Lawyers Collective HIV/AIDS Unit

"ACCESS TO AFFORDABLE MEDICINES"

CAMPAIGN WORKSHOP

August 11, 12, 2001

BACKGROUND MATERIALS

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BACKGROUND MATERIALS INDEX

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How can you get the medicines you need to survive?

I G L H R C

TOO MANY PEOPLE ARE INFECTED, TOO MANY HAVE DIED

The HIV/AIDS epidemic has killed over 18 million people throughout the world in less than two decades, and over 34 million people are currently infected.

AND MEDICINES ARE TOO EXPENSIVE

One-third of the world's population lacks access to essential drugs to treat life-threatening diseases, including AIDS. In the most impoverished parts of the world that number is more than 50%. Serious illnesses such as tuberculosis (TB), malaria, and meningitis continue to claim millions of lives in the developing world due to the lack of affordable treatment. In the case of TB, most of the 100,000 people suffering from multi-drug resistant strains are unable to afford the new standard combination treatment, which costs approximately US$15,000 per year. And according to the World Health Organization, in developed countries a course of one year's treatment for HIV infection costs the equivalent of four to six months' salary. Antiretroviral drugs have become the standard of care in treating HIV infection in developed countries—but nearly 95% of the world's 34 million people with HIV live outside of those countries. In developing countries one year's HIV treatment--if it were available--would consume 30 years of the average person's income.

PRICE IS NOT THE ONLY FACTOR

There are many barriers to access to essential medicines. Supply and storage problems, substandard drug quality, irrational selection of drugs, wasteful prescription and use, inadequate production, insufficient drug research and development (R&D) and prohibitive prices are all barriers to access.

AND MEDICINES BY THEMSELVES ARE NOT THE SOLUTION

The struggle for access to affordable medicines is one part of a larger HIV/AIDS public health crisis. 95% of people with HIV live in poor countries, and the vast majority of these do not have access to very basic health care. Clean water, nutrition, health care infrastructure, and/or trained medical personnel are often not available either.

BUT NO SOLUTION IS POSSIBLE WITHOUT AFFORDABLE MEDICINES!

FIVE WAYS TO GET THE AFFORDABLE MEDICINES YOU NEED

We will examine five strategies that may help you get affordable medicines. Each one has pros and cons and none of them offers a guaranteed success.

These five strategies are:

- Getting the law on your side: your right to health
- Getting the law on your side: monopolies don't make a "free market"
- Getting the prices of medicines down though importation from cheaper markets
- Getting the prices of medicines down through cheaper manufacturing
- Getting medicines for free

STRATEGY 1: GETTING THE LAW ON YOUR SIDE: YOUR RIGHT TO HEALTH

What does it mean?

The right to health care is a basic human right. It is recognized in international treaties and in the national constitutions and laws of many countries.

Article 25 of the Universal Declaration of Human Rights affirms that: *"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control."*

Article 12 of the International Covenant on Economic, Social and Cultural Rights recognizes *"the right of everyone to the enjoyment of the highest available standard of mental and physical health."* It requires governments, among other steps, to take necessary measures for the *"prevention, treatment, and control of epidemic, endemic, occupational and other diseases,"* as well as to create *"conditions which would assure to all medical service and medical attention in the event of sickness."*

Despite this clear mandate, in some countries the right to health is not guaranteed in the constitution, or it is not implemented by the government. Sometimes governments say they recognize the right to health, but still exclude or discriminate against people with HIV/AIDS.

What can you do?

You can change the laws of your country or bring a case to court (a national or sometimes international court) in order to broaden the right to health care.

It is important to know your country's laws and constitution, and in particular what rights are guaranteed there. The same applies for knowledge of the international conventions that have been signed by your country and the rights included in those. You can find all major international human rights conventions, as well as the lists of countries who signed them, at http://www1.umn.edu/humanrts/treaties.htm.

It may also be good to review samples of laws from other countries, international law in the field of the right to health as well as the field of human rights for people with HIV/AIDS. The documents can be useful because of their persuasive value or even as drafts for legislation in your own country.

Different countries follow different political and legislative systems in the processes by which laws are changed. It is best if you form alliances with other sectors of civil society and work within the system in your country in order to change the laws. Some international human rights organizations, including the International Gay and Lesbian Human Rights Commission (IGLHRC), may be able to offer some resources and technical assistance. A list of organizations is attached at the end.

Pros and cons?

The right to health care is a basic human right. If it is not recognized as such in your country, your government may deny that they have a responsibility to ensure that you have access to health care. If, on the other hand, your government accepts that responsibility, the remaining question is *how* it will provide health care and medications--not *whether* it will provide them or not.

The end result of your efforts may be more legal protections for people with HIV/AIDS and a legal recognition of their right to health care. If, however, the case or legislation you are working on does not yield a "good" court decision or an improvement in the laws, you may end up worse off than when you started.

Or if you live in a country where the government routinely disregards its own laws and the sentences of the courts, then legal victories may set a good precedent but remain ineffective.

Or the government may wish to implement laws guaranteeing access to health care, but may claim it lacks the money to do so, particularly when medicines are too expensive. Later on we will address ways to bring down the price of medicines. It is certainly true that the prices of medicines must come down. But your government's priorities in spending must be looked at with a critical eye. Is the government continuing to buy expensive military technology while people die of AIDS? Misplaced priorities are not the same thing as a lack of money, and are no excuse for inaction.

Example A: Salvadorans and Costa Ricans Get Medicines By Law

On April 28, 1999 Odir Miranda, President of the Salvadoran Association of People Living with AIDS (ATLACATL) filed a complaint with the Salvadoran Supreme Court requesting that the Salvadoran Institute

of Social Security, the nation's health care provider, give antiretroviral medications to people with AIDS. Almost half a year had passed and the Supreme Court had not yet issued a ruling.

Odir sent a letter in September to the Interamerican Commission on Human Rights asking for immediate intervention. Odir accused the Salvadoran government of discrimination against people with AIDS in the provision of health care.

The Interamerican Commission on Human Rights is a commission that can rule on human right violations in the Americas, and its rulings have legal weight over the whole continent, from Argentina to Canada. The Commission only acts in cases where all legal remedies at the national level have been exhausted, in other words, when every possible legal avenue at home was tried and did not work. Odir argued that the Commission should hear his case as an emergency, and he cited the fact that the Supreme Court was delaying its reply and that because of this delay more and more people were dying.

The Interamerican Commission on Human Rights took the case and issued a ruling on February 29, 2000, ordering the government of El Salvador to begin supplying antiretroviral medications to the 26 surviving Salvadorans who appeared mentioned in the September petition. The petition had contained the names of 36 people living with AIDS, out of which ten had died between the September filing and the Commission's ruling. The emergency order was given for six months while legal proceedings continue in El Salvador.

The Commission ordered the Salvadoran government to: *"provide medical attention necessary to protect the life and health of Jorge Odir Miranda Cortez and the other 25 aforementioned people...In particular the Commission solicits that your illustrious government provide antiretroviral medications necessary to avoid the death of the aforementioned persons, as well as hospital attention, other medications and nutritional support which strengthen the immune system and impede the development of illnesses and infections."*

Even though the case refers exclusively to the 25 people with AIDS mentioned in the claim, the decision of the Commission sets an important precedent and may be useful to others too.

A similar process had happened in Costa Rica three years earlier. In 1997 the Costa Rican Supreme Court had ordered the government there to provide medications to 4 persons with AIDS. Shortly thereafter the National Health Care system began to give the medications to others too. At the moment 800 Costa Ricans are reported to receive antiretroviral medications.

STRATEGY 2: GETTING THE LAW ON YOUR SIDE: MONOPOLIES DON'T MAKE A FREE MARKET

What does it mean?

Big drug companies defend their high prices in two ways, by saying the "free market" sets these prices, and by saying its prices are necessary to produce new and better medicines. These claims are untrue. The prices reflect privileges— privileges which some governments assign to inventors. And the privileges do not always reflect the real costs of researching and developing the new medicines.

International law and the laws of many countries recognize certain privileges for a company that has invented a new product. These privileges, called *patents*, generally give the inventor a temporary monopoly to produce and market their new product.

This temporary monopoly is given to compensate the inventor for research and development costs, and to encourage the inventor to continue developing new products. The ultimate goal of the patents has been described in an international treaty, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This treaty sets guidelines for countries to establish patents, and respect each other's patents. Article 7 of TRIPS explains that the patents are granted to: *"contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."* In other words, the patents are a temporary reward to the inventor not because of the invention *per se*, but because of the promise that the benefits of that invention will be *"transferred and disseminated... in a manner conducive to social and economic welfare."*

Patents are temporary: inventing something does not give you control over the invention forever. Patents do usually last a long time, sometimes 20 years or more. However, some inventions are urgently needed, and cannot wait this long to be widely used and distributed. That is why the same treaty (TRIPS) provides for measures to overcome the patents, particularly *"in order to protect public health and nutrition"* (article 8

of TRIPS). Two of these measures are explained in the next two sections:

Getting the prices of medicines down through importation from cheaper markets

Getting the prices of medicines down through cheaper manufacturing

And For Which Countries?

Some countries grant and honor patents and others do not. Each country can decide for itself how it wants to treat the temporary monopolies that other countries give to inventors. However, right now, all countries fall into one of these two categories:

1/ *Countries which have not signed the TRIPS agreement.* These countries do not have to respect the patent system. They may suffer heavy political pressure and even trade sanctions in order to force them to change their domestic laws to include patent protections (also called *intellectual property rights* law).

2/ *Countries which are members of the World Trade Organization.* These countries have signed the TRIPS agreement, promising to change their domestic laws to include patent protection. These countries are given a period of time to change their laws. All of them, except the ones designated "least developed countries," technically should have changed their domestic laws already, but many have not done so yet. The "least developed countries" have more time, a *transitional period,* until 2006.

We have provided an attachment at the end with a list of member countries of the World Trade Organization, and of those members who have been designated "least developed." It is important to know the status of your country. This information has an effect on the price of medicines in your country.

If your country is a member of the World Trade Organization and has not updated its patent laws (in other words, they are not *TRIPS compliant*), it is probably under intense pressure from the United States, the European Union, and the pharmaceutical companies

Sometimes the United States, the European Union, and the corporations pressure countries to pass patent protections, which are even stronger than they need to be under international law. Such "stronger" patent laws (sometimes referred to as *"TRIPS-Plus"*) protect international corporations by giving their patents extra power. In the process they limit the measures that you can take to get the affordable medicines you need. They favor patents over patients, and over the right to health.

All these pressures may be heavier on countries that are not designated "least developed," because they have no transitional period until 2006. "Least developed countries" are also pressured to pass restrictive laws now, *before* the required deadline of 2006.

What can you do?

Investigate what is the state of patent laws in your country (are these laws in place? in progress? non-existent?). If your country is not a member of the World Trade Organization, defend its right to decide for itself about which patent protections it will enforce. If your country is a member, then it is probably developing new legislation about patents. If your country is classified as "least-developed," patent laws should not be implemented in national legislation before the required deadline of 2006.

When legislation is introduced in any country, ensure that the laws that are being proposed meet only the standard minimum requirements of TRIPS—that they are not "TRIPS-Plus." In other words, ensure that when national laws are reviewed to include TRIPS requirements, *parallel imports* and *compulsory licensing* are included. (We will define these terms in Strategies 3 and 4). The laws should include simple administrative procedures for granting *compulsory licenses*. You can seek the support of the World Health Organization in this process.

Patent law may be complicated. The terms may be foreign. Sometimes the details seem too technical and intimidating. It is helpful to seek the assistance of a lawyer or an organization that specializes in the field. A list of resources is attached at the end.

It is important to remember that while the details may seem complicated, the overall picture should not be. Your goal is to ensure that patents for medicines are not more restrictive than they need to be, because as a general rule of thumb the stronger the monopoly is the more restricted the access to the medications will be.

Pros and cons?

It is important to be vigilant about the development of patent law in your country. As explained above, restrictive patent laws will likely end up raising the price and limiting the availability of medications.

There is enormous pressure on countries to become part of the "global market" and play by rules set in the global North. Because of this, it is unlikely that you will succeed in making your country's patent laws more lenient than they are now. You can, however, help to

keep the situation from getting worse, by building a coalition of concerned citizens to help your government preserve the legal status quo.

Such advocacy will probably not help you get new medications on the market in your country. However, you will be laying the legal groundwork to get the prices of existing medications down through cheaper manufacturing, or importing from countries where the drug is cheaper.

Example B: Pressures Against Thailand to Change the Law

Under United States pressure, the Thai passed a bill that restricts the use of *compulsory licenses* in Thailand. This law offers conditions that are much more restrictive than the rules set out in the TRIPS agreement, the internationally accepted standard. One of these conditions is the creation of the Safety Monitoring Program (SMP).

In Thailand patent protection is effective only for products invented after 1992. However, all new drugs introduced to the Thai market must pass through a Safety Monitoring Program (SMP) that usually lasts four years. During that time no generic drug companies can produce the medication (same drug, without the brand name), so the drug remains monopolized.

A 1999 joint report of the World Health Organization and Medecins Sans Frontieres (Doctors Without Borders) concluded that the high cost of medications in Thailand is linked to the monopolies caused by patent protections or by the SMP.

Example C: India Produces its Own Medicines

The Indian drug industry is a good example of what happens when companies are given the authority to produce drugs for the local market without paying daunting licensing fees. Currently, Lariam, a treatment for malaria, costs US$37 in the United States and $4 in India, while the AIDS treatment AZT cost US$239 per month in the United States and US$48 in India. If and when India is forced to honor patents for medicines, these lower prices may disappear. And India may be pressuured to legislate a "TRIPS-Plus" law.

STRATEGY 3: GETTING THE PRICES OF MEDICINES DOWN THROUGH IMPORTATION FROM CHEAPER MARKETS

What does it mean?

In the global economy, companies sell the same item for different prices in different places. A major corporation may offer drugs in one country for a significantly lower price than in another.

Suppose you could buy medicine in another country for half the price that the same drug costs in your own country. If you and others could shop around the world, find the place where the medicine is cheapest, and then bring it to your country—if you could import the medicine from the least expensive supplier—you could make medicine available to people who cannot afford it now. But, because of market pressures, the company would probably be forced to cut the price it is charging for the medicine in your country, as soon as it became available more cheaply.

This process is really no different than searching for bargains at the market. It is how truly "free markets" work. But there is a technical term for doing such bargain-hunting on an international scale. It is called *parallel importing*. In effect you are importing parallel to the company which sells the medicines in your country at a higher price-- and doing so without that company's permission.

Parallel importing is very common around the world for a variety of products--pianos, automobiles, motorcycles, chemicals, medicines, computers, cameras, music CDs. In fact, most every country has some trade in parallel imports. Many European countries have significant trade in pharmaceutical parallel imports, mostly within the European Union itself--but also from outside the Union, from the United States and other countries.

In general, parallel importing is legal under international law (TRIPS), and can be an attractive option when the same patented product is being sold for different prices in different markets.

Parallel importing is an important option to increase access to medicines, because there are in fact substantial price differences for medicines in different national markets. These price differences are due to local market conditions, including the degree of competition for a product. In some countries the

medicine may be produced and sold by a number of manufacturers, while in others only one company has the right (or patent) to do so. For example, according to a Medecins Sans Frontieres (Doctors Without Borders) study, the price of a 200 mg capsule of fluconazole, an anti-fungal drug, when sold as a brand-name drug under patent and with no competition, range from US$9.34 in South Africa to US$27.60 in Guatemala. The exact same drug sold by the same company costs 300% in Guatemala! If Guatemala "parallel imported" the medicine from South Africa, it could substantially reduce its price.

What can you do?

Governments, private health care groups, and non-profit health agencies that buy bulk supplies of medicines could engage in parallel importing of medicines to lower national public health expenditures for life-saving drugs. Since parallel importing is permitted under international law (TRIPS), it is important that you make sure that your governments, and other entities in your country are aware of their right to exercise this price-reducing option, and make full use of it.

Even if your government is fully aware of the advantages of parallel importing, and willing to make use of this legal measure, there may be a great deal of pressure from governments in the West (where the major pharmaceutical drug companies reside) *not* to exercise this option. Drug companies, which hold patents to the medications, pressure their governments to keep developing countries from shopping around the world for the best drug prices. Western governments threaten to use trade sanctions against states that use parallel importing. The drug companies may establish restrictive contracts with their distributors in each country, prohibiting them from reselling the drug in other countries.

Drug companies use many arguments to justify their position; some of these are detailed in the *pros and cons* section. Yet probably a major reason for their opposition is based on the real fear that if every country could search for the lowest price for a certain drug, eventually prices would drop everywhere, and the drug companies' profits would drop too. They will use their political power to stop practices that threaten their profits.

Parallel importing medicines requires some of the same work that we outlined in the previous section. You can help your government defend its own right to use parallel importing, and help it stand up to international pressure aimed at changing its practices and laws. Depending on how cooperative your government is, you can work with government officials to implement the parallel importing of specific medicines. You can support your government as it withstands pressure from abroad, and you can organize a campaign to shame the drug companies into allowing you and your government to prioritize public health concerns and the full enjoyment of the right to health.

Pros and cons?

Parallel importing helps to take advantage of different global prices for medicines, and may ensure that you are getting the medicines for the lowest price possible. It also creates greater competition in your own country, which forces local distributors to lower their prices to match the best price internationally.

Drug manufacturers who oppose parallel imports make a number of arguments against their use. For example, they allege that parallel imports may be substandard or even counterfeits, or that they may be difficult to support or service. The issue of the quality of medications is a valid and important concern. It is a concern that should apply to *all* medications. The same regulations and quality controls can and should be applied consistently to all medications, whether parallel imported or not.

Some drug companies argue that parallel trade should be stopped to prevent developing countries from marketing cheap drugs in rich countries. Rich countries want to protect their own manufacturers and markets; they do not want to lose the profits that come from selling the medicines at a higher price in their own markets. Europe, the United States, and Japan have already passed legislation to prevent poorer countries from marketing medications there. However, even if one accepts the protectionism of the rich countries, there is no reason why poor countries should not be able to buy products in rich countries for their own use, when prices are lower there due to competition in the larger US and European markets.

Remember, though: even the lowest available price worldwide for the patented medication may still be beyond the reach of many poor countries! Parallel importing only takes advantage of existing variations in price. It cannot bring the price to a point that the poorest countries can pay. You may need to look at other, more time-consuming options, to manufacture the medication at a price that is lower than any on the market today. These options will be addressed in the next section.

Example D:
The Patented Price of Fluconazole

Wholesale prices of fluconazole
200 mg capsules in US$
in September 1999

South Africa	$9.34
USA	$10.00
Kenya	$10.50
Guatemala (public sector)	$11.90
France	$12.60
Spain	$13.37
Guatemala (private sector)	$27.60

Source: Price Differences of Fluconazole, Differences and Conclusions (MSF, November, 1999)

The prices on the table above represent price for the brand-name version of the drug, as sold by the manufacturer holding a patent.

STRATEGY 4: GETTING THE PRICES OF MEDICINES DOWN THROUGH CHEAPER MANUFACTURING

What does it mean?

Imagine that you need a particular medicine to treat a serious infection that you have. You go to your local drug manufacturer and ask them if they produce this medicine and distribute it to local hospitals and dispensaries. They tell you that they would like to produce this medicine but that only one company is allowed to produce it because that company has a patent (they have "monopoly rights" to make and sell this medicine). You explain to the local drug-maker that while it is true that only one company has a patent on the medicine, there are some ways to get around this--*and that they are legal.*

One way is by going to the drug company that holds the patent (the *patent-holder*) and requesting that they issue the local drug maker a *voluntary license* to produce a *generic* version of the drug (the same drug, but without the brand-name). The local manufacturer would offer to pay the patent-holder some set amount (a *royalty*) for the privilege of making the drug. The patent-holder keeps its patent but voluntarily gives a license to the local drug maker.

Then, the local manufacturer could make the drug, using local workers, scientists, technicians, and distributors, and sell it in your country. Most likely, producing and distributing the generic version of the drug locally would cost far less than the price charged by the patent-holder.

Suppose that the patent-holder will not provide the local drug maker with a voluntary license. There are still some legal options available, and you can work with your government to use these options. Under international law, your government can *compel* the patent-holder to license production of the drug to a local manufacturer. If there is no drug company in your country to make the drug --because it is too complicated or because there are no manufacturers in your country --your government could still compel the patent holder to license production to some other generic producer *outside* your country, and buy it from them.

Either way, this is called *compulsory licensing.*

Compulsory licensing is the granting of a license to a third party without the consent of the patent holder. The patent holder in turn receives compensation for issuing the license.

A compulsory license may be issued on various grounds of general interest--including public health.

Compulsory licensing is legal under international law. Article 31 of the TRIPS agreement states that countries which are members of the World Trade Organization may ***"use the subject of a patent without the authorisation of a right holder, including use by the government or third parties authorised by the government"*** when justified by the public interest. Article 31 also says ***"the right holder shall be paid adequate remuneration ... taking into account the economic value of the authorisation."***

Compulsory licensing also needs to be legal under national legislation. As we said earlier, it is important that the laws of your country are not "TRIPS-Plus," in other words, it is important that the laws of your country do not have "stronger" patent laws than they need to have under international law.

Historically, compulsory licensing has been used to serve the greater good of society, by restricting the monopoly rights of patent holders. Today countries grant them in a wide range of fields such as computers, nuclear energy, music recordings and biotechnology.

However, the use of compulsory licensing for HIV/AIDS drugs or other life-saving medicines has encountered heavy political opposition. Drug companies and some governments in the industrialized countries have opposed compulsory licensing for these

medicines. The United States' government has applied strong pressure to Thailand, South Africa, and other countries to stop them from using compulsory licensing.

What can you do?

Countries should ensure simple administrative procedures for granting compulsory licenses. In many countries, compulsory licensing is part of the patent law. For example, France's law authorizes compulsory licensing when patented drugs *"are only made available to the public in insufficient quantities or quality or at abnormally high prices."* In many countries, HIV/AIDS drugs for opportunistic infections and antiretrovirals are maintained at such high prices through the exclusive marketing rights granted to patent holders. TRIPS clearly states that countries can use compulsory licensing to defend themselves against these prices.

Here, again, this strategy is similar to Strategy 2: you need to ask what your country's patent laws say. Activists from developing countries can begin by finding out what their countries' laws say about compulsory licenses and parallel imports. You can then lobby to change the laws if they do not permit compulsory licensing or if they are more restrictive than international trade agreements demand. And you can support your government in standing up to pressure from the developed North.

Pros and cons?

Many international consumer advocacy groups are urging developing countries to implement TRIPS provisions for compulsory licensing so that their populations can have access to essential medicines.

On the other hand any attempt at requesting a compulsory license for medicines is likely to be met with very strong opposition by the pharmaceutical companies and the developed countries where they are based. As of the writing of this document (July 2000) we know of no HIV/AIDS drugs that have successfully been licensed and produced in any country in the developing world. Compulsory licensing remains a possibility that is legal and should be used, but it requires a concerted effort by local activists and government, as well as international support, in order to overcome the obstacles and pressures against it.

Example E: The Generic Price of Fluconazole

Wholesale prices of fluconazole
200 mg capsules in US$
in September 1999

Thailand	$0.60
Cambodia (generic produced in India)	$1.50

Source: Price Differences of Fluconazole, Differences and Conclusions (MSF, November, 1999)

Compare these prices with the patented prices in Example D.

Example F: Under Pressure, Thailand Drops Compulsory Licensing and Produces Other Generic Medicines

On November 1999 the Government Pharmaceutical Organization of Thailand (GPO) initiated legal proceedings to get a compulsory licensing for the manufacture and sale of the drug ddI. Three months later, and after intense pressure from the United States' government and the drug manufacturer, the Ministry of Public Health announced that it would not try to get the compulsory license of ddI because they feared that the enforcement of compulsory licensing under the Thai patent law would result in trade sanctions. The pressure on Thailand was most heavy because the pharmaceutical interests did not want to set a 'precedent' of a case where the compulsory licensing of medications actually worked.

Thai physicians and patients were particularly outraged when they discovered that ddI was invented by the US government and is licensed on an exclusive basis to the US drug manufacturer Bristol-Myers Squibb.

Since in Thailand patent protection is effective only for products invented after 1992, the GPO found a way out of compulsory licensing. The GPO is producing at present generic versions of d4T, ddI, and AZT. However these productions are not under compulsory licensing agreements. They are productions of drugs or versions of drugs that were never patented in Thailand.

In the case of ddI, the GPO is producing generically a non-patented powder version, which it sells for 26 baht per 100 milligrams (about 67 US cents). That is almost half the price of the patented version of ddI, which sells for 49 baht (about US$1.26) per 100 milligram tablet.

These generic productions outside of compulsory licensing will not work in countries that have older patent laws. But even for those countries, compulsory licensing remains an option.

STRATEGY 5: GETTING MEDICINES FOR FREE

What does it mean?

Recently, multinational pharmaceutical companies have announced plans for HIV drug donation programs as part of their effort to address the AIDS epidemic in the developing world. Here we will discuss the meaning of AIDS drug donations and how they can be used to improve access to medications for people living with HIV/AIDS.

There are also many small-scale drug donation programs run by individuals or organizations. Through these, some people living with HIV/AIDS have obtained drugs—although the rich and well-connected have benefited most. But hundreds or thousands of lives have been saved.

What can you do?

The pharmaceutical companies are under pressure to lower the prices of life-sustaining medications. But for them it is easier to give medicines away rather than face fair pricing and a competitive generic markets. The pharmaceutical companies will then increasingly offer drug donation programs as an alternative to parallel importing, compulsory licensing, and generic competition. It is important to know how to negotiate an effective donation program is worthwhile.

What does it take to start a campaign for meaningful donations in your country? Broadly speaking, you might:

1) Work with your government and the pharmaceutical company to secure a sustainable and ethical donation. Ensure that a guaranteed constant supply of quality medicines (well before their expiration date), to be distributed in an equitable fashion. Be careful of the conditions set by the donor, which may unnecessarily narrow the scope of the donation or create an undue burden on the health care delivery system in your country.

2) Help make sure donations adhere to drug donation guidelines set by the World Health Organization.

3) Have a National Drug Donation Policy in place, to help lower procurement prices

4) Work to adopt a national Essential Drug List, to determine what drugs are needed according to the disease patterns in your country.

5) Work to remove policies that create barriers to access to medications.

Pros and cons?

The United States has seen a 60% decrease in AIDS deaths since a triple drug combination, or Highly Active Antiretroviral Therapy (HAART), became the preferred treatment for HIV. In much of the world, these therapies are virtually inaccessible. 92% of the world's population makes do with 8% of the money the world spends on AIDS.

Drug donations are one way to get drugs to people. Corporate donations however are only a stop-gap solution. Drug companies may place unacceptable conditions on the donations; and they can cut them off at any time.

A recent study by the World Health Organization showed that many drugs donated to countries by pharmaceutical companies were drugs deemed "non-essential" by the recipient country, and in one third of donation cases, the drugs were either expired or did not meet the World Health Organization's guidelines for shelf-life. Such donations are dangerous to health. Donations can also burden on the recipient country's already overloaded distribution systems. "Donation programs" are often a veiled excuse for pharmaceutical companies to get tax breaks or to "dump" surplus materials taking up space in their warehouses.

Reducing HIV-related drug prices to a fair rate, and allowing fair competition from generic manufacturers, is a better long-term answer to the need for affordable medicines. However, as long as pharmaceutical companies continue to use this as a response to the global AIDS crisis, you should consider negotiating the best possible drug donation programs—while still pushing for permanent solutions, and for broader access to treatment worldwide.

When you ask pharmaceutical companies to make their products more affordable and accessible to people dying in your country, you are also making a demand for your right to health. Drug companies, like all other subjects of all states, are obliged by human rights standards to respect and promote the right to health. Morally, they must answer positively to your demands. *By offers of a drug donation, a company admits its responsibility for ensuring this right.* You should hold

them accountable to follow through. Drug donations are one more way to enjoy increased access to health care.

Example G: South Africa Gets "Expensive" Gifts With Many Strings Attached

Recently, Pfizer, Inc. offered to provide its patented drug, fluconazole, to South Africans with cryptococcal meningitis at no cost. Not long after its announcement of the donation program, treatment activists learned that the "gift" was so restricted as to be counterproductive.

Fluconazole's effectiveness depends on a lifelong daily dosing regimen: but Pfizer planned to offer the drug for only 2.5 years. The time limit makes it impossible for the South African government to develop a long-term program for treating the disease. And since the time limit coincides with the expiration of Pfizer's patent on the drug, there are suspicions that Pfizer may be trying to use the 'donation' to give samples of the drug away in the hopes of getting South African doctors accustomed to using the brand name version (Pfizer's version) of fluconazole even after the patent expires.

In addition, though fluconazole treats numerous lethal infections in people living with HIV/AIDS, Pfizer insisted on limiting its offer to one disease, and only in one country. When activists in Central America requested Pfizer duplicate their offer for HIV-positive people there, they were flatly rejected. At this time, Pfizer continues to negotiate the specifics of its program with the South African Ministry of Health

General Resources

There are several non-governmental ad inter-governmental international organizations, some with regional and local offices, working on campaigns, advocacy and grassroots activism toward increasing access to medicines global by challenging the negative effects of international trade policies.

AIDS Empowerment and Treatment International (AIDSETI)

International group of and for people living with HIV/AIDS, to empower associations of PWAs in the South by supporting their positive living and surviving skills programs and by providing a medical safety net to ensure the survival of members and leaders.

P.O. Box 27143
Washington D.C., USA 20038-7143
Fax: +1-(202) 614-0035
Email: DHOUSDEN@AIDSETI.ORG
http://www.aidseti.org

AIDS Treatment News

Internationally recognized newsletter with resources for people with HIV/AIDS who are looking for information on new therapies and different treatment options.

John S. James, Publisher
PO Box 411256
San Francisco, CA 94141
Tel: +1-415-255-0588
http://www.aidsnews.org/

Consumers International

A worldwide non-profit federation of consumer organizations, dedicated to the protection and promotion of consumer interests. The organization promotes the rational use of essential drugs, universal quality health care services and patients' rights. Consumers International has co-founded three global health networks: the International Baby Food Action Network; the Health Action International (campaigning for fairer health and drug policies) and The Pesticides Action Network.

Head Office
Postal Address:
24 Highbury Crescent
London
N5 1RX
United Kingdom
Tel: +44 171 226 6663
Fax: +44 171 354 0607
E-mail: consint@consint.org
http://www.consumersinternational.org/

Consumers International Offices:
Regional Office for Africa (ROAF)
Postal Address:
11 Connaught Road
Avondale
Harare
Zimbabwe
Tel: +263 4 302 283
Fax: +263 4 303 092
E-mail: roaf@harare.iafrica.com

Sub-Regional Office for West & Central Africa
Postal Address:
Villa No. 9, Debut de la VDN x Bourguiba
Casier Postale No. 2
Dakar-Fann
Senegal

Tel: +221 24 80 06
Fax: +221 24 80 06
E-mail: ci-pwca@ndar.enda.sn

Regional Office for Asia Pacific (ROAP)
Postal Address:
PO Box 1045
10830 Penang
Malaysia
Tel: +60 4 229 1396
Fax: +60 4 228 6506
E-mail: ciroap@pc.jaring.my
Office Address:
250-A Jalan Air Itam
10460 Penang
Malaysia

South Pacific Consumer Protection Programme (SPCPP)
Postal Address:
PO Box 43-148
Wainuiomata
New Zealand
Tel: +64 4 564 8317
Fax: +64 4 564 8317
E-mail: cispcpp@xtra.co.nz
http://www.spcpp.org.nz/

Regional Office for Latin America & the Caribbean
Postal Address:
Las Hortensias 2371
Providencia, Santiago
Chile
Tel: +56 2 335 1695
Fax: +56 2 231 0773
E-mail: consint@entelchile.net
http://www.consumersint-americalatinaycaribe.cl/

Sub-Regional Office for Central America
Postal Address:
Colonia Dolores
Pasaje Rosales No. 2 Casa 309
San Salvador
El Salvador
Tel: +503 242 2506
Fax: +503 242 2506

Programme for Developed Economies and Economies in Transition
Postal Address:
24 Highbury Crescent
London
N5 1RX
United Kingdom
Tel: +44 171 226 6663
Fax: +44 171 354 0602
E-mail: progs@consint.org
http://193.128.6.150/consumers/about/history.html

Consumer Project on Technology

Extensive background and documents on intellectual property and health care. This site includes recent and archival information on general policy issues (compulsory licensing, parallel imports, trademark issues, Bolar and other research provisions, scope of patents, data exclusivity, orphan drug legislation, generic competition, etc.), as well as specific drug pricing data and information on trade disputes related to the pharmaceutical industry. Very thorough collection of legal texts on the issues.

Consumer Project on Technology
P.O. box 19367
Washington DC 20036
Phone (202) 387-8030
Fax: (202) 234-5176
contact: cgavin@cptech.org
http://www.cptech.org
http://www.cptech.org/ip/health/

Global Network of People Living with HIV/AIDS (GNP+)

The Global Network of people living with HIV/AIDS (GNP+) is a global network for and by people with HIV/AIDS.

GNP+
P.O. Box 11726 Haarlemmerplein 17
1001 GS Amsterdam 1013 HP Amsterdam
Netherlands
Tel - 31 20 423 4114
Fax - 31 20 423 4224
E-mail : gnp@gn.apc.org
http://www.hivnet.ch/gnp/index.html

Health Action International (HAI)

HAI is a non-profit, global network of health, development, consumer and other public interest groups in more than 70 countries working for a more rational use of medicinal drugs. HAI represents the interests of consumers in drug policy and believes that all drugs marketed should be acceptably safe, effective, affordable and meet real medical needs. HAI campaigns for increasing access to essential drugs in a globalized economy

http://www.haiweb.org/

For Western and Eastern Europe, North America and Africa
HAI-Europe Coordinating Office
Jacob van Lennepkade 334-T
1053 NJ Amsterdam
tel +31.20.6833684
fax +31.20.6855002
e-mail hai@hai.antenna.nl

For Latin America
Coordinator AIS
Asociación Acción Internacional para la Salud
Aptdo. 41-128
Lima, Peru
tel +51.1.3461502
fax +51.1.3461502
e-mail ais@amauta.rcp.net.pe
http://ekeko2.rcp.net.pe/AIS-LAC/

For Asia and Pacific Region
HAI /Action for Rational Drug Use (ARDA)
c/o Consumers International- Regional Office for Asia Pacific (ROAP)
P.O.Box 1045 10830
Penang, Malaysia
tel +60.4.2291396
fax +60.4.2286506
e-mail ciroap@pc.jaring.my
http://www.consumersinternational.org/directory/regions/roap4.html

For Africa
http://www.haiweb.org/regional/HAI-africa-info.html

Health Global Action Project (GAP) Coalition

US - based coalition of AIDS treatment activists, consumer groups, doctors, and social justice advocates. This is a good site for information about grassroots organizing and protests on US trade policies affecting access to treatment. Press materials are extensive. This is a volunteer-run coalition of AIDS treatment activists.

http://www.aids.org/healthgap/
http://www.durban2000march.org/

International Council of AIDS Service Organizations (ICASO)

ICASO is a network of community-based AIDS organizations. They have produced a background paper on compulsory licensing and parallel importing, in English, Spanish, and French.

"Compulsory Licensing and Parallel Importing: What do They Mean? Will They Improve Access to Drugs for People Living with HIV/AIDS? A Background paper for NGOs." (in Spanish, French and English), International Council of AIDS Service Organizations (July) at http://www.icaso.org/compulsory.html

ICASO
Central Secretariat
399 Church Street, 4th Floor
Toronto, ON
CANADA M5B 2J6
Tel: (1-416) 340-2437 (main reception)
Fax: (1-416) 340-8224
http://www.icaso.org

AfriCASO – African Regional Secretariat
ENDA Tiers Monde
54, rue Carnot, B.P. 3370
Dakar SENEGAL
Tel: (221) 823-1935
Fax: (221) 823-6615
Email: africaso@enda.sn
http://www.africaso.org
Contact: Moustapha Gueye

APCASO – Asia/Pacific Regional Secretariat
Malaysian AIDS Council
12 Jalan 13/48A
The Boulevard Shop Office
off Jalan Sentul 51000 Kuala Lumpur
Malaysia
tel: (603) 4045-1033
fax: (603) 4043-9178
Email: apcaso@pd.jaring.my
http://www.31stcentury.com/apcaso/
Contact: M. Puravalen/Susan Chong

EuroCASO – European Regional Secretariat
Groupe sida Geneve
17 rue Pierre-Fatio
CH-1204 Geneva, SWITZERLAND
Tel: (41-22) 700-1500
Fax: (41-22) 700-1547
Email: eurocaso@hivnet.ch
http://www.hivnet.ch/eurocaso/
Contact: Florian Hübner

LACCASO – Latin American and the Caribbean Regional Secretariat
Acción Ciudadana contra el SIDA – ACCSI.
Av. Rómulo Gallegos, Edif. Maracay, Apto. 21, El Marqués
CARACAS 1071 - VENEZUELA.
Tel: (58-2) 232 7938
Tel/Fax: (58-2) 235 9215
Email: laccaso@internet.ve
http://www.laccaso.org
Contact: Edgar Carrasco

NACASO – North America Regional Secretariat
Canadian AIDS Society
900-130 Albert Street
Ottawa, Ontario
Canada, K1P 5G4
Fax: (1-613) 563-4998
Email: SharonB@cdnaids.ca

International Gay and Lesbian Human Rights Commission

IGLHRC is a US-based, non-profit, non-governmental organization, whose mission is to protect and advance the human rights of all people and in particular communities subject to discrimination or abuse on the basis of sexual orientation, gender identity, or HIV status. IGLHRC maintains a Campaign for Access to Treatment.

IGLHRC
C/o Human Rights Watch
350 Fifth Avenue, 34th Floor
New York, NY USA 10118
Tel. +(1-212) 216-1256
FAX +(1-212) 216-1876
email: karyn@iglhrc.org
http://www.iglhrc.org
http://www.iglhrc.org/campaigns/accesstotreatment/index.html

Médecins Sans Frontières (MSF/Doctors Without Borders)

MSF is an independent humanitarian medical aid agency operating in 84 countries and committed to two objectives: providing medical aid wherever it is needed, regardless of race, religion, politics or sex; and raising awareness of the plight of the people they help. MSF has launched an Access to Essential Medicines Campaign. The campaign is designed to mobilize MSF's volunteers and people who support MSF's vision for improving the health of populations in danger. The project has three pillars: health exceptions to trade agreements, overcoming access barriers, and stimulating research and development for neglected diseases

International Office
Médecins Sans Frontières
Rue de la Tourelle, 39
1040 BRUXELLES
Belgium
Tel:+32 (2) 280.18.81
Fax:+32 (2) 280.01.73
http://www.accessmed-msf.org

Panos Institute

The Panos Institute exists to stimulate debate on global environment and development issues.

Publication: "Beyond Our Means? The Cost of Treating HIV/AIDS in the Developing World"

Panos, Main Office
9 White Lion St
London N1 9PD
United Kingdom
tel +44 (0)20 7278 1111
fax +44 (0)20 7278 0345
email panos@panoslondon.org.uk
http://www.panos.org.uk

People's Health Assembly

The goal of the People's Health Assembly is to re-establish health and equitable development as top priorities in local, national and international policy-making, with primary health care being the strategy to achieve these priorities. The Assembly aims to draw on and support people's movements in their struggles to build long-term and sustainable solutions to health problems.

Publication: "Globalisation and Liberalisation of Healthcare Services: WTO and the General Agreement on Trade in Services," K. Balasubramaniam at http://www.pha2000.org/issue_bala1.htm

People's Health Assembly
International Secretariat Secretariat
Gonoshasthaya Kendra
PO Mirzanagar, Savar
1344 Dhaka
Bangladesh
tel: 880-2-770 8316
fax: 880-2-770 8317
e-mail: phasec@pha2000.org
http://www.pha2000.org

The Third World Network

The Third World Network is an independent non-profit international network of organizations and individuals involved in issues relating to development, the Third World and North-South issues.

Publication: "Pharmaceuticals, Patents and Profits: South Deprived of Lifesaving Drugs," Third World Network,

Third World Network,
228 Macalister Road,
10400
Penang, Malaysia.
Tel: 60-4- 2266728 / 2266159
Fax: 60-4-2264505
E-mail: twn@igc.apc.org , twnet@po.jaring.my
http:// www.twnside.org.sg

Treatment Access Forum

This is an electronic listserve discussion group that includes many issues of treatment access in developing countries. Starting in late March 1999, there are many reports, documents, and personal messages on compulsory licensing and related issues of trade policy and access to essential medical technology. You do not

need to register to read the messages; you can, however, register free of charge. If you have e-mail access only, you can still participate; send a message to: treatment-access@hivnet.ch.

http://www.hivnet.ch:8000/treatment-access/tdm

Treatment Action Campaign

The Treatment Action Campaign (TAC)'s main objective is to campaign for greater access to treatment for all South Africans, by raising public awareness and understanding about issues surrounding the availability, affordability and use of HIV treatments. TAC campaigns against the view that AIDS is a 'death sentence'. TAC aims to (1) ensure access to affordable and quality treatment for people with HIV/AIDS; (2) prevent and eliminate new HIV infections; and (3) improve the affordability and quality of health-care access for all. TAC has launched a defiance campaign to import generic medication into South Africa.

TAC
PO Box 31104
Braamfontein 2017
South Africa
e-mail: info@tac.org.za
Ph: 27 11 403 7021
Fax: 27 11 403 2106
email: info@tac.org.za
http://www.tac.org.za
http://www.durban2000march.org/

Treatment Action Group (TAG)

The Treatment Action Group (TAG) is a US-based organization dedicated to fighting in order to find a cure for AIDS and to ensure that all people living with HIV receive the necessary treatment, care, and information they need to save their lives. TAG focuses on the AIDS research effort, both public and private, the drug development process, and the health care delivery systems.

Publication: "Exploring the American Response to the Global AIDS Pandemic," by Derek Link with Mark Harrington, at
www.aidsinfonyc.org/tag/activism/global.html

Contact: ggonsalves@msn.com
http://www.aidsinfonyc.org/tag/

UNAIDS

As the main United Nations advocate for global action on HIV/AIDS, the Joint United Nations Programme on HIV/AIDS (UNAIDS) is responsible for leading, strengthening, and supporting an expanded response to a) prevent the transmission of HIV, b) provide care and support, c) reduce the vulnerability of individuals and communities to HIV/AIDS, and d) alleviate the impact of the epidemic.

UNAIDS, 1211 Geneva 27, Switzerland
http://www.unaids.org

The following documents can be found at:
http://www.who.int/medicines/docs/pagespublications/hiv_relatedpub.htm

"Patent Situation of HIV/AIDS-related Drugs in 80 Countries" (UNAIDS/WHO)
(also:
http://www.unaids.org/publications/documents/health/access/patsit.doc)

"Pharmaceuticals and the WTO TRIPS Agreement: Questions and Answers" (UNAIDS/WHO)

"Essential drugs used in the care of people living with HIV: sources and prices," Joint UNAIDS-UNICEF SD-WHO/EDM Project, (2/2000)

Other relevant UNAIDS/WHO documents:

"Access to Drugs: UNAIDS Technical Update" (March 2000)
http://www.unaids.org/publications/documents/health/access/accestue.pdf

"UNAIDS Initiative on Accelerated Access to HIV/AIDS Care"

"HIV/AIDS and Human Rights: International Guidelines" (United Nations, 1998)
Office of the United Nations High Commissioner for Human Rights, 1211 Geneva 10, Switzerland or,
UNAIDS, 1211 Geneva 27, Switzerland

"Guidelines for Drug Donations," World Health Organization (WHO) (1999) at
http://www.drugdonations.org

"NGO Perspectives on Access to HIV-Related Drugs in 13 Latin American and Caribbean Countries (UNAIDS)" at
http://www.unaids.org/publications/documents/health/access/una98e25.pdf

VSO

VSO is an international development charity that works through volunteers. VSO is responding the HIV/AIDS crisis with the Treatment for Life campaign, which aims to increase the availability of medicines and by working with overseas partners to help prevent further spread of infection.

See their report, "Drug Deals: Medicines, Development and HIV/AIDS," at
http://www.vso.org.uk/campaign/drugdeals.pdf

http://www.vso.org.uk/

Women's Environment and Development Organization (WEDO)

WEDO is an international advocacy network actively working to transform society to achieve a healthy and peaceful planet with social, political, economic and environmental justice for all through the empowerment of women, in all their diversity, and their equal participation with men in decision-making from grassroots to global arenas.

Publication: "A Gender Agenda for the WTO," WEDO Primer, Women and Trade (Nov. '99) at
http://www.wedo.org/global/wedo_primer.htm

WEDO
355 Lexington Avenue, 3rd Floor
New York, New York 10017, USA
Tel: 212-973-0325
Fax: 212-973-0335
E-mail: wedo@igc.org
gopher://gopher.igc.apc.org/11/orgs/wedo
http://www.wedo.org/

Information Specific to Drug Donations

Aid for AIDS

Aid For AIDS is a US-based non-profit organization founded to support the clinical care of HIV-infected Latin Americans living in the United States and throughout Latin America through a small-scale drug donation program.

Aid for AIDS
515 Greenwich St
New York, NY 10013
USA
Tel: (001) (212) 337-8043
Fax: (001) (212) 337-8045
info@aid4aids.org
http://www.aidforaids.org

AIDS Empowerment and Treatment International (AIDSETI)

Contact them (see address in first section) for more information on their program, "The African AIDS Network (AAN)," which is a program of AIDSETI that collects surplus medications from across the United States and closely monitors their distribution to AIDS patients in six African countries. The AAN also provides support referrals for HIV/AIDS patients and technical support for doctors in Africa.

Global Network of People Living with HIV/AIDS (GNP+)

Contact them (see their address in previous section) and ask for their "Guidelines for the Donation of Medication"

Wemos Foundation

Wemos is a Dutch NGO that addresses international health issues through policy advocacy and education activities They maintain a web site on drug donations, in seven languages: http://www.drugdonations.org

Wemos Foundation, PO Box 1693
1000 BR Amsterdam
The Netherlands
Fax: +31-20-468-6008
Phone +31 20-468-8388
Pharmaceuticals@wemos.nl
http://www.wemos.nl
http://www.drugdonations.org

Other Resources for Reference

World Trade Organization

See the full text of the Trade Related Aspects of Intellectual Property (TRIPS) Agreement at the World Trade Organization's website:

http://www.wto.org/

Pharmaceutical Manufacturers' Association

Pharmaceutical industry lobbying group.

http://www.phrma.org

We gratefully acknowledge the invaluable assistance and input provided by Mobilization Against AIDS (MAA).

If you have any comments additions or edits, please contact us:

International Gay and Lesbian Human Rights Commission (IGLHRC)
1360 Mission St., Suite 200
San Francisco, CA 94103 USA
Tel. +1-(415) 255-8680 FAX +1-(415) 255-8662
Satellite Office:
C/o Human Rights Watch
350 Fifth Avenue, 34th Floor
New York, NY 10118 USA
Tel. +1-(212) 216-1256 FAX +1-(212) 216-1876
iglhrc@iglhrc.org
http://www.iglhrc.org

APPENDIX : WTO Member Countries As of June 14, 2000

137 members on 14 June 2000, with dates of membership
(see in http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm)

Angola ..... 23 November 1996
Antigua and Barbuda ..... 1 January 1995
Argentina ..... 1 January 1995
Australia ..... 1 January 1995
Austria ..... 1 January 1995
Bahrain ..... 1 January 1995
Bangladesh ..... 1 January 1995
Barbados ..... 1 January 1995
Belgium ..... 1 January 1995
Belize ..... 1 January 1995
Benin ..... 22 February 1996
Bolivia ..... 12 September 1995
Botswana ..... 31 May 1995
Brazil ..... 1 January 1995
Brunei Darussalam ..... 1 January 1995
Bulgaria ..... 1 December 1996
Burkina Faso ..... 3 June 1995
Burundi ..... 23 July 1995
Cameroon ..... 13 December 1995
Canada ..... 1 January 1995
Central African Republic ..... 31 May 1995
Chad ..... 19 October 1996
Chile ..... 1 January 1995
Colombia ..... 30 April 1995
Congo ..... 27 March 1997
Costa Rica ..... 1 January 1995
Côte d'Ivoire ..... 1 January 1995
Cuba ..... 20 April 1995
Cyprus ..... 30 July 1995
Czech Republic ..... 1 January 1995
Democratic Republic
of the Congo ..... 1 January 1997
Denmark ..... 1 January 1995
Djibouti ..... 31 May 1995
Dominica ..... 1 January 1995
Dominican Republic ..... 9 March 1995
Ecuador ..... 21 January 1996
Egypt ..... 30 June 1995
El Salvador ..... 7 May 1995
Estonia ..... 13 November 1999
European Communities ..... 1 January 1995
Fiji ..... 14 January 1996
Finland ..... 1 January 1995
France ..... 1 January 1995
Gabon ..... 1 January 1995
The Gambia ..... 23 October 1996
Georgia ..... 14 June 2000
Germany ..... 1 January 1995
Ghana ..... 1 January 1995
Greece ..... 1 January 1995
Grenada ..... 22 February 1996
Guatemala ..... 21 July 1995
Guinea Bissau ..... 31 May 1995
Guinea ..... 25 October 1995
Guyana ..... 1 January 1995
Haiti ..... 30 January 1996
Honduras ..... 1 January 1995
Hong Kong, China, ... 1 January 1995
Hungary ..... 1 January 1995
Iceland ..... 1 January 1995
India ..... 1 January 1995
Indonesia 1January 1995
Ireland ..... 1 January 1995
Israel ..... 21 April 1995
Italy ..... 1 January 1995
Jamaica ..... 9 March 1995
Jordan ..... 11 April 2000
Japan ..... 1 January 1995
Kenya ..... 1 January 1995
Korea, Republic of ..... 1 January 1995
Kuwait ..... 1 January 1995
The Kyrgyz Republic ..... 20 December 1998
Latvia ..... 10 February 1999
Lesotho ..... 31 May 1995
Liechtenstein ..... 1 September 1995
Luxembourg ..... 1 January 1995
Macau, China ..... 1 January 1995
Madagascar ..... 17 November 1995
Malawi ..... 31 May 1995
Malaysia ..... 1 January 1995
Maldives ..... 31 May 1995
Mali ..... 31 May 1995
Malta ..... 1 January 1995
Mauritania ..... 31 May 1995
Mauritius ..... 1 January 1995
Mexico ..... 1 January 1995
Mongolia ..... 29 January 1997
Morocco ..... 1 January 1995
Mozambique ..... 26 August 1995
Myanmar ..... 1 January 1995
Namibia ..... 1 January 1995
Netherlands
For the Kingdom in Europe
and for the Netherl. Antilles 1 January 1995
New Zealand ..... 1 January 1995
Nicaragua ..... 3 September 1995
Niger ..... 13 December 1996
Nigeria ..... 1 January 1995
Norway ..... 1 January 1995
Pakistan ..... 1 January 1995
Panama ..... 6 September 1997
Papua New Guinea ..... 9 June 1996
Paraguay ..... 1 January 1995
Peru ..... 1 January 1995
Philippines ..... 1 January 1995
Poland ..... 1 July 1995
Portugal ..... 1 January 1995
Qatar ..... 13 January 1996
Romania ..... 1 January 1995
Rwanda ..... 22 May 1996
Saint Kitts and Nevis ..... 21 February 1996
Saint Lucia ..... 1 January 1995

Saint Vincent & the Grenadines	1 January 1995
Senegal	1 January 1995
Sierra Leone	23 July 1995
Singapore	1 January 1995
Slovak Republic	1 January 1995
Slovenia	30 July 1995
Solomon Islands	26 July 1996
South Africa	1 January 1995
Spain	1 January 1995
Sri Lanka	1 January 1995
Suriname	1 January 1995
Swaziland	1 January 1995
Sweden	1 January 1995
Switzerland	1 July 1995
Tanzania	1 January 1995
Thailand	1 January 1995
Togo	31 May 1995
Trinidad and Tobago	1 March 1995
Tunisia	29 March 1995
Turkey	26 March 1995
Uganda	1 January 1995
United Arab Emirates	10 April 1996
United Kingdom	1 January 1995
United States	1 January 1995
Uruguay	1 January 1995
Venezuela	1 January 1995
Zambia	1 January 1995
Zimbabwe	5 March 1995

WTO Least-Developed Member Countries As of June 14, 2000

http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm

The WTO recognizes as least-developed countries (LDCs) those countries which have been designated as such by the United Nations. There are currently 48 least-developed countries on the UN list, 29 of which to date have become WTO members.

Angola, Bangladesh, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Congo, Democratic Republic of the, Djibouti, Gambia, Guinea, Guinea Bissau, Haiti, Lesotho, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Niger, Rwanda, Sierra Leone, Solomon Islands, Tanzania, Togo, Uganda, Zambia,

Six additional least-developed countries are in the process of accession to the WTO. They are: Cambodia, Laos, Nepal, Samoa, Sudan and Vanuatu.

There are no WTO definitions of "developed" or "developing" countries. Developing countries in the WTO are designated on the basis of self-selection although this is not necessarily automatically accepted in all WTO bodies.

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Médecins Sans Frontières

Health Action International

Consumer Project on Technology

Drug Policy at the 53rd World Health Assembly May 2000

Improving Access to Essential Medicines: Confronting the Crisis

One-third of the world's population lacks access to essential drugs. In the most impoverished parts of Africa and of Asia that number is more than 50%.[i] Because of that fact, many effective medicines remain out of reach to people in developing and Eastern and Central European countries. Long-time killers such as tuberculosis (TB) and malaria continue to claim millions of lives in the developing world. Very few people in this region have access to medicines that are the standard in industrialised countries. The AIDS epidemic is also exacerbated by lack of access to medicines--95% of the 34 million people with HIV/AIDS remain without access to treatment.[ii]

Many factors contribute to the problem of limited access to essential medicines. Unavailability can be caused by logistical supply and storage problems, substandard drug quality, irrational selection of drugs, wasteful prescribing and use, inadequate production, insufficient drug research and development (R&D) and prohibitive prices.

WHO's response

The Revised Drug Strategy (RDS) was adopted by the World Health Assembly (WHA) in 1986 (WHA39.27). The RDS is a comprehensive policy designed to ensure equitable access to essential drugs of acceptable quality. It promotes the development of national drug policies including such elements as drug legislation, independent drug information, control of unethical promotion and inappropriate drug donations, safety, efficacy, quality of drugs and rational use of drugs. The Essential Drugs Concept is the cornerstone of such a policy. The WHO Model List of Essential Drugs is a key element of the RDS and applies to both the private and public sectors.

In a series of resolutions, the WHA has reaffirmed its commitment to the RDS

and has adapted the strategy to enable WHO to address current issues relating to pharmaceuticals. WHO uses the RDS to support countries as they develop national drug policies.

International trade and WHO

Last year's Assembly ended with a resounding show of support for the RDS (resolution WHA52.19). The resolution gave WHO the firm mandate to expand its work on a range of trade-related issues affecting access, quality, and rational drug use. It specifically asked the WHO to study the effects of international trade regulations on health and to assist countries in implementing trade regulations while addressing public health needs and priorities.[iii]

"WHO has a mandate to make public health a priority in trade agreements, but has been relegated to the background in the WTO decision-making process" said a recent letter published in *The Lancet* .[iv] WHO's Director General confirmed this fact when she stated that WHO was invited to attend the recent trade ministerial in Seattle "not as a participant, but as an active and vocal observer"[v] The WHO Director General's progress report on the RDS (A53/10) made to the Executive Board in January paints a picture of a cautious approach regarding pharmaceuticals and trade.

Since last year's Assembly, the WHO has expressed the need to implement the TRIPs taking health concerns into consideration and has advocated using the safeguards that are offered in the TRIPs agreement. The WHO has also come out strongly in favour of policies that encourage the production and use of generic medicines. [vi] Although WHO has developed clear policy statements in recent months on strategies related to trade that help increase access to medicines, it can do much more to fulfil its mandate.

WHO needs to be a pro-active participant in global trade issues that affect access to medicines. The market fails when it comes to providing for the poor. Strong public commitment and government intervention are needed to ensure access and equity in health care. In the international arena the WHO should be a strong leading force "not an observer".

Dr Gro Harlem Brun

In her address to the
"Access
to HIV drugs is part o
system."
[viii]

Translating the Essent
today's
reality

Since 1977, the
WHO's
Essential Drugs Con

Global trade regulation and access to drugs

Globalisation and the international regulation of trade are becoming increasingly linked to health policy. Concerns about the consequences of globalisation and international trade agreements on access to drugs were first raised during the 1996 World Health Assembly in a resolution on the RDS[ix].

The World Trade Organization's (WTO) agreement on trade-related aspects of intellectual property rights (TRIPs) is the most important international agreement on the protection of patents, copyright and trademarks. TRIPs obliges all WTO

member states to provide 20 years of patent protection for medicines. Industrialised countries should have implemented the TRIPs by 1996, developing countries had to introduce national regulation on intellectual property by the year 2000, and least developed countries have until 2006. Intellectual property (IP) protection provides clear benefits. However, there are also costs. A good IP system extends IP protection in some areas, but provides exceptions or limitations on IP rights in others. For each country, the best IP regime will depend upon its own situation, including its level of income, stage of development and its own legal traditions.

Patent protection plays a role in stimulating drug research, but most of the global R&D is focused on the health needs of the developed world. In addition, the market monopoly conferred by patents leads to higher prices for new medicines. There are concerns that the implementation of TRIPs will lead to further drug price increases and will have harmful effects on developing countries' capacity to produce affordable, generic versions of life-saving drugs.

Why is the WHO's input needed in trade policy?

Globalisation and new international trade rules demand new approaches to protect and advance the basic human right of access to health care. As the international organisation mandated to protect public health, the WHO's input is needed now as countries create national laws that are consistent with the TRIPs and because the WTO will be interpreting TRIPs provisions. Strong public health input is needed at both national and international levels. The Director-General's report *HIV/AIDS: confronting the epidemic* (WHA53/6) and draft resolution (EB105.R17) refer to member states' need for WHO's advice on options allowed within the TRIPs to increase access to HIV/AIDS-related medicines.

The objectives and principles of the TRIPs agreement (articles 7 and 8) provide a strong public interest framework for the interpretation and implementation of intellectual property rights. Developing countries in particular should be actively encouraged to use this framework to the fullest. In reality, just the opposite is the case.[xviii] Countries that attempt to use TRIPs provisions to increase availability of essential drugs have come under tremendous pressure to change their legislation, even when the proposed legislation did not violate international agreements. Developing countries do not receive technical assistance that enables them to use safeguards to counterbalance the negative effects of patent protection.

WHO's support is vital to withstand such pressure. For example, there are a number of country disputes currently taking place which involve legislation on compulsory licensing of essential medicines, generic competition and other related issues. WHO has an important role to play in these discussions. It should assist countries and other stakeholders by providing briefing documents outlining policy options and by giving technical assistance. The joint WHO-UNAIDS missions to Thailand and Western Africa that looked into the patent situation of HIV/AIDS-related drugs are good examples of how the WHO can

Trade disputes invo

Concerns about the

The Bangui Agreem

In francophone Africa

What is compulsory

Compulsory licensing

Parallel imports

Parallel imports are c

The lack of R & D fo world's most common dise

Infectious diseases k

In developing countri month's wages. In many poor

support member states.[xix]

years' income.[xvii]

Recommendations for Action:

For WHO:

- Provide pro-active measures and strong public health leadership in the area of access to essential drugs.
- Actively support differential pricing policies that lead to a dramatic price reduction for drugs in developing countries. WHO should develop strategies for differential pricing policies and actively advocate for implementation.
- Issue technical briefings on the following issues:

  * the role of generic competition in increasing affordability of drugs and policy options to speed up the introduction of generic products;
  * how to issue a compulsory license in general, and on public health grounds;
  * drug price control options for developing countries;
  * the effects of financial requirements such as tariffs and taxes that inappropriately increase drug prices.

- Review the Essential Drugs List to ensure that the Essential Drugs Concept responds to current epidemiological trends. This can be done by including a second group of drugs—not included now because of cost consideration—with guidance on how to increase affordability and how to ensure the rational use of these drugs.
- Provide member states with advice and technical guidance to ensure that international trade agreements, including TRIPs, do not have a detrimental effect on public health and to ensure that safeguards of the TRIPs to address the negative effects of patents are used to the fullest. One way to do this would be to take part in WIPO missions and trainings on TRIPs implementation.
- In cooperation with WIPO, develop a model law for intellectual property protection for use by developing countries.
- Encourage the development of a working group on access to essential medicines at the World Trade Organisation as called for in the Amsterdam statement (see http://www.haiweb.org/campaign/novseminar/amsterdam_statement.html).
- Support the need for inclusion of health concerns in trade negotiations.
- Monitor systematically the effects of TRIPs on access to drugs, drug prices, technology transfer and pharmaceutical research and development.
- Develop, in co-operation with other relevant organisations, an essential research agenda for neglected diseases.
- Take a leading role in devising new and innovative approaches to stimulating research in essential medicines, including:

  * increased public and donor funding of research and development with assurances of guaranteed public access;

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* compulsory research obligations, such as requirements that companies reinvest a percentage of pharmaceutical sales into R&D for neglected diseases, either directly or through public or private sector R&D programmes;
* development of neglected disease legislation that stimulates public investment for communicable disease vaccines and medicines.

- WHO in cooperation with international organisations, national governments and drug companies needs to actively support developing countries to increase drug development capacity. This includes proactive technology transfer projects.

By member states:

- Reaffirm commitment to developing, implementing, and monitoring national drug policies and take all necessary steps in order to ensure equitable access to essential drugs.
- Ensure that when national laws are reviewed to include TRIPs requirements, parallel imports and compulsory licensing are included. Seek support from the WHO in this process.
- Ensure that national drug policies include mechanisms to make needed medicines affordable, including means to remove inappropriate taxes.
- Assure the provision of affordable drugs through implementation of a strong generic drug policy, bulk purchasing, negotiations with pharmaceutical companies and adequate financing.
- Least developed countries should not implement TRIPs in national legislation before the required deadline of 2006.
- Ensure that national patent laws include the possibilities for compulsory licensing and parallel import. This should include simple administrative procedures for granting compulsory licenses.
- National governments and organisations will have to address the market failure that has led to the abandonment of R&D for neglected diseases. This requires political will, a strong commitment to prioritise health considerations and the enforcement of rules, regulations and other mechanisms to effectively stimulate drug development for neglected diseases.

What is compulsory licensing?

Compulsory licensing is one of the TRIPs provisions that can help address the negative effects of patent monopolies. Compulsory licensing is the granting of a license to a third party without the consent of the patent holder. It is a legal or administrative procedure and should be set out in national legislation. A compulsory license may be issued on various grounds of general interest including public health. The patent holder receives adequate remuneration for the license. Compulsory licensing is a legal option, consistent with the TRIPs agreement (article 31). Countries should ensure simple administrative procedures

for granting compulsory licenses. In many countries, compulsory licensing is part of the patent law. For example, France's law on this issue authorises compulsory licensing when patented drugs "are only made available to the public in insufficient quantities or quality or at abnormally high prices".[xii] ⇧

Translating the Essential Drugs Concept into today's reality

Since 1977, the WHO's Essential Drugs Concept has been a major contribution to improving access to medicines in developing countries. Essential drugs are "those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms".[xiii] The inclusion criteria are proven safety and efficacy, well-understood therapeutic qualities and cost. Without the cost criteria the list would be longer. Presently fewer than 20 drugs on the list are patent-protected products.

Twenty-three years after the publication of the first Essential Drugs List, the WHO's model list remains one of the most important public health tools available. The list suggests a limited number of drugs with a good benefit/risk ratio and an affordable price which help health care providers make rational choices and meet the majority of medical needs.

Since its first edition, the WHO's model list has been updated many times; the eleventh edition was published in December 1999. Today WHO's Essential Drugs List faces many pressures. Because cost is one of the list's inclusion criterion, the latest list cannot respond to new epidemiological trends. This is the case, for example, with diseases such as Shigellosis and TB that can no longer be treated with first-line treatment because of drug resistance. In some countries, HIV/AIDS is the most pressing public health problem. However, antiretroviral therapies are not included on the WHO model list except for the very limited indication of mother-to-child transmission.

Critics argue that second-line drugs such as new and expensive antibiotics and antiretrovirals should not be added to the WHO list because they would undermine the Essential Drugs Concept, are too expensive, or are difficult to use. But can the list continue to ignore so much suffering? Clearly this dilemma needs to be addressed.

Adding such drugs to the WHO Essential Drugs List calls for caution: this second group of drugs must be clearly distinguishable from the first-line treatment drugs which are more affordable and easy-to-use. They should be included with published guidance on how to use them and how to ensure their affordability. ⇧

The lack of R & D for the world's most common diseases

Infectious diseases kill 17 million people every year, 90% of whom live in developing countries.[xiv] In the absence of effective, affordable and easy-to-use medicines to fight these diseases, respiratory infections, malaria, and

tuberculosis (TB) remain the leading causes of death and illness in African, Asian and South American countries. These regions are home to four-fifths of the world population.

Today, science and technology are sufficiently advanced to provide the necessary medicines to control these leading killers. However, research and development (R&D) for new medicines for so-called tropical diseases, which correspond largely to the diseases affecting poor countries, has come to a standstill. Only a few percent of the world-wide expenditure on health R&D (estimated at a total of US$50-60 billion a year) is devoted to the development of such medicines. For example, 0.2% of the global pharmaceutical research budget is spent on acute respiratory infections, TB and diarrhoea, while 18% of the deaths are attributable to these diseases.[xv]

Current R&D priorities are set by an increasingly consolidated multinational drug industry, and are based on economic priorities (i.e. maximising return to shareholders) rather than on global health needs. As a result, drug development is focused on the health requirements of the wealthiest population, shifting increasingly from life-threatening diseases towards life-style 'diseases'.

The results for the global drug development outcome are severe: of the 1,233 new drugs (new chemical entities) that came on the market between 1975 and 1997, only 13 were targeted specifically at tropical, infectious diseases.[xvi] Meanwhile, resistance renders many infections unresponsive to older, cheaper anti-infectious drugs, and in some instances large pharmaceutical companies have simply discontinued production of "old", cheap, and effective tropical disease drugs because of insufficient profit margins. Communicable diseases justifiably warrant the term 'Neglected Diseases'.

Drug development costs are substantial. Dedicated expenses for development of a given drug can range from less than US$1 million to tens of millions of dollars. If one includes adjustments for risk and the costs of financing the investments, the cost is higher, but how much higher is a matter of controversy. Representatives of the pharmaceutical industry claim development expenses, including risk and capital costs, are hundreds of millions of US dollars. There are questions about the accuracy of the assumptions used in the industry estimates as well as the relevance. For example, the industry estimates assume companies fund all of the clinical and pre-clinical research, and for many important drugs, the government's role in funding research is significant. ⇧

(For more information, see
http://www.cptech.org/ip/health/econ/howmuch.html)

Parallel imports

Parallel imports are cross border trade in a product without the manufacturer's permission. It can be an attractive option when the same product is being sold for different prices in different markets For example, a pricing study carried out by Health Action International in 1999 showed that Glaxo Wellcome's acyclovir

800 mg in Malaysia costs US$316. The same product was being sold by the same company in India for US$89. This is a result of generic competition in India. Prices for Smithkline Beecham's amoxycillin (Amoxil) range from: US$6 in Pakistan, US$13 in Canada, US$8 in New Zealand, US$25 in The Philippines, US$22 in Malaysia, and US$14 in Indonesia. [xiii] Parallel imports are the global version of shopping around for the best value and are permitted under the TRIPs agreement. Clearly it is not in the interest of developing countries at this point to restrict parallel imports of pharmaceuticals. Many European countries already benefit from significant parallel trade in order to reduce the overall cost of medicines.

Some drug companies say that parallel trade should be stopped to prevent inexpensive drugs from developing countries from entering the markets of rich countries. Already, this is not permitted by national legislation in Europe, the United States, Japan and other developed countries. Moreover, there is no reason to prevent poor countries from engaging in parallel trade. In particular, there is no reason why poor countries should not be able to buy products in rich countries, when prices are lower due to competition in the larger US and European markets. ⇧

Trade disputes involving access to drugs

In 1997 South Africa decided to amend its 1965 Medicines Act to include compulsory licensing and parallel imports in accordance with the provisions of the TRIPs. The multinational pharmaceutical industry brought legal action against the South African State claiming that the new law was unconstitutional. In addition, the US government issued trade sanctions against South Africa to pressure the country to change its proposed medicines law. The European Commission added its voice to the US complaints. The United States Trade Representative even went as far as to cite unwelcome views expressed by South Africa at the World Health Assembly as a basis for sanctions(see http://www.cptech.org/ip/health/sa).

In Thailand the right to issue compulsory licenses for pharmaceuticals was limited by the Thai government following a US threat to increase tariffs on imported Thai wood products and jewellery.[x] The US policy came under fierce attack from AIDS activists, public health activists, consumer groups and international NGOs. In response to the pressure the US was forced to declare a change in US policy with regard to intellectual property rights and access to medicines. Under the new policy the US Trade representative (USTR) and the Department of Health and Human Services (HHS) will work together to establish a process to analyse health issues that arise in the application of US trade-related intellectual property law and policy.

In 1999, the US had disputes regarding intellectual property and health care in 42 countries of which 37 were developing countries[xi]. ⇧

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(see also www.cptech.org/ip/health/country/allcountries.html).

Concerns about the effects of TRIPs

- Increased patent protection leads to higher drug prices. The number of new essential drugs under patent will increase but the drugs will remain out of reach to people in developing countries because of their high prices. As a result, the access gap between developed and developing countries will grow.
- Enforcement of the WTO rules will have an effect on local manufacturing capacity and will remove a source of generic, innovative, quality drugs on which poorer countries depend.
- It is unlikely that the TRIPs agreement will encourage adequate research and development in developing countries for diseases such as malaria and TB. There are also inadequate incentives for the research-based pharmaceutical industry to invest its increased revenues towards the development of essential medical technologies.
- Developing countries are under pressure from industrialised countries and industry to implement patent legislation that goes beyond the obligations of the TRIPs agreement. This is called "TRIPs plus" protection. "TRIPs plus" is patent legislation that provides stronger protection of intellectual property than the TRIPs agreement requires or does not include safeguards such as compulsory licensing that are provided in TRIPs to counteract the negative effects of patent protection. An example of a "TRIPS plus" patent law is a law that does not allow for the issuing of a compulsory license or parallel imports.
- Industrialised countries and the World Intellectual Property Organization (WIPO) offer expert assistance to help countries become TRIPs compliant. This technical assistance however does not take into account the specific needs of the health sector of developing countries and both of these institutions are under strong pressure to advance the point of view of large companies that own patents and other intellectual property rights. ⇧

The Bangui Agreement:"TRIPs plus" in Western Africa

In francophone African countries, patents are granted through a regional patent office called the African Intellectual Property Organization or OAPI, which acts as a national patent office for all OAPI member states. Patents are granted and regulated according to the Bangui Agreement which constitutes the patent law of all these countries. Although the majority of OAPI members are least-developed countries, the Bangui Agreement was recently revised to comply with the TRIPs before the year 2000. Despite the unaffordability of many essential drugs in Western Africa, the new Bangui Agreement is more stringent than the TRIPs Agreement and provides little manoeuvring room in case of patent abuse. Compulsory licences are only available provided that the patented drug can be

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manufactured locally when in reality there is little manufacturing capacity in the region. Parallel imports are only possible between OAPI member states whereas lower prices might be found in other parts of the world. As a result, patent holders enjoy greater protection than the public interest in OAPI member states. ⇧

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About the organisations

Health Action International (HAI) is a network of more than 200 consumer, health, development action and other public interest groups involved in health and pharmaceutical issues world-wide.

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Médecins Sans Frontières (MSF) offers assistance to populations in distress, to victims of natural or man-made disasters and to victims of armed conflict without discrimination and irrespective of race, religion, creed or political affiliation. MSF was awarded the 1999 Nobel Peace Prize.

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Consumer Project on Technology (CPT) is a US-based, non-profit research and advocacy organisation created by consumer advocate Ralph Nader. Its activities focus on information technologies, intellectual property and research and development.

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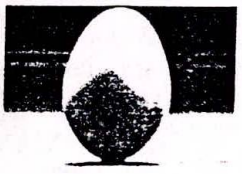
FACT SHEET: TRIPS AND PHARMACEUTICAL PATENTS

Philosophy: TRIPS attempts to strike a balance



The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations.

The agreement covers a wide range of subjects, from copyright and trademarks, to integrated circuit designs and trade secrets. Patents for pharmaceuticals and other products are only part of the agreement.

April 2001

Contents

The balance works in three ways:

- Invention and creativity in themselves should provide social and technological benefits. Intellectual property protection encourages inventors and creators because they can expect to earn some future benefits from their creativity. This encourages new inventions, such as new drugs, whose development costs can sometimes be extremely high, so private rights also bring social benefits.

- The way intellectual property is protected can also serve social goals. For example, patented inventions have to be disclosed, allowing others to study the invention even while its patent is being protected. This helps technological progress and technology dissemination and transfer. After a period, the protection expires, which means that the invention becomes available for others to use. All of this avoids "re-inventing the wheel".

- The TRIPS Agreement provides flexibility for governments to fine tune the protection granted in order to meet social goals. For patents, it allows governments to make exceptions to patent holders'

The TRIPS Agreement

Article 7
Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8
Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to

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rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled.

What is the basic patent right? back to top

Patents provide the patent owner with the legal means to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions.

A patent is not a permit to put a product on the market back to top

A patent only gives an inventor the right to prevent others from using the patented invention. It says nothing about whether the product is safe for consumers and whether it can be supplied. Patented pharmaceuticals still have to go through rigorous testing and approval before they can be put on the market.

protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

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Main Identity

From: Daniel Lee <daniel@iglhrc.org>
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Sent: Monday, August 06, 2001 2:56 PM
Subject: HealthGAP/IGLHRC Statement

WHERE ARE OUR RIGHTS?
THE DRAFT DECLARATION OF COMMITMENT AND ITS GAPS

A statement by the Health GAP Coalition and the International Gay and Lesbian Human Rights Commission

The draft Declaration of Commitment on HIV/AIDS acknowledges the value of human rights in the struggle against the pandemic. Yet it does so only partly and in piecemeal fashion. Commitment is no help without consistency. The draft's extensive promises are silent about the principles which might motivate and sustain them. When it comes to the values undergirding action, there is a gap. Our rights are missing.

Under "Leadership," the draft urges States to "fully protect and promote human rights and fundamental freedoms for all, including the right of enjoyment of the highest attainable standard of physical and mental health." We agree. Both the language and the action steps of the rest of the document, however, still do not fully envision the concrete responsibilities this entails.

The Declaration is a crucial opportunity for the global community to endorse and further a comprehensive rights-based response to HIV/AIDS. Only such a response will make the right to health a lived reality rather than convenient rhetoric. Only such a response will guarantee the dignity, and lengthen the lives, of all those affected by HIV/AIDS.

PART ONE: THE RIGHT TO HEALTH

We begin with the section on **Care , Support, and Treatment.** By detaching itself dangerously from the right to health, this section fails to recognize three crucial points:

1) *Treatment is prevention.* Treatment strengthens prevention efforts, provides an incentive to HIV testing, expands local health infrastructure, addresses stigma and discrimination against people living with HIV, and improves delivery of care and response. The first sentence should read:

Care, support and treatment are inextricably linked to prevention and are fundamental elements of an effective response.

2) *Treatment is a right.* It is not a privilege accorded to the advantaged, nor a mere means to another end. It is an aspect of the universal right to the highest attainable standard of health. Governments can take steps toward implementing this right immediately-without waiting till 2003 or 2005. This section should express States' commitments:

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To outlining and implementing immediate and clear action steps for increasing access to treatment and care, with express and concrete standards. Steps toward this end should address interrelated issues including: treatment for STDs and opportunistic infections; palliative care; nutrition; diagnostics; "best practice" clinical management of HIV disease; education of communities about HIV treatment through culturally appropriate materials; and training of physicians and health-care professionals.

Support, treatment, and care are an aspect of the right to the highest attainable standard of physical and mental health. Strategies on the national level should begin immediately to work toward implementation of that right. States can begin immediately to train physicians, health-care advocates, and community professionals in appropriate strategies for managing HIV/AIDS; can identify and take concrete steps to enhance existing health infrastructure for introduction and delivery of HIV-related medicines and care; can identify and establish national programs and successful community-based models of HIV treatment; and can immediately establish mechanisms to prioritize care and support for individuals with symptomatic late-state HIV or late-stage AIDS, and their families.

Similarly, the Declaration should call, at the international level, for:

Strategies to research and promote best practices for providing anti-retroviral treatment in resource-limited settings, including publishing and disseminating models.

3) *The barriers to effective treatment are international.* Developing countries cannot overcome them on their own. The section on treatment irresponsibly calls only for national strategies, without addressing the four major international barriers to treatment:

← *debt*
← *pricing*
← *intellectual property standards*
← *global trade practices and systems.*

The Declaration should reinstate language included in its previous draft, and cut from this one, calling for strategies to

Address factors affecting the provision of essential drugs, including technical and system capacity, prices, international trade rules and intellectual property rights.

The Declaration should state, in language drawn from the resolution unanimously adopted this year by the UN Commission on Human Rights:

All States should:
a) Refrain from taking measures which would deny or limit equal access for all States and for all persons to preventive, curative, or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them;
b) Ensure that their actions as members of international organizations take due account of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, and that the application of international agreements promotes broad access to such pharmaceuticals or technologies;
c) Adopt legislation or other measures to safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies from any limitations by third parties;
d) Adopt all appropriate positive measures to maximize the resources allocated for this purpose.

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The World Health Organization and the World Intellectual Property Organization, in cooperation with other agencies, should assist countries in developing patent and other legislation aimed at implementing the right to health. To this end they should develop a library of model legislation and other resources for technical assistance.

This section of the Declaration should also affirm that States:

Support the establishment of a special fund which will, among other activities, purchase medicines, raw materials, and other competitively available commodities--including medical technologies and prophylaxis and palliative care--at best world prices through a transparent bidding process, from multiple suppliers including generic manufacturers. The program must provide its services for regional entities and governments, but also for other providers including non-governmental organizations and charitable and workplace programs. Medicines for tuberculosis, malaria, and other life-threatening diseases affecting developing countries should be eligible for purchase, as well as medicines for HIV and its opportunistic infections. Medicines purchased should be made available for free distribution to the peoples of non-OECD countries. Decision-making with regard to the procurement program must be transparent, and governed by international health experts and representatives from civil society, including representatives of people living with HIV/AIDS, with full representation of developing countries.
This program should also assist countries to expedite and harmonize both drug registration and quality assurance. The program should work with suppliers to create and maintain a common dossier of product information, including information typically required for drug registration.

The description of this fund, in the section on **Resources,** must contain clear guidelines for its governance. The section on **Resources** should state:

The fund should be housed within the United Nations system, drawing upon the expertise in bulk procurement within United Nations agencies. Governance and advisory bodies of the Fund should be drawn from international health experts; representatives of civil society, including people living with HIV/AIDS; and representatives of the governments of developing countries. Decision-making should be fully transparent, and contributors to the fund should not impose conditions upon donations. Steps, including compulsory recusal, should be taken to prevent conflict of interest, and commercial interests should not be represented on the governance board.

The section on **Resources** should also state:

Recognizing the interrelatedness of treatment and prevention, the fund should strive for parity in allocating resources to both areas.

PART TWO: STIGMA, VULNERABILITY, AND HUMAN RIGHTS

In the section on **HIV/AIDS and Human Rights,** the draft rightly states that "Respect for human rights reduces vulnerability to HIV/AIDS," and calls for "respect for the rights of people living with HIV/AIDS." The concrete steps envisioned, however, fall far short of an effective response.

The draft sees *discrimination* overwhelmingly in terms of discrimination against people living with HIV/AIDS-and thus neglects or evades those other forms of discrimination and abuse which contribute to the spread of the epidemic. This is conspicuous in the transition from this section to the following section on **Reducing Vulnerability.** The draft indicates that States must protect the *rights* of people living with HIV/AIDS, but must protect the *health* of vulnerable populations. Yet vulnerable populations demand to be regarded in a rights-based framework. Their health cannot be furthered unless their rights are expressly recognized and respected.

In the section on **HIV/AIDS and Human Rights,** the Declaration should call on States to:

Enact or strengthen legislation offering protection against all forms of discrimination, consistent with the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights and their interpretations; and implement programs to educate against discriminatory treatment of vulnerable groups in all aspects of government and society, including but not restricted to the health care and criminal justice systems.

In the section on **Reducing Vulnerability,** the Declaration should call on States to:

Ensure that all measures taken to promote and protect the health of vulnerable populations are inclusive and educational, rather than restrictive or punitive; that they are devised, implemented, and evaluated with full regard to States' obligations with respect to human rights; and that communities affected are fully consulted in their development and implementation.

The Declaration should also state, in the same section:

All proposed or existing strategies or policies with regard to HIV/AIDS--at local, national, or international levels, and in prevention, care, treatment, research, and other areas--should be examined with a view to their differential impact on populations made vulnerable by discrimination, and with a view to ensuring that they are non-discriminatory in intent, implementation, and impact.

The draft segregates *gender* into a few short paragraphs, without seeing it as an essential, structuring factor in the spread of the epidemic. In the section on **Human Rights and HIV/AIDS,** the Declaration should affirm that States will immediately:

Recognize that women are particularly affected by and burdened by the AIDS pandemic. From young girls to grandmothers, they are disproportionately affected by the breakdown of family, social, and civic structures. They are sources of care and support within the family; they are subjected to violence both within and outside it; they are breadwinners in still-discriminatory economic situations; they are often deprived of political rights which would enable them to voice their needs. Women's inequality in political, economic, social, cultural, civil, private and other fields further contributes to the spread of HIV/AIDS. Moreover, the particular situations of women are often neglected in considerations of research, prevention, treatment and care. The very lives of women are sometimes treated as secondary in decisions about treatment, or ignored in the course of research.
States should take all necessary measures to eliminate all forms of discrimination against women and the girl child, and to remove all obstacles to gender equality and the advancement and empowerment of women. States should ensure women's full participation on the basis of equality in all spheres of society, including participation in the decision-making process and access to power. States should ensure the full enjoyment by women and the girl child of all

human rights and fundamental freedoms, and take effective action against violations of these rights and freedoms. The human rights of women include their right to have control over and decide freely and responsibly on matters related to their sexuality, including sexual and reproductive health, free of coercion, discrimination and violence.

The Declaration should also state:

All proposed and existing strategies and policies with regard to HIV/AIDS--at local, national, or international levels, and in prevention, care, treatment, research, and other areas--should be examined from a gender perspective and with a view to their differential impact on men and women, including the human rights of women.

Gender-disaggregated data should be produced in evaluating all strategies and policies.

In this spirit, in the section on **Prevention,** the roles and needs of women must be expressly acknowledged. The Declaration should affirm that States will:

Establish programs to create and improve prevention tools allowing greater options and greater control of decision-making to women, in the realm of their own sexuality and HIV/AIDS. Both political will and resources, including the resources of developed countries, must be devoted to developing such tools, which include availability of, and education in the use of, microbicides and barrier forms of contraception.

This paper was prepared by the Health GAP (Global Access Project) Coalition and the International Gay and Lesbian Human Rights Commission (IGLHRC).

The Health GAP Coalition is a network of US-based AIDS activists, public health experts, human rights groups, fair trade advocates, and concerned individuals dedicated to eliminating barriers to global access to affordable life-sustaining medicines for people living with HIV/AIDS. It can be reached at: PO Box 22439, Philadelphia PA 19143 USA
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IGLHRC's mission is to document and advocate against human rights abuses based on HIV status, sexual orientation, or gender identity. IGLHRC cooperates with the efforts of thousands of activists and organizations worldwide. It can be reached at: 1360 Mission St., Suite 200, San Francisco CA 94103 USA
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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.

B. The Agreement on Trade-Related-Intellectual-Property (TRIPS)

- *"Globalization and Access to Pharmaceuticals": TRIPS Explained*
  World Health Organization

- *Fact Sheet: TRIPS and Pharmaceutical Patents*
  World Trade Organization

- *"Compulsory Licensing and Parallel Importing: What Do They Mean?"*
  Margaret Duckett, International Council of AIDS Service Organizations (ICASO)

Box 2. Articles of the TRIPS Agreement of greatest relevance to pharmaceuticals

Topic (TRIPS Article)	Key phrasing from TRIPS agreement (Note that a number of articles contain further specific conditions, exceptions and exemptions which are spelled out in TRIPS or other referenced agreements.)
Nondiscrimination (Articles 3 and 4)	*"National Treatment...*Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property..." *"Most-Favoured-Nation Treatment...*With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members..."
Parallel importation ("exhaustion of patent rights") (Article 6)	*"Exhaustion...*For the purposes of dispute settlement under this Agreement, subject to the provisons of Articles 3 [National Treatment] and 4 [Most-Favoured-Nation Treatment], nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."
Objectives of TRIPS (Article 7)	*"Objectives...*The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."
Protection of public health (Article 8)	*"Principles...*Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."
Process and product patents (Article 27)	*"Patentable Subject Matter...*patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application...[P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."
Subject matter which may be excluded from patentability (Article 27)	*"Patentable Subject Matter...*Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health..." "Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."
Exceptions which facilitate prompt marketing of generic drugs ("Bolar" provisions) (Article 30)	*"Exceptions to Rights Conferred...*Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."
Compulsory licensing (Article 31)	*"Other Use Without Authorization of the Right Holder...*Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the [twelve] provisions shall be respected."
20-year minimum term of protection (Article 33)	*"Term of Protection...*The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."
Reversal of burden of proof for process patents (Article 34)	*"Process Patents...Burden of Proof...*For the purposes of civil proceedings in respect of the infringement of the rights of the owner...if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process."
Data protection and Exclusivity (Article 39)	*"Protection of undisclosed information...*In the course of ensuring effective protection against unfair competition...Members shall protect undisclosed information...and data submitted to governments or governmental agencies..."
Transitional arrangements for developing country WTO Members (Articles 65 and 66)	Specific transitional arrangements are provided for developing and least-developed countries (see TRIPS text).
Transfer of technology and technical cooperation (Articles 66 and 67)	"Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base...[and] shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members."
Mailbox filings (Article 70:8)	"Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall: (a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed..."
Review (Article 71:1)	"The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement."

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Perspectives on Medicines

No. 3 March 2001
World Health Organization
Geneva

Globalization, TRIPS and access to pharmaceuticals

A new era in global trade

Creation of the World Trade Organization

The World Trade Organization (WTO) is the international organization dealing with rules of trade between nations. Although the WTO became officially operational only in January 1995, it is the successor to the GATT multilateral trading system founded in 1947. In becoming Members of the WTO, countries undertake to abide by its rules. As of 30 November 2000, the WTO counted 140 Members.

The WTO is charged with setting the legal ground rules for international trade. Its objectives are to promote: (1) non-discrimination (2) progressive liberalization of barriers to trade (3) predictable policies and transparency (4) competition and (5) special provisions for developing countries.

WTO Agreements

In joining the WTO, Members adhere to 18 specific agreements annexed to the Agreement establishing the WTO. They cannot choose to be party to some agreements but not others (with the exception of a few "plurilateral" agreements that are not obligatory). Of greatest relevance to the health sector are: the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS); the Agreement on Technical Barriers to Trade (TBT); the General Agreement on Tariffs and Trade (GATT); and the General Agreement on Trade in Services (GATS).

Of these agreements, TRIPS is expected to have the greatest impact on the pharmaceutical sector. The TBT Agreement should be of particular concern to producing countries, since its implementation may affect export markets.

Implementation and dispute settlement

The WTO Agreement is a treaty that creates international obligations among its Members. These obligations include refraining from taking actions that are inconsistent with the agreement, and implementing certain provisions via national legislation.

The various parts of the WTO Agreement, including the TRIPS Agreement, require that such national legislation embodies certain specific standards. However, in many areas, the WTO Agreement affords considerable discretion in how its obligations are implemented. This discretion, combined with the potential health impact of national legislation, make it imperative that, health officials work closely with other parts of government, such as the trade department, and use top-level legal, trade and pharmaceutical expertise when legislation is being drafted. (See Box 1.)

Box 1. Points for policy-makers

- TRIPS establishes intellectual property standards for WTO Members, historically based on the standards of developed countries.
- TRIPS requires patent protection for all products and processes, with a minimum duration of 20 years from the original date of filing, without any special consideration for pharmaceuticals.
- The TRIPS Agreement permits Members some discretion in enacting and amending their laws and regulations, which can help promote public health goals.
- When establishing standards of patentability for pharmaceuticals countries should consider the implications for health of those standards. Standards which are too broad may lead to inappropriate extension of patent life beyond the period required by TRIPS.
- WTO free trade provisions can stimulate generic competition and reduce the prices for off-patent drugs, but TRIPS may also significantly delay the introduction of new generic drugs, depending on the way national legislation is designed and implemented.
- Developing countries should be cautious about enacting legislation more stringent than the TRIPS requirements ("TRIPS-plus").

Disputes can arise when countries differ in their interpretation of the WTO Agreement. The WTO provides a dispute settlement process that may proceed from a consultation phase, to the establishment of and decision by a dispute settlement panel, and appeal to the Appellate Body. Trade sanctions may only be imposed if the dispute settlement process has run its course and the losing country has failed to comply with the decision made. For this reason, WTO Members

may not unilaterally impose trade sanctions based on alleged failures to comply with TRIPS.

Key requirements of the TRIPS Agreement

The TRIPS Agreement introduced global minimum standards for protecting and enforcing nearly all forms of intellectual property rights, including those for pharmaceuticals. The Agreement's 73 Articles cover basic principles, standards and use of patents, enforcement, dispute settlement and a range of other subjects. The key requirements for pharmaceuticals are described below and summarized in Box 2.

Patent protection

Members must provide patent protection for a minimum of 20 years from the filing date of a patent application, for any invention, including of a pharmaceutical product or process, that fulfils the criteria of novelty, inventive step and usefulness (subject to certain exceptions X see Box 2).

Rights conferred

TRIPS specifies the rights conferred on a patent owner, but allows for limited exceptions and compulsory licensing, subject to specified conditions. The Agreement also contains provisions on: protection of undisclosed information (including test data); actions to address anti-competitive practices; protection of trademarks (relevant to generic substitution and combating counterfeit drugs); and enforcement.

Transitional arrangements

TRIPS provides transitional periods during which countries are required to bring their national legislation and practices into conformity with its provisions. The latest dates for WTO Members were/are: 1996 for developed countries; 2000 for developing countries (as a general rule); 2005 for developing countries who had not introduced patents before joining the WTO; and 2006 for least-developed countries.

TRIPS specifically recognizes the economic, financial, administrative and technological constraints of the least-developed countries. It therefore provides the possibility for further extension of the transitional period.

Public health and TRIPS

International conventions before TRIPS did not specify minimum standards for patents. Over 40 countries provided no patent protection for pharmaceuticals, many provided only process and not product patents, and the duration of patents was much less than 20 years in many countries.

From the health sector's perspective, intellectual property standards, including those specified in TRIPS, should take protection of public health into account. However, current standards X historically derived from those of developed countries X are not necessarily appropriate for countries struggling to meet health and development needs. Developing countries can therefore use the flexibility of TRIPS provisions and its safeguards to protect public health.

Patentability

What can be patented? TRIPS specifies patents must be available for all discoveries which "...are new, involve an inventive step and are capable of industrial application (Article 27)."

The difference between the number of new drugs ("new chemical entities"), that are developed globally each year, and the number of patents awarded for new uses of a drug, processes, dosage forms, formulations and different forms of the same molecule, including patents on genes and genomic sequences is enormous. The latter is influenced by national legislation and practices

Yet because "new" and "inventive" are not defined, countries must establish their own criteria for these terms. They should remember that patentability standards which are too broad can contribute to "evergreening". This means that the effective patent life for a new medicine is extended beyond the 20-year TRIPS minimum. Therefore, Ministries of Health must work closely with other ministries to formulate and/or revise national patent legislation to ensure that it takes public health needs into account.

Generic drugs

Promotion of generic drugs requires appropriate legislation and regulations, reliable quality assurance capacity, professional and public acceptance of generic drugs, and economic incentives and information for both prescribers and consumers. The TRIPS Agreement does not prevent Members from requiring generic labelling and allowing generic substitution.

Trade liberalization can increase competition and reduce prices for generic drugs that are already on the market. But if the wording and implementation of TRIPS-compliant national legislation and regulations are inappropriate, the introduction of new generic drugs can be delayed. The economic cost to governments, households and public health can be enormous.

Prompt introduction of generic drugs can be facilitated by: drafting appropriate legislation and regulations on patentability; use of exceptions to exclusive rights which permit early testing and approval of generics ("Bolar" provision) (including allowing access to pre-registration test data); and compulsory licensing.

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Box 3. Checklist for policy-makers

Government process and resources:

- ☐ Identify trade-and-pharmaceuticals focal point within Ministry of Health.
- ☐ Establish contacts, perhaps a working group, with trade and other key ministries.
- ☐ Obtain reliable specialized legal advice.
- ☐ Develop a mechanism to monitor the health impact of new trade agreements.

National patent and related legislation should:

- ☐ Promote standards of patentability that take health into account.
- ☐ Establish process and product patents for 20 years.
- ☐ Incorporate exceptions, trademark provisions, data exclusivity and other measures to support generic competition.
- ☐ Permit compulsory licensing, parallel importation and other measures to promote availability and ensure fair competition.
- ☐ Permit requests for extension of transitional period for TRIPS implementation, if needed and if eligible.
- ☐ Carefully consider national public health interests before instituting TRIPS-plus provisions (see text).

Compulsory licensing

Compulsory licensing enables a competent government authority to license the use of an invention to a third party or government agency without the consent of the patent-holder. The patent-holder, however, retains intellectual property rights and "shall be paid adequate remuneration" according to the circumstances of the case (Article 31). In the pharmaceutical sector compulsory licenses have been used to stimulate price-lowering competition and to ensure availability of needed medicines. Most developed countries and many developing countries now provide for compulsory licensing through national legislation.

A comprehensive patent regime should include adequate provision for the granting of compulsory licenses. Grounds for compulsory licensing may include public interest, problems linked with national emergencies such as epidemics, public non-commercial use, or anti-competitive practices (Article 31). Whether or not compulsory licenses are issued, national legislation which provides for compulsory licensing allows governments to provide the medicine in the case of abuse of rights by the patent-holder, or commercial non-availability. Any such use should be authorized predominantly for the supply of the domestic market of the Member authorizing such use (Article 31f).

Compulsory licenses must be granted on a non-exclusive basis. Since the TRIPS Agreement provides for non-discrimination between locally produced and imported products (Article 27:1), a compulsory license may be granted for importation to satisfy local needs (Article 31).

Parallel imports

Parallel importation is importation, without the consent of the patent-holder, of a product legally marketed in another country by the patent-holder or by another authorized party. The aim of parallel importing is to promote and assure price competition for patented products by allowing importation of equivalent patented products marketed at a lower price in another country by or with the consent of the patent-holder. In TRIPS terminology, the patent-holder's rights to control the international movement of a pharmaceutical have been "exhausted" when the product has been placed on a market by or with the consent of the patent-holder.

The TRIPS Agreement does not prohibit Members from applying the principle of international exhaustion – that is, allowing parallel importation of patented pharmaceuticals once they have been placed on the market in any country. Article 6 explicitly states that disputes relating to exhaustion are not subject to the WTO dispute settlement process.

TRIPS-plus provisions

"TRIPS-plus" is a non-technical term which refers to efforts to: extend patent life beyond the 20-year TRIPS minimum; limit compulsory licensing in ways not required by TRIPS; and limit exceptions which facilitate prompt introduction of generics.

Since the public health impact of TRIPS requirements have yet to be fully assessed, WHO recommends that developing countries be cautious about enacting legislation that is more stringent than the TRIPS requirements.

Non-WTO Members

As of December 2000, over 50 WHO Member States were either not WTO Members or had observer status only at the WTO. From a public health perspective, countries which are not bound by TRIPS should evaluate TRIPS requirements, and incorporate into national legislation and trade-related practices those elements which clearly benefit national public health interests.

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Evaluating impacts of trade agreements

Protection of intellectual property rights aims to promote innovation by providing an incentive to invest in research and development. Yet the TRIPS Agreement, which seeks to fulfil this aim, has proven to be one of the most controversial WTO agreements. At least four questions are commonly raised from a public health perspective (Box 4). In view of the impact that the TRIPS Agreement could have on pharmaceuticals, WHO (in accord with World Health Assembly Resolution WHA52.19) is using these four questions to monitor and analyse the effects of globalization and trade agreements on the pharmaceutical sector.

Concurrently, having been awarded observer status on an ad hoc basis by the WTO Council for TRIPS, WHO is able to monitor all relevant issues under discussion at WTO that may have implications for the health sector.

Box 4. Key questions for monitoring the public health impact of TRIPS

1. Are newer essential drugs more expensive than they would have been if not under patent?
2. Is the introduction of generic drugs being slowed?
3. Are more new drugs for neglected diseases being developed?
4. Are transfer of technology and direct foreign investment in developing countries increasing or decreasing?

WHO perspectives on access to drugs

Access to health is a human right

Access to essential drugs is part of the human right to health. Access to essential drugs depends on: (1) rational selection and use of medicines (2) sustainable adequate financing (3) affordable prices and (4) reliable health and supply systems. Since most poor people in developing countries currently pay for health care, including drugs, out of their own pockets, access to medicines is particularly sensitive to cost. Governments, the UN family, the private sector and civil society each have vital roles and responsibilities in achieving universal access to essential drugs. (See Box 5.)

Patents are an effective stimulator of research and development

Patent protection has been an incentive for research and development for new drugs. But questions remain as to whether the patent system will ensure investment in medicines needed by the poor. Of the 1223 new chemical entities developed between 1975 and 1996, only 11 were for the treatment of tropical diseases. The ma. fails when it comes to ensuring adequate pharmaceutical research and development (R&D) for neglected diseases such as malaria, a range of other tropical diseases and tuberculosis. Strong public sector involvement, including through public-private partnerships, is necessary to ensure development of new drugs for developing country priority health problems.

Affordability of essential drugs is a public health priority

Current financial resources are woefully inadequate for meeting the health care and medicine needs of the world's poorest populations. Governments, donor agencies and development banks all have a vital role to play in increasing those resources. But affordable prices are also very important.

Among the four elements needed to ensure access, the affordability of essential drugs X specifically those still on patent X is most likely to be affected by trade agreements. Patent protection awards exclusive rights to an invention and prevents generic competition. But poorer populations in developing countries should not be expected to pay the same price as do the wealthy for newer essential drugs. TRIPS-compliant mechanisms can be used to lower drug prices.

Other options to improve affordability include exchange of price information; price competition and price negotiation within public procurement and insurance schemes; price controls; reduced duties and taxes; improved distribution efficiency; reduced distribution and dispensing costs and reduced marketing expenses.

Essential drugs are not simply another commodity X TRIPS safeguards are crucial

WHO supports countries in the use of WTO/TRIPS-related safeguards, as appropriate, to enhance affordability and availability of existing medicines, while not discouraging the development of needed new medicines. These safeguards include setting standards for patentability which reflect public health concerns, legislative provision for compulsory licensing, exceptions to exclusive rights and other measures which promote generic competition, and extension of the transitional period. Parallel importation of a patented drug from countries where it is sold more cheaply can also be authorized by governments.

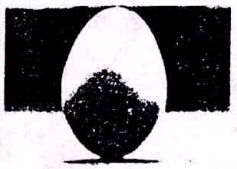
Based on available experience, WHO does not recommend applying TRIPS-plus requirements or extending TRIPS requirements to non-WTO Members before the public health impacts of so doing have been fully assessed.

Box 5. WHO perspectives on access to drugs

1. Access to essential drugs is a human right.
2. Essential drugs are not simply another commodity.
3. Patent protection has been an effective incentive for research and development for new drugs.
4. Patents should be managed in an impartial way, protecting the interests of the patent-holder, as well as safeguarding public health principles.
5. WHO supports measures which improve access to essential drugs, including application of TRIPS safeguards.

Countries must develop informed approaches to health and trade

Countries with least capacity for interpreting and acting on international trade agreements have most at risk in terms of access to medicines. WHO will continue to provide independent data and technical assistance to countries to help them develop informed approaches to trade and health at national, sub-regional and regional levels. Countries are advised to carefully monitor the implementation of the TRIPS Agreement in order to formulate comprehensive proposals for the future review of the TRIPS Agreement as provided for in Article 71:1. A network of legal experts who have specialized knowledge and understanding of international trade agreements, pharmaceuticals and public health is also being developed as a resource for developing countries.



FACT SHEET: TRIPS AND PHARMACEUTICAL PATENTS.

Obligations and exceptions

Under TRIPS, what are member governments' obligations on pharmaceutical patents?

April 2001

Contents

This fact sheet has been prepared by the Information and Media Relations Division of the WTO Secretariat to help public understanding. It is not an official interpretation of the WTO agreements or members' positions

IN GENERAL (see also "exceptions") back to top

Patenting: WTO members have to provide patent protection for any invention, whether a product (such as a medicine) or a process (such as a method of producing the chemical ingredients for a medicine), while allowing certain exceptions. *Article 27.1.* Patent protection has to last at least 20 years from the date the patent application was filed. *Article 33*

Non-discrimination: Members cannot discriminate between different fields of technology in their patent regimes. Nor can they discriminate between the place of invention and whether products are imported or locally produced. *Article 27.1*

Three criteria: To qualify for a patent, an invention has to be new ("novelty"), it must be an "inventive step" (i.e. it must not be obvious) and it must have "industrial applicability" (it must be useful). *Article 27.1*

Disclosure: Details of the invention have to be described in the application and therefore have to be made public. Member governments have to require the patent holder to disclose specifications of the patented product or process and they may require the patent holder to reveal the best method for carrying it

The TRIPS Agreement

Article 27
Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whethe products or processes, in all fields of technology, provided that they are n involve an inventive step and are capable of industrial application (5). Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragr. 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the plac of invention, the field of technology whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevent within their territory of the commer exploitation of which is necessary to protect ordre public or morality, including to protect human, animal c plant life or health or to avoid seriou prejudice to the environment, provic that such exclusion is not made mer because the exploitation is prohibite by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surg

out. *Article 29.1*

Exceptions back to top

ELIGIBILITY FOR PATENTING back to top

Governments can refuse to grant patents for three reasons that may relate to public health:

- inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health — *Article 27.2*
- diagnostic, therapeutic and surgical methods for treating humans or animals — *Article 27.3a*
- certain plant and animal inventions — *Article 27.3b*.

Under the TRIPS Agreement, governments can make limited exceptions to patent rights, provided certain conditions are met. For example, the exceptions must not "unreasonably" conflict with the "normal" exploitation of the patent. *Article 30*.

Continue >

methods for the treatment of humar animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the producti of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by an combination thereof. The provisions this subparagraph shall be reviewed years after the date of entry into for of the WTO Agreement.

Article 29
Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose invention in a manner sufficiently cl and complete for the invention to be carried out by a person skilled in the and may require the applicant to indicate the best mode for carrying c the invention known to the inventor the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applica for a patent to provide information concerning the applicant's corresponding foreign applications a grants.

Article 30
Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation o the patent and do not unreasonably prejudice the legitimate interests of patent owner, taking account of the legitimate interests of third parties.

Article 33
Term of Protection

The term of protection available sha not end before the expiration of a period of twenty years counted from

filing date. (8)

Footnote:

(5) For the purposes of this Article, terms "inventive step" and "capable industrial application" may be deem by a Member to be synonymous with terms "non-obvious" and "useful" respectively.
> back to reference

(8) It is understood that those Members which do not have a systen original grant may provide that the t of protection shall be computed fron the filing date in the system of origi grant.
> back to reference

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RESEARCH EXCEPTION AND "BOLAR" PROVISION back to top

Many countries use this provision to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.

In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval — for example from public health authorities — without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision. *Article 8*

This has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this. (The case was titled "Canada — Patent Protection for Pharmaceutical Products")

ANTI-COMPETITIVE PRACTICE, ETC back to top

The TRIPS Agreement

Article 8
Principles

[...]

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices wh unreasonably restrain trade or adver affect the international transfer of technology.

SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES

Article 40

1. Members agree that some licensi practices or conditions pertaining to intellectual property rights which restrain competition may have adver effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices o conditions that may in particular cas

The TRIPS Agreement says governments can also act, again subject to certain conditions, to prevent patent owners and other holders of intellectual property rights from abusing intellectual property rights, "unreasonably" restraining trade, or hampering the international transfer of technology. *Articles 8 and 40*

COMPULSORY LICENSING back to top

Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. In current public discussion, this is usually associated with pharmaceuticals, but it could also apply to patents in any field – and the TRIPS Agreement does prohibit discrimination between fields of technology.

The agreement allows compulsory licensing as part of the agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. But the term "compulsory licensing" does not appear in the TRIPS Agreement. Instead, the phrase **"other use without authorization of the right holder"** appears in the title of Article 31. Compulsory licensing is only part of this since "other use" includes use by governments for their own purposes.

Compulsory licensing and government of a patent without the authorization of its owner can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder.

For example: Normally, the person or company applying for a licence must

constitute an abuse of intellectual property rights having an adverse eff on competition in the relevant mark As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantb conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

[...]

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The TRIPS Agreement

Article 31
Other Use Without Authorization of Right Holder

Where the law of a Member allows fc other use of the subject matter of a patent without the authorization of right holder, including use by the government or third parties authoriz by the government, the following provisions shall be respected:

[...]

(b) such use may only be permitted prior to such use, the proposed user made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions an that such efforts have not been successful within a reasonable perio time. This requirement may be waiv by a Member in the case of a nationa emergency or other circumstances o extreme urgency or in cases of publi non-commercial use. In situations of national emergency or other circumstances of extreme urgency, t right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public no commercial use, where the governm or contractor, without making a pat search, knows or has demonstrable grounds to know that a valid patent will be used by or for the governmer

have first attempted, unsuccessfully, to obtain a voluntary licence from the right holder on reasonable commercial terms – *Article 31b*. If a compulsory licence is issued, adequate remuneration must still be paid to the patent holder – *Article 31h*.

However, for "national emergencies", "other circumstances of extreme urgency" or "public non-commercial use" (or "government use") or anti-competitive practices, there is no need to try for a voluntary licence – *Article 31b*.

Compulsory licensing must meet certain additional requirements. In particular, it cannot be given exclusively to a single licensee, and usually it must be granted mainly to supply the domestic market. Compulsory licensing cannot be arbitrary.

WHAT ARE THE GROUNDS FOR USING COMPULSORY LICENSING? back to top

The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing. In Article 31, it does mention national emergencies, other circumstances of extreme urgency and anti-competitive practices – but only as grounds when some of the normal requirements for compulsory licensing do not apply, such as the need to try for a voluntary licence first.

PARALLEL IMPORTS, GREY IMPORTS AND 'EXHAUSTION' OF RIGHTS back to top

Parallel or grey-market imports are not imports of counterfeit products or illegal copies. These are products made and marketed by the patent owner (or trademark- or copyright-owner, etc) in one country and imported into another

the right holder shall be informed promptly;

(c) the scope and duration of such u shall be limited to the purpose for which it was authorized, and in the c of semi-conductor technology shall o be for public non-commercial use or remedy a practice determined after judicial or administrative process to anti-competitive;

[...]

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

[...]

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking in account the economic value of the authorization;

[...]

(k) Members are not obliged to app the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practic determined after judicial or administrative process to be anti-competitive. The need to correct an competitive practices may be taken account in determining the amount o remuneration in such cases. Compet authorities shall have the authority t refuse termination of authorization i and when the conditions which led t such authorization are likely to recu

[...]

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The TRIPS Agreement

Article 6
Exhaustion

For the purposes of dispute settleme under this Agreement, subject to the provisions of Articles 3 and 4 nothing this Agreement shall be used to addr

country without the approval of the patent owner.

For example, suppose company A has patented a drug, which it makes under patent in the Republic of Belladonna and the Kingdom of Calamine, but sells at a lower price in Calamine. If a second company buys the drug in Calamine and imports it into Belladonna at a price that is lower than company A's price, that would be a parallel or grey import.

The legal principle here is "exhaustion", the idea that once company A has sold its product (in this case, in Calamine), its patent is exhausted and it no longer has any rights over what happens to that product.

The TRIPS Agreement simply says that none of its provisions, except those dealing with non-discrimination ("national treatment" and "most-favoured-nation treatment"), can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute. In other words, even if a country allows parallel imports in a way that might violate the TRIPS Agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved. *Article 6* the issue of the exhaustion of intellectual property rights.

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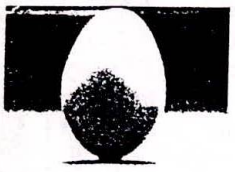
TRIPS: DRUG PATENTS, TECHNICAL NOTE

Pharmaceutical patents and the TRIPS Agreement



The purpose of this note is to describe those provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) that relate to the standards of patent protection to be accorded to inventions in the area of pharmaceuticals.

11 July 2000

See also:
> Fact sheet: TRIPS and pharmaceutical patents (includes extracts of the TRIPS Agreement)

To set this discussion in context, it is useful to recall three basic features of the TRIPS Agreement:

- that, together with some 25 other legal texts, it is an integral part of the Agreement Establishing the World Trade Organization (and therefore subject to the WTO dispute settlement system);
- that it covers not only patents but all the other main areas of intellectual property rights; and
- that it lays down not only the minimum substantive standards of protection that should be provided for in each of these areas of intellectual property, but also the procedures and remedies that should be available so that rights holders can enforce their rights effectively.

The basic balance in the TRIPS Agreement back to top

Finding a balance in the protection of intellectual property between the short-term interests in maximizing access and the long-term interests in promoting creativity and innovation is not always easy. Doing so at the international level is even more difficult than at the national level. Perhaps nowhere do these issues excite stronger feelings than in regard to pharmaceutical patents, where tension between the need to provide incentives for research and development into new drugs and the need to make existing drugs as available as possible can be acute.

The TRIPS Agreement attempts to find an appropriate balance. Its Article 7 entitled "Objectives" recognizes that the protection of intellectual property should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of users and producers of

Footnotes:

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TRIPS Counc

technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations. It is not an Agreement about simply maximizing the level of protection for intellectual property; rather, it emerged from a genuine negotiating process where the need for balance was very much to the fore.

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What pharmaceutical inventions must be patentable under the TRIPS Agreement? back to top

The main rule relating to patentability is that patents shall be available for any invention, whether a product or process, in all fields of technology without discrimination, where those inventions meet the standard substantive criteria for patentability – namely, novelty, inventive step and industrial applicability. In addition, Members are required to make grant of a patent dependent on adequate disclosure of the invention and may require information on the best mode for carrying it out. Disclosure is a key part of the social contract that the grant of a patent constitutes since it makes publicly available important technical information which may be of use to others in advancing technology in the area, even during the patent term, and ensures that, after the expiry of the patent term, the invention truly falls into the public domain because others have the necessary information to carry it out.

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Three types of exception to the above rule on patentable subject-matter are allowed. These may be of interest from a public health perspective:

- inventions the prevention of whose commercial exploitation is necessary to protect *ordre public* or morality, including to protect animal or plant life or health;
- diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and
- certain plant and animal inventions.

What are the rights conferred by a patent under the TRIPS Agreement? back to top

The minimum rights that must be conferred by a patent under the TRIPS Agreement follow closely those that were to be found in most patents laws, namely the right of the patent owner to prevent unauthorized persons from using the patented process and making, using, offering for sale, or importing the patented product or a product obtained directly by the patented process.

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Term of protection back to top

Under the TRIPS Agreement, the available term of protection must expire no earlier than 20 years from the date of filing the patent application. It should be noted that, although the issue of patent term extension to compensate for regulatory delays in the marketing of new pharmaceutical products was raised in the Uruguay Round negotiations, the TRIPS Agreement does not contain an obligation to introduce such a system. (1)

Limitations/exceptions to these rights back to top

Under the TRIPS Agreement, patent rights are not absolute but can be subject to limitations or exceptions. These can be put into three categories:

- the Agreement allows limited exceptions to be made by Members provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. Thus, for example, many countries allow third parties to use a patented invention for research purposes where the aim is to understand more fully the invention as a basis for advancing science and technology. The WTO Panel in *Canada – Patent Protection for Pharmaceutical Products* decided that this provision, allowing limited exceptions, covered a provision of Canadian law which permits the use by generic producers of patented products, without authorization and prior to the expiry of the patent term, for the purposes of seeking regulatory approval from public health authorities for the marketing of their generic version as soon as the patent expires. (This provision is sometimes referred to as the "regulatory exception" or as a "Bolar" provision.) The Panel Report was adopted by the WTO Dispute Settlement Body on 7 April 2000;

- the Agreement also allows Members to authorize use by third parties (**compulsory licences**) or for public non-commercial purposes (**government use**) without the authorization of the patent owner. Unlike what was sought by some countries in the negotiations, the grounds on which this can be done are not limited by the Agreement, but the Agreement contains a number of conditions that have to be met in order to safeguard the legitimate interests of the patent owner. There is not space to discuss all of these here, but two of the main such conditions are that, as a general rule, an effort must first have been made to obtain a voluntary licence on reasonable commercial terms and conditions and that the remuneration paid to the right holder shall be adequate in the circumstances of each case, taking into account the economic value of the

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licence;

- the Agreement recognizes the right of Members to take measures, consistent with its provisions, against anti-competitive practices and provides more flexible conditions for the grant of compulsory licences where a practice has been determined after due process of law to be anti-competitive. For example, each of the conditions specifically referred to above for the grant of compulsory licences may be relaxed in these circumstances. The Agreement also provides for consultation and cooperation between Members in taking action against anti-competitive practices;

- the TRIPS Agreement makes it clear that the practices of WTO Members in regard to the exhaustion of intellectual property rights (e.g. a Member's decision to have a national exhaustion regime, under which right holders can take action against parallel imports, or an international exhaustion regime, under which they cannot) cannot be challenged under the WTO dispute settlement system, provided that they do not discriminate on the grounds of the nationality of right holders.

Other policy instruments back to top

It should be remembered that governments have a range of public policy measures before them outside the field of intellectual property to address issues of access to and prices of drugs. For example, many countries use price or reimbursement controls. Article 8 of the TRIPS Agreement makes it clear that WTO Members may, in formulating or amending their rules and regulations, adopt measures necessary to protect public health and nutrition, provided that such measures are consistent with the provisions of the Agreement.

Transition provisions back to top

The TRIPS Agreement lays down some rather complicated transition provisions which give countries periods of time in order to adapt their legislation and practices to their TRIPS obligations, which periods differ according to the type of obligation in question and the stage of development of the country concerned. Here we will limit the discussion to those transition provisions which relate to the application of the obligations on substantive standards for the protection of pharmaceutical inventions. For these purposes, the obligations should be divided into two categories:

(i) the obligations relating to the introduction of product patent protection for pharmaceutical products in those

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developing and least developed countries which do not yet grant it. Since most developing and least developed country Members of the WTO already provide for product patent protection for pharmaceuticals, a relatively small number of countries are concerned (2);

(ii) obligations regarding process patents for this group of countries and all patent protection obligations for other developing and least developed countries.

With respect to the second category above, the basic rule is that developing country Members had until 1 January 2000 and least developed country Members have until 1 anuary 2006 to meet the obligations in question. At that time, the rules of the TRIPS Agreement will apply not only to new patent applications but also to patents still under protection in their territories.

With respect to the first category of situations referred to above, the developing countries in question have until 1 January 2005 to apply product patent protection to pharmaceutical products and the least developed countries until 1 January 2006. Notwithstanding proposals to the contrary, the TRIPS Agreement does not require the bringing under protection of pharmaceutical inventions that were in the "pipeline" in these countries at the time of entry into force of the WTO. (3) However, with effect from the entry into force of the WTO (1 January 1995), these countries have been under an obligation to provide a system whereby applications for patents for pharmaceutical product inventions can be filed (often referred to as a "mailbox" system). These applications do not have to be examined until after 1 January 2005 (or 1 January 2006 in the case of least developed countries). If found to be patentable by reference to their filing (or priority) date, a patent would have to be granted for the remainder of the patent term counted from the date of filing. In the event that a pharmaceutical product that is the subject of a "mailbox" application obtains marketing approval prior to the decision on the grant of a patent, an exclusive marketing right of up to five years will have to be granted provided that certain conditions are met.

Concluding remarks back to top

It will be noted that most developing and least developed countries already grant patent protection for pharmaceutical products. In these countries, the TRIPS Agreement will therefore not lead to fundamental changes in this regard, although a certain amount of adjustment in legislation, for example in respect of patent term and compulsory licencing, may be necessary. With respect to the fairly limited number of countries that did not provide patent protection for pharmaceutical products at the time of entry into force of the WTO Agreement, some, including Brazil and Argentina, have decided to bring such protection into effect more quickly than is required under the TRIPS Agreement.

It will also be noted that the TRIPS Agreement pays considerable attention to the need to find an appropriate balance between the interests of rights holders and users and that this was an important theme in the negotiations. This is not only reflected in the basic underlying balance related to disclosure and providing an incentive for R&D, but also in the limitations and exceptions to rights that are permitted and in the transition provisions.

It should also be appreciated that the protection of pharmaceutical inventions is one aspect of a much wider agreement, covering not only the protection of intellectual property in general in a coherent and non-discriminatory way but also further liberalization and strengthening of the multilateral trading system as a whole. While it is true that some countries put particular emphasis on TRIPS matters in the Uruguay Round negotiations, it is also true that other countries attached great importance to other areas, for example textiles and agriculture. It is our belief, and a belief shared by all WTO Members, that a strong and vibrant multilateral trading system is essential for creating conditions for economic growth and development worldwide. This in turn provides for the generation of the resources required to tackle health problems.

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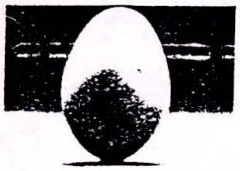
TRIPS and pharmaceutical patents: fact sheet



The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations.

The agreement covers a wide range of subjects, from copyright and trademarks, to integrated circuit designs and trade secrets. Patents for pharmaceuticals and other products are only part of the agreement.

April 2001

This fact sheet has been prepared by the Information and Media Relations Division of the WTO Secretariat to help public understanding. It is not an official interpretation of the WTO agreements or members' positions

See also:
> Pharmaceutical patents and the TRIPS Agreement
A more technical explanation.

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PHARMACEUTICALS AND AGRICULTURAL CHEMICALS

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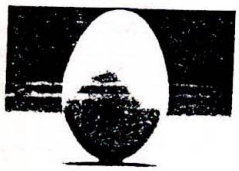

FACT SHEET: TRIPS AND PHARMACEUTICAL PATENTS

Developing countries' transition periods

Provisions for developing countries, economies in transition from central planning, and least-developed countries

April 2001

Contents

This fact sheet has been prepared by the Information and Media Relations Division of the WTO Secretariat to help public understanding. It is not an official interpretation of the WTO agreements or members' positions

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Developing countries and economies in transition from central planning did not have to apply most provisions of the TRIPS Agreement until 1 January 2000. The provisions they did have to apply deal with non-discrimination. *Article 65.2 and 65.3*

Least-developed countries have at least until 1 January 2006 — this may be extended. *Article 66.1*

(Developed countries had until 1 January 1996, one year after the TRIPS Agreement took effect. *Article 65.1*)

Most new members who joined after the WTO was created in 1995 have agreed to apply the TRIPS Agreement as soon as they joined. *Determined by each new member's terms of accession*

PHARMACEUTICALS AND AGRICULTURAL CHEMICALS back to top

Some developing countries are delaying patent protection for pharmaceutical products (and agricultural chemicals) until 1 January 2005.

This is allowed under provisions that say a developing country that did not provide product patent protection in a particular area of technology when the TRIPS Agreement came into force (on

The TRIPS Agreement

Article 65
Transitional Arrangements

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member sh be obliged to apply the provisions of this Agreement before the expiry of general period of one year following date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further perioc four years the date of application, a: defined in paragraph 1, of the provis of this Agreement other than Article 4 and 5.

3. Any other Member which is in th process of transformation from a centrally-planned into a market, fre enterprise economy and which is undertaking structural reform of its intellectual property system and fac special problems in the preparation implementation of intellectual prope laws and regulations, may also benef from a period of delay as foreseen ir paragraph 2.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology no protectable in its territory on the general date of application of this

1 January 1995), has up to 10 years to introduce the protection. *Article 65.4*

However, for pharmaceuticals and agricultural chemicals, countries eligible to use this provision (i.e. countries that did not provide protection on 1 January 1995) have two obligations.

They must allow inventors to file patent applications from 1 January 1995, even though the decision on whether or not to grant any patent itself need not be taken until the end of this period – *Article 70.8*. This is sometimes called the **"mailbox"** provision (a metaphorical "mailbox" is created to receive and store the applications). The date of filing is significant, which is why the mailbox provisions were set up. It is used for assessing whether the application meets the criteria for patenting, including novelty ("newness").

And if the government allows the relevant pharmaceutical or agricultural chemical product to be marketed during the transition period, it must – subject to certain conditions – provide the patent applicant an **exclusive marketing right** for the product for five years, or until a decision on a product patent is taken, whichever is shorter. *Article 70.9*

Which countries are using the extra transition period? The answer is not entirely straightforward. Thirteen WTO members – Argentina, Brazil, Cuba, Egypt, India, Kuwait, Morocco, Pakistan, Paraguay, Tunisia, Turkey, United Arab Emirates and Uruguay – have notified "mailbox" systems to the TRIPS Council, indicating that at that time they did not grant patent protection to pharmaceutical products. It is also possible that there are a few other WTO Members who should have notified but have not done so.

Some of these have now introduced pharmaceutical patent protection – such as Argentina, Brazil, Guatemala, Morocco and Turkey.

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Agreement for that Member, as defir in paragraph 2, it may delay the application of the provisions on prod patents of Section 5 of Part II to sucl areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 2, 3 or 4 shall ensure that any chang in its laws, regulations and practice made during that period do not resul a lesser degree of consistency with t provisions of this Agreement.

Article 66
Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constrai and their need for flexibility to creat viable technological base, such Mem shall not be required to apply the provisions of this Agreement, other t Articles 3, 4 and 5, for a period of 1(years from the date of application as defined under paragraph 1 of Article The Council for TRIPS shall, upon dul motivated request by a least-develo country Member, accord extensions (this period.

[...]

Article 70
Protection of Existing Subject Matte

[...]
8. Where a Member does not make available as of the date of entry intc force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions (Part VI, provide as from the date of entry into force of the WTO Agreeme a means by which applications for patents for such inventions can be fi

(b) apply to these applications, as (the date of application of this Agreement, the criteria for

patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority d of the application; and

(c) provide patent protection in accordance with this Agreement as f the grant of the patent and for the remainder of the patent term, count from the filing date in accordance w Article 33 of this Agreement, for tho of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject o patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisi of Part VI, for a period of five years after obtaining marketing approval i that Member or until a product patei granted or rejected in that Member, whichever period is shorter, provide that, subsequent to the entry into fc of the WTO Agreement, a patent application has been filed and a pate granted for that product in another Member and marketing approval obtained in such other Member.

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Compulsory Licensing and Parallel Importing

What do they mean? Will they improve access to essential drugs for people living with HIV/AIDS?

Background Paper
International Council of AIDS Service Organizations (ICASO)

July 1999

Acknowledgements
Margaret Duckett, author

Author's Note: This paper draws substantially on material prepared and distributed from a number of sources including the Consumer Project on Technology, and postings on the Treatment Access Forum, an electronic listserve discussion group.

Grateful Thanks are also extended to Richard Burzynski, David Patterson and David Garmaise for their editorial comments.

1. Introduction

Since 1998, treatment activists have increasingly been talking about the effect of international trade laws on access to essential drugs, especially HIV-related medications. Recently, these issues have been the subject of considerable debate among treatment activists, pharmaceutical companies, governments and academics.

This document aims to provide people with sufficient information to participate fully in the debate, and to help people better understand the potential for advocacy work on these matters in their own countries and with their own governments. If this is the first time you have considered some of the issues covered in this paper, please treat this document as a starting point; collect more information, read further, and talk about the issues with other individuals and groups.

2. Background

Thanks to new drug therapies, many people living with HIV/AIDS in most developed countries are now able to live relatively healthy lives. Combination anti-retroviral therapies allow HIV-positive people to reduce their viral load significantly, in some cases to undetectable levels, thus enabling many individuals to return to the workplace. In developing countries and countries in transition, however, these and many other therapies used to treat HIV infection and related illnesses are unavailable for a simple reason: they are not affordable. Even for those few who may be able to afford them, sometimes pharmaceutical companies conclude that the potential market is too small to bother with licensing and distribution arrangements.

The issue of the cost of drug therapies is of immense importance in relation to HIV/AIDS. Over 89% of people currently living with HIV/AIDS reside in countries ranked in the lowest 10% in the world in terms of gross national product. Even in slightly wealthier countries in Southeast Asia, there are major cost constraints. At the Bamrasnaradura hospital in Bangkok, Thailand, for example, only 20 of the 2000 patients who seek treatment each month can afford the triple drug cocktails that have become the standard of care in developed countries.

Ways to lessen or remove the gap in access between developed countries and developing countries are increasingly being explored. This paper describes two strategies that are being considered to bring down the price of drug therapies:

- parallel importing, which involves bringing drugs in from another country; and
- compulsory licensing, which involves using a legal intervention to restrict the monopoly rights of existing patent holders and make generic drugs more available.

This paper also provides a list of other strategies to reduce the costs of essential drugs.

It should be noted that in the developing world the specific access to treatment needs of each country may be different. Only countries with more developed medical infrastructures have the widespread capacity to use combination anti-retroviral drugs. For other countries, it may be more important to obtain greater access to anti-microbial and other prophylactic (disease preventing) drugs.

3. Parallel Importing

Parallel importing consists of purchasing proprietary drugs from a third party in another country, rather than directly from the manufacturer, and taking advantage of the fact that pharmaceutical companies sometimes charge significantly lower prices in one country than in another. For instance, in Britain, where parallel importing is common, the list price for Glaxo Wellcome's Retrovir is £125, but consumers can purchase the same proprietary drug imported from other European countries for as little as £54.

Price for the same product can vary widely among countries because of many factors,

such as differences in intellectual property rules, differences in local incomes, and the degree of competition among producers. For example, a 1998 study by the Consumer Project on Technology found prices for SmithKline Beecham's version of Amoxil was $8 in Pakistan, $14 in Canada, $16 in Italy, $22 in New Zealand, $29 in The Philippines, $36 in Malaysia, $40 in Indonesia, and $60 in Germany.[1]

By permitting some form of parallel imports, countries can shop around and get better prices, using market forces to lower national expenditures on a range of goods, including pharmaceuticals. In the European Union (EU), parallel importing of patented products is widely used and is seen as very effective at equalizing prices.

Since the creation of the World Trade Organization[2] (WTO), the United States Government has been extremely aggressive in attacking parallel imports by other countries. Nevertheless, parallel imports of a range of goods routinely flow into the United States itself.

Parallel importing of generic drugs is also possible.

For many countries, particularly in Africa, parallel importing may well be the best way to improve access to essential drugs because of limited local capacity to produce raw materials and undertake drug manufacturing.

4. Compulsory Licensing

To understand the concept of compulsory licensing, one has to first understand what a patent is. A patent is a legal title granted by government allowing a temporary monopoly (for a specified number of years) for the production and sale of an invention or discovery. Compulsory licensing is the term given to a legal approach that permits the manufacture and use of generic drugs without the agreement of the patent holder.

The issue of patent protection has received increasing attention internationally since the establishment of WTO in 1995. In deciding to become a member of WTO, a country must agree to follow its rules. A certain number of treaties are therefore binding on all WTO member countries.

One such treaty is the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), which sets out minimum standards in relation to intellectual property. All WTO member countries have to comply with these standards by changing their national regulations (where necessary) to follow the provisions of the agreement. With respect to drugs, the major difference between TRIPS and previous multilateral agreements is that TRIPS requires countries to grant patent protection to pharmaceutical products for a minimum period of 20 years.

Nevertheless, the TRIPS Agreement does leave WTO member countries with a certain amount of freedom. Countries are allowed, under certain conditions, to issue compulsory licenses against the will of the patent holder. For example, for a country with high HIV seroprevalence, the government could decide that it is in the public interest to ensure that

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appropriate drugs are manufactured locally and made available at a cheaper price. Such action should be legal under the TRIPS Agreement (though lawyers may argue about the exact requirements). (It should also be noted that the TRIPS Agreement does not prohibit parallel importing.)

However, many countries are under strong pressure (particularly from the United States and the multinational pharmaceutical industry) to adopt legislation that provides a higher level of patent protection than is required by TRIPS and international trade law. A number of countries have adopted (or are considering) legislation that is far more restrictive than required, including not allowing compulsory licensing.

Complete patent protection - i.e., for 20 years from date of filing - would certainly increase the access gap between the North and the South, particularly in relation to the treatment of HIV/AIDS.[3],[4]

5. The Consumer Perspective

Price should not be the sole or main determining factor for access to any drug.

ICASO and other international non-governmental organizations (NGOs) acknowledge that effective patent protection is a prerequisite for a successful, innovative pharmaceutical industry. But effective patent legislation should balance all interests and provide protection against abuse by the patent holder. The present international trade rules, which permit compulsory licensing, offer sensible ways of doing this.

The Indian drug industry is a good example of what happens when companies are given the authority to produce drugs for the local market without paying exorbitant licensing fees. India operates under an unregulated system (at time of writing). Lariam, a treatment for Malaria costs $37 in the United States, but only $4 in India. AZT, an AIDS treatment, costs $239 per month in the United States, but only $48 in India. The lower prices in India still deliver a very high return to the Indian pharmaceutical company (CIPLA) and its stockholders.

Under TRIPS, compulsory licenses could be granted to produce essential medicines to treat life-threatening diseases. This would produce results that are similar to the unregulated system in India.

6. Commonly Asked Questions

Would increased use by developing countries of compulsory licensing and parallel importing be a serious threat to research and development funding for new drugs?

The International Federation of Pharmaceutical Manufacturers Associations (IFPMA), which represents the research-based pharmaceutical industry and other manufacturers of prescription medicines, argues that compulsory licensing discourages research and

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development. IFPMA suggest that compulsory licensing will slow the search for effective new medicines that are needed to address existing and emerging public health challenges. Specifically, IFPMA states that use of compulsory licensing will lessen development of new AIDS drugs and other drugs for infectious diseases.

There is no doubt that research and development (R&D) for new drugs is expensive. R&D costs should be recovered during the initial years of marketing. Currently, most of the R&D costs are recovered from sales in industrialised countries where most of the patients have health insurance. The main question is whether patients in poor countries should also pay for these costs.

Although the majority of the world's population live in developing countries, these countries represent only a small proportion of the global pharmaceutical market. Africa, for example, accounts for only 1.3 percent of that market. Consequently, lower prices for essential drug therapies in developing countries should not be a serious threat to R&D funding.

The very small size of the global pharmaceutical market represented by developing countries is the reason why only extremely limited investments are made into the diseases that mainly or solely affect people in developing countries.

Richard Laing, Associate Professor, Department of International Health, Boston University School of Public Health, has argued[5] that the global pharmaceutical market is so large (over $400 billion per year) and the proportional contribution of Africa, Southeast Asia, and the Commonwealth of Independent States to both turnover and profit so small, that these markets could be completely isolated from the global total and pharmaceutical manufacturers would not be affected in any measurable way.

In addition, universal or widespread health insurance in most industrialised countries ensures that the burden of drug costs is rarely substantial for any individual. This is in marked contrast to the situation in most developing countries.[6]

How much return on R&D is required to ensure further drug development?

There is considerable debate about what level of return (i.e., profit) is required for marketed drugs, to compensate both for the R&D done for that product and for the R&D done in unsuccessful attempts to develop other drugs.

IFPMA states that the risks with R&D are largely borne by the research-based pharmaceutical, biotechnology and vaccine industries, which invest tens of billions of dollars annually in research and development. Thus, IFPMA argues, the only feasible model for promoting innovation in the high-risk and resource-intensive pharmaceutical industry is to guarantee the companies that invest in research an adequate period of exclusive rights for their products.

IFPMA also states that research-based pharmaceutical companies are socially responsible, and that Merck, Pfizer, Glaxo-Wellcome, SmithKline Beecham and other companies have made major financial and corporate commitments to addressing diseases that affect developing countries through product donation programmes and price

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concessions.

The costs of drug development are not small. One of the most detailed studies of the costs of clinical trials was reported in a 1991 Journal of Health Economics paper.[7] The authors found that the total cost of drug development can be as high as $500 million per drug. However, with respect to HIV-related drug therapies, it has usually been governments (rather than drug companies) that have paid for initial development, pre-clinical research and clinical research. For the pharmaceutical companies, this significantly lowers the costs of bringing these products to market. For example, the costs of securing Federal Drug Authority (FDA) approval in the United States for HIV/AIDS drugs have been estimated to be only about $25 million per drug.[8]

Many people[9] have argued that the industry does not in fact engage in any significant effort to find cures to illnesses - i.e., that the efforts are superficial and primarily restricted to the refinement of government-produced products (e.g., T-20, ddI) or the development of alternative copycat drugs to government-sponsored efforts (e.g., the protease inhibitors, new nucleoside analogues). This is particularly obvious in the case of HIV disease where every class of drug was discovered, tested and developed by government agencies. Among these drugs are ddI, AZT, d4t, Ritonavir (including the structure of the proteinase enzyme), and T-20.

Some support for the position that drug prices are not related to replacement of R&D costs is provided by the current price for Pentamidine. Pentamidine was a cheap treatment developed to treat sleeping sickness. However, when it was found to be effective in the treatment of AIDS-related PCP (pneumocystis carinii pneumonia), the price of Pentamidine increased 500%. A recent survey of 20 African and Southeast Asian Countries conducted by UNAIDS found that Pentamidine is now available in only one of these countries.

How will compulsory licensing and parallel importing affect the quality of drugs?

Some people argue that compulsory licensing and parallel importing will lead to cheaper but poorly performing drugs and that these drugs will then enter the markets of both developing and developed countries. They point out that with patented products, pharmaceutical manufacturers allocate significant resources to developing trustworthy sources of raw materials; building manufacturing facilities that can be counted on for consistent and high quality products; using and maintaining distribution systems that allow every government or individual buying the drug access to products upon demand; and refining products to remove substances that cause side effects.

There are issues around drug quality, but they are not related to compulsory licensing or the production of generic drugs. With or without compulsory licensing, sub-standard, expired and counterfeit drugs are increasingly found in international and local markets. Control of production, importing and exporting of drugs varies greatly among countries. Hundreds of people have died as a result. Paradoxically, although global standards for drugs are becoming more demanding, 10 to 20% of sampled drugs in developing countries fail quality control tests. Only one developing country in six has a fully functional drug regulation system. The Revised Drug Strategy adopted by the 52nd

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World Health Assembly commits all countries to ensure that all aspects of national drug policy, including quality control of available drugs, receive increased attention.

7. Other Means of Lowering Drug Prices

To lower the cost of HIV/AIDS drug therapies in developing countries, a number of approaches have been tried or are currently being used, of which parallel importing and compulsory licensing are but two. The following is a brief description of some of the other approaches:

Therapeutic value pricing. This approach has been adopted in Australia. The Pharmaceutical Benefit Pricing Authority (an official, independent body) determines the drug price on the basis of therapeutic value. When a new drug becomes available for marketing, the benefits and health outcomes of the new drug are carefully compared with similar, existing drugs and a comparative price is estimated. For example, a new drug may provide a small benefit compared to an existing drug, so the Pricing Authority may declare that the government will be willing to purchase the new drug at a 10% increase over the price of the existing drug. The manufacturer then determines if it wishes to sell its drug at this price. Sometimes, negotiation for a mutually acceptable price can take months.

Pooled procurement. For countries with small national populations, pooled procurement may be an option. This has been tried in the Caribbean, where seven different countries have joined together to purchase drugs. This approach, which started in the 1980s, has enabled these countries to reduce prices by around 50%. In addition, this combined operation has allowed the countries involved to develop a single multi-country unit with expertise in drug evaluation and price negotiation.

Negotiated procurement. Large organizations buying drugs in large amounts can also bring down prices. For instance, some large health maintenance organisations in the United States have been able to negotiate significantly lesser prices than the official price of a drug (i.e., more than official discounts for bulk orders).

Planned donations. In the past, many countries have received donations of about-to-expire stocks of drugs. The World Health Organization (WHO) is now encouraging planned donation programmes for drugs that are still in use. For example, Johnson and Johnson now have a planned giving programme (addressing a range of diseases), with three years of donations planned three years in advance.

Lobbying Pharmaceutical Companies. UNAIDS has lobbied pharmaceutical companies to lower the prices of their drugs in developing countries. Their current four-country treatment pilot initiative has resulted in slightly lower initial prices for retroviral and other drugs bought through the pilot program. In addition, treatment activists in many countries have been lobbying many pharmaceutical companies directly for some years. One result was the decision by GlaxoWellcome in 1997 to halve the then cost of an annual course of AZT -- the price is still substantial, however.

8. Future Action

In May 1999, the 52nd World Health Assembly in Geneva passed a resolution[10] which urges countries to "explore and review their options under international agreements, including trade agreements, to safeguard access to essential drugs." It charges WHO with, "monitoring and analysing the pharmaceutical and public health implications" of these agreements.

As part of the process, NGOs are working with WHO to develop a monitoring system to enable NGOs, WHO and others to track drug prices and to assess the level of access to essential drugs.

In a statement to delegates at the 52nd World Health Assembly, ICASO called on governments, the United Nations and other development agencies, and NGOs active in the health sector, to ensure that access for essential medications receives priority in all societies.

This discussion paper aims to provide people with a greater knowledge of the role that parallel importing and compulsory licensing can play in improving access. ICASO will continue to monitor efforts to improve access to drug therapies for people living with HIV/AIDS, and will ensure regular feedback is provided to members regarding progress.

ICASO encourages all NGOs and PWA groups to inquire about the status of their domestic law provisions covering compulsory licensing and parallel importing, and to lobby for changes in these laws if they are more restrictive than the requirements of the TRIPS Agreement. If domestic governments request it, technical assistance to frame their laws to meet the requirements of TRIPS is available from the World Intellectual Property Organization. Decision makers in the health sector can obtain useful information from *Globalization and access to drugs: perspectives on the WTO/TRIPS agreement*, a WHO/DAP publication that discusses the impact of trade agreements in the pharmaceutical field and offers guidance on how to interpret the requirements. See the section on Further Information for more details.

Similarly, the ICASO document *Stories from the Frontlines* (see the section on Further Information) may provide ideas on how to mobilise interest and support among key decision-makers in improving treatment access.

Some things that you can do at the local and national levels include:

- set up a study group of key NGOs to review this document and discuss the issues for your country;
- copy this document and pass it out at local meetings;
- translate it in your local language (ICASO has initially distributed it in English, French and Spanish; if you make a translation please let ICASO know so that it can pass on your translation to others);
- speak to your national AIDS programme manager (if appropriate) about the issues;

- start a dialogue with a pharmaceutical company (if there is one in your country) about the issues from your perspective, and try to find some common ground.

9. Further Information

Websites and E-Mail Discussion Forums

Treatment Access Forum
http://www.hivnet.ch:8000/treatment-access/tdm
This is an electronic listserve discussion group that includes many issues of treatment access in developing countries. Starting in late March 1999, there are many reports, documents, and personal messages on compulsory licensing and related issues of trade policy and access to essential medical technology. You do not need to register to read the messages; you can, however, register free of charge. If you have e-mail access only, you can still participate; send a message to: <treatment-access@hivnet.ch>.

Consumer Project in Technology Website
http://www.cptech.org/ip/health/cl/
For extensive background and documents, see the pages on intellectual property and health care maintained by James Love of the Consumer Project on Technology. This well-designed site includes sections on the 1999 Geneva meeting, South Africa disputes, compulsory licensing, parallel imports, data exclusivity, and other issues of intellectual property and access to essential medicines.

Health Action International
http://www.haiweb.org/
Health Action International (HAI) was one of the main NGO players involved in the WHO revised drug strategy recommendations. See particularly *Globalization and Pharmaceuticals: Implications for Public Health*, a policy paper prepared by HAI (full text or summary). From the home page, select News and scroll down to Policy Papers.

Médecins sans frontières (Doctors Without Borders)
http://www.msf.org/advocacy/accessmed/
Médecins sans frontières (MSF) is another NGO that was involved in the WHO revised drug strategy recommendations. The website listed above contains a number of articles on access to essential drugs. MSF lawyers and doctors are frequently called upon to respond to media inquiries on international AIDS issues, specifically around compulsory licensing issues.

WTO/TRIPS Agreement
http://www.wto.org/wto/intellec/intellec.htm

World Health Organization Publications

For distribution and sales of all WHO publications contact WHO at 1211 Geneva 27,

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Switzerland; Tel: +41.22.791 2476 or via the Internet on http://www.who.ch

Essential Drugs Monitor, Double Issue No. 25 and 26 (1998) World Health Organization Action Programme on Essential Drugs and Vaccines. (This issue focuses on managing drug supply.) The Essential Drugs Monitor is published in English, French, Spanish and Russian and is provided to appropriate personnel free of charge.

Managing Drug Supply. The Selection, Procurement, Distribution, and Use of Pharmaceuticals. 2nd Edition. Management Sciences for Health in collaboration with the World Health Organization Action Programme on Essential Drugs. Kumarian Press 1997 ISBN 1-56549-047-9.

WHO Model Prescribing Information: Drugs used in HIV-related Infections. World Health Organization 1999 WHO/DMP/DSI/99.2.

Other Sources

Correa CM. **The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: new standards for patent protection.** European Intellectual Property Review, 1994, 16 (8): 327-335. Analysis of the main provisions of the TRIPS Agreement on patents, and in particular the extension of patentability, criteria for patentability, the non-discrimination clause, the rights conferred by a patent and the exceptions, conditions for patent applications, compulsory licences, the reversal of the burden of proof and transitional provisions.

Globalization and Access to Drugs. Perspectives on the WTO/TRIPS Agreement Health Economics and Drugs. DAP Series No. 7, (1999) World Health Organization, 2nd edition. An overview of the limitations on pharmaceutical patents provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Contact: Documentation Centre, Essential Drugs and Other Medicines, World Health Organization, 1211 Geneva 27, Switzerland. E-mail: <darec@who.ch>.

HIV/AIDS and Human Rights: Stories from the Frontlines. International Council of AIDS Service Organizations (ICASO). June 1999. Among other subjects, 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. This and other ICASO documents can be accessed via the ICASO website: <http://www.icaso.org>.

10. Glossary

Compulsory License: Authorisation for a government or company to make and sell a product (such as a drug, for example) without the permission of the patent holder. Compulsory licenses are generally issued on the basis of public interest - e.g., public health or defence.

Essential Drugs: Those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage form. The WHO Model List of Essential Drugs is intended to be flexible and adaptable to many different situations; exactly which drugs are regarded as essential remains a national responsibility.

Generic Drug: A pharmaceutical product usually manufactured without a license after the expiry of patent or other exclusivity rights. For example, Aspirin is a widely available generic drug.

Parallel Importing: Products that are imported into a country without authorisation of the patent holder in that country and that have been made available in another country by the patent holder or under license.

Patent: A title granted by the public authorities conferring a temporary monopoly (up to 20 years) for the production and sale of an invention or discovery.

Proprietary drug: A pharmaceutical product made and sold under a brand name

TRIPS: The Agreement on Trade-Related Aspects of Intellectual Property Rights (or TRIPS) covers a new field in multinational trade law. The agreement describes minimum standards that member countries of the World Trade Organisation (WTO) must adopt in order to ensure that new products, including drugs, are protected by patents. These new standards should be integrated into national laws by specified deadlines, which depend on the current patent laws and development status of any given country.

ENDNOTES

1. 1. $ indicates US dollar in all cases in this paper.

2. 2. The World Trade Organization (WTO) developed out of the General Agreement on Tariffs and Trade (GATT). GATT was a treaty signed in 1947 by 23 countries aimed at promoting and regulating international trade. Various "rounds" of international trade negotiations eventually developed into the agreement to create the WTO, with all matters relating to international trade being placed within its legal responsibility. Prior to the creation of the WTO, the GATT did not address the issue of the level of protection that should be given to intellectual property; countries had adopted a range of approaches to drug patents.

3. 3. According to Health Action International, a number of drugs considered essential from a health point of view are not on the WHO Essential Drugs List because of their current costs.

4. 4. See Pecoul et al (**JAMA** Jan 27 1999 Vol 281, 4: 361-367) who argue that removal of compulsory licensing and other means to manufacture generic drugs would remove a source of essential drugs on which poorer countries depend, and would also have a

detrimental long term effect on local manufacturing capacity.

5. 5. Laing, R. Global Issues of Access to Pharmaceuticals and Effect of Patents. Presentation at the AIDS and Essential Medicines and Compulsory Licensing Meeting, Geneva, March 26-27, 1999.

6. 6. "The inequities are striking," says Dr Jonathan Quick, Director of Essential Drugs and Other Medicines at WHO. "In developed countries a course of antibiotics can be bought for the equivalent of two or three hours' wages. One-year's treatment for HIV infection costs the equivalent of four to six months' salary. And the majority of drug costs are reimbursed. In developing countries, a full course of antibiotics to cure simple pneumonia may cost one month's wages. In many of these countries one year's HIV treatment - if it were purchased - would consume 30 years' income. And the majority of households must buy medicines with money from their own pockets." Quote taken from Press Release WHA/13 22 May 1999 WHO to Address Trade and Pharmaceuticals.

7. 7. DiMasi, JA, Hansen, RW, Grabowski, HG & Lasagna, LJ **Health Econ**. 10, 107-142 (1991).

8. 8. Love, J **Nature** 397, 202 (1999) 21 January 1999.

9. 9. Multiple postings on the Treatment Access Forum electronic discussion group (1999).

10. 10. Resolution EB103/1999/R1 Revised Drug Strategy.

C. International Efforts

- *Declaration of Commitment on HIV/AIDS*
  United Nations General Assembly Special Session on HIV/AIDS

- Global Health Fund:
  - *Communiqué*, G8 Statement
  - Statement of the Secretary General, Kofi Annan
  - Contributions Pledged to the Global AIDS Health Fund
  - Press Releases, Médècines-sans-Frontières

- Inspiring Country Efforts:
  - *"Frequently Asked Questions"*, Treatment Action Campaign, South Africa
  - *"Look At Brazil"*, Tina Rosenberg
  - *"National AIDS Drug Policy"*, Ministry of Health of Brazil

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UNITED NATIONS
SPECIAL SESSION
ON HIV/AIDS

Global Crisis–Global Action

25-27 June 2001 New York

27 June 2001

DECLARATION OF COMMITMENT ON HIV/AIDS

"Global Crisis – Global Action"

1. We, Heads of State and Government and Representatives of States and Governments, assembled at the United Nations, from 25 to 27 June 2001, for the twenty-sixth special session of the General Assembly convened in accordance with resolution 55/13, as a matter of urgency, to review and address the problem of HIV/AIDS in all its aspects as well as to secure a global commitment to enhancing coordination and intensification of national, regional and international efforts to combat it in a comprehensive manner;

2. Deeply concerned that the global HIV/AIDS epidemic, through its devastating scale and impact, constitutes a global emergency and one of the most formidable challenges to human life and dignity, as well as to the effective enjoyment of human rights, which undermines social and economic development throughout the world and affects all levels of society — national, community, family and individual;

3. Noting with profound concern, that by the end of the year 2000, 36.1 million people worldwide were living with HIV/AIDS, 90 per cent in developing countries and 75 per cent in sub-Saharan Africa;

4. Noting with grave concern that all people, rich and poor, without distinction of age, gender or race are affected by the HIV/AIDS epidemic, further noting that people in developing countries are the most affected and that women, young adults and children, in particular girls, are the most vulnerable;

5. Concerned also that the continuing spread of HIV/AIDS will constitute a serious obstacle to the realization of the global development goals we adopted at the

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Millennium Summit;

6. Recalling and reaffirming our previous commitments on HIV/AIDS made through:

- The United Nations Millennium Declaration of 8 September 2000;
- The Political Declaration and Further Actions and Initiatives to Implement the Commitments made at the World Summit for Social Development of 1 July 2000;
- The Political Declaration and Further Action and Initiatives to Implement the Beijing Declaration and Platform for Action of 10 June 2000;
- Key Actions for the Further Implementation of the Programme of Action of the International Conference on Population and Development of 2 July 1999;
- The regional call for action to fight HIV/AIDS in Asia and the Pacific of 25 April 2001;
- The Abuja Declaration and Framework for Action for the Fight Against HIV/AIDS, Tuberculosis and other Related Infectious Diseases in Africa, 27 April 2001;
- The Declaration of the Ibero-America Summit of Heads of State of November 2000 in Panama;
- The Caribbean Partnership Against HIV/AIDS, 14 February, 2001;
- The European Union Programme for Action: Accelerated Action on HIV/AIDS, Malaria and Tuberculosis in the Context of Poverty Reduction of 14 May 2001;
- The Baltic Sea Declaration on HIV/AIDS Prevention of 4 May 2000;
- The Central Asian Declaration on HIV/AIDS of 18 May 2001,

7. Convinced of the need to have an urgent, coordinated and sustained response to the HIV/AIDS epidemic, which will build on the experience and lessons learned over the past 20 years;

8. Noting with grave concern that Africa, in particular sub-Saharan Africa, is currently the worst affected region where HIV/AIDS is considered as a state of emergency, which threatens development, social cohesion, political stability, food security and life expectancy and imposes a devastating economic burden and that the dramatic situation on the continent needs urgent and exceptional national, regional and international action;

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9. Welcoming the commitments of African Heads of State or Government, at the Abuja Special Summit in April 2001, particularly their pledge to set a target of allocating at least 15 per cent of their annual national budgets for the improvement of the health sector to help address the HIV/AIDS epidemic; and recognizing that action to reach this target, by those countries whose resources are limited, will need to be complemented by increased international assistance;

10. Recognizing also that other regions are seriously affected and confront similar threats, particularly the Caribbean region, with the second highest rate of HIV infection after sub-Saharan Africa, the Asia-Pacific region where 7.5 million people are already living with HIV/AIDS, the Latin America region with 1.5 million people living with HIV/AIDS, and the Central and Eastern European region with very rapidly rising infection rates; and that the potential exists for a rapid escalation of the epidemic and its impact throughout the world if no specific measures are taken;

11. Recognizing that poverty, underdevelopment and illiteracy are among the principal contributing factors to the spread of HIV/AIDS and noting with grave concern that HIV/AIDS is compounding poverty and is now reversing or impeding development in many countries and should therefore be addressed in an integrated manner;

12. Noting that armed conflicts and natural disasters also exacerbate the spread of the epidemic;

13. Noting further that stigma, silence, discrimination, and denial, as well as lack of confidentiality, undermine prevention, care and treatment efforts and increase the impact of the epidemic on individuals, families, communities and nations and must also be addressed;

14. Stressing that gender equality and the empowerment of women are fundamental elements in the reduction of the vulnerability of women and girls to HIV/AIDS;

15. Recognizing that access to medication in the context of pandemics such as HIV/AIDS is one of the fundamental elements to achieve progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health;

16. Recognizing that the full realization of human rights and fundamental freedoms for all is an essential element in a global response to the HIV/AIDS pandemic, including in the areas of prevention, care, support and treatment, and that it reduces vulnerability to HIV/AIDS and prevents stigma and related discrimination against people living with or at risk of HIV/AIDS;

17. Acknowledging that prevention of HIV infection must be the mainstay of the national, regional and international response to the epidemic; and that prevention, care, support and treatment for those infected and affected by HIV/AIDS are

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mutually reinforcing elements of an effective response and must be integrated in a comprehensive approach to combat the epidemic;

18. Recognizing the need to achieve the prevention goals set out in this Declaration in order to stop the spread of the epidemic and acknowledging that all countries must continue to emphasize widespread and effective prevention, including awareness-raising campaigns through education, nutrition, information and health-care services;

19. Recognizing that care, support and treatment can contribute to effective prevention through increased acceptance of voluntary and confidential counselling and testing, and by keeping people living with HIV/AIDS and vulnerable groups in close contact with health-care systems and facilitating their access to information, counselling and preventive supplies;

20. Emphasizing the important role of cultural, family, ethical and religious factors in the prevention of the epidemic, and in treatment, care and support, taking into account the particularities of each country as well as the importance of respecting all human rights and fundamental freedoms;

21. Noting with concern that some negative economic, social, cultural, political, financial and legal factors are hampering awareness, education, prevention, care, treatment and support efforts;

22. Noting the importance of establishing and strengthening human resources and national health and social infrastructures as imperatives for the effective delivery of prevention, treatment, care and support services;

23. Recognizing that effective prevention, care and treatment strategies will require behavioural changes and increased availability of and non-discriminatory access to, inter alia, vaccines, condoms, microbicides, lubricants, sterile injecting equipment, drugs including anti-retroviral therapy, diagnostics and related technologies as well as increased research and development;

24. Recognizing also that the cost availability and affordability of drugs and related technology are significant factors to be reviewed and addressed in all aspects and that there is a need to reduce the cost of these drugs and technologies in close collaboration with the private sector and pharmaceutical companies;

25. Acknowledging that the lack of affordable pharmaceuticals and of feasible supply structures and health systems continue to hinder an effective response to HIV/AIDS in many countries, especially for the poorest people and recalling efforts to make drugs available at low prices for those in need;

26. Welcoming the efforts of countries to promote innovation and the development of domestic industries consistent with international law in order to increase access to medicines to protect the health of their populations; and noting that the impact of international trade agreements on access to or local

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manufacturing of, essential drugs and on the development of new drugs needs to be further evaluated;

27. Welcoming the progress made in some countries to contain the epidemic, particularly through: strong political commitment and leadership at the highest levels, including community leadership; effective use of available resources and traditional medicines; successful prevention, care, support and treatment strategies; education and information initiatives; working in partnership with communities, civil society, people living with HIV/AIDS and vulnerable groups; and the active promotion and protection of human rights; and recognizing the importance of sharing and building on our collective and diverse experiences, through regional and international cooperation including North/South, South/South cooperation and triangular cooperation;

28. Acknowledging that resources devoted to combating the epidemic both at the national and international levels are not commensurate with the magnitude of the problem;

29. Recognizing the fundamental importance of strengthening national, regional and subregional capacities to address and effectively combat HIV/AIDS and that this will require increased and sustained human, financial and technical resources through strengthened national action and cooperation and increased regional, subregional and international cooperation;

30. Recognizing that external debt and debt-servicing problems have substantially constrained the capacity of many developing countries, as well as countries with economies in transition, to finance the fight against HIV/AIDS;

31. Affirming the key role played by the family in prevention, care, support and treatment of persons affected and infected by HIV/AIDS, bearing in mind that in different cultural, social and political systems various forms of the family exist;

32. Affirming that beyond the key role played by communities, strong partnerships among Governments, the United Nations system, intergovernmental organizations, people living with HIV/AIDS and vulnerable groups, medical, scientific and educational institutions, non-governmental organizations, the business sector including generic and research-based pharmaceutical companies, trade unions, media, parliamentarians, foundations, community organizations, faith-based organizations and traditional leaders are important;

33. Acknowledging the particular role and significant contribution of people living with HIV/AIDS, young people and civil society actors in addressing the problem of HIV/AIDS in all its aspects and recognizing that their full involvement and participation in design, planning, implementation and evaluation of programmes is crucial to the development of effective responses to the HIV/AIDS epidemic;

34. Further acknowledging the efforts of international humanitarian organizations combating the epidemic, including among others the volunteers of the International Federation of Red Cross and Red Crescent Societies in the most

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affected areas all over the world;

35. Commending the leadership role on HIV/AIDS policy and coordination in the United Nations system of the UNAIDS Programme Coordinating Board; noting its endorsement in December 2000 of the Global Strategy Framework for HIV/AIDS, which could assist, as appropriate, Member States and relevant civil society actors in the development of HIV/AIDS strategies, taking into account the particular context of the epidemic in different parts of the world;

36. Solemnly declare our commitment to address the HIV/AIDS crisis by taking action as follows, taking into account the diverse situations and circumstances in different regions and countries throughout the world;

Leadership

Strong leadership at all levels of society is essential for an effective response to the epidemic

Leadership by Governments in combating HIV/AIDS is essential and their efforts should be complemented by the full and active participation of civil society, the business community and the private sector

Leadership involves personal commitment and concrete actions

At the national level

37. By 2003, ensure the development and implementation of multisectoral national strategies and financing plans for combating HIV/AIDS that: address the epidemic in forthright terms; confront stigma, silence and denial; address gender and age-based dimensions of the epidemic; eliminate discrimination and marginalization; involve partnerships with civil society and the business sector and the full participation of people living with HIV/AIDS, those in vulnerable groups and people mostly at risk, particularly women and young people; are resourced to the extent possible from national budgets without excluding other sources, inter alia international cooperation; fully promote and protect all human rights and fundamental freedoms, including the right to the highest attainable standard of physical and mental health; integrate a gender perspective; and address risk, vulnerability, prevention, care, treatment and support and reduction of the impact of the epidemic; and strengthen health, education and legal system capacity;

38. By 2003, integrate HIV/AIDS prevention, care, treatment and support and impact mitigation priorities into the mainstream of development planning, including in poverty eradication strategies, national budget allocations and sectoral development plans;

At the regional and subregional level

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39. Urge and support regional organizations and partners to: be actively involved in addressing the crisis; intensify regional, subregional and interregional cooperation and coordination; and develop regional strategies and responses in support of expanded country level efforts;

40. Support all regional and subregional initiatives on HIV/AIDS including: the International Partnership against AIDS in Africa (IPAA) and the ECA-African Development Forum Consensus and Plan of Action: Leadership to Overcome HIV/ AIDS; the Abuja Declaration and Framework for Action for the Fight Against HIV/AIDS, Tuberculosis and Other Diseases; the CARICOM Pan-Caribbean Partnership Against HIV/AIDS; the ESCAP Regional Call for Action to Fight HIV/ AIDS in Asia and the Pacific; the Baltic Sea Initiative and Action Plan; the Horizontal Technical Cooperation Group on HIV/AIDS in Latin America and the Caribbean; the European Union Programme for Action: Accelerated Action on HIV/AIDS, Malaria and Tuberculosis in the context of poverty reduction;

41. Encourage the development of regional approaches and plans to address HIV/AIDS;

42. Encourage and support local and national organizations to expand and strengthen regional partnerships, coalitions and networks;

43. Encourage the United Nations Economic and Social Council to request the regional commissions within their respective mandates and resources to support national efforts in their respective regions in combating HIV/AIDS;

At the global level

44. Support greater action and coordination by all relevant United Nations system organizations, including their full participation in the development and implementation of a regularly updated United Nations strategic plan for HIV/AIDS, guided by the principles contained in this Declaration;

45. Support greater cooperation between relevant United Nations system organizations and international organizations combating HIV/AIDS;

46. Foster stronger collaboration and the development of innovative partnerships between the public and private sectors and by 2003, establish and strengthen mechanisms that involve the private sector and civil society partners and people living with HIV/AIDS and vulnerable groups in the fight against HIV/AIDS;

Prevention

Prevention must be the mainstay of our response

47. By 2003, establish time-bound national targets to achieve the internationally agreed global prevention goal to reduce by 2005 HIV prevalence among young

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men and women aged 15 to 24 in the most affected countries by 25 per cent and by 25 per cent globally by 2010, and to intensify efforts to achieve these targets as well as to challenge gender stereotypes and attitudes, and gender inequalities in relation to HIV/AIDS, encouraging the active involvement of men and boys;

48. By 2003, establish national prevention targets, recognizing and addressing factors leading to the spread of the epidemic and increasing people's vulnerability, to reduce HIV incidence for those identifiable groups, within particular local contexts, which currently have high or increasing rates of HIV infection, or which available public health information indicates are at the highest risk for new infection;

49. By 2005, strengthen the response to HIV/AIDS in the world of work by establishing and implementing prevention and care programmes in public, private and informal work sectors and take measures to provide a supportive workplace environment for people living with HIV/AIDS;

50. By 2005, develop and begin to implement national, regional and international strategies that facilitate access to HIV/AIDS prevention programmes for migrants and mobile workers, including the provision of information on health and social services;

51. By 2003, implement universal precautions in health-care settings to prevent transmission of HIV infection;

52. By 2005, ensure: that a wide range of prevention programmes which take account of local circumstances, ethics and cultural values, is available in all countries, particularly the most affected countries, including information, education and communication, in languages most understood by communities and respectful of cultures, aimed at reducing risk-taking behaviour and encouraging responsible sexual behaviour, including abstinence and fidelity; expanded access to essential commodities, including male and female condoms and sterile injecting equipment; harm reduction efforts related to drug use; expanded access to voluntary and confidential counselling and testing; safe blood supplies; and early and effective treatment of sexually transmittable infections;

53. By 2005, ensure that at least 90 per cent, and by 2010 at least 95 per cent of young men and women aged 15 to 24 have access to the information, education, including peer education and youth-specific HIV education, and services necessary to develop the life skills required to reduce their vulnerability to HIV infection; in full partnership with youth, parents, families, educators and health-care providers;

54. By 2005, reduce the proportion of infants infected with HIV by 20 per cent, and by 50 per cent by 2010, by: ensuring that 80 per cent of pregnant women accessing antenatal care have information, counselling and other HIV prevention services available to them, increasing the availability of and by providing access for HIV-infected women and babies to effective treatment to reduce mother-to-child transmission of HIV, as well as through effective interventions for HIV-

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infected women, including voluntary and confidential counselling and testing, access to treatment, especially anti-retroviral therapy and, where appropriate, breast milk substitutes and the provision of a continuum of care;

Care, support and treatment

Care, support and treatment are fundamental elements of an effective response

55. By 2003, ensure that national strategies, supported by regional and international strategies, are developed in close collaboration with the international community, including Governments and relevant intergovernmental organizations as well as with civil society and the business sector, to strengthen health care systems and address factors affecting the provision of HIV-related drugs, including anti-retroviral drugs, inter alia affordability and pricing, including differential pricing, and technical and health care systems capacity. Also, in an urgent manner make every effort to: provide progressively and in a sustainable manner, the highest attainable standard of treatment for HIV/AIDS, including the prevention and treatment of opportunistic infections, and effective use of quality-controlled anti-retroviral therapy in a careful and monitored manner to improve adherence and effectiveness and reduce the risk of developing resistance; to cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes, in order further to promote innovation and the development of domestic industries consistent with international law;

56. By 2005, develop and make significant progress in implementing comprehensive care strategies to: strengthen family and community-based care including that provided by the informal sector, and health care systems to provide and monitor treatment to people living with HIV/AIDS, including infected children, and to support individuals, households, families and communities affected by HIV/AIDS; improve the capacity and working conditions of health care personnel, and the effectiveness of supply systems, financing plans and referral mechanisms required to provide access to affordable medicines, including anti-retroviral drugs, diagnostics and related technologies, as well as quality medical, palliative and psycho-social care;

57. By 2003, ensure that national strategies are developed in order to provide psycho-social care for individuals, families, and communities affected by HIV/AIDS;

HIV/AIDS and human rights

Realization of human rights and fundamental freedoms for all is essential to reduce vulnerability to HIV/AIDS

Respect for the rights of people living with HIV/AIDS drives an effective

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response

58. By 2003, enact, strengthen or enforce as appropriate legislation, regulations and other measures to eliminate all forms of discrimination against, and to ensure the full enjoyment of all human rights and fundamental freedoms by people living with HIV/AIDS and members of vulnerable groups; in particular to ensure their access to, inter alia education, inheritance, employment, health care, social and health services, prevention, support, treatment, information and legal protection, while respecting their privacy and confidentiality; and develop strategies to combat stigma and social exclusion connected with the epidemic;

59. By 2005, bearing in mind the context and character of the epidemic and that globally women and girls are disproportionately affected by HIV/AIDS, develop and accelerate the implementation of national strategies that: promote the advancement of women and women's full enjoyment of all human rights; promote shared responsibility of men and women to ensure safe sex; empower women to have control over and decide freely and responsibly on matters related to their sexuality to increase their ability to protect themselves from HIV infection;

60. By 2005, implement measures to increase capacities of women and adolescent girls to protect themselves from the risk of HIV infection, principally through the provision of health care and health services, including sexual and reproductive health, and through prevention education that promotes gender equality within a culturally and gender sensitive framework;

61. By 2005, ensure development and accelerated implementation of national strategies for women's empowerment, promotion and protection of women's full enjoyment of all human rights and reduction of their vulnerability to HIV/AIDS through the elimination of all forms of discrimination, as well as all forms of violence against women and girls, including harmful traditional and customary practices, abuse, rape and other forms of sexual violence, battering and trafficking in women and girls;

Reducing vulnerability

The vulnerable must be given priority in the response

Empowering women is essential for reducing vulnerability

62. By 2003, in order to complement prevention programmes that address activities which place individuals at risk of HIV infection, such as risky and unsafe sexual behaviour and injecting drug use, have in place in all countries strategies, policies and programmes that identify and begin to address those factors that make individuals particularly vulnerable to HIV infection, including underdevelopment, economic insecurity, poverty, lack of empowerment of women, lack of education, social exclusion, illiteracy, discrimination, lack of information and/or commodities for self-protection, all types of sexual exploitation

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of women, girls and boys, including for commercial reasons; such strategies, policies and programmes should address the gender dimension of the epidemic, specify the action that will be taken to address vulnerability and set targets for achievement;

63. By 2003, develop and/or strengthen strategies, policies and programmes, which recognize the importance of the family in reducing vulnerability, inter alia, in educating and guiding children and take account of cultural, religious and ethical factors, to reduce the vulnerability of children and young people by: ensuring access of both girls and boys to primary and secondary education, including on HIV/AIDS in curricula for adolescents; ensuring safe and secure environments, especially for young girls; expanding good quality youth-friendly information and sexual health education and counselling service; strengthening reproductive and sexual health programmes; and involving families and young people in planning, implementing and evaluating HIV/AIDS prevention and care programmes, to the extent possible;

64. By 2003, develop and/or strengthen national strategies, policies and programmes, supported by regional and international initiatives, as appropriate, through a participatory approach, to promote and protect the health of those identifiable groups which currently have high or increasing rates of HIV infection or which public health information indicates are at greatest risk of and most vulnerable to new infection as indicated by such factors as the local history of the epidemic, poverty, sexual practices, drug using behaviour, livelihood, institutional location, disrupted social structures and population movements forced or otherwise;

Children orphaned and made vulnerable by HIV/AIDS

Children orphaned and affected by HIV/AIDS need special assistance

65. By 2003, develop and by 2005 implement national policies and strategies to: build and strengthen governmental, family and community capacities to provide a supportive environment for orphans and girls and boys infected and affected by HIV/AIDS including by providing appropriate counselling and psycho-social support; ensuring their enrolment in school and access to shelter, good nutrition, health and social services on an equal basis with other children; to protect orphans and vulnerable children from all forms of abuse, violence, exploitation, discrimination, trafficking and loss of inheritance;

66. Ensure non-discrimination and full and equal enjoyment of all human rights through the promotion of an active and visible policy of de-stigmatization of children orphaned and made vulnerable by HIV/AIDS;

67. Urge the international community, particularly donor countries, civil society, as well as the private sector to complement effectively national programmes to support programmes for children orphaned or made vulnerable by HIV/AIDS in

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affected regions, in countries at high risk and to direct special assistance to sub-Saharan Africa;

Alleviating social and economic impact

To address HIV/AIDS is to invest in sustainable development

68. By 2003, evaluate the economic and social impact of the HIV/AIDS epidemic and develop multisectoral strategies to: address the impact at the individual, family, community and national levels; develop and accelerate the implementation of national poverty eradication strategies to address the impact of HIV/AIDS on household income, livelihoods, and access to basic social services, with special focus on individuals, families and communities severely affected by the epidemic; review the social and economic impact of HIV/AIDS at all levels of society especially on women and the elderly, particularly in their role as caregivers and in families affected by HIV/AIDS and address their special needs; adjust and adapt economic and social development policies, including social protection policies, to address the impact of HIV/AIDS on economic growth, provision of essential economic services, labour productivity, government revenues, and deficit-creating pressures on public resources;

69. By 2003, develop a national legal and policy framework that protects in the workplace the rights and dignity of persons living with and affected by HIV/AIDS and those at the greatest risk of HIV/AIDS in consultation with representatives of employers and workers, taking account of established international guidelines on HIV/AIDS in the workplace;

Research and development

With no cure for HIV/AIDS yet found, further research and development is crucial

70. Increase investment and accelerate research on the development of HIV vaccines, while building national research capacity especially in developing countries, and especially for viral strains prevalent in highly affected regions; in addition, support and encourage increased national and international investment in HIV/AIDS-related research and development including biomedical, operations, social, cultural and behavioural research and in traditional medicine to: improve prevention and therapeutic approaches; accelerate access to prevention, care and treatment and care technologies for HIV/AIDS (and its associated opportunistic infections and malignancies and sexually transmitted diseases), including female controlled methods and microbicides, and in particular, appropriate, safe and affordable HIV vaccines and their delivery, and to diagnostics, tests, methods to prevent mother-to-child transmission; and improve our understanding of factors which influence the epidemic and actions which

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address it, inter alia, through increased funding and public/private partnerships; create a conducive environment for research and ensure that it is based on highest ethical standards;

71. Support and encourage the development of national and international research infrastructure, laboratory capacity, improved surveillance systems, data collection, processing and dissemination, and training of basic and clinical researchers, social scientists, health-care providers and technicians, with a focus on the countries most affected by HIV/AIDS, particularly developing countries and those countries experiencing or at risk of rapid expansion of the epidemic;

72. Develop and evaluate suitable approaches for monitoring treatment efficacy, toxicity, side effects, drug interactions, and drug resistance, develop methodologies to monitor the impact of treatment on HIV transmission and risk behaviours;

73. Strengthen international and regional cooperation in particular North/South, South/South and triangular cooperation, related to transfer of relevant technologies, suitable to the environment in prevention and care of HIV/AIDS, the exchange of experiences and best practices, researchers and research findings and strengthen the role of UNAIDS in this process. In this context, encourage that the end results of these cooperative research findings and technologies be owned by all parties to the research, reflecting their relevant contribution and dependent upon their providing legal protection to such findings; and affirm that all such research should be free from bias;

74. By 2003, ensure that all research protocols for the investigation of HIV-related treatment including anti-retroviral therapies and vaccines based on international guidelines and best practices are evaluated by independent committees of ethics, in which persons living with HIV/AIDS and caregivers for anti-retroviral therapy participate;

HIV/AIDS in conflict and disaster affected regions

Conflicts and disasters contribute to the spread of HIV/AIDS

75. By 2003, develop and begin to implement national strategies that incorporate HIV/AIDS awareness, prevention, care and treatment elements into programmes or actions that respond to emergency situations, recognizing that populations destabilized by armed conflict, humanitarian emergencies and natural disasters, including refugees, internally displaced persons and in particular, women and children, are at increased risk of exposure to HIV infection; and, where appropriate, factor HIV/AIDS components into international assistance programmes;

76. Call on all United Nations agencies, regional and international organizations, as well as non-governmental organizations involved with the provision and

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delivery of international assistance to countries and regions affected by conflicts, humanitarian crises or natural disasters, to incorporate as a matter of urgency HIV/AIDS prevention, care and awareness elements into their plans and programmes and provide HIV/AIDS awareness and training to their personnel;

77. By 2003, have in place national strategies to address the spread of HIV among national uniformed services, where this is required, including armed forces and civil defence force and consider ways of using personnel from these services who are educated and trained in HIV/AIDS awareness and prevention to assist with HIV/ AIDS awareness and prevention activities including participation in emergency, humanitarian, disaster relief and rehabilitation assistance;

78. By 2003, ensure the inclusion of HIV/AIDS awareness and training, including a gender component, into guidelines designed for use by defence personnel and other personnel involved in international peacekeeping operations while also continuing with ongoing education and prevention efforts, including pre-deployment orientation, for these personnel;

Resources

The HIV/AIDS challenge cannot be met without new, additional and sustained resources

79. Ensure that the resources provided for the global response to address HIV/AIDS are substantial, sustained and geared towards achieving results;

80. By 2005, through a series of incremental steps, reach an overall target of annual expenditure on the epidemic of between US$ 7 billion and US$ 10 billion in low and middle-income countries and those countries experiencing or at risk of experiencing rapid expansion for prevention, care, treatment, support and mitigation of the impact of HIV/AIDS, and take measures to ensure that needed resources are made available, particularly from donor countries and also from national budgets, bearing in mind that resources of the most affected countries are seriously limited;

81. Call on the international community, where possible, to provide assistance for HIV/AIDS prevention, care and treatment in developing countries on a grant basis;

82. Increase and prioritize national budgetary allocations for HIV/AIDS programmes as required and ensure that adequate allocations are made by all ministries and other relevant stakeholders;

83. Urge the developed countries that have not done so to strive to meet the targets of 0.7 per cent of their gross national product for overall official development assistance and the targets of earmarking of 0.15 per cent to 0.20 per cent of gross national product as official development assistance for least

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developed countries as agreed, as soon as possible, taking into account the urgency and gravity of the HIV/ AIDS epidemic;

84. Urge the international community to complement and supplement efforts of developing countries that commit increased national funds to fight the HIV/AIDS epidemic through increased international development assistance, particularly those countries most affected by HIV/AIDS, particularly in Africa, especially in sub-Saharan Africa, the Caribbean, countries at high risk of expansion of the HIV/AIDS epidemic and other affected regions whose resources to deal with the epidemic are seriously limited;

85. Integrate HIV/AIDS actions in development assistance programmes and poverty eradication strategies as appropriate and encourage the most effective and transparent use of all resources allocated;

86. Call on the international community and invite civil society and the private sector to take appropriate measures to help alleviate the social and economic impact of HIV/AIDS in the most affected developing countries;

87. Without further delay implement the enhanced Heavily Indebted Poor Country (HIPC) Initiative and agree to cancel all bilateral official debts of HIPC countries as soon as possible, especially those most affected by HIV/AIDS, in return for their making demonstrable commitments to poverty eradication and urge the use of debt service savings to finance poverty eradication programmes, particularly for HIV/AIDS prevention, treatment, care and support and other infections;

88. Call for speedy and concerted action to address effectively the debt problems of least developed countries, low-income developing countries, and middle-income developing countries, particularly those affected by HIV/AIDS, in a comprehensive, equitable, development-oriented and durable way through various national and international measures designed to make their debt sustainable in the long term and thereby to improve their capacity to deal with the HIV/AIDS epidemic, including, as appropriate, existing orderly mechanisms for debt reduction, such as debt swaps for projects aimed at the prevention, care and treatment of HIV/AIDS;

89. Encourage increased investment in HIV/AIDS-related research, nationally, regionally and internationally, in particular for the development of sustainable and affordable prevention technologies, such as vaccines and microbicides, and encourage the proactive preparation of financial and logistic plans to facilitate rapid access to vaccines when they become available;

90. Support the establishment, on an urgent basis, of a global HIV/AIDS and health fund to finance an urgent and expanded response to the epidemic based on an integrated approach to prevention, care, support and treatment and to assist Governments inter alia in their efforts to combat HIV/AIDS with due priority to the most affected countries, notably in sub-Saharan Africa and the Caribbean and to those countries at high risk, mobilize contributions to the fund from public and private sources with a special appeal to donor countries, foundations, the

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business community including pharmaceutical companies, the private sector, philanthropists and wealthy individuals;

91. By 2002, launch a worldwide fund-raising campaign aimed at the general public as well as the private sector, conducted by UNAIDS with the support and collaboration of interested partners at all levels, to contribute to the global HIV/AIDS and health fund;

92. Direct increased funding to national, regional and subregional commissions and organizations to enable them to assist Governments at the national, subregional and regional level in their efforts to respond to the crisis;

93. Provide the UNAIDS co-sponsoring agencies and the UNAIDS secretariat with the resources needed to work with countries in support of the goals of this Declaration;

Follow-up

Maintaining the momentum and monitoring progress are essential

At the national level

94. Conduct national periodic reviews involving the participation of civil society, particularly people living with HIV/AIDS, vulnerable groups and caregivers, of progress achieved in realizing these commitments and identify problems and obstacles to achieving progress and ensure wide dissemination of the results of these reviews;

95. Develop appropriate monitoring and evaluation mechanisms to assist with follow-up in measuring and assessing progress, develop appropriate monitoring and evaluation instruments, with adequate epidemiological data;

96. By 2003, establish or strengthen effective monitoring systems, where appropriate, for the promotion and protection of human rights of people living with HIV/AIDS;

At the regional level

97. Include HIV/AIDS and related public health concerns as appropriate on the agenda of regional meetings at the ministerial and Head of State and Government level;

98. Support data collection and processing to facilitate periodic reviews by regional commissions and/or regional organizations of progress in implementing regional strategies and addressing regional priorities and ensure wide dissemination of the results of these reviews;

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99. Encourage the exchange between countries of information and experiences in implementing the measures and commitments contained in this Declaration, and in particular facilitate intensified South-South and triangular cooperation;

At the global level

100. Devote sufficient time and at least one full day of the annual General Assembly session to review and debate a report of the Secretary-General on progress achieved in realizing the commitments set out in this Declaration, with a view to identifying problems and constraints and making recommendations on action needed to make further progress;

101. Ensure that HIV/AIDS issues are included on the agenda of all appropriate United Nations conferences and meetings;

102. Support initiatives to convene conferences, seminars, workshops, training programmes and courses to follow up issues raised in this Declaration and in this regard encourage participation in and wide dissemination of the outcomes of: the forthcoming Dakar Conference on Access to Care for HIV Infection; the Sixth International Congress on AIDS in Asia and the Pacific; the XII International Conference on AIDS and Sexually Transmitted Infections in Africa; the XIV International Conference on AIDS, Barcelona; the Xth International Conference on People Living with HIV/AIDS, Port of Spain; the II Forum and III Conference of the Latin American and the Caribbean Horizontal Technical Cooperation on HIV/AIDS and Sexually Transmitted Infections, La Habana; the Vth International Conference on Home and Community Care for Persons Living with HIV/AIDS, Changmai, Thailand;

103. Explore, with a view to improving equity in access to essential drugs, the feasibility of developing and implementing, in collaboration with non-governmental organizations and other concerned partners, systems for voluntary monitoring and reporting of global drug prices;

We recognize and express our appreciation to those who have led the effort to raise awareness of the HIV/AIDS epidemic and to deal with its complex challenges;

We look forward to strong leadership by Governments, and concerted efforts with full and active participation of the United Nations, the entire multilateral system, civil society, the business community and private sector;

And finally, we call on all countries to take the necessary steps to implement implement this Declaration, in strengthened partnership and cooperation with other multilateral and bilateral partners and with civil society.

G8 Statement

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COMMUNIQUÉ

Genoa, 22 July 2001

1. We, the Heads of State and Government of eight major industrialised democracies and the Representatives of the European Union, met in Genova for the first Summit of the new millennium. In a spirit of co-operation we discussed the most pressing issues on the international agenda.

2. As democratic leaders, accountable to our citizens, we believe in the fundamental importance of open public debate on the key challenges facing our societies. We will promote innovative solutions based on a broad partnership with civil society and the private sector. We will also seek enhanced co-operation and solidarity with developing countries, based on a mutual responsibility for combating poverty and promoting sustainable development.

3. We are determined to make globalisation work for all our citizens and especially the world's poor. Drawing the poorest countries into the global economy is the surest way to address their fundamental aspirations. We concentrated our discussions on a strategy to achieve this.

A Strategic Approach to Poverty Reduction

4. The situation in many developing countries - especially in Africa - calls for decisive global action. The most effective poverty reduction strategy is to maintain a strong, dynamic, open and growing global economy. We pledge to do that.

5. We will also continue to provide effective development assistance to help developing countries' own efforts to build long-term prosperity. Consistent with the conclusions of the LDC III Conference and the Millennium Declaration, we support a strategic approach centred on the principles of ownership and partnership. In the common interest of donors and recipients of aid, we shall ensure the efficient use of scarce resources.

6. Open, democratic and accountable systems of governance, based on respect for human rights and the rule of law, are preconditions for sustainable development and robust growth. Thus, we shall help developing countries promote:

- accountability and transparency in the public sector
- legal frameworks and corporate governance regimes to fight corruption

- safeguards against the misappropriation of public funds and their diversion into non-productive uses
- access to legal systems for all citizens, independence of the judiciary, and legal provisions enabling private sector activity
- active involvement of civil society and Non Governmental Organisations (NGOs)
- freedom of economic activities.

We, for our part, will:

- implement fully the OECD Bribery Convention
- support efforts in the UN to pursue an effective instrument against corruption
- encourage Multilateral Development Banks (MDBs) to help recipient countries strengthen public expenditure and budget management.

Debt Relief and Beyond

7. Debt relief – particularly the Enhanced Heavily Indebted Poor Countries (HIPC) Initiative – is a valuable contribution to the fight against poverty, but it is only one of the steps needed to stimulate faster growth in very poor countries. We are delighted twenty-three countries have qualified for an overall amount of debt relief of over $53 billion, out of an initial stock of debt of $74 billion. We must continue this progress.

8. In particular we look to countries affected by conflict to turn away from violence. When they do, we confirm that we will strengthen our efforts to help them take the measures needed to receive debt relief. We confirm that HIPC, in conjunction with reforms by the countries to ensure strong domestic policies and responsible lending by donors, is designed to lead to a lasting exit from unsustainable debt.

9. Beyond debt relief, we focussed our discussion on three mutually reinforcing elements:

- greater participation by developing countries in the global trading system
- increased private investment
- initiatives to promote health, education and food security.

10. Open trade and investment drive global growth and poverty reduction. That is why we have agreed today to support the launch of an ambitious new Round of global trade negotiations with a balanced agenda.

11. While opening markets through global negotiations provides the greatest economic benefit for developing countries, we fully endorse measures already taken to improve market access for the least developed countries (LDCs), such as Everything But Arms, Generalised Preferences and all other initiatives that address the same objectives. We confirm our pledge made at the UN

LDC III Conference to work towards duty-free and quota-free access for all products originating in the least developed countries. We support efforts made by LDCs to enter the global trading system and to take advantage of opportunities for trade-based growth.

12. Increased market access must be coupled with the capacity to take advantage of it. Thus, to help developing countries benefit from open markets, we will better co-ordinate our trade related assistance to:

- provide bilateral assistance on technical standards, customs systems, legislation needed for World Trade Organisation (WTO) membership, the protection of intellectual property rights, and human resource development
- support the work of the Integrated Framework for Trade-Related Technical Assistance
- encourage the international financial institutions to help remove obstacles to trade and investment, and establish the institutions and policies essential for trade to flourish
- urge countries to mainstream trade expansion by including it in their poverty reduction strategies.

13. Increased private sector investment is essential to generate economic growth, increase productivity and raise living standards. To help developing countries improve the climate for private investment, we urge MDBs and other relevant international bodies to support domestic reform efforts, including the establishment of public-private partnerships and investment-related best practices, as well as codes and standards in the field of corporate governance, accounting standards, enhanced competition and transparent tax regimes. We call on the World Bank to provide additional support for programmes that promote private sector development in the poorest countries. To promote further investments in the knowledge-based economy, we call on the WTO and the World Intellectual Property Rights Organisation, in collaboration with the World Bank, to help the poorest countries comply with international rules on intellectual property rights.

14. Official development assistance (ODA) is essential. We will work with developing countries to meet the International Development Goals, by strengthening and enhancing the effectiveness of our development assistance. We commit ourselves to implement the landmark OECD-DAC Recommendation on Untying Aid to LDCs which should increase aid effectiveness and achieve more balanced effort-sharing among donors.

15. At Okinawa last year, we pledged to make a quantum leap in the fight against infectious diseases and to break the vicious cycle between disease and poverty. To meet that commitment and to respond to the appeal of the UN General Assembly, we have launched with the UN Secretary-General a new Global Fund to fight HIV/AIDS, malaria and tuberculosis. We are determined to make the Fund operational before the end of the year. We have committed $1.3 billion. The Fund will be a public-private partnership

and we call on other countries, the private sector, foundations, and academic institutions to join with their own contributions – financially, in kind and through shared expertise. We welcome the further commitments already made amounting to some $500 million.

16. The Fund will promote an integrated approach emphasising prevention in a continuum of treatment and care. It will operate according to principles of proven scientific and medical effectiveness, rapid resource transfer, low transaction costs, and light governance with a strong focus on outcomes. We hope that the existence of the Fund will promote improved co-ordination among donors and provide further incentives for private sector research and development. It will offer additional financing consistent with existing programmes to be integrated into the national health plans of partner countries. The engagement of developing countries in the purpose and operation of the Fund will be crucial to ensure ownership and commitment to results. Local partners, including NGOs, and international agencies, will be instrumental in the successful operation of the Fund.

17. Strong national health systems will continue to play a key role in the delivery of effective prevention, treatment and care and in improving access to essential health services and commodities without discrimination. An effective response to HIV/AIDS and other diseases will require society-wide action beyond the health sector. We welcome the steps taken by the pharmaceutical industry to make drugs more affordable. In the context of the new Global Fund, we will work with the pharmaceutical industry and with affected countries to facilitate the broadest possible provision of drugs in an affordable and medically effective manner. We welcome ongoing discussion in the WTO on the use of relevant provisions in the Trade-Related Intellectual Property Rights (TRIPs) agreement. We recognise the appropriateness of affected countries using the flexibility afforded by that agreement to ensure that drugs are available to their citizens who need them, particularly those who are unable to afford basic medical care. At the same time, we reaffirm our commitment to strong and effective intellectual property rights protection as a necessary incentive for research and development of life-saving drugs.

18. Education is a central building block for growth and employment. We reaffirm our commitment to help countries meet the Dakar Framework for Action goal of universal primary education by 2015. We agree on the need to improve the effectiveness of our development assistance in support of locally-owned strategies. Education – in particular, universal primary education and equal access to education at all levels for girls – must be given high priority both in national poverty reduction strategies and in our development programmes. Resources made available through the HIPC Initiative can contribute to these objectives. We will help foster assessment systems to measure progress, identify best practices and ensure accountability for results. We will also focus on teacher training. Building on the work of the G8 Digital Opportunities Task Force (dot.force), we will work to expand the use of information and communications technology (ICT) to train teachers in best practices and strengthen education strategies. We

especially encourage the private sector to examine new opportunities for investment in infrastructure, ICT and learning materials. We encourage MDBs to sharpen their focus on education and concentrate their future work on countries with sound strategies but lacking sufficient resources and to report next year to the G8. We support UNESCO in its key role for universal education. We will also work with the International Labour Organisation (ILO) to support efforts to fight child labour and we will develop incentives to increase school enrolment.

19. We will establish a task force of senior G8 officials to advise us on how best to pursue the Dakar goals in co-operation with developing countries, relevant international organisations and other stakeholders. The task force will provide us with recommendations in time for our next meeting.

20. As the November 2001 "World Food Summit: Five Years Later" approaches, food security remains elusive. Over 800 million people remain seriously malnourished, including at least 250 million children. So a central objective of our poverty reduction strategy remains access to adequate food supplies and rural development. Support to agriculture is a crucial instrument of ODA. We shall endeavour to develop capacity in poor countries, integrating programmes into national strategies and increasing training in agricultural science. Every effort should be undertaken to enhance agricultural productivity. Among other things, the introduction of tried and tested new technology, including biotechnology, in a safe manner and adapted to local conditions has significant potential to substantially increase crop yields in developing countries, while using fewer pesticides and less water than conventional methods. We are committed to study, share and facilitate the responsible use of biotechnology in addressing development needs.

21. We shall target the most food-insecure regions, particularly Sub-Saharan Africa and South Asia, and continue to encourage South-South co-operation. We will support the crucial role international organisations and NGOs play in relief operations. We believe national poverty reduction and sectoral strategies should take due account of the nutritional needs of vulnerable groups, including new-borns and their mothers.

Digital Opportunities

22. ICT holds tremendous potential for helping developing countries accelerate growth, raise standards of living and meet other development priorities. We endorse the report of the Digital Opportunity Task Force (dot.force) and its Genoa Plan of Action that successfully fulfilled the Okinawa mandate. The direct participation of representatives from public, private and non-profit sectors, as well as that of developing countries' governments, presents a unique formula for ensuring that digital technologies meet development needs. We will continue to support the process and encourage all stakeholders to demonstrate ownership, to mobilise expertise and resources and to build on this successful co-operation. We will review the implementation of the Genoa Plan of Action at our next Summit on the basis

of a report by the G8 Presidency. We also encourage development of an Action Plan on how e-Government can strengthen democracy and the rule of law by empowering citizens and making the provision of essential government services more efficient.

A Legacy for the Future

Environment

23. We confirm our determination to find global solutions to threats endangering the planet. We recognise that climate change is a pressing issue that requires a global solution. We are committed to providing strong leadership. Prompt, effective and sustainable action is needed, consistent with the ultimate objective of the UN Framework Convention on Climate Change of stabilising greenhouse gas concentrations in the atmosphere. We are determined to meet our national commitments and our obligations under the Convention through a variety of flexible means, drawing on the power of markets and technology. In this context, we agree on the importance of intensifying co-operation on climate-related science and research. We shall promote co-operation between our countries and developing countries on technology transfer and capacity building.

24. We all firmly agree on the need to reduce greenhouse gas emissions. While there is currently disagreement on the Kyoto Protocol and its ratification, we are committed to working intensively together to meet our common objective. To that end, we are participating constructively in the resumed Sixth Conference of the Parties in Bonn (COP6) and will continue to do so in all relevant fora. We welcome the recent deepening of discussions among the G8 and with other countries.

25. We reaffirm that our efforts must ultimately result in an outcome that protects the environment and ensures economic growth compatible with our shared objective of sustainable development for present and future generations.

26. We welcome Russia's proposal to convene in 2003 a global conference on climate change with the participation of governments, business and science as well as representatives of civil society.

27. We recognise the importance of renewable energy for sustainable development, diversification of energy supply, and preservation of the environment. We will ensure that renewable energy sources are adequately considered in our national plans and encourage others to do so as well. We encourage continuing research and investment in renewable energy technology, throughout the world. Renewable energy can contribute to poverty reduction. We will help developing countries strengthen institutional capacity and market-oriented national strategies that can attract private sector investment in renewable energy and other clean technologies. We call on MDBs and national development assistance agencies to adopt an

innovative approach and to develop market-based financing mechanisms for renewable energy. We urge the Global Environment Facility (GEF) to continue supporting environmental protection on a global scale and fostering good practices to promote efficient energy use and the development of renewable energy sources in the developing world, and stress the need to commit adequate resources to its third replenishment. We thank all those who participated in the work of the Renewable Energy Task Force established in Okinawa. G8 energy ministers will hold a meeting in the coming year to discuss these and other energy-related issues.

28. We are looking forward to the World Summit on Sustainable Development (WSSD) in Johannesburg in 2002, an important milestone in the Rio process. The three dimensions of sustainable development – enhancing economic growth, promoting human and social development and protecting the environment – are interdependent objectives requiring our concerted action. We will work in partnership with developing countries for an inclusive preparatory process with civil society on a forward looking and substantial agenda with action-oriented results. We welcome the recent adoption of the Stockholm Convention on Persistent Organic Pollutants (POPs) and will strongly promote its early entry into force.

29. We are committed to ensuring that our Export Credit Agencies (ECAs) adhere to high environmental standards. We therefore agreed in Okinawa to develop common environmental guidelines for ECAs, drawing on relevant MDB experience. Building on the progress made since last year, we commit to reach agreement in the OECD by the end of the year on a Recommendation that fulfils the Okinawa mandate.

Food safety

30. Fully aware of the paramount importance of food safety to our peoples, we will continue to support a transparent, scientific and rules-based approach and will intensify our efforts to achieve greater global consensus on how precaution should be applied to food safety in circumstances where available scientific information is incomplete or contradictory. We value the ongoing dialogue between governments, scientists, consumers, regulators, and relevant stakeholders in civil society. This must be based on the principle of openness and transparency. We recognise our responsibility to promote a clear understanding by the public of food safety benefits and risks. We shall strive to provide consumers with relevant information on the safety of food products, based on independent scientific advice, sound risk analysis and the latest research developments. We believe an effective framework for risk management, consistent with the science, is a key component in maintaining consumer confidence and in fostering public acceptance.

31. We welcome the outcome of the recent Bangkok conference on new biotechnology food and crops and the ad hoc meeting of regulators from OECD countries and Russia. We encourage the relevant international organisations to follow up the conference, as appropriate, within their own

respective mandates. Furthermore, we welcome the establishment of the joint FAO / WHO Global Forum of Food Safety Regulators. We also appreciate the work of the Inter-Academy Council in publicising balanced professional views on the science of food safety. All these meetings demonstrate our commitment to a process of dialogue aimed at strengthening public confidence in food safety.

Increasing Prosperity in a Socially-Inclusive Society

Employment

32. In the firm belief that economic performance and social inclusion are mutually dependent, we commit to implement policies in line with the recommendations of the G8 Labour Ministers Conference held in Torino last year. We welcome the increased activity of older persons who represent, as stated in the G8 Turin Charter "Towards Active Ageing", a great reservoir of resources for our economies and our societies.

Combating transnational organised crime and drugs

33. We reaffirm our commitment to combat transnational organised crime. To this end, we strongly endorse the outcome of the G8 Justice and Interior Ministers Conference held in Milano this year. We encourage further progress in the field of judicial co-operation and law enforcement, and in fighting corruption, cyber-crime, online child pornography, as well as trafficking in human beings.

34. Following up on the G8 ad hoc Meeting of Drug Experts held in Miyazaki last year and the recent London Conference on the global economy of illegal drugs, we will strengthen efforts to curb the trafficking and use of illegal drugs.

To the citizens of Genova

35. We are grateful to the citizens of Genova for their hospitality, and deplore the violence, loss of life and mindless vandalism that they have had to endure. We will maintain our active and fruitful dialogue with developing countries and other stakeholders. And we will defend the right of peaceful protestors to have their voices heard. But as democratic leaders, we cannot accept that a violent minority should be allowed to disrupt our discussions on the critical issues affecting the world. Our work will go on.

Next Summit

36. We accept the invitation of the Prime Minister of Canada to meet again next year in the province of Alberta, Canada on 26-28 June.

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THE SECRETARY-GENERAL

STATEMENT AT PRESS EVENT

Genoa, 20 July, 2001

Mr. Prime Minister,
Distinguished Heads of State and Government,
Ladies and Gentlemen,

Thank you, Prime Minister, for that extraordinary expression of support for the global fight against HIV-AIDS. The commitment and resources of the G-8 countries are indispensable if we are to win this battle. By joining it as vigorously and comprehensively as you have today, you - all of you - have given new meaning to leadership and solidarity in the 21st century, and I salute you for it. In this effort, there is no us and them, no developed and developing countries, no rich and poor -- only a common enemy that knows no frontiers and threatens all peoples.

Our meeting today is the culmination of a year-long process of awareness, engagement and mobilization on the issue of HIV-AIDS. For the first time, we are seeing the emergence of a response to this deadly disease that begins to match the scale of the epidemic itself. Governments, multilateral organizations, the private sector and civil society are all engaged in an unprecedented effort to defeat an epidemic that to date has infected an estimated 36 million people and claimed 22 million lives. At the Abuja Summit in April, African leaders made clear their commitment to the fight against AIDS. And at the United Nations General Assembly Special Session in June, the world came together to set common targets for reducing the spread of AIDS and alleviating its impact.

Our priorities should be clear: First, to ensure that people everywhere - particularly the young - know what to do to avoid infection. Second, to stop perhaps the most tragic form of HIV transmission - from mother to child. Third, to provide treatment for all those infected. Fourth, to redouble the search for a vaccine, as well as a cure. Fifth, to care for all whose lives have been devastated by AIDS, particularly the orphans - and there are 13 million of them today - and their numbers are growing.

The battle against AIDS will not be won without the necessary resources. We need to mobilize an additional seven to ten billion dollars a year to fight this disease world-wide. Part of these funds will be found in increased domestic budgets in countries in every part of the world. In Africa, leaders are rising to the challenge, and African Governments have pledged to increase their health budgets significantly. This is laudable, but it is not enough.

African and other developing countries will need substantial assistance to meet the needs of their peoples. That is why the United Nations General Assembly endorsed the establishment of a Global AIDS and Health Fund, which all sides now agree must become operational by the end of this year. The Fund has already received more than $1 billion in contributions - from Governments, foundations, businesses and private citizens. This is a very good beginning. But much, much more is needed. I therefore call on Governments, civil society, foundations and individuals to contribute to the fight against AIDS in any way they can.

Mr. Prime Minister,
Excellencies,

I see the contributions by your Governments as evidence of your determination to follow through on the Millennium Declaration issued at the United Nations last year. Let me recall today three of its most pressing commitments: your

pledges to "have halted and, begun to reverse, the spread of HIV/AIDS" by 2015; to halve, by the same date, the proportion of the world's people living in extreme poverty; and to spare no effort to free humanity "from the threat of living on a planet irredeemably spoilt by human activities."

The magnitude and the urgency of the AIDS epidemic has created an extraordinary global response to one of these challenges, based on partnership, solidarity and enlightened leadership. We must all remember that while HIV/AIDS affects both rich and poor, the poor are much more vulnerable to infection, and much less able to cope with the disease once infected. Your leadership and commitment today will serve to give new strength and inspiration to the thousands of health-care workers, teachers and community leaders fighting this disease in the poorest parts of the world, and the millions suffering from its effects. They will know that the world is finally summoning the will -- and committing the resources -- to win this war for all humanity.

Thank you.

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OFFICE OF THE SPOKESMAN FOR THE SECRETARY-GENERAL

CONTRIBUTIONS PLEDGED TO THE GLOBAL AIDS AND HEALTH FUND

DATE	CONTRIBUTOR	PLEDGES US$	TOTAL US$
	Donations by private individuals	115,423	1,395,041,068
7 August 2001	Kuwait	1,000,000	1,394,925,645
30 July 2001	Stupski Family Foundation	40,000	1,393,925,645
25 July 2001	Cheng Design & Construction	145	1,393,885,645
25 July 2001	Price Systems, LLC	500	1,393,885,500
21 July 2001	Italy	200,000,000	1,393,885,000
20 July 2001	Russia	20,000,000	1,193,885,000
18 July 2001	Canada	98,000,000	1,173,885,000
18 July 2001	European Commission	100,000,000	1,075,885,000
13 July 2001	Germany	131,000,000	975,885,000
11 July 2001	Byers Choice, Ltd.	10,000	844,885,000
5 July 2001	Niger	50,000	844,875,000
3 July 2001	Japan	200,000,000	844,825,000
27 June 2001	Andorra	100,000	644,825,000
27 June 2001	Luxembourg	2,500,000	644,725,000
26 June 2001	Austria	1,000,000	642,225,000
26 June 2001	Liberia	25,000	641,225,000
25 June 2001	Zimbabwe	1,000,000	641,200,000
25 June 2001	Uganda	2,000,000	640,200,000
25 June 2001	Nigeria	10,000,000	638,200,000
19 June 2001	Bill and Melinda Gates Foundation	100,000,000	628,200,000
8 June 2001	Winterthur Insurance (Credit Suisse)	1,000,000	528,200,000
31 May 2001	France	127,000,000	527,200,000
31 May 2001	United Kingdom	200,000,000	400,200,000
11 May 2001	United States	200,000,000	200,200,000
8 May 2001	International Olympic Committee	100,000	200,000
3 May 2001	Secretary-General Kofi Annan*	100,000	100,000

*The Secretary-General pledged the proceeds of the Philadelphia Liberty Medal he was awarded on

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4 July 2001.

Figures provided by the United Nations Fund for International Partnerships.

For background information on the Fund, click here.

Contributions to the Fund can be made through the United Nations Foundation.

USEFUL LINKS:

UNAIDS UNICEF UNDP UNFPA UNDCP UNESCO WHO WORLD BANK

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Information dated 20.07.2001

U.S. at odds with Europe over rules on world drug pricing

By DONALD G. McNEIL Jr
This article first appeared in The New York Times

Before the United Nations has even raised up to $10 billion for its new fund to fight AIDS, the Bush administration and the European Union are engaged in a behind-the- scenes struggle over how that money will be spent, particularly on pharmaceutical drugs.

Communications between the United States trade representative and his European Union counterpart, obtained by The New York Times, show starkly opposing views on several key issues.The Bush administration, like the giant pharmaceutical companies, opposes the creation of any system to regulate world drug prices, or the creation of a database where prices could simply be posted. The administration, while it has dropped moves against Brazil's production of cheap generic drugs, emphasizes that patent rights must be protected and wants the companies left alone to offer discounts when they see fit.

The Europeans appear to be siding with poor countries and campaigners for cheaper drugs.

No unified European position has yet been laid out, but different leaders and European Council resolutions favor a "tiered pricing system," endorse the right of poor countries to shop for cheap generic drugs from countries that ignore Western patents, and favor the creation of a worldwide database to show prices for all drugs from any supplier and to indicate whether the supplier is considered reliable.While acknowledging that patents are important, the Europeans often note that they are blamed for driving up the cost of health care, and emphasize the exceptions to patent rights contained in world trade treaties.

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"Basically, the European Union is saying that it doesn't want the fund to turn into a subsidy for Big Pharma, and the U.S. is saying the reverse," said Ellen 't Hoen, a drug price specialist at Doctors Without Borders, a medical charity that has led the fight for lower-priced drugs.The United Nations' global fund to fight AIDS was proposed by Secretary General Kofi Annan at a special General Assembly in June. He asked donors to contribute $7 billion to $10 billion a year. So far, only about $1 billion has been committed.

The rules governing the new fund are expected to be one topic discussed when President Bush meets the leaders of the world's seven wealthiest nations and Russia this week in Genoa, Italy.The Europeans - to the frustration of the Bush administration - have not defined what they mean by a tiered pricing system, although the assumption is that it would mean low prices for poor countries, high prices for rich ones and some sort of system for verifying that it was working.

Some leading members of the European Parliament appear to favor a system like that used for getting vaccines and contraceptives to the third world. For those, the pharmaceutical multinationals and their generic competitors in countries like India submit bids to international agencies like Unicef or the United Nations Population Fund, which handle distribution costs. The vaccines or contraceptives sell for a fraction - sometimes as little as one two- hundredths - of their prices in developed countries, and the makers still turn a small profit.Price cuts by the multinational companies have been voluntary, in response to public indignation and counteroffers from generic producers.

The most obvious targets of the drive are anti-retroviral AIDS drugs, which 18 months ago cost as much as $10,000 a year per patient, and now are offered by generic makers for as little as $350 per year.But AIDS also makes the body susceptible to secondary diseases like malaria, tuberculosis, pneumonia, meningitis, fungal infections and cancer. Pressure on pharmaceutical companies to offer poor countries discounts on virtually all therapeutic drugs is thus expected to mount.The extent of the European-American debate is outlined in a letter sent in late June by Robert B. Zoellick, the United States trade representative, to Pascal Lamy, his counterpart on the European Commission.

In the letter, a copy of which was obtained by The Times, Mr. Zoellick expressed his distress that the commission was endorsing a tiered system. The Bush administration is "opposed to the creation of an international institution or convention to regulate drug prices," Mr. Zoellick wrote. "I also would question establishment of a verification process." Further, he stated that "we have practical and legal concerns with

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the concept of maintaining a database on drug prices." The database, he wrote, would be "difficult to keep accurate" and "the sharing of drug pricing information can at times present problems under U.S. antitrust laws."

An official in Mr. Zoellick's office said the letter had two purposes. "One, we're challenging them to be specific about what they mean by a tiered pricing system," he said. "And, two, we're communicating that we're pretty skeptical."

Mr. Zoellick wrote that he was troubled by the reasons that Mr. Lamy's colleagues had offered for tiered pricing, including the argument that cheap drugs were still not available in Africa. Repeating an argument often made by spokesmen for the drug industry, he wrote that it was "more likely the result of the enormous infrastructure problems plaguing this region, rather than drug prices."

Millions of AIDS-infected Africans live in cities with hospitals or within walking distance of rural clinics, and have enough clean water to take pills. Many African countries now treat tuberculosis, which involves essentially the same regimen as AIDS requires - a daily handful of pills and occasional lab tests. Standard "first-line" tuberculosis drugs, however, are priced much lower than anti-retrovirals; recently, drug companies began voluntarily lowering the prices of their "second-line" tuberculosis drugs, which are prescribed if other drugs are ineffective.

Mr. Zoellick's letter concluded by saying that the drug companies ought to be trusted. "We should expect companies to sell at the lowest possible prices," he wrote. "However, it appears to me that many companies are now doing so; there is no indication that their pricing commitments are short-term or of such limited quantity that we should doubt their sincerity."

Doctors Without Borders argued at a drug price conference in April that relying on the good will of pharmaceutical companies was not a sound approach for battling AIDS. The companies, the charity argued, deeply slashed their prices last year "only after immense international public pressure began to jeopardize the industry's image."

The official in Mr. Zoellick's office confirmed that the Bush administration still backed the policy started under the Clinton administration of not seeking trade sanctions on African countries that legitimately used patent-nullifying provisions under World Trade Organization treaties to get AIDS drugs. "And," he added, "about three weeks ago, we settled our W.T.O. dispute with Brazil. That's gone down fairly poorly with the pharmaceutical companies."

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Related Links

For more information about
MSF at the Genoa G8

This article first appeared in
The New York Times

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Information dated 20.07.2001

Global Health Fund must not be a subsidy for the drug industry

As theG8 announces details of Global Health Fund, access to affordable medicines for the poor must be a priority.

Genoa, Italy - This afternoon at 5pm, the G8 heads of state will announce the constitution of the Global Health Fund. But there is no clear plan for how the fund are to be used. MSF is particularly concerned about the lack of policy to ensure the purchase of the most affordable medicines and other health commodities.

An article in today's New York Times today raises concerns over a split between the US and EU over how the money should be spent.

"Without a deliberate strategy to ensure the funding can be used to purchase from generic producers, including those in the South, the fund will be mainly a subsidy to the European and American drug industries," says MSF's Ellen 't Hoen. "We are here at the G8 to demand that the government of the richest countries in the world put people's lives over profits of industry. An equitable pricing system and restarting research and development for neglected diseases are a key part of improving access to life-saving medicines in the developing world."

Fourteen million people die of infectious diseases every year. 90% of them live in developing countries. Many of the victims of these diseases die because they have no access to the medicines they need.

Related Links

Read the New York Times article:
U.S. at odds with Europe over rules on world drug pricing

Visit:

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Information dated 23.07.2001

G8 window dresses while poor die from lack of medicines

"The richest countries of the world refuse to address more fundamental solutions to the access to medicines crisis", says an MSF spokesperson.

Genoa, Italy, July 21, 2001 - The G8 governments and the UN Secretary-General announced the constitution of a global health fund designed to tackle infectious diseases in developing countries.

More money and new money are needed in the fight against diseases of the poor, but the amount committed is nowhere near what is required. Pledges to the fund, currently at $1.2 billion, are shamefully low. Governments call upon multinationals and the private sector to contribute. Among these are the pharmaceutical companies whose pricing policies are a fundamental part of the problem.

The G8 governments have been preparing a global health fund for a year. In that time, 14 million people will have died from infectious and parasitic disease; 90% of these deaths will have occurred in developing countries.

"There are serious organisational concerns with the fund. There is still no clear statement regarding who makes the decisions, on what the funds are to be spent, and no policy to ensure that the fund will be used to purchase medicines at the lowest possible cost," says Ellen 't Hoen from the medical aid organisation M&eaacute;decins Sans Frontiè:res. "Without these basic commitments, it will be a long time before the fund contributes to saving lives. In its current state, it is little more than window dressing."

The crisis of lack of access to essential medicines faced by developing countries is much greater than can be solved by a global fund. A fundamental change in the medicines market is needed, embracing multiple

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strategies that will lead to equitable drug prices. Such strategies should include:

- a flexible interpretation of the WTO agreements on intellectual property to ensure that pharmaceutical patents do not stand in the way of producing and purchasing affordable medicines
- the promotion of the production and use of generic medicines
- a tiered pricing system to ensure that medicines in developing countries are affordable
- public investment in research and development for neglected diseases.

"The richest countries of the world refuse to address more fundamental solutions to the access to medicines crisis," says Ellen 't Hoen. "The current fund makes the richest countries look good, but will have very little impact on the lives and health of people.

Related Links

As the G8 announces details of Global Health Fund, access to affordable medicines for the poor must be a priority.
Global Health Fund must not be a subsidy for the drug industry

For more information about:
MSF at the Genoa G8

TAC

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Frequently Asked Questions

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development costs false?
    - What is wrong with the argument that the US and EU are justified in protecting their industries, because the cost of developing drugs has been borne entirely by these countries.
    - Is it true that major drug company research and development is increasingly focused on developing non-essential recreational drugs?
    - Won't compulsory licenses result in job losses for South Africans?
- Questions about the Defiance Campaign
    - What is the Christopher Moraka Defiance Campaign Against Patent Abuse?
    - Who was Christopher Moraka and why was the campaign named after him?
    - What is the point of the defiance campaign?
    - Is TAC planning to supply generic fluconazole to the entire country?
    - Does the Defiance Campaign break the law?
    - How long will the Defiance Campaign continue?
    - How will the generic medication be distributed?
    - How does TAC know that the generic fluconazole it is importing is of good quality?
    - What has happened to Pfizer's offer to donate fluconazole?
    - What are the drugs that TAC intends to target?
- Questions about preventing mother-to-child transmission of HIV
    - Do all pregnant mothers with HIV transmit the virus to their children?
    - Howmany mother-to-child transmissions occur yearly in South Africa?
    - How can mother-to-child transmission be prevented?
    - Isn't infant formula milk associated with higher infant mortality rates in poor countries? What about `Breast is Best'?
    - How long do HIV-positive infants live?
    - Should the government afford to implement a country-wide mother-to-child transmission prevention (mtctp) programme.
    - Isn't the government only obligated to implement mother-to-child transmission prevention if it is within its available resources?
    - Won't implementing an mtctp programme result in a large number of orphans?
    - What other spin-offs are there to an mtctp programme?
    - Why hasn't the government implemented a country-wide mtctp programme?
    - Is it true that TAC is taking legal action against the government for not implementing an mtctp programme?
    - Does taking legal action against the government mean that TAC is anti-government or anti-ANC?
    - The government has announced that it will implement pilot mother-to-child transmission programmes using Nevirapine. What is this all about?
    - Does the Democratic Alliance have a good record on HIV?

Questions about TAC

When was TAC started?

TAC was started on the 1st of December 1998, Human Rights Day.

What are the objectives of TAC?

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TAC's objectives are as follows:

1. Highlight disparities and problems in access to treatment and campaign to have them eliminated, with particular emphasis on HIV/AIDS.
2. Highlight problems with South Africa's health-care infrastructure and campaign to have them eliminated.
3. Educate ourselves and the public about treating HIV.
4. Educate people about how to live healthier and better with HIV/AIDS.

How is TAC trying to achieve its objectives?

TAC is conducting a number of campaigns. You can find out more about these on the `activity.htm`Activities web page.

How do I join TAC?

TAC does not have an official membership list. However, the organisation is in constant need of volunteers to help with the enormous workload. See the Contact Us`contact.htm` web page for details on how to contact one of the TAC offices.

Is TAC concerned only with HIV health-care issues?

TAC's primary focus is definitely health-care issues affecting people with HIV in South Africa. However, the organisation is concerned about other epidemics as well, such as Tuberculosis (TB). At the moment, the extent of the HIV epidemic consumes all our resources, but in the future we will make an effort to highlight other issues.

Questions about HIV/AIDS

How do we know that HIV causes AIDS?

The evidence is overwhelming. Over a period of time, usually between 2 and 10 years, the Human Immunodeficiency Virus (HIV) destroys an infected person's immune system. Once the immune system becomes sufficiently weak, the infected person is prone to being attacked by opportunistic diseases. There are many opportunistic diseases, including, but not limited to, TB, cryptococcal meningitis, PCP and Karposi Sarcoma. The immune systems of healthy people can fight off many of the diseases which attack people with HIV, but if left untreated, they can often be fatal or de-habilitating for people with HIV. When the immune system has deteriorated very badly and the infected person regularly falls ill with opportunistic diseases, the person is said to have Acquired Immune Deficiency Syndrome (AIDS). For an excellent explanation of the evidence that HIV causes AIDS, see Scientific American Article `sciam.htm`. For a detailed and more complicated explanation, see NIH article `nihart.doc`.

Someone who claims that HIV does not cause AIDS is referred to as an AIDS denialist or dissident. The arguments of the denialists have been discredited.

e active ingredient is supplied by a Swiss company and has been certified.
Th The WHO has inspected Biolab's premises and found them to be of good quality.
- Biolab has an ISO 9001 certificate for its production facilities.
- Biozole is registered and used in Thailand. It is used in many Asian countries.
- Medicins Sans Frontieres (Doctors Without Borders), the 1999 Nobel Peace Prize Winners, uses Biozole. They have recommended Biozole to us.
- TAC has visited the Biolab site. It was clean and the company's labour practices were acceptable.

What has happened to Pfizer's offer to donate fluconazole?

This is a good question and should be directed to Pfizer. The offer was made in mid-2000. Not a single capsule of donated fluconazole has reached a patient yet. Pfizer is negotiating the offer with the government but despite persistent rumours no agreement has been reached. TAC was party to the early stages of the negotiations and was witness to the bad faith negotiating style of Pfizer. In July the company released a false press statement aimed to coincide with immense activist pressure they were experiencing at the International AIDS Conference in Durban South Africa. The statement announced that Pfizer had reached an agreement with the South African government. The Minister of Health stated that she was furious at this premature announcement at the Global March for Treatment Access organised by TAC and Health-GAP on 9 July 2000.

Thus far it has been clear that the offer of the donation was a mere publicity stunt, but one that has been at the expense of people's lives.

What are the drugs that TAC intends to target?

TAC is focusing on the following essential medications which are the source of excessive profits:

- fluconazole under patent to Pfizer
- ddI and d4T under patent to Bristol Myers Squibb
- ABC, 3TC and AZT under patent to Glaxo Wellcome.
- nevirapine under patent to Boehringer Ingleheim

At the moment TAC is only importing fluconazole. In the future we will investigate importing anti-retrovirals.

Questions about preventing mother-to-child transmission of HIV

Do all pregnant mothers with HIV transmit the virus to their children?

No. There is some debate as to the precise transmission rate, which seems to differ within about a 20% range from study to study. It seems that 30% is a reasonable figure to use, but a recent study in Zimbabwe found a transmission rate of just over 40%.

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Assuming a 30% rate, transmission occurs as follows in a typical sample of 100 births:

- 5 infections occur in early pregnancy
- 15 infections occur in late pregnancy and during birth
- 10 infections occur as a result of breast-feeding

Howmany mother-to-child transmissions occur yearly in South Africa?

The prevalence of the virus is not stable, so from year to year the numbers have been increasing. In 1999, it was estimated that over 60,000 mother-to-child HIV infections occurred.

How can mother-to-child transmission be prevented?

By giving the mother and child anti-retroviral treatment and encouraging mothers to use infant formula milk, mother-to-child transmission can be reduced substantially. There are a number of possible anti-retroviral regimens that can be used: (1) long-course AZT, (2) short-course AZT and (3) Nevirapine, among others. Long-course AZT is the most expensive, but also the most effective. TAC is advocating that short-course AZT or Nevirapine are minimum appropriate solutions for South African public antenatal clinics.

Short-course AZT requires the mother to take AZT from the 36th week of pregnancy. The Nevirapine regimen is much simpler and requires the mother to take Nevirapine once during labour and for a Nevirapine syrup to be given to the child once after birth.

Using the transmission rate of 30%, the number of infections that can be prevented using the latter two regimens coupled with infant formula milk is estimated to be *at least* 15, but probably closer to 20, per 100 births. Using the numbers discussed in Question [*]:

- 5 infections that occurred early in pregnancy cannot be prevented
- approximately 10 of the 15 infections that occur in late pregnancy or just before birth will be prevented
- 10 infections due to breast-feeding will be prevented.

Isn't infant formula milk associated with higher infant mortality rates in poor countries? What about `Breast is Best'?

Breast is normally best and infant formula milk is associated with higher infant mortality rates for mothers who are HIV-negative. However, for mothers who are HIV-positive the overall effect is to substantially reduce mortality by reducing the number of transmissions.

It is easiest to understand the effect of transmission rates by looking at the numbers. If 100 HIV-positive *breast-feeding* mothers are given Nevirapine or short-course AZT, then using the numbers discussed in Question [*]then:

- 5 infections that occurred early in pregnancy cannot be prevented
- 10 babies who were HIV-negative at birth even without the anti-retroviral treatment will still contract HIV through breast-feeding

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- approximately 5 of the 10 babies whose infection was prevented through the anti-retrovirals will now become infected through breast-milk

This comes to a total of approximately 5 infections averted as opposed to the 15 to 20 that would be averted if infant formula milk was used.

How long do HIV-positive infants live?

Assuming HIV-positive babies do not receive anti-retroviral therapy, they live on average 2 years.

Should the government afford to implement a country-wide mother-to-child transmission prevention (mtctp) programme.

By not implementing a country-wide programme, the following clauses in the South African constitution are being infringed by the government:

1. right of mothers to make reproductive choices
2. right to health-care
3. right to dignity and equality
4. best interests of the child.

Isn't the government only obligated to implement mother-to-child transmission prevention if it is within its available resources?

Yes, but it is within the government's resources. A number of independent studies published in prestigious peer-reviewed medical journals have shown that an mtctp programme is affordable. For a detailed analysis see this document `mtctcost`. Actually an mtctp programme would probably save the state money, because of the cost saved on not having to treat HIV-positive children?

Won't implementing an mtctp programme result in a large number of orphans?

It is not ethical to let children to die so that they don't become orphans. This is not even an ethic used in warfare. Besides, TAC is campaigning for all people, including mothers, to have access to HIV treatments.

What other spin-offs are there to an mtctp programme?

There is evidence that the counselling that mothers get with an mtctp programme results in a reduction of unsafe sex practices. In addition, by finding out their HIV status, mothers are in a better position to plan for the future and to make decisions that can help them live healthier, longer lives.

Why hasn't the government implemented a country-wide mtctp programme?

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This is a question that should be put to the government. TAC has done this and received vague answers which avoid the issue.

Is it true that TAC is taking legal action against the government for not implementing an mtctp programme?

Yes. However, preparation for the court case has taken longer than expected. In addition, when TAC announced its intentions, the government announced that it would implement a pilot programmes in all provinces which has affected our preparation. Unfortunately, TAC has few resources and most of the TAC activists involved in the court case preparation do so on a part-time basis without any pay, and have full-time job commitments.

TAC is therefore taking the following approach. The legal action is being prepared meticulously and in detail. Civil society organisations are being solicited to join us in the court case against the government.

Does taking legal action against the government mean that TAC is anti-government or anti-ANC?

No. TAC is not aligned to any political party. Actually, most, but not all, TAC activists are ANC members or supporters. However, the government is failing to combat the HIV problem appropriately and it is necessary for the TAC to do everything we can to change the government's attitude to the disease. Ideally, TAC would like the government to lead us in the fight against HIV.

The government has announced that it will implement pilot mother-to-child transmission programmes using Nevirapine. What is this all about?

In response to public pressure, the government has announced that it will implement a mother-to-child transmission pilot projects. We understand the details of this implementation to be the following:

- The Nevirapine regimen will be used.
- Each province must implement at least two sites, where a site is defined as a set of clinics or hospitals that handles at least 3000 pregnancies a year.
- Provinces may implement more than 2 sites if they wish.

Superficially, this pilot programme might seem to be substantial progress, but on careful examination one discovers that if the provinces implement the minimum requirement, then:

9 provinces X 2 sites X 3000 pregnancies = 54,000 pregnancies

There are approximately 1,000,000 births in public antenatal clinics in South Africa a year. Therefore, the pilot programme ensures that a small minority, approximately 6%, of mothers will be part of the mtctp programme.

Therefore TAC has decided to write to every provincial MEC for health to determine precisely what each

province is intending to implement. We will also write to the Department of Health requesting a precise explanation of the details of the pilot programme.

Does the Democratic Alliance have a good record on HIV?

No. The DA, which is composed of the old National Party and the Democratic Party, has a terrible track record when it comes to fighting HIV. The DP opposed the legislation introduced by government to make the importation of generic medication easier. The National Party's track record against HIV when they were in power was worse than the current government. They ignored the disease for the most part and a minister of health under the National Party stated that HIV is a disease of people with poor morals.

It is quite concerning that just over a month before the local elections the DA's Tony Leon took an unprecedented interest in HIV. It suggests that the DA is using HIV purely for election propaganda purposes. On the other hand, the government has not helped the situation by releasing confusing messages on HIV, not implementing a country-wide mtctp programme and giving credence to AIDS denialists.

About this document ...

Frequently Asked Questions

This document was generated using the **LaTeX**2htm translator Version 98.1p1 release (March 2nd, 1998)

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Date: Thu, 2 Aug 2001 09:37:00 -0400 (EDT)
From: "Sharonann Lynch" <salynch00@earthlink.net>
Reply-To: <healthgap@CritPath.Org>
To: "Multiple recipients of list" <healthgap@CritPath.Org>
Subject: NEWS: TAC threatens to sue SA gov't over Nevirapine

<snip>
In an attempt to force the government to move more quickly, an AIDS activist group, the Treatment Action Campaign (TAC), has threatened to file a lawsuit against the government this week. If the government doesn't promise in writing to provide Nevirapine to all HIV-positive pregnant women, the group will file suit, claiming that the constitutional right to reproductive freedom has been violated.

</snip>

South Africa faces suit over cheap AIDS drug Activists say the government is slow to provide a drug doctors say cuts the risk of AIDS for babies.
Nicole Itano Special to The Christian Science Monitor

08/02/2001
Christian Science Monitor

Twice a month, Nora Motshelanoka travels across the sprawling metropolis of Johannesburg. Her destination: a tiny concrete wing of Soweto's Chris Hani Baragwanath Hospital. She is 4-1/2 months pregnant, diagnosed as HIV-positive, and very much alone. No one in her community knows about her HIV-status, and she lives in fear that she may pass the deadly virus to her unborn child.

Mrs. Motshelanoka's one source of support is her bimonthly visit to the hospital, where she receives counseling and routine prenatal care. When she nears her delivery date, she will be given a single dose of Nevirapine, an antiretroviral drug that tests have shown can halve the likelihood of AIDS being transmitted to her child.

"When I first found out, I cried every night. I asked God why this had to happen to me," Motshelanoka says. "Now I think maybe my baby will be healthy."

Baragwanath Hospital is one of only a handful of hospitals in South Africa that treats HIV-positive pregnant women, such as Motshelanoka. AIDS groups say the government has been slow to make the drug widely available to the estimated 25 percent of pregnant women in South Africa who are HIV-positive.

In the wake of the highly publicized lawsuit by international drug companies earlier this year to block generic drugs, the German pharmaceutical Boehringer Ingelheim, the producers of Nevirapine, offered to provide the drug free for the next five years. But the South African government hasn't accepted the offer.

One AIDS group is now threatening to sue the government if Nevirapine is not made more widely available, but the government says that concerns about the drug's safety still need to be addressed.

An estimated 2.5 million South African women of child-bearing age have been diagnosed as HIV-positive. Without treatment, the South African government calculates that more than 100,000 HIV-positive babies will be born in the country this year.

At Baragwanath Hospital, the world's second-largest maternity hospital, nearly 30 percent of the 16,000 women who give birth here are diagnosed as HIV-positive.

The Department of Health has pledged to implement Nevirapine pilot programs in two sites in each of the country's nine provinces, which they say would reach an estimated 90,000 pregnant women each year. But only two provinces now have pilot programs up and running.

At Baragwanath, the inexpensive Nevirapine therapy is privately funded and run through an independent unit of the University of the Witwatersrand. Another province, controlled by the opposition Democratic Alliance Party, is running its own program - using a different, more expensive drug.

The government says the pilot programs are needed to answer questions of drug resistance and toxicity.

"We believe the drug has proved effective in preventing intrapartum transmission at the time of birth, but it's the practices thereafter and sustainability that require looking at," says Jo-Anne Collinge, a spokeswoman for the Department of Health.

She says Nevirapine is only a small part of a successful mother-and-child program, and that other essential components - HIV-counseling, prenatal health care, and the provision of formula to newborns - are complicated and expensive to implement, especially in rural areas.

But Boris Jivkov, an obstetrician in the Perinatal HIV Research Unit, says, "We have shown them a model of how mother-to-child transmission can be reduced." He argues that providing HIV-positive women with Nevirapine, at an estimated cost of $3 per woman, is far more cost effective than treating HIV-positive children.

He says that 95 percent of the pregnant women at Baragwanath now choose to take a voluntary HIV test. Money from international donors is paying for all women who test positive to have access to Nevirapine.

"Basically, what the they're [the health department] doing is repeating what research we've already done," says Dr. Jivkov.

In an attempt to force the government to move more quickly, an AIDS activist group, the Treatment Action Campaign (TAC), has threatened to file a lawsuit against the government this week. If the government doesn't promise in writing to provide Nevirapine to all HIV-positive pregnant women, the group will file suit, claiming that the constitutional right to reproductive freedom has been violated.

"If a mother wants to have a child, and there is Nevirapine available that can prevent the transmission from the mother to the baby, the government has the obligation to provide that to the mother," says Mandla Majola, Western Cape coordinator for TAC.

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Sharonann Lynch
Health GAP Coalition
212-674-9598

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The New York Times Magazine

Look at Brazil

Patent laws are malleable. Patients are educable. Drug companies are vincible. The world's AIDS crisis is solvable.

By TINA ROSENBERG

Forum

- Should foreign governments be permitted to manufacture their own AIDS drugs?

Someday, we may look back on the year 2001 with nostalgia for a time when AIDS was merely a health catastrophe. Soon, AIDS in Africa will be doing more than killing millions every year. It will destroy what there is of Africa's economy and cause further instability and, perhaps, war. In the year 2010, the country of South Africa will be almost one-fifth poorer than it would have been had AIDS never existed. Throughout Africa, the disease has ravaged the young, urban and mobile.

It has robbed schools of their teachers and hospitals of their doctors and nurses. Businesses are depleted by the need to cope with sick and dying employees. AIDS takes the breadwinner, leaving millions of destitute elderly and orphans who will grow up without going to school, many on the streets. As they lose their productive citizens, the nations themselves face collapse.

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At the moment, however, AIDS in Africa is only a plague of a severity not seen since the Black Death killed at least a quarter of Europe in the 14th century. A 15-year-old in South Africa has a better than even chance of dying of AIDS. One in five adults is infected with H.I.V. Hospitals are filled with babies so shriveled by AIDS that nurses must shave their heads to find veins for intravenous tubes. Seventeen million people have died prolonged and miserable deaths from AIDS, and that number is dwarfed by what lies ahead.

While Africa is the region most ravaged, the disease is exploding elsewhere as well. India says it has four million infected; it may well have five times as many. Its AIDS epidemic bears a terrifying resemblance to South Africa's a few years ago -- AIDS is widespread in every risk group, and health care is inadequate. The Caribbean has the second-highest rate of infection after sub-Saharan Africa. More than one in 50 adults is H.I.V.-positive, and because the epidemic is primarily spread heterosexually there, most of the population is at risk. In Eastern Europe and the former Soviet Union, the number of infected nearly doubled in the last year.

Tina Rosenberg writes editorials for The Times. Her last article for the magazine was about children abducted during El Salvador's civil war.

Until a year ago, the triple therapy that has made AIDS a manageable disease in wealthy nations was considered realistic only for those who could afford to pay $10,000 to $15,000 a year or lived in societies that could. The most that poor countries could hope to do was prevent new cases of AIDS through educational programs and condom promotion or to cut mother-to-child

transmission and, if they were very lucky, treat some of AIDS's opportunistic infections. But the 32.5 million people with H.I.V. in the developing world had little hope of survival.

This was the conventional wisdom. Today, all of these statements are false.

The Raphael de Paula Souza hospital sits on the outskirts of Rio de Janeiro. It is a one-story plaster building with peeling blue paint and barefoot boys playing in the parking lot. Nothing in its appearance suggests that it might serve as a model for treating AIDS worldwide.

The AIDS clinic is run by Ademildes Navarini, who spends her days seeing patients like Rogério. He is 26, has tuberculosis as well as AIDS and suffers from an AIDS-related brain infection, toxoplasmosis. The infection has affected his speech, and now he gropes for words. He removes his T-shirt using only his left arm. His right arm and his right leg hang limp.

Of all the tools available to poor countries, compulsory licensing is what the drug companies fear the most, since it represents the most direct assault on control of their patents.

Rogério is followed by Jerdinete, a 46-year-old middle-class woman who came in for tests a year ago because of stomach problems -- and was stunned to find she had AIDS. The only way she could have got it, she says, was from her husband, whom she had presumed faithful. When she told him that she was sick, he left her.

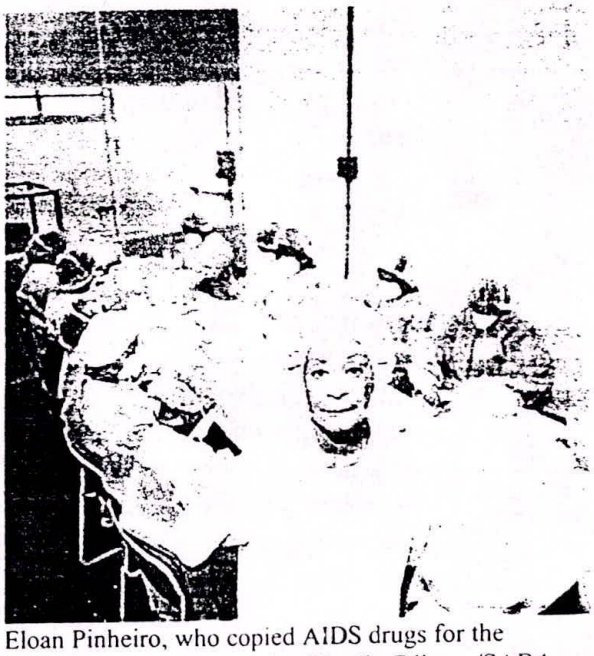
Jerdinete is followed by Maura, H.I.V.-positive but asymptomatic, and her 7-year-old son, Emerson, whose H.I.V. was diagnosed 10 months ago but has undoubtedly been infected since birth. Emerson, a handsome, curly-haired boy, kisses his mother's cheek, puts his arm around her neck and caresses her face as she sits on a stool. A year ago, Emerson's hair started to fall out. He got diarrhea and started losing weight. The family went in for testing, and their fears were confirmed. Maura, whose husband also has AIDS and tuberculosis, stopped working to stay home with Emerson. "He's the reason for my life," she says, squeezing her son.

If Rogério, Jerdinete and Emerson lived in any other poor nation, their future would be achingly foreseeable. But here's the news from Raphael de Paula Souza hospital: each of these patients will walk out with a plastic bag filled with bottles of antiretrovirals -- AZT and ddI and the protease inhibitors and other components of the

triple cocktail that, for the lucky, have turned AIDS into a chronic disease. Rogério, who started taking triple therapy three weeks before I met him, has gotten much better. He will be scarred by toxoplasmosis, Navarini says, but will improve a little more. Jerdinete and Emerson, on triple therapy for months, are doing fine. And Ademildes Navarini is the happy exception in third-world medicine, an AIDS doctor who can make her patients healthy again instead of merely holding their hands and watching them die.

Since 1997, virtually every AIDS patient in Brazil for whom it is medically indicated gets, free, the same triple cocktails that keep rich Americans healthy. (In Western Europe, no one who needs AIDS treatment is denied it because of cost. This is true in some American states, but not all.) Brazil has shredded all the excuses about why poor countries cannot treat AIDS. Health system too fragile? On the shaky foundation of its public health service, Brazil built a well-run network of AIDS clinics. Uneducated people can't stick to the complicated regime of pills? Brazilian AIDS patients have proved just as able to take their medicine on time as patients in the United States.

Ah, but treating AIDS is too expensive! In fact, Brazil's program almost certainly pays for itself. It has halved the death rate from AIDS, prevented hundreds of thousands of new hospitalizations, cut the transmission rate, helped to stabilize the epidemic and improved the overall state of public health in Brazil.



Eloan Pinheiro, who copied AIDS drugs for the government. Photograph by Claudio Edinger/SABA. for The New York Times.

Brazil can afford to treat AIDS because it does not pay market prices for antiretroviral drugs -- the most controversial aspect of the country's plan. In 1998, the government began making copies of brand-name drugs, and the price of those medicines has fallen by an average of 79 percent. Brazil now produces some triple therapy for $3,000 a year and expects to do much better, and the price could potentially drop to $700 a year or even less.

Brazil is showing that no one who dies of AIDS dies of natural causes. Those who die have been failed -- by feckless leaders who see weapons as more alluring purchases than medicines, by wealthy countries (notably the United States) that have threatened the livelihood of poor nations who seek to manufacture cheap medicine and by the multinational drug companies who have kept the price of antiretroviral drugs needlessly out of reach of the vast majority of the world's population.

But one major reason that only Brazil offers free triple therapy is that, until now, there was no Brazil to show that it is possible. A year and a half ago, practically nobody was talking about using triple therapy in poor countries.

Today, it is rare to find a meeting of international leaders where this idea is not discussed. International organizations like the United Nations AIDS agency, Unaids, and nongovernment groups like Médecins Sans Frontières are starting to help countries try to replicate Brazil's program. Brazil has offered to transfer all its technology and provide training in the practicalities of treating patients to other countries that want to make drugs and will supply them to patients free. Even the drug companies, hoping to head off more damaging assaults on their patent rights and improve their tattered image, have acknowledged the need to charge less for their products in poor nations. They have begun to make limited offers of cheap drugs.

In other words, the debate about whether poor countries can treat AIDS is over. The question is how.

Pharmaceutical manufacturers argue that many countries are very far from able to administer a program of triple therapy, and they are right. But Brazil shows that poor nations can do it. Others will be able to follow if they get substantial international help.

Also in This Issue

Survival of the Pushiest

Mark Burnett, the producer of 'Survivor,' has not only created the mother of all reality shows; he may also have revolutionized how the business of television is done.

Hong Kong's Queen of Pulp Moves On
Having played to the crowds for years, Maggie Cheung tries paring it down.

Stronger Than Steel
Next week Three Rivers Stadium is being blown up. But it will live on as a testament to those four Super Bowls the Steelers won a generation ago -- and to all the things Pittsburgh still wants to be.

Index to this week's New York Times Magazine

The drug companies are wrong, however, on how to make AIDS drugs affordable. Their solution -- limited, negotiated price cuts -- is slow, grudging and piecemeal. Brazil, by defying the pharmaceutical companies and threatening to break patents, among other actions, has made drugs available to everyone who needs them. Its experience shows that doing this requires something radical: an alteration of the basic social contract the pharmaceutical companies have enjoyed until now.

By the terms of that contract, manufacturers, in return for the risks of developing new drugs, receive a 20-year monopoly to sell them in some nations at whatever prices they choose. The industry has thrived under this contract. And so have we, the rich. The system has conquered an unimaginable range of diseases. But for billions of people the medicines have remained out of reach. Poor countries, it is now clear, must violate this contract if they are to save their people from AIDS.

Brazil has been able to treat AIDS because it had what everyone agrees is the single most important requirement for doing so: political commitment. At the beginning of 1999, Brazil's economy was skidding into crisis. President Fernando Henrique Cardoso was under great pressure to cut the budget by abandoning the AIDS program. He rejected that advice, deciding that treating AIDS was a priority.

Such commitment has its roots in the gay community. Although AIDS is now a disease of the poor in Brazil, the first Brazilians infected were gay men. In a country famously open about matters sexual, gays were much more activist and better organized than in most other nations, and AIDS carried less of the stigma that has elsewhere led people simply to deny its existence.

Then the movement found an unlikely ally in José Sarney, Brazil's first civilian president after the country emerged from military rule in 1985 and a conservative who led a pro-military party during the dictatorship. In 1996, scientists at the world AIDS conference in Vancouver announced that triple therapy with a protease inhibitor could reduce viral load to undetectable levels. Finally, there was a treatment for AIDS. "A doctor friend informed me about what was going on in Vancouver," Sarney told me. "I saw that most of the medicine in the cocktail would not be available to the poor, and I felt that we were talking about the survival of the species."

Sarney proposed a law that guaranteed every AIDS patient state-of-the-art treatment. It passed. At the same time, Brazil was carrying out an aggressive AIDS prevention program, financed by the World Bank. Activist groups were the keystone, distributing millions of

free condoms.

Surveys show that there are about 530,000 H.I.V.-positive people in Brazil. Four-fifths do not know they are infected. Of those who have been identified as needing antiretroviral therapy, however (some 90,000 at the moment), virtually all can get it, even homeless people, even people in the middle of the Amazon, says Paulo Teixeira, who runs Brazil's AIDS program. A slim, elegant man of 52, Teixeira has been an AIDS doctor since 1983 and director of the country's AIDS efforts for a year.

The treatment and prevention programs complement each other -- another powerful reason to begin treating AIDS in poor countries. Treating AIDS helps to limit its spread, as people with a lower viral load are less contagious. The availability of lifesaving treatment is also a powerful lure for people to get an AIDS test.

"Treatment brings people into the hospital, where you can talk to them," says Serafim Armesto, a psychologist who works with AIDS patients at the General Hospital of Nova Iguaçu, a major hospital in a working-class town a short drive from Rio. "You can work with them to prevent the spread of AIDS and further disease."

The programs have paid off. In 1994, the World Bank estimated that by 2000 Brazil would have 1.2 million H.I.V.-positive people. In fact it had half that many. The epidemic has stabilized, with some 20,000 new cases each year for the last three years. The treatment program has cut the AIDS death rate nationally by about 50 percent so far, and each AIDS patient is only a quarter as likely to be hospitalized as before.

Treating AIDS also fights other diseases. The incidence of tuberculosis in H.I.V.-positive patients has dropped by half. AIDS has also helped to mobilize people to fight for better health care. "In 1999, the Health Ministry had problems getting its budget passed for AIDS, TB and other

Dr. Ademildes Navarini at the Raphael de Paula Souza

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hospital. Photograph by Claudio Edinger/SABA. for The New York Times.

diseases," says Pedro Chequer, Teixeira's predecessor as head of the AIDS program and now the Unaids director for the southern part of South America. "There are now 600 nongovernmental groups that work on AIDS. They demonstrated in the street for a higher budget for all diseases, not just for AIDS, and these protests were covered in the press." The money was restored.

The Health Ministry spent $444 million on AIDS drugs in 2000 -- 4 percent of its budget. The only study of the program's benefits so far shows that the decline in hospitalizations from opportunistic infections from 1997 to 1999 saved the Health Ministry $422 million. But the tally of benefits should also take into account the savings from treatment's contribution to a halving of the expected infection rates and the productivity of those who no longer need to stay home or care for the sick.

"When we started with triple therapy," Teixeira says, "the main criticism from developed countries was that we didn't have the conditions for antiretroviral treatment. They said it would be dangerous for other countries, that we would create resistance."

Antiretrovirals, if taken incorrectly, can indeed create a more resistant strain of virus in the patient -- and in anyone to whom it is transmitted. Patients must stick to a rigorous and complicated schedule of pills, some taken with food, some without, and they must keep to this program (at least this is the current thinking) every day for the rest of their lives.

Yet the worries of rich countries that the poor and uneducated will mess things up for the rest of us have proved unfounded. Any nation that provides its AIDS patients with antiretrovirals must also provide them with help and training to take the medicine correctly. Brazil is doing just this, although it has meant turning nurses into organizers of nature hikes and clinics into baby-formula warehouses.

In Ademildes Navarini's clinic at Raphael de Paula Souza hospital, a nurse's aide, Denise Feliciano, spends a large part of her day drawing suns and moons with a purple marker. Today she is preparing Rogério, the patient recovering from toxoplasmosis, to go home with a bag of medicine. Rogério has been taking antiretrovirals for three weeks, and he may or may not be taking them correctly. "What time do you take your pills?" she asks. She waits while he counts. He stops at 6, groping for the next number. Seven? she supplies. Eight?

Rogerio makes a noise at 8.

How many pills do you take at 8 at night?

"Three," he says, but he is holding up two fingers. It is not clear whether Rogério is confused or merely has trouble expressing himself. The toxoplasmosis has also affected his eyesight; he knows how to read, but he can't see.

Feliciano sits down next to him and takes out his bag of medicine, a sheet of paper and her marker. "O.K., how do you take Biovir?" she says.

They go through each drug, with Feliciano drawing suns and moons on the boxes of pills and making a list on a separate sheet in a large purple hand. She estimates that 30 percent of patients have trouble keeping to their schedules, the same figure I heard from doctors and health workers at other hospitals. Most patients, everyone agreed, eventually understand how to take their medicine.

But that doesn't mean they take it. "Many don't understand the need for treatment, and they abandon it at the first side effects," says Armesto, the psychologist in Nova Iguaçu's clinic. "It can become a vicious circle -- no food, no money -- so they can't take their medicine properly, so they get opportunistic diseases, so they can't work, they get depressed, and that leads them further away from treatment."

In 1999, the AIDS program conducted a survey of more than 1,000 patients in São Paulo. It found that 69 percent achieved 80 percent adherence, which means they took their medicine properly 80 percent of the time. According to Margaret Chesney, a professor of medicine at the University of California at San Francisco who studies behavioral factors in AIDS treatment, this rate is not sufficient to control the virus - which can kill even people who take their medicine faithfully - but it is no different from adherence rates in the United States. A study in San Diego showed that 72 percent of patients took their medicine 80 percent of the time.

The São Paulo study found that the most important factor in patient falloff was missing a doctor's appointment. Next came the level of instruction and support available at the clinic, followed by a patient's income and education. "Patient adherence depends directly on the quality of the services provided," Teixeira says. "People in bad economic situations have more difficulties, but we can overcome them if we provide good service."

The study reinforced Brazil's attempt to offer patients more

sustained and varied help. AIDS officials expanded their training programs for people who work with patients. AIDS sufferers get free bus passes. Clinics ask local churches and Lions Clubs for food and baby formula. They recruit patients to sit in the waiting room and talk with other patients about their problems and to run Alcoholics Anonymous-style groups. The nurse at Nova Igua&#u recently took one group on a nature hike to a waterfall, because the patients seemed to be getting depressed.

"When we realize the patient is no longer coming to appointments, we send a telegram to ask them to come in and tell us why they stopped," says Rosa Maria Rezende, the social worker in Nova Iguaçu's clinic. "Then we try to overcome that. We want them to be more interested in the struggle to live. It is not their attitude toward medicine that matters; it is their attitude toward life."

At first glance, it would seem that brazil has advantages that are hard to duplicate. It has a well-organized network of civic groups, which were essential to building support for the program, designing it and making it work. It is a big country, with a large market for drugs. It has a health care system, however patchy. And while it is a poor country, it is a rich poor country.

Some countries will be unable to follow - they are too corrupt or war-torn or venally governed or not governed at all. In many of the African nations most ravaged by AIDS, the annual health budget comes to less than $10 per capita. This reflects the twisted priorities of leaders, many of whom can find sufficient money when they need to buy weapons. And health care is worsening thanks to AIDS itself, as doctors and nurses are among those most ravaged by the disease. But millions and millions of AIDS patients live in countries that could emulate Brazil, although they would need international help. These include virtually all the countries of Latin America and Eastern Europe, most of Asia and the former Soviet Union and at least 10 countries in sub-Saharan Africa. Pilot programs in Ivory Coast and Uganda show that at well-run clinics, patients have the same rate of adherence as in Europe and the United States.

Brazil shows how a nation can create an AIDS infrastructure atop an unstable foundation. Fairly good in Brazil's rich regions, health care is bad to nonexistent in poor ones. The country has one of the lowest rates of life expectancy and highest rates of infant mortality in Latin America. "When we passed the bill, we had to rely on a distribution network that didn't exist," former President Sarney says.

It seems absurd to suggest that countries that will not spend 10 cents to cure an infant with diarrhea should spend thousands of dollars on her mother's AIDS drugs. But in Brazil, there has been no trade-off. The program has very likely saved the Health Ministry money,

improved the treatment of other diseases and - very important - fostered a vocal lobby for better health care. For countries with a poor health infrastructure, an internationally financed AIDS program could be a way to develop a network of clinics and trained workers who might also be able to cure diarrhea.

So why have other countries not done it? One reason is indifferent, or even hostile, leadership. Kenya's president, Daniel Arap Moi, only very recently reversed his opposition to condom use. AIDS carries such a stigma that the response of some African leaders has been to deny there is a problem. Other governments are too corrupt or incompetent to organize prevention programs, much less treatment. But for most countries, even middle-income poor countries, the biggest hurdle is cost. Whether AIDS treatment eventually pays for itself is irrelevant; they cannot afford to get started.

Nowhere are the lost opportunities more tragic than in South Africa. According to Unaids, South Africa has more than four million infected, and the epidemic is growing geometrically. It is a wealthy country by African standards, with a relatively good health infrastructure and laboratories that could manufacture generic drugs.

But South Africa has done nothing to treat AIDS. The biggest obstacle is President Thabo Mbeki, in other ways a sane and responsible leader, who has inexplicably decided that he is not convinced H.I.V. causes AIDS. Absurdly, it has become politically incorrect to talk about treating AIDS in South Africa - because it would acknowledge that H.I.V. is the cause. Mbeki's musings, as well as an intense political battle in South Africa about the country's AIDS priorities, delayed the institution of even a program to cut mother-to-child transmission.

India, the country that probably has the largest epidemic, is another dismaying example. India does not recognize patents on medicine, and world trade rules do not require it do so until 2005. Indian firms lead the world in the manufacture of generic AIDS drugs. The managing director of Cipla Ltd., an Indian generic manufacturer that meets international quality standards, told me in December that he could make a triple therapy for $500 per year, plus another $200 in packaging costs, "and prices are likely to come down as we improve our techniques." Does India provide its sick with free AIDS treatment? It does not.

But treating AIDS is gradually creeping into the realm of the possible for many countries. AIDS is now bad for business in Africa, and African leaders are hearing a clamor for treatment from the middle class. Several African countries have good prevention programs, which was all they believed possible to do. Now they are

starting to think about treatment as well.

While Brazil's ability to reach patients encourages other nations, far more important is its success in lowering the cost of medicine. This is the news that can now allow other countries to dream about treating AIDS.

Eloan Pinheiro is a soft-spoken, ever-smiling 55-year-old chemist who spent the first part of her career as chief of formulation for the Brazilian subsidiaries of two multinational drug companies. Now Pinheiro is tormenting her former colleagues. She is the director of Far-Manguinhos, a government pharmaceutical research lab and factory named for the industrial neighborhood of Rio where it is located. In 1998, with the costs of importing brand-name drugs mounting, Brazil's health minister asked Pinheiro to analyze and copy the world's major AIDS drugs. Far-Manguinhos and Brazil's six other state pharmaceutical factories now make seven of the 12 antiretrovirals taken by Brazilians with AIDS. Pinheiro buys raw materials from India and Korea.

From the drug companies' point of view, the assembly lines below Pinheiro's second-floor office are humming with the violation of intellectual property rights, 40,000 times an hour. Brazil's 1996 law recognizing patents on medicine, passed to comply with the rules of the World Trade Organization, specifies that anything commercialized anywhere in the world by May 14, 1997, would forever remain unpatented in Brazil. That covers a lot - all the first-generation antiretrovirals like AZT, ddI, d4T, 3TC. It covers nevirapine, one of the nonnucleoside reverse transcriptase inhibitors, which, like protease inhibitors, make up the third drug in the triple cocktail. And by a few weeks, it covers the protease inhibitor indinavir. And at the end of last year, Brazil was causing tremors in the pharmaceutical industry by preparing to produce copies of Stocrin, a Merck antiretroviral that came out after 1996, which is patented in Brazil. Since Brazil started making generics of AIDS drugs, their cost has plummeted. The price of AIDS drugs with no Brazilian generic equivalent dropped 9 percent from 1996 to 2000. The price of those that compete with generics from Brazilian labs dropped 79 percent. But just the credible threat of generic competition is enough to get manufacturers to lower their prices.

There is no legal reason that other countries cannot do the same. Most drugs, including antiretrovirals, have never been patented in most sub-Saharan African countries, so those countries are free to make or import generics. Even countries that do respect patents on medicines have this possibility. This is important, because every country joining the World Trade Organization must pass laws respecting medical patents - the reason Brazil did. But there is a W.T.O. loophole that allows countries to make copies of patented

items in certain situations, including that of a national emergency. According to a W.T.O. official, governments could also choose to import generic drugs instead of making them. They can get what is called a compulsory license - in effect, they seize a patent - and manufacture or import a generic copy of a drug, paying the patentholder a reasonable royalty. Of all the tools available to poor countries, compulsory licensing is what the drug companies fear the most, since it represents the most direct assault on control of their patents. The United States has issued compulsory licenses in situations far less dire than those of AIDS-ravaged poor nations. Recent ones have been for tow trucks, stainless-steel wheels and corn seeds. Such licenses are common remedies in antitrust cases.

But although trade rules provide legal ways for poor nations to get cheap medicine, there are other obstacles. Many do not even know it is legal. Countries that have tried to manufacture generic medicine have fallen under debilitating pressure from pharmaceutical companies and from Washington.

In Thailand, such pressure kept the government from making cheap antiretrovirals until last year. Thailand has long made zidovudine, the knockoff of Glaxo Wellcome's AZT. But two drugs are needed to slow AIDS, and Thailand was blocked from making the other components of dual therapy - ddI, d4T and 3TC. Bristol-Myers Squibb sells ddI and d4T under the brand names Videx and Zerit. Glaxo sells 3TC under the name Epivir. None of the three were patented in Thailand because they came out before 1992, when the nation passed patent protections for medicine. Thailand's state drug factory was preparing to produce generic ddI when Bristol obtained a patent on the antacid buffer used to pack Videx into pill form. Krisana Kraisintu, the head of the factory, told me that Bristol also prevented the producers of the raw materials for ddI from selling to her. She was only able to make a generic ddI - in powder form - recently. (Bristol failed to respond to questions despite repeated requests over the course of a month.)

With Zerit and Epivir, Bristol and Glaxo took advantage of a controversial safety monitoring period passed in 1993 at American urging. It gives drugs up to five or six years of market exclusivity while generics undergo special safety tests - a law the World Health Organization and Unaids says "unnecessarily delays generic competition." Thailand was able to make generic d4T only when Zerit exited the program last year and is only now beginning to make generic 3TC.

The drug companies' actions are particularly distasteful because neither Bristol nor Glaxo invented these drugs or discovered their use in AIDS therapy. Glaxo's 3TC was discovered and patented for AIDS use by BioChem Pharma, a Canadian company, which licensed the drug to Glaxo. d4T was synthesized by the Michigan

Cancer Foundation in 1966, using public funds. Its application for AIDS was discovered at Yale University, which holds the patent, using grants from the federal government and Bristol. In the United States, Bristol's Zerit sells for $4.50 for 40 milligrams. Pharmaceutical manufacturers never disclose their costs, but one indication of Bristol's markup is that Pinheiro can sell her version for 30 cents - and it is possible her costs are higher than Bristol's, since the multinationals have access to cheaper raw materials.

The National Institutes of Health discovered ddI's use as an AIDS therapy. The N.I.H. then licensed the drug to Bristol for a 5 percent royalty, with the stipulation that Bristol's pricing take into account the health and safety needs of the public. But Bristol sells Videx for $1.80 in the United States for a 100-milligram tablet, while Far-Manguinhos in Brazil can sell the generic equivalent for 50 cents. The contract has a fair-pricing clause, but it has never been enforced.

The drug companies' influence has been greatly magnified because the United States trade officials have put the full weight of American trade pressures to work on their behalf. And one official told me that until very recently, "it was pretty rare" that his agency ever considered the health consequences. The statements in the trade representative's annual reports and trade watch lists document a shameful history of successful American efforts to get Thailand to pass patents on medicine, to abolish the pharmaceutical review board that monitored drug prices, to pass the safety monitoring period of market exclusivity and to refrain from issuing compulsory licenses. Here is one example from the trade representative's 1997 national trade estimate for Thailand: "The Thai legislature is expected in 1997 to consider a bill abolishing the pharmaceutical review board. This measure would advance objectives of American manufacturers."

It seems absurd to suggest that countries that will not spend 10 cents to cure an infant with diarrhea should spend thousands of dollars on her mother's AIDS drugs. But in Brazil, there has been no trade-

Numerous countries have been placed on the trade representative's Special 301 Watch List because of pharmaceutical patent disagreements. The list is a precursor to trade sanctions, but simply appearing on it is a form of sanction because it discourages investment. It turns a country's business sector and commerce ministry against generic production - and with such powerful opposition, local health officials lose. "When I wanted to produce generics, I was told, 'Don't move, because we're afraid of trade retaliation,'" Kraisintu says. "All of us know that the reason for all these things is pressure from the United States and multinational

off.

companies." Thailand sells a fifth of its exports to the United States.

The drug industry's dominance over American trade policy on pharmaceuticals finally crashed over South Africa. In 1997, South Africa, which does respect pharmaceutical patents, amended its laws to allow compulsory licensing of essential medicines, including AIDS drugs. Pharmaceutical companies sued. The suit is still going on.

Although Clinton administration officials acknowledged that what South Africa proposed was legal under the World Trade Organization, it declared war. President Clinton and Vice President Gore lobbied their counterparts, Nelson Mandela and Thabo Mbeki, then the deputy president. Friends of the drug companies in Congress passed a requirement that the State Department report on Washington's efforts to stop South Africa before the country could receive American aid. It reported in February 1999, that "all relevant agencies of the U.S. government . . . have been engaged in an assiduous, concerted campaign to persuade the government of South Africa to withdraw or modify" the relevant parts of the law.

This was a bizarre policy for an administration that claimed a special relationship with South Africa. But there was no role in the process of decisions about trade pressures for voices that countered those of industry. This resulted in egregious blind spots. In August 1998, I talked with an American trade official who worked on South Africa's medicines act. He told me that until a few months before I spoke to him, he was unaware of the dimensions of South Africa's AIDS problem. "Nobody brought it to my attention that it was a major health crisis," he said.

Today, this official is better informed. The administration changed its policy after activist groups began heckling Vice President Gore at his campaign appearances. When reporters, and later Gore aides, began to take notice, the administration told South Africa it could issue compulsory licenses for essential medicines as long as it stayed within world trade rules. Over the next year, the administration announced that health officials would participate in decisions about pharmaceutical disputes and pledged not to block compulsory licenses in the rest of sub-Saharan Africa and Thailand and in other countries on a case-by-case basis.

But pressure from other parts of the administration continued. In February 2000, William Daley, then the commerce secretary, traveled to Brazil and Argentina with Raymond Gilmartin, the C.E.O. of Merck, and a vice president of Pfizer in tow. Before he went, Daley told students that one purpose of his trip to Brazil was to talk about "serious concerns our companies have" with medical

patent laws. In Argentina, he threatened trade sanctions over the issue.

Overall, however, the Clinton administration went through a real conversion. Countries that displease American pharmaceutical manufacturers no longer land on a trade watch list if the trade representative believes they have a health emergency. But this could be reversed in five minutes by President Bush - and probably will be, since the industry is likely to be even more influential in the Bush administration than it has been under President Clinton. Pharmaceutical manufacturers give money to both political parties - $23 million in the last election cycle, according to the Center for Responsive Politics - but 69 percent of it went to Republicans. The drug industry also spends $75 million or so on lobbying every year.

From the beginning of the aids epidemic, the major drug makers clung to the idea of one planet, one price. Or worse - some drugs cost more in Kenya than in Norway. The strategy has earned them a public image almost as malignant as that of tobacco companies. By last year, they were also facing the growing threat of generics and the loss of Washington's automatic trade support. Early in 2000, several companies began to discuss the idea of lowering their prices in the third world.

In May 2000, Glaxo Wellcome, Merck, Boehringer-Ingelheim, F. Hoffmann-La Roche and Bristol announced a program called Accelerating Access, promising to sell drugs at deep discounts to poor countries that met certain standards. The price cuts the drug companies fought until last year have now become their solution to the world's AIDS crisis.

The companies have restricted their discounts, demanding that recipient countries properly administer the medicine. But the restrictions also keep the program small, controlled and largely secret. Each price cut for each drug in each country is negotiated separately. Glaxo was the only company to specify a price reduction publicly, announcing it would cut Combivir from $16 to $2 a day. And while about 20 countries are talking to the drug companies, only Senegal and Uganda have so far signed agreements to receive cut-price antiretrovirals. The discounts are impressive - Senegal will be able to buy triple therapy for as low as $1,000 per year per person. But just a few hundred people will benefit, most of them rich enough to pay themselves. In Uganda, about a thousand people will get the drugs, but they will all pay for them.

The pharmaceutical industry argues that collaborative efforts like this one are the way to make AIDS medicine affordable in the third world. But the program is too crabbed. "Why don't they just lower their prices in poor countries?" asks Ellen 't Hoen, who works in the

Médecins Sans Frontières campaign to help poor countries get needed medicines. "Having country-by-country confidential negotiations is not justified. This way, it stays in the charity corner and it hampers the development of more sustainable ways to get medicines to people." The industry's control over the program serves another purpose: the companies can use it to head off the practices they fear most, chiefly compulsory licensing. The document announcing the plan calls on the recipients of their largess to "respect intellectual property" - code for "stay away from compulsory licensing." And countries are complying, many of them out of ignorance.

Every single drug company executive I spoke with argued that if countries turn to compulsory licensing, new discoveries could eventually slow. "If we are to continue with research and development, then countries that participate in the program must provide conditions basic to innovation," Tadeu Alves, the chief of Merck's Brazil subsidiary, said during a panel at an AIDS conference in Rio. Those conditions, he said, included a free market, price structures that provide incentive to innovation and respect for intellectual property.

The drug companies' argument is in essence a defense of high profits. Even in the United States, the cost of drugs is provoking questions about whether continued research and development really depends on giving companies a 20-year monopoly to charge whatever price they choose, especially since they are often marketing other people's discoveries. The manufacturers generally spend twice as much on marketing and administration as they do on research and development. The real threat that third-world generics pose to pharmaceutical companies is that of blowback in rich nations. They worry that publicity about generic prices will fuel the American demand for cheap imports or price controls. They fear that patent seizures in the third world could loosen intellectual property rights in the first world.

Innovation would certainly suffer if pharmaceutical manufacturers could not charge high prices in their primary markets, although how high is open to debate. But applying this argument to Ukraine or Uganda is a scare tactic. No manufacturer depends on profits in Africa, which will account for 1.3 percent of worldwide drug sales next year, to motivate the search for new medicines. And companies can sell their AIDS drugs at very steep discounts - some at 90 percent or more off the American price - and still profit.

Once they realized that Brazil was solidly behind its generic drug program, the pharmaceutical companies have made the best of it, and they have not suffered. In fact, the government is buying 20,000 daily doses of Crixivan (Merck's brand of indinavir), a tenth of the drug's worldwide sales. Merck had to meet Pinheiro's price for

indinavir, the generic. But the company can do this and still profit. "The half-million infected today are patients of tomorrow," Tadeu Alves told me.

The same thing may soon happen with Merck's Stocrin, which is patented in Brazil. Pinheiro is threatening to get a compulsory license to make the generic. The threat will most likely force Merck to drop the price or voluntarily license Pinheiro to make the generic or sell Stocrin. And this arrangement will be profitable for Merck, which shows no sign of shutting its labs because of Brazil. Yet the pharmaceutical industry continues to paint the ongoing battle against generics in impoverished nations as Armageddon. Glaxo has even stopped the Indian generic manufacturer Cipla from selling a knockoff of a Glaxo AIDS drug in Ghana. Ghana's share of the international antiretroviral market is virtually zero.

If wealthy countries and the united nations agencies they influence chose to make AIDS treatment available to every citizen of the earth in the most efficient and cost-effective manner possible, the program would look very much like Unicef's global system of vaccination. When Unicef began a campaign to vaccinate the world's children in the early 1980's, many scoffed. But today vaccination rates top 80 percent, saving three million lives a year and preventing crippling diseases in tens of millions more. This is one of the world's most significant public health victories.

Who pays to vaccinate a child in Angola? We do, without much complaint. Antiretrovirals, of course, do not cost pennies per dose. But they would be a lot cheaper than they are today if the World Health Organization or Unaids used a Unicef-like system, which has dropped the price of vaccines to a thirtieth of their American price in some cases. The W.H.O. could buy antiretrovirals for third-world use from reliable generic suppliers like Cipla in India or brand-name manufacturers if they were willing to lower their prices. The economies of scale and guaranteed markets could drop the price of a year's triple therapy to below the $700 that Cipla could muster today.

This is a price many countries could afford, especially when balanced against the savings in hospitalizations. But everyone agrees that AIDS treatment will require North America and Europe to purchase the medicines and to help set up the necessary health care network. In my calculus, applying the Unicef system to AIDS would cost $3 billion a year in antiretrovirals alone, assuming five million patients at $600 a year. And the cost will increase as countries reach more patients. This is a large sum of money. It seems somewhat smaller, however, next to the wards of shaven-head babies - or the collapse of a continent.

It is difficult to imagine the Bush administration endorsing such a global plan. There are, however, smaller, worthwhile steps the administration could take if it were so inclined. At minimum, it should bury forever the bad old policy of intimidating countries that want to make or buy generics, especially through compulsory licensing. The administration should also encourage agencies like the World Health Organization and Unaids to facilitate these purchases and the necessary training to make them work.

There are also laws already on the books, which the Clinton administration chose not to carry out, that could promote the cheap production of at least some antiretrovirals. One such law allows the government to seize patents of drugs that were discovered at government labs or with substantial public funds if the patent holder is not meeting public health needs - for example, by charging too much. James Love, who runs the Consumer Project on Technology, a Ralph Nader-affiliated advocacy group, argues that it applies to five antiretrovirals. Love would like to see the government license them to a nonprofit corporation that would produce the drugs cheaply for both the first- and third-world markets.

But the Bush administration is unlikely to be so inclined, because the drug companies have other ideas. "Merck and other companies appreciate that our products need to be more affordable in the developing world," Jeffrey Sturchio, a Merck spokesman, told me, echoing every pharmaceutical maker. "We are willing to sit down and be a constructive partner. Compulsory licensing is unnecessary." But compulsory licensing seems very necessary. Merck would have little interest in constructive partnership in Brazil - or anywhere - if that threat did not exist.

This is the larger lesson of Brazil: AIDS can become a manageable disease in the third world, but it takes power, in addition to other things. The ability to pull the price of AIDS drugs within reach of those who need them may someday come from the backing of some international organization, or the pharmaceutical industry might find religion. But at the moment, it arises only from the threat to make or buy generic drugs. AIDS is turning the third world's human landscape into a parched wasteland. Brazil has shown that, armed with the power of competition, a government can do more than sit and watch the desert encroach.

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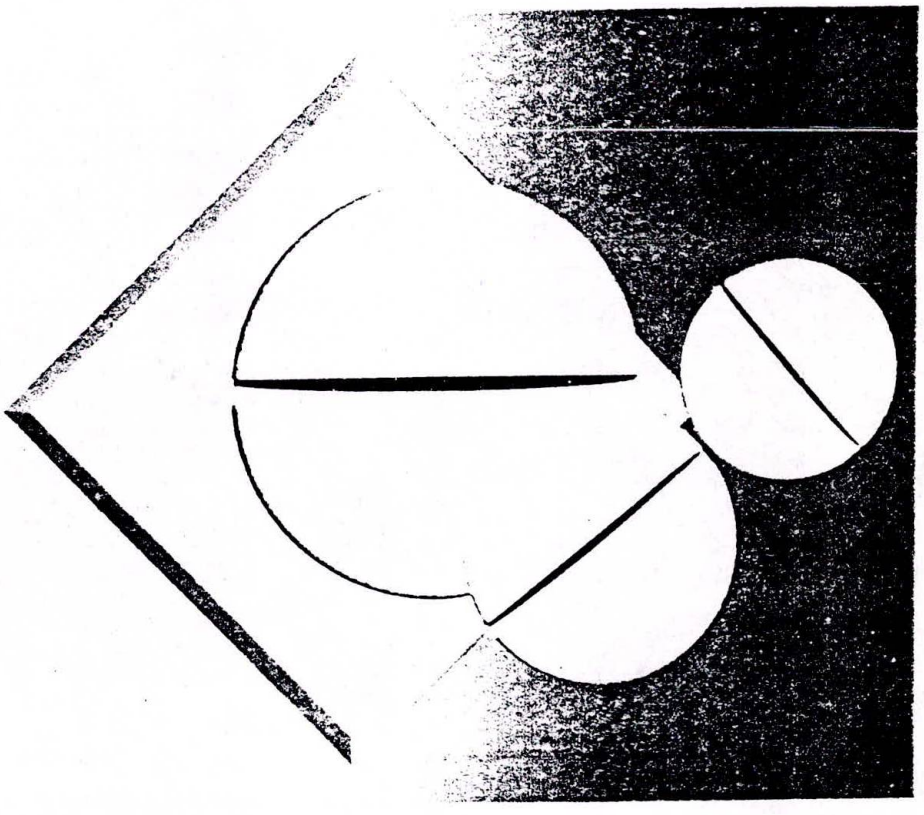
January 28, 2001

Ministry of Health of Brazil



National AIDS Drug Policy

Ministry of Health - Brazil

National AIDS Drug Policy

Brazil
May 2001

Foreword

The Brazilian HIV/AIDS drug policy has been highly debated and criticised, particularly at the time of its implementation by the national authorities in the early 90s. The dearth of trained health professionals and the poor structure of the health services, the lack of laboratories capable of monitoring the infection, and the patients' capacity of adhering to treatment were hotly questioned. National and international experts and health professionals, managers of programs of prevention and care of people living with HIV/AIDS, staff responsible for the budgetary and financial execution of public monies and international organisations argued amid reports of treatment assessment and cost-benefit studies and projections both favourable and contrary to the implementation of a such a costly policy for the State.

However, fortunately, reality not only corroborated our policy; over and above, the statements of its most optimistic defenders were outdone by their remarkably positive results. The quality of the government-provided services is reflected by the significant improvement in the health status and in the control of the infection among people living with HIV/AIDS. To this more immediate consequence of the antiretroviral regimens recommended by the Brazilian Ministry of Health one must add several social, economic and political benefits, both palpable and yet to be achieved, without precedent in the history of Public Health in our country.

At the present time, the success of the program for the free and universal distribution of these drugs to every patient who needs them cannot be doubted. In addition, its repercussion may contribute to the global debate on the access of people living with HIV/AIDS to antiretroviral treatment, with strong priority to the poorest countries, which bear the heaviest brunt of an epidemic that, according to UNAIDS data, was responsible for 5.3 million new infections and 3 million AIDS deaths in 2000 alone.

The so-called developing countries suffer from the lack of public resources, social problems and political oppression. AIDS has shown, in bright and sharp colours, all the contrasts unveiled by the epidemic in these countries when its threat does not elicit a response or is not tackled with the responsibility, competence and a humanist and solidary planning that are necessary.

This document retraces the most recent history of the unquestionable advances in laboratory care and in the treatment of HIV infection and assesses its development from the perspective of the unique Brazilian experience in the efforts for the prevention and control of the epidemic.

Paulo R. Teixeira
Co-ordinator
Brazilian Program of Sexually Transmissible Diseases and AIDS

AIDS drugs policy in Brazil

Background

The Brazilian population is estimated at 169,5 million people. From 1980 until December 2000, 203,353 AIDS cases were reported to the National STD and AIDS Program (NAP) of the Ministry of Health (MoH). 151,298 of them are males and 52,055 females; 7,086 are children. It is estimated that 536,000 Brazilians are infected with HIV. Since 1996, the incidence rate has stabilised around 14 cases per 100.000 population. The number of new cases reported in the last five years was approximately 22,000 per year.

The Ministry of Health's policy for the care of people living with HIV/AIDS includes, among several other initiatives, the creation of the Laboratory Network for the Quantification of Viral Load and CD4+ and CD8+ cell counts, the organisation of health care services, the support to the organisation of People Living with HIV/AIDS and to projects carried out by Non-Governmental Organisations, and the creation of a program for the free and universal access to antiretroviral drugs through the public health network.

This program, begun in the early 90s with the distribution of AZT capsules, was expanded and consolidated in 1996 by Congressional Bill 9113, of 13 November 1996, that guarantees every patient the access, free of direct costs, to all the medication required for his/her treatment, including protease inhibitors (since December 1996), following treatment criteria and guidelines set forth by the MoH. The Ministry thus created two advisory committees, with the mandates to define a Consensus on the Recommendations and Guidelines for the Use of Antiretroviral Therapy in Adults and Adolescents and a second similar consensus on treatment for children. The committees meet periodically at least once a year, to review the recommendations and adjust them to the updated scientific knowledge and the availability of new drugs.

According to the current recommendation, the use of antiretroviral drugs is indicated for all symptomatic HIV-infected patients, asymptomatic patients with significant laboratory changes, for HIV+ pregnant women, aiming at the reduction of vertical transmission, and for the prophylaxis of HIV infection in health professionals after exposure to potentially contaminated biological material.

Infrastructure of the system for HIV+ patient care

In the past 5 years, the MoH has adopted the strategy of offering modalities of care that favour outpatient care, such as Specialised Care Services (148), Day Hospitals (69) and Therapeutic Home Care (52), which complement the care provided by the 362 Accredited Hospitals for HIV/AIDS care. The availability of these care modalities has enabled a higher quality of life for the patient and lower costs of care. It is important to highlight that these figures do not include all services available for HIV+ patients, reflecting only those that have the infrastructure defined by the MoH as a requirement of a specialised care service and have requested their accreditation as such.

A study of the direct costs of AIDS care in Brazil in 1996, carried out by the Foundation Institute of Economic Research – FIPE, with the support of NAP, comparing the average costs per day of hospital stay, proved that the cost of conventional hospitalisation (US$ 97.31) was twice that of Day Hospital admission (US$ 47.02) and almost nine fold higher than Therapeutic Home Care (US$ 11.31).

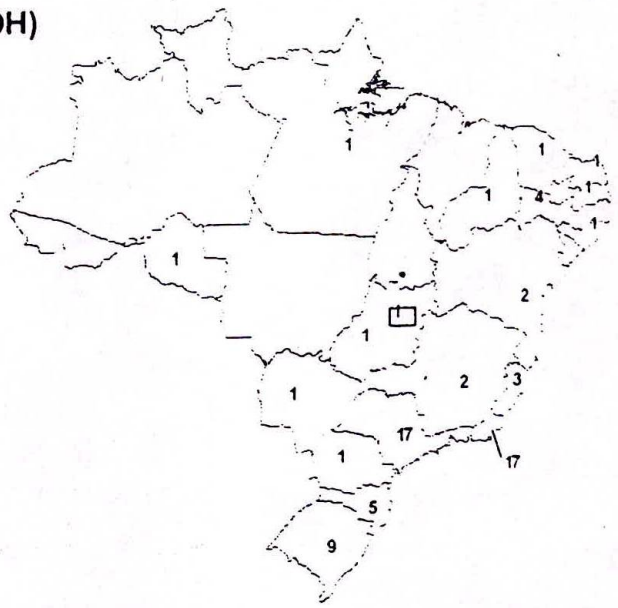
The Brazilian policy of acess to antiretroviral therapy has resulted in a shift of the morbidity and mortality profile of HIV infection and thus in the profile of service utilisation. In the past years, the demand for outpatient services has grown significantly with a decrease in the demand for Home Care, Day Hospital and Conventional Hospitalisation.

Distribution of specialized care services (SCS) on HIV/AIDS.

N° SCS = 148

Projects funded but not actually implemented yet are not shown.

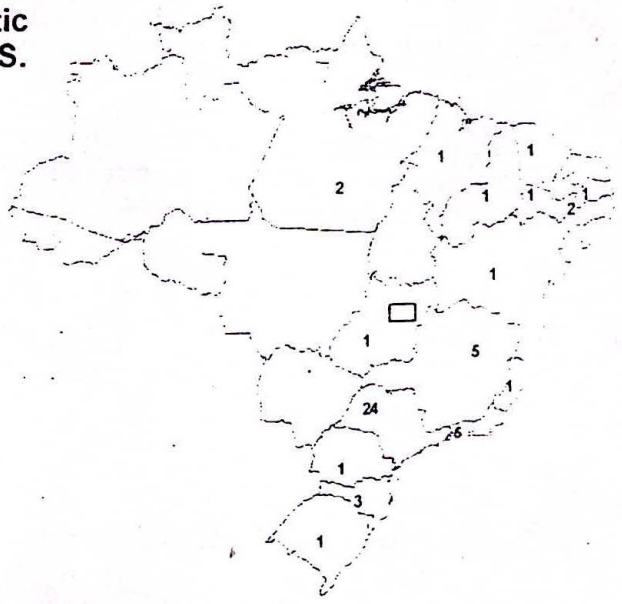
Distribution of Day Hospitals (DH) for HIV/AIDS care.



Nº DH = 69

Projects funded but not actually implemented yet are not shown.

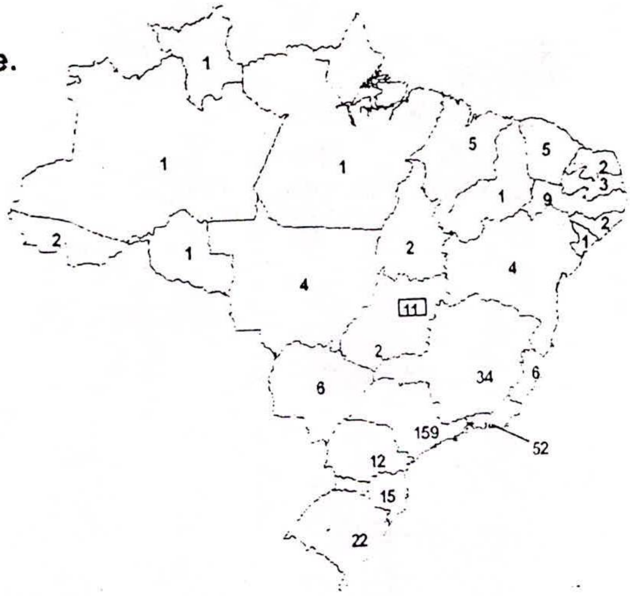
Distribution of Home Therapeutic Care Projects (HTC) on HIV/AIDS.



Nº HTC = 52

Projects funded but not actually implemented yet are not shown.

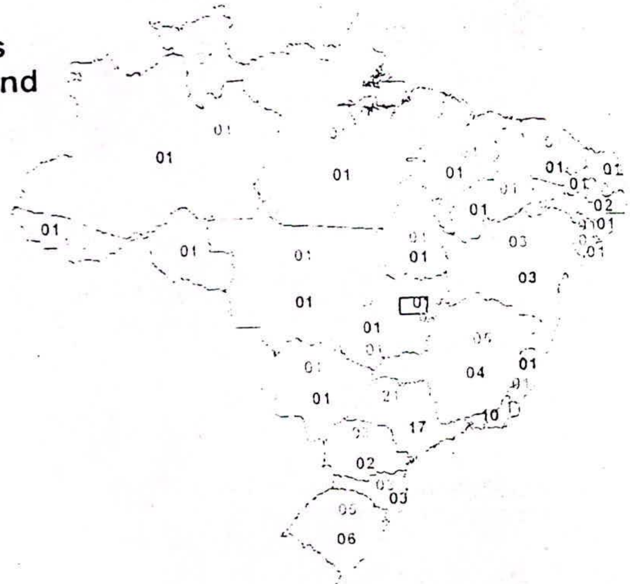
Distribution of Accredited Hospitals (AH) for HIV/AIDS care.



Nº AH = 362

Concomitant to the drug distribution policy, NAP has endeavoured to strengthen the public laboratories and implement the National Network of Laboratories for T CD4+ Lymphocyte Counts (70) and for HIV Viral Load Quantification (63). This network carries out the tests required for the indication of antiretroviral therapy and chemoprophylaxis of opportunistic infections, as well as for the appropriate monitoring of patients under treatment. In 2001, 422 thousand viral load tests and 422 thousand T CD4+ lymphocyte counts are expected, corresponding to a total expenditure of approximately US$ 18 million (unitary costs of US$ 15 per CD4+ test and US$ 29 per viral load test).

National network of laboratories for TCD4+ lymphocyte counts and viral load quantification - 2001



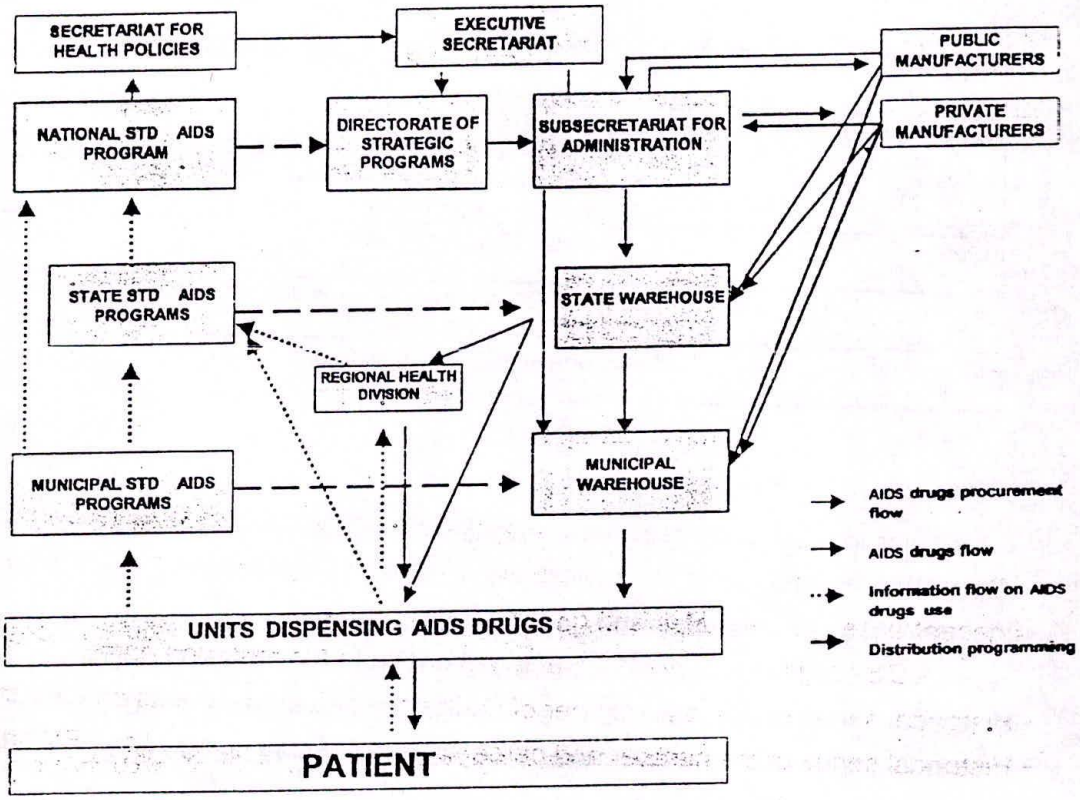
Viral load = 63 Lab.

T CD4+ = 70 Lab.

Source: MOH/Brazil

AIDS Drugs Logistic System

Logistics of AIDS Drugs - Ministry of Health



This flowchart shows the functioning of the AIDS drugs logistic system. Brown arrows indicate the procurement flow within the MoH, which starts with the programming of needs, done by NAP; green arrows demonstrate distribution programming; blue arrows, the different drug flows from delivery by the manufacturers to dispensation to the patient; and red arrows, the flow of information from the patient to NAP, including data essential for the distribution and procurement programming.

The current list of antiretrovirals provided by the MoH includes 13 drugs (5 nucleoside analog reverse transcriptase inhibitors-NRTI, 3 non-nucleoside analog reverse transcriptase inhibitors-NNRTI, and 5 protease inhibitors-PI), in 27 pharmaceutical presentations.

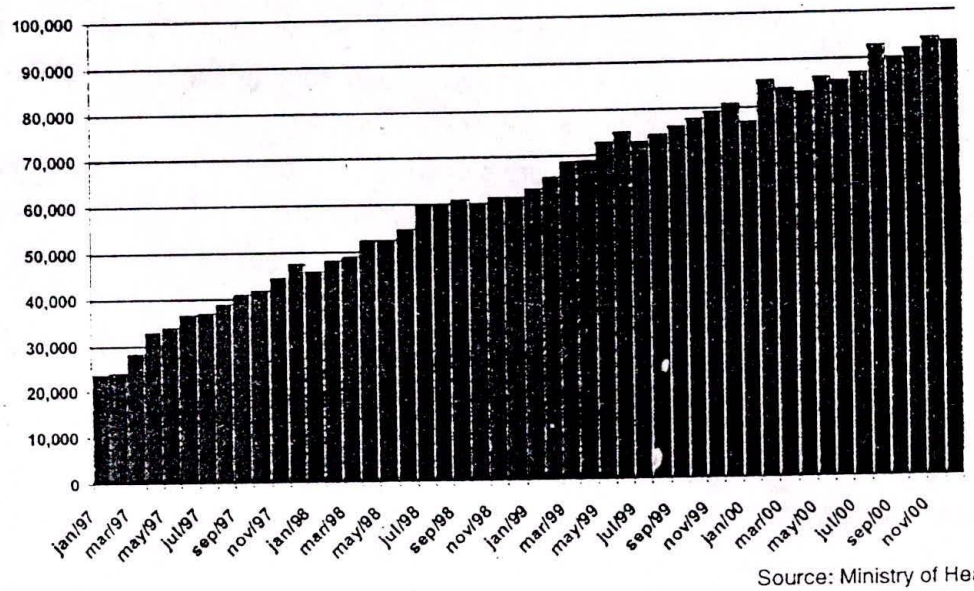
Year of first distribuition	Antiretroviral drugs
1991	zidovudine capsule 100 mg
1992	zidovudine oral solution
1993	didanosine 25 and 100 mg tablets
1996	zalcitabine 0.75 mg tablet, injectable zidovudine, lamivudine 150 mg tablet, saquinavir 200 mg capsule and ritonavir 100 mg capsule
1997	indinavir 400 mg capsule, lamivudine oral solution, stavudine 30 and 40 mg capsules
1998	ritonavir oral solution, didanosine pediatric powder, zidovudine+lamivudine 300+150 mg tablet, nelfinavir 250 mg tablet and pediatric powder, nevirapine 200 mg tablet, stavudine pediatric powder and delavirdine 100 mg tablet
1999	efavirenz 200 mg capsule
2000	efavirenz 50 and 100 mg capsules for pediatric patients and nevirapine oral suspension
2001	amprenavir 150 mg capsule and oral solution

It is important to highlight that while the Federal Government is responsible for ARV drugs, the procurement and distribution of drugs for treating opportunistic diseases is decentralised to the states and municipalities.

AIDS drugs needs are estimated according to the following data:

- Historical series of the total number of adult and paediatric patients on ARV therapy
- Historical series of the number and percentage of patients using each ARV drug and each therapeutic regimen
- New recommendations on ARV therapy

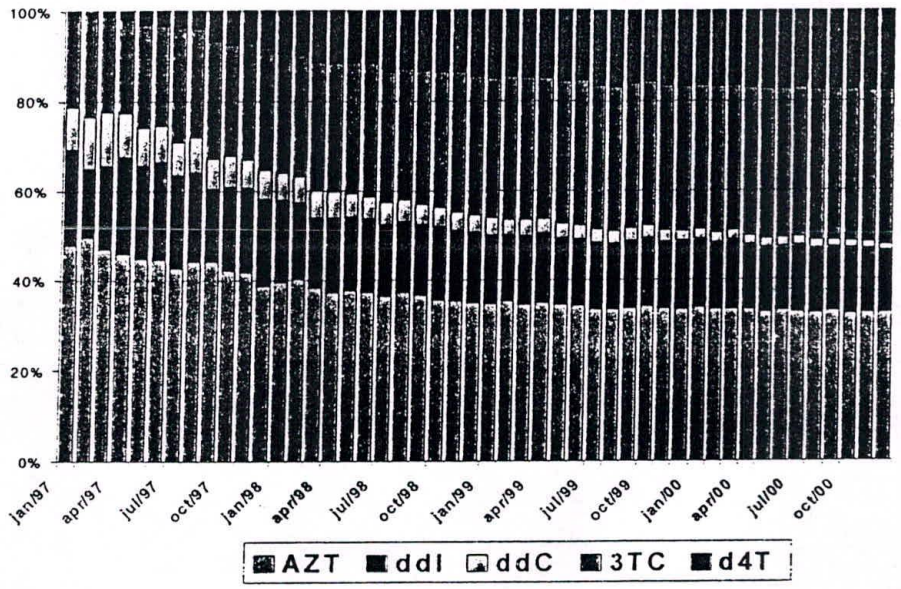
Number of HIV+ patients on ARV in the Brazilian Public Health System (Jan/97 - dec/00)



Source: Ministry of Health/Brazil

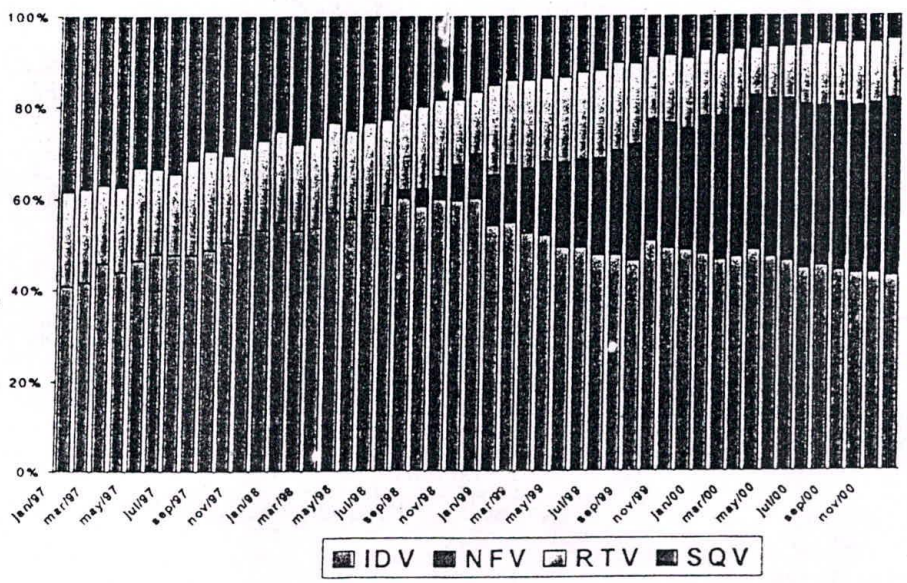
There are currently 98,000 infected individuals on antiretroviral treatment; 95% of which are adults and adolescents and 5% children (<13 years old). As a comparison, in January 1997, approximately 23,000 people benefited from the free access policy.

% distribution of NRTI use.
Brazil. Jan/97 - Dec/2000



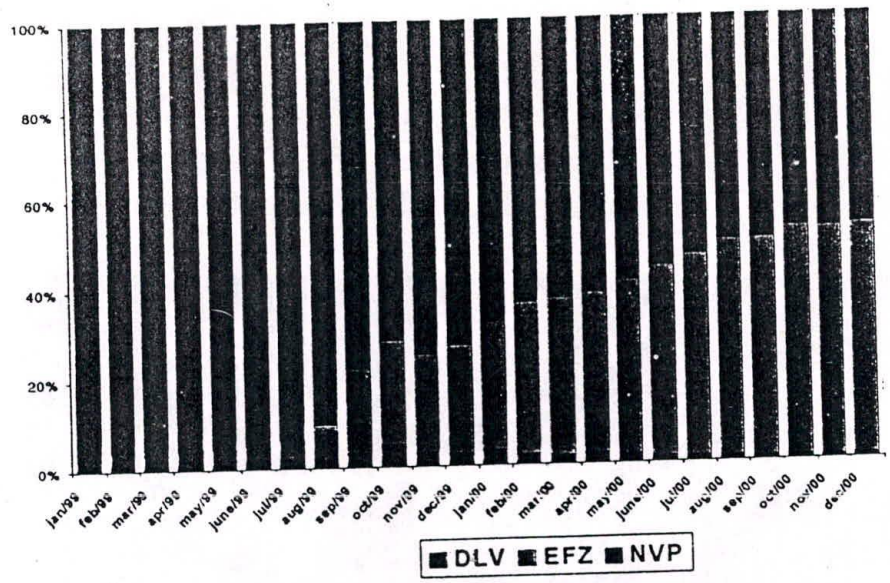
Source: Ministry of Health/Brazil

% distribution of PI use.
Brazil. Jan/97 - Dec/2000



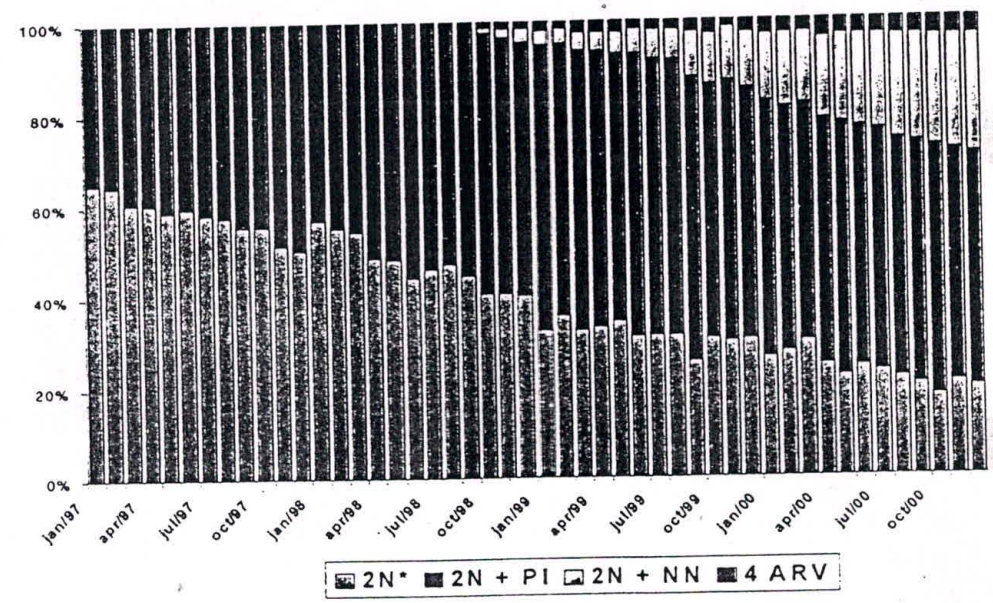
Source: Ministry of Health/Brazil

% distribution of NNRTI use. Brazil. Jan/99 - Dec/2000



Source: Ministry of Health/Brazil

% of patients by ARV regimen. Brazil, Jan/97 - Dec/2000

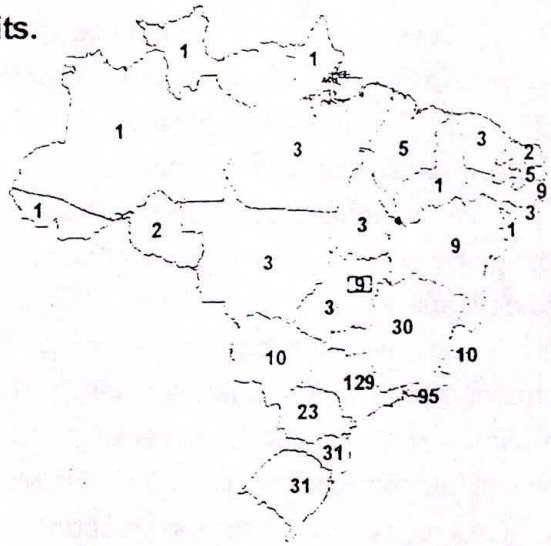


*Estimated data

Source: Ministry of Health/Brazil

Drug procurement is usually carried out once a year and complies with the Brazilian laws governing public bidding. Deliveries are usually divided in three to four consignments.

AIDS drugs dispensing units. Brazil, 2001



TOTAL = 424

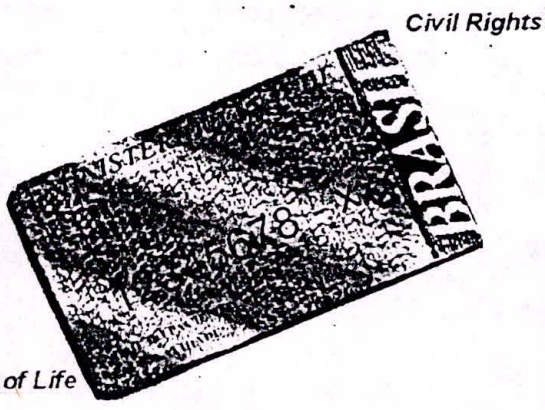
Patients receive ARV drugs in the Units Dispensing AIDS Drugs, which usually are the pharmacies of HIV/AIDS outpatient services. Currently there are 424 such units throughout the country.

NAP has developed a Computerised System for the Control of Drug Logistics (SICLOM), with the following main characteristics:

- Nation-wide patient register
- Registration linked to the individual drug dispensing unit
- Validation of the register and dispensation, using MoH criteria.
- Computerisation of the dispensing units
- Certification of the ARV prescription through a magnetic card
- Patient information on the appropriate use and storage of drugs
- Daily transfer of data to the NAP by telephone data transmission

SICLOM has been implemented in the 111 largest Dispensing Units, which account for approximately 65% of patients on ARV therapy in Brazil. A managerial module for SICLOM is now being developed by NAP.

Computerized System for the Logistical Control of Drugs



National production of antiretroviral drugs

Domestic production started in Brazil in 1993, with AZT by the private company. In the following year, AZT production in the public sector was begun by LAFEPE, Laboratório do Estado de Pernambuco. Domestic AIDS drugs production comprises 7 ARVs: zidovudine (AZT), didanosine (ddI), zalcitabine (ddC), lamivudine (3TC), stavudine (d4T), indinavir and nevirapine, and by the association zidovudine+lamivudine (AZT + 3TC). Three ARV drugs distributed by the MoH – amprenavir, efavirenz and nelfinavir - are under patent protection.

The national production of zalcitabine and stavudine started in 1997, that of didanosine in 1998, lamivudine and zidovudine+lamivudine in 1999 and of indinavir and nevirapine in 2000.

Public laboratories manufacturing ARVs are: Far-Manguinhos/FIOCRUZ/MoH, Fundação para o Remédio Popular/SP, Laboratório Farmacêutico do Estado de Pernambuco, Fundação Ezequiel Dias/MG, Indústria Química do Estado de Goiás, and Instituto Vital Brasil/RJ. In 2000, Far-Manguinhos provided approximately 30% of the ARV drugs used in Brazil, corresponding to 45% of the funds spent in purchases from national manufacturers. Eight Far-Manguinhos products – zidovudine capsules, didanosine tablets, lamivudine tablets, zidovudine+lamivudine tablets, zalcitabine tablets, stavudine capsule, indinavir capsule and nevirapine tablet - have been approved in bioequivalence tests and thus are eligible for licensing as a generic drug.

The quality control of the antiretrovirals distributed by the MoH is done by: (1) mandatory statement from the competent health authority in the country of manufacture, certifying that the plant complies with the Good Manufacturing Practices (GMP); (2) preliminary inspection of the pharmaceutical plant before the first delivery of the product; (3) monitoring of the production of the first batches; (4) in the early phases of the procurement contract, analysis of batches purchased at laboratories accredited by the National Health Surveillance Agency/MoH; and (5) starting in 2001, mandatory bioequivalence testing of all drugs purchased. Bioequivalence tests, certifying drug interchangeability, are a recent achievement of the Brazilian National Drug Policy, guaranteed by the 1999 Generic Drugs Bill. The Brazilian bioequivalence process comprises pharmaceutical, clinical, analytic and statistical testing. Clinical studies are carried out mainly by the quantification of the drug or its active metabolite in the circulation (most commonly in blood, plasma or serum samples) of healthy volunteers, who receive the drugs being tested and the reference drugs at different times, in single or multiple dose regimens. This is a complex study and it requires the submission of a research project, experimental protocol, free and informed consent form, and approval by the Committee of Ethics in Research.

Drug expenditures and decrease of ARV therapy costs

The Federal Government's expenditures with the purchase of antiretrovirals was approximately US$ 34 million in 1996, US$ 224 million in 1997, US$ 305 million in 1998, US$ 336 million in 1999 and US$ 303 million in 2000; it is estimated that they will reach US$ 422 million in 2001. Between 1999 and 2000, in spite of increased numbers of patients on treatment and of the proportion of patients on more complex and expensive regimens, there was a reduction in the overall costs of drug procurement. These expenditures corresponded to 0.2% of the MoH budget in 1996, 1.2% in 1997, 1.8% in 1998, 3.2% in 1999, and 2.9% in 2000, with an estimated 2.9% in 2001. In terms of GDP, they have ranged between 0.004% in 1996 to 0.06% in 1999.

MOH expenditures on ARV drugs (1996-2001)

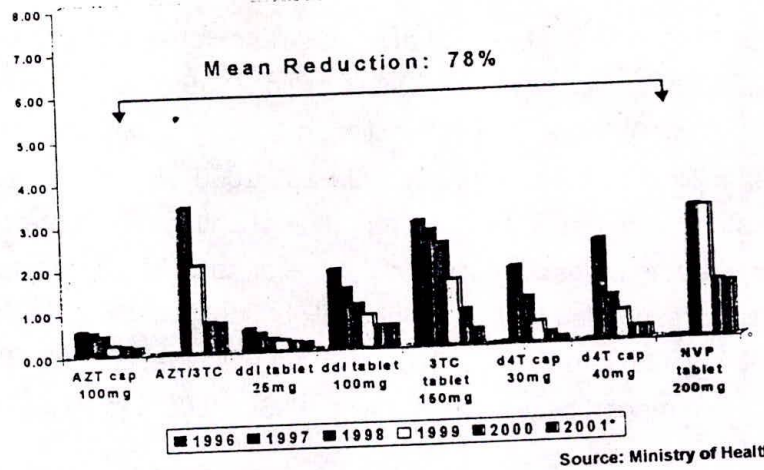
Year	Million US$	Average nº patients	% MOH budget
1996	34	-	0.2
1997	224	35,900	1.2
1998	305	55,600	1.8
1999	336	73,000	3.2
2000	303	87,500	2.9
2001*	422	105,000	2.9

* estimated data

Source: NAP/MoH

The prices of antiretroviral drugs purchased by the MoH have shown a declining trend over the past few years, largely due to the MoH investments to foster the production by public manufacturers and to the policy of price negotiation in the case of single exclusive manufacturers. The most significant drops are seen in the prices of drugs that are domestically produced, both by private national companies and especially by public manufacturing laboratories, and in prices negotiated with multinational companies that have adopted the system of differentiated prices, according to the Human Development Index and rate of HIV infection in the country's adult population.

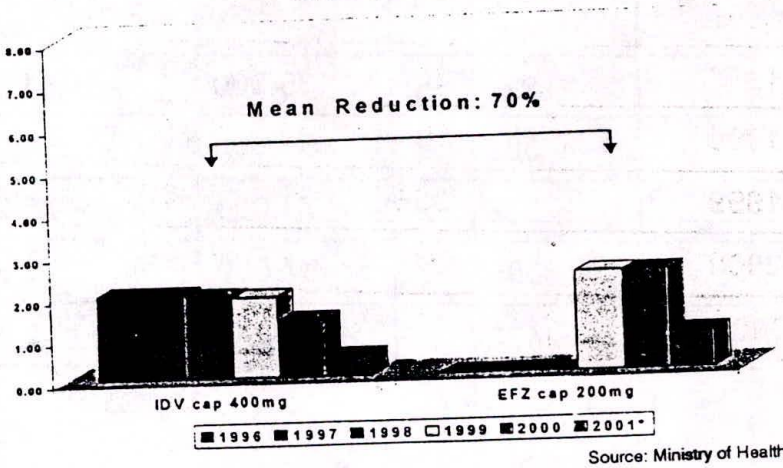
Price evolution (in US$) of ARV for adult use with domestic production. Brazil, 1996 - 2001



Source: Ministry of Health/Brazil

*Estimated data

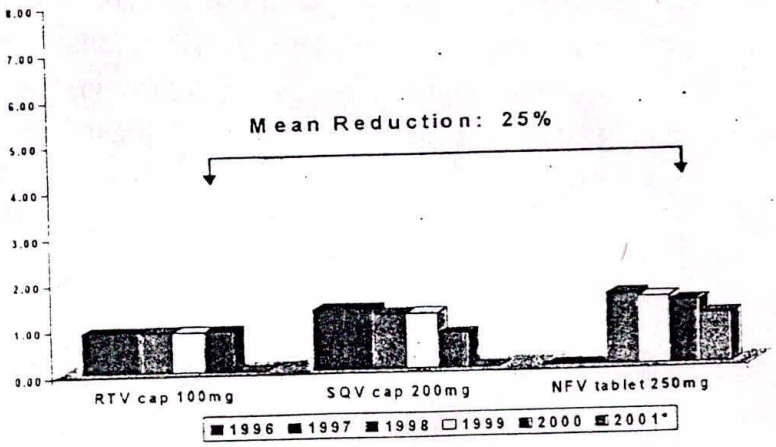
Price evolution (in US$) of ARVs, with negotiation based on differenciated prices (HDI and HIV prevalence in the country). Brazil, 1996 - 2001



Source: Ministry of Health/Brazil

*Estimated data

Price evolution (in US$) of imported ARVs for adult use. Brazil, 1996 - 2001



Source: Ministry of Health/Brazil

*Estimated data

Prices of ARV drugs. Brazil. 1996 a 2001

DRUG	Unit price US$[1]					
	1996	1997	1998	1999	2000	2001[2]
DIDANOSINE 25 mg Tab	0.52	0.41	0.26	0.23	0.19	0.16
DIDANOSINE 100 mg Tab	1.85	1.39	1.02	0.76	0.50	0.49
DIDANOSINE POWDER FOR BOTTLE/ORAL SOLUTION 4g	(a)	(a)	60.19	37.81	38.15	33.48
LAMIVUDINE 150 mg Tab	2.90	2.70	2.39	1.51	0.81	0.34
LAMIVUDINE ORAL SOLUTION 240ml BOTTLE/10 mg/ml	(a)	45.57	31.18	12.05	12.54	(b)
ESTAVUDINE 30 mg Tab	(a)	1.75	1.03	0.46	0.21	0.19
ESTAVUDINE 40 mg Cap	(a)	2.32	1.02	0.64	0.27	0.27
ESTAVUDINE POWDER FOR ORAL SOLUTION 200mg BOTTLE	(a)	(a)	41.79	35.10	34.45	(b)
ZALCITABINE 0.75 mg Tab	1.55	1.08	0.58	0.18	0.08	(d)
ZIDOVUDINE 100 mg Cap	0.56	0.53	0.45	0.21	0.18	0.15
ZIDOVUDINE 10 mg/ml ORAL SOLUTION 200 ml BOTTLE	10.22	9.17	8.47	6.30	4.47	(b)
INJECTABLE ZIDOVUDINE 10 mg/ml 20 ml vial	13.40	11.93	11.07	2.46	2.11	1.75
ZIDOVUDINE+LAMIVUDINE 300 mg + 150 mg Tab	(a)	(a)	3.38	2.01	0.70	0.68
EFAVIRENZ 50 mg Cap	(a)	(a)	(a)	0.65	0.65	(b)
EFAVIRENZ 100 mg Cap	(a)	(a)	(a)	1.3	1.3	(b)
EFAVIRENZ 200 mg Cap	(a)	(a)	(a)	2.32	2.32	0.84
DELAVIRDINE 100 mg Tab	(a)	(a)	0.48	0.48	(d)	(d)
NEVIRAPINE 200 mg Tab	(a)	(a)	3.04	3.02	1.28	1.25
NEVIRAPINE 10 mg/ml ORAL SUSPENSION 240 ml BOTTLE	(a)	(a)	(a)	(a)	55.87	(b)
AMPRENAVIR 150 mg Cap	(a)	(a)	(a)	(a)	(a)	0.72
AMPRENAVIR 15 mg/ml ORAL SOLUTION 240 ml BOTTLE	(a)	(a)	(a)	(a)	(a)	99.76
INDINAVIR 400 mg Cap	2.00	2.00	1.94	1.91	1.34	0.47
NELFINAVIR 250 mg Tab	(a)	(a)	1.53	1.45	1.36	1.08
NELFINAVIR POWDER FOR ORAL SOLUTION 7.2 g BOTTLE	(a)	(a)	52.40	52.40	(b)	(c)
RITONAVIR 100 mg Cap	0.90	0.90	0.88	0.88	0.88	(c)
RITONAVIR 80 mg/ml ORAL SOLUTION 240 ml BOTTLE	(a)	222.41	168.94	168.94	168.94	(b)
SAQUINAVIR 200 mg Cap	1.31	1.31	1.19	1.19	0.75	(c)

(a) ARV not offered by the MoH in the year
(b) procurement not programmed in the year
(c) procurement in progress
(d) ARV no longer purchased by the MoH

Source: NAP and Directorate for Strategic Programs/MoH

Notes: (1) ARV purchased in R$ converted in US$ using the mean year exchange rate. except for 2001
(2) preliminary data
(3) 2000 data estimated by Far-Manguinhos

A study designed to assess the impact of the domestic ARV production on the cost of treatment between 1997 and 2000, using the average cost per patient/day in 1997 as a baseline and taking into account the increase of the number of patients on treatment, estimated that, had the 1997 cost remained constant, the expenditure would have been between US$ 200 million and US$ 250 million higher, and total ARV therapy costs would have exceeded US$ 400 million in 2000. Considering only indinavir and nevirapine, drugs that are part of the triple therapy, whose domestic production was started in 2000, it was estimated that savings were greater than US$ 80 million, accounting for approximately 30% of the total costs in the year.

In a second moment, the study assessed the economic impact of domestic AIDS drug production, by comparing average patient/day costs calculated for 2000 with prices in the private US sector and in the public Canadian sector (British Columbia). In relation to Canadian prices, the economy was calculated as approximately US$ 200 million; in relation to US prices, of 540 million dollars.

The same study assessed the impact of annual costs of ARV therapy in the years 2001-2004, in case of continuing patent protection of nelfinavir and efavirenz, using as baseline data:

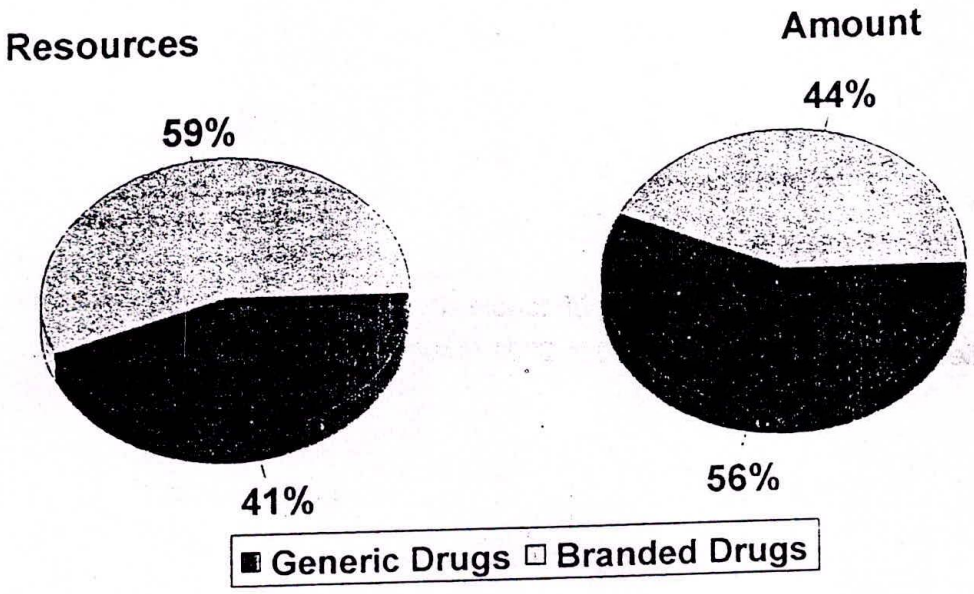
- The proportion of nelfinavir and efavirenz in the period 2001-2004, estimated by statistical methods, assuming that ARV use will keep its current rate of increase until the first semester of 2001 and stabilise in early 2003.
- The projected average costs of ARV therapy per patient/day in 2001-2004, based on the trend of variation of drug costs in 1997-2000. Two different projections were made for nelfinavir and efavirenz. The first assumes the beginning of domestic production in the second semester of 2001, and costs for 2001-2004 were projected with the same declining trend observed in 1999-2000 after the start of national production of triple therapy drugs. The second assumes continuing import of the drugs with prices unchanged.

According to this study, if domestic production of both drugs is started, the average cost of ARV therapy by patient/day will fall by approximately 30% in 2001 and the cost of ARV drugs will remain close to US$ 300 million in the following years, in spite of the expected increase in the number of patients in treatment to 160,000 by the end of 2004.

On the other hand, if both drugs continue to be imported, with no price reduction, there would be an additional cost of US$ 425 million in the period 2001-2004.

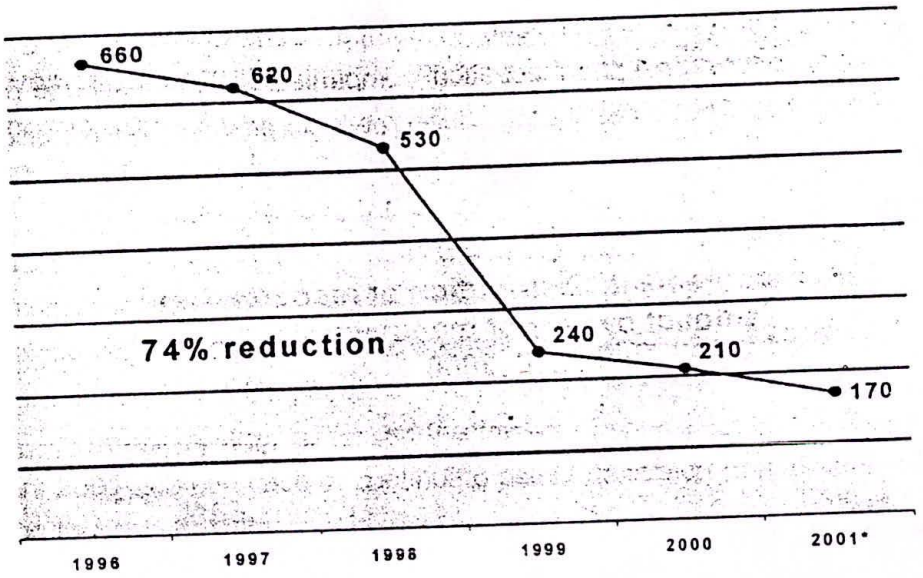
In 1999, 47% of antiretroviral drugs, accounting for 19% of the expenditures, were purchased from national companies (92.5% from public and 7.5% from private manufacturers); 53%, corresponding to 81% of the expenditures, were purchased from multinational pharmaceutical companies. In 2000, 56% of ARVs (41% of the expenditures) were purchased from national companies and 44% (59% of the expenditures), from multinational pharmaceutical companies. It is interesting to point out that, some drugs that were domestically produced were still provided by multinational companies, which lowered their prices and won governmental bids.

ARV procurement: Distribution of resources and amount by type of manufacturer. Brazil, 2000



This reduction of ARV prices in Brazil led to a considerable decrease in the costs of AZT chemoprophylaxis for the control of HIV vertical transmission (complete ACTG 076) from US$ 660 in 1996 to US$ 170 in 2001 (74% variation).

Costs of ZDV chemoprophylaxis (in US$) for the reduction fo vertical transmission - ACTG 076. Brazil, 1996 - 2001

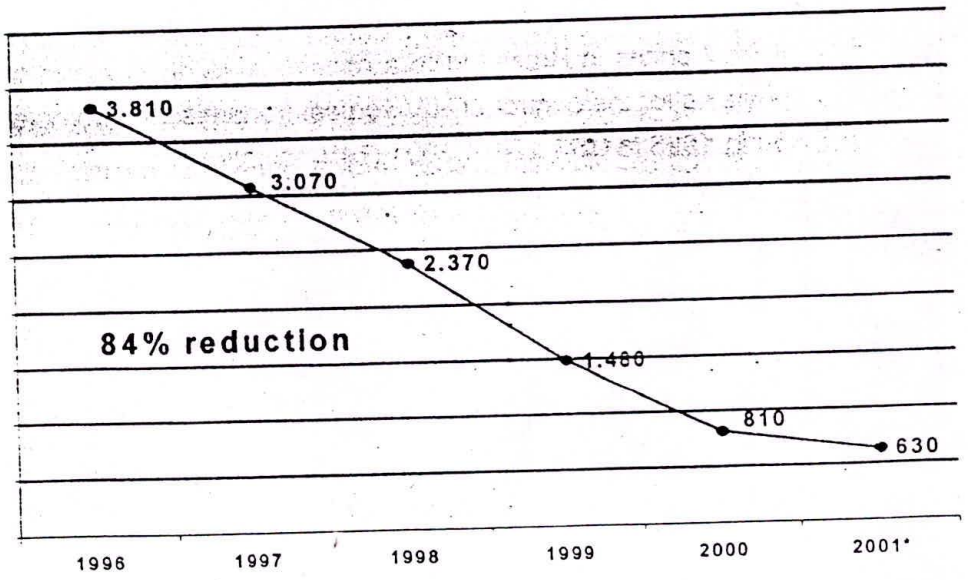


Source: Ministry of Health/Brazil

*Preliminary data

The mean weighted cost of double NRTI therapy dropped from US$ 3,810 per patient/year in 1996 to US$ 630 in 2001 (preliminary data), with a 84% reduction.

Mean cost (in US$) of double NTRI therapy per patient/year. Brazil, 1996 - 2001

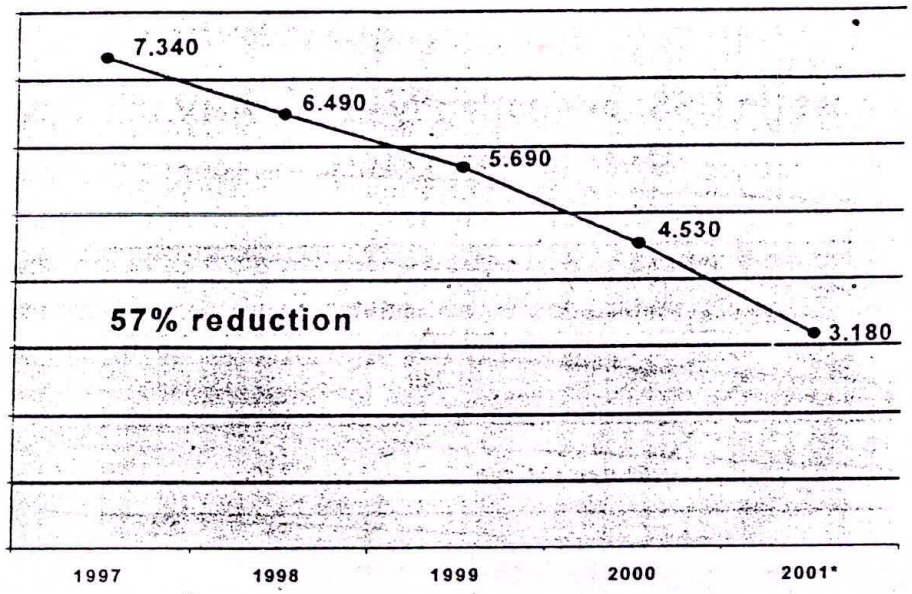


Source: Ministry of Health/Brazil

*Preliminary data

The reduction of the mean weighted cost of triple regimens including PIs or NNRTIs is estimated at 57% and 66%, respectively.

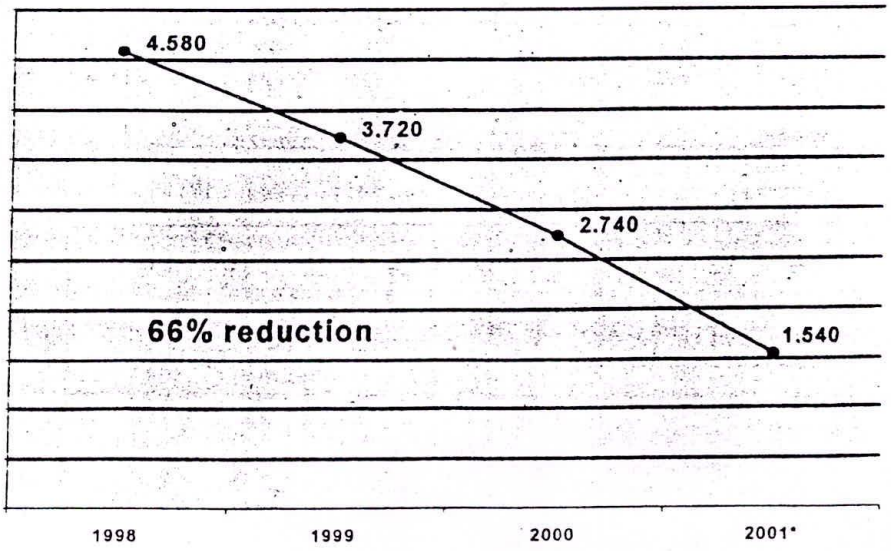
**Mean cost (in US$) of triple therapy (2 NTRI + PI) per patient/year.
Brazil, 1996 - 2001**



*Preliminary data

Source: Ministry of Health/Brazil

**Mean cost (in US$) of triple therapy (2 NTRI + NNRTI) per patient/year.
Brazil, 1998 - 2001**

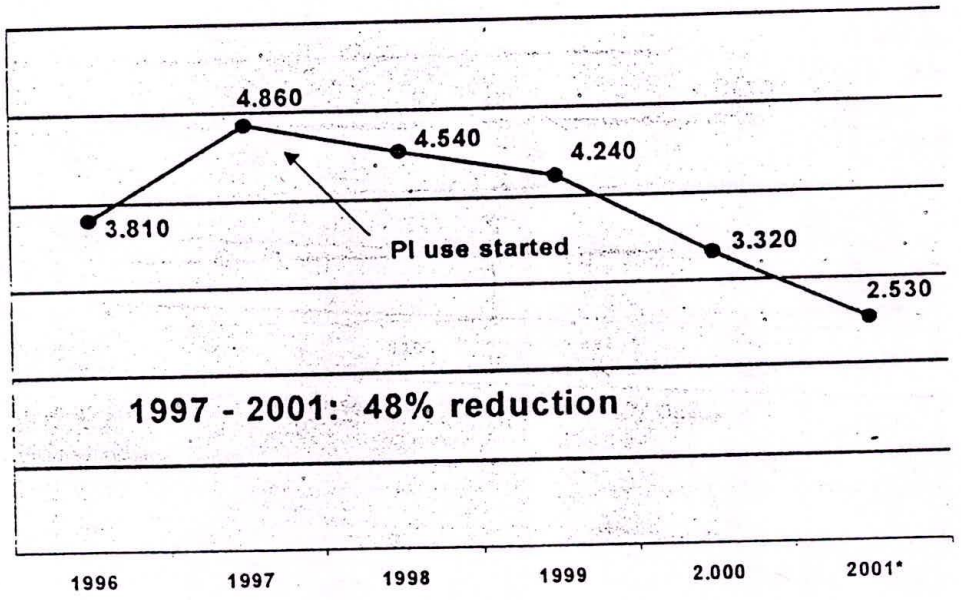


*Preliminary data

Source: Ministry of Health/Brazil

The mean weighted cost per patient/year on ARV therapy showed an increase between 1996 and 1997, associated with the beginning of PI distribution. In 2001, this cost should be 48% lower (US$ 4,860 in 1997; US$ 2,530 in 2001, according to preliminary data), in spite of the proportional increase in the number of patients using more complex and expensive therapeutic regimens.

Mean cost (in US$) per patient/year on ARV therapy. Brazil, 1996 - 2001



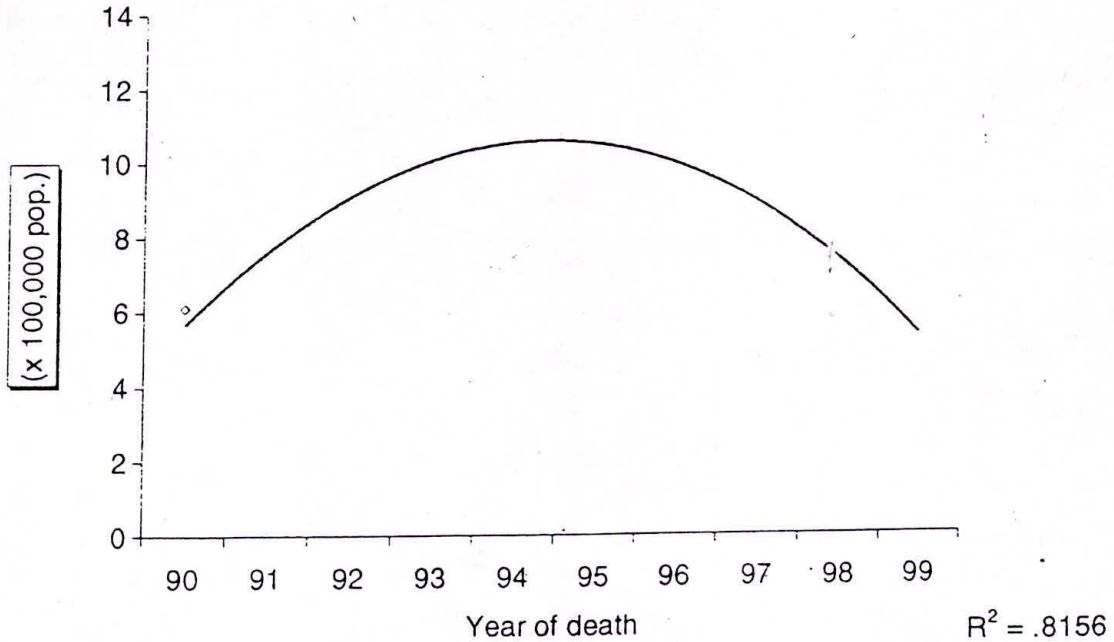
*Preliminary data

Source: Ministry of Health/Brazil

Impact of the antiretroviral therapy

The policy of providing ARV drugs policy guarantees a longer survival for HIV+ individuals, minimising the impact of the epidemic on the population groups infected, particularly those in productive age ones. Moreover, the universal access program, together with other initiatives, such as the more widespread use of chemoprophylaxis for the main opportunistic infections and the different types of care available (Day Hospital and Home Care), has allowed a decrease in the need for hospital admissions, with a consequent reduction of costs, as well as a fall in the frequency of opportunistic infections. As for the decrease in deaths, a marked reduction in AIDS-related mortality has been observed in recent years. In 1995, the AIDS death rate was 12.2 per 100,000 population; in 1999, it had dropped to 6.3/100,000 population, a reduction of approximately 50%. In large urban centres such as São Paulo and Rio de Janeiro (which account for more than 31% of the known AIDS cases in the country), the decrease in mortality has been even more marked, of approximately 70% (SP - 54%, Rio - 73%) in the period 1995-2000 (data up to August 2000).

Trend of aids death rates.
Brazil, 1990 - 1999



As to costs, some studies have shown that the price of antiretroviral therapy is largely offset by the reduction of costs with drugs for the treatment of opportunistic infections and with the ensuing hospitalisations. The analysis of data at the MoH has shown a significant drop in the number of hospitalisation/patient; it estimated that approximately 234,000 AIDS-related hospital admissions were prevented in the period 1997-2000, with US$ 677 million savings for the Unified Health System. In the case of CMV infection, for instance, a condition affecting individuals at an advanced stage of HIV infection and that may cause blindness, data on the use of ganciclovir for its treatment show a 69% decrease in the period 1997–1999; in the past two years, this meant a savings of approximately US$ 34 million.

Adherence to antiretroviral therapy

Combined antiretroviral therapy not only contributes to a longer life span for HIV+ individuals but also to a better quality of life, directly related to a better physical and emotional status. These individuals, mostly in the economically active age group, remain productive and thus do not divert Social Security funds with illness aid, retirement pensions for disability reasons, and other such benefits.

It is clear that patient adherence to multiple doses therapeutic regimens is crucial to the clinical management of this disease, since non-adherence to antiretroviral treatment is directly linked to the development of viral resistance, the consequent therapy failure and the emergence of multiresistant viral strains.

A study carried out in São Paulo has shown that certain characteristics of users' groups are risk factors for non-adherence, particularly less than 4 years of schooling and lack of personal income.

The history of HIV+ individuals registers the overcoming obstacles, mainly those related to adjustments of lifestyle and issues pertaining to the stigma of the disease. One critical moment is the beginning of treatment, when the need to accept the condition and to establish a reliable rapport with the physician and the health services is clearly seen.

The health services have an extremely important role in overcoming treatment-related difficulties, and their dialogue and negotiation abilities are crucial.

Antiretroviral adherence in Brazil seems very similar to that seen in First-world countries. However, the rates achieved everywhere are still far from the desired levels. A study on adherence that defined it as taking 80% or more of the total prescribed doses has shown 69% adherence among more than one thousand patients interviewed. Similar studies carried out in Baltimore (202 patients), London (114 patients) and San Francisco (388 patients) demonstrated similar rates (60%, 75% and 78%, respectively).

Comparative results of ARV therapy adherence studies.

Site	Nº patients	% compliance	Adherence rate
São Paulo/Brazil	1141	80	69
Baltimore/USA	202	80	60
London/UK	114	80	75
San Francisco/USA	388	80	78
Madrid/Spain	366	90	57,6

Co-operation between Brazil and other developing countries

A considerable part of the success achieved by the Brazilian drug distribution program is due to the development of quality generic antiretroviral drugs by Brazilian manufacturing laboratories, at costs significantly below those practised in the international market. The Brazilian expertise in AIDS drug manufacturing was offered to developing countries, particularly in Africa, during the XIII International AIDS conference held in Durban, South Africa, in July 2000. In a spirit of co-operation and international solidarity, Brazil can currently promote the transfer of technology for the establishment of industrial ARV production poles. Such transfer includes technical support for the design and construction of the production plant, manufacturing of drugs as capsules and tablets (all produced in Brazil), training in quality control of raw materials and transfer of analytic methods. Some countries, like South Africa and Uganda, have shown an interest in obtaining the Brazilian technology and others, like Chile, Burkina Faso, Barbados and Guatemala, in direct drug purchase, through point co-operation actions.

Brazil has signed co-operation agreements with four Portuguese-speaking African countries (Angola, Mozambique-Guiné-Bissau and São Tomé and Príncipe). Seven other African countries have shown an interest in exchanges with Brazil – Portuguese-speaking Cape Verde and English-speaking Namibia, Zimbabwe, South Africa, Kenya, Nigeria and Botswana.

D. The HIV/AIDS Context

- *"Community-based approaches to HIV treatment in resource-poor settings"*
  Paul Farmer, F Lændre, J Mukerjee, M Sidonise Claude, P Nevil, MC Smith-Fawzi, S Koenig, A Castro, M Becerra, J Sachs, A Attaran J Yong Kim; The Lancet

- *"Preventing antiretroviral anarchy in sub-Saharan Africa"*
  AD Harries, DS Nyangulu, NJ Hargreaves, O Kaluwa, FM Salaniponi; The Lancet

- *"Friend or Foe? Looking to International Law in the Struggle of Access to Treatment for HIV/AIDS"*
  Jonathan Berger, Paper Presented at the "Post UNGASS Meeting: Social and Economic Rights in Global HIV/AIDS Epidemic", hosted by the Centre for Economic and Social Rights

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Viewpoint

Community-based approaches to HIV treatment in resource-poor settings

Paul Farmer, Fernet Lándre, Joia S Mukherjee, Marie Sidonise Claude, Patrice Nevil, Mary C Smith-Fawzi, Serena P Koenig, Arachu Castro, Mercedes C Becerra, Jeffrey Sachs, Amir Attaran, Jim Yong Kim

Lancet 2001; **358:** 404-09

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Last year, HIV surpassed other pathogens to become the world's leading infectious cause of adult death. More than 90% of deaths occur in poor countries, yet new antiretroviral therapies have only led to a drop in AIDS deaths in industrialised countries. The main objections to the use of these agents in less-developed countries have been their high cost and the lack of health infrastructure necessary to use them. We have shown that it is possible to carry out an HIV treatment programme in a poor community in rural Haiti, the poorest country in the western hemisphere. Relying on an already existing tuberculosis-control infrastructure, we have been able to provide directly observed therapy with highly-active antiretroviral therapy (HAART) to about 60 patients with advanced HIV disease. Inclusion criteria and clinical follow-up were based on basic laboratory data available in most rural clinics. Serious side-effects have been rare and readily managed by community-health workers and clinic staff. We discuss objections to the widespread use of HAART, and suggest that directly-observed therapy of chronic infectious disease with multidrug regimens can be highly effective in settings of great privation as long as there is sustained commitment to uninterrupted care that is free to the patient.

Why AIDS prevention alone is insufficient

The dimensions of the global HIV crisis are such that predictions termed alarmist a decade ago are now revealed as sober projections.[1] In 2000, HIV overtook tuberculosis as the world's leading infectious cause of adult deaths. HIV has, in fact, overtaken the 1918 influenza epidemic as the most devastating communicable cause of adult death since the bubonic plague of the 14th century.[2] The social impact of HIV has been particularly severe in Africa, where an estimated 14 million children have been orphaned by AIDS; if trends hold, 40 million African children will be orphaned by the close of this decade.[3,4] Because poverty and social inequalities are leading co-factors in HIV transmission, the virus promises to wreak similar havoc in India and other parts of Asia.[5] At the same time, AIDS mortality has dropped precipitously in affluent countries, in large part because of access to highly-active antiretroviral therapy (HAART).[6,7,8] This ever-widening outcome gap is evident globally.

The response of the affluent countries and their institutions--from aid agencies, non-governmental organisations, and the pharmaceutical industry--has been insufficient. (The death toll and increasing HIV incidence are the most eloquent rebuke to contrary assessments.) The quasitotality of AIDS assistance to the heavily-burdened countries has consisted of the promotion of education and condom distribution to prevent HIV transmission. It has taken two decades to acknowledge the central irony of AIDS prevention: "Towards the end of the second decade of the AIDS pandemic, we still have no good evidence that primary prevention works."[9] Many of those at greatest risk already know that HIV is a sexually transmitted pathogen and that condoms could prevent transmission. Their risk stems less from ignorance and more from the precarious situations in which hundreds of millions live; gender inequality adds a special burden, and is the main reason that, globally, HIV incidence is now higher among women than among men.[10,11]

Clearly, the prevention strategies currently in use will not inflect HIV incidence among the poorest populations, even though these prevention strategies have proven effective in settings from San Francisco to Thailand and merit greater support. Other complementary strategies, including vaccines protective against clades prevalent in Africa, are needed if the most vulnerable are to be protected.

The acknowledgment that there is the need for better prevention is important, and it is also time to turn our attention to the more than 30 million individuals already living with HIV.[12] They need more than palliative care. The programmes extolled as "community-based care" or "home care" are inadequate whenever these terms are euphemisms to describe what amounts to hospice, and not very good hospice at that: no real analgesia, no antifungals, too few antibacterials, and no parenteral lines for rehydration.

There is an unmentioned elephant in the conference rooms of many scientific meetings: the prospect of providing HAART to those living with both poverty and HIV. Even though this describes 90% of the potential beneficiaries of recent therapeutic developments, use of HAART in poor countries is rarely the primary topic of discussion in scientific congresses. Access to treatment is, however, the primary topic of discussion in communities beset by HIV, just as it is the primary topic of discussion among AIDS activists. Some groups in sub-Saharan Africa already express hostility to humanitarian organisations and funders who express interest only in education and condom promotion. We report our experience of treating HIV disease in a poor community in rural Haiti and examine the main objections to making HAART available in resource-poor settings.

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One community's experience: the HIV Equity Initiative

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One community's experience: the HIV Equity Initiative

Haiti is by all conventional criteria the poorest country in the western hemisphere and one of the poorest in the world:[13] per capita gross national product (GNP) is around US$400; unemployment exceeds 70%; and fewer than one in 50 Haitians have regular employment.[14] Not coincidentally, Haiti is also the hemisphere's most HIV-burdened country.[15] In 1999, UNAIDS reported national HIV seroprevalence as 5% among women attending antenatal clinics--and rates were twice as high in urban slums.[11] The latest estimates of life expectancy at birth are 475 years for men and 492 years for women, with HIV considered the chief contributor to premature adult death.[16]

Initially an urban epidemic, HIV prevalence is lower in rural Haiti, where we have worked for more than 15 years. Most of the local inhabitants in the lower Central Plateau are peasant farmers working small plots of infertile land. Many are sharecroppers. Local health indicators are worse than national estimates.

Our clinical facility, founded in 1985 in the middle of a settlement of individuals displaced by a hydroelectric dam, documented its first case of HIV disease in 1986. Following international convention, prevention efforts were tightly linked to education and condom promotion.[17] These efforts have been hampered by political violence and resulting migration, and by gender inequality and poverty, which conspire to make the male condom an imperfect prevention measure. Thus, HIV transmission continued in spite of aggressive prevention campaigns.[18]

Our modest therapeutic efforts have been aggressive when compared with other clinics in poor, rural regions of the less-developed world. Shortly after the publication of the ACTG-076 trial,[19] we began offering zidovudine to pregnant women to block mother-to-child transmission. More than 90% of women offered HIV testing accepted it after zidovudine was made available free of charge; dramatic declines in vertical HIV transmission ensued. In 1997, we began offering post-exposure prophylaxis with a three-drug regimen (usually zidovudine, 3TC, and a protease inhibitor) to victims of rape or professional injury.[20] Beginning in late 1998, a small number of patients with long-standing HIV disease who no longer responded to syndromic treatment of opportunistic infections were offered directly observed HAART.

Inclusion criteria for HAART have not been codified rigidly, but follow a certain logic in the absence of CD4 lymphocyte counts and viral-load testing. Patients assessed for HAART are those with chronic enteropathies or other forms of HIV-associated wasting; patients with presumed neurological complications of HIV (encephalopathy, distal- sensory, or other polyneuropathies); those with repeated opportunistic infections unresponsive to antibacterials and antifungals; and patients with severe leukopaenia, anaemia, or thrombocytopaenia (panel 1). Assessments are done by two physicians, one with infectious-disease training.

Panel 1: **Guidelines for inclusion in DOT-HAART project, Clinique Bon Saveur**

- Absence of active tuberculosis
- Recurrent opportunistic infections difficult to manage with antibacterials or antifungals
- Chronic enteropathy with wasting
- Otherwise unexplained and significant weight loss
- Severe neurologic complications attributable to HIV

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- Severe leukopaenia, anaemia, or thrombocytopaenia

Patients diagnosed with active tuberculosis are not offered HAART because most respond to antituberculous therapy and are subsequently symptom-free for long periods of time, often years. It is significant, then, that most patients diagnosed with HIV infection present with active tuberculosis, as figure 1 shows.[21]

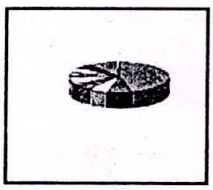

Figure 1: **Presenting diagnoses in 200 patients with HIV disease, Clinique Bon Sauveur, 1993-95**

From reference 21.

In our clinic, directly observed therapy with HAART (DOT-HAART) is modelled on successful tuberculosis-control efforts. That is, each HIV patient has an *accompagnateur* (often a community-health worker) who observes ingestion of pills; responds to patient and family concerns; and offers moral support (figure 2). Social support--including assistance with children's school fees--is included in services offered. Monthly meetings, in which patients discuss their illness and other concerns, are notable for high attendance (figure 3).

Figure 2: **Accompagnateur training, Thomonde, Haiti**

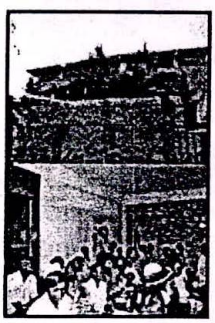

Figure 3: **Medical and human-resources infastructure necessary to implement DOT-HAART**

Top: Thomas J White Center, Cange, Haiti.Bottom: monthly patient meetings notable for high attendance.

Response to HAART in an initial cohort of 60 patients has been dramatic (panels 2-4). Side-effects have been rare and readily managed (only six patients have required a change in regimen). As elsewhere, patients receiving HAART are far less likely to require admission to hospital than are patients with untreated HIV disease.[22] In the event that ambulatory care is not feasible for the initiation of HAART or for the treatment of an acute illness, patients with HIV are admitted to

the general ward, which is in a facility separate from the tuberculosis ward.

Panel 2: **Enna, 26-years-old**

Enna has already had six children. Born to an impoverished family in Savanette, she was sent to Port-au-Prince as a *restavèk*--a child servant--at 10 years of age: "I used to mop the floor and cook. I also used to babysit." Enna was not paid but "they gave me food to eat." At age 14, she was raped: "A man who was a friend of the family where I was staying raped me. He waited until no one was home, then he jumped on me. I was just a child; I did not know what was happening. This happened four times, and then I was pregnant. The family [in Port-au-Prince] sent me away." Enna returned to Savanette, where she almost died in childbirth. She later sold produce in regional markets and in Port-au-Prince. At 18 years of age, while sleeping in a communal market depot, Enna was raped by three men. "I didn't see them, so what could I tell the police? Besides, I was afraid of the police." Enna regards "my entire life as a disaster. I had three children for two different men, but neither of them would help me [financially]." In 1997, sapped by recurrent fevers and chronic diarrhoea, she was diagnosed with tuberculosis and HIV co-infection. Treated for tuberculosis, she gained weight but later developed oropharyngeal candidiasis and mental slowing. She lost weight and had intermittent diarrhoea. Enna received zidovudine during her sixth pregnancy, but the newborn baby died of severe jaundice. When her weight dropped to 108 lb, she was started on a regimen of zidovudine, 3TC, and efavirenz. She gained 9 lb in the first 6 months of therapy and now has no symptoms.

Panel 3: **St Ker, 41-years-old**

St Ker, is from the village of Savanette. After completing 4 years of primary school, his parents could no longer pay tuition. "I went to Port-au-Prince to learn how to become a welder. I worked in factories." He lost his first job when the company he worked for was sold. He has since been intermittently employed. St Ker fathered two children, but his marriage foundered: "We used to argue about money. Then I became sick and she left me." He later struck up a relationship with another woman, who bore him another child, but by then, the summer of 1998, he was too sick to work. He had chronic diarrhoea and weight loss.

"I wandered from clinic to clinic [in Port-au-Prince], but no one could tell me what was wrong. So I came back here." St Ker was diagnosed with HIV in June 1999, when he presented to our clinic with cachexia, chronic enteropathy, anaemia, and mucocutaneous candidiasis. He was treated with broad-spectrum antibacterials and loperamide, but continued to lose weight. He suffered cognitive decline and by May 2000, was too weak to stand. When his weight dropped to 90 lb, St Ker was started on a regimen of zidovudine, 3TC, and efavirenz.

"I feel that these drugs have been miraculous. My diarrhoea stopped and I started to gain weight." His candidiasis and odynophagia disappeared by December 2000, when St Ker weighed 140 lb. He is ready to resume his work as a welder.

Panel 4: **Adeline, 34 years old**

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Adeline, 34 years old, was born in the village of Kay Epin. Of Adeline's eight siblings, five are living. Her parents are peasant farmers, although her father supplements his income by helping to run a local school. Adeline grew up in the village, leaving rarely except to accompany her mother to market. When she was 18, she left for Port-au-Prince to continue her primary education. Adeline didn't remain in school for long-- her grades were poor; the cost of tuition, high--and she ended up in a part-time vocational school, where she learned to sew and embroider. She lived with a sister in Cité Soleil, a slum on the northern edge of the city. Finding enough to eat was a constant struggle. Not long after her arrival, Adeline married Joel, a young man from the Central Plateau. Joel fell ill shortly after their son was born, and Joel died only a year later. Adeline does not know what killed him, but now assumes it was HIV. When Adeline's son was about 2 years old, she met Ronald, the father of her second child. He's still around, she notes, "but I'm no longer with him. He doesn't help me at all with feeding these children. I never see him."

During her early twenties, Adeline had an episode of pneumonia, which led her back to our clinic. She was also diagnosed with herpes zoster, which led to her diagnosis of HIV infection. For almost 10 years, Adeline's therapy was limited to treatment of opportunistic infections. By early 1999, Adeline's chronic enteropathy no longer responded to antimotility agents. By October, she weighed 79 pounds and could no longer get out of bed. In November 1999, Adeline began therapy with zidovudine, 3TC, and indinavir. Her diarrhoea disappeared within 2 weeks; she gained 26 pounds in the first 5 weeks of treatment.

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Expanding the HIV Equity Initiative

We believe that if DOT-HAART can be implemented in the devastated Central Plateau of Haiti it can be implemented anywhere. Our experience further suggests that HIV therapy can reinvigorate flagging prevention efforts. Although AIDS remains a stigmatised disease in Haiti, we believe that access to effective therapy has lessened AIDS related-stigma. The demand for HIV testing, and the opportunity for counselling, has risen since HAART was made available.

During the next 3 years, we hope to expand the HIV Equity Initiative to better meet the needs of the population of Central Haiti. Another nurse, an archivist, and a second social worker would represent the first full-time employees of the initiative. A part-time HIV prevention and care clinician will also work with the team based in Haiti.

Even though we initially enrolled only about 60 patients in the DOT-HAART programme, we achieved nearly full coverage in parts of the catchment area: using the enrolment criteria noted in panel 1, we have been able to treat most patients with signs and symptoms suggestive of advanced HIV disease. If the catchment area served consists of 250 000 individuals, the seroprevalence of HIV is about 5% among sexually active adults, and sexually active adults aged 15-40 years comprise 30% of the population, some 3750 HIV-positive individuals would live within the catchment area. If 10% of these patients meet enrolment criteria, then about 375 patients would need HAART. With additional staff, the treatment of 375 patients is well within the capacity of many district hospitals in less-developed countries. With national and international support, a larger number of patients could be enrolled in life-saving therapy.

How might patients be equitably and effectively enrolled in a DOT-HAART project? They must of course want to be treated, but we have yet to meet one who does not. Until tests of viral load, CD4 count, or other surrogate markers are available, simple clinical criteria can identify those most likely to benefit from HAART. The most important--weight loss or decreased body-mass index--has been shown to predict survival and disease progression in HIV infection.[23,24] Other criteria include the presence of a wasting enteropathy; severe neurological complications of HIV; severe leukopaenia, anaemia, or thrombocytopaenia; or recurrent opportunistic infections unresponsive to antibacterial or antifungal therapy.[25-27] In collaboration with colleagues at the Association François-Xavier Bagnoud, we are developing more formal inclusion criteria, but these need not be based on tests and measures unavailable in rural clinics in poor countries.

Many have expressed concern that HAART is too complicated for settings without specialists to guide therapy. It is true that rifamycins decrease blood concentrations of protease inhibitors; as noted, however, most patients who present with tuberculosis do not need concurrent anti-retroviral therapy. Furthermore, HAART in resource-poor settings need not rely on protease inhibitors. Given adequate financing, we plan to base our initial regimen on a combination of two reverse-transcriptase inhibitors and a non-nucleoside reverse-transcriptase inhibitor. Another promising possibility, already available in the USA, is the triple-nucleoside-analogue pill--zidovudine and 3TC together with abacavir, the most potent drug in its class. Such a fixed-dose combination would make DOT-HAART significantly simpler than tuberculosis treatment and would preserve protease inhibitors and non-nucleosides for cases of suspected or documented treatment failure.

Some have expressed alarm regarding the spread of drug-resistant virus if HAART is used where health infrastructure is weak. Just as it is possible to exaggerate the complexity of these regimens, so too is it possible to confound the main causes of acquired resistance. Most are to be found in settings such as the USA, where HIV patients face concurrent problems such as housing instability, lack of medical insurance, drug addiction, and lack of access to addiction-treatment programmes. Furthermore, there is in resource-poor settings no history of the widespread use of monotherapy with nucleoside reverse-transcriptase inhibitors. The use of monotherapy, once the rule in HIV therapy in the USA and Europe, is a leading contributor to the widespread existence of drug-resistant strains there. If tuberculosis offers an instructive example, drug resistance is far less likely to emerge where DOT is used from the outset and where drugs are made available to those who need them most.

Funding for expansion of this pilot project was sought from a number of international agencies charged with responding to AIDS; all declined to support this effort on the grounds that the drug costs were too high to meet so-called sustainability criteria. Pharmaceutical companies were approached for contributions or concessional prices but referred us back to the same international agencies that had already termed the project unsustainable.

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Objections to HAART in resource-poor settings

The two primary objections to use of HAART in poor communities have been the high costs of the medications and the lack of infrastructure necessary to deliver them effectively. The debate regarding pricing of antiretrovirals has been reviewed elsewhere.[28,29] As noted, there is little science to drug pricing. Several firms, including one based in India, have developed very low-cost formulations of zidovudine, 3TC, D4T, ddI, and nevirapine. The monthly retail cost of three drugs is already as low as US$83, as compared with US$768 per month from

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manufacturers in the USA.[30]

The second chief objection has been that poor countries lack the infrastructure necessary to deliver HAART. Much is made of the complexity of HIV management, which would defeat, according to conventional wisdom, the overburdened and undertrained health personnel in the countries most affected by HIV. In poor countries, HIV therapy is the privilege of local elites (who have, almost invariably, far lower rates of infection than the poor majority) and of a small number who live in capital cities and have access to specialty clinics partnered with first-world research universities.

There is merit to observations regarding weak implementation capacity, since health infrastructures are manifestly deplorable in most HIV-endemic areas. But there is reason to believe that minor modifications could improve local capacity to care for those sick with advanced HIV disease. One is the fact that we have piloted a DOT-HAART project in one of the poorest parts of the poorest country in the western hemisphere. Another is that other chronic infections have been well managed in equally poor settings.

Tuberculosis offers important lessons. Although tuberculosis remains a ranking cause of premature death, some extremely poor countries with high burdens of tuberculosis have low tuberculosis mortality rates. These countries have often been those adopting the DOTS strategy (directly observed therapy, short-course).[31] Since prompt diagnosis and effective therapy mean less transmission, treatment is prevention.

Tuberculosis treatment is easily as complex as HIV therapy, since both consist of a multidrug regimen (most initiate tuberculosis therapy with four drugs). Although fixed-dose combinations can reduce pill burden, the number of pills is not the primary determinant of outcome. The chief innovations have been directly-observed therapy; treatment that is without interruption and free of charge to the patient; and good case holding. Adjuvant social services further boost adherence and thus outcomes, which can be excellent in settings of enormous privation.[32,33] These innovations require political will at high government levels.

Some argue that the way in which tuberculosis is treated is not relevant to HIV care, since tuberculosis treatment lasts only 6-8 months whereas HIV therapy must be ongoing. For sceptics, the effective treatment of multidrug-resistant tuberculosis (MDR-TB) in impoverished regions may offer a more compelling example. MDR-TB treatment is more than three times as long as short-course therapy. The same arguments now heard in policy discussions of AIDS--high drug prices and complexity of management render antiretroviral therapy impracticable for use in resource-poor settings--were advanced to dissuade those seeking to treat MDR-TB in poor countries. Working in rural Haiti and in a slum in Lima, Peru, our group pioneered a community-based strategy to treat MDR-TB. Using strict DOT and the same standards of care as in tertiary medical centres in the USA or Europe, we achieved results better than those reported in industrialised countries.[34] Patients tolerated drug regimens more complex and far more toxic than HAART, with low rates of abandonment. We called this approach "DOTS-Plus," because it incorporates the managerial strengths of the DOTS strategy but relies on drug-susceptibility testing to determine treatment regimens appropriate for each patient.[35,36] This strategy is now being replicated in the former Soviet Union, where MDR-TB constitutes a growing problem.

Furthermore, the WHO, humanitarian groups such as Médecins Sans Frontières, and partners in the pharmaceutical industry developed a coordinated strategy of pooled procurement and distribution of second-line antituberculosis drugs. Concessional prices were offered to agencies able to demonstrate to a

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Green Light Committee their capacity to use these drugs prudently and to work under the aegis of a national tuberculosis programme.[37] This mechanism offers a concrete example of how coalitions can promote the prudent use of antibiotics while at the same time lowering drug prices by as much as 90%.

Tuberculosis offers examples of what needs to be done once the international community acknowledges that HIV is an international public-health emergency. Tuberculosis control, considered a public good, is by convention financed publicly. Patients do not pay for their own treatment, since those unable to pay remain sick and often infectious, perpetuating the epidemic; patients unable to pay regularly acquire resistance to first-line drugs and, subsequently, transmit drug-resistant strains of *Mycobacterium tuberculosis*. With tuberculosis, good treatment is prevention of both transmission and drug resistance.

Again, HIV offers important parallels. Although few would have predicted otherwise, we now have proof that high viral load is a strong predictor of HIV transmission.[38] HAART drops viral load to undetectable levels in most patients, and should be considered central to the AIDS-prevention arsenal.

Finally, tuberculosis offers a cautionary note. Reviewing published work reveals confident claims that rifampin would prove too expensive for use in less-developed countries; rifampin is now central to DOTS, advanced by the WHO and the World Bank as one of the most cost-effective interventions available.[39] The spread of MDR-TB across national boundaries makes different standards of care--treatment for the affluent, no treatment for the poor--unacceptable on epidemiological grounds. For some, double standards of care have long been objectionable on moral grounds.[40]

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Rethinking costs and benefits

We believe that much of the policy debate regarding the role of HAART in responding to AIDS has been misguided. The belief that treatment may be reserved for those in wealthy countries whereas prevention is the lot of the poor might be less repugnant if we had highly effective preventive measures. We do not. We have argued that we need better preventives, including vaccines, and also a campaign to make HAART available to those who need it most. Where HIV is the leading cause of adult death, a basic minimum package that does not include antiretrovirals is not worthy of the name. We have instituted a very different basic minimum package in one of the poorest parts of the world (panel 5), and believe that policy makers should take note. DOT-HAART is a safe way to provide a minimum package that includes HAART.

Panel 5: **Basic minimum package for HIV in endemic settings**

- Post-exposure prophylaxis for rape and professional accidents
- Aggressive AIDS prevention programmes, including barrier methods
- Maternal-child transmission package (including milk supplements)
- Social assistance to HIV-affected families, including orphans
- Diagnosis and treatment of opportunistic infections and sexually transmitted diseases
- HAART with DOT

We also argue that it is wise to avoid confident claims regarding "appropriate technology". Brazil has introduced sophisticated assays of viral load costing a small fraction of test costs in the USA; it has manufactured many antiretrovirals

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small fraction of cost costs in the USA, it has manufactured many antiretrovirals locally. Cipla, the Indian pharmaceutical company, has introduced a substantial formulary of antiretrovirals at a small fraction of the cost in Europe and North America. These developments lead us to a consideration of the economics of intervening to slow the spread of HIV and to diminish the death toll.

In settings of affluence, it seems as if no expense is too great in order to prolong life, even when patients are elderly and have irreversible conditions. In sub-Saharan Africa and Haiti, where HIV is the reason for plummeting life expectancies and for increasing numbers of orphans, we discern fairly overt obstructionism to the use of HAART. Leaving aside all moral arguments, any economic logic that justifies as acceptable the orphaning of children is unlikely to be sound, since the cost to society, though difficult to tabulate, is far higher than the cost of prolonging parents' lives so that they can raise their own children. Furthermore, HAART causes a dramatic drop not only in mortality, but also in the number of opportunistic infections and consequent number of admissions to hospital.[22] HAART has already been declared cost-effective in Europe, North America, and even Brazil, where HIV has become, for many, a chronic infection.[41,42]

Health economists suggest that a life-saving intervention that costs between two to three times the gross national product (GNP) per year-of-life saved represents a reasonable expenditure.[43] Even by this crude calculus, it should be clear that in South Africa or Botswana, for example, a three-drug HAART regimen at generic prices would prove a sound investment by any criteria as long as drugs are used correctly. Even in Haiti, where GNP is about US$400 per annum, a regimen that costs US$800 per year--again, well within our grasp even now--will be a wise expenditure even before considering favourable impact on transmission.

We conclude by acknowledging that our DOT-HAART project is a humble enough example. A small, effective pilot project might not warrant mention in the international medical literature if widespread paralysis had not led to a near-universal absence of DOT-HAART projects in regions such as rural Haiti, with minimum health infrastructure but high rates of both HIV and poverty. We know from experience that repeated claims of unfeasibility are simply not true. Multiple research projects carried out in sub-Saharan Africa have shown that more-developed world diagnostic tests can be used to follow viral load and to reveal the genotype of drug-resistant strains of HIV. It is time that more-developed world therapeutics follow.

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Viewpoint

Preventing antiretroviral anarchy in sub-Saharan Africa

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Combination antiretroviral therapy has dramatically improved the survival of patients living with HIV and AIDS in industrialised countries of the world. Despite this enormous benefit, there are some major problems and obstacles to be overcome.[1] Treatment of HIV-infection is likely to be lifelong.[2] Unfortunately, many HIV-infected individuals cannot tolerate the toxic effects of the drugs, or have difficulty complying with treatment which involves large numbers of pills and complicated dosing schedules. Poor adherence to treatment leads to the emergence of drug-resistant viral strains that need new combinations of drugs or new drugs altogether.

Use of antiretroviral therapy in sub-Saharan Africa

About 70% of the estimated 361 million people in the world with HIV and AIDS live in sub-Saharan Africa, and 84% of all the estimated deaths due to HIV and AIDS since the start of the pandemic have occurred in this region.[3] Africa is the epicentre of this pandemic, yet ironically is the region least able to offer any challenge or opposition to

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ironically is the region least able to offer any challenge or opposition to the devastation caused by the virus. With a few exceptions, strategies to prevent the spread of HIV have been unsuccessful. Good quality HIV counselling and testing services are few and far between, clinical care and the resources to treat opportunistic infections are minimal, and for most people with HIV and AIDS, there is no access to antiretroviral drugs.

This state of affairs might change. Five large pharmaceutical companies agreed in May, 2000, to significantly reduce the cost of antiretroviral drugs to create better access for people in poor countries. An Indian drug company, Cipla, has created a three-tiered pricing offer to make antiretroviral drugs more accessible to resource-poor countries, and has offered to produce a combination of lamivudine, stavudine, and nevirapine at an annual cost of US$350 for Médecins Sans Frontières, US$600 for governments, and US$1200 for individuals.[4] There is even talk that the G8 countries might pay for antiretroviral drugs for resource-poor countries.

Access to antiretroviral drugs could be an important component of a strategy to support people living with HIV and AIDS as well as preventing transmission of infection. People may be more willing to undergo voluntary counselling and testing and disclose their HIV status if there is the possibility of getting effective treatment. By reducing viral load, antiretroviral drugs might also reduce the risk of sexual transmission.[5] Sick people will be able to return to work. Parents will stay alive longer, thus delaying the time when children become orphans. The rate of mother-to-child-transmission will be reduced.

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Dangers of antiretroviral therapy in sub-Saharan Africa

Widespread, unregulated access to antiretroviral drugs in sub-Saharan Africa could lead to the rapid emergence of resistant viral strains, spelling doom for the individual, curtailing future treatment options, and leading to transmission of resistant virus. There are few physicians skilled in the use of antiretroviral drugs. The health infrastructure is incapable of monitoring viral load, immune status, or side-effects of the drugs. Drug procurement and distribution systems are weak, and drug interruptions are likely. Theft of drugs from health institutions for sale in markets, shops, private clinics, and across national borders is a real concern. There are no monitoring systems in place to check on drug adherence or drug effectiveness. Horton cites a recent report from Harare, Zimbabwe, where introduction of antiretroviral drugs has resulted in a situation of antiretroviral "anarchy" and chaos.[6]

Thus, it is not just a matter of providing antiretroviral drugs, but also that they must be provided within a structured framework. There has to be a system to ensure regular procurement and distribution, good patient management, monitoring, and assessment. Is this possible? We believe that it is feasible to put such a system in place in the public-health sector based on the successful model adopted for tuberculosis control, the national tuberculosis control programme, to initiate a combined tuberculosis and antiretroviral drug programme.

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National tuberculosis control programmes

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National tuberculosis control programmes

The overall objective of tuberculosis control is to reduce mortality, morbidity, and transmission of the disease until it no longer poses a threat to public health. The strategy is simple. Standardised combination chemotherapy is provided to, at least, all sputum smear-positive tuberculosis patients. This treatment cures the disease and prevents future transmission of infection within the community. Targets for tuberculosis control include curing 85% of detected new smear-positive tuberculosis cases and detecting 70% of the existing cases. To achieve a high cure rate is the highest priority because tuberculosis programmes with high cure rates are thought to attract a large number of existing cases within their catchment areas.

The success of this strategy depends on the implementation of a tuberculosis control policy package, so called Directly Observed Treatment, Short course (DOTS).[7,8] DOTS has a five-point policy package (panel 1), associated with nine key operations (panel 2). DOTS-tuberculosis programmes have better data on case finding, more smear-positive pulmonary tuberculosis cases, and better treatment outcomes than tuberculosis programmes which do not use DOTS.[9,10] In 1997, for example, the treatment success rate for smear-positive tuberculosis patients treated under DOTS-programmes was 78% globally.[10] Rates of treatment completion are lower in DOTS programmes in high HIV-prevalent countries in sub-Saharan Africa. This is not because the delivery of DOTS is worse, but principally because of high case fatality rates due to HIV coinfection.[11]

Panel 1: **Tuberculosis control policy package**

- Government commitment
- Case detection through passive case finding
- Administration of standardised short-course chemotherapy to at least all confirmed sputum smear positive cases of tuberculosis under proper management conditions
- Establishment of a system of regular drug supply
- Establishment and maintenance of a monitoring system

Panel 2: **Key operations of a national tuberculosis control programme**

- Establish a national tuberculosis programme with a central unit
- Prepare a tuberculosis programme manual
- Establish the recording and reporting system
- Initiate a training programme
- Establish microscopy services
- Establish treatment services within the health care system
- Secure a regular supply of drugs and diagnostic material
- Design a plan of supervision
- Prepare a programme development plan especially for funding

Although DOTS is a successful strategy, its implementation is not easy. By 1998, only 21% of all smear-positive tuberculosis cases globally had

been treated by a DOTS-tuberculosis programme[11]. Adequate funding is essential, and it is important to note that most large DOTS-tuberculosis programmes which have done well have been supported by international donor agencies, the World Bank, or WHO.[12]

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Framework for an antiretroviral programme in sub-Saharan Africa

The overall objective of an antiretroviral programme would be to reduce mortality, morbidity, and transmission of HIV. The strategy would be to use standardised, combination antiretroviral therapy for HIV seropositive patients with symptoms. The targets for antiretroviral therapy would be lifelong treatment once the patient has started on therapy and drug adherence rates of 90% or greater. Achievement of excellent adherence rates is the highest priority because this is the best way of reducing the emergence of drug-resistant HIV infection.

We suggest five key elements in our proposed antiretroviral policy package, similar to that adopted for tuberculosis control:

Government commitment

The aim should be nationwide coverage, similar to a permanent health system activity, with technical leadership from a central antiretroviral unit that is integrated with the national tuberculosis control programme. Regional or provincial units with dedicated personnel should also be set up in order to facilitate the work of the central unit. Antiretroviral drugs should not be introduced in isolation, but must be part of an essential package of care that includes voluntary counselling and testing, psychosocial support, palliative care, home based care, essential drugs for the treatment and prevention of opportunistic infections including sexually transmitted infections, and nutritional support.

Case detection through passive case finding

The focus should be on HIV seropositive patients with symptoms, who should undergo voluntary counselling and HIV testing. The spectrum of illness and the clinical features allowing access to antiretroviral drugs would need to be worked out. For example, patients fulfilling the WHO case definition for AIDS in Africa,[13] or patients with common systemic diseases such as tuberculosis, pneumonia, chronic diarrhoea, bacteraemia, or systemic fungal infections could be considered candidates for antiretroviral drugs if they tested HIV-positive. In countries with limited resources, it is not feasible to offer symptom-free HIV-infected individuals antiretroviral therapy. Experience in industrialised countries has shown that early therapy is associated with cumulative side-effects, poor adherence, and the development of multidrug resistance, and these factors probably outweigh the net benefits of lengthening life.[2]

Standardised antiretroviral regimens

The drug combination needs to be simple and have the least number of side-effects. Protease inhibitors are associated with many side-effects, and because of interactions with anti-tuberculosis drugs,[14] are probably best avoided in sub-Saharan African countries with a high HIV-

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best avoided in sub-Saharan African countries with a high HIV-tuberculosis burden. The choice of the most appropriate regimen depends on efficacy, cost, and safety issues,[15] and would require expert consultation. It would also be prudent to decide what drugs might be used for salvage antiretroviral therapy when drug resistance, side-effects, or both become a problem.

Proper case management ensures patient adherence by supervised administration of tablets (directly observed therapy). However, there are some important differences from the supervision of antituberculosis treatment. Antiretroviral therapy is lifelong and there is at present no once-a-day regimen. DOT for antiretroviral drugs therefore has to be flexible, and will probably only work if the site of supervision is in or close to home and the supervisor or supervisors are trusted and reliable.

Establishment of a regular drug supply

A mechanism needs to be set up for regular and uninterrupted procurement, distribution, and safe storage of antiretroviral drugs, building on the structures used in national tuberculosis control programmes.

Establishment and maintenance of a monitoring system

In each antiretroviral treatment unit an antiretroviral register should be maintained to record individual patient information. There should be regular reporting on a quarterly basis of the cumulative as well as the quarterly results of case finding and follow-up.

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Why have a joint programme?

In most of sub-Saharan Africa there have been repeated requests for tuberculosis control and AIDS control programmes to work together. A joint tuberculosis and antiretroviral initiative could provide a real focus for collaboration. An independent and parallel antiretroviral treatment and delivery system could be implemented, but we believe that such a step would be counter-productive.

It would be more cost-effective to build on the infrastructure already on the ground for tuberculosis control. Good national tuberculosis control programmes have the experience of providing, monitoring, and supervising care of patients for long periods of time, and are in a position to develop and implement a structure within which antiretroviral drugs can be effectively and safely administered. Given that HIV is the main driving force behind the current epidemic of tuberculosis, an integrated programme has a greater chance of affecting the tuberculosis burden in Africa than any course of action embarked on by tuberculosis control programmes alone. Further, tuberculosis is the main opportunistic infection resulting from HIV, and therefore many of the patients will be common to both programmes. How will adverse side-effects be managed when patients are on both antituberculosis treatment and antiretroviral drugs if patients are treated by two different programmes? Will DOT for antituberculosis treatment and for antiretroviral drugs be administered by different DOT providers if the programmes run in parallel? Accessing a dedicated antiretroviral drug unit may still be a stigmatising event for many people, whereas an

integrated service could help to reduce this stigma.

One potential risk of a joint programme is that nosocomial tuberculosis might be acquired by HIV-positive patients when accessing antiretroviral therapy. This concern needs to be addressed in the physical design of the joint programme offices and the logistics of how infectious tuberculosis patients and non-tuberculosis patients access the services.

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Key operations of a joint programme

We believe that an integrated tuberculosis and antiretroviral drug programme is the best way forward. Various key operations need to be established and sustained:

A central unit should be established that has an overall programme manager, with two deputy managers (one in charge of a national tuberculosis programme and one in charge of antiretroviral therapy) reporting to the programme manager. The central unit is responsible for the operational running of all aspects of the programme. Regional (provincial) tuberculosis and antiretroviral therapy officers should be established and maintained in each region: this would be a matter of retraining the present regional tuberculosis officers in the management of antiretroviral drugs. External technical assistance may be needed for the initial setting up of the central unit.

One important function of the central unit will be to regularly monitor antiretroviral drug resistance, possibly through surveys carried out every 1 to 2 years. This will inform the programme about appropriateness of the current drugs, and will help to indicate when a change in drug combinations is needed. Given the technical complexities of drug resistance monitoring, there would need to be external support for this activity.

The tuberculosis and antiretroviral programme should report on a 6-monthly basis, and whenever required, to a programme steering group consisting of senior Ministry of Health personnel, director of the national AIDS control programme, technical experts, and donors.

A joint programme manual should be prepared. This manual becomes an expansion of the national tuberculosis programme manual. In addition to the manual on tuberculosis control, the manual should contain information about the structure and function of the joint programme. The manual should be updated regularly.

A recording and reporting system should be established. Separate registers need to be developed for recording case finding and follow-up status: these should be based on the registers used for tuberculosis control. Treatment cards and patient identity cards similar to those used for patients with tuberculosis need to be created for the recording of antiretroviral DOT. Forms need to be made for quarterly reporting. Registers, cards, and reporting forms allow information on the number of cases starting treatment within a quarter, the cumulative number of cases on treatment, and their current follow-up status to be collected in a standardised way at each treatment unit. The information can be compiled and collated at the central unit, and is vital for assessing the use and effectiveness of antiretroviral drugs, and for planning drug procurement needs.

procurement needs.

At each treatment unit there should be a number of individuals responsible for implementing the programme. There should be at least two coordinators responsible for the registration, recording, and reporting of tuberculosis cases and patients taking antiretroviral drugs. With specific regard to antiretroviral treatment, this would involve registration of patients, maintenance of confidentiality, administration of drugs, patient education, recording and reporting on cases, drug ordering, and drug security. There should also be a doctor or clinical officer who is responsible for doing ward rounds on tuberculosis wards, for ensuring care of HIV-related complications, for referring patients for the treatment of sexually transmitted infections, for monitoring the efficacy of antiretroviral therapy, and for recognising and managing side-effects associated with antiretroviral treatment. In the industrialised world, antiretroviral drug efficacy is monitored by regular measurements of viral load and CD4-lymphocyte counts, supplemented by assays of viral resistance. This would be impossible for most hospital laboratories in Africa. Efficacy can realistically only be monitored by measurements of weight and clinical examination. However, a system could be set up that annual or 6-monthly blood tests be taken for measurements of plasma viral load in a special reference laboratory. Recognising and managing adverse drug-effects in a resource-poor environment will also not be easy. Principal toxicities include mitochondrial dysfunction, hypersensitivity, lipodystrophy, as well as more drug-specific side-effects.[16] A system of systematically monitoring patients clinically, with a referral system for more detailed laboratory examination will need to be explored.

There should also be a team of trained counsellors to provide HIV counselling and psycho-social support, referral to home-based care groups, and linkage between hospital services and the community. These staff need to be appropriately trained. It is essential that personnel can effectively deliver the care, and training should therefore be linked to an examination system so that officers can only use antiretroviral drugs when they can demonstrate that they know how to use them, how to recognise side-effects, and when to institute referral for more detailed investigation.

Voluntary HIV counselling and testing services must be established. Antiretroviral drugs should not be allowed to start in any treatment unit unless there is access to voluntary counselling and testing. These services also need to monitor their own activities using a confidential system. Regular quality control of HIV testing, as is done with sputum smear examination, should be put in place. There should also be supervision of the quality of counselling services, and the central unit might consider a central unit counsellor whose main role is to supervise and monitor quality of services in each treatment unit. If nationwide coverage is envisaged then treatment units, with the tuberculosis and antiretroviral therapy team, are best set up within all central, provincial, district, and mission hospitals.

A regular supply of antiretroviral drugs and diagnostic material must be secured. Antiretroviral drugs and HIV testing kits, along with anti-tuberculosis drugs and reagents and consumables for tuberculosis diagnosis, should be procured centrally, and distributed on a regular basis to treatment units. Knowledge of previous notification of AIDS cases in a quarter and the cumulative number of AIDS cases on treatment will allow a rational system of drug ordering. A rigorous system of monitoring drug use is also essential in order to safeguard antiretroviral drugs and prevent abuse.

antiretroviral drugs and prevent abuse.

Plans of supervision need to be prepared on an annual basis by central and regional unit staff. Supervision of treatment units should be undertaken on a quarterly basis. Case finding and follow-up, and up-to-date data on drug supplies should be collected into structured proforma.

A long-term programme development plan should be drawn up with all stakeholders laying out the vision, strategy, activities, reporting mechanisms, and above all the budget and sources of funding. Nationwide coverage cannot be done at once and a phased approach to antiretroviral therapy will be necessary. The chosen triple-combination therapy should be rigorously piloted in the first phase with intensive clinical and laboratory monitoring to ensure that the regimen is safe and well tolerated. The aim will be to define simple and robust clinical management algorithms for the monitoring of treatment and complications, because in most districts laboratory monitoring will not be realistic. Additionally the difficult problem of defining antiretroviral treatment failure will be tackled.

While this study is taking place, the pilot districts earmarked for feasibility studies should be strengthening their infrastructure and expanding their staff to make a basic essential package of care for people living with AIDS available in preparation for the arrival of antiretroviral drugs. Once these pilot districts are ready, the feasibility of using antiretroviral drugs integrated into the national tuberculosis control programme structure and activities will have to be tested. To test this integration will not be easy because the population will soon know where feasibility studies are taking place, and it is likely that there will be huge demand from patients outside the district. Strict criteria for including HIV-infected patients in district feasibility studies will be needed. These feasibility studies should include social science and health systems input to ensure that programmes are designed as equitably as possible and to monitor the social impact of taking these regimens long-term, especially on the poorest sectors of society. If the feasibility studies are successful, then the programme could be expanded and used throughout the country.

A resource-poor country itself will be unable to support an antiretroviral programme, and long-term donor support will be needed. This support is more likely to come if the AIDS control programme and the tuberculosis and antiretroviral therapy programme have developed a working, costed, development plan.

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Conclusion

We believe that such a structure may enable antiretroviral drugs to be used effectively and safely within sub-Saharan African countries. Having this framework in place, integrated with a tuberculosis control programme, might appeal to donors who otherwise might be reluctant to embark on support for such care. The details of how the structure is implemented need to be worked out, and will no doubt vary from country to country.

However, there is an important caveat to this viewpoint. Many countries in sub-Saharan Africa are embarking on the process of health-sector reform, which incorporates among other things a sector-wide approach to health and decentralisation of services to district level. Vertical

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disease control programmes, such as DOTS tuberculosis programmes, do not fit well into this new approach to the way health services are delivered, and there have been examples of tuberculosis control efforts floundering when health sector reform is introduced.[17] It is important for control programme staff and health planners to work closely together in this reform process to ensure that regular drug supplies, supervision, monitoring, and recording are maintained and continued in an uninterrupted fashion.

The structure we propose also needs to take account of other approaches to antiretroviral therapy. In Brazil, nearly 20% of HIV-infected individuals receive antiretroviral therapy at no cost through the public health system,[15] and lessons need to be learnt about how this is working in practice. Elsewhere, small numbers of patients receive drugs at subsidised cost through donor supported projects. Small treatment units based around community-care groups and supported by non-governmental organisations are already springing up in needy areas. More information needs to be gathered about the role of private pharmacies and the private sector in managing antiretroviral therapy, and decisions will need to be made about whether the private sector should be regularised and come into line with the structure used in the public-health institutions. Whatever approach is used, it is vital that the emergence of drug resistance is minimised and drug efficacy protected.

The costs of such an antiretroviral programme will be large. UNAIDS has estimated that the most basic HIV prevention and care package in Africa would cost about US$3 billion annually.[18] With the addition of provision of antiretroviral therapy and palliative treatment at a cost of US$500 per person per year for 5 million people with symptoms the budget rises to about US$75 billion annually. According to Attaran and Sachs,[18] this could be afforded by the international community. The benefits which could be reaped in Africa are potentially enormous. There is the possibility that the wise and judicious use of antiretroviral therapy could begin to reverse some of the appalling health and development indicators that have become associated with HIV and AIDS in the last few years. In South Africa, it has been estimated that triple-combination antiretroviral therapy for 25% of the HIV-1-positive population could prevent a 3-year decline in life expectancy and more than 400 000 incident AIDS cases.[19]

An antiretroviral programme would introduce the most advanced level of care for people with HIV and AIDS who in most countries are not receiving even the minimum standard. Thus, such a programme may be criticised right from the start. However, antiretroviral drugs are already being provided in many countries in a chaotic fashion.[6] We believe that a structured system of antiretroviral provision is urgently needed in sub-Saharan Africa. If this is combined with an essential package of care, the lot of patients living with AIDS could improve and drug resistance be curtailed.

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FRIEND OR FOE? LOOKING TO INTERNATIONAL LAW IN THE STRUGGLE FOR ACCESS TO TREATMENT FOR HIV/AIDS

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POST-UNGASS MEETING: SOCIAL AND ECONOMIC RIGHTS IN THE GLOBAL HIV/AIDS EPIDEMIC, HOSTED BY THE CENTER FOR ECONOMIC AND SOCIAL RIGHTS
NEW YORK CITY: THURSDAY, JUNE 28TH 2001

Two claims dominate discussions of access to essential treatments for HIV/AIDS and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). First, TRIPS permits sufficient regulatory flexibility to deal with crises such as the AIDS pandemic. Second, TRIPS is too restrictive. As a lawyer, I see the reality as lying somewhere between these two positions. As an activist, I see merit is pursuing both arguments.

There can be no doubt that TRIPS has strengthened the international protection of intellectual property (IP) so as effectively to narrow the scope of national patent policies. Nevertheless, the agreement does not prevent—and indeed contemplates and permits—the taking of certain legal steps to ensure meaningful reductions in drug prices. Properly interpreted in accordance with recognized principles of international law and in the light of the Universal Declaration of Human Rights (UDHR) and the ICESCR, TRIPS permits countries such as South Africa to take certain regulatory steps to ensure the accessibility of essential drugs, which include but are not limited to compulsory licensing, early working provisions and exclusions from patentability.

Meaningful reductions in prices are achievable in two distinct ways. First, the co-operation of the patent holder may be sought either by governments seeking to enter into agreements for the supply of affordable medicines, or by manufacturers seeking voluntary licenses for the production, marketing and sale of generic alternatives, subject to a royalty payment. Second, the state may regulate prices, either directly or indirectly. Direct regulatory mechanisms include price controls on the sale of pharmaceutical products and the parallel importation of patented products from where they are sold at the lowest international price, with indirect price regulatory mechanisms seeking to take full advantage of market processes by ensuring the introduction of real competition in the form of generic manufacturers, intended to result in sustainable price reductions as the brand name pharmaceutical industry is forced to compete for its market share. While TRIPS does not regulate price controls and parallel importation, it has much to say regarding indirect price regulatory mechanisms, probably the most effective and sustainable regulatory options. It would be a mistake to see the two approaches to price reductions as separate. While the manners of regulation may be distinct, their operation will often be cumulative. The very existence of coercive regulatory measures may serve as an incentive for patent holders to negotiate meaningful price reductions, or voluntary licenses on terms favourable to both generic manufacturers and the public.

The issues I am addressing today relate to two relationships: first, the relationship between international trade law and international human rights law; second, the relationship between international law and domestic law. Let me begin with the first.

As the WTO's Dispute Settlement Body's primary function is to interpret trade agreements, and given that it is a creature of a treaty, its jurisdiction is primarily limited to applying the provisions of agreements such as TRIPS.[1] Nevertheless, the Vienna Convention on the Law of Treaties (Vienna Convention) requires that interpretation take account of "any relevant rules of international law applicable in the relations between the parties".[2] Indeed, the Appellate Body in the *Hormones* case recognized that the "direction [in Article 3.2 of the Dispute Settlement Understanding] reflects a measure of recognition that the [GATT] is not to be read in clinical isolation from public international law."[3] Flowing from this finding, it is not difficult to argue that where possible, TRIPS is to be interpreted in accordance with international law more broadly. It therefore follows that TRIPS is to be read in the light of international human rights instruments such as the UDHR and the ICESCR, the latter of which recognizes a right to the highest attainable standard of health as well as limited intellectual property rights.

But not everything can be solved by legal gymnastics and creative interpretation. Sometimes language is clear. Sometimes doors are shut. And when this happens, human rights activists may wish to argue that international human rights law takes precedence of international trade law. I am not convinced that even the most progressive and liberal interpretation of international law supports such a finding.

The second relationship—international law and domestic law—is more complex. When it relates to international economic law, many of us become strident defenders of national sovereignty. Not so in relation to international human rights law. The international law/domestic law relationship has two interrelated legs. First, to what extent is international law binding? Second, to what extent should international dispute settlement bodies defer to national interpretations of international obligations?

To the extent that international treaties are binding, they are generally only binding as between nations. In South Africa, for example, it seems to be the case that binding treaties that have not been incorporated into domestic law cannot be "applied directly by South African courts", but rather "might be employed as a guide to the interpretation of an ambiguous statute or as evidence of a customary rule of international law".[4] This appears to be the consensus position amongst leading authorities on the subject. *Oppenheim's International Law*, for example, states that—

> [a] national law which is in conflict with international law must in most states be applied as law by national courts, which are not competent themselves to adapt the national law so as to meet the requirements of international law . . . Furthermore, if a state's internal law is such as to prevent it from fulfilling its international obligations, that failure is a matter for which it will be held responsible in international law.[5]

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[1] James Cameron & Kevin R. Gray, "Principles of International Law in the WTO Dispute Settlement Body", (2001) 50 Int'l Comp. L.Q. 248 at 264.

[2] Article 31(3)(c).

[3] *EC—Measures Concerning Meat and Meat Products*, Report of the Appellate Body, WT/DS26 and 48/AB/R (16 January 1998) at 17 [hereinafter *Hormones*].

[4] John Dugard, "Public International Law", in Matthew Chaskalson et al, eds. *Constitutional law of South Africa* (Revision Service 5, 1999) (Kenwyn, South Africa: Juta & Co., Ltd., 1999) at 13-3.

[5] R. Jennings & A. Watts (eds.), *Oppenheim's International Law*, 9th ed., Vol. I (Longman, 1992) at 84.

The degree to which such treaties are binding in domestic law varies across jurisdictions. Under the South African Constitution, for example, TRIPS is only binding in so far as it does not violate the Constitution. But under international law, the position is not so clear. Article 46(1) of the Vienna Convention provides that "[a] State may not invoke the fact that its consent to be bound by a treaty has been expressed in violation of a provision of its internal law regarding competence to conclude treaties as invalidating its consent unless that violation was manifest and concerned a rule of its internal law of fundamental importance." Quite clearly, states are not bound by those provisions of treaties that are in clear conflict with their constitutions.[6] But what exactly constitutes a manifest breach remains unclear.

This leads me to my next point: deference. When the European Court of Human Rights applies the margin of appreciation in deference to national laws, many of us are outraged. When the Dispute Settlement Body of the WTO refuses to do so, the same people are outraged. Is this a question of wanting to have our cake and to eat it too?

Customary international law supports the deferential approach to treaty interpretation. The principle of *in dubio mitius* requires that if more than one possible term can be ascribed to an ambiguous term, preference be given to the meaning that is less onerous on the party assuming an obligation.[7] This is a useful argument to make regarding the interpretation of TRIPS, but perhaps not so desirable in connection with broader issues of access to health care under domestic law, where international law provides greater levels of protection for poor people. On what basis, therefore, should deference proceed?

Recognizing that "effective international cooperation depends in part upon the willingness of sovereign states to constrain themselves by relinquishing to international tribunals at least minimum power to interpret treaties and articulate international obligations", Croley and Jackson argue that some deference to national decisions may be necessary—even in relation to treaty interpretation—provided there is a "focus on an appropriate allocation of power between international and national governments, and if one is willing to recognize that nation-states ought still to retain powers for effective governing of national (or local) democratic constituencies in a variety of contexts and cultures."[8] In essence, they argue, "[s]ome trade-off is necessary."[9]

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[6] In countries where the legal system is based on the principle of constitutional supremacy, a national constitution is clearly an "internal law of fundamental importance."

[7] Cameron & Gray, *supra* note 1 at 256. Recognized in *Hormones* as a "supplementary means of interpretation" (Hormones, *supra* note 3 at para. 165), the principle is described as follows:

> The principle of *in dubio mitius* applies in interpreting treaties, in deference to the sovereignty of states. If the meaning of a term is ambiguous, that meaning is to be preferred which is less onerous to the party assuming an obligation, or which interferes less with the territorial and personal supremacy of a party, or involves less general restrictions upon the parties.

(*Oppenheim's International Law*, *supra* note 5 at 1278, cited in *Hormones*, *supra* note 3 at para. 165, n.154.)

[8] Steven P. Croley & John H. Jackson, "WTO Dispute Procedures, Standard of Review, and Deference to National Governments", (1996) 90 Am. J. Int'l L. 193 at 211. The DSU itself is silent on the appropriate standard of review, "but there are some clauses that might support a cautious approach by the WTO panels." (John H. Jackson, "The Great 1994 Sovereignty Debate: United States Acceptance and Implementation of the Uruguay Round Results", (1997) 36 Colum. J. Transnat'l L. 157 at 182, referring to Article 3(2).

[9] Croley & Jackson, *supra* note 8 at 212.

Helfer provides an interesting approach to the issue of deference and standard of review,[10] arguing in the context of copyright law that "states should enjoy the most deference when they seek to strike a balance between the exclusive rights of authors and the rights and interests of the public and future authors in obtaining access to copyrighted works."[11] In particular, he argues, TRIPS jurists should "recognise that they cannot stand in the shoes of national actors and re-balance these competing goals. They should thus permit courts, legislatures and administrative bodies a wide margin of appreciation to set the balance they consider appropriate."[12]

Seeing the tension in copyright issues as a clash between free expression and IPR protection, Helfer cautions that if "TRIPs jurists [were] to constrain states' use of IPR exceptions and limitations to achieve free expression goals, they might well be asking states to act in contravention of their own constitutional or human rights obligations and to place the interests of foreign intellectual property owners over the civil and political liberties of their own citizens."[13]

The difficulty in developing principles according to which such "deference" should take place is reduced by referring to Article 46(1) of the Vienna Convention. As mentioned above, states are not bound by those provisions of treaties that are in clear conflict with their constitutions. Faced with a choice between various possible interpretations, a treaty interpreter should therefore prefer the interpretation that is consistent with the relevant national constitution to any alternative interpretation that is inconsistent with that constitution. Where a national constitution is silent on issues such as access to health care, for example, no reason for deference would exist. Where a country had failed to provide access to health care, it would be very difficult to justify the failure on the basis of a constitutional obligation.

A principled approach to deference would also consider the purpose for which the particular national policy was intended. A great degree of deference would be required when a member state is discharging its constitutional or other international law duties, or, for example, when it is legislating in respect of TRIPS-recognized public policy goals, such as public health and technology transfer. Less deference would be justified in other circumstances, such as practices that which do not give effect to internationally recognized public policy goals.

The recent victory against the brand-name drug industry in South Africa provides food for thought. Arguably, South Africa's regulatory framework for accessing essential treatments is now in place. What we need now is action—the issuing of compulsory licenses,[14] the local manufacture or importation of generic antiretroviral drugs and drugs such as fluconazole (to target opportunistic infections such as cryptococcal meningitis and oesophageal and vaginal thrush), and the parallel importation of acyclovir (to treat shingles and herpes). Just getting the regulatory framework in place dos not necessarily translate into action.

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[10] Laurence R. Helfer, "A European Human Rights Analogy for Adjudicating Copyright Claims Under TRIPs", (1999) 1 E.I.P.R. 8. The author suggests that jurisprudence developed by the European Court of Human Rights under the European Convention of Human Rights would serve as a useful guide to the approach to interpretation under TRIPS.

[11] *Ibid.* at 14.

[12] *Ibid.*

[13] *Ibid.* at 15.

[14] In terms of section 4 of the Patents Act, 57 of 1978, either the Minister of Health or the Minister of Trade and Industry could issue a compulsory license.

In the context of TRIPS, barriers to access are not limited to intellectual property issues. Affordability is a necessary but not sufficient condition for accessibility. A number of interesting questions arise.

- How do we force governments to comply with their international human rights obligations in the absence of a real enforcement mechanism? International trade law works because the WTO dispute resolution mechanism has teeth.
- How do we assure that governments take advantage of whatever regulatory flexibility exists under TRIPS, understanding that in the context of the HIV/AIDS pandemic, direct challenges against developing countries at the WTO may very well give way to more "subtle" forms of coercion?
- How do we ensure that a progressive, rights-based understanding of TRIPS serves as the staring point for any discussions regarding regulatory flexibility? How do we ensure that increased flexibility is expressly included in TRIPS?
- How can we use domestic constitutions (where applicable) and international human rights law to force reluctant governments not only to put the requisite regulatory frameworks in place, but also to use such frameworks?
- How do we force such governments to provide antiretroviral therapy when it is cost-effective to do so?

Particularly in the developing world, access to treatments for HIV/AIDS is reliant on political will. Where it does not exist, it will have to be forced.

E. Other

- *"Pharmaceutical Research and Development Myths: The Case Against The Drug Industry's R&D Scare Card"*
  A Report By Public Citizen, July 23, 2001

- *Questions and Answers: The Drug Pricing and Control Order*
  The National Pharmaceutical Pricing Authority

Public Citizen

Rx R&D Myths: The Case Against The Drug Industry's R&D "Scare Card"

July 23, 2001
(Click Here for PDF Versions of the Report, Appendix A-Office of Technology Assessment Study- and Appendix C-National Institutes of Health Report)
(Click Here for the Press Release)

Executive Summary

This new Public Citizen report reveals how major U.S. drug companies and their Washington, D.C. lobby group, the Pharmaceutical Research and Manufacturers of America (PhRMA), have carried out a misleading campaign to scare policy makers and the public. PhRMA's central claim is that the industry needs extraordinary profits to fund expensive, risky and innovative research and development (R&D) for new drugs. If anything is done to moderate prices or profits, R&D will suffer, and, as PhRMA's president recently claimed, "it's going to harm millions of Americans who have life-threatening conditions." But this R&D scare card – or canard – is built on myths, falsehoods and misunderstandings, all of which are made possible by the drug industry's staunch refusal to open its R&D records to congressional investigators or other independent auditors.

Using government studies, company filings with the U.S. Securities and Exchange Commission and documents obtained via the Freedom of Information Act, Public Citizen's report exposes the industry's R&D claims:

- The drug industry's claim that R&D costs total $500 million for each new drug (including failures) is highly misleading. Extrapolated from an often-misunderstood 1991 study by economist Joseph DiMasi, the $500 million figure includes significant expenses that are tax deductible and unrealistic scenarios of risks.

- The actual after-tax cash outlay – or what drug companies really spend on R&D – for each new drug (including failures) according to the DiMasi study is approximately $110 million. (That's in year 2000 dollars, based on data provided by drug companies.) (See Section I)

- A simpler measure – also derived from data provided by the industry – suggests that after-tax R&D costs ranged from $57 million to $71 million for the average new drug brought to market in the 1990s, including failures. (See Section II)

- Industry R&D risks and costs are often significantly reduced by taxpayer-funded research, which has helped launch the most medically important drugs in recent years and many of the best-selling drugs, including all of the top five sellers in one recent year surveyed (1995).

- An internal National Institutes of Health (NIH) document, obtained by Public Citizen through the Freedom of Information Act, shows how crucial taxpayer-funded research is to top-selling drugs. According to the NIH, taxpayer-funded scientists conducted 55 percent of the research projects that led to the discovery and development of the top five selling drugs in 1995. (See Section III)

- The industry fought, and won, a nine-year legal battle to keep congressional investigators from the General Accounting Office from seeing the industry's complete R&D records. (See Section IV) Congress can subpoena the records but has failed to do so. That might owe to the fact that in 1999-2000 the drug industry spent $262 million on federal lobbying, campaign contributions and ads for candidates thinly disguised as "issue" ads. (See accompanying report, "The Other Drug War: Big Pharma's 625 Washington Lobbyists")

- Drug industry R&D does not appear to be as risky as companies claim. In every year since 1982, the drug industry has been the most profitable in the United States, according to *Fortune* magazine's rankings. During this time, the drug industry's returns on revenue (profit as a percent of sales) have averaged about three times the average for all other industries represented in the Fortune 500. It defies logic that R&D investments are highly risky if the industry is consistently so profitable and returns on investments are so high. (See Section V)

- Drug industry R&D is made less risky by the fact that only about 22 percent of the new drugs brought to market in the last two decades were innovative drugs that represented important therapeutic gains over existing drugs. Most were "me-too" drugs, which often replicate existing successful drugs. (See Section VI)

- In addition to receiving research subsidies, the drug industry is lightly taxed, thanks to tax credits. The drug industry's effective tax rate is about 40 percent less than the average for all other industries. (See Section VII)

- Drug companies also receive a huge financial incentive for testing the effects of drugs on children. This incentive called pediatric exclusivity, which Congress may reauthorize this year, amounts to $600 million *in additional profits* per year for the drug industry – and that's just to get companies to test the safety of several hundred drugs for children. It is estimated that the cost of such tests is less than $100 million a year. (See Section VIII)

- The drug industry's top priority increasingly is advertising and marketing, more than R&D. Increases in drug industry advertising budgets have averaged almost 40 percent a year since the government relaxed rules on direct-to-consumer advertising in 1997. Moreover, the Fortune 500 drug companies dedicated 30 percent of their revenues to marketing and administration in the year 2000, and just 12 percent to R&D. (See Section X)

Introduction

Major U.S. drug companies and their trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), have carried out a campaign to scare policy makers and the public. The central claim of PhRMA's campaign is ominous: if anything is done to restrain high U.S. prescription drug prices, then research and development (R&D) to find new drugs for life-threatening diseases will suffer.

Alan Holmer, president of PhRMA, recently played this "R&D scare card" while on National Public Radio's "Talk of the Nation" program.

"Believe me," Holmer warned, "if we impose price controls on the pharmaceutical industry, and if you reduce the R&D that this industry is able to provide, it's going to harm my kids and it's going to harm those millions of other Americans who have life-threatening conditions."[1]

Later in the program, to reinforce his argument, Holmer made the claim that research costs "$500 million just to get one medicine to market."

The drug industry's "R&D scare card" is built on the premise that drug companies need extraordinary profits – about three times those of the average Fortune 500 company – in order to conduct expensive and risky research on innovative new drugs. But evidence shows the research isn't as expensive, risky or innovative as the industry claims.

Instead, the evidence shows that such research may cost far less than $500 million for every new drug – and may be less than $100 million for every new drug (including failed drugs). The evidence also shows that the drug industry isn't all that innovative, as it produces far more "me-too" or copycat drugs of little medical importance than life-saving medicines.[2] And, the evidence suggests that drug industry research isn't all that risky because

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the industry is awash in profits while lightly taxed and heavily subsidized. In fact, an internal National Institutes of Health (NIH) study obtained by Public Citizen shows that taxpayer-funded scientists and foreign universities conducted 85 percent of the published research studies, tests and trials leading to the discovery and development of five blockbuster drugs.[3] It's no wonder the drug industry fought all the way to the Supreme Court to keep its R&D records hidden from congressional investigators.

In all, the evidence shows that the drug industry's R&D scare card is, in reality, an R&D "canard" – that is "an unfounded or false, deliberately misleading story."

I. Deconstructing the $500 Million Myth

The story of PhRMA's R&D canard starts with the drug industry's repeated – and unchallenged – claim that it costs $500 million to develop a new drug, including money spent on failures. The $500 million figure has become ubiquitous and widely accepted. Unfortunately, it is misleading at best and inaccurate at worst.

Public Citizen calculated more realistic R&D costs using methodology modeled after that employed by the congressional Office of Technology Assessment (OTA) in its 354-page report, "Pharmaceutical R&D: Costs, Risks and Rewards," published in 1993. (See Appendix A)

These are our findings:

- As the OTA noted, "the industry's collective response to charges that drug prices are too high or are increasing too fast has been to point to the high and increasing cost of pharmaceutical R&D." Specifically, "industry representatives have pointed to academic studies of the average cost of bringing a new pharmaceutical compound to the market."[4]

- This decade, industry representatives have pointed to one academic study above all for the $500 million figure. That is a 1991 study by Joseph DiMasi of the Tufts Center for the Study of Drug Development. PhRMA representatives have acknowledged that the $500 million figure is an extrapolation, adjusted for inflation and changes in research and development, based on the Tufts Center study.[5] DiMasi estimated the *pretax* cost of developing certain new drugs, including failures, at $231 million in 1987.[6]

- OTA later revised DiMasi's $231 million figure with significantly higher opportunity cost of capital. (Opportunity cost of capital is a calculation of what a R&D expenditure might be worth had the money been invested elsewhere. DiMasi used a 9 percent annual rate of return to calculate the cost of capital. OTA used a rate that went from 10 to 14 percent over time.) OTA put the "upper bound of the

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full capitalized cost" of R&D per new drug at $359 million in 1990 dollars. Inflated to year 2000 dollars, this estimate becomes $473 million, and it has been rounded up to $500 million by the industry.

- The Tufts Center for the Study of Drug Development is a self-described "independent research group affiliated with Tufts University." The center's sponsors include some of the world's largest drug companies such as Merck, Pfizer and Bayer.[8] According to the Tufts Center, corporate sponsors get to "help shape strategic objectives" and "influence key Center activities."[9]

- DiMasi's study relied on data provided by 12 drug companies.[10] This information has not been independently verified, nor checked for accuracy. The OTA issued this warning about DiMasi's data: "Any company that understood the study methods and the potential policy uses of the study's conclusions could overestimate costs without any potential for discovery. Thus, the motivation to overestimate costs cannot be discounted."[11]

- It's important to note that DiMasi's study only focuses on the cost of developing "new chemical entities" (NCEs), which he defines as drugs that have never been tested before in humans.[12] (His definition of NCE differs only slightly from the Food and Drug Administration definition of a new molecular entity, or NME.[13]) Furthermore, DiMasi focuses only on "self-originating" NCEs, which are new entities developed by companies as opposed to those they acquire from other research organizations. Many new drugs approved for market are not NCEs, but are new dosage forms or new combinations of existing drugs.[14] Thus, DiMasi focuses only on the most expensive new drugs, not *all* new drugs, resulting in a *higher* cost estimate.

- DiMasi's original $231 million figure does not represent what companies *actually spend* to discover and develop new molecular entities. Rather, it includes the cost of all failed drugs and the expense of using money for drug research rather than other investments. It also *does not* account for huge tax deductions that companies get for R&D. Therefore, it substantially *overestimates* net expenditures on R&D.

- According to the OTA, "The net cost of every dollar spent on R&D must be reduced by the amount of tax avoided by that expenditure. Like all business expenses, R&D is deductible from a firm's taxable income."

- The OTA revised DiMasi's calculation, subtracting the expenses that are tax deductible under Section 174 of the federal tax code and the opportunity cost of capital.

- The tax deduction reduces the cost of R&D by the amount of the

corporate marginal tax rate (currently 34 percent). This means, in effect, that every dollar spent on R&D costs $0.66.[15] The OTA concluded that DiMasi's original $231 million figure (in 1987 dollars) was $171 million (in 1990 dollars) after accounting for the R&D tax deduction.

- The opportunity cost of capital accounts for slightly more than half (51 percent) of DiMasi's total figure. After subtracting tax deductions and the opportunity cost of capital, OTA found that DiMasi's after-tax R&D cash outlay for a new NME was $65.5 million (in 1990 dollars). That is the estimate of how much the drug companies in DiMasi's study actually spent on new chemical entities, including failures.

- It should be noted that five of the seven previous R&D cost studies that DiMasi references *did not* include opportunity cost of capital in their calculations.[16]

- Public Citizen inflated this figure to year 2000 dollars and found that actual after-tax cash outlay for NCEs (including failures) was $110 million – based on DiMasi's data.
(See Table 1)

- It's important to stress that this is the R&D cost for new chemical entities – which require the most expensive type of research – not all new drugs brought to market. The R&D costs for all new drugs brought to market, based on PhRMA's own data, is detailed in Section II.

- Several additional points about DiMasi's estimate: First, it does not account for R&D tax credits available to the drug industry (these are different from the R&D deductions). DiMasi estimated that R&D tax credits amounted to a 6.8 percent subsidy for R&D expenditures from 1978 to 1986.

- Second, DiMasi assumes an FDA review time of 30 months in his calculations. FDA review time has dropped dramatically since 1991 and now averages 11 to 17 months. DiMasi said a one-year decrease in review time would cut his R&D estimate by $19 million (in 1987 dollars, or $29 million in year 2000 dollars).

- Third, evidence suggests that the time required to conduct clinical trials on new drugs is also decreasing – particularly for the most efficient companies. A January 2000 report by the Tufts Center for the Study of Drug Development stated that clinical testing time declined by 19 percent for drugs approved in 1996-1998 when compared with drugs approved in 1993-1995.[17] In addition, the five quickest pharmaceutical companies shaved, on average, more than one-year off the industry-wide median time (5.7 years) for clinical research.[18]

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- Fourth, the advent of new technologies such as genomics and combinatorial chemistry, has led, according to investment analysts at Lehman Brothers, "to a growing school of thought that the cost of discovering new biological targets and the cost of creating drug leads is falling."[19]

- Finally, it should be stressed that DiMasi's estimate of R&D costs was far higher than in previous studies, including one published by the pharmaceutical industry in 1987. That study by S.N. Wiggins put the pre-tax cash outlay per NCE at $65 million (in 1986 dollars).[20] After-taxes, the figure becomes $67 million in year 2000 dollars.

Table 1
Comparative Analysis of Pharmaceutical R&D Costs
($ millions per New Chemical Entity)

Study (Year)	Expressed in Dollars for Which Year	Pre-tax Including Cost of Capital (9%)	Pre-tax Excluding Cost of Capital	After-tax Actual Cash Outlay*
DiMasi Original (1991)	1987	$231	$114	$61.6**
Office of Technology Assessment (1993)	1990	$259	$127	$65.5
Public Citizen (2001)	2000	$341	$167	$110.2***

* Excludes the opportunity cost of capital. **DiMasi did not calculate after-tax costs; the $61.6 million figure was calculated by Public Citizen based on the 46 percent corporate tax rate in effect at the time of the expenditures DiMasi studied. *** The $110 million figure is calculated using the current corporate tax rate of 34 percent; this is the rate used to deduct R&D expenses from taxable income.

II. PhRMA's Own Data Contradicts the $500 Million Claim

Not all R&D is created equal. DiMasi studied the most expensive of all new drugs. Only 36 percent of drugs the FDA approved for market in the 1990s were NMEs (similar to DiMasi's NCEs). The others were mostly new combinations of drugs or new formulations of existing drugs. (For example, from pill to syrup form.)

The drug industry's own data about this larger universe of new drugs reveal that the actual cash outlay for a new drug is far less than $500 million – and perhaps as low as $57 million per drug in recent years (including failures).

Here's how Public Citizen arrived at this conclusion:

PhRMA's annual survey lists aggregate R&D spending by year in two categories: domestic (spending in the U.S. by both foreign and domestic companies) and abroad (spending overseas by U.S.-based companies.)

Public Citizen uses PhRMA's domestic spending for its analysis, in part, because that's what DiMasi did when he ran a check on his study using aggregate data. His reasoning: "We include only domestic expenditures in our analysis under the assumption that the foreign expenditures of U.S.-owned firms will be directed primarily to non-U.S. introductions."[21] (Public Citizen has calculated R&D costs with combined domestic-overseas spending in Appendix B. Spending in the last decade ranges between $69 million and $87 million per drug.)

According to PhRMA, U.S. and foreign drug companies spent $139.8 billion on domestic R&D in the 1990s.[22] During that same period, the U.S. Food and Drug Administration approved 857 new drugs for market.[23] Simple division suggests that drug companies spent $163 million on R&D for every new drug approved for market in the U.S. in the 1990s (expressed in year 2000 *pre-tax* dollars).

This measure is very generous to the industry. It counts total R&D expenditures – which include salaries, equipment, overhead, lab tests (pre-clinical) and clinical trials.[24] And it counts all failed drugs as well as successful drugs. In addition, it uses PhRMA's own R&D figures, which have not been independently verified and may be inflated with marketing research costs.[25] Finally, it uses pre-tax figures; in fact, R&D expenses are tax deductible and every dollar spent on R&D has a net cost of only $0.66.

A more accurate measure – according to pharmaceutical experts such as Stephen Schondelmeyer, director of the PRIME Institute at the University of Minnesota – would account for R&D tax deductions and the approximate seven-year lag between R&D spending and drug approval. (DiMasi said "approvals in one year should be associated with R&D expenditures lagged 2 to 12 years."[26]) Therefore, a more accurate measure would compare R&D spending for 1994 to new drug approvals for the year 2000.

To be even more accurate, the measure should account for years in which R&D spending on new drugs was extraordinarily high or low. In other words, it should smooth out the peaks and valleys. Thus, this measure would compare R&D spending over seven-year periods with new drug applications (NDAs) approved over corresponding seven-year periods. An annual average should be calculated for each period, which has the effect of smoothing out peaks and valleys. (See Appendix B for more detailed methodology)

The results? From 1984-1990, PhRMA reported that R&D spending totaled $32.8 billion. (That's domestic R&D spending by U.S. companies and foreign-based companies.[27]) Adjusted for inflation, that total is $48.2 billion

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in year 2000 dollars. Divide that amount by the number of new drugs (563) approved from 1990-1996 and it appears that $85.6 million was the average R&D cost for every new drug approved in that period (in pre-tax dollars). After subtracting tax deductions, worth 34 cents on the dollar, the actual cost plummets to $56.5 million.

For new drugs approved in the more recent seven-year NDA period 1994-2000, the average pre-tax cost of R&D was $107.6 million. Adjusting for R&D tax deductions makes the figure $71.0 million. (See Table 2)

Table 2
Average R&D Cost per New Drug Approved During the 1990s
(Rolling 7-Year Average with 7-Year Lag,
$ in millions, all in year 2000)

Domestic R&D Spending Only

7-Year R&D Period	Average Annual R&D Spending	7-Year NDA Period	Average Annual NDA's Approved	Pre-Tax R&D Spending per New Drug	After-Tax R&D Spending per New Drug
1988-1994	$10,255.3	1994-2000	95.3	$107.6	$71.0
1987-1993	$9,387.8	1993-1999	91.3	$102.8	$67.9
1986-1992	$8,473.3	1992-1998	92.4	$91.7	$60.5
1985-1991	$7,613.0	1991-1997	88.6	$86.0	$56.7
1984-1990	$6,887.1	1990-1996	80.4	$85.6	$56.5

Source: Spending data comes from Pharmaceutical Research and Manufacturers of America, PhRMA Annual Survey, 2000; NDA data comes from U.S. Food and Drug Administration, Center for Drug Evaluation and Research, December 31, 2000. (All spending figures have been inflated to year 2000 dollars.)
Note: Domestic R&D includes expenditures within the United States by research-based pharmaceutical companies.

Two additional notes:

Some might quarrel with the seven-year lag, arguing that in accounting terms, today's R&D expenses are paid by today's revenue. Thus, R&D spending in any year ought to be compared with drugs brought to market that same year. This study rejects that argument. It doesn't reflect the reality that R&D spending invariably precedes the marketing of a drug and our purpose is to understand what it costs to bring a drug to market, not how that R&D is paid for in accounting terms. In addition, as noted earlier, DiMasi agrees that spending should be lagged two to 12 years. Nevertheless, Public Citizen calculated R&D spending for current drug approvals and current research expenditures in Appendix B and found that spending remained close to $100 million per drug, with costs in the 1990s ranging from $99 million to $118 million per drug.

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Finally, it has also been suggested that our analysis should focus only on NCEs or NMEs because that's what DiMasi studied, and that's where the bulk of industry R&D is spent, and those new compounds are the drugs that make the industry risky. That analysis is below (see Table 3) although our intent was not to mirror DiMasi in this section. Rather, this section aims to point out that there are many kinds of drugs approved each year – not just the elite group in DiMasi's study. More important, PhRMA's R&D spending figures – the figures that it constantly touts – are for all drugs, not just NMEs or NCEs. So it's only fitting to compare PhRMA's spending for all drugs to all drugs approved for market. (That said, an all-NME analysis shows R&D spending of $114 million to $150 million per drug.)

Table 3
Average R&D Cost per New Molecular Entity During the 1990s
(Rolling 7-Year Average with 7-Year Lag, $ in millions)

Domestic R&D Spending Only

7-Year R&D Period	Average Annual R&D Spending	7-Year NME Period	Average Annual NME's Approved	Pre-Tax R&D Spending per NME	After-Tax R&D Spending per NME
1988-1994	$7,588.9	1994-2000	33.4	$227.02	$149.8
1987-1993	$6,947.0	1993-1999	33.1	$209.61	$138.3
1986-1992	$6,270.2	1992-1998	31.9	$196.82	$129.9
1985-1991	$5,633.6	1991-1997	31.9	$176.84	$116.7
1984-1990	$5,096.4	1990-1996	29.6	$172.34	$113.7

Source: Spending data comes from Pharmaceutical Research and Manufacturers of America, PhRMA Annual Survey, 2000; NDA data comes from U.S. Food and Drug Administration, Center for Drug Evaluation and Research, December 31, 2000. (All spending figures have been inflated to year 2000 dollars.)
Note: Domestic R&D includes expenditures within the United States by research-based pharmaceutical companies.

III. U.S. Taxpayers Play A Crucial Role in Pharmaceutical R&D

Drug companies stress how difficult it is to discover new drugs – particularly innovative life-saving drugs. But the evidence suggests it's not all that risky because the federal government is doing much of the crucial research. The National Institutes of Health (NIH) budget reached $20.3 billion in fiscal year 2001 (a 14 percent increase over FY 2000) with much of that money going to research that ultimately helps with the discovery and development of pharmaceuticals – how much exactly is hard to say. The NIH admits it doesn't track its spending on drug development. NIH officials claim it's a tough task because so much NIH work is basic research into diseases that is converted years later – often through several other related

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discoveries that build on one another – into a marketed drug.[28]

What we do know is that several studies have shown that many important and popular drugs were developed with taxpayer support. That's why publicly-funded researchers have 90 Nobel Prizes compared to just four by industry scientists, although the industry spends more on R&D.[29] For instance:

- A study by a Massachusetts Institute of Technology (MIT) scholar of the 21 most important drugs introduced between 1965 and 1992 found that publicly funded research played a part in discovering and developing 14 of the 21 drugs (67 percent).[30]

- 45 of the 50 top-selling drugs from 1992-1997 received government funding for some phase of development, according to an investigation by *The Boston Globe*. In all, taxpayers spent at least $175 million helping to develop these 50 drugs.[31]

Publicly-funded Researchers Conducted Most Studies Behind Blockbuster Drugs

An NIH internal document obtained by Public Citizen through the Freedom of Information Act ("NIH Contributions to Pharmaceutical Development," February 2000, see Appendix C) reveals much more detail about the importance of taxpayer-funded research to drug companies.

The NIH report looked closely at the role of public research in developing the most popular drugs in the U.S. To avoid well-known NIH success stories, such as the agency

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A) Drug Pricing and Objectives

Q.1 What are the Objectives of the Drug Policy ?

Ans. As per the Modifications in Drug Policy, 1986 announced in September, 1994, the main objectives of the Drug Policy are as under :

a. ensuring abundant availability, at reasonable prices of essential and life saving and prophylactic medicines of good cuality;
b. strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;
c. creating an environment conducive to channelising new investment into the pharmaceutical industry with a view to encourage cost-effective production with economic sizes and introducing new technologies and new drugs;
d. and strengthening the indigenous capability for production of drugs.

Q.2 What is the "Drugs (Prices Control) Order (DPCO, 1995)" ?

Ans. The Drugs Prices Control Order, 1995 is an order issued by the Government of India under Sec. 3 of Essential Commodities Act, 1955 to regulate the prices of drugs. The Order interalia provides the list of price controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by Govt., penalties for contravention of provisions etc. For the purpose of implementing provisions of DPCO, powers of Govt. have been vested in NPPA.

Q.3 Why the DPCO is issued under Essential Commodities (EC) Act ?

Ans. Drugs are essential for health of the society. Drugs have been declared as Essential and accordingly put under the Essential Commodities Act.

Q.4 Are all the drugs marketed in the country under price control ?

Ans. No, Only 74 out of about 500 commonly used bulk drugs are kept under statutory price control. All formulations containing these bulk drugs either in a single or combination form fall under price controlled category. However, the prices of other drugs can be regulated, if warranted in public interest.

Q.5 What is NPPA and its role ?

Ans. National Pharmaceutical Pricing Authority (NPPA), was established on 29th August 1997 as an independent body of experts as per the decision taken by the Cabinet committee in September 1994 while reviewing Drug Policy. The Authority, interalia, has

been entrusted with the task of fixation/revision of prices of pharmaceutical products (bulk drugs and formulations), enforcement of provisions of the Drugs (Prices Control) Order and monitoring of the prices of controlled and decontrolled drugs in the country.

B) Features of DPCO

Q.6 How are the prices of drugs in the controlled category regulated ?
Ans. As per the provisions of DPCO, NPPA fixes two types of prices viz. Ceiling prices and Non-ceiling prices for medicines in the controlled category.

Q. 7 What is "Ceiling Price" ?
Ans. In the case of each bulk drug, which is under price control a single maximum selling price is fixed that is applicable throughout the country.

To achieve uniformity in prices of widely used formulations, the Modifications in Drug Policy envisage that there should be ceiling prices for commonly marketed standard pack sizes of price controlled formulations which would be obligatory for all, including small scale units, to follow. Powers under para 9 of DPCO, 1995 are exercised for fixation/revision of ceiling prices. The ceiling price fixed/revised by NPPA are notified in the Gazette of India (Extraordinary) from time to time. The ceiling prices are usually notified as exclusive of excise duty, local tax, etc.

Q.8 What is "Non-Ceiling Price" ?
Ans. Non - ceiling prices fixed by NPPA under para 8(1), (2) and (4) and para 11 of DPCO, 1995 are specific to a particular pack size of scheduled formulation of a particular company. Hence they are formulation specific and company specific. The prices fixed for non-ceiling packs are communicated to the respective firms by issuing office orders. In such order, usually excise duty element is shown separately. However, local taxes are not included in the Non-ceiling price.

Q.9 Whether NPPA has any role to regulate prices of non-scheduled drugs ?
Ans. The manufacturer of a non-scheduled drugs (drugs not under direct price control) is not required to take price approvals from NPPA for such drugs. However, NPPA is required to monitor the prices of such drugs and take corrective measures where warranted and their includes the power to fix and regulate such prices.

Q.10 What margins are allowed to a Wholesaler and a Retailer as per DPCO, 1995 ?
Ans. For scheduled (controlled) drugs the margin is fixed at 16% as per para 19 of the DPCO, 1995 which is reproduced below :

1. "A Manufacturer, distributor or wholesaler shall sell a formulation to a retailer, unless otherwise permitted under the provisions of this order or any order made thereunder, at a price equal to the retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen per cent thereof in the case of Scheduled drugs".
2. "Notwithstanding anything contained in sub-paragraph (1), the Government may by a general or special order fix, in public interest, the price of formulations sold to the wholesaler or retailer in respect of any formulation the price of which has been fixed or revised under this Order". For non-scheduled formulations the companies are at liberty to decide the margin. However, it is reported by the

industry that the prevailing normal trade margin in respect of some decontrolled formulations is 20% for retailers and 10% for wholesalers.

C) Punishment for Violation

Q.11 What are the punishments for violating the DPCO, 1995 ?
Ans. Contravention of any of the provisions of DPCO, 1995 is punishable in accordance with the provision of the Essential Commodities Act, 1955. As per Sec. 7 of Essential Commodities Act, the penalty for contravention of DPCO is minimum imprisonment of 3 months, which may extend to seven years and the violator is also liable to a fine.

Q.12 What happens if a manufacturer sells a medicine above the price approved by the Government ?
Ans. If a manufacturer sells a medicine at a price higher than the price approved/ fixed for the product the manufacturer is liable for prosecution under Essential Commodities Act and also liable to deposit the amount with the Government accrued due to charging of prices higher than those fixed or notified by the Government.

D) Enforcement Agencies

Q.13 Who are the national level, state level and district level authorities that are responsible for enforcement of fixed prices ?
Ans. The National Pharmaceutical Pricing Authority, the FDA/ Drugs Controller of the State, and Drugs Inspector of the District are the enforcing authorities at National / State/ District Levels.

Q.14 Who are the local level authorities to whom the compliant can be made ?
Ans. The area State Drug Controller/Joint Drug Controller/ Deputy Drug Controller/Assistant Drug Controller / Drugs Inspector etc. of the state concerned. Complaints can be lodged with anyone of these.

Q.15 Where can a consumer lodge a complaint regarding overcharging and quality of drugs sold ?
Ans. Charging more than printed MRP of a medicine attracts the penal provisions of Drugs Price Control Order, 1995. Quality aspects of a medicine attract the provisions of Drugs and Cosmetic Act, 1940. The FDA/ Drugs Control Organisation of the State is the enforcing agency of Drugs and Cosmetics Act and DPCO at state level. Therefore, all complaints on prices as well as quality of medicines can be lodged with the Drugs Inspector of the District or the State Drug Controller. Complaints regarding violation of prices can be lodged with NPPA directly also.

E) Retail price and labeling requirements

Q.16 What is a retail price ?
Ans. A retail price is a price at which a formulation / medicine is sold to a consumer/user. The manufacturer of the formulation is required to print such a price on the label of the product. In case of controlled formulations the retail price is a price arrived at or fixed in accordance with the provisions of Drugs (Prices Control) Order, 1995.

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Q.17 What is the essential/ mandatory information that is required to be printed on the label of the medicine pack ?
Ans. The following information is required to be printed on the label of a medicine under the Drugs and Cosmetics Act and DPCO, 1995.

a. Name of the formulation
b. Composition of the formulation
c. Pack Size
d. Address of the manufacturer
e. Manufacturing License Number
f. Date of manufacture
g. Expiry Date
h. Maximum Retail Price (Excluding Local Taxes) etc.

Q.18 Labels of the medicines carry words 'local taxes extra'; which are these and what are the rates ?
Ans. They generally include Sales Tax and Octroi. Whenever the manufacturer pays the Central Sales Tax (CST) the same is also included. They are to be paid by the customer.

Q.19 What is the total amount required to be paid for a medicine ?
Ans. The printed MRP (Maximum Retail Price) plus local taxes is the maximum payable amount. However, a medicine can be sold below this price.

Q.20 If a retailer sells medicines by breaking packing, what price can he charge ?
Ans. If a retailer sells loose quantity (unpacked) the price of such medicine should not exceed pro-rata amount of the price printed on the label of the container, plus 5% thereof.

Q.21 Can consumer ask for the price list of medicines being sold by a chemist/retailer ?
Ans. Yes. Every retailer is required to display the price list and the supplementary price list furnished by the manufacturer/ importer on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

Q.22 Is it mandatory for a chemist/ retailer to issue cash receipt for sale of medicines ?
Ans. Yes. Every chemist/ retailer is required to issue a receipt for sale of medicines and maintain the copies of cash/ credit memos.

F) General reasons for price increases in medicines

Q.23 Why are the prices of medicines rising ?
Ans. The reasons for rise in the prices of medicines are :

i. rise in the price of bulk drugs;
ii. rise in the cost of excipients used in the production of medicines like Lactose, Starch, sugar, glycerine, solvent, gelatine capsules etc.;
iii. rise in the cost of transport, freight rates;

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iv. rise in the cost of utilities like fuel, power, diesel, etc.;
v. for imported medicines, rise in the c.i.f. price and depreciation of the Rupee;
vi. changes in taxes and duties.

G) Price Fixation procedures

Q.24 What is the methodology for fixation of bulk drug price ?
Ans. Methodology for fixation/revision of bulk drug prices is as under :

As per para 3 of DPCO, 1995, bulk drug prices are fixed by the NPPA to make it available at a fair price from different manufacturers. These prices are fixed from time to time by notification in the official gazette.

The following steps are involved in fixation/revision of bulk drug prices :-

1. Collection of data by issuing questionnaire/Form I of DPCO, 1995 to the companies and from cost-audit report etc.
2. Verification of data by plant visits, when required.
3. Preparation of actual cost statement.
4. Preparation of technical parameters to be adopted for working out fair price of the bulk drug.
5. Preparation of estimated cost based on actual cost and technical parameters. Fair price is calculated by providing returns as specified in sub para (2), para 3 of DPCO, 1995 as opted by the individual manufacturer.
6. Fixation of fair price of bulk drug by considering weighted average cost, °rd cut-off level of production studied.
7. Notification of bulk drug price in official Gazette.
8. The fair prices may be further revised, if asked for by the manufacturers, based on escalation formula for change in major raw materials and utilities rates.

Q.25 What is the methodology for fixation of price of formulation ?
Ans. Para 8 of DPCO, 1995 lays down the rules and procedure for fixing prices of formulations. Para 7 of the DPCO lays down the formula for calculation of retail price of formulation.

The circumstances that warrant price fixation of formulation are :-

i. Revision in the prices of bulk drugs(Sub-Para(2) of para 8 of DPCO, 1995)
ii. Introduction of new packs (Sub -Para (6) of para 8)
iii. Change in various norms etc. notified by Government under para 7.
iv. Other reasons which may be cited by the manufacturer.

In order to seek price approval , the firm manufacturing the pack has to make an application in Form -III appended to the DPCO, if it is locally manufactured; or Form-IV, appended to the DPCO, 1995, if it is imported.

Applications received in NPPA from manufacturers in Form III for indigenous formulations and from importers in Form IV (as prescribed under DPCO, 1995) are considered for price fixation/revision. The retail prices of indigenously produced formulations are worked out as per the formula given in para 7 of the DPCO, 1995. For indigenously manufactured formulations, the Maximum Allowable Post-manufacturing Expenses (MAPE) is allowed upto 100%. For imported formulations MAPE is upto 50% of landed cost.

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Q.26 What is Suo-motu pricing ?

Ans. The NPPA also fixes/revises prices of both bulk drugs and formulations on suo-motu basis, where it is felt that manufacturers are not filing their applications as per the provisions of the DPCO, 1995 after the decrease in bulk drug prices and statutory duties, etc. Hence, with a view to passing on the benefits of such decreases to the consumers, suo-motu price is fixed. For example, as per para 8(2) of DPCO, 1995, the manufacturers are to apply for price revision of formulations within a period of thirty days of price fixation/revision of bulk drug(s). If they fail to comply with this during the prescribed time, suo- motu action is taken as per para 9(2) of DPCO, 1995 for ceiling prices, and as per para 8(2) and para 11 of DPCO, 1995 for non-ceiling packs.

Q.27 What is Pro-rata Pricing ?

Ans. NPPA has issued notification on pro -rata pricing on 27.01.98. According to this notification, the manufacturers of all the scheduled formulation pack sizes different from the notified pack sizes under sub- paragraphs (1) and (2) of the paragraph 9 of the DPCO, 1995, shall have to work out the price for such pack sizes, in respect of tablets and capsules of the same strength or composition packed in different strips or blisters, on pro-rata basis of the latest ceiling price fixed for such formulations under sub-paragraphs (1) and (2) of para 9 of the DPCO, 1995. This was done to ensure that :-

i. manufacturers are not forced to approach frequently for price approvals for different pack sizes and
ii. the manufacturers do not change the pack sizes in a bid to remain out of price control.

Every formulation of a bulk drug included under schedule 1 of DPCO, irrespective of pack size, strength, dosage form must be marketed only at price fixed by Government, with adjustment for pro-rata price wherever required. However, the manufacturers in the Small Scale Industry (SSI) category may avail exemption from seeking price fixation from NPPA in respect of Scheduled Formulations not covered under ceiling prices provided they have submitted a declaration to NPPA as per S.O.No.134(E) dated 2nd March, 1995 and obtained approval for the same from NPPA.

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