

Access to Essential AIDS Medications: A Medical Student Call to Action

Overview

HIV/AIDS is the most important health crisis of our time. It is a disease which is threatening the existence of populations around the world and leaving in its wake orphans, decimated work forces and a terrifying cycle of poverty and death. Currently worldwide, approximately 40 million people are currently infected, with 95% of those infected living in the developing world. In some countries one in five are HIV positive and that number is growing. Eight to ten thousand people die every day from complications of the AIDS virus. These deaths create overwhelming voids: the loss of parents and spouses, the loss of entire countries' productive workforce, the loss of millions of lives around the world. Many have compared it with the Black Death which ravaged Europe in the 15th century; but there is a crucial difference: HIV is treatable.

Life extending medications are currently available to many in the developed world. These drugs do not cure AIDS, but they can greatly prolong life and improve the quality of life. As a result of access to antiretroviral medications (ARVs) and other medications necessary for the treatment of opportunistic infections, AIDS-related mortality in the US and Europe has decreased by over 70%. Further, access to treatment boosts prevention efforts in two ways: 1)the availability of successful therapy provides incentive for getting HIV testing and 2)those with decreased viral loads as a result of ARVs are less likely to transmit the virus. However, less than 5% of the 42 million people living with HIV have access to these medications and this is tantamount to a death sentence.

HPSAAN and its component organizations do not accept the current situation in which those in the industrialized world have access to vital medications while those in developing nations are left behind to die. It is crucial that future health professionals fight this brutal inequality which has essentially placed differential value on lives according to the economic status of country of origin. It is in this spirit of urgency and humanity that we are joining in the fight for access to essential AIDS medications.

Who controls the access to essential AIDS medications?

Many people and organizations bear the responsibility of creating a pro-health system where essential AIDS medications are readily accessible. Globally, multilateral organizations such as the World Trade Organization (WTO) and Free Trade Area of the Americas (FTAA) may help increase access by encouraging the production and trade of cheap generic medications while other multilateral organizations such as the World Health Organization and UNAIDS influence access by advocating for the right to essential medications; governments of countries must take the initiative to make access to AIDS medications a priority and create legislation to reflect this priority; at the local level, health providers must know about AIDS medications in order that they are able to provide them to their patients. In the private sector, pharmaceutical companies should contribute to long-term solutions, by supporting legislation which allows for generics to

be produced for poor countries and by reducing prices for essential medications in a predictable way. Private corporations with workforce in the developing world should also create an atmosphere of corporate responsibility in which employers help provide the healthcare and treatment for their workforce and families.

There are currently numerous barriers to accessing appropriate treatment. Lack of funding is one such obstacle (see our section on the Global Fund for AIDS, TB and Malaria). Developing countries generally cannot afford to pay for non-generic medications and may not have the capital to fund fledgling pharmaceutical industries. Additionally, many developing nations have the burden of debt and structural adjustment regimes limiting the monies spent on health (see our section on Debt Forgiveness). Fortunately, since September of 2000, the increase of generic competition in the pharmaceutical industry has significantly decreased the price of ARVs. AIDS therapy now costs as little as US\$295 per patient per year compared to US\$10 000 one year ago.

In part this increase in manufacturing of generics is due to the Doha Declaration, signed in November 2001 by the US and other WTO members. This agreement states that the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.” Thus, while the TRIPS agreement aims to protect patent rights, the Doha Declaration specifically reaffirms a country’s right to override drug company patents in the interests of public health. Countries requiring medications, such as ARV’s, may issue a compulsory licence which allows countries to produce needed medications without the permission of the patent holder. Under the current WTO rules, there is no clear provision for the poorest of countries who have neither the money to buy medications nor the capacity to produce their own. This issue is currently being debated. The US Trade Representative (Robert Zoellick) under pressure from large US-based pharmaceutical companies has proposed that any solution to this problem only be applicable to drugs for a limited number of diseases. This goes against the Doha Declaration that clearly states patents should not interfere with public health, no matter the disease.

Taking Action: What Can I Do?

There are 3 main goals for the AMSA Essential Medications Campaign:

1. Education
2. Overcoming Barriers To Access At Home and Abroad
4. Pharma Fairness

1. Education: It is vital that we educate ourselves and our peers on this issue. This section contains some basic information as well as links to more extensive resources on the subject. AMSA members can also increase awareness by inviting speakers to their school, organization or regional conference. Speakers are available through MSF, HealthGAP, ACT UP and Essential Action as well as other local groups.

- Organize a lunch-time talk
- Contact your regional conference coordinator and check if there are available workshop times
- Email interesting articles or websites to listservs you are on
- Create a discussion group around this issue

2. Overcoming Barriers to Access At Home and Abroad: Locally there are campus-based campaigns which are vital to increasing access to essential medications. Many US universities do R&D to create new medications and then allow large pharmaceutical companies to market and sell the medications. Universities, dedicated to the public interest, have a responsibility to ensure that their research reaches the people who need it most. Thus, universities who hold drug patents can the drug's accessibility. One such successful campaign took place at Yale University. A coalition of students and faculty requested that Yale, the patent-holder of d4T (an ARV) negotiate with Bristol-Myers-Squibb, the distributor of d4T. Yale successfully worked with BMT to eliminate barriers to d4T's access in Africa.

- University of Minnesota Campaign: The University of MN's patent policy prevents a life-saving AIDS drug from reaching millions who need it. The University of MN is the inventor and patent-holder on crucial elements of the HIV/AIDS treatment abacavir (ABC), classified by the WHO as an "essential medicine." The University currently licenses its ABC patents exclusively to the pharmaceutical company GlaxoSmithKline (GSK). GSK, however, refuses to provide ABC at affordable prices in developing nations.

The University of MN has the power to change its licensing policy to ensure global access to essential medications. The University of MN's current agreement with GSK runs counter to the University's Mission Statement, which commits it to "making the knowledge and resources created and preserved at the University accessible to the citizens of the state, the nation and the world." As a tax and tuition-financed institution, the University of MN has an obligation to look beyond profit when lives are at stake.

- Sign the petition at www.essentialmedicines.org and ask the University to: 1) draw upon its powers as patent-holder to make the HIV/AIDS drug abacavir affordable in developing (non-OECD) countries and 2) reconfigure its current patent licensing policy to ensure the delivery of essential medicines, treatments and procedures to developing (non-OECD) countries.
- Visit www.essentialmedicines.org for upcoming information on other campus campaigns (e.g. at Emory University).

Globally, it is vital that we, future healthcare professionals, demonstrate our commitment to access to medications! We can demand that our national officials work towards creating a fair and equitable healthcare market. Usually the officials dealing with patent law work in Ministries of Commerce, Ministries of Trade, or Ministries of Finance.

Specifically, the US Trade Representative is Robert Zoellick. Organizing and participating in call-in days or letter writing campaigns can help convince the USTR that access to medications is important to US citizens. There are several upcoming events when essential medications will be discussed by the WTO and FTAA. On September ?? the WTO Ministerial will be meeting in Cancun, Mexico and in November 1, the FTAA will be meeting in ?? Quito, Mexico. During these meetings, the issues of access to essential medications will be center stage. Intellectual property rights and compulsory licensing will be among the major issues. Prior to these meetings it will be vital to demand that our representatives fight for access to medications. Call in days and letter-writing campaigns as well as demonstrations are all good methods of letting our officials know that access to essential medications is important to the healthcare professional students. Below is some important contact information and a sample call in day talking points:

- Robert Zoellick, US Trade Representative
- Peter Frederick Allgeier, Deputy US Trade Representative: Pallgeier@ustr.gov or (202) 395-5114
- Dorothy Dwokin, Assistant US Trade Representative on WTO and Multilateral Affairs
- Regina Vargo, Vice-Ministerial Representative to the FTAA: Rvargo@ustr.gov or (202) 395-5190
- Kira Alvarez, Negotiating Group of FTAA Intellectual Property Rights: KAlvarez@ustr.gov or (202) 395-6864
- WTO and Multilateral Affairs: (202) 395-3063
- Intellectual Property Rights: (202) 395-4510

Office of the US Trade Representative
600 17th Street, NW
Washington, DC 20508

Sample Call-in Script

Hello, my name is _____. I am a member of the Health Professional Student AIDS Advocacy Network and a member of AMSA/PHR. I am calling because we are requesting that US representatives to the WTO Ministerial meeting in May make access to essential medications a priority. Is there someone to whom I may speak about this matter?

Hello, my name is _____. I am a member of the Health Professional Student AIDS Advocacy Network and a member of AMSA/PHR. We are a group of healthcare professional students committed to the fight against global AIDS. I am aware that one of the issues to be discussed at this meeting will be paragraph 6 of the Doha Declaration. As there are over 42 million people in the world living with HIV/AIDS and only 5% of whom are receiving vital life-extending treatment, we believe it is vital that the US, a world leader, take proactive steps in increasing access to treatment. We would like to request that paragraph 6 make no limitations or barriers on compulsory licensing.

3. Pharma Fairness

Is the price right for pharmaceuticals? What drives costs and how can we contain them? What about R&D? There are a lot of great articles on these subjects! Please follow the links below.

Carey J, Barrett A. Drug Prices: What's Fair? [Business Week, Dec 10, 2001](#).

Connolly C. Price Tag for a New Drug: \$802 Million. Findings of Tufts University Study Are Disputed by Several Watchdog Groups. [Washington Post, December 1, 2001, A10](#).

Doha WTO Ministerial 2001. [Declaration on the TRIPS Agreement and public health](#), adopted November 14, 2001.

Editorial: Patent protection versus public health. [Lancet 2001\(10 Nov\);238\(9293\)](#).

Schieppati A, Remuzzi G, Garattini S. Modulating the profit motive to meet needs of the less-developed world. [Lancet 2001\(10 Nov\);238\(9293\):1638-41](#).

Goozner M. The Price Isn't Right. [The American Prospect, Sept 11, 2000](#).

Gerth J, Stolberg SG. Drug Companies Profit From Research Supported by Taxpayers. [New York Times, April 23, 2000](#).

Weissman R. AIDS and Developing Countries: Democratizing Access to Essential Medicines. [Foreign Policy in Focus 1999\(Aug\);4\(23\)](#).

Trouiller P, Olliaro PL. Drug development output: what proportion for tropical diseases? [Lancet 1999\(Jul 10\);354\(9173\):156](#).

Gross CP, Anderson GF, Powe NR. The relation between funding by the National Institutes of Health and the burden of disease. [NEJM 1999\(Jun 17\);340\(24\):1881-87](#).

FAQs!! (From the MSF Essential Medications Website)

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

In many developing countries, particularly in urban centers, the necessary infrastructure exists to provide antiretroviral therapy today. Small pilot programmes in Uganda, Côte d'Ivoire, and Senegal, 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.

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

MSF's 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.

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

It is 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. The priority now is to boost research into simplifying treatment protocols, especially for resource-poor settings. 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.

4. Will lowering drug prices for poor countries hurt research and development (R&D) for new medicines?

No. Developing countries make up such a small part of drug industry revenue, that it is unlikely that lowering prices for developing countries will hurt R&D. 77% of the \$406 billion worldwide drug market projected for 2002 will be in North America, Europe, and Japan. All of Africa accounts for just over 1%. When asked if a price cut for Merck's AIDS drugs would take away some of the incentive for R&D, Guy Macdonald, Vice President for Anti-Infectives, replied "It absolutely does not. We are totally committed to our research and development in the area of HIV and AIDS." Furthermore, the industry is one of the most profitable in the world. In 1998, the top ten companies enjoyed \$108.1 billion in sales, of which \$34.7 billion was profit — at 32.1%, this is one of the highest average profit margins of any industry worldwide. Finally, it is notable that companies consistently spend more on marketing and administration than on R&D.

5. How do international trade policies impact access to medicines? What is TRIPS and why does it matter?

Globalisation and the international regulation of trade are becoming increasingly linked to health. The World Trade Organisation's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), is the most important international agreement on protection of patents, copyrights, and trademarks. TRIPS does not establish a uniform international law, but sets out minimum guidelines for intellectual property protection that must be met by all WTO Members by 2006 at the latest. TRIPS treats medicines in the same way as any other patented product — such as compact discs or video games. It is a threat to public health in poor countries because it gives patents on medicines for a minimum of 20 years, which grants a monopoly to patent-holders during that time. This will lead to further increases in drug prices and negatively impact the

developing world's ability to produce affordable generic alternatives to branded drugs. Nonetheless, there are safeguards within TRIPS that developing countries can write into their national laws in order to protect public health. These safeguards include compulsory licences, parallel imports, and strategies to accelerate the introduction of generics (discussed below).

6. What is compulsory licencing?

Compulsory licences allow the production or import of a generic medicine, without the consent of the patent holder. Patent-holders receive adequate compensation. Compulsory licences may be issued by public authorities for various reasons, including public health or emergency. They are neither a form of pirating, a legal loophole, nor a way of stealing intellectual property. Compulsory licences are legal under the TRIPS Agreement, are considered a regular feature of any good intellectual property legislation, and are commonly used by industrialised countries such as the US. France authorizes compulsory licences when patented drugs "are only made available to the public in insufficient quantities or quality or at abnormally high prices." Both private entities and governments can typically apply for a compulsory licence. Countries should design fast, simple procedures for granting compulsory licences to make full use of this safeguard.

7. What is parallel importing?

Parallel importation allows a country to shop around for the best price of a branded drug on the global market, without the permission of the patent-holder. It is an attractive option for developing countries when the same branded medicine is being sold for different prices in different markets. For example, it would allow a country like Mozambique, where 100 units of Bayer's ciprofloxacin (500mg) costs \$740, to import the same product from India where Bayer sells it for the much lower price of \$15, due to vigorous generic competition. Many European countries, such as the United Kingdom, benefit from significant parallel trade to reduce the overall cost of medicines. Parallel importing does not involve the purchase of generics.

Resources

www.healthgap.org

www.accessmed-msf.org/index.asp

www.cptech.org

www.healthactionaids.org

www.amsa.org

www.essentialmedicines.org

www.actupny.org