Untangling the Web of Antiretroviral Price Reductions:

A pricing guide for the purchase of ARVs for developing countries

Upcoming 12th Edition - Pre-publication price analysis - July 2009

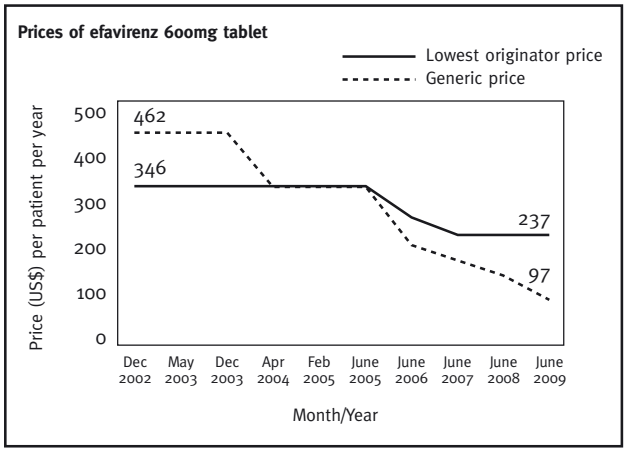
CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

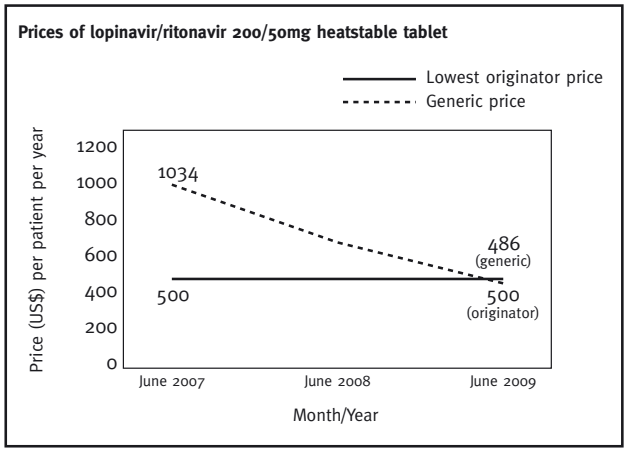
MEDECINS SANS FRONTIERES

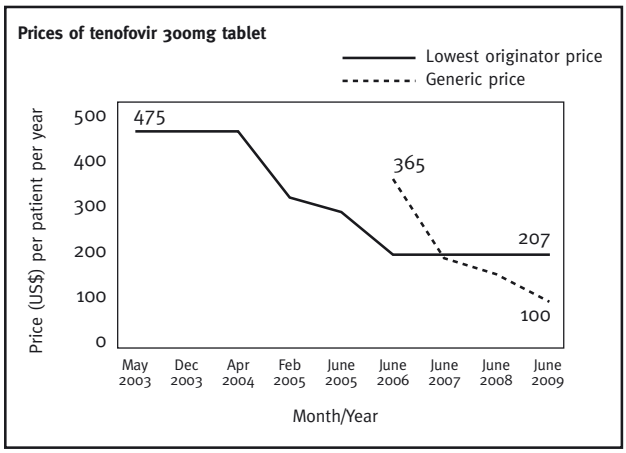
The 12th edition of 'Untangling the Web', Médecins Sans Frontières' annual analysis of antiretroviral (ARV) price reductions is upcoming. This paper serves as a pre-publication price analysis, offering highlights of the major ARV price decreases - including for tenofovir disoproxil fumarate (TDF), efavirenz (EFV), lopinavir/ritonavir (LPV/r) and paediatric lamivudine/stavudine/nevirapine (3TC/d4T/NVP). It also features the first published price of a new ARV class, the integrase inhibitor, of which raltegravir (RAL) is the first marketed compound.

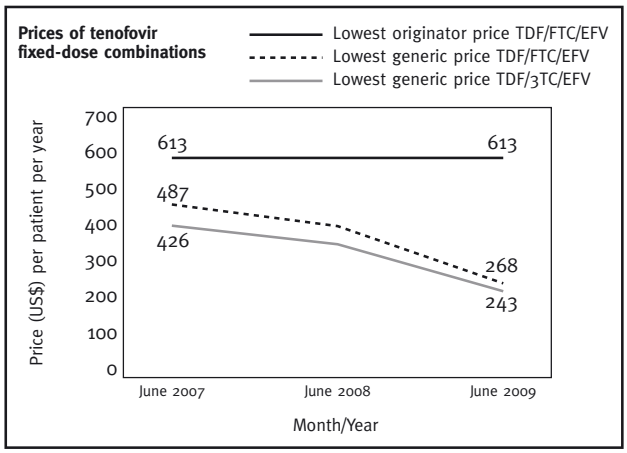
Key price reductions

Over the past year, a number of key ARVs have shown steep price drops. Compared to 2008, LPV/r 200/50 mg (heat-stable tablet) shows a price decrease of 31%, the price of EFV 600 mg tablet has dropped by 36%, and TDF 300 mg tablet has fallen by 37%. Significantly, it is the first time that the generic price of LPV/r heat-stable tablet is lower than the originator, once again showing that generic competition is the most effective way of bringing prices down.









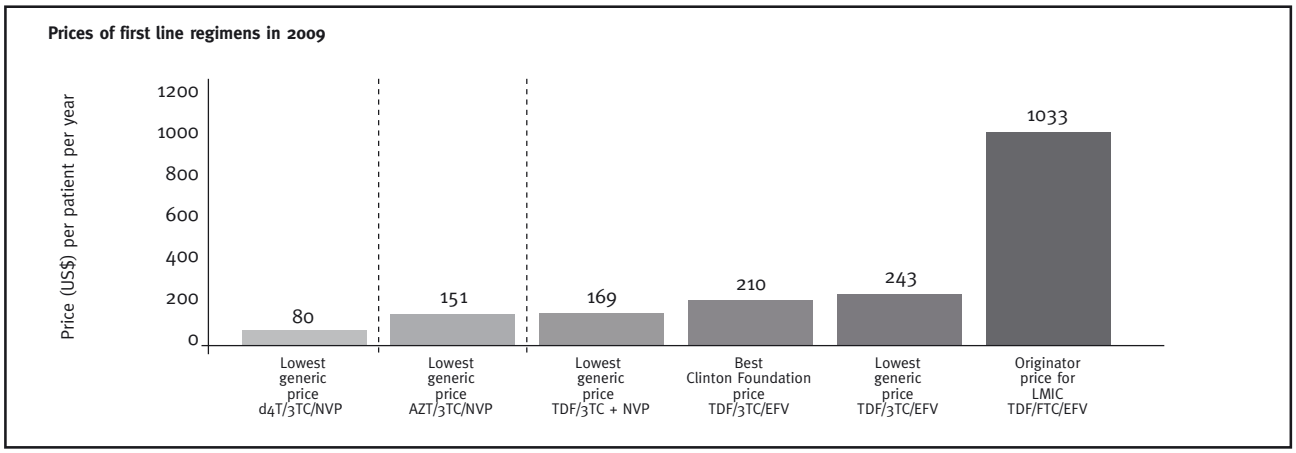
As for generic three-in-one fixed-dose combinations (FDCs), prices have also dropped considerably over the last two years - by 43% for tenofovir/lamivudine/efavirenz (TDF/3TC/EFV), to US$ 243 per patient per year (ppy) and by 45% for tenofovir/emtricitabine/efavirenz (TDF/FTC/EFV), to US$ 268 ppy.

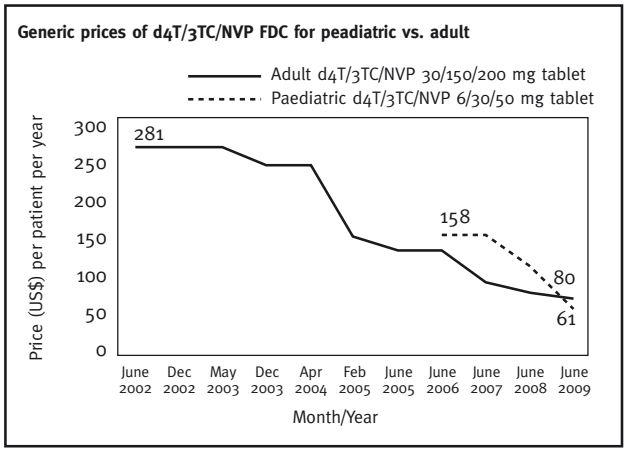
However, the originator prices for single components such as tenofovir and efavirenz, as well as for the fixed-dose combinations tenofovir/emtricitabine/efavirenz (TDF/FTC/EFV) and heat-stable lopinavir/ritonavir have not changed in the past two years.

First-line regimens – TDF and AZT prices converging

Since the 2006 revision of WHO Guidelines on Antiretroviral Therapy for HIV Infection in Adults and Adolescents, which recommended moving away from d4T-containing regimens in order to avoid or minimise the predictable toxicities, the generic price of TDF-containing regimens have dropped considerably.

They are now comparable to zidovudine (AZT)-containing regimens, the other first-line recommended in WHO guidelines,. At US$ 169 per patient per year (ppy) for TDF/3TC+NVP and US$ 151 ppy for AZT/3TC/NVP, they are approaching the price of older, d4T-containing regimens, which now stand at US$ 80 ppy. However, for lower middle income countries (LMIC) affected by patent barriers, the originator TDF/FTC/EFV fixed-dose combination remains unchallenged by generic competitors and the price remains high at US$ 1033.





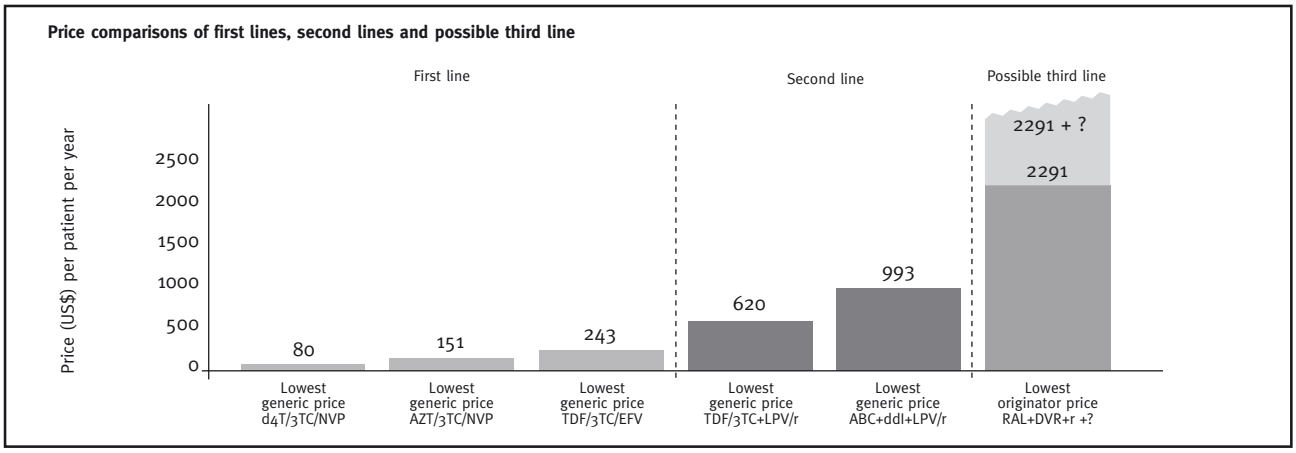
Paediatric fixed dose combinations – slow progress

While treating adults with FDCs has been possible since 2001, the first FDC for paediatric patients has only been available since 2006. The commonly-used first-line, stavudine/lamivudine/nevirapine 6/30/50 mg tablet is now available at US$ 61 ppy, and costs less than the adult 30/300/200 mg tablet, at US$ 80 ppy.

Newer antiretrovirals – no competition, soaring prices

For the first time, raltegravir (RAL), the first compound of a new ARV class, the integrase inhibitor, is offered to low income countries at US$ 1,113 ppy. This drug can potentially be used in patients failing second-line regimens together with other drugs, although the optimal treatment combination is yet to be defined.

But the combination of RAL and darunavir+ritonavir (DVR+r) is still extremely high, costing up to US$ 2,291 ppy in developing countries. This is at least 29 times the cost of cheapest first-line ARV and four times the cost of cheapest second-line ARV.



Summary

Some key ARVs prices have decreased much more than expected this year and this has important implications for governments or implementers in regimen selections, especially in deciding to move away from a d4T-containing regimen. For many years, the d4T-containing regimen has played a crucial role in ART rollout, due to its availability in fixed-dose combination and most importantly its low cost which enable millions to access ART. It is a good time to invest in a more robust, tenofovir containing first line such as TDF/3TC/EFV which is one pill once a day. While the price is still higher than a d4T-containing regimen there is a need to generate volume and competition to further decrease price.

It is also important to note that the drug price to treat paediatric patients is less than that of adults now. Every effort should be made to ensure scaling up treatment in paediatric population is done at the same time as for adults.

Price is still a major barrier for access to newer ARVs. We are now starting to see the effect on access to affordable medcines, of the Word Trade organizations (WTO) TRIPS agreement which requires pharmaceutical patents. These newer ARV's are under patent in key generic manufacturing countries such as India, which means that there will not be the automatic generic competition that has been so crucial to lowering prices in the past. Action is needed to keep the door open for competition.

It will take routine use of public health safeguards in the TRIPS such as compulsory licenses, voluntary licenses with no restrictive conditions attached and new mechanism such as the UNITAID Medicines patent pool to ensure ongoing access for those in need.

Inaction is not an option. Increased global patenting which is systematically reducing the possibilities of producing generics, has changed the rules of the game and will keep prices high for newer medicines. This puts serious strain on and threatens the sustainability of national AIDS treatment programmes that are already struggling to implement and scale up treatment.