ACT UP PARIS

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What is at stake in access to anti-HIV/AIDS generic medicines?

Since multitherapies were launched, international donors have been claiming that the cost of such medicines is too high for them to pay for the medical care of people living with HIV/AIDS in poor countries.

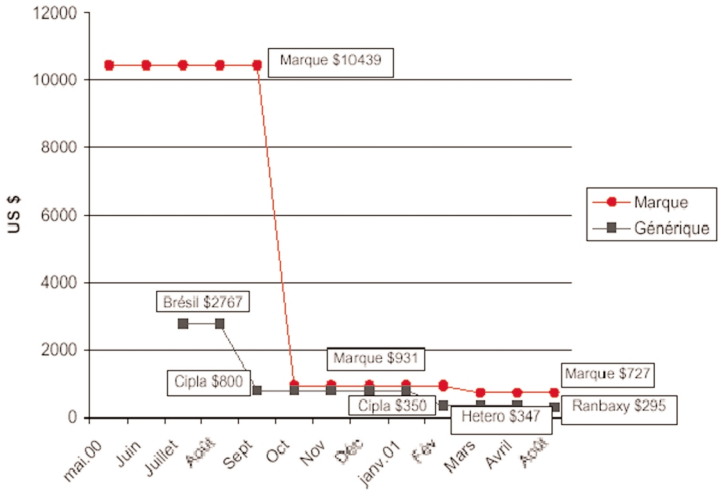
The cost of antiretroviral medicines is a difficult problem, but so is the very high cost of some treatments for opportunistic illnesses(nizorat, fluconazol, acyclovir etc), or of diagnostic tests and monitoring tools.

For two years, however, generic copies of particularly expensive antiretrovirals have been produced in developing countries by public institutions (Brazil, Thailand) or private companies (India) and sold at much lower prices than those of brand-name drugs by patent holders.
Thus we are no longer constrained to accept a market monopoly, which has had serious repercussions in terms of prices.

Since 1998 all our attempts to ask patent holders to lower their prices had resulted only in scanty price reductions, but generic competition made prices plummet within a year. The graph below gives an idea of the impact of generic competition on the prices of patented drugs between July 2000 and August 2001.

The impact of the competition of generic drugs

the lowest prices/per year and per patient for the tritherapy: stavudine+lamivudine+nevirapine (MSF data)



In October 2000 an Indian producer launched a generic tritherapy for $ 800 a year, which represented a saving of more than 90% in comparison with the prices of multinational corporations. In February 2001 his price dropped to $350. In October 2001 the price of another producer came down to $295. Right now the lowest prices are close to $200.

The marketing of these low-cost generic drugs immediately resulted in Big Pharma adjusting its own prices despite the fact that until then it had adamently refused to accede to the entreaties of UN agencies and grant significant price reductions to developing countries.

Thus the marketing of generic antiretrovials has proved two things:

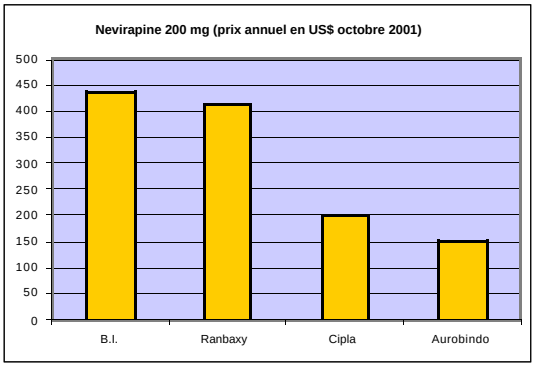
- that medicines can be sold at prices much lower than those of western pharmaceutical companies(we do not know the marginal costs of production yet, but they must undoubtedly be lower than the prices of generic producers)

-that generic competition is the most efficient means to get a drastic and lasting reduction in the prices of medicines. Such competition is much more persuasive and efficient than occasional charitable donations by patent holders enjoying a monopoly situation.

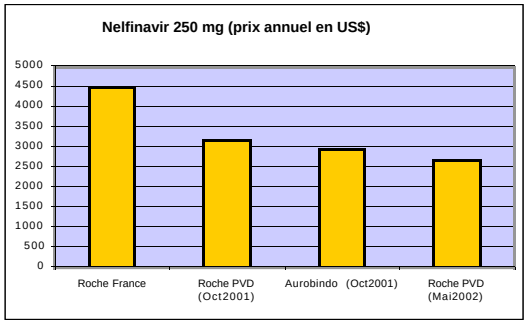
This is why access to low-cost treatments or lower drug prices in poor countries cannot be expected without generic competition. Any attempt at negotiating only with brand-name manufacturers has the negative effect of bypassing the driving force behind lasting low prices and of subjecting developing countries to the benevolence and demands of a few multinational corporations.

In the same way one cannot expect to set up a system of differential prices that can be operational and enable developing countries to obtain truly adjusted prices without making sure that generic competition is implemented.

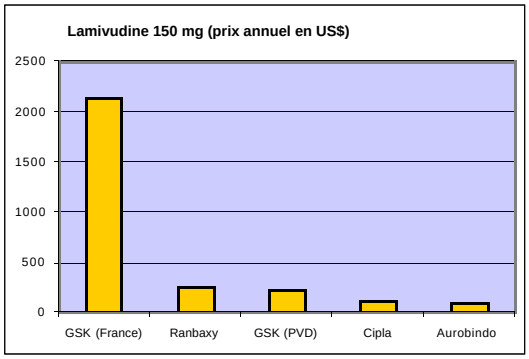
Prices comparaison, Nevirapine
(MSF data)



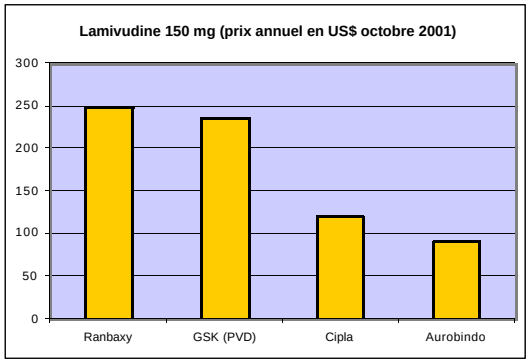
Price comparaison, Nelfinavir
(MSF & Act Up-Paris data)



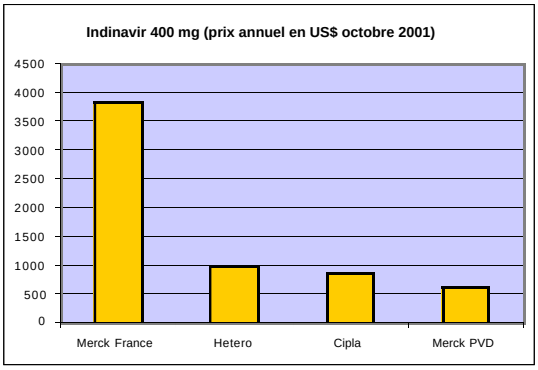
Price comparaison, Lamivudine
(MSF & Act Up-Paris data)



Price comparaison, Lamivudine
(MSF data)



Price comparaison, Indinavir
(MSF & Act Up data)



Access to medicines and intellectual property

In a number of developing countries brand-name companies have not registered patents for the medicines they sell. These countries are thus free to manufacture, import or export generic copies of these products (no need to respect intellectual property)[1].

However, research-based pharmaceutical companies are more and more inclined to register patents for the treatments they produce and sell in all countries:

-because the threat of competition has grown;

-because all countries are bringing their legislations into line with international regulations(respect intellectual property and WTO agreements);

Therefore as international rules are in the process of being respected in all countries, they have everything to gain from registering their patents.

The only solution left for developing countries is then to resort to the exceptions allowed by international agreements (compulsory licences) allowing the production or import of generic medicines.

Since the marketing of the first generics few have been the countries that have tried to manufacture or import generics:

-research-based companies have long claimed and spread the idea that countries did not have the right to resort to these medicines;

-even when they were well informed about their rights, most countries were reluctant to confront brand-name firms as they were afraid of retaliatory measures by these firms and the governments backing them.

Pressure was brought on some countries by trade reprisals, the threat of legal proceedings or court action. The United states even brought a complaint before the WTO Dispute Settlement body against the policy of the Brazilian government, which it finally dropped in June 2001.

Without any other alternative some countries have, however, dared to resort to generics:

-Indian companies have produced numerous medicines;

-Thailand was put under a lot of pressure, but finally manufactured a powdered version of ddl as well as fluconazole;

-Brazil has produced different medicines that were not patented in the country and even issued a compulsory licence to produce Nelfinavir to force Roche to lower its price(Nelfinavir is used by a quarter of the 100 000 patients who are treated for AIDS in Brazil).

After long and fruitless negotiations with Roche to obtain a lower price, the Brazilian government announced it would issue a compulsory licence to produce Nelfinavir. The Health Minister, José Serra, then decided to ask the public institution, Far-Manguinhos, to produce this drug at a cost 40% lower than the price of Roche, which represented a saving of 88 million reals per year for Brazil.

Under such pressure, the Swiss pharmaceutical company finally accepted to lower the price of nelfinavir by 40%. The agreement put an end to a six months' long conflict.

This case shows the importance for countries to manufacture generics on their own or import them; such a capacity gives them more leeway and much more influence in negotiations with brand-name companies.

In the awesome climate imposed by Big Pharma and developed countries, the mobilization of civil society and international public opinion as well as of numerous developing countries forced Member States to clarify the situation during the last WTO Ministerial Conference and reaffirm some of the rights of poor countries.

1. This is not the case in most of the countries with manufacturing capacities, and where most of the drugs are patented.

The Doha TRIPS and Health Declaration

The WTO Agreements on intellectual property state that a sovereign Member State has the possibility of producing or importing a product after negotiations with a patent holder if the governement considers it has not reached a satisfactory agreement for its country.

Such stipulations are included in the national legislations of all developed countries and they often resort to them in fields other than health.

However, such a right was questioned when it concerned developing countries and generic medicines.

If for three years the pressures and threats of developed countries and pharmaceutical companies have brought the production of generics and their export to the least developed countries to a standstill, **at the Doha Ministerial conference, governments were declared free to produce and import the patented medicines that they needed. By declaring that « each Member has the right to issue compulsory licences and is free to determine the grounds on which such licences can be issued », the 142 Member States clearly stated that public health concerns override commercial interests-even regardless of situations of national health emergency.**

From now on the developed countries that bring pressure on developing countries trying to improve access to medicines, or resort to bilateral sanctions, would be liable to WTO condemnation.

Thus, **with compulsory licences countries with a production capacity can from now on produce the whole range of anti-AIDS treatments and particularly the most recent treatments that are not available at affordable prices in developing countries(amprenavir, lopinavir, tenofovir, for example).**

As for the countries that are not able to produce these medicines themselves, they are theoretically able to import those that they need from countries that produce low-cost generics.

A decisive factor in the negotiations at Doha was the American episode on the treatment of anthrax after September 11.

"The United States and other developed countries are discovering what it is like to be confronted with a public health urgency and the terrible difficulties the poorest countries have been encountering for years to have access to medicines.
Le Monde, November 6, 2001

Testifying before Congress on October 23, on the closely-argued negotiations with Bayer, the producer of the antibiotic ciprofloxacine used to fight anthrax, Tommy Thompson, the US Secretary of Health and Human Services, declared: " I can assure you we are not going to pay the price they are the asking for". Bayer started by asking for a price between $1.75 and $1.85 the tablet and" I can assure you they are far from the target" Thompson added speaking to journalists. Tommy Tompson had also stated before Congress that in case Bayer did not lower its price, the American government could override Bayer's patent and issue a compulsory licence for a generic copy of Cipro."
Le Monde, November 6, 2001

The Post Doha Situation : The Right to Export, Negotiations at the TRIPS Council

However, Doha was not a complete victory : all the provisions of the TRIPS Agreement were not clarified at Doha. In particular generic producers were refused the possibility of exporting generics to countries without any production capacity by developed countries.

The majority of people with AIDS and the majority of sick people in general live in countries that are not able to produce the medicines they need on their own, thus exports from generics-producing countries are necessary.

At the end of the Doha Conference, the TRIPS Council was instructed to find an expeditious solution to this problem before the end of 2002. Negotiations are right now taking place at the TRIPS Council which met on June 24,25 and 26.

The United States is opposed to any measure leading to the long-lasting development of exports. The European union, eager to appear as a mediator between the United States and developing countries and define an international middle-of-the road consensus, has put forward a legal solution which is nevertheless unworkable for poor countries.

The next meeting of the TRIPS Council will be determining.
Its outcome depends on the fighting spirit of developing countries.

Going out into the Field Again

Since Doha brand-name pharmaceutical companies have adopted a double strategy:

Being out in the field:

- being present in developing countries by making offers to these countries (market penetration);

- making deals with developing countries(accelerating Access Initiative);

- fostering rumours on the bad quality of generics.

Blocking generics:

- On the one hand, through pressures on institutions such as the Global Fund to discourage developing countries from submitting proposals using generics;

- On the other hand, by lobbying governmental and international institutions to legally block any recourse to generics thanks to bilateral, regional or international agreements on intellectual property : the Free Trade of the Americas Agreement, the Bangui Agreementtec; the TRIPS Council.

However, right now more and more countries are girding themselves up for a fight to import or produce generics(Ghana, Niger, Cameroon, Uganda etc) They are getting information on the procedures to be adopted, learning about the various prices offered, and buying generic medicines from the few existing producers.

The European Union Returns to the Bosom of Big Pharma, Betraying People with HIV/AIDS

Pascal Lamy, the European trade representative, who presented himself as the spearhead of the fight for access to medicines , is finally returning to the bosom of Big Pharma as shown by the proposals of the European Commission in the negotiations at the TRIPS Council.

Last November at Doha the Member States of the WTO instructed the TRIPS Council to find a solution before the end of 2002 making it possible for generic producing countries to export generics to countries which aren't producing themselves.

Now the proposals of the European Commission, which play down the importance of universally recognized public health needs, run counter to the spirit of the Doha declaration on "TRIPS and Public Health", and restrict the export of generics by all possible means:

1) through discrimination :

For the European Commission, countries wishing to use generics would have to prove they are sufficiently poor, weak or incapable of producing generics on their own, that their needs are genuine or that the illness they are combating is sufficiently serious(cf www.actupp.org/article510.htlm -- in French only). According to Gaëlle Krikorian of Act Up-Paris : « not only is the procedure obscene, but the Commission simply denies the sovereignty of such countries and the fundamental rights of their people. It denies the fact that sick people in poor countries who suffer from illnesses or symptoms that are not deadly, but severely debilitating, such as arthritis, chronic depression or polio, have the same rights as people in rich countries to have access to health care or live without pain. »

2) through constraint :

The European Commission is trying to impose on producing as well as importing countries a whole array of restrictions and safeguards the only purpose of which is to limit the very production of generics.

For Act Up-Paris, « such measures are absurd as well as unethical. It is up to rich countries, which already have the means at their disposal to regulate and control imports, to make sure they monitor imports at their own borders. »

Besides, by requiring from countries wishing to import generics that they give innumerable guarantees and justify the legitimacy of their policy in many different ways, the European Commssion makes them the easy targets for the very same pressures and threats that have prevented them so far from issuing compulsory licences and obtaining generics.
Thereby it serves only one interest, that of the pharmaceutical lobby, which dreads the coming of pharmaceutical products onto the markets of rich countries.

Pascal Lamy claims « he has been fighting for two years to make the international community aware of the necessity of a drastic cut in the price of medicine to combat the major epidemics of the South » But the battle is not over for the sick and their right to benefit from the export of generics is at stake.

Pascal Lamy asserts « it is possible to modify the broad lines of globalization in a way that serves the interests of communities. » However, by putting forward the question of differential pricing- which is nothing but an agreement with brand-name companies- he only serves the interests of pharmaceutical companies and dismisses the fundamental question of the export of generics.
Europe and the WTO are expected, on the contrary, to allow countries wishing to use generics to do so as easily as if they were able to produce them on their own.

Today the future of sick people and all developing countries is at stake: they must learn about the different possibilities to have access to the lowest prices.

At Doha we won a battle : the right of countries to use generics. From now onward, sick pople must have access to these medicines and developing countries must be able to get huge supplies of them.

Long-term access to antiretrovirals and other particularly expensive medical products depends on the development of local production, bulk procurement of generics and the transfer of technology.

The number of producers in developing countries must increase rapidly; developing countries must be able to negotiate with partners other than proprietary firms and no longer have to submit to the demands of these companies.

Summary of pharmaceutical companies' best ARV price offers for developing countries

Comparaison des prix les plus bas proposés dans les pays en développement

Prices are shown in US$ per adult patient per year. Les pris sont exprims en dollar US par patient et par an.

(source MSF, june 2002)

Nucleoside Reverse Transcriptase Inhibitors (NRTIs) / Analogues nucléosidques

NRTI (Abbreviations)	Abacavir (ABC)	didanosine (ddI)	lamivudine (3TC)	Stavudine (d4T)	zalcitabine (*) (ddC)	zidovudine (ZDV or AZT)
Strength (mg)	300	100	150	40	0.75	300
Trade name in Europe/US	Ziagen (GSK)	Videx (BMS)	Epivir (GSK)	Zerit (BMS)	Hivid (Roche)	Retrovir (GSK)
Daily dose	2	4	2	2	3	2
BMS (US)		310		55		
GSK (UK)	1387		234			584
Roche (US)					**161**	
Aurobindo (India)		**197**	**66**	**31**		**140**
Cipla (India)		426	126	53		198
GPO (Thailand)		650	163	73		277
Hetero (India)	**1372**	248	93	47		183
Ranbaxy (India)			100	49		180

(*) Zalcitabine was not included in the 12th Edition of the WHO Essential Medicines List. For daily dose, "Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents", by the Panel on Clinical Practices for the Treatment of HIV, 2001, was taken as reference document (see Bibliography).

Prices are shown in US$ per adult patient per year. Unless otherwise noted prices are FOB for generic Manufacturers, and at least CIF for originator companies. All prices in other currencies than dollars were converted at the rate in force when the offer was made. Prices are rounded up to whole numbers for easier comparison. Annual costs are calculated according to the daily doses given in the WHO document "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 2002 (see Bibliography). Suppliers have not necessarily been assessed for quality standards, procurement agencies should follow their own procedures in this respect.

Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)/ Analogues non nucléosidiques

NNRTI (Abbreviation)	efavirenz (EFV)	nevirapine (NVP)
Strength (mg)	200	200
Trade name in Europe/US	Stocrin (Merck & Co., Inc.)	Viramune (Boehringer-Ingelheim)
Daily dose	3	2
Boehringer-Ingelheim (Germany)		438
Merck & Co., Inc. (US)	500 (*)	
Aurobindo (India)	**438**	**112**
Cipla (India)	589	208
GPO (Thailand)		244
Hetero (India)	658	146
Ranbaxy (India)	570	166

(*) The price for Stocrin 600 mg is the same as 3x200 mg, according to the same conditions given in Table 2.

Prices are shown in US$ per adult patient per year. Unless otherwise noted prices are FOB for generic Manufacturers, and at least CIF for originator companies. All prices in other currencies than dollars were converted at the rate in force when the offer was made. Prices are rounded up to whole numbers for easier comparison. Annual costs are calculated according to the daily doses given in the WHO document "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 2002 (see Bibliography). Suppliers have not necessarily been assessed for quality standards, procurement agencies should follow their own procedures in this respect.

Protease Inhibitors (PIs) / Inhibiteur de protéase

PI (Abbreviation)	amprenavir (*) (APV)	indinavir (IDV)	nelfinavir (NFV)	ritonavir (r)	saquinavir (#) sgc (SQV sgc)
Strength (mg)	150	400	250	100	200
Trade name in Europe/US	Agenerase (GSK)	Crixivan (Merck & Co., Inc.)	Viracept (Roche)	Norvir (Abbott)	Fortovase (Roche)
Daily dose	16	6 (**)	10 (***)	2 (§)	10 (##)
Abbott (US)				**83**	
GSK (UK)	**3176**				
Merck & Co., Inc. (US)		600			
Roche (US)			2704		**1342**
Aurobindo (India)		**589**	**1533**	336	
Cipla (India)		913	2026		
GPO (Thailand)					
Hetero (India)		986	2007	343	
Ranbaxy (India)		786			

(*) Amprenavir was not included in the 12th Edition of the WHO Essential Medicines List. For daily dose, "Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents", by the Panel on Clinical Practices for the Treatment of HIV, 2001, is used as a reference (see Bibliography)

(**) Please note that "Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents", by the Panel on Clinical Practices for the Treatment of HIV, 2001, is used as a reference (see Bibliography). According to the WHO document "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 2002 (see Bibliography), IDV should be used combination with ritonavir as a booster (800mg IDV plus 100mg ritonavir twice daily): it will be included in the next edition.

(***) The daily dose is 1250 mg twice daily (see in the Bibliography both "Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents", by the Panel on Clinical Practices for the Treatment of HIV, 2001 and WHO document "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 2002).

(§) The daily dose is 100mg twice daily, for use as booster medication (see "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 2002, and the WHO Essential Medicine List, 12th Edition, April 2002)

(#) Saquinavir is also available as hard-gel formulation from both Roche and generic manufacturers.

(##) Please note that according to the WHO document "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 2002, SQV should be used with ritonavir as a booster (1000 mg SQV plus 100 mg ritonavir twice daily); when combined with ritonavir either the soft gel capsules or the hard gel capsules can be used.

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Fixed Dose Combinations (FDCs) . Combinaison

Combination	lopinavir+ ritonavir (LPV/r)	3TC +d4T	3TC + d4T	ZDV +3TC	ZDV + 3TC NVP	ABC+3TC+ZDV	3TC+ d4T+ NVP	3TC+ d4T+ NVP
Strength (mg)	133.3 + 33.3	150 + **30**	150 + **40**	300+150	300 + 150 + 200	300+150+300	150 +**30**+200	150 +**40**+200
Therapeutic class	2 PIs	2 NRTIs	2 NRTIs	2NRTIs	2 NRTIs + 1 NNRTI	3NRTIs	2 NRTIs + 1 NNRTI	2 NRTIs + 1 NNRTI
Trade name in Europe/US	Kaletra (Abbott)			Combivir (GSK)		Trizivir (GSK)		
Daily dose	6	2	2	2	2	2	2	2
Abbott (US)	**500**							
GSK (UK)				730		2409		
Aurobindo (India)				**204**				
Cipla (India)		162	173	292	**419**		361	361
GPO (Thailand)				407			325	358
Hetero (India)	3833	135	141	276		**1648**	**281**	**286**
Ranbaxy (India)		**128**	**139**	265			287	295

Prices are shown in US$ per adult patient per year. caramUnless otherwise noted prices are FOB for generic Manufacturers, and at least CIF for originator companies. All prices in other currencies than dollars were converted at the rate in force when the offer was made. Prices are rounded up to whole numbers for easier comparison. Annual costs are calculated according to the daily doses given in the WHO document "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 2002 (see Bibliography). Suppliers have not necessarily been assessed for quality standards, procurement agencies should follow their own procedures in this respect.