Program on Information Justice and Intellectual Property

American University | Washington College of Law

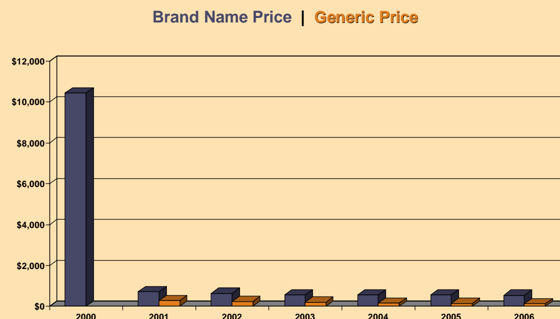
Promoting Global Access to Second Generation Treatment in The Second Decade After TRIPS

Generic Competition Lowered Prices for the First HAART Regimens

- Antiretroviral treatments were originally priced at over $10,000 per patient per year (PPPY), placing them far out of reach for most people with HIV/AIDS.
- In March 2001, Cipla offered triple-drug therapy for $350 PPPY in developing countries. Facing competition, brand-name firms offered lower prices to developing countries as well.
- Additional generic competitors entered the market, eventually driving prices for first line HAART regimens as low as $132 pppy.
- Generic competition was possible because most of the first antiretrovirals were not patented in important producing countries including India, Brazil and Thailand. In South Africa, generic competition was enabled through licenses granted to settle a Competition Commission complaint lodged by AIDS treatment activists.

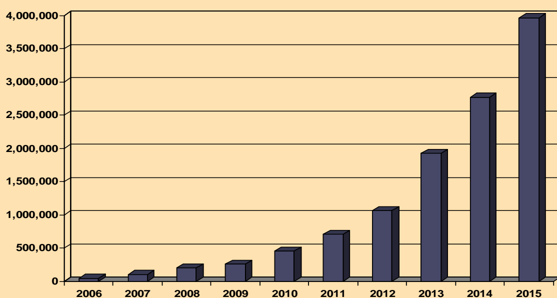
Lowest Price for d4T+3TC+NVP for Poorest Countries Reported by MSF

Brand Name Price | Generic Price



Source: Médecins Sans Frontières, *Untangling the Web of Price Reductions: a Pricing Guide for the Purchase of ARVs for Developing Countries.* Editions 1-9, published 2001 through 2007.

UNAIDS Estimates of People Needing Second-Line HAART



Source: UNAIDS Secretariat. *Scenario's of Uptake of ARV Therapy in Resoutce-Limited Settings.* 25 October, 2005.

Effective Treatment Requires Access to Second-Generation Medicines

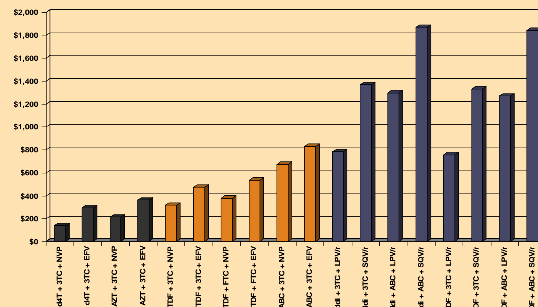
- As the number of people on treatment increases, more people with HIV/AIDS will develop resistance to first-line therapies.
- There are currently an estimated 80-100,000 people in resource-limited countries taking second-line therapies. UNAIDS estimates that the number of people in need of second-line HAART regimens will increase four-fold by 2010, and explode to nearly 4 million by 2015.
- Access to newer medicines is also needed for more effective first-line treatments. WHO now recommends that developing country first-line treatment programs include several newer medicines, including tenofovir and emtricitabine. Current guidelines recommend phasing out the use of stavudine, an older medicine which has serious side effects.

Second-Line and Second-Generation Regimes Face Less Competition

- Whereas the lowest price for a treatment regime of AIDS drugs supplied by competitive markets is now under $150 PPPY, the average price for a second line regime is over $1,700 in low income countries and $5,229 in middle income countries.
- Unlike the earlier AIDS medicines, many newer antiretrovirals do not face generic competition. Today, middle income countries with the potential to produce generics, including India, Brazil and Thailand, must grant pharmaceutical patents as required by the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).
- Until recently, Abbott Laboratories was the only producer of a heat stabilized ritonavir-boosted protease inhibitor, Kaletra, and it has refused to grant licenses to generic suppliers

WHO-Recommended HAART Regimens
Lowest price for poorest countries reported by MSF

First Line, 2003 Guidelines | First Line, 2006 Guidelines | Second Line, 2006 Guidelines



Source: Médecins Sans Frontières, *Untangling the Web of Price Reductions: a Pricing Guide for the Purchase of ARVs for Developing Countries.* 9th Edition, July, 2006.

DECREE OF DEPARTMENT OF DISEASE CONTROL, MINISTRY OF PUBLIC HEALTH, REGARDING

EXPLOITATION OF PATENT ON DRUGS & MEDICAL SUPPLIES BY THE GOVERNMENT

ON COMBINATION DRUG BETWEEN LOPINAVIR & RITONAVIR

Article 51 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542)states that, for the public use, ministry or department may exploit any patent without further negotiation with the patent holder. This implication makes clear that, for non-commercial use, especially in public affairs of the government such as public health services, government is well within its rights.

The situation of HIV spreading is the key problem of Thai public health. More than 1 million Thais have been infected with HIV, among this, more than 500,000 people are still alive. These infected individuals will eventually need long-term uses of antiretroviral drugs to maintain their productive lives.. The Thai Government has launched a policy of universal access to anti-retrovirals since 1st October 2003, and has a budget specifically allocated for them. However, it is still difficult to get accessed to some effective and safer anti-retrovirals. The high price of these patented anti-retrovirals have hindered their accessibility under the universal access policy because of patent protection by law, then there's no competition. The government cannot allocate enough budget. However, budget for health services in the national health security system allocated for HIV /AIDS patients in the fiscal year 2007 (B.E. 2550) is only 3,855.6 million baht for the target group of 108,000 patients. Some of this group have resistance to the first line ARVs and have to move to the second line.

Lopinavir + Ritonavir under the tradename Kaletra is a highly effective and safe anti-retroviral. It is also placed in the Thailand's National List of second line Anti-retrovirals. Because it's protected by patent, no one can produce or import to share the market. So, it's price is much higher than generic products in some other country. With this higher price, the budget allocated from the Thai Government can only cover some patients with it, whereas

Compulsory Licenses Will Be Increasingly Necessary

- In the last year, both Thailand and Brazil have moved to create competitive markets for the supply of generic versions of newer AIDS drugs through TRIPS-compliant compulsory licenses.
- The 2001 Doha Agreement on TRIPS and Public Health affirmed that "[e]ach member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."
- Importantly for producing countries like South Africa, Thailand and Brazil, TRIPS Article 31(k) authorizes countries to permit unlimited exports of generic medicines where a compulsory license is granted to remedy anticompetitive practices by patent holders, including anticompetitive refusals to license generic suppliers.
- To promote sufficient competition in supply, and the demand needed for economies of scale, to achieve sustainable pricing of newer medicines, many more countries may have to break open restrictive drug markets with compulsory licenses.

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