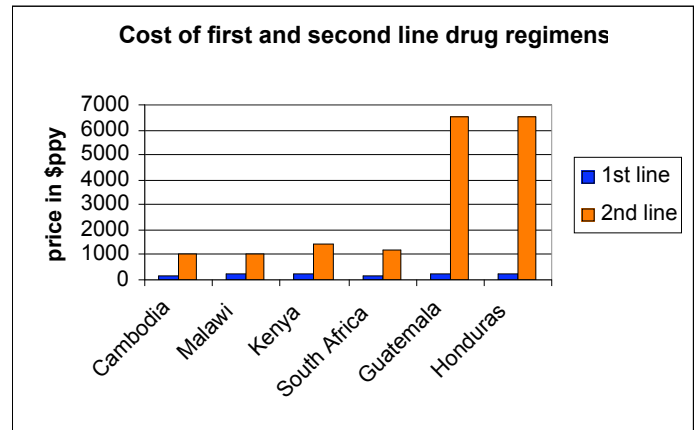


The Second Wave of the Access Crisis: Unaffordable AIDS Drug Prices...Again

A few years after the historic fall in first-line AIDS drug prices from over \$10,000 to \$175 per patient/year, people living with HIV/AIDS are again facing the possibility that life-saving drugs will be priced out of their reach. Médecins Sans Frontières (MSF) warns that urgent action is needed to ensure a continuous supply of affordable medicines to those who need them.

The Looming 'second-line' Problem: Since 2003, there has been a push to offer antiretroviral treatment (ART) to people living with HIV/AIDS in resource-poor settings. Today, the World Health Organization (WHO) estimates that 1 million people are on ART in the developing world. But these patients are facing a looming crisis. Experience from places where ART has long been widely available, such as Brazil, the US or Europe, shows that after a few years, the "first-line" of ART no longer works for many patients, who must then switch onto a "second-line" regimen. However, second-line drugs are far more expensive than first-line drugs. In Kenya, for example, MSF pays **US\$1400** per patient/year for a second-line regimen, compared to only **US\$200** for first-line drugs - that's a **7-fold** price difference. In middle-income developing countries that price difference can be even more dramatic. In Guatemala, a second-line regimen costs **US\$6500** - **28 times** more than the first line treatment.



What do these price differences mean?: For example, in Guatemala, providing second-line drugs to 10% of all patients in the MSF program would increase total drug spending by **360%**. In South Africa, treating the 58 patients on second-line drugs in the MSF program costs the same as treating over 550 patients who are still on first-line. Clearly, high prices for providing just a few patients with second-line drugs can quickly outstrip a program's or health facility's ability to pay. The number of patients requiring second-line therapy is only expected to rise as people living with HIV/AIDS will need access to newer treatment.

"As an MSF doctor having worked in HIV treatment programs in different countries, I have experienced the miracle of being able to put people on ART and watch the immediate face of death disappear as 1st-line ARV medications have become more widely available. But the miracle won't last forever. We are now starting to see some patients who are failing on the 1st-line regimen. Because second-line drugs are not accessible, death's face is re-emerging. WTO rules mean that as doctors, we are denied the ability to continue the miracle of prolonging lives."

– Dr. Nicolas Durier, MSF-China

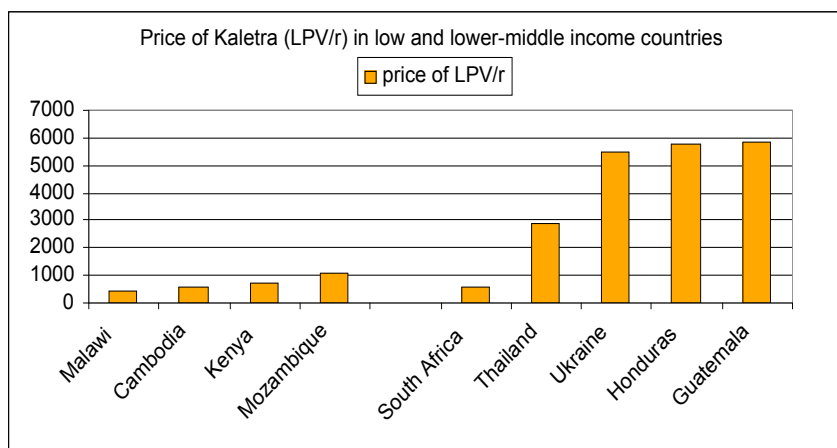
What does the WTO have to do with it?

Affordable and available ART became a reality because there were no pharmaceutical patents in key producing countries, like India and Brazil. But the WTO's patent rules are causing generic sources of new medicines to dry up. In early 2005, the WTO's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) was fully implemented in India and other developing countries that do not yet grant pharmaceutical patents. As a result, access to affordable new drugs is likely to become much more difficult. From 2005 onwards, all new drugs are subject to at least 20 years of patent protection, except in

least developed countries where existing production capacity is limited. This widespread patent-protection is already stifling generic competition, making much-needed second-line ART nearly **30 times** more expensive than the most affordable first-line drugs.

Is voluntary differential pricing the answer?: To get access to newer drugs that are still under monopoly, many programs rely on a system called "voluntary differential pricing" from the large drug companies. In principle, this means that developing countries can buy drugs at lower prices than wealthy countries. But MSF's experience trying to access drugs at these reduced prices has made clear that the system is seriously flawed - it does not get medicines to all who need them. A survey conducted in MSF projects in nine countries showed that when medicines are only available from a single producer, they are still very expensive. For example,

GlaxoSmithKline's price for **abacavir** in the poorest countries is about US\$ 890 per patient/year - this single drug costs **4 times more** than the 3 drugs of a first-line treatment combined. Second, prices that pharmaceutical companies announce are often not available in reality, because companies have not registered or marketed the drugs in countries eligible for differential pricing. For instance, Gilead's tenofovir (brand name: Viread) is fully registered in only 6¹ of the 95 countries where the company offers it for a differential price. And third, some companies do not offer discounts to middle-income countries - this is the case of



lopinavir/ritonavir (brand name: Kaletra) in Thailand, Latin America and Ukraine, where programmes pay **US\$4,000 to 6,000** per patient/year for this 1 drug alone. **Didanosine E.C.**, a drug used in many second-line regimens, costs about **US\$400** in Cameroon (a median price in the survey), even though a WHO study recently found **production costs are about 1/4 of that (US\$94)**, including a 14% profit margin. Clearly, there is room for prices to fall further if robust generic competition were to take place.

What are the solutions?: In light of these new challenges, countries that have the capacity to manufacture generic drugs (such as **Brazil, Thailand, India and China**) need to routinely exercise their right to do so despite patents. Safeguards like **compulsory licenses and government use** that were affirmed in the 2001 WTO Doha Declaration enable the production of more affordable medicines. However, to ensure access to medicines for all, **an easy and economically viable mechanism is needed** for export of generic medicines produced under a compulsory license. But the recent decision of the WTO to amend the TRIPS Agreement, based on a mechanism that has failed to prove it can increase access to medicines, shows that the WTO is ignoring the day-to-day reality of drug production and procurement.

The so-called '**August 30th decision**,' which was designed in 2003 to allow production and export of generic medicines, has long been viewed by MSF and public health groups as **overly cumbersome and inefficient**. To date there is no experience using the mechanism - not one patient has benefited from its use - despite the fact that newer medicines, such as second-line AIDS drugs, are priced out of reach of poor patients. Delaying the amendment would have been a far better option, as it would have ensured the possibility of testing and improving the mechanism in practice. The amendment has made permanent a **burdensome drug-by-drug, country-by-country decision-making process**, which does not take into account the fact that economies of scale are needed to attract interest from manufacturers of medicines. Without the pull of a viable market for generic pharmaceutical products, manufacturers are not likely to want to take part in the production-for-export system on a large scale. And without competition among several manufacturers, MSF fears it will be extremely difficult to ensure that prices of newer medicines will fall the way first generation AIDS medicines did - patients the world over will have to pay the price.

MSF is therefore asking WTO Members to:

1. **Re-affirm their political commitment** to the Doha Declaration on TRIPS and Public Health, issued at the 2001 WTO Ministerial, and fully implement the declaration in national law and drug procurement policies.
2. **Provide evidence** by the end of 2006 demonstrating that the amendment ('August 30') to the TRIPS agreement can effectively meet global needs for affordable generic medicines.
3. **Assess the existing measures** put in place by the WTO to facilitate access to medicines, identify the barriers to full implementation of the Doha Declaration, and propose robust and workable ways to eliminate the negative effects that drug patents have on access to essential medicines.

For more information, see www.accessmed-msf.org, or contact:

Ellen 't Hoen: +33.62.2375.871 or +856-9173-7268 or Gloria Chan: +852 9276 7884 or +852 2959 4255

Médecins Sans Frontières (MSF) began offering antiretroviral therapy (ART) in its programmes in 2000. As of December 1st 2005, MSF is providing ART to over 57,000 patients in over 50 projects in a total of 29 countries. Since 1999, MSF has also been campaigning internationally for better access to essential medicines.

¹ Bahamas, Gambia, Kenya, Rwanda, Uganda, Zambia.