

FAQ: HIV & AIDS TREATMENT ACCESS

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ARVs & Treatment

Is antiretroviral treatment necessary to combat HIV/AIDS?

Yes. A few years after infection with HIV, the virus weakens the patient's immune system to the point where the first "opportunistic infections" appear. HIV itself does not kill, it is opportunistic infections – such as tuberculosis and pneumonia – that do. Medicines to treat most opportunistic infections are available (though they are often too expensive for the majority of patients). But treating opportunistic infections is only a temporary solution, since HIV continues to attack the immune system. After one infection is cured, others inevitably follow. Antiretroviral (ARV) drugs are needed in order to combat HIV directly and are an important part of a comprehensive approach to addressing the epidemic. They do not cure AIDS, but can improve a patient's quality of life and prolong survival when taken consistently. Over the last six years, the introduction of ARVs in Europe and the US has cut AIDS deaths by over 70%. In Brazil, the use of ARVs cut AIDS mortality by 51% from 1996-1999. Treatment is also a powerful incentive to get tested, providing a strong boost to prevention efforts. We cannot afford to wait to extend treatment.

Should treatment take precedence over prevention activities?

Prevention and treatment are BOTH essential and complementary components of combating disease. Field experience has shown that prevention efforts are boosted when treatment is also made available.

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

The high price of medicines is one of many barriers to providing ARV treatment for people living with AIDS in developing countries. Other barriers include political will, social stigma, health infrastructure, and insufficient funding. But until recently, the prices of ARVs were so high that wide scale treatment programs were unthinkable. Since September 2000, the injection of generic competition into the global ARV market has catalyzed a dramatic drop in drug prices. As a result, medical, academic, and political leaders are now beginning to tackle other barriers to treatment. With the prices of drugs tumbling, there is no longer any excuse to deny medical treatment to the millions who are already ill.

Is it even possible to provide free access to ARV treatment in poor countries?

Yes, an increasing number of countries around the world have programs that offer free ARV treatment. Botswana was one of the first countries in Africa to establish a national antiretroviral therapy program, beginning in 2002 and progressively expanding across the country. Treatment is provided free of charge in the public sector. This has in turn stimulated demand for voluntary HIV counseling and testing. Brazil began offering free and universal access to triple-combination antiretroviral treatment in 1996. Today about 160,000 people receive free treatment through the public health system. This includes 17 antiretroviral drugs, eight of which are domestically produced generic drugs and nine are imported brand-name drugs. The government estimates that provision of treatment early in the epidemic has saved Brazil more than US\$ 2 billion in health-care costs since the beginning of the epidemic.

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

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

Do developing countries need second-line drugs because patients there don't adhere to medicine and so are causing the emergence of super-drug-resistant strains of HIV?

The complexity of AIDS treatment makes patient adherence a challenge in BOTH wealthy and poor settings. However, results from the few existing programs are encouraging. With limited health infrastructure, Brazil has dramatically reduced illnesses and deaths from AIDS, and enjoys treatment adherence rates that match those in the US (around 70% of patients taking their medicines properly 80% of the time). In much poorer Uganda and Côte d'Ivoire, well-run pilot projects have also demonstrated that adherence rates can match those of Europe and the US. But, in the normal course of HIV disease, patients become resistant to first line drugs in 4-7 years in both the wealthy and poor nations. As such, second generation drugs are needed in the US and Europe—and must be made available to those in the Global South.

Prices, Patents, and Generics

Are generic medicines the best way to bring prices down?

Yes. When generic competition is introduced, prices will fall—historically by up to 95%. For example, after the Brazilian government began producing AIDS drugs generically, prices dropped by 82%. In contrast, the prices of drugs with no generic competitor dropped by only 9%. Likewise, generic competition reduced the price of a triple-combination of antiretrovirals from \$10,000 to \$300 in one year.

Do patents block access to medicines?

When medicines are under patent in a country, the patent-holder has a monopoly on the drug for a minimum of 20 years and can charge whatever price will maximize profit. This prevents the entry of generic competition. In developing countries, this translates into prices that are not affordable for the patient so people die without access.

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

No. Profits from sales in developing countries are insignificant in creating incentives for future research and development. The U.S. drug industry is already the most profitable industry in the world. Pharmaceutical sales in the countries in question are an infinitesimal portion of total global sales (\$518 billion in 2004). All of Africa makes up just 0.4% of the global market; all developing countries combined (Africa, Asia, and Latin America) comprise less than 11.5% of global drug sales. U.S. drug companies make most of their sales (88.5%), and an even higher portion of their profits, from the rich markets of North America, Europe, and Japan. They don't need to squeeze blood from poor consumers in Thailand and other developing countries in order to bring a new medicine to the market. Finally, it is notable that companies consistently spend more on marketing and administration than on R&D.

Why not ask companies simply to donate the drugs?

Drug donations are not a long-term solution to the access crisis. Donations usually do not cover global need and are limited in time and place; they often come with burdensome restrictions on recipient health ministries; they often require extra administrative work, diverting scarce resources from health systems; they can distort rational drug use; tax deductions given for donations may cost donor countries more than other options. Considering the weaknesses, donations should neither be relied-upon, portrayed, nor promoted as the best way to improve access to medicines.

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

No. Patents are granted on a national basis -- there is no such thing as an international patent. Therefore, if a drug is not patented in a country, it is perfectly legal for a generic company to produce or import a version of that drug in that country. Companies can also export generics to other countries where that drug is not under patent. A concrete example is the AIDS drug zidovudine (AZT). GlaxoSmithKline holds the patent for AZT in the US and Europe, but it does not have a patent for AZT in Ghana. This means that Ghana can legally produce or import a generic version of AZT, and is not in any way infringing on the patent rights of GlaxoSmithKline. In India, there is no product patent for AZT. This means that a generic company like Cipla, based in Bombay, can legally produce and export AZT to a country like Ghana.

What is compulsory licencing?

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

What is parallel importing?

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

How much does it cost to research and develop a new drug?

An accurate answer is impossible, since companies do not divulge R&D costs per drug, and methods for calculating this figure are highly controversial. The industry estimates that R&D for each new drug ranges from \$350-\$500 million. These estimates cover many costs, including compounds that have failed, overhead, and opportunity cost. In contrast, independent estimates range from \$30-\$160 million. In addition, R&D is often funded by the public sector. According to the World Bank, half of the current R&D expenditure worldwide, estimated at \$70-\$90 billion, is funded publicly. Many of the drugs marketed by private companies were originally discovered with public funding, including the AIDS drugs stavudine (d4T), zidovudine (AZT), didanosine (ddI), zalcitabine (ddC), abacavir, and ritonavir.

Aren't generic drugs always of lower quality than branded products? Wouldn't that be setting a double-standard for developing countries?

No. In many countries, such as India, Mexico, Thailand, Brazil, Colombia, Canada, South Korea, Argentina, Spain and the US there are strong generic pharmaceutical industries that produce quality drugs. Many of these generic drugmakers produce and export drugs under sub-contract for drug companies in North America, Europe and Japan. Generic companies in developing countries often have manufacturing plants that have been certified by foreign governments as well as their own national authorities.

Generic drugmakers, like proprietary manufacturers that make brand name drugs, should always be examined for quality and good manufacturing practices. This is the primary responsibility of national drug regulatory authorities. MSF supports testing of drugs to meet standards for quality and is advocating for UN agencies to provide support to developing countries by pre-qualifying generic producers of medicines where appropriate, as in the case of anti-retrovirals and other drugs needed in HIV/AIDS.