ACCESS TO AFFORDABLE TREATMENT FOR HIV/AIDS: THE ISSUES

AIDS Law Unit Legal Assistance Centre

July, 2002

INTRODUCTION

Although there is currently no cure for HIV/Aids, treatment has, however, been developed which significantly slows down the progression of the disease. There are a number of important issues surrounding access to treatment for HIV/AIDS,

some of which are raised here.

What is HAART?

Because HIV belongs to a group of viruses called *retroviruses*, treatment to fight HIV infection is known as *antiretroviral therapy (ART)* or *anti-HIV treatment*. Because we have learned that the best way to treat HIV effectively is with a combination of at least three antiretroviral drugs (ARV's), this multiple-medication approach is often referred to as *HAART*, which stands for *Highly Active* 

AntiRetroviral Therapy

How does it work?

For many thousands of people living with HIV or AIDS (PWAs), HAART has extended life and improved health. In many cases, when effective drugs are available, their use can result in significantly restoring the body's the ability to fight off the infections that once would have been fatal. So instead of what many would have once considered an inevitable downhill slide into illness and death, there is now hope that — for those living in parts of the world where the drugs are available — disease progression can be slowed down or even reversed.

HAART has allowed those fortunate enough to have access to ARV's to live full and productive lives for as long as 20 years. With access to HAART, HIV has become a manageable disease similar to diabetes.

### Are ARV's dangerous to use?

Yes, ARV's can be dangerous to use. Any medication, if not used properly and if used in incorrect amounts, is dangerous. Only a small percentage of people who are on HAART have experienced side effects, but ARV's should nevertheless be used in conjunction with proper medical advice and supervision. PWA's who are considering taking this medication should only do so after having consulted with a trained physician. ARV's, however, <u>do</u> work, and the consequences of not getting treatment, are far more serious and almost always fatal.

### Is antiretroviral treatment necessary to combat HIV/AIDS?

Yes. A few years after infection with HIV, the virus weakens the patient's immune system to the point where the first "opportunistic infections" appear. HIV itself does not kill; it is opportunistic infections – such as tuberculosis and pneumonia – that do. Medicines to treat most opportunistic infections are available, but treating opportunistic infections is only a temporary solution, since HIV continues to attack the immune system. After one infection is cured, others inevitably follow. Antiretroviral (ARV) drugs are needed in order to combat HIV directly and are an important part of a comprehensive approach to addressing the epidemic. They do not cure AIDS, but can improve a patient's quality of life and prolong survival when taken consistently. In Brazil, the use of ARVs has cut AIDS mortality by 51% from 1996-1999. Treatment is also a powerful incentive to get tested, providing a strong boost to prevention efforts. While ARV

treatment cannot be implemented immediately everywhere, we cannot afford to wait to extend treatment where possible.

## What are the barriers to access to medicines for AIDS in developing countries?

The high price of medicines is one of many barriers to providing ARV treatment for people living with AIDS in developing countries. Other barriers include political will, social stigma, health infrastructure, and insufficient funding. Until recently, the prices of ARVs were so high that wide scale treatment programmes were unthinkable. Since September 2000, the injection of generic competition into the global ARV market has catalysed a dramatic drop in drug prices. As a result, medical, academic, and political leaders are now beginning to tackle other barriers to treatment. An example of this from our region can be found in Botswana, where the government has begun a countrywide programme of providing access to ARV's for all PWA's who require it. With the prices of drugs tumbling, there is no longer any excuse to deny medical treatment to the millions who are already ill.

# How much does treatment for AIDS cost today? How low could the prices go?

A triple-combination of ARVs costs US\$10,000 - US\$15,000 per patient per year in the US and Europe. However, generic drug producers have offered to sell the equivalent medicines for as low as US\$300 per patient/year. Competitive pressure from the generic producers, combined with public pressure on drug companies, has also pushed down the prices of branded drugs to around US\$700-US\$1000. With expanded production, prices could fall to as low as US\$200. At these levels, ARVs will be brought within reach of many more patients, and with international donor support and commitment from national governments can be delivered to even more.

### What are generic drugs?

Generic drugs are "copies" of drugs manufactured and patented by major pharmaceutical companies. The quality of these "copies" varies, but there are a number of effective generic drugs in existence. There are high-quality cheap generics for most of the ARV's and for drugs that cure opportunistic infections. If generic drugs are used for combating HIV in Namibia, many more people will be able to afford them and the state will probably be able to supply them to all people with AIDS who cannot afford to buy them.

## Aren't generic manufacturers stealing intellectual property and breaking the law?

No. Patents are granted on a national basis -- there is no such thing as an international patent. Therefore, if a drug is not patented in a country, it is perfectly legal for a generic company to produce or import a version of that drug in that country. Companies can also export generics to other countries where that drug is not under patent. As none of the ARV's are under patent in Namibia, there is nothing to stop our government from importing cheaper generic drugs and providing them to those who need them.

# Surely the main obstacles to access to medicines are not patents but poverty and inadequate health services?

In many developing countries, including Namibia, and particularly in urban centers, the necessary infrastructure exists to provide antiretroviral therapy today. Small pilot programmes in Uganda, Côte d'Ivoire, Senegal and South Africa, and widescale treatment programmes in Brazil and other Latin American countries, have demonstrated that it is possible. It is possible to start treatment programmes today, while simultaneously conducting operational research to

learn the best ways of delivering care in resource-poor settings. Simpler drug regimens and diagnostic methods, coupled with medical training and infrastructure investment, will be necessary to expand treatment quickly to other areas with limited resources. But we cannot afford to wait any longer. Infrastructure challenges are not a valid excuse to continue denying medical treatment to those in need.

## Will focusing on treatment for people who are already HIV-positive detract from prevention efforts?

Field experience has shown that treatment and prevention efforts are both necessary and complementary strategies for combating the HIV epidemic. People have little incentive to get tested to find out their HIV status without the possibility of treatment. Once people know their status, they can modify their behavior to reduce transmission. New efforts to combat the HIV pandemic must include treatment in order to be effective.

# Will providing antiretroviral drugs in developing countries cause the emergence of super-drug-resistant strains of HIV?

For many people, the anti-retroviral drugs only work for a temporary period (usually a few years). After that, a mutated form of the virus develops in the body that cannot be controlled by the medication. When this happens, the virus is said to be resistant to the drug regimen and the patient must switch to another drug regimen. By adhering to their treatment regimens strictly, people with HIV can use the medications much longer before drug resistance occurs.

It is also believed that patients who do not closely adhere with their drug regimens run a higher chance of developing drug-resistant strains of HIV. Patients may find adherence difficult due to a number of factors, including complicated drug dosing regimens or interruptions in drug supply due to high prices. The complexity of AIDS treatment makes patient adherence a challenge in BOTH wealthy and poor settings. However, results from the few existing programmes are encouraging. With limited health infrastructure, Brazil has dramatically reduced illnesses and deaths from AIDS, and enjoys treatment adherence rates that match those in the US (around 70% of patients taking their medicines properly 80% of the time). In much poorer Uganda and Côte d'Ivoire, well-run pilot projects have also demonstrated that adherence rates can match those of Europe and the US. A combination of three drugs in one pill, to be taken twice a day, already exists, and another is currently being developed -- these are steps in the right direction. In wealthier countries, fear of non-adherence has never been an acceptable reason to deny a patient life-saving treatment. It should not be acceptable in poorer ones.

# Isn't anti-retroviral therapy much too complicated to be used successfully in resource-poor settings?

Medecins Sans Frontieres and others are currently providing triple therapy in a number of pilot projects in developing countries around the world, including least developed countries such as Malawi and Cameroon, as well as in Khayalitsha, in the Western Cape province of South Africa. Their experiences so far are very encouraging, but it is clear that in order to expand such programmes dramatically, it will be necessary to introduce simpler treatment protocols, and cheaper and less complicated monitoring tools. In Botswana, despite problems with implementing their programme, the government has followed through on its commitment, and is continuing efforts to provide ARV's countrywide.

Why do people in Namibia and other poor countries not have access to anti-retroviral medication or the treatments for opportunistic infections?

In Namibia, the price of the cheapest triple-drug anti-retroviral therapy is well over N\$1000 per month, which is completely out of reach for most Namibians. The same applies to the treatments for some opportunistic infections

The problem is not unique to Namibia, but applies to most poor countries, particularly in Africa, but also Asia and South America.

## Aren't generic manufacturers stealing intellectual property and breaking the law?

No. Patents are granted on a national basis -- there is no such thing as an international patent. Therefore, if a drug is not patented in a country, it is perfectly legal for a generic company to produce or import a version of that drug in that country. Companies can also export generics to other countries where that drug is not under patent.

#### Conclusion

Although anti retroviral treatment is not a cure for HIV/AIDS, the provision of affordable ARV treatment can effectively break the current connection between HIV/AIDS and inevitable death, and can turn HIV/AIDS into a chronic manageable disease. Access to this treatment can both lengthen and improve the quality of life of people living with HIV/AIDS in Namibia. It will create an opportunity for people living with HIV/AIDS in Namibia to continue contributing to Namibian society, to care for their children and loved ones, and, most importantly, to carry on living.

Why, then, is affordable anti retroviral treatment not available in Namibia?