CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

MEDECINS SANS FRONTIERES

Médecins Sans Frontières responds to Hudson Institute report on drug prices

A US think-tank, the Hudson Institute[1], has issued a report which claims that generic AIDS drugs are more expensive than originator (or "brand-name") drugs.

The report by the Hudson Institute distorts data presented in an MSF report on antiretroviral prices called "Untangling the Web of Price Reductions: a Pricing Guide for the Purchase of ARVs for Developing Countries".

The Hudson Institute's report has numerous factual errors and inaccuracies. Here we correct the most significant ones:

1. **The report constructs a false average to claim that originator ARVs are cheaper than generics.**

The report chooses 13 ARVs, mixing drugs of different classes (NRTIs, NNRTIs, protease inhibitors), drugs used for first-line and for second-line therapy and drugs of widely different prices -- and then averages their price. This is a false way of constructing an average.

The medically meaningful way to compare drug prices is to make comparisons of recommended triple therapy combinations. This type of comparison shows how much it costs to treat a real-life patient, using generic and originator drugs.

Following is a price comparison of two WHO-recommended first-line triple combinations:

A) stavudine (40mg), lamivudine, nevirapine:
- Generic (triple FDC pre-qualified by WHO): US$244
- Originator (three separate pills): US$562

B) zidovudine, lamivudine, nevirapine:
- Generic (triple FDC): US$277
- Originator (double FDC plus single nevirapine): US$675

[1] The Hudson Institute's main funders include the Pharmaceutical Research and Manufacturers of America (PhRMA), the US pharmaceutical industry's trade association, as well as US pharmaceutical company Eli Lilly.

2. **The report makes a false comparison between generic fixed-dose combinations and originator fixed-dose combinations.**

There are only three originator FDCs currently available.

The first, ritonavir-boosted lopinavir (Kaletra), is a newer drug and the originator manufacturer charges an exorbitant price ($500 per patient per year in African and least developed countries). There is little generic competition to this drug, as it is relatively new. This shows that, in the absence of generic competition, originator compounds will be dramatically more expensive.

The second, ABC/3TC/AZT (Trizivir), has been proven to be a sub-optimal treatment[2] and is not recommended as first-line treatment by WHO.

And for the third – AZT/3TC (Combivir) – the report misquotes the correct prices: the lowest price WHO pre-qualified generic costs $197, versus $237 for the originator version.

3. **The report ignores the fact that the most widely used triple fixed-dose combinations are only available from generic manufacturers.**

Of the four WHO-recommended first-line combinations, only two are available as triple FDCs. Today, these triple FDCs are only available from generic manufacturers. These FDCs are inexpensive and have positive implications for patient compliance, and therefore reduce the risk of resistance.

Until now, originator companies have not made triple FDCs because the patents on them are held by separate companies. Several US and European companies are now starting discussions to develop some new fixed-dose combinations and co-blister packaging.

4. **The report makes false claims about the safety, quality and efficacy of generic medicines.**

The World Health Organization has "pre-qualified" an expanding range of generic ARVs -- proving the therapeutic equivalence of specific generic drugs with the originator product through extensive reviews including of the results of bio-equivalence studies (a requirement of WHO pre-qualification). In this way the WHO pre-qualification project (which uses experts from national drug regulatory agencies) has found that listed generics are just as effective and safe as the originator drugs.

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[2] Gulick RM, Ribaudo HJ, Shikuma CM, et al. "Triple nucleoside regimens vs. efavirenz-containing regimens for the initial treatment of HIV-1 infection." N Engl J Med. 2004 April 29; 350 (18): 1850-61.

5. **The report fails to acknowledge why second-line drugs are more expensive.**

For one specific class of ARVs -- protease inhibitors -- generic prices are higher than originator prices, as indicated in "Untangling the Web".

The reason for this is that there is as yet no effective generic competition for these drugs. Protease inhibitors are a very recently developed class of ARVs. Generic manufacturers have only just started to produce these drugs and demand for them is still low, meaning that generic companies have not been able to establish economies of scale. In general if there are only one or a few generic competitors they tend to price close to the originator's price – dramatic drops in drug prices usually start when the "rule of five" kicks in (five competitors are active in the market).

This lack of effective generic competition is why originator companies have been able to charge very high prices for these drugs. For example, the WHO-recommended second-line treatment protocol costs US$1285, more than five times the price of the lowest-priced first-line treatment.

6. **The report makes false comparisons by misstating the prices of generic medicines.**

The report makes false comparisons by comparing originator prices with the average of all generic versions of this compound. Below, originator prices are compared to the lowest-priced WHO pre-qualified generic version. As the chart shows, in all but one case the generic is less expensive than the originator.

Single Dose ARV Drugs	Originator Drug Price (US$ pp/py)	Lowest-priced WHO pre-qualified generic version (US$ pp/py)
Lamivudine	$69	$55
Zidovudine	$212	$140
Efavirenz 600mg	$347	$347
Efavirenz 200mg	$500	$329
Stavudine 40mg	$55	$26
Stavudine 30mg	$48	$21
Nevirapine	$438	$80

7. **The report adds 10% for transportation costs to all generic prices, but does not do so for originator prices.**

Some originator products do not include transportation costs in their stated price – something not acknowledged by the Hudson Institute.

Many generic companies do not include transportation. This is made clear in Table 2 of "Untangling the Web", when it specifies the delivery conditions of specific price offers.

In all cases, MSF includes prices as communicated by companies, and indicates the delivery conditions as specified by companies. These conditions are not uniform and comparison is therefore difficult, as is stated in the introduction to "Untangling the Web".

8. **The report makes false claims about differential prices available from originator companies.**

The Hudson Institute report uses the lowest-available originator price throughout, but ignores the facts outlined in "Untangling the Web" that these prices are not available in all developing countries.

Originator companies' "differential pricing" systems have major holes in them. For example, enteric-coated didanosine (the once-daily easier-to-swallow formulation) has no differential price in any developing country; if a developing country wants to buy the product, it must pay the same price as in Europe and North America. Further, some developing countries are excluded from some or all price reductions from originator companies, and originator companies' patents may block developing countries' access to medicines.

In comparison, generic price offers are accessible in most developing countries.

9. **The report fails to acknowledge the role of competition between generic and originator producers.**

Even where originator prices are relatively low in comparison to generics, this is largely due to the presence of competition. Drugs for which there is no competition are consistently higher-priced.

This is made clear in "Untangling the Web" -- generic competition has been a major factor in reducing the price of ARVs from US$12,000 in the year 2000 to less than US$300 today.

Conclusion

The Hudson Institute's report is not credible, and does not further the debate about access to medicines in developing countries.

MSF's report "Untangling the Web" is meant to inform those procuring ARVs in developing countries and provide them with data that will help in negotiations with suppliers. We believe the report is successful at meeting this objective.

For more information about Médecins Sans Frontières' Campaign for Access to Essential Medicines, please visit: http://www.accessmed-msf.org/