HIV/AIDS medicines pricing report

Setting objectives: is there a political will?

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Rapport publié le 6 juillet 2000 par Médecins Sans Frontières

CAMPAIGN FOR
ACCESS
TO
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MEDICINES

HIV/AIDS medicines pricing report. Setting objectives: is there a political will?

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July 6, 2000

MEDECINS SANS FRONTIERES

ABSTRACT

BACKGROUND: Ninety five percent of people with HIV/AIDS live in developing countries, and the vast majority of them do not have access to medicines that are prolonging and improving the lives of people with HIV/AIDS in industrialized countries. **METHODS**. This report compares institutional prices of 10 essential drugs for HIV/AIDS in 8 countries and examines the affect on prices of generic availability and patent status. Justifications for high prices of originator branded products including the role of government in R&D, and time-to-approval, are also explored. **RESULTS.** According to analysed data, the minimum price for AIDS drugs in the countries studied is, on average 82% less than the US price. Price differences have significant repercussions. For example, the report points out that it costs the Brazilian public health system the same amount to treat 1,000 people living with HIV/AIDS per month as it does the Ugandan government to treat 228 individuals. **DISCUSSION**. The widely divergent prices found, puts into question current drug pricing and highlights the lack of transparency with regard to the relationship between production costs and prices. On the other hand, it is clear that competition from the generic industry, and international institutions involvement, leads to dramatic reductions in prices. **RECOMMENDATIONS**. There are several mechanisms to improve access to more affordable drugs, even if the country in need is already compliant with the TRIPS agreement. Available information suggests that it is feasible to bring yearly treatment cost with ARVs down to US$200 per patient, per year, in developing countries. The conclusion to the report is that the means to dramatically reduce prices are within reach, but what is needed is the political will to mobilise resources on a global scale.

THE PRICE INFORMATION PRESENTED IN THIS REPORT IS NOT EXHAUSTIVE AND SHOULD ONLY BE CONSIDERED AS AN INDICATION OF THE VARIATION IN PRICES BETWEEN COUNTRIES FOR GIVEN DRUGS.

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A. INTRODUCTION

The lack of access to effective drugs in developing countries is part of a greater HIV/AIDS public health crisis. Ninety five percent of people with HIV live in poor countries, and the vast majority do not have access to medicines that could prolong and improve their lives.

In countries hardest hit by the HIV epidemic, life expectancy is 10 years lower today than at the beginning of the epidemic, and child mortality is expected to more than double in the next few years. Some 13 million children around the world have lost their mother or both parents to AIDS[i]. The disease is also decimating young adults, the engine of developing country economies. In Malawi, for example, nearly a third of the country's school teachers are infected with HIV.

Since the launch of Protease Inhibitors (PIs) in 1996, triple therapy - 2 Nucleoside Reverse Transcriptase Inhibitors (NRTI) + 1 PI - has led to a reduction of mortality among people with AIDS. Triple therapy with 2 NRTI + 1 Non Nucleoside Reverse Transcriptase Inhibitor (NNRTI) have shown similar levels of efficacy. "Data from the US illustrates that highly active antiretroviral therapy has reduced AIDS-related mortality by 75% and morbidity by 73% over a period of 3 years".[ii] But the price of these treatments is such that only AIDS patients from industrialized countries can be treated. Yearly treatment cost ranges between US$10,000-US$15,000. GDP per capita in developing countries ranges from US$140 to US$6,190.[iii]

Médecins Sans Frontières (MSF) has so far mainly been working on the prevention of HIV/AIDS, but now recognizes that it is essential to move into treatment that would allow people to live healthier and longer lives and continue to contribute to their families and society. Treatment also strengthens preventive efforts by increasing peoples' willingness to get tested. In turn, once people know their status they tend to adopt safer behaviours. With increased knowledge about HIV, the stigma surrounding the disease also declines.

However, doctors need drugs to care for HIV-infected people. Without them they are simply managing decline and death. These drugs must be available, affordable, and properly used. While rational drug use is still a major challenge, the goal of access to affordable medicines is an issue of growing concern.

The World Health Organization (WHO) updates and publishes a Model List of Essential Drugs (EDL)[iv] every two years. One of the criteria for inclusion on this list is reasonable price. A number of clearly essential drugs, including those for treating HIV/AIDS, have not been included mainly because of their prohibitive cost.

Which drugs are essential for HIV/AIDS in developing countries?
Advanced HIV-disease is a complex syndrome that presents a variety of symptoms and medical conditions, many of which are manageable with drugs. The classes of drugs most important to people living with HIV are:
• anti-infective agents to treat or prevent opportunistic infections (OIs);
• palliative drugs to relieve pain, physical and mental discomfort;
• antiretrovirals (ARVs) to limit the damage that HIV does to the immune system and to prevent mother-to-child transmission (MTCT).

MSF has developed certain criteria, linked both to available scientific data and MSF field experience, for the selection of drugs that are essential for HIV/AIDS care in developing countries.

These are:

- Drugs effective in the prevention and treatment of life-threatening and frequent OIs (seen in >5% of AIDS patients in Africa, Asia or South America):

  - tuberculosis;
  - oesophageal candidiasis;
  - bacterial infections;
  - toxoplasmosis;
  - pneumocystic infections;
  - cryptococcosis;
  - cryptosporidiosis-isosporiosis;
  - penicillinases (South-East Asia).
  - drugs currently recommended by WHO/UNAIDS for primary prevention of opportunistic infections are isoniazide and cotrimoxazole.

- Palliative drugs that significantly improve the well-being of patients such as antalgics and anti-diarrheal drugs.

- Antiretrovirals that can be used in drug combination regimens in limited resource settings (which can easily be prescribed and monitored on a clinical basis and with simple laboratory tests). Easy administration is an additional justification to include a specific drug (e.g. AZT/3TC combination, plus efavirenz).
- Compounds to prevent mother-to-child transmission (AZT, NVP) and to use as post-exposure prophylaxis (AZT+3TC).

Drugs excluded from the priority list are:

– Those which are too complex to administer and monitor, or that have limited efficacy. These criteria exclude drugs used for atypical mycobacteria, cytomegalovirus, Kaposi's sarcoma, lymphoma treatment drugs and PIs.
– "Third-line" drug choices (e.g. pentamidine) where first- and second-line drugs are included and expected to be effective in the vast majority of cases.

Which drugs are priorities? Where should the battle be focused?

There are two categories of drugs for which efforts should be mounted in countries most affected by AIDS:

1. old drugs for which the availability of cheap generics is limited;
2. drugs under patent in countries where pharmaceutical product patents are in force.

Table 1: PRIORITY TREATMENTS AND ACCESSIBILITY			
	Drugs for prevention and/or treatment OIs	**Palliative care treatment**	**Antiretrovirals**
No price-linked access problem	cotrimoxazole dapsone 1st line TB drugs 1st line antibiotics miconazole or nystatin	anti-inflammatory drugs carbamazepine/amitriptyline codeine diazepam lidocaine gel loperamide non-morphinic antalgics (tramadol)	
Limited availability of cheap generics	albendazole[1] amoxicilin/ clavulanic acid amphotericine B ceftriaxone itraconazole pyrimethamine-sulfadiazine-calcium folinate	aciclovir buprenorphine morphine (oral)	
First patent still valid in country of origin	ciprofloxacin fluconazole ofloxacin		didanosine (ddI) efavirenz lamivudine (3TC) nevirapine (NVP) stavudine(d4T) zidovudine (AZT) AZT/3TC combination

This report presents a limited comparative analysis of drug prices and patent status in a few selected countries. The role that the public sector has played in the discovery and development of each product is also reviewed, as is global revenue for each of the branded products.

[1] In the US, albendazole benefits from exclusive marketing rights as an orphan drug until 11 June 2003.

B. METHODOLOGY

This report examines drugs that are patented in many countries, such as ciprofloxacin, didanosine, efavirenz, fluconazole, lamivudine, nevirapine, stavudine, zidovudine and zidovudine plus lamivudine. It also looks at ceftriaxone, which is no longer patented in most countries, but still remains expensive.

For each drug listed, a comparison is made between its US price and its price in the eight countries where data was collected. These countries were chosen to exemplify the impact on prices when generic alternatives to originator brand products are available.

Comparing prices between countries is inherently difficult because of:

- the problem of comparing official exchange rates and real currency values; [v]
- differences in pharmaceutical distribution channels (private versus public sector, retail versus wholesale);
- different strengths and pharmaceutical dosages;
- price fluctuations over time, etc.

Prices used in this study are defined as "institutional prices" meaning the non-commercial price (amount paid for a drug by a public or non-profit institution and/or NGO). Whenever possible, prices are expressed to the first decimal point, for ease of comparison.

The institutional price is only part of the picture. Many people access drugs through the private sector and pay higher prices. For example, in South Africa, most people buy their daily dose of fluconazole from the private sector where it costs US$21.4, instead of the public tender price of US$ 4.1 used in this report.

Annexes 2 to 11 at the end of the document present the following information for each drug: therapeutic class, indication, inclusion on WHO's Essential Drug List or argument for future inclusion, patent status, world sales of the originator's brand drug and examples of alternative sources of supply.

C. DATA PRESENTATION

Table 2 summarizes the findings for each country and drug. Complete data for each drug is presented in the annexes. Prices presented are not necessarily the lowest found in each country.

Table 2: Best price found for drugs produced by reliable manufacturers, in US$

	Ceftria-xone 1 g vial	**Ciproflo-xacin** 250 mg tablet	**Didano-sine** 100 mg capsule	**Efavi-renz** 200 mg capsule	**Flucona-zole** 200 mg capsule	**Lamivu-dine** 150 mg capsule	**Nevira-pine** 200 mg capsule	**Stavu-dine** 40 mg capsule	**Zidovu-dine** 100 mg capsule	**Zidovu-dine +lamivu-dine** 300+150 mg capsule
Brazil	N/A	N/A	**0.5**	2.3	N/A	**0.8**	2.5	**0.3**	**0.2**	**0.7**
Colombia	7.2	**0.05**	**0.8**	3.3	**0.4**	**1.7**	4.3	2.4	**0.7**	N/A
Guatemala	**1.8**	**0.05**	2.3	3.4	**0.6**	2.4	N/A	4.2	**0.4**	**3.9**
India	**1.8**	N/A	N/A	N/A	**0.6**	**0.5**	**2.1**	**0.6**	**0.2**	**0.9**
South Africa	10.9	0.40	*0.7	*2.4	4.1	1.1	*3.0	*2.5	0.4	1.5
Thailand	**1.7**	**0.06**	**0.7**	2.7	**0.3**	2.5	3.5	**0.4**	**0.2**	2.3
Uganda	*4.4	***0.14**	1.3	N/A	*1.3	1.6	*4.7	3.1	0.7	3.7
US (wholesale price)	N/A	3.40	1.8	4.4	12.2	4.5	4.9	4.9	1.7	9.8
Price differential: US vs best price		**68.0 x**	**3.6 x**	**1.9 x**	**40.6 x**	**9.0 x**	**2.3 x**	**16.3 x**	**8.5 x**	**14.0 x**
Price differential: US vs best price (%)		98%	72%	48%	98%	89%	56%	94%	88%	93%

Prices of drugs produced by a manufacturer other than the originator of the brand drug are highlighted in **bold**.
N/A indicates that prices were not available at the time this report was written.
* non-institutional prices

D. ANALYSIS OF RESULTS

1. Different prices in different countries

The minimum price in the developing countries studied is, on average, 82% less than the US price, as a result of the availability of generic products. If we exclude efavirenz from this calculation, for which no generic was identified, and nevirapine for which only one generic was identified, the average reduction is of 90%. Therefore, in most cases, even if prices were reduced by 85% (as has been offered by some pharmaceutical companies), they would still not be lower than the prices currently offered by generic producers.

There are also remarkable differences in the prices charged for originator's brand drugs in different countries. For example, Diflucan®'s price (Pfizer's 200 mg fluconazole capsule) in Thailand is nearly 49% less than in Guatemala (US$6.2/US$11.9). Another example is Rocephine® (Roche's 1 g ceftriaxone vial) which is 33% less expensive in Colombia than in South Africa (US$7.2/US$10.9).

It is clear from this report that for many treatments companies sell the same product at very different prices in different countries. The existence of market monopolies is the single most important determinant of these differences.

Other factors influencing national prices include: tariffs and taxes, price controls, government price negotiations and mark-ups.

2. Impact of competition on prices

Fluconazole is not patented in Thailand. Before fluconazole was produced as a generic in 1998, Pfizer sold it for US$7. per 200 mg capsule. Three Thai companies began production and Pfizer dropped its price to US$3.6, even though generic companies were charging much less. For example, in August 1999, Biolab was charging US$0.6. After initially responding to generic competition, Pfizer increased its price in Thailand back up to US$6.2 in March 2000, while Biolab's price decreased to US$0.3 (20.7 times cheaper than Pfizer's price).

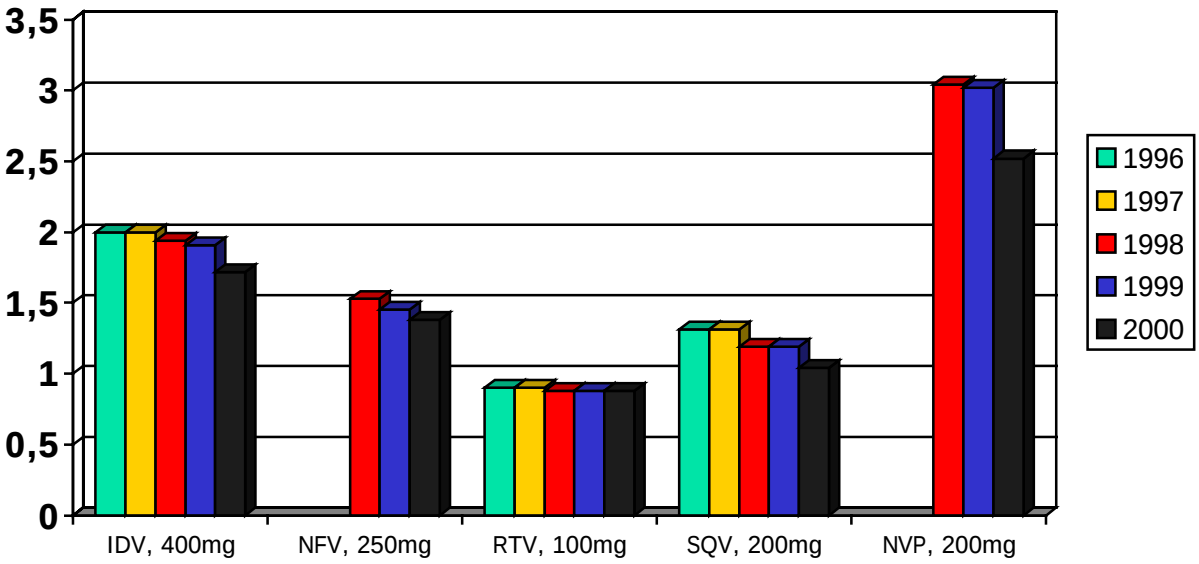
This dramatic price reduction means that fluconazole is now readily available to patients. Solely because of the price change, cryptococcal meningitis has become a treatable illness in Thailand.

Multinational companies have had to contend with similar competition from Cipla in India. Glaxo Wellcome's lamivudine (3TC) 150 mg tablet costs 78% less in India than in the US. This is their lowest price identified in this report.

One of the most striking examples of what is possible comes from Brazil. Locally produced ARVs are sold at a fraction of their global prices. A generic form of zidovudine is 14 times cheaper in Brazil than in the US.[vi,]

Graph 1. Prices of Brazilian Antiretrovirals
Price stability without generic competition

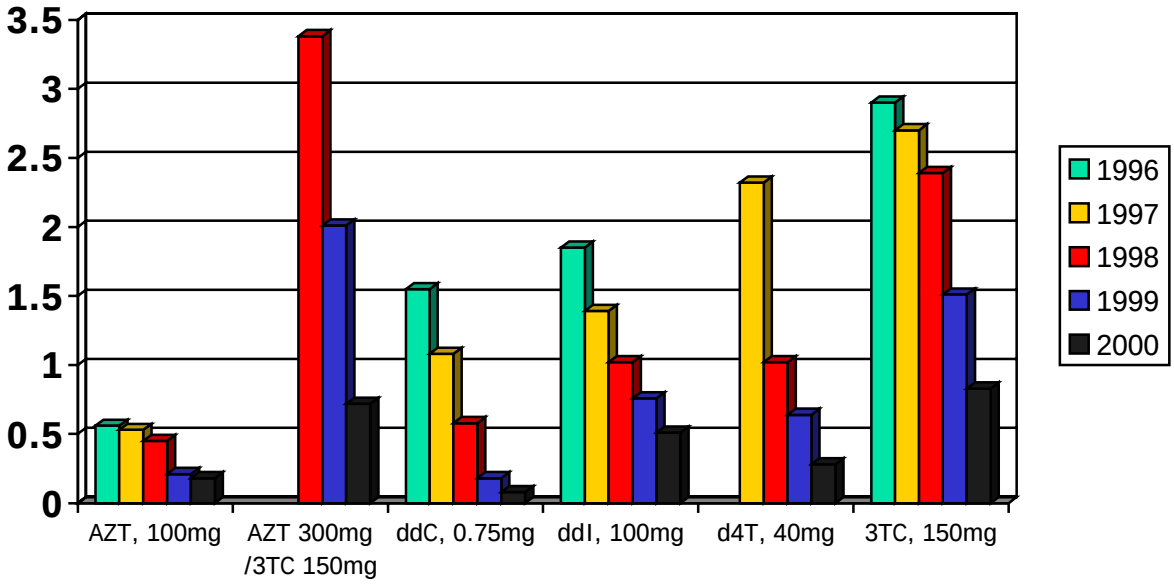
Average reduction: 9% (without IDV in 2000 when it was generic)



Source: UNAIDS, Brazilian Department of Health[vi,vii]

Graph 2. Prives of Brazilian Antiretrovirals
Price reduction from generic competition

Average reduction: 79%



Source: UNAIDS, Brazilian Department og Health[vi,vii]

3. Current cost of treatment regimens

Example 1: sexually transmitted diseases

Treatment of gonorrhea with ciprofloxacin, indicated when there is resistance to first-line antibiotics, is not very expensive on an individual basis because it is administered in a single dose (500mg/adult). Nonetheless, when only the originator's brand drug is available, treatment can be eight times more expensive than in countries where Bayer does not have a monopoly. For example, in South Africa the public tender cost of Ciproxin® (Bayer's ciprofloxacin, 2 x 250mg tablet) in 1999 was US$ 0.8 as compared with US$ 0.1 (2x250mg tablet) in Guatemala, where non-proprietary ciprofloxacin was acquired in the 2000 public tender from a well-known alternative manufacturer (Ranbaxy).

Example 2: Cryptococcal meningitis secondary prophylaxis (fluconazole 200 mg daily)

Nowadays, it costs an HIV/AIDS patient living in Thailand US$9 per month to prevent cryptococcal meningitis, a life-threatening disease. But if this person happens to be in South Africa, he/she will pay US$123 per month for the same product supplied by the public sector (nearly 14 times more). To purchase this same drug from the private sector would cost 71.4 times more.

Example 3: antiretroviral therapy using a combination of ddI 400 mg + d4T 80 mg daily

In Brazil, where these two antiretrovirals are produced locally as generics, the total monthly cost of dual therapy combination is the cheapest at US$78 per month, followed by Thailand, where both products are also available locally as generics, at US$96 per month. In Uganda, where no generics are available, the total cost comes to US$342 per month, that is 4.4 times more than in Brazil, and 3.5 times more than in Thailand.

In other words, it costs the Brazilian public health system the same amount to treat 1,000 people living with HIV/AIDS per month as it does the Ugandan government to treat 228 people living with HIV/AIDS per month (excluding the cost of diagnostics and other expenses).

Example 4: AZT/3TC 600/300 mg + NVP 400 mg daily

In Brazil, the AZT/3TC combination is produced locally (NVP will be produced by the end of this year). Total monthly cost of triple therapy is around US$192, while in Thailand, where none of these are available as generics, the total cost comes to US$348 (1.8 times more expensive).

In other words, it costs the Brazilian public health system the same amount to treat 1,000 people living with HIV/AIDS as it does the Thai government to treat 552 people living with HIV/AIDS (excluding the cost of diagnostics and other expenses).

The availability of cheaper drugs had enabled the Brazilian Government to provide antiretrovirals to more than 80,000 citizens by the end of 1999, which led to a more than 50% drop in AIDS-related mortality between 1996 and 1999.[vii] In 1997 there were 580,000 people living with HIV/AIDS in Brazil.[viii] In this middle-income country, this allowed the

government to save more than US$472 million on hospitalisations and treatment for opportunistic infections between 1997 and 1999. This demonstrates that when ARVs are available at affordable levels, in addition to the high social cost of not providing them there are real financial costs. It can become more expensive for a government **not** to offer ARVs than to provide them, because of the high cost associated with caring for people with AIDS.

4. Previous international procurement initiatives

Similar price differentials have been recorded in other areas. For example, through concerted international efforts, prices of vaccines essential for the prevention of infectious diseases, which constitute a huge burden on developing countries, were brought down without affecting quality (table 3). A further example is that of contraceptives (table 4).

Table 3: Comparison of 1999 vaccine prices per paediatric dose US domestic vs PAHO Prices

Vaccine	OPV (Oral Polio Vaccine)	MMR (1-dose vials)	Measles (1-dose vials)	Recombinant Hepatitis B (1-dose vials)	Hib (10-dose vials)
US private sector (catalogue) price/dose*	$ 10.93 (1-dose vials)	$ 27.46	$ 10.40	$ 24.20	$ 15.88
US government (CDC) price per dose*	$ 2.90 (1-dose vials)	$ 14.69	$ 6.51	$ 9.00	$ 4.75
price differential: US private vs public sector	3.8 x	1.9 x	1.6 x	2.7 x	3.3 x
PAHO price per dose	$ 0.087 (10-dose vials)	$ 0.88	$ 0.68	$ 0.92	$ 2.18
price differential: US government vs PAHO prices	33.3 x	16.7 x	9.6 x	9.8 x	2.18 x

Source: PAHO (Pan-American Health Organization), WHO - 1999

Table 4: Comparison of 2000 contraceptives prices US domestic vs UNFPA prices

US $	Condoms	Oral contraceptives	Injectable contraceptives
UNFPA	0.02 / pc	0.14-0.23 per cycle	0.70 / dose
US wholesale	0.59 / pc	24 / cycle	35 / dose
US retail	0.83 / pc	30 / cycle	65 / dose
price differential US retail vs UNFPA	42 x	130-214 x	93 x

Source: UNFPA, 2000

PUBLIC INVOLVEMENT IN RESEARCH AND DEVELOPMENT

Pharmaceutical companies claim that high prices are necessary to fund research and development, yet the data presented confirms that for five of the six ARVs analysed (see annexes 4, 7, 8, 9 and 10), public funding played a significant role in drug discovery and/or clinical research. The Pharmaceutical Research and Manufacturers of America (PhRMA), an industry group, estimate that private industry finances 43% of drug development.[ix] The important role played by national governments is evidenced by the fact that patents for important AIDS drugs are in the hands of the US government. This is the case for two drugs covered in this report: didanosine and stavudine (annexe 4 and annexe 9 respectively).

Besides research and development, long time-to-approval is another justification for high prices cited by industry. However, antiretrovirals have the shortest time-to-approval of any class of drugs: a mean of 44.6 months, half the industry average of 87.4 months.[x] The cost of clinical trials for these drugs is further reduced by heavy government sponsorship: more than a third of patients enrolled in US trials participated in trials funded by the US government.[xi]

Whatever the true investment of the pharmaceutical industry in researching and developing antiretrovirals, these drugs have earned the companies consistent revenue. Between 1997 and 1999, Glaxo Wellcome's sales for AZT, 3TC, and Combivir® (a one-pill combination of AZT and 3TC) totalled more than US$3.8 billion. Bristol-Myers Squibb sold more than US$2 billion worth of d4T and ddI over the same period.

E. DISCUSSION

Currently there are approximately 32.3 million cases of HIV/AIDS in developing countries (95% of global estimate of 34.3 million). More than 2.5 million people die each year from the disease. The introduction of antiretrovirals has dramatically reduced mortality in wealthy countries, but the course of the disease has not been significantly altered in poor countries. There are diverse factors that affect access to medicines: quality of diagnosis, accurate prescribing, selection, distribution and dispensing of medicines. But one of the most significant barriers to access is the price of drugs. Currently, in most poor countries the prices of HIV drugs condemn people with AIDS to premature death.

This report compares a wide range of prices of brand name and generic drugs both between and within countries. The widely divergent prices for the 10 selected products put into question current pricing practices and highlight the lack of transparency with regard to the relationship between production costs and prices.

A series of factors influence prices:

1) **Monopoly rights.** When multinational drug companies have exclusive marketing rights, they tend to demand maximum possible prices, catering to country elites and leaving their drugs out of reach of the vast majority of people living in developing countries. There are no links between prices and public health needs or buying power.

2) **Generic production.** The presence or absence of generic competition in the market is a key determinant of pricing levels. Competition brings down prices dramatically. The example of Brazil is the most striking in the report. However, there are some exceptions, data also point to situations (such as with fluconazole in Thailand) in which multinational companies sometimes choose to sell patented products at a steep premium, even when they are faced with aggressive, low-priced competitors.

3) **Price/cost disconnect.** The ability of generic manufacturers to charge extremely low prices shows that prices of branded products bear no relation to production costs. From the data, we see that generic manufacturers, which must turn a profit to survive, are able to sell medicines at a fraction of the price of branded products. In order for developing country governments to address their acute AIDS crises, it seems appropriate to attempt to facilitate access to low-cost, quality generic production. As they are now, research and development costs should be borne by wealthy countries.

4) **Internationally co-ordinated programs.** The report includes historical data from vaccine and contraceptive procurement models in an effort to demonstrate what is possible when international organisations, national governments and pharmaceutical companies work together to meet priority health concerns (oral contraceptive prices are 130-240 times cheaper in poor countries than in the US). Is the current UNAIDS initiative with five pharmaceutical companies to reduce prices by five times a response of adequate magnitude to the current pandemic?

Mechanisms to reduces the cost of HIV/AIDS treatment:

1) **Role of generics.** The most recent patent of all products in this report was granted for efavirenz on 17 August 1992, before many developing countries put their patent

systems into effect. This means that practically speaking, generic versions of all of these products could be made available today in a significant number of developing countries; countries only need to identify quality affordable suppliers and register these products with regulatory authorities. However, patent status is a national issue and needs to be researched on a country-by-country basis.

2) **Intellectual property rights: public health safeguards**. Since the creation of the World Trade Organization (WTO) in 1994, and the completion of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, more and more countries (WTO had 137 member states as of 14 June 2000[xii]) are obligated to grant 20 year patent protection for drugs. According to the TRIPS agreement, this minimum standard must be enshrined in national law by 2006 in all signatory countries. Developing countries had a deadline of January 2000, with some exceptions, while least developed countries have until 2006 to change national laws. In practical terms this means that poor countries will soon lose access to affordable life-saving medicines unless they write TRIPS safeguard provisions into their national laws. Three safeguards are paramount:

   One element of TRIPS that is designed to mitigate the negative consequences of granting monopoly rights is **compulsory licensing** (article 31). According to this article, WTO member states may allow the use of a patent by a third party without the owner's consent. There are no limitations within TRIPS regarding the grounds for issuing a compulsory license, only conditions to be fulfilled. For instance, a potential user must make efforts to obtain a license on reasonable commercial terms before a government can issue a compulsory license. However, even this condition can be waived "in cases of national emergency, other circumstances of extreme urgency, public non-commercial use (…)".[xiii] In any case where compulsory licenses are granted for medicines, all normal safety, quality and efficacy standards would be respected.

   A second critical safeguard is **parallel imports,** which is based on the principle of exhaustion of rights (TRIPS article 6). When enshrined in national law, this allows cross border trade in a patented product without the manufacturer's permission. Parallel imports allow countries to import brand name products from countries where they are sold by the patent holder or licensee at lower prices.

   Finally, national laws should include **"Bolar"** provisions. This allows generic manufacturers to begin preparing generic production and completing regulatory procedures before patents expire so that upon expiration they can immediately begin selling their products. This provision means that less expensive generic products can be available much more rapidly after patents expire.

F. RECOMMENDATIONS

1. Governments from both developed and developing countries, WHO, UNAIDS, NGOs, with the input of both proprietary and generic pharmaceutical companies, should work together to find sustainable solutions for countries that do not have adequate access to life-saving and other key medicines.

2. International comparative price studies should be carried out by international organisations such as WHO or UNAIDS on an ongoing basis to give developing countries the tools to spend their health budgets more effectively. They should include both raw material and finished product prices, taking into account internationally recognised quality standards. The UN agencies were given a mandate to undertake this activity in a WHA resolution that was adopted in May 2000.[xiv]

3. Least-developed countries should take advantage of the transitional period allowed within the WTO agreements. They are not obligated to change their national laws to be compliant with TRIPS until 2006. When new laws are drafted, ministries of health should be involved in the process, and should seek advice and counsel from United Nations specialised agencies including WHO, which has a mandate to provide technical assistance on this issue.

4. In countries in which patent protection presents a barrier to access to medicines, international organisations should actively support countries' efforts to improve access. This can be achieved through the following means:

   ⇒ the government, or an individual or organisation can request a ***voluntary license.*** This will allow life-saving drugs to be supplied by the generic industry (through imports or by local production), and will bring prices down;

   ⇒ if a voluntary license cannot be obtained then a ***compulsory license*** can be granted by national governments;

   ⇒ also, if a required drug is patented in the country, and it is sold in other countries by the same company at a lower price, ***parallel importing*** from a second country is an option to be considered.

5. UN organisations (WHO or UNAIDS) should support national governments by beginning international procurement of AIDS drugs. They should immediately put out tenders to the proprietary and generic industry for mass procurement of opportunistic infection and anti-HIV medicines. National governments would then be able to access low cost medicines to support their national AIDS programmes. The UN should use previous vaccine and contraception procurement projects as a guide.

6. Technology transfer should be supported by international organisations and national governments as a way to guarantee a sustainable production of affordable medicines. For those countries with considerable production experience, the goal should be to begin producing primary materials in addition to formulating products.

7. According to initial information, the five company/UNAIDS initiative would reduce antiretroviral prices by 85 % (or 6.7 times less).[xv] This would bring the cost of antiretrovirals down to US$2,250 per year, per patient. This sum is still far too expensive for the vast majority of people living in developing countries. However, generic manufacturers in Brazil and Thailand are confident of their ability to produce antiretrovirals that would result in a yearly triple combination price of US$200. This cost

level will make it possible for developed countries, international organisations and donor agencies to contribute significantly to increasing access to combination therapy, and for developing countries to make allocations within their national budgets.

CONCLUSION

While antiretroviral treatment has reduced AIDS-related mortality by over 70% in developed countries, these revolutionary therapies have been denied to people in developing countries.

Unless these treatments are made more widely available, HIV/AIDS will continue cutting a broad swath through many developing countries.

If the price of combination therapy were reduced to US$200 a year, millions of people would have access to drugs that can prolong their lives. This is feasible according to information from generic producers and historical experiences from vaccine and contraceptive initiatives.

Although there are additional costs associated with treating people with HIV/AIDS, price reductions of this scale would allow developing countries, in partnership with developed countries, international organisations and donors, to tackle the problem of providing care for people with HIV/AIDS.

The means to accomplish this are available. What is needed is the political will to mobilise resources on a global scale to combat this pandemic.

As an organisation that cares for people with AIDS, MSF believes that the time has come to respond to the ethical imperative to provide treatment to people who are in need.

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