(ECHO)
Dr. M. B. Dlamini	(Immanuel Medical Centre)
Sara Nam	(London School of Hygiene and Tropical Medicine)
Dr. Themba Moeti	(Ministry of Health)
Dr. K. Seipone	(Ministry of Health)
Nthoyapelo Motshwane	(Ministry of Finance and Development Planning)
Lillian Moremi	(Ministry of Lands and Housing)
Helen Kadira	(Morupule S Group)
Moses Senne	(The Moshul Group)
Gocious Pleko	(The Moshul Group)
Dr. Banu Khan	(Private practioner)
C. Sungwa	(Star Pooly Health Clinic, Mogoditshane)
Dr. Linda Malinga	(Southern Africa HIV Clinicians Society, Botswana)
Dr. Kwame Ampomah	(UNAIDS)
Mona Drage	(UNAIDS)
Viola Morgan	(UNDP)
Senny Obuseng	(UNDP)
Dorothy Okhola Baong	(UNICEF)
Jonathan Lewis	(UNICEF)
Gloria Jacques	(University of Botswana; BONELA Board member)
Aaron Cope	(United States Embassy)
Onneetse Makhumalo	(Women & Law in Southern Africa)

Appendix II: Glossary

3TC	Lamivudine, an antiretroviral drug
AIDS	Acquired Immune Deficiency Syndrome: the late stage of HIV disease characterised by an ill-functioning immune system, allowing opportunistic infections to more easily weaken and damage the body
ARV	Antiretroviral drugs used to combat, for example, HIV
AZT	Zidovudine, an antiretroviral drug
BONELA	Botswana Network on Ethics, Law and HIV/AIDS
CD4	A type of white blood cell, the levels of which are used to approximate the severity of the condition of a person infected with HIV
CRO	Contract Research Organisation: a class of companies often employed by generic manufacturers to conduct safety and related research into their products
DRU	Drug Regulatory Unit: an agency or other governmental office tasked with ensuring the safety and efficacy of drugs in a country
FDA	Food and Drug Administration: the drug regulatory unit of the United States
FDC	Fixed Dose Combination: a pill that includes a set ratio of various drugs; designed to reduce the number of pills the patient is required to take
HIV	Human Immunodeficiency Virus: the retrovirus of the lentivirus family believed to cause AIDS
IP	Intellectual Property
PEPFAR	President's Emergency Plan for AIDS Relief: US programme aimed at combating the disease around the world
TRIPS	Trade-Related Aspects of Intellectual Property Rights: A World Trade Organization document specifying the obligations of member nations to the owners of intellectual property
UNAIDS	Joint United Nations Programme on HIV/AIDS
VAT	Value-Added Tax
WHO	World Health Organization
WTO	World Trade Organization

Credits

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Past Lessons and Future Outlook

13 August 2005

Maharaja Conference Centre, Gaborone

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The Botswana Network on Ethics, Law and HIV/AIDS is a non-governmental organisation committed to integrating an ethical, legal and human rights approach into Botswana's response to the HIV/AIDS epidemic.

