Access to HIV/AIDS Treatment in Developing Countries

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The vast majority of people in developing countries who are living with HIV/AIDS are unable to access life-saving treatment for HIV infection and related opportunistic infections. This problem is not unique to people living with HIV/AIDS; it affects all people with serious diseases and conditions. The obstacles to access can be divided into two broad categories:

- the high cost of drugs; and
- poor health infrastructures.

This fact sheet explores the problems in each category. First, the context is described. Then, the issues related to the high cost of drugs are discussed. This is followed by an overview of the issues related to health infrastructures. Finally, a list of resources is provided where more information can be obtained.

This information sheet is intended to provide readers with a basic understanding of the issues. Before reading the text, please consult the note on terminology on Page 2.

The Context

EPIDEMIOLOGY. At the end of 2000, there were 36.1 million people living with HIV/AIDS in the world. More than 95% of them live in developing countries, where 20 million people have already died from AIDS and over 8,000 more die each day. It is estimated that about 15,000 more people are infected with HIV every day around the world.[1]

PER CAPITA INCOME. Average annual per capita (i.e., per person) income in high-income countries in 1999 was $25,730.[2] In sub-Saharan Africa and in South Asia, it was $500 and $440 respectively.[3]

PER CAPITA HEALTH SPENDING. Annual per capita spending on health in North America and Western Europe is more than $1,500. In Latin America, the figures range from $41 in Guatemala to $792 in Argentina. In contrast, in most of Africa and Asia, annual per capita health expenditure is under $20.[4]

OTHER PRIORITIES. All countries face competing demands for limited resources. Under-resourced countries have difficulty meeting even basic needs, such as clean water, adequate housing and nutrition, and decent schools and highways. Many developing countries also face serious epidemics of other diseases, such as tuberculosis and malaria.

THE MARKET FOR DRUGS. Developed countries account for the vast majority of the global market for prescription drugs. North America, Western Europe and Japan alone represent 80% of the market. By contrast, Africa accounts for just 1%.

The High Cost of Drugs

THE ISSUE

Drugs for the treatment of HIV/AIDS are priced out of the reach of all but a tiny number of persons living with HIV/AIDS in developing countries. While the introduction of antiretroviral therapies has benefited persons living with HIV/AIDS in developed countries mortality rates have dropped by over 70% these treatments remain largely inaccessible to people in developing countries.

The annual cost of triple combination antiretroviral therapy in the United States ranges from $10,000 to

$15,000. Drugs for the treatment of opportunistic infections are also very expensive.

Although the price of drugs is not the only issue affecting access, it is a significant barrier and one that is common to all developing countries, whatever their stage of development.

Pharmaceutical Patents, International Agreements and Drug Prices

Like other inventions, drugs are often protected by patents. When a drug is patented by its manufacturer, other companies are not permitted to make or sell copies of the drug. The manufacturer has a monopoly on sales. The Agreement on Trade Related Aspects of Intellectual Property Rights ("the TRIPS agreement") is the main international agreement governing patent rights. All countries that are part of the World Trade Organization are bound by TRIPS (though the least developed countries have been given until January 1, 2006 to comply). TRIPS requires that countries grant 20-year patent protection to new drugs and that they modify their patent laws accordingly.

The prices of patented drugs are very high. Brand-name pharmaceutical manufacturers argue that high prices are needed to fund research and development. However, treatment activists respond (1) that these manufacturers are among the most profitable in the world; (2) that these manufacturers provide insufficient financial accounting (particularly with respect to their research and development costs) to justify the prices of their products; (3) that the research and development costs of many drugs (including many HIV/AIDS drugs) are partially (often significantly) financed by governments and non-profit agencies; and (4) that research and development costs are more than recovered from sales to people in developed countries, so there is no justification for keeping prices high in developing countries.

Efforts To Improve Access

A number of avenues are being pursued to lower the costs of HIV/AIDS treatments in developing countries. Some of these avenues are described below.

Price Reductions and Drug Donations

As a result of considerable pressure from activists, governments and international agencies, some of the brand-name pharmaceutical companies have lowered

NOTE ON TERMINOLOGY

This information sheet uses the term **developing country** to describe countries that are poor in resources and the term **developed country** to describe wealthier nations. It is important to keep in mind that developing countries are at different stages of development and so cannot always be lumped together as one. For example, some developing countries have more sophisticated health infrastructures and greater resources at their disposal than others.

Although this information sheet focuses on the problems of accessing treatment in developing countries, it is important to acknowledge that there are people in developed countries who face similar problems accessing treatment and that there are people in developing countries (a tiny minority) who have the money to obtain adeq uate treatment. It is also important to not assume that conditions are the same throughout a country or region. In many countries, both developed and developing, health infrastructures in major urban areas are much better than in rural areas.

Antiretroviral therapies are drugs that stop or suppress the activity of a retrovirus, such as HIV.

CD-4 counts are a measure of the extent of suppression of the immune system.

Combination therapy refers to the use of a combination of antiretroviral drugs, usually three or more. Combination therapy has become a standard of care in treating HIV infection in developed countries..

Opportunistic infections are infections that do not normally affect healthy people but that can cause disease in people with weakened immune systems (due to HIV/AIDS or other conditions).

Viral load refers to the amount of virus in a person's body, usually measured in the blood stream.

the prices of their drugs or given drugs away free in developing countries.

For example, in March 2001, Merck announced discounts of 90% for two of its HIV/AIDS drugs in Sub-Saharan Africa. The offer was later extended to Romania and parts of Central and South America. In June 2001, GlaxoSmithKline announced price reductions of about 80% for three HIV/AIDS drugs in 63 countries. That same month, following several limited price reductions for its drug fluconazole, Pfizer said it would give the drug away free to AIDS patients in the least developed countries.

As welcome as price reductions are, there are several limitations to this approach:

- It takes a long time to convince pharmaceutical manufacturers to lower prices. Negotiations are very arduous.
- There are usually conditions attached to the price reductions. Sometimes the reductions apply only to drugs sold in the public sector; or they apply only to some developing countries; or they are only for some indications. Sometimes they are for a limited period of time.
- The reduced prices are usually still too expensive for most people in developing countries.

There are usually conditions attached to drug donations as well. Furthermore, there are questions about whether price reductions and drug donations are a sustainable solution, and whether this is the best approach to take. Discounts can be eliminated or reduced after they are put into effect, and drug donations can be discontinued. Developing country health systems need a reliable source of inexpensive essential medicines and should not have to rely on the whims of company goodwill. Developing the capacity to manufacture generic copies of patented drugs and to import cheaper drugs (see below) may be a better solution.

Getting Governments and the Private Sector to Pay

Some developing country governments have the resources to pay for HIV/AIDS treatments. Brazil, in addition to bringing about substantial price reductions through generic manufacturing (see below), fully subsidizes the costs of many antiretroviral therapies and treatments for opportunistic infections for 90,000 persons living with HIV/AIDS in that country. This has resulted in a drop of over 50% in AIDS-related deaths in Brazil.

In some countries, governments have been sued in the courts over their failure to meet their legal obligations to provide HIV/AIDS treatments to people who need them. This approach has met with some success in countries where the right to health is enshrined in the constitution. In the Latin American countries of Argentina, Costa Rica, El Salvador and Venezuela, the courts have ruled that governments must provide the treatments. However, the court orders are not always fully implemented for a number of reasons, not the least of which is that the governments indicate that they have difficulty subsidizing the high costs of HIV/AIDS treatments.

In May and June of 2001, two large companies in South Africa Anglo-American and Daimler/Chrysler South Africa announced that they would pay for HIV/AIDS medications for infected workers and spouses. These companies recognized that their work forces were being decimated by HIV/AIDS and that it was in the companies' best interests to provide free medications.

Also, over the years, there have been several attempts to establish funds to help purchase HIV/AIDS treatments for people in developing countries. When used in combination with other approaches outlined in this section, like price reductions and compulsory licensing, such funds could be extremely helpful in making HIV/AIDS drugs affordable. Currently, through the auspices of the United Nations, there is an effort underway to establish a Global AIDS and Health Trust

Fund. Many details still need to be worked out, such as how large the fund will be; whether it will cover both HIV/AIDS prevention and treatment; whether it will address infrastructure issues (see below); and which diseases other than HIV/AIDS will be included.

Compulsory Licences

Governments can issue licences to companies to manufacture generic copies of patented drugs (without the approval of the patent holder). These are called "compulsory licences" and they are allowed under TRIPS. Governments have to enact legislation authorizing compulsory licensing. The generic manufacturer has to provide adequate compensation to the patent holder such as through a royalty on the sale of the drug. This is a legal way of breaking the patent holder's monopoly.

No country has yet used compulsory licensing for drugs used in the treatment of HIV/AIDS, largely because of intense pressure from industrialized countries and the multinational pharmaceutical manufacturers. In some cases, these countries and manufacturers have tried to coerce developing countries into adopting patent legislation that is more restrictive than what TRIPS requires and that outlaws compulsory licensing (and parallel importing as well). The United States government has even threatened trade sanctions. In response to pressure from treatment activists in the United States, the U.S. Government has pledged to refrain from bullying countries in this manner.

What would happen if compulsory licensing were used? Brazil, Thailand and India are three countries that have authorized generic manufacturing of HIV/AIDS drugs. They have succeeded in reducing prices substantially. A daily dose of the antiretroviral drug AZT costs $10.00 in the United States, but only $1.08 in Brazil. A daily dose of fluconazole, a drug used to treat certain opportunistic infections, costs $12.20 in the United States, but sells for as little as $0.29 in Thailand and $0.64 in India. Technically, these countries did not use compulsory licensing. Instead, they authorized generic manufacturing while they were still excluded from the provisions of TRIPS. But the effect is the same: generic manufacturing sharply lowered prices.

Unfortunately, TRIPS appears to allow compulsory licensing only when the generic drugs are manufactured primarily for local (i.e., in-country) use. This might prevent a company that had received a compulsory licence from exporting its products to another country that may not have the capacity to manufacture generic drugs.

Voluntary Licences

A pharmaceutical manufacturer could issue voluntary licences to a local manufacturer to produce a generic version of its drug. In exchange, the local manufacturer would pay compensation to the patent holder. This would be very similar to compulsory licensing, except that the patent holder would willingly issue the licence. Treatment activists in South Africa attempted (without success) to convince Pfizer to issue a voluntary licence for fluconazole.

Parallel Importing

When a country imports a drug sold (or authorized for sale) by the patent holder in other countries, for resale at home, without the consent of the patent holder, this is called parallel importing. TRIPS permits parallel importing.

Parallel importing can result in lower prices because the patent holder often sells its drugs at different prices in different countries. For example, in September 1999, Pfizer was selling a daily dose of fluconazole at prices that ranged from $9.35 in South Africa to $13.37 in France and to $27.60 in Guatemala. Obviously, the price reductions achieved through importation would not be as significant as those that can be obtained from compulsory licensing.

TRIPS does not permit the importation of generic copies of drugs into countries where the drugs are protected by

a patent. Attempts to import generic HIV/AIDS drugs into South Africa and Ghana have been staunchly resisted by the brand-name pharmaceutical manufacturers.

Other Avenues

The following are brief descriptions of some of the other measures that are being utilized or explored to bring prices down.

DISTRIBUTION PIPELINES. This involves taking surplus medications from developed countries and distributing them to people in developing countries. One of the most successful initiatives of this type has been the United States-Venezuela Air Bridge.

BULK BUYING. This involves several countries getting together to make joint purchases of HIV/AIDS treatments. This has helped to reduce prices in the countries of the Caribbean.

TECHNOLOGY TRANSFER. This involves selling the rights to drugs developed with public funds to countries directly, or to a body like the World Health Organization (WHO), rather than to pharmaceutical manufacturers. This already happens with vaccines for some major illnesses. Because the patents for these vaccines are held by WHO, the vaccines have been distributed at cost to developing countries. With respect to HIV/AIDS treatments, however, at this stage this is just an idea that is being discussed.

DEBT CANCELLATION. Eliminating the debt of resource-poor countries would enable these countries to invest more resources in improving access to treatments, both by buying medicines and by improving health infrastructures.

Poor Health Infrastructures

In addition to the problem of unaffordable drugs, and the lack of clean water and adequate nutrition, some developing countries have inadequate health infrastructures for providing care and treatment. For example:

- There are too few clinics, hospital beds and laboratories. For example, the number of hospital beds per 1,000 population is 0.3 in Bangladesh and 1.6 in Botswana (compared to 4.0 in the United States and 8.7 in France).[5]
- There is a shortage of competent health care professionals. Medical facilities are often understaffed. For example, the number of doctors per 100,000 population is 16 in sub-Saharan Africa and between 33 and 48 in South Asia (compared to between 200 and 300 in developed countries).[5] For nurses, the disparities are similar.
- In the rural areas of Africa and Asia, where most people live, the proportion of doctors, nurses and hospital beds is even lower.[5]
- There is often a lack of medical and laboratory equipment for doing diagnostic testing.
- Health care professionals and laboratory technicians are often not adequately trained.
- Drug distribution systems are often non-existent or incomplete.

For persons living with HIV/AIDS, these infrastructure problems have several repercussions:

- HIV cannot be properly diagnosed.
- Correct treatment cannot be properly prescribed.
- The best care cannot be provided.
- It can be difficult or impossible to access CD-4 and viral load diagnostic testing to measure how well the antiretroviral therapies are working and to monitor the emergence of drug resistance. Because HIV mutates rapidly, the virus can become resistant to the drugs. When that happens, patients need to change their mix of antiretroviral drugs. But these tests are very expensive and many laboratory technicians in the developing world lack the equipment and training to perform the tests.

As well, the lack of adequate food, clean water, and electricity for refrigerating drugs, can make it difficult for persons living with HIV/AIDS in developing countries to comply with their treatment regimens.

This section provides information on several relevant publications, some organizations working on this issue, and two email discussion forums.

Resources

PUBLICATIONS

AIDS Drugs for Africa. Article in *Scientific American*, November 2000. P. 98-103. This article provides an overview of access to treatment issues in an African context. It is not available online.

Beyond Our Means? The cost of treating HIV/AIDS in the developing world. PANOS Institute. 2000. This booklet provides an overview of the issues around access to treatments in the developing world. It uses case studies from one Asian and two African countries to illustrate the issues. The booklet can be accessed via the PANOS web site at www.oneworld.org/panos/.

Compulsory Licensing and Parallel Importing: What do they mean? Will they improve access to essential drugs for people living with HIV/AIDS? International Council of AIDS Service Organizations (ICASO). July 1999. This is a background paper that explains the concepts of compulsory licensing and parallel importing. The paper can be accessed via the ICASO web site at www.icaso.org.

Formula for fairness: Patient rights before patent rights. Oxfam. Part of Oxfam's Company Briefing Papers series. The paper examines the role of one of the brand-name pharmaceutical companies Pfizer in keeping drug prices high. It provides an overview of the issues, describes the role of TRIPS and patents in drug pricing, discusses the pharmaceutical manufacturers' lobbying efforts, and recommends ways to make drugs more accessible. The paper can be downloaded from Oxfam Canada's web site at www.oxfam.ca.

HIV/AIDS and Human Rights: Stories from the Frontlines. International Council of AIDS Service Organizations (ICASO). June 1999. Among other topics, this document describes how NGOs have improved access to treatments for persons living with HIV/AIDS by fighting in the courts, by lobbying politicians, by using the media, by organizing public actions, and by setting up distribution pipelines. The document can be accessed via the ICASO web site at www.icaso.org.

How Can You Get the Medicines You Need to Survive? International Gay and Lesbian Human Rights Commission (IGLHRC). This document explains the issues and provides practical advice on how activists can work to improve access in their countries. The document can be accessed via the IGLHRC web site at www.iglhrc.org.

Medicine Shouldn't Be a Luxury. MSF Canada. This brochure describes the problems of accessing essential medicines and outlines a plan of action to address the various dimensions of the problem (health issues in global trade, availability and affordability of existing drugs, and research and development on neglected diseases). Hard copies are available from MSF Canada offices. For a list of the offices, consult the MSF Canada web site at www.msf.ca.

We Can Use Compulsory Licensing and Parallel Imports: a South African Case Study. Treatment Action Campaign. AIDS Law Project. This paper presents an overview of the issues from a South African perspective. It also examines two pieces of legislation in South Africa that could be used to improve access to essential medicines. The paper can be accessed via the AIDS Law Project web site at www.hri.ca/partners/alp/.

Note: Additional publications are available on the web sites of some of the organizations listed below.

ORGANIZATIONS: CANADA

The organizations listed here are currently establishing a Canadian coalition to address issues related to global access to treatments.

Canadian HIV/AIDS Legal Network
Richard Elliott, Director, Policy and Research
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Email: relliott@aidslaw.ca
www.aidslaw.ca

The Canadian HIV/AIDS Legal Network is a national community-based organization that engages in legal and ethical analyses and policy development. The Legal Network is working with its partner organization, the AIDS Law Project South Africa, to address access to treatment issues. The Network's web site (www.aidslaw.ca) contains a page with key resources on access to treatment in developing countries, such as articles, papers, reports, and links to key web sites. The Network also operates a resource centre open to the public which contains documents on access to treatment.

Canadian Treatment Advocates Council (CTAC)

Louise Binder, Chair
Tel: 416 422-2179, Fax: 416 422-2900
Email: CTAC@sympatico.ca

CTAC is a national organization directed by people living with HIV/AIDS, dedicated to ensuring the research and development of safe and effective HIV/AIDS treatments, and equitable, affordable and timely access to all HIV treatments. Within Canada, CTAC has focused on, among other issues, the reform of the drug review systems, including post approval surveillance and drug pricing. CTAC has expanded its work to include international issues through a collaborative relationship with other national and international organizations that have a focus on access to treatment and related issues.

Interagency Coalition on AIDS and Development (ICAD)

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ICAD is a coalition of international development organizations, AIDS service organizations and others. Its aim is to lessen the impact of HIV/AIDS on resource-poor communities and countries. In addition to producing this information sheet, ICAD is involved in other activities related to global access to treatments.

Médecins sans frontières / Doctors Without Borders Canada (MSF Canada)

Marie Hélène Bonin, National Coordinator
Campaign for Access to Essential Medicines
Tel: 613 241-4949, Fax: 613 241-4411
Email: mhbonin@msf.ca Web www.msf.ca

(See the description of MSF and the Campaign For Access to Essential Medicines in the listing for Médecins sans frontières under "Organizations: Other Countries" below). In Canada, MSF's Campaign is supported by the Canadian Medical Association. To find out more about the Canadian campaign, consult the MSF Canada web site at www.msf.ca /access.

Oxfam Canada

Mark Fried, Communications and Advocacy Coordinator
Tel: 613-237-1698, ext. 231, Fax: 613-237-0542
Email: markf@ott.oxfam.ca Web: www.oxfam.ca

Oxfam Canada is an international development and humanitarian relief organization supporting local community development in twenty countries in Africa and Latin America. It undertakes advocacy and outreach campaigns in Canada on issues relevant to development, including access to medicine. (See also Oxfam International below.)

ORGANIZATIONS: OTHER COUNTRIES

Consumer Project on Technology (CPT)

Tel: 202 387-8030, Fax: 202 234-5176
Email: love@cptech.org Web: www.cptech.org

CPT is a U.S.-based, non-profit research and advocacy organization created by consumer advocate Ralph Nader. Its activities focus on information technologies, intellectual property and research and development.

Health Global Access Project (GAP) Coalition

Email: network@atdn.org Web www.healthgap.org

Health GAP is a U.S.-based coalition of organizations and individuals advocating for debt cancellation and dedicated to increasing access to essential medications and technologies in countries facing an escalating AIDS epidemic. The Coalition operates the Global Treatment Action Campaign (GTAC), which is a global network for communication and organization for access to essential medications for HIV and other diseases. GTAC has its own Website at www.globaltreatmentaccess.org/.

HIV & AIDS Treatment Action Campaign (TAC)

Tel: 011 403-0265, Fax: 011 403-2106
Email: shasha@netactive.co.za Web: www.tac.org.za

TAC is a coalition of human rights, social justice and AIDS treatment activists in South Africa engaged in grassroots activism and government advocacy on access to treatment issues.

International Gay and Lesbian Human Rights Commission (IGLHRC)

Tel: 415 255-8680, Fax: 415 255-8662
Email: iglhrc@iglhrc.org Web: www.iglhrc.org

The mission of IGLHRC is to protect and advance the human rights of all people and communities subject to discrimination or abuse on the basis of sexual orientation, gender identity or HIV status. IGLHRC responds to human rights violations around the world through documentation, advocacy, coalition building, public education and technical assistance. IGLHRC has developed considerable expertise on access to treatment issues and is actively working to improve access.

Médecins sans frontières / Doctors Without Borders (MSF)

Tel: 32 2 280-1881, Fax: 32 2 280-0173
Email: daniel_berman@geneva.msf.org
Web: www.msf.org

MSF is an independent humanitarian medical aid agency committed to providing medical aid wherever it is needed, regardless of race, religion, politics or sex, and raising awareness of the plight of the people it helps. Upon receiving the Nobel Peace Prize for its humanitarian and medical relief work, MSF launched the Campaign for Access to Essential Medicines to ensure access to essential drugs for all. Details on the campaign can be found on the MSF web site at www.accessmed.msf.org. The web site describes the campaign objectives, actions and accomplishments. It also offers a wide range of reference materials on the target diseases and medicines (HIV/AIDS, tuberculosis, malaria, Kala Azar and sleeping sickness), mainly in English but with some materials also in French.

Oxfam International (OI)

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OI is a federation of 12 international development and relief organizations, including Oxfam Canada and Oxfam Quebec. The members of OI work in 120 countries in Africa, Asia and Latin America, supporting local community development, humanitarian relief and reconstruction and policy advocacy on development-related issues. Oxfam International is currently waging a campaign ("Cut the Cost") to improve access to medicines, through reform of patent rules and changes in pharmaceutical company policy. The campaign's web site is www.oxfam.org.uk/cutthecost.

EMAIL DISCUSSION FORUMS

Treatment Access Forum

Web: www.hivnet.ch:8000/topics/treatment-access/

This electronic forum includes many issues on access to treatments in developing countries. There are a variety of reports and messages available on the web site. If you have email access only, you can still participate: send a message to treatment-access@hivnet.ch.

Pharm-Policy Mailing List

Web lists.essential.org/mailman/listinfo/pharm-policy

This forum discusses pharmaceutical policies, particularly those involving intellectual property, technology transfer and pricing. Available only through email. To join, go to the web site or send an email message to pharm-policy-request@lists.essential.org with the word "help" in the subject line.

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1 *AIDS Epidemic Update: December 2000.* Joint United Nations Programme on HIV/AIDS and the World Health Organization.
2. All costs in this information sheet are shown in United States dollars.
3 *World Development Report 2000*. World Bank.
4 *World Development Indicators 2000*. World Bank.
5 *Beyond Our Means? The cost of treating HIV/AIDS in the developing world.* Panos Institute 2000.

ICAD's aim is to lessen the impact of HIV/AIDS in resource-poor communities and countries. We are a coalition of Canadian international development organizations, AIDS service organizations and other interested organizations and individuals.

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Additional copies are available on the ICAD Web site at www.icad-cisd.com

Le feuillet "Accès aux médicaments anti-VIH/sida dans les pays en développement" est disponible en français.

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