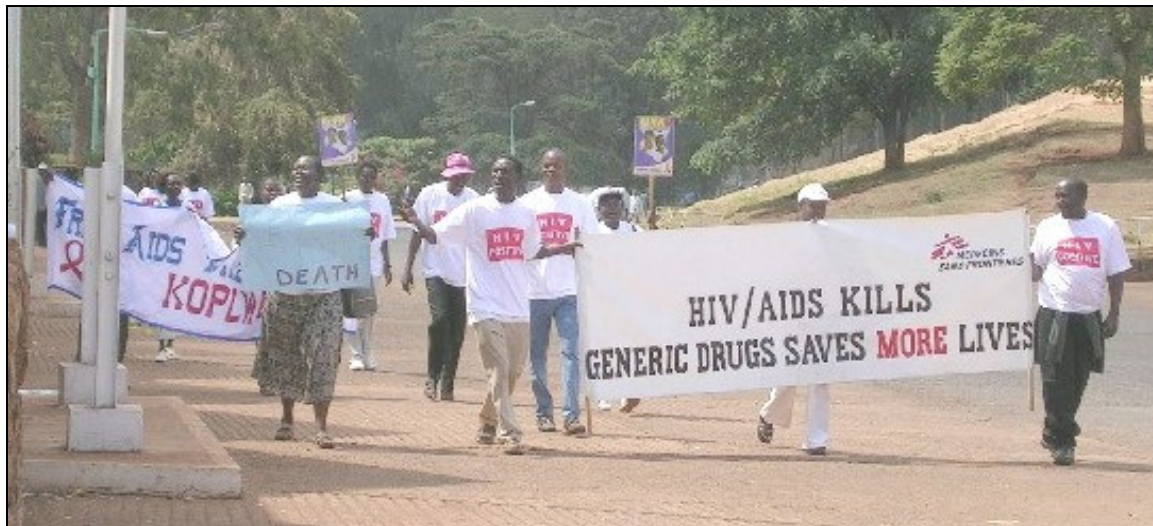




Q&A: The pharmaceutical industry and access to ARVs in Africa

What has been the role of the pharmaceutical industry in the provision of antiretroviral (ARV) medicines?

The private pharmaceutical industry remains the most important source for the global supply of ARVs today. While the *research-based pharmaceutical companies* have been responsible for development of many of the medicines used to treat HIV/AIDS, the *generic industry* for its part has contributed enormously to making widespread treatment possible in the developing world, because of their innovative fixed dose combination tablets (FDCs) and their more affordable prices relative to their brand-name equivalents. FDCs mean that all the required medicines can be combined into one pill which often patients take just once or twice a day.



Treatment activists in Nairobi stage a demonstration in March 2005.

Are pharmaceutical companies involved in initiatives to increase access to ARVs?

In 1998, the Joint United Nations Programme on HIV/AIDS (UNAIDS) launched the Drug Access Initiative in partnership with five research-based pharmaceutical companies: Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co and Hoffmann-La Roche¹. At the end of 2001, responsibility for this initiative, renamed the Accelerated Access Initiative (AAI), was transferred to the World Health Organisation (WHO). The intention of AAI is to provide developing countries with both access to

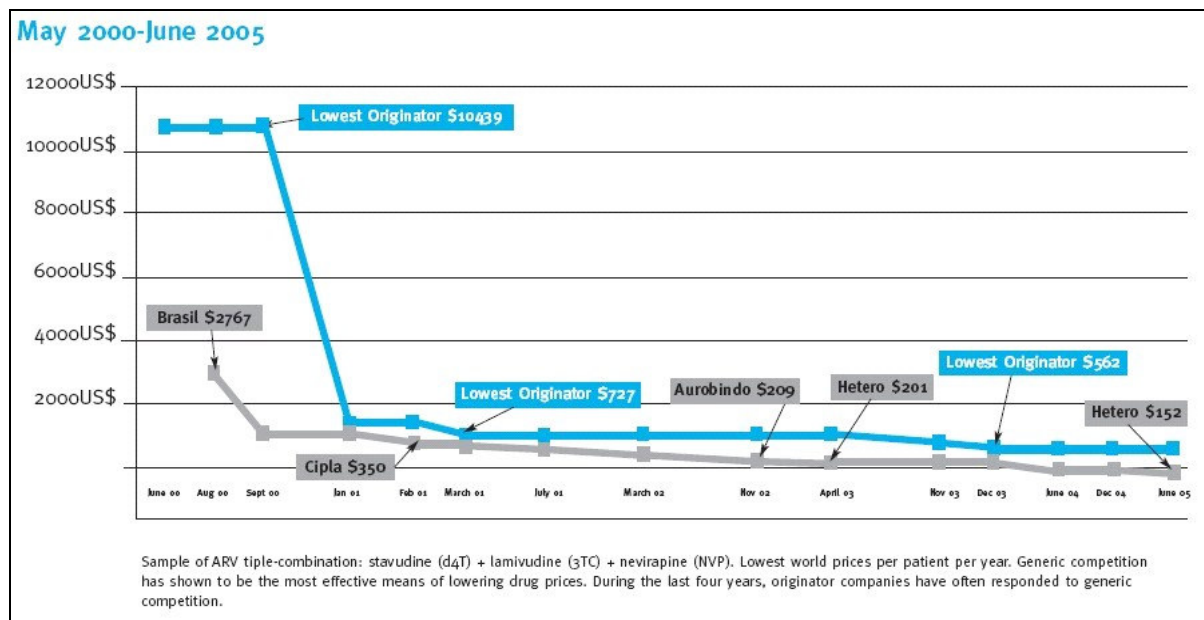
¹ Abbott has now joined, so there are now 6 participating companies.

branded ARV medicines at the lowest possible prices and also technical support for the implementation of national access programmes for ARV treatment.

It is widely agreed that both the pressure from countries like Brazil to issue compulsory licences (see below) and the competition from companies that produce generic medicines have had the largest impact on the price reductions for ARVs. Grassroots pressure groups, such as South Africa's Treatment Action campaign, have also done a lot to make ARVs more available.

The launch of the UNAIDS initiative resulted in participating companies reducing their prices for triple ARV therapy from US\$12,000 to \$7000 per patient per year. Around the time when AAI moved to WHO, negotiations resulted in further reductions to \$1200. At this point, the Indian generics industry had also entered the scene with offers of \$600 for the same combination. When Côte d'Ivoire announced that it was ready to accept the offer from the Indian manufacturer Cipla, Bristol-Myers Squibb and Merck made a further price reduction to \$800.

Currently, four Indian generic companies² offer triple combination therapy at less than half of the lowest price offered by companies participating in AAI. As of June 2005, the lowest generic price for triple combination therapy was \$152.³ This is less than half the price of offers made by research-based companies participating in the UN Accelerating Access Initiative (AAI). Presumably, the generic medicine manufacturers' prices could be reduced still further if the scale of production was higher.



This graph, from the MSF publication "Untangling the Web", shows the effect of generic competition on medicines prices: <http://www.accessmed-msf.org/documents/untanglingtheweb%208.pdf>

² Cipla, Hetero, Aurobindo, Ranbaxy.

³ Médecins Sans Frontières (2005) Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries, MSF, Geneva.

Has the industry-backed AAI worked?

The following factors have constrained the impact of AAI:

- High price of ARVs: Even though prices have been reduced, the ARVs offered through the AAI participating companies remain unaffordable to most countries in need. They are usually more than double the price offered by generic companies. Some analysts have argued that middle-income countries have benefited most from the AAI program to date because of their lower incidence of HIV infection coupled with their higher per capita incomes, thus allowing them to pay the AAI prices.⁴
- High price of diagnostic test kits and reagents: Many of these test kits and reagents, needed for biological follow-up of treatment, are brand-name products.



A pharmacy stocking ARVs in Hoima town in western Uganda. Picture source: WHO

⁴ For example, with an HIV infection rate of 1.5%, universal access in Chile would cost 0.5% of GDP, compared with 17% in some sub-Saharan African countries.

Do patents on medicines have an impact on access to ARVs?

People in developing countries continue to pay more for medicines because of patents. HAI Africa and its partners believe that facilitating the entry of generics, and therefore generic competition, is the only possible way to further reduce prices.

Some African countries have developed or are developing intellectual property (IP) laws that permit compulsory licensing (CL) as one of the means to reduce medicines prices. CL is a term used when governments are allowed to grant a license for the production or import of medicines without permission from the patent holder when the medicines are required for public health interests. Compulsory licenses are one of the flexibilities under the World Trade Organisation's Trade-related Aspects of Intellectual Property Rights (TRIPS). This agreement is one which binds all WTO member countries to set minimum standards for IP protection in their own laws.

Compulsory licensing is an important instrument, allowable by TRIPS, to help ensure that medicines are available to meet public health needs. A few developing countries, including Zambia and Mozambique are attempting to use compulsory licenses. The impact of these measures are yet to be seen. CLs have proven to be an effective bargaining tool for several developing countries in negotiating reduced prices with patent holders. Brazil and lopinavir/ritonavir (Kaletra®) is a good example. Here, the threat to issue a compulsory license has been used to increase the leverage of other equitable pricing mechanisms.⁵

Can pharmaceutical companies give voluntary licenses for medicines to be produced?

Although companies sometimes license their patents voluntarily for strategic reasons, the more common model in producing countries is for companies to work through their local affiliates. There are now a few examples of voluntary licenses that have been issued in African countries, and these should be monitored for impact. In Kenya, for example, GSK and BI gave voluntary licenses to a local manufacturer, Cosmos, although only after difficult negotiations and considerable delays.

What more should the industry do?

There are a number of things the industry could do to improve access to HIV/AIDS treatment. The industry should develop more fixed dose combinations, once daily formulations and more paediatric formulations. They should carry out more extended stability studies for conditions experienced in African countries (e.g. their climates), register their ARVs in all countries in need of them, and adopt simple and transparent pricing policies.

⁵ "Brazil Reaches 11th Hour Deal on Drug Patent", AIDS Map News, May 2005, <http://www.aidsmap.com/en/news/83C0EF16-F9EC-4A9C-8200-5E07E99CB38D.asp>