ACT UP PARIS

Acces to Generics and Intellectual Property

In many developing countries doctors and patients do not have access to the tests, treatments or vaccines they need as they do not have the money to pay for them. One of the reasons which explains the high prices of these health products is the monopoly given by patents to the pharmaceutical companies which market them.

What is the connection between patents and the prices of medicines? What is the international legislation on intellectual property and what are the consequences for public health? How can people afford these treatments? How can people at the national level have access to essential medicines? These are the questions we are going to deal with.

I. Generics[1]

Right now more than 40 million people are living with AIDS. Despite an international mobilization, 95% of all the people in the world who are infected with HIV/AIDS do not yet have access to the essential medicines which can keep them alive. Every day 10, 000 people die of AIDS for lack of treatment.

To broaden access to anti-Aids medicines in developing countries, and for every country to be able to implement a national program of access to treatments, it is absolutely necessary to be able to use medicines which are really affordable in proportion to the income of the countries, and to develop the least costly procurement strategies for each country.

1 — Why is the price of a drug so important?

Since multitherapies were invented, international donors have been using the high prices of medicines as an excuse to justify their refusing to commit themselves to paying the medical care of people infected with HIV/AIDS in developing countries. When the money is raised, it is used to a great extent to pay for too costly treatments for a limited number of people. When patients and their families must directly pay for medicines out of their own pockets, they simply cannot afford them most of the time.

Thus the prices of medicines are a major hurdle blocking a broader access to treatments in poor countries. This problem concerns ARVs, but also some treatments for opportunistic diseases which are particularly costly(nizoral, fluconazol, acyclovir etc), or the products used to make a diagnosis or to monitor patients.

(1) According to the WHO, a generic drug is a pharmaceutical product which is the equivalent of a brand-name product, and which is generally produced without a licence from the company which holds the patent. It is a copy which can be marketed when there is no patent on the brand-name product in a country, when the patent has expired, when there is no legislation protecting intellectual property, or when a voluntary or compulsory licence has been granted to bypass the patent. In this paper the term is used for copies of medicines which are less costly than patented drugs, generally because no patent has been registered to protect a brand-name medicine, or because no legislation has been adopted, even if in other countries patents forbidding the marketing of generics competing with brand-name drugs have been registered.

2 — Do people have to put up with the price of medicines?

The production of generic copies of antiretrovirals from 2000 onward has shown that the prices of medicines are not inevitable and could plummet.

In October 2000 an Indian producer launched a generic tritherapy for $800 a year. This 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 another producer came up with the price of $250. In April 2003 it was possible to have access to tritherapies for little more than $200 a year.
For three years generic versions of antiretrovirals have been produced by publicly-owned companies (Brazil, Thailand) or by private companies (India)

and sold at prices much lower than the prices of multinational corporations which own brand-name drugs.
By enabling countries to get out of a monopoly context, this has had particularly important consequences in terms of prices, and has notably forced pharmaceutical corporations to match the prices of generics producers.

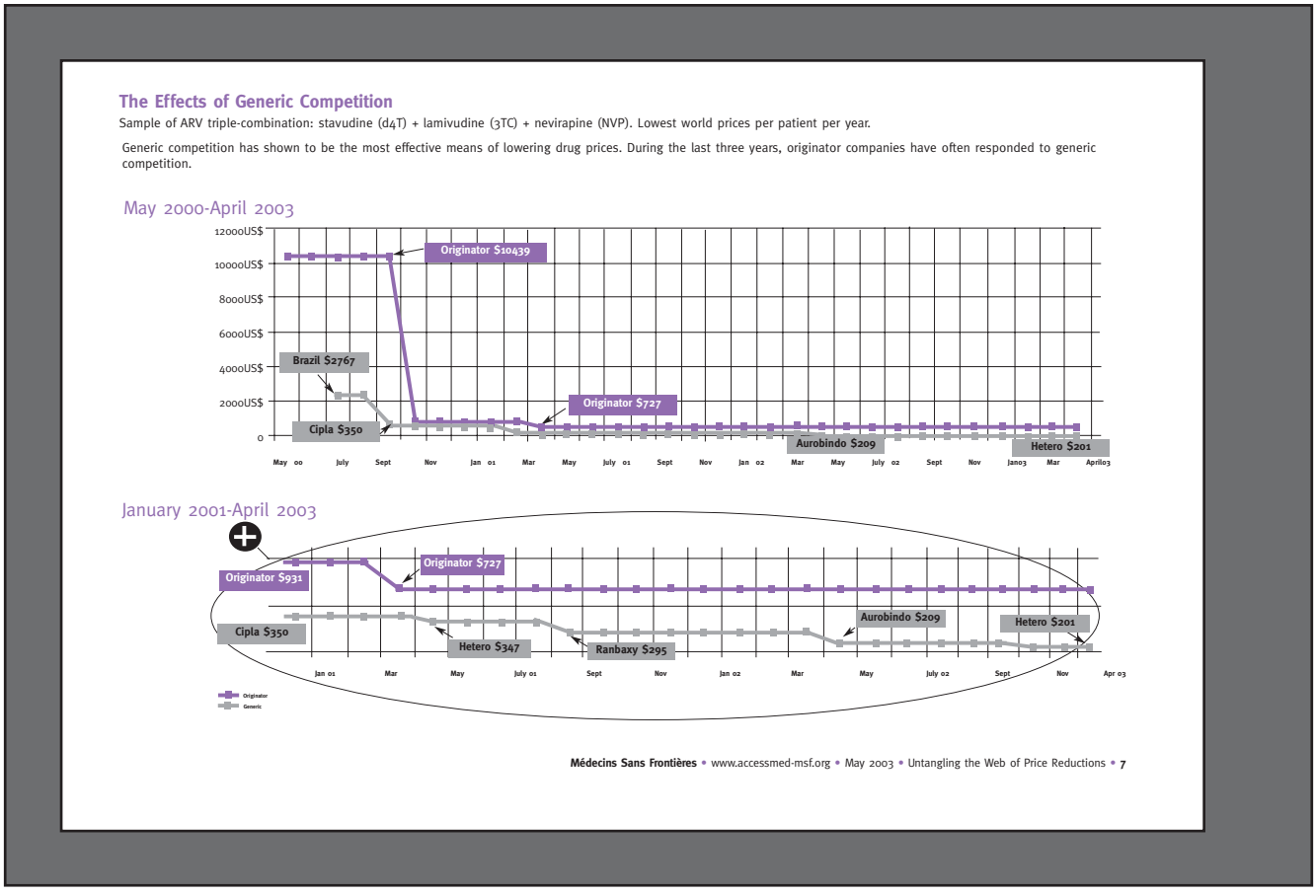
The production of generic antiretrovirals has thus proved:
1) **that drugs can be sold at much lower prices than the industry has always claimed was possible** (we do not know yet what their cost prices are, but they undoubtedly are lower than the prices of generics producers)
2) **that in the absence of a monopoly, competition among producers is the most efficient mechanism to get a drastic and lasting drop in drug prices**, and this much more than the philanthropy or charitable actions of Big Pharma can achieve.

The graph below shows the consequences of the competition of generic drugs on the drop in prices of brand-name pharmaceuticals between May 2000 and April 2003 (source: MSF): The lowest prices per year and per patient for the tritherapy, Stavudine (d4T) + Laminvudine (3TC) + Nevirapine (NVP).

3 — What about the quality of generics?

The quality of a medicine is essential, whether it is a brand-name drug or a copy. Many generics producers are capable of producing drugs of high quality. Having said this, **it is up to every government to guarantee the quality of the medicines which are allowed to be marketed in its country.**
In cooperation with other organizations of the United Nations, the **WHO** has launched **a programme of pre-qualification of antiretrovirals which enables people to identify the producers whose manufacturing processes comply with international norms, which is one of the fundamental requirements to guarantee the quality of a product.**

Thus a list of providers whose AIDS medicines have been considered of high quality has been drawn up(cf:www.who.int/medicines). The objective is to help governments give their people access to health products of good quality at the lowest prices possible.
At present the WHO must increase the financial resources it has devoted to this program, in order to speed up the process and make the information available as rapidly as possible on the generic versions of recent products.



4 — Are ARV generics available in developing countries?

Since the first generics were produced, **many developing countries have manufactured or imported these drugs only cautiously** for several reasons:
-because brand-name companies have been claiming for a long time that countries did not have the right to use these drugs, which has become a commonly held idea;
-because even when countries were aware of their rights, they did not dare to oppose Big Pharma, as they were afraid of reprisals on the part of pharmaceutical corporations and the developed countries behind them.
And it is true that some pressure was exerted on some countries; there was economic retaliation, there were threats of court action, and legal proceedings were started. The United States even took legal action against Brasilia's policy in the World Trade Organization (WTO), which it gave up in June 2001.

However, two major cases enabled governments to leap into the breach and move forward. In 2001 the 39 companies which sued the South-African government to attempt to block access to generics, had to surrender. In November 2001 the WTO recognized the right of developing countries to use such products (cf p.4).

Nowadays many companies have started producing ARV generics because the survival of their people was at stake.
Thailand under much pressure has finally produced a powder version of ddI as well as fluconazole. Brazil has been manufacturing various ARVs which were not patented in the country, which was much less costly than buying such products from multinational corporations. In August 2001, after long and unsuccessful negociations with Roche, the Brazilian government announced its intention to issue compulsory licences (cf p.6) to produce some nelfinavir.
The Brazilian Ministry of Health had thus decided to make the state company, Far-Manguinhos, produce the generic at a price 40% lower than Roche was asking. Under this pressure the Swiss pharmaceutical firm finally reduced its price in the same proportion. This example shows how important it is for countries to be able to manufacture generics themselves or import them, because they have more leeway and much more power in their negociations with brand-name companies, but also because this way they can choose from different suppliers.

Nowadays, as many countries import small quantities of generics, it is up to governments to shift into high gear and implement the most efficient and least costly public health and procurement policies to enlarge access to medicines as quickly as possible.

Cf Tables comparing prices (MSF data 2003).

II. The Impact of Intellectual Property on Access to Medicines

1 — The World Trade Organization: a few dates

1994 - The TRIPS agreement

"TRIPS" means Trade Related Aspects of Intellectual Property Rights. It was one of the agreements of the World Trade Organization which was part of the final Agreement reached in the multilateral negotiations of the Uruguay Round. It was signed in April 1994 in Marrakech by the 125 Member States of the WTO at the time. This Agreement aims at harmonizing the protection of intellectual property at the global level, particularly in the field of industrial property: patents, copyrights, trademarks etc. **It lays down minimum standards of protection of intellectual property for WTO Members.** The Member States are thus required to implement these rules in their national legislation according to a timetable set out by the WTO, a timetable which varies according to the level of development of Member States. **The protection of intellectual property applies to all inventions and therefore to health products among others.**

2001 – The Doha Declaration

Instigated by an international movement fighting for access to anti-AIDS treatments, a declaration was signed in November 2001 by all the WTO member States : the Doha Declaration or "TRIPS Declaration and Public Health".

This declaration recognizes the right of countries to override the intellectual property rights of pharmaceutical companies to promote public health and broader access to medicines for all, regardless of diseases. This agreement should be implemented "in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all"; "each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted", which means that a country can, under certain conditions, import or manufacture copies of medicines which are patented in its territory.

2003 – The Agreement of August, 30

After the Doha Conference there remained a crucial problem which had to be solved by the WTO Member States: **how would countries which do not produce medicines get generic drugs**, or how could those that have the capacity to produce medicines export them?
On August 30, 2003, the WTO reached an agreement on generic medicines. Despite the opposition of the United States, **this agreement does not limit the scope of diseases; it applies to all diseases**

without any kind of restriction.
However, at the end of particularly hard negotiations with developed countries, it appears that **the agreement has set up a mechanism which has thrown up administrative, legal, economic and political obstacles to ensure export of generic medicines.** Taking up a mechanism put forward by the European Union to which the US delegates added another more restrictive layer, the outcome of almost two years of negotiations is very disappointing. A huge complicated system of procedures which imposes numerous constraints, and compulsory notifications, and requires information to be provided, proofs to be given and demonstrations to be made, the system set out in this agreement is a true obstacle course. Furthermore, as a result of this agreement, developing countries are more defenceless against the manoeuvres of those who are not favourable to generics and can systematically refer to the WTO to attempt to block any attempt of a poor country to obtain generics.

2 – The implementation of the TRIPS agreement

a) Dates of application of the agreement at the national level

Before the Uruguay Round many governments did not issue patents on pharmaceutical products in their territories. Henceforward all WTO Member States must implement the TRIPS Agreement. Some countries have already brought their legislation into line with this agreement (they are said to be TRIPS-compliant). Many countries have not yet done so. As is made clear in the TRIPS Agreement, **a period of transition has been granted to developing countries to introduce the rules on patents into their national regulations**. Initially until 2006 for the least developed countries, the period was extended until **2016** in the Doha Declaration (paragraph 7).

b) What are patents? How do they affect access to medicines?

The system of patents consists in governments granting an exclusive right to the owner of an invention in order to enable the inventor to make up for his investments in research. The patent holder thus has a **monopoly** to use, manufacture, sell and import a patented product (art.28 of the TRIPS Agreement). **The duration of a patent is 20 years from the date the patent application is filed** (Art.33 of the TRIPS Agreement). Any new pharmaceutical product or manufacturing process can thus be protected (Art.27.I of the TRIPS Agreement) and generic copies cannot be marketed during the duration of the patent. **When the patent expires, it is said that the product becomes public domain; it can be copied, manufactured and marketed by other public or private companies.**
This system was set up to encourage innovation and thus the discovery of new drugs. Even though the pharmaceutical companies which own patents make huge profits and more than recover the funds invested in research, pharmaceutical innovation has, however, markedly slowed down since the 70's. Thirty years ago, more than 100 new drugs were marketed every year. In 2002 only 32 new drugs were marketed in the United States. Besides, these new treatments are quite often very much like older treatments. If their prices are 35% to 100% higher than those of reference products, the benefits, however, in terms of effectiveness and tolerance are very similar so that it becomes difficult to speak of real innovation.
Furthermore, **international organizations have noticed that the monopoly conferred by patents to corporations has blocked access to health products in developing countries**. As a matter of fact, it precludes competition and prevents the implementation of public health policies resorting to generic products. Prices are generally too high for these products to be affordable. A report by an IMF economist has demonstrated the particularly negative impact of the implementation of WTO regulations in developing countries. In Argentina it notably led to an increase of more than 70% in prices and a drop of 50% of consumption for the products which, as a result of patent protection, a monopoly was instituted. Thus the implementation of the TRIPS Agreement in many countries has led to less access to health products which was already quite inadequate.

c) How are patents implemented?

Legislation on patents is national (or possibly regional when there is a regional agreement among several countries and a regional office is entitled to issue patents). Thus there is no global patent. Each country is alone responsible for the patents it accepts to issue or not in its territory. An inventor who files a patent application has to do so in each country. And the protection given by the patent, if it is issued, applies only within the territorial borders of the country.
By filing patent applications pharmaceutical companies gain a manufacturing and marketing monopoly for their products. Nowadays when most countries implement international intellectual property regulations, companies almost automatically file patent applications in each country.
In the past these companies often only filed patent applications in countries which had a potentially competitive pharmaceutical industry or which constituted sufficiently attractive markets- this was the case of very few countries in Africa as **the whole continent represents only 1,3% of the global trade in medicines**.
Thus in quite a number of developing countries many drugs are not protected; the result is that the country is

free to produce, import or export generic versions. To discover the list of patented drugs in a country, one has to consult the national office of intellectual property of the country.

d) What are the legal exceptions to the right conferred by patents?

If the WTO Member States must implement the rules on intellectual property, the TRIPS Agreement allows some exceptions.

Compulsory Licences

A compulsory licence is a mechanism in the TRIPS Agreement in which copies of a health product can be produced or imported without the consent of the patent holder, but provided he is given financial compensation. Governments as well as private firms can apply for a compulsory licence. It is called "compulsory" for such licences are granted by the judiciary or administrative authority of the country. Such a possibility in the TRIPS Agreement is often used by developed countries in areas other than health.
This right was stated again in the Doha Declaration. (Art.5.b): " Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."
In order to protect public health (Art.8 & Art. 31b of the TRIPS Agreement and Art.5C of the Doha Declaration) a state can resort to a compulsory licence. It can equally do so if the medicine is produced by the patent holder in insufficient quantities, or its quality is inadequate, or the price is abnormally high.
For the government to be able to grant a compulsory licence, the potential User (a producer or an importer) is required to have unsuccessfully attempted to obtain a voluntary licence contract, that is the agreement of the patent holder to use his patent on reasonable commercial conditions. (Art.31.b of the TRIPS Agreement). **This pre-condition cannot be skipped except in cases of extreme urgency, public non-commercial use and adjudicated anti-competitive practice.** This is what happened in South Africa in October 2003 when the Competition Commission concluded that the two companies, GlaxoSmithKline and Boehringer Ingelheim, had taken advantage of their dominant position in refusing to issue voluntary licences to local pharmaceutical companies so they could produce generics at a low price. This decision now allows South Africa to manufacture locally or import the following products: AZT (Retrovir), Lamivudine (3TC), the combination AZT+Lamivudine (Combivir) and Nevirapine(Viramune).

The abuse of rights, such as the absence of local working of a patented invention, can also be a ground on which to grant a compulsory licence.
Article 8.2 of the TRIPS Agreement authorizes Member States "to take appropriate measures...in order to prevent the abuse of intellectual property rights". For sectors of vital importance, if the patent holder does not manufacture the product locally, the national legislation of a country can force him to grant a compulsory licence to a local manufacturer. A compulsory licence can also be issued by a government to manufacture a product locally or to import it in order to improve the supply of the domestic market or the price conditions.

Compulsory licences are one of the best means to ensure competition between brand-name products and copies in order to get the lowest prices. This is why developing countries must include in their legislation the flexibilities set out in the TRIPS Agreement and the Doha Declaration in order to be able to adopt compulsory licences as easily and as quickly as possible.

One episode that played a major role in the Doha battle was the American antrax crisis after the september 11 attacks.

"The United States and other developed countries have discovered what a situation of public health emergency is like and the plight of developing countries to have access to medicines, problems that the poorest countries have been confronted with for years". (…)
Testifying before the US Congress on October 23, US Health and Human Services Secretary Tommy Thompson declared concerning the tough negociations
with Bayer, the manufacturer of the antibiotic Ciprofloxacin used to treat anthrax : "I can assure you that we are not going to pay the price they are asking for." Bayer started asking between $1.75 and $1.85 per pill "and I can assure you they are far short of the target", Thompson added in front of journalists. Thompson also assured Congress that in case Bayer did not lower its price, the American government could withdraw FDA approval of its drug and buy a generic version of Cipro." *Le Monde*, November 6, 2001.

Another exception: Article 30 of TRIPS

Apart from compulsory licences, Article 30 gives the possibility of using the patent object without the authorization of the patent holder. "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." **When reasons of public interest justify it, the public authorities of a country can thus authorize the exploitation of a patent object by another person without the consent of the patent holder.**

e) Parallel imports

The TRIPS Agreement does not prohibit parallel imports of identical patented products. **Parallel imports allow a country to import brand-name pro-**

ducts which are less expensive than in the country without the authorization of the patent holder. Parallel imports are important for countries when the price of a product varies a lot from one country to another. Many European countries resort to parallel imports to lower the cost prices of medicines.

f) The Bolar exception

This exception, which is used by some developed countries authorizes generic product manufacturers to carry out clinical tests to prove their product is bio-equivalent to the brand-name product before the patent expires. This allows them to manufacture generics and bring them onto the market immediately after the patent expires. It allows the producer of generic medicines to gain time by preparing the drug and filling out in advance the application papers required by the regulation authorities to market the product.

3 — What is at stake today?

a) Testing the Geneva Agreement of August 30, 2003 on exports

Today every country and all sick people must avail themselves of the various possibilities that exist in order to have access to medicines at the lowest prices possible. **Therefore the August 30 Agreement on exports must be put to the test as quickly as possible. If it does not work, this must be shown as quickly as possible and countries must adapt their national strategies to have access to the least expensive medicines.**

b) Alternatives strategies

There are other ways than the August 30 Agreement to enable countries to export. **Article 31.f** of the TRIPS Agreement states that the use of a compulsory licence "shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use". This means that 49%% of its production can be exported freely without the country bothering about the constraints added by the August 30 Agreement. **Article 30** of the TRIPS Agreement, which deals with exceptions to rights conferred, leaves a margin of freedom and could equally be used to allow exports. In the same way **Article 31.k** on anticompetitive practices can also be used by governements.

c) Goverments must commit themselves

The WTO negociations on the question of medicines are not over. The WTO Member States must now include the possibility for countries to export generics as an amendment to the TRIPS Agreement itself. The August 30 deal is a declaration, but not an amendment to the agreement on intellectual property. Thus countries have an opportunity to simplify the proposed mechanism and obtain a truly workable solution.

We won a battle in Doha : the right for countries to use generics was acknowledged. Sick people must now be able to enjoy this right in all the countries where it is not possible to pay the prices of Big Pharma. The number of producers in developing countries must increase. The trade in high quality generics must develop so that developing countries can give up negociating only with brand-name companies and no longer have to submit to the demands of these companies.
This is why, **when a country has to conform with the WTO Agreements, it must use the margins of freedom as much as possible(compulsory licences, parallel imports etc) given by the TRIPS Agreement. To circumscribe the negative impact of patents and prevent monopoly situations which penalize their people, countries must include the safeguards set out in the agreements in their legislation and thus encourage the introduction of generic drugs.**

Besides, **the least developed countries, which do not have to abide by the regulations on intellectual property before 2006 or 2016, must absolutely take advantage of this situation which allows them to manufacture or import freely and not implement restrictive legislation ahead of time, or modify their legislation to take advantage of this situation.**

Countries must equally refuse more restrictive provisions on intellectual property than those in the WTO Agreements. Right now, developed countries(The United States, the European Union etc) have repeatedly attempted to impose more restricting measures on developing countries than those required by the WTO (called TRIPS+) in the context of bilateral or regional agreements. Nothing legal justifies such new constraints. Developed countries are not allowed to demand them and developing countries must refuse them.
Often these are clauses extending patent terms beyond the 20 years required by the TRIPS Agreement, or preventing the use by the authorities of a country of clinical data (provided by the originator pharmaceutical company) to authorize the marketing of generics, by imposing market exclusivity.

For more information:

http://www.cptech.org/ip/wto/p6
— Consumer Project on Technology
http://www.healthgap.org/camp/trade.html
— Health Gap
http://www.accessmed-msf.org — MSF
http://www.who.int — WHO

Act Up-Paris: Gaëlle Krikorian — galk@noos.fr
— http://www.actupparis.org

Data on the drug prices, *Médecins Sans Frontières*, May 2003

Table 1b – Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

All prices are in US$. Prices are given both for a yearly adult dose and by unit.

For details on eligibility and offer restrictions for countries and institutions, please refer to tables 2a and 2b.

Products on the WHO list of Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS drugs and diagnostics of acceptable quality (Sixth edition, 5th May 2003) are in **bold** and have an **asterisk *** next to the price. Always check website for most recently updated list. Best prices are in **bold & underlined**. Incoterms vary according to manufacturers.

Annual cost is calculated according to the daily doses given in the WHO 'Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach' (June 2002) and/or the 'Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents' from the Panel on Clinical Practices for the Treatment of HIV (2002).

NNRTI (Abbreviation)	**efavirenz (EFV)**	**efavirenz (EFV)**	**nevirapine (NVP)**
Strength (mg)	200	600	200
Trade name in Europe/US	Stocrin® or Sustiva® (Merck & Co., Inc.)(**)	Stocrin®or Sustiva® (Merck & Co., Inc.)(**)	Viramune® (Boehringer-Ingelheim)
Daily dose	3	1	2
Boehringer-Ingelheim (Germany)			**438* (0.600/unit)**
Merck & Co., Inc. (US)	500 (0.457/unit)(†)	**346.75 (0.950/unit)**(†)	
Aurobindo (India)	**438 (0.400/unit)**		112 (0.153/unit)
Cipla (India)	462 (0.422/unit)	462 (1.267/unit)	**208* (0.285/unit)**
GPO (Thailand)			244 (0.334/unit)
Hetero (India)	548 (0.500/unit)		**105 (0.144/unit)**
Ranbaxy (India)		578 (1.583/unit)	**166* (0.228/unit)**

(**) Known as Sustiva® (BMS) in US, Canada, UK, Republic of Ireland, France, Spain, Italy and Germany.
(†) Prices given in this table are for Low Human Development Index (HDI) countries plus medium HDI countries with adult HIV prevalence of 1% or greater.
In table 2c, prices for medium HDI countries with adult HIV prevalence less than 1%, are given.

Table 1e – Fixed Dose Combinations (FDCs)

All prices are in US$. Prices are given both for a yearly adult dose and by unit.
For details on eligibility and offer restrictions for countries and institutions, please refer to tables 2a and 2b.

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(es)	PI	NRTI	NRTI	NRTI	NRTI + NNRTI	NRTI	NRTIs + NNRTI	NRTI + 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* (0.228/unit)**							
GSK (UK)				**329* (0.450/unit)**		**1241* (1.700/unit)**		
Aurobindo (India)				**204 (0.280/unit)**				
Cipla (India)		162 (0.222/unit)	172 (0.236/unit)	**292* (0.400/unit)**	418 (0.573/unit)		304 (0.417/unit)	304 (0.417/unit)
GPO (Thailand)				407 (0.558/unit)			325 (0.445/unit)	358 (0.490/unit)
Hetero (India)	3833 (1.750/unit)	135 (0.185/unit)	141 (0.193/unit)	276 (0.378/unit)	**383 (0.525/unit)**	1648 (2.258/unit)	**281 (0.385/unit)**	**286 (0.392/unit)**
Ranbaxy (India)		**125* (0.171/unit)**	**135 (0.185/unit)**	**265* (0.363/unit)**			285 (0.390/unit)	292 (0.400/unit)

Products on the WHO list of Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS drugs and diagnostics of acceptable quality (Sixth edition, 5th May 2003) are in **bold** and have an **asterisk (*)** next to the price. Always check website for most recently updated list. Best prices are in **bold & underlined**. Incoterms vary according to manufacturers.

Annual cost is calculated according to the daily doses given in the WHO 'Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach' (June 2002) and/or the 'Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents' from the Panel on Clinical Practices for the Treatment of HIV (2002).

Data on the drug prices, *Médecins Sans Frontières*, May 2003

Table 1: Summary of selected pharmaceutical companies' best ARV price offers for eligible developing countries

Table 1a – Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

All prices are in US$. Prices are given both for a yearly adult dose and by unit.

For details on eligibility and offer restrictions for countries and institutions, please refer to tables 2a and 2b.

NRTI (Abbreviation)	abacavir (ABC)	didanosine (ddI)	didanosine (ddI)	lamivudine (3TC)	lamivudine (3TC)	stavudine (d4T)	stavudine (d4T)	zidovudine (ZDV or AZT)
Strength (mg)	300	100 (§)	EC 400	150	300	30	40	300
Trade name Europe/US	Ziagen® (GSK)	Videx® (BMS)	Videx® (BMS)	Epivir® (GSK)	Epivir® (GSK)	Zerit® (BMS)	Zerit® (BMS)	Retrovir® (GSK)
Daily dose	2	4	1	2	1	2	2	2
BMS (US)		**310* (0.212/unit)**	Not applicable			**49* (0.066/unit)**	**55* (0.075/unit)**	
GSK (UK)	**986* (1.350/unit)**			**128* (0.175/unit)**				**274* (0.375/unit)**
Aurobindo (India)		197 (0.135/unit)		66 (0.090/unit)			**31 (0.043/unit)**	**140 (0.192/unit)**
Cipla (India)	**821 (1.125/unit)**	426 (0.292/unit)	**271 (0.741/unit)**	**126* (0.172/unit)**	**124 (0.340/unit)**	48 (0.065/unit)	53 (0.072/unit)	**198* (0.271/unit)**
GPO (Thailand)		650 (0.445/unit)		163 (0.223/unit)			73 (0.100/unit)	277 (0.380/unit)
Hetero (India)	1325 (1.815/unit)	**185 (0.127/unit)**		**65 (0.089/unit)**			**31 (0.042/unit)**	175 (0.240/unit)
Ranbaxy (India)			335 (0.917/Unit)	**100* (0.137/unit)**		**36 (0.049/unit)**	47 (0.064/unit)	**180* (0.246/unit)**
Combinopharm (Spain)								**292* (0.400/unit)**

(§) BMS sells ddI (Videx®) in other doses (per mg price remains the same)

Products on the WHO list of Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS drugs and diagnostics of acceptable quality (Sixth edition, 5th May 2003) are in **bold** and have an **asterisk *** next to the price. Always check website for most recently updated list. Best prices are in **bold & underlined**. Incoterms vary according to manufacturers.

Annual cost is calculated according to the daily doses given in the WHO 'Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach' (June 2002) and/or the 'Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents' from the Panel on Clinical Practices for the Treatment of HIV (2002).

Table 1d - Protease Inhibitors (PIs)

All prices are in US$. Prices are given both for a yearly adult dose and by unit.

For details on eligibility and offer restrictions for countries and institutions, please refer to tables 2a and 2b.

PI (Abbreviation)	indinavir (IDV)	nelfinavir (NFV)	ritonavir (r)	saquinavir hard gel capsules (SQV hgc)
Strength (mg)	400	250	100	200
Trade name in Europe/US	Crixivan® (Merck & Co. Inc.)	Viracept® (Roche)	Norvir® (Abbott)	Invirase® (Roche)
Daily dose	4 (**)	10 (***)	2 (§)	10 (#)
Abbott (US)			**83* (0.114/unit)**	
Merck & Co., Inc. (US)	400 (0.274/unit)			
Roche (Switzerland)		**880* 0.241/unit(†)**		**920* 0.252/unit**(†)
Aurobindo (India)	393 (0.269/unit)	1533 (0.420/unit)	336 (0.460/unit)	
Cipla (India)	406 (0.278/unit)	2026 (0.555/unit)	1084 (1.485/unit)	
Hetero (India)	**387 (0.265/unit)**	1500 (0.411/unit)	219 (0.300/unit)	1335 (0.366/unit)
Ranbaxy (India)	467 (0.320/unit)			

Products on the WHO list of Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS drugs and diagnostics of acceptable quality (Sixth edition, 5th May 2003) are in **bold** and have an **asterisk *** next to the price. Always check website for most recently updated list. Best prices are in **bold & underlined**. Incoterms vary according to manufacturers.

Annual cost is calculated according to the daily doses given in the WHO 'Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach' (June 2002) and/or the 'Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents' from the Panel on Clinical Practices for the Treatment of HIV (2002).

For Roche, prices are given in Swiss Francs and were converted in US$ (1 US$ = 1.40 CHF on 15 April 2003)

(**) The daily dose referred to is 800mg IDV twice daily with ritonavir 100mg twice daily as booster. The prescribing information given by the manufacturer is 800mg three times daily
(***) The daily dose referred to is 1250 mg twice daily although the dosage of 9 tablets (3 tablets three times a day) can also be used.
(§) The daily dose referred to is 100mg twice daily, for use as booster medication. This dose is not indicated in the manufacturer's label.
(#) Invirase should be used in combination with low-dose ritonavir as Saquinavir/Ritonavir 1000mg/100mg twice daily
(†) Prices given in this table are for sub-Saharan Africa and Least Developed Countries as UN defined. In table 2c, also prices for Low Income and Lower Middle Income Countries, as classified by the World Bank, are given.