Untangling the web of price reductions:

a pricing guide for the purchase of ARVs for developing countries

10th Edition

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CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

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BACKGROUND

This is the tenth edition of *Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries*. The report was first published by Médecins Sans Frontières (MSF) in October 2001[1] in response to the lack of transparent and reliable information about prices of pharmaceutical products on the international market – a factor which continues to significantly hamper access to essential medicines in developing countries.

The purpose of this document is to provide information on prices and suppliers that will help purchasers make informed decisions when buying antiretrovirals (ARVs). This report is a pricing guide and does not include detailed information about the quality of the products listed. For further information on quality, please see box 1.

Since the first edition of "*Untangling*," prices of some ARVs have fallen significantly, mainly due to competition between multiple producers. However, MSF finds that there are still common problems affecting the availability of the most needed essential medicines for both adults and children. These include: (1) that in the absence of competition from multiple producers, companies may charge prohibitive prices, (2) that there are considerable limitations and problems linked to differential prices, and (3) that in the particular case of paediatric ARVs, the lack of an attractive pharmaceutical market and the slow process in the preparation of standardized guidelines for treatment has led to the fact that many adapted formulations continue to be lacking.

These problems are particularly pressing in the case of the most recent ARVs, including those recommended in the 2006 WHO treatment guidelines[2] for both first- and second-line.

Box 1: Quality issues

This report is a pricing guide and does not include detailed information about the quality of the products listed. However, price should not be the only factor determining procurement decisions. Readers and purchasers wishing to obtain more information about drug quality are therefore encouraged to consult "Prequalification programme manufacturers and suppliers whose HIV-related medicines have been found acceptable, in principle, for procurement by UN agencies," (known as the WHO prequalification list), a project initiated by the World Health Organization (WHO) and developed in collaboration with other United Nations organisations. This project evaluates pharmaceutical manufacturers and products according to WHO recommended standards of quality and compliance with Good Manufacturing Practices. It is part of an ongoing process that will expand as the participation of suppliers increases. Not all the products listed in this report have been prequalified by WHO, and only some of them are used by MSF in its own projects. Products included in the last edition of the WHO prequalification list (Revised 55th edition, published 22 June 2007) appear in **bold** in the tables. Please consult the WHO website (*http://mednet3.who.int/prequal/*) for the latest list of prequalified products and for information on the status of dossier assessment.

New WHO treatment guidelines and their impact on price

Whereas most of the regimens previously recommended included stavudine (d4T) or zidovudine (AZT), the 2006 WHO treatment guidelines have added an improved first-line treatment based on combinations including Abacavir (ABC) and tenofovir disoproxil fumarate (TDF) as new NRTI options. TDF is now becoming an emerging preferred first-line option because of its toxicity profile and increased availability in developing countries (including as FDC). It should be administered in combination with two drugs – one being either lamivudine (3TC) or emtricitabine (FTC)[1], the other being either efavirenz (EFV) or nevirapine (NVP).

The improved first-line regimen therefore represents only a change in one drug – replacing d4T or AZT with TDF. But using such an improved first-line, based on TDF+ 3TC+NVP, would increase the annual cost of treating an adult for one year in a developing country from US$ 99 (with the triple FDC of 3TC /d4T/NVP) to US$ 426 in the best case[2].

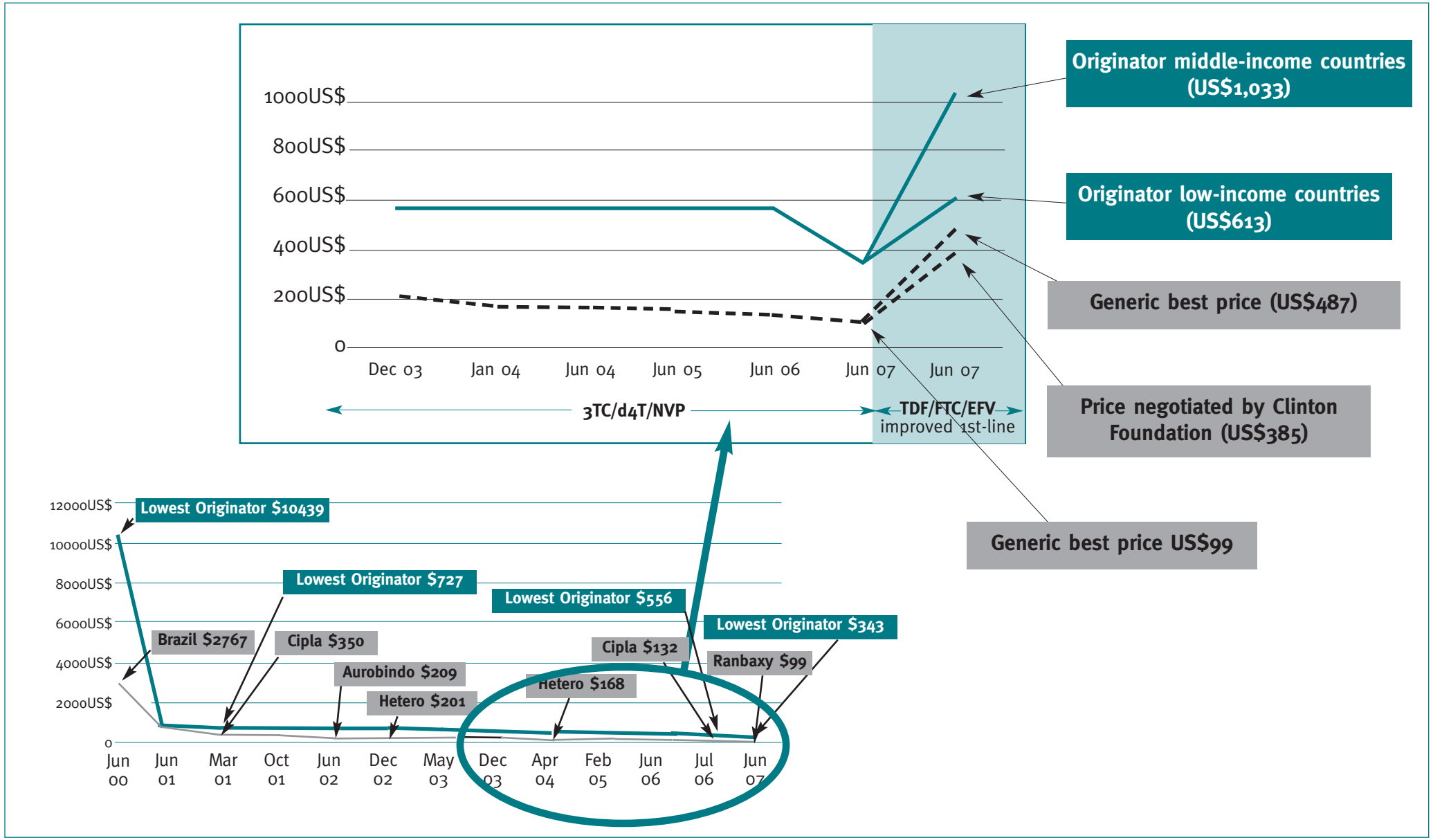
In 2007, a technical consultation was convened by WHO in order to propose simplified treatment protocols and develop standardised second-line regimens based on the options currently recommended in 2006 ART guidelines[3]. In the case of failure to the d4T- or AZT-based first-line of treatment, the preferred recommended second-line regimens are now TDF + 3TC + heat-stable protease inhibitor (lopinavir/ritonavir (LPV/r) or atazanavir/ritonavir (ATV/r)) or ABC + ddI + heat stable protease inhibitor (LPV/r or ATV/r). However, if TDF or ABC has been used in the first-line regimen, AZT + 3TC +

1WHO guidelines state "FTC is an equivalent alternative to 3TC as it is structurally related to 3TC, shares the same efficacy against HIV and Hepatitis B virus and has the same resistance profile" [2]

2 Clinton foundation has negotiated a price of US$ 339 ppy for the FDC TDF/3TC/EFV (Annex 10)

3 At time of publication, standardized regime is going to press

Graph 1: Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest prices per patient per year. Improved first line: tenofovir (TDF) + emtricitabine (FTC) + efavirenz (EFV)



heat-stable protease inhibitor (LPV/r or ATV/r) was considered as the most suitable 2nd line combination.

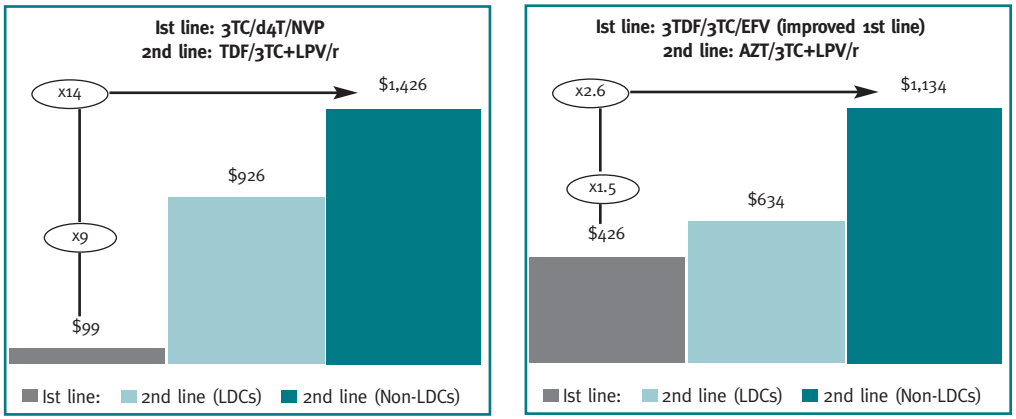
The establishment of simplified and standardised second-line guidelines represents a major breakthrough as it gives a clear message to manufacturers to focus on developing a relatively small range of products. This is expected to have an impact on the price. However, contrary to 3TC and AZT, boosted protease inhibitors are under patent in most countries and therefore priced significantly higher because of a lack of competition.

(1) ARVS AND COMPETITION: THE RETURN OF THE PRICE CRISIS?

Competition among multiple manufacturers is the main factor that has made prices of older ARVs come down. Treating an adult patient for one year with a triple antiretroviral first-line regimen may now be as low as US$ 99. Such reduced prices were a necessary prerequisite for the scaling up of AIDS treatment to the levels we see today. Graph 1 provides a good illustration of how prices charged by originator manufacturers fall as competitors enter the market.

However, the improved first-line and second-line regimens now recommended by WHO include newer drugs that are more expensive, as few generic competitors exist and demand is still low. There is therefore a serious risk that the price crisis seen five years ago, with life-saving ARVs priced out of reach of those in need, is set to return. A closer look at Graph 1 shows how the move towards improved first-line as recommended by WHO may have drastic consequences in terms of prices that must be addressed.

Graph 2: The chart shows how WHO recommendations impact price. The standardization of second-line contributes to the decrease in price as compared to last year; second-line in LDCs ranged from US$700 to 1,200 depending on the regimen used and over US$5,000 in non-LDCs. Another reason for the drop in prices of second-line is the reduction of the price of LPV/r (see chart 3). However, the use of an improved first-line significantly increases the price.



Patent barriers

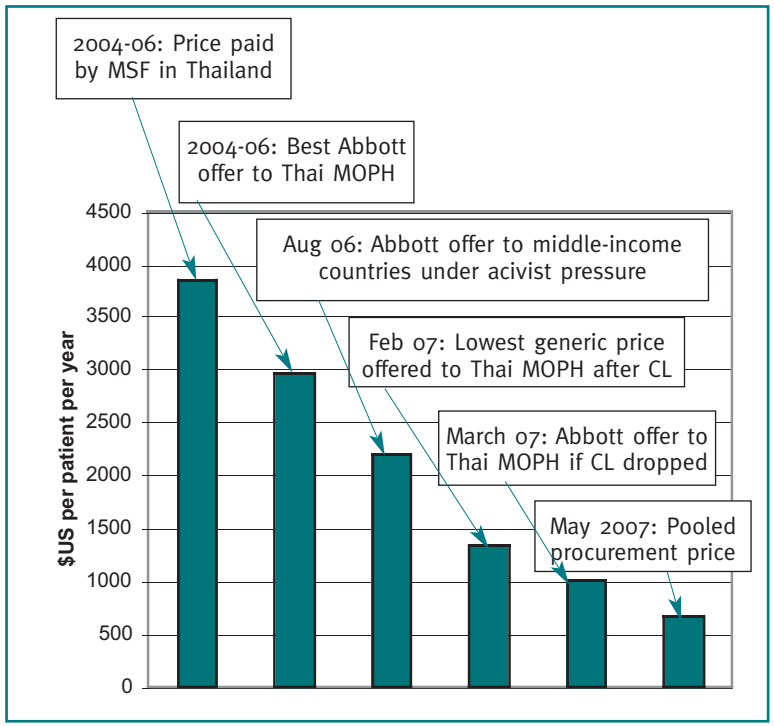
The main reason why competition was possible for older ARV products is that there were no patents in developing countries with pharmaceutical production capacity, such as Brazil, India or Thailand. This is no longer the case. Although Least Developed Countries (LDCs) are not obliged under the World Trade Organization (WTO) rules enshrined in the 2001 Doha Declaration to grant or enforce pharmaceutical product patents until at least 2016, other developing countries saw this transition period end in January 2005[5]. This includes countries with significant manufacturing capacity, such as India, a major source of WHO prequalified generic ARVs, which were required to introduce new pharmaceutical patent legislation in order to comply with WTO rules. It is crucial to note that changes in patent laws in countries with manufacturing capacity also affect other countries that depend on imports from these countries.

The new 2005 Indian Patents Act does not affect medicines that were invented before 1995. However, patent applications could be filed in India from 1995 onwards. The Indian patent offices have started to examine thousands of pending patent applications, and patents on key AIDS medicines may be granted.

If a patent were granted for a medicine for which generic versions were available before January 2005, it would not stop Indian generic manufacturers who already produce from continuing to market the medicine, provided they have made a "significant investment." Indeed, the 2005 Indian Patents Act stipulates an automatic licensing system, which allows for the continued production of the generic version upon payment of a "reasonable" royalty.

If a patent were granted for a medicine, but no generic version was marketed before 2005, only patent holders would have the right to produce this medicine, unless India, and other countries where the drug is under patent, make use of the flexibilities enshrined in the Doha

Graph 3: Prices for lopinavir/ritonavir offered to Thailand and other middle-income countries. MOPH, Ministry of Public Health; CL (compulsory license. Note: In May 2007, the Thai MOPH was still paying the price for LPV/r offered by Abbott in August 2006. Later offers by Abbott had conditions unacceptable to the Thai MOPH (no further price reduction and withdrawal of CL).Ford N, Wilson D, Costa Chaves G, Lotrowska M, Kijtiwatchakul K. Sustaining access to antiretroviral therapy in developing countries: lessons from Brazil and Thailand. AIDS 2007. 21;4:S21-S29.



Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health. They could, for example, authorise governmental use or issue compulsory licenses, thereby giving a third party the right to produce, market, export and import generic versions of the patented product. This is the case in Thailand, which issued compulsory licenses for three medicines, including the AIDS drugs EFV and LPV/r in November 2006 and January 2007, respectively, and Brazil, which did the same for EFV in May 2007. Under the pressure of these measures, companies typically reduce prices of their drugs (See graph 3).

Therefore, the situation for new drugs, such as second-line ARVs and improved first line is about to change radically. Faced with the emergence of resistance and the arrival of improved products on the market, the new WHO guidelines include newer ARVs for both first- and second-line treatment for which competition, if any, would be limited. In the absence of competition, the price of treatment based on these newer ARVs is currently extremely high (see graph 2). This is true for both those therapies recently introduced in wealthier countries and for any future drugs that are still in research and development – all of which are needed to tackle the epidemic in developing countries, too. Unless the price crisis can be resolved, however, it is unclear how these recent or newer drugs can be made available at sustainable and affordable prices in the developing world.

(2) THE LIMITATIONS OF COMPANY DIFFERENTIAL PRICING SCHEMES

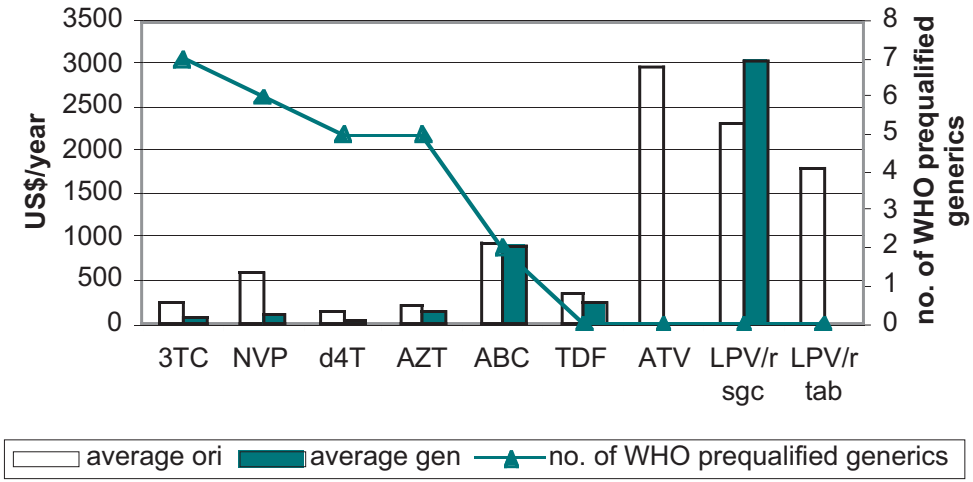
When originator companies apply discounted prices on ARVs, each has different eligibility criteria, which is a considerable source of confusion for purchasers.

Box 2: Limiting the scope of patentability

On a more positive note, the 2005 India Patents Act includes key provisions to ensure that patents are not used to artificially extend monopolies on medicines at the expense of the public. First, Section 3(d) of the law states that patents should not be granted on derivatives of known molecules, such as salts, polymorphs or combinations, unless efficacy is improved. Second, in order to make sure that patents are not unduly granted, third parties can seek to oppose a patent before it is granted, on the basis of such provisions[4]. However, the Swiss pharmaceutical company Novartis undertook a legal challenge to Section 3(d) of India's Patents Act in the High Court in Chennai after one of its patent applications was rejected on the basis of this provision. 400,000 people worldwide have urged Novartis to drop the case because of the devastating consequences Novartis's action could have on access to medicines across the developing world [45]. At the time of going to press, a ruling was pending.

Most originator companies offer their most discounted prices only to a certain group of countries, usually to Least Developed Countries (LDCs) and countries in sub-Saharan Africa. These prices are referred to in this document as 'first category prices'. Other companies do it differently: Merck extends first category prices to countries ranked as 'low' and 'medium' on the Human Development Index with HIV prevalence rates greater than 1%; GlaxoSmithKline offers differential prices for their products to all Global Fund grantees; and Gilead has established its own list of eligible countries using mixed criteria, including some middle-income countries. This means that if a country qualifies for the discounted prices offered by one company, it may not necessarily be included in the list of eligible countries of another company.

Certain manufacturers (such as Merck, Roche and Abbott) also offer second category prices for some middle-income countries. These are almost twice as high as the first category prices. Also, Bristol-Myers Squibb (BMS) places all southern African countries in its second category prices, including countries as poor as Mozambique and others with the highest prevalence rates in Africa.



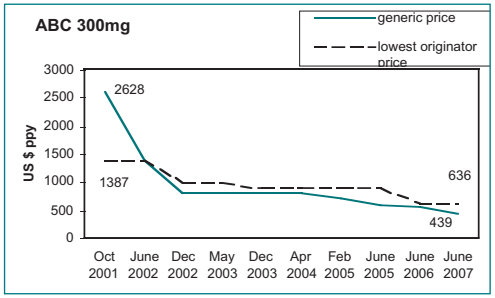
Graph 4: This chart shows real transaction prices as reported by the GPRM from January 2006 to June 2007. It shows that for more recent ARVs, competition is very limited. As a result, the lowest price offered by the originator remains high, as do generic prices. Moreover, there are still no generic versions prequalified by WHO for some of the newest ARVs, limiting demand. In the case of older ARVs for which generic competition is much less restricted, prices have dropped much lower and price offers by originators more or less match generic prices.(LPV/r sgc: old formulation that requires refrigeration. LPV/r tab: new tablet form that does not require refrigeration).

Companies' price offers can vary over time as a result of generic competition or public pressure. When a competitor enters the market, originator companies usually drop prices to levels slightly above the prices offered by generic manufacturers. The graph 4 illustrates this case:

Although some patients benefit from differential prices, prices for new drugs are still too high, mainly because there is no or not enough competition. In the absence of competition, prices of new drugs will never drop to the level of first-line drugs. Insufficient generic competition for newer drugs can be explained by a number of factors:

- The market for these products is still relatively small;
- Until now, the lack of a standardised second-line regimen means the market is fragmented, making it difficult for generic companies to make choices as to which products to prioritise;
- Patents are pending in India and in many cases have already been granted in other emerging economies with production capacity such as Brazil, Thailand, China. Even if some of these patents are not granted in India, generic manufacturers are hesitant to invest in the development of several of these new products.
- Even if several of these patents are not granted in India and clear recommendations are made for specific products, experience has shown that it takes at least two to three years for a generic manufacturer to produce and several more years for prices to come down.

A typical example is Abacavir, (see Graph 5) a drug that has a patent pending in India and for which generic productions began slowly. In the beginning, these generic versions were more expensive than the originator



Graph 5: Evolution of the lowest price quoted for eligible developing countries since 2001

product. Once multiple generic producers entered the market, prices began to fall. Today there are two WHO prequalified generics that are cheaper than the originator version. However prices today still remain too high.

In addition, products provided under these schemes frequently remain unavailable in countries because products are not registered or marketed. Registration of a medicine allows it to be marketed in a country after evaluation of the product dossier by the relevant National Drug Regulatory Authority (NDRA). In order to purchase or import a drug into a country, it must be registered there. Non-registered or non-marketed drugs become unattainable for all but those who can obtain a special authorisation for import from the Ministry of Health. In several countries, including Uganda, Guatemala, Honduras, Laos and Ethiopia, Médecins Sans Frontières' experience has shown that obtaining such authorisations to import non-registered drugs can be extremely complex and time-consuming.

The problem is compounded by the fact that National Drug Regulatory Authorities' procedures for registering the products are often slow, even if companies do everything necessary to get approval. Fast-track registration procedures should be put in place for new products of relevant interest for public health, based on WHO prequalification or on registration in highly-regulated countries.

The pace of registration of ARVs (including generic formulations as they become available), is of critical importance. It is strongly recommended for countries to accelerate registration of needed ARVs, applying fast-track procedures for WHO prequalified products, and thus avoiding unnecessary delays. Offers of differential prices, however loudly trumpeted, are meaningless if a manufacturer does not take the step of registering the product in countries where it is needed.

Differential pricing practices alone can therefore not be considered the solution for increasing worldwide access to essential drugs. Access to life-saving medicines for the poorest populations should not depend on the goodwill of private companies.

(3) PAEDIATRIC HIV/AIDS IS NEGLECTED BY MOST COMPANIES:

Until recently, most small children were treated with liquid formulations. These syrups or oral solutions are ill-adapted for use in remote settings, as they are complex to reconstitute and administer, can have an unpleasant taste, and are cumbersome to transport and store. They are also expensive. A major difference is also that adult treatment exists in fixed-dose combinations, whereas production of paediatric FDCs is just beginning. In the absence of adapted formulations, some children are still being treated by opening adult capsules or breaking adult tablets. However, this non-standard practice presents significant risks of under- or over-dosing children.

Developments in the course of the last year have brought some improvement. Several generic manufacturers have introduced paediatric FDCs for first-line therapy (such as the FDC d4T/3TC/NVP manufactured by both Cipla and Ranbaxy). The prices of these formulations are included in this report.

Not all problems have been resolved by this move, however. The dosages of these existing FDCs differ from each other, since guidance from WHO on recommended dosages came too late for manufacturers. The slowness of WHO in giving clear recommendations has created a problem that risks delaying the development of paediatric FDCs, and, ultimately, the administration of adequate treatment for children. Another major problem for which no solution is on the horizon is that there are no second-line formulations in the pipeline for children and more formulations are needed to complete the spectrum of regimens needed in an AIDS programme.

Donors and international organisations need to prioritise paediatric AIDS therapy, and work proactively to encourage much-needed R&D for this neglected group of patients. Manufacturers should be encouraged to produce adapted products, as recommended by WHO. The WHO prequalification project must prioritise these products as well, by outlining the requirements needed for the qualification of the new formulations. If necessary, support should be organised to help manufacturers speed up the completion of their product dossiers.

FINAL CONSIDERATIONS

According to UNAIDS and WHO, an estimated 250,000 to 350,000 deaths were averted in 2005 because of expanded access to AIDS treatment. This picture must be balanced with the 2.9 million people who died of AIDS-related illnesses in 2006. Of these, more than 380,000 were children[48]. Proactive efforts must be taken. These must not only focus on increasing the number of patients on treatment, but

also on providing them with the best possible treatment, which includes ensuring that those who begin treatment will receive second- and even third-line treatment at affordable prices, when they eventually need it.

95% of the people living with HIV live in developing countries. Research and development (R&D) for diagnostics, medicines, preventive therapies and vaccines, for children, mothers, and adults must be conducted to develop products that are affordable and suitable for use in remoter settings. The need for these specific medical tools is clear. This echoes the recent decision by the 2006 World Health Assembly to draw up a strategy and plan of action to secure an enhanced and sustainable basis for needs-driven, essential health R&D.

Patents should not be a barrier to accessing affordable medicines, increasing generic competition and assuring that the appropriate FDCs, including those for children, are developed. Flexibilities in both international and national patent rules exist to allow for this and there is no excuse for obstructing the use of these safeguards. However, despite the medical urgency, it seems that the political will to do so is often lacking.

METHODOLOGY

As with previous editions, MSF sent questionnaires to both originator and generic companies, asking them to provide the following information about ARV prices for developing countries: price per unit (or per daily dose), restrictions that apply to each of the prices quoted (eligibility criteria), and any additional specificity applicable to the quoted prices. The data were collected up to 15 June 2007.

All originator companies marketing ARVs were included in the survey. But the list of generic producers is by no means exhaustive[7]. Indeed, only those generic companies having at least one antiretroviral prequalified by WHO on the date the questionnaires were sent out are included in the survey.

Some important preliminary remarks on the data presented in this report:

- The information on prices given in this document only relates to ARVs. It does not include other costs linked to antiretroviral treatment, such as diagnosis, monitoring or treatment of opportunistic infections. For information on the prices of these products, please consult the most recent edition of "Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS," published yearly by UNICEF, UNAIDS, WHO, and MSF[8].

- The prices listed here are those quoted as sale prices by the manufacturers. The prices paid by the consumer might be higher because of add-ons (such as import taxes and distribution mark-ups), or may be lower if subsidised.

- Companies might use different trade terms (known as incoterms[9]). Prices quoted by all generic companies, in addition to Roche, Abbott and Gilead are "FCA" or "FOB," meaning that transport, international freight and insurance costs are not included. Remaining companies listed in this report do include freight and insurance in their prices. Prices have nevertheless not been adjusted. As recently demonstrated by the US General Accountability Office, these differences do not undermine their essential comparability [10].

- Originator companies have different eligibility criteria for countries and entities, as explained in the introductory chapter. The different categories of prices are detailed in the product cards. Please, refer to table 2 for explanations on different eligibility criteria quoted by companies.

- Generic companies normally do not impose restrictions on prices, except for Aspen and Cipla. But occasionally generic companies may negotiate prices different from those quoted here.

- The Clinton HIV/AIDS Initiative,[11] for example, negotiates prices for ARVs and diagnostic tests with generic companies on behalf of national AIDS programmes included in their consortium. To date, the Clinton Foundation has reached agreements with six ARV manufacturers to lower the prices of 20 ARV formulations, both paediatric and adult (see annex 10).

- Information on patents is only indicative and should be checked with national authorities. It should in no way form the basis of a procurement decision.

- Information on the WHO pre-qualification status must always be checked in the WHO website (http://mednet3.who.int/prequal/).

How to read the product cards?

General information:
For each of the ARVs, general information on the history of the product and relevant WHO guidance is provided [2,14].

Table 1: Prices quoted by companies for eligible developing countries
All prices are quoted in US$. Conversions have been made on the day the price information was received using the currency converter site: www.oanda.com. Prices are rounded up to the third decimal for unit price and to the nearest whole number for yearly price per patient.

The annual cost of treatment per patient (ppy) has been calculated according to WHO dosing schedules, multiplying the unit price (one tablet or capsule) by the number of units required for the daily dose and by 365. The price of the smallest unit is included in brackets.

For paediatric treatments, prices are calculated for a 10 kg child using recommended dosing based on weight bands as it appears in the WHO treatment guidelines[2]. This is an estimate, as the weight of a child increases during any given year. When it was not possible to calculate the dose for a 10 kg child, only the unit price is indicated.

To know whether a country is eligible for a given price of a given company, please refer to table 2 and the list of countries for each category given in the annexes.

Products included in the most recent edition of the WHO prequalification list
(Revised 55th edition, published 22th June 2007) appear in **bold** in the tables. Readers and purchasers wishing to obtain more information about the quality of ARVs are encouraged to consult the WHO prequalification project website (http://mednet3.who.int/prequal/) **as this list is updated very frequently**. Initiated by WHO in 2001, and developed in collaboration with other United Nations agencies, this project evaluates pharmaceutical manufacturers and products according to WHO recommended standards of quality and Good Manufacturing Practices.

Chart 1: Evolution of the lowest price quoted by companies for eligible countries since 2001
This chart shows the price evolution over time, for both originator and generic products, as quoted to MSF surveys since 2001. When they exist, only generic products that are WHO prequalified are considered for the graph. If no generic is WHO prequalified yet, the lowest possible price is taken into account.

Spotlight on access issues
In this new edition, we have tried to summarise the most salient issues related to access to each product, with the aim of facilitating informed decisions at country level, taking into account the problems and obstacles that may be encountered when trying to gain access to a product at the best price.

Note: "Untangling the Web of Price Reductions" is a reliable pricing guide and cannot be regarded as a company price list. It is crucial that any purchaser verify prices and availability as well as quality status directly with the supplier before procurement. Médecins Sans Frontières has made every effort to ensure the accuracy of prices and other information presented in this report but MSF makes no representations or warranties, either expressed or implied, as to their accuracy, completeness or fitness for a particular purpose. Inclusion of a product in this document does not indicate MSF purchases or uses the product.

ABACAVIR (ABC)

General information

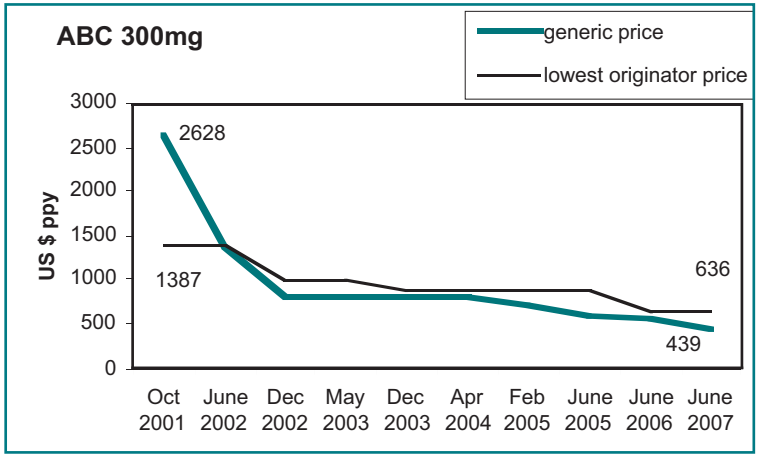
- Therapeutic class: HIV-1 and HIV-2 nucleoside reverse transcriptase inhibitor (NRTI)
- Indicated for first- and second-line, for adults, adolescents and children (WHO 2006 guidelines[2])
- Originator company, and product brand name: GlaxoSmithKline (GSK), Ziagen
- First approval by US Food and Drug Administration (FDA): 17th December 1998
- Included in the WHO Model List of Essential Medicines (EML)[14]
- World sales of originator product for 2006 US$ 230 million,[15] 2005 US$ 268 million,[15] and 2004 US$ 290 million.[16]

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	GSK	Aurobindo	Cipla (CF)	Hetero	Matrix (CF)	Ranbaxy
Eligibility restrictions		See table 2	none	none	none	none	none
ABC 300 mg tablets	2	**636 (0.871)**	**429 (0.587)**	**456 (0.625)**	548 (0.750)	439 (0.602)	473 (0.648)
ABC 20 mg/ml oral solution	10 ml	**380 (0.104/ml)**	**310 (0.085/ml)**	420 (0.115/ml)			

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.



Evolution of the lowest price quoted for eligible developing countries since 2001

As of June 2007, there are four WHO pre-qualified generic sources of ABC and the lowest product is considered here

Since 2001 the Originator price has reduced by 53% while the generic price has reduced by 83%

Spotlight on access issues:

There is a need for greater competition between manufacturers to reduce prices further. At US$ 636 ppy, the current lowest price for the originator product (for ABC alone) is over six times the price of the triple FDC used in most first-line regimens today (3TC/d4T/NVP).

In addition, because of GSK's eligibility restrictions, potential non-African buyers of ABC that are not funded by the Global Fund have no access to the lowest prices for the GSK product.

In 2006, 24 countries reported in the WHO GPRM purchasing ABC 300 mg tablets. [13] Over 70% of these countries reported paying an average unit price higher than GSKs lowest price offer - El Salvador for example paid over US$ 2,227 ppy, more than three times GSK's lowest price offer.

Although the ABC molecule was developed in the 1980s, GSK applied for a patent in 1997 on abacavir sulphate. This may hamper generic competition. If the Indian patent office grants the patent, Indian manufacturers who did not have their product marketed before January 2005 may have to withdraw their products from the market. Indian NGOs and patient groups have filed an opposition to the patent application for ABC sulphate. [46]

Although ABC was included as part of first-line NRTI backbone in the most recent WHO recommendations for paediatric treatment, no company has yet developed a child-friendly version. GSK has recently scored the ABC tablet to increase accuracy of halving the tablets, but more work still needs to be done for children.

ATAZANAVIR (ATV)

General information

- Therapeutic class: HIV-1 and HIV-2 protease inhibitor (PI)
- Indicated for second-line, for adults and adolescents (WHO 2006 guidelines[2])
- Originator company, and product brand name: Bristol-Myers Squibb (BMS), Reyataz
- First approval by US Food and Drug Administration (FDA): 20th June 2003
- Not included in the WHO Model List of Essential Medicines (EML)[14]
- World sales of originator product for 2006 US$ 931 million,[17] 2005 US$ 696 million,[17] 2004 US$ 369 million,[18] 2003 US$ 81 million.[18]

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	BMS	
		Category 1	Category 2
Eligibility restrictions		See table 2	
ATV 150 mg caps	2*	353 (0.484)	425 (0.582)
ATV 200 mg caps	--	(0.602)	(0.732)

* The dose of ATV must be boosted with RTV 100 mg once a day[2]

Spotlight on access issues:

ATV is one of the protease inhibitors recommended by WHO for second-line treatment, and is the most patient-friendly PI as it requires the patient to take only two 150 mg pills once a day.

Until recently, no differential price existed and the price, at more than US$ 5,000 per adult patient per year, was prohibitive for developing countries.[40] The required addition of ritonavir (RTV) as a booster must also be considered in the final cost of using ATV.

In 1997-98, BMS applied for patents on ATV in many countries, including in India. Indian NGOs and patient groups have filed an opposition to the patent application for ATV.[46] Unrestrained generic competition from Indian companies will only be possible if the patent is rejected by the Indian patent office or if the Indian government is willing to grant compulsory licenses to Indian generic manufacturers.

BMS has granted a voluntary license to two generic manufacturers (Emcure and Aspen) to manufacture and sell ATV. Under the conditions of the license, sales of these products are restricted to Sub-Saharan Africa. As yet, no ATV products are available from these companies.[41]

ATV is not yet licensed for children, so there are no paediatric formulations available.

DIDANOSINE (ddI)

General information

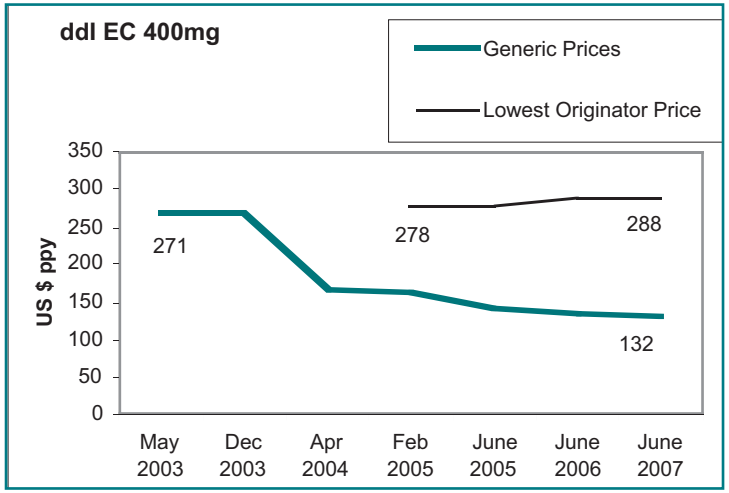
- Therapeutic class: HIV-1 and HIV-2 nucleoside reverse transcriptase inhibitor (NRTI)
- Indicated for second-line, for adults, adolescents and children (WHO 2006 guidelines[2])
- Originator company, and product brand name: Bristol-Myers Squibb (BMS), Videx, Videx EC
- First approval by US Food and Drug Administration (FDA): October 1991 for chewable tablets; October 2000 for enteric-coated capsules.
- Included in the WHO Model List of Essential Medicines (EML)[14]
- World sales of originator product: 2005, US$ 174 million. 2004, $274 million. 2003, US$ 354 million[21]
- The National Institutes of Health (NIH), a US government research institute, developed ddI. The NIH licensed the drug to Bristol-Myers Squibb, in exchange for a 5 to 6 % royalty on sales[22]. NIH basic patents on ddI are expired in US, but BMS holds patents on improved formulations, which run until 2012 and 2018.

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	BMS		Aurobindo	Cipla (CF)	Ranbaxy (CF)
		Category 1	Category 2			
Eligibility restrictions		See table 2		None	None	None
ddI 25 mg tablets	5	**212 (0.116)**	**416 (0.228)**		(0.063)	
ddI 50 mg tablets	xx	**(0.158)**	**(0.228)**		(0.079)	
ddI 100 mg tablets	4	**310 (0.212)**	**352 (0.241)**	**234 (0.160)**	171 (0.117)	321 (0.220)
ddI 150 mg tablets	xx	**(0.308)**	**(0.334)**	**(0.235)**	(0.167)	
ddI 200 mg tablets	xx	**(0.425)**		**(0.315)**	(0.232)	(0.210)
ddI 250 mg enteric coated capsules	1	**223 (0.611)**	**239 (0.655)**	127 (0.350)	103 (0.283)	156 (0.427)
ddI 400 mg enteric-coated capsules	1	**288 (0.789)**	**309 (0.846)**	208 (0.570)	132 (0.363)	248 (0.679)
ddI 2 g powder for reconstitution (10 mg/ml)	12ml	**276 (12.59/2g)**	**293 (13.496/2g)**	**47 (2.160/2g)**		

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.



Evolution of the lowest price quoted for developing countries since 2001

As of June 2007, there are no WHO pre-qualified generic sources of ddI 400 mg EC. The lowest available generic price is therefore given here. In the absence of strong pre-qualified competition, originator prices have not changed in the last few years.

Spotlight on access issues:

The use of the enteric-coated (EC) ddI is increasing, as it is one of the drugs included in WHO treatment guidelines for second-line treatment. [2] There is an urgent need to have generic versions prequalified by WHO, and to improve access to these products as scaling up occurs.

With only 66 countries, the list of countries eligible for Bristol-Myers Squibb's differential prices is too limited - it also excludes middle-income countries, for which BMS has no pricing policy. Crucially, the product is not always available in the countries that are defined as eligible.

In 2006, 18 countries reported in WHO GPRM purchasing ddI 400 mg enteric-coated capsules [13] Almost half reported an average unit price greater than the BMS lowest price offer, with Bolivia and El Salvador reporting prices over six times this value.

In addition, ddI EC 125 mg, which is the best-adapted option for children, has no differential price yet. The price at more than US$ 1000 ppy is prohibitive for the developing world. [40] There are currently no generic companies manufacturing this product. For children, the only options are therefore buffered tablets that come with a high pill burden, or ddI powder for reconstitution that requires multiple dilutions to obtain the final concentration, must be refrigerated after reconstitution and must be discarded after 30 days.

EFAVIRENZ (EFV)

General information

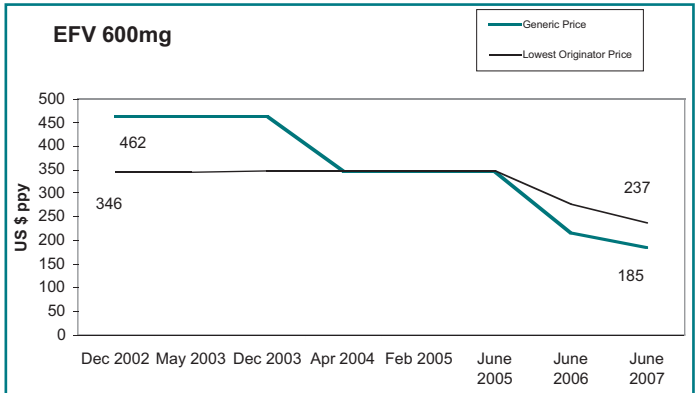
- Therapeutic class: HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI)
- Indicated for first- and second-line, for adults, adolescents and children (WHO 2006 guidelines[2])
- Originator companies, and product brand names: Bristol-Myers Squibb (BMS), Sustiva, or Merck, Stocrin
- First approval by US Food and Drug Administration (FDA): 17th September 1998
- Included in the WHO Model List of Essential Medicines (EML)[14]
- World sales of originator product: 2006 US$ 791 million[17], 2005 US$ 680 million, 2004 US$ 621 million and 2003 US$ 544 million[21]
- Efavirenz was developed by Dupont Pharma and is now marketed by BMS. Merck has the marketing license in several countries.

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	Merck		Aurobindo	Cipla (CF)	Hetero	Matrix (CF)	Ranbaxy (CF)	Strides (CF)
		Category 1	Category 2						
Eligibility restrictions		See table 2		None	None	None	None	None	None
EFV 50 mg capsule	--	**(0.120)**	**(0.210)**	**(0.100)**					
EFV 100 mg capsule	--			**(0.185)**					
EFV 200 mg capsule	3	**394 (0.360)**	**821 (0.750)**	**233 (0.267)**	226 (0.206)	219 (0.200)		**210 (0.192)**	219 (0.200)
EFV 600 mg tablet	1	**237 (0.650)**	**657 (1.800)**	**201 (0.550)**	**218 (0.597)**	201 (0.550)	187 (0.512)	**185 (0.506)**	**219 (0.600)**
EFV 30 mg/ml suspension	--	**(0.094/ml)**	**(0.151/ml)**	(0.069/ml)					

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.



Evolution of the lowest price quoted for eligible developing countries since 2001

As of June 2007, there were four WHO prequalified generic sources of EFV 600 mg. The lowest WHO prequalified generic product is given here.

Spotlight on access issues:

EFV is a key drug for first-line treatment. Although EFV has been marketed for a considerable period already, its price is still very high, with the single originator product (EFV alone) priced at more than twice the price of the most widely used triple FDC (3TC/d4T/NVP).

All generic products are almost three times cheaper than Merck's second category price. Some countries are still purchasing the originator product, however. In 2005, according to GPRM, some countries reported purchasing EFV at more than US$ 800 ppy. In 2006, the highest transaction reported was El Salvador at US$ 706 ppy[13]

In Brazil, where this product is under patent, EFV alone took up 14% of the National Aids Budget in 2005. [23] Today, 38% of patients on antiretroviral therapy in Brazil take this drug. Despite these growing patient numbers and numerous negotiations with Merck, the price of EFV had remained at US$ 576 ppy since 2003. In early 2007, Brazil therefore issued a compulsory license to import generic EFV from India - the country has now received its first delivery of a WHO prequalified generic, at a cost of US$ 165 ppy. This represents a reduction in the forecasted budget to 2012 of over US$ 226 million.[49]

Despite having received FDA approval in 1998, EFV has still not been studied in children under three years of age.

EMTRICITABINE (FTC)

General information

- Therapeutic class: HIV-1 nucleoside reverse transcriptase inhibitor (NRTI)
- Indicated for first-line, for adults (WHO 2006 guidelines[2])
- Originator company and product brand name: Gilead, Emtriva
- First approval by US Food and Drug Administration (FDA): July 2003
- Included in the WHO Model List of Essential Medicines (EML)[14]
- World sales of originator product: 2006 US$ 36.3 million, 2005 US$ 47.4 million, 2004 US$ 57.6 million[24].
- Emtricitabine was developed by Emory University in 1996. The University agreed to waive their right to a royalty on sales within the Gilead Access Program[25].
- Patents on the basic molecule are due to expire in 2010-2011.

Spotlight on access issues:

FTC is neither registered nor marketed in developing countries, but is available co-formulated with TDF.

According to WHO treatment guidelines, 'FTC is an equivalent alternative to 3TC as it is structurally related to 3TC, shares the same efficacy against HIV and hepatitis B virus and has the same resistance profile.' [2]

When making the choice between FTC and its closest equivalent 3TC, national AIDS programmes and others should therefore take into account that there are potential intellectual property issues that could affect this product in some countries - while its older therapeutic equivalent, 3TC, could be free of such restrictions.

INDINAVIR (IDV)

General information

- Therapeutic class: HIV-1 and HIV-2 protease inhibitor (PI)
- Indicated for second-line, for adults (WHO 2006 guidelines)[2]
- Originator company and product brand name: Merck, Crixivan
- First approval by US Food and Drug Administration (FDA): March 1996
- Not included in the WHO Model List of Essential Medicines (EML)
- Merck applied for patents in 1992 for the use in the treatment of AIDS.

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	Merck		Aurobindo	Cipla	Ranbaxy
		Category 1	Category 2			
Eligibility restrictions				None	None	None
400 mg caps	4*	**400 (0.274)**	**686 (0.470)**	432 (0.296)	321 (0.220)	639 (0.292)

*The dose of IDV must be boosted with RTV 100 mg twice a day[2]

Note from Merck: Crixivan is indicated for use at 800 mg every eight hours. Data from published studies and treatment guidelines suggest that Crixivan can also be used in combination with ritonavir in the following dosing regimens: 800/100 mg, 800/200 mg or 400/100 mg, both administered orally twice daily.

Spotlight on access issues:

In 2006, 34 countries reported transactions in WHO GPRM, with nine reporting average purchases over US $ 700 ppy.[13]

LAMIVUDINE (3TC)

General information

- Therapeutic class: HIV-1 and HIV-2 nucleoside reverse transcriptase inhibitor (NRTI)
- Indicated for first- and second-line for adults and adolescents, and for first-line only for children (WHO 2006 guidelines[2])
- Originator company, and product brand name: GlaxoSmithKline (GSK), Epivir
- First approval by US Food and Drug Administration (FDA): November 1995
- Included in the WHO Model List of Essential Medicines (EML)[17]
- World sales of originator product: 2006 US$ 398 million, 2005 US$ 398 million[26], 2004 US$ 549 million[15].
- Patent status: the patent holder is IAF Biochem International SA (Canada). GSK pays a 14 % royalty to the Canadian firm[30].

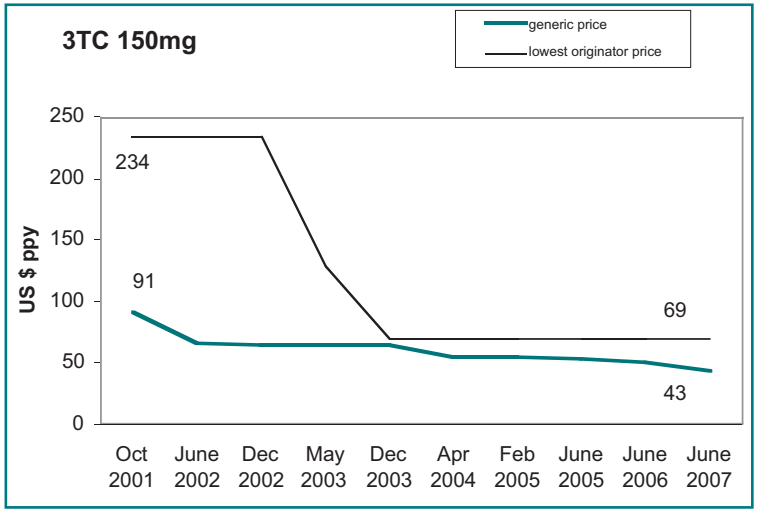
Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	GSK	Aspen	Aurobindo	Cipla (CF)	Hetero	Matrix (CF)	Ranbaxy	Strides
Eligibility restrictions		See table 2	See table 2	None	None	None	None	None	None
3TC 150 mg tablet	2	**69 (0.095)**	**xx**	**47 (0.064)**	**51 (0.070)**	53 (0.073)	**49 (0.067)**	**43 (0.059)**	**46 (0.063)**
3TC 300 mg tablet	1			**56 (0.155)**	55 (0.150)			66 (0.180)	
3TC 10 mg/ml oral solution	10 ml	**102 (0.028/ml)**	xx	**44 (0.012/ml)**	**66 (0.018/ml)**				
3TC 25 mg granules	--								(2.20)
3TC 50 mg granules	--								(2.70)

XX For prices on these products please contact Aspen directly

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.



Evolution of the lowest price quoted for eligible developing countries
As of June 2007, there are seven WHO prequalified generic sources of 3TC 150 mg. The lowest priced WHO prequalified product is given here.

Spotlight on access issues:

Lamivudine is a product in high demand, whose price has substantially decreased over recent years. As of June 2007, there are seven generic versions prequalified by WHO.

In 2006, most countries reported to the WHO GPRM having paid the lowest price available, whether for the generic or the originator product. Some transactions, however, were reported at double the price or more – El Salvador for example paid US$ 180 ppy for GSK´s product.[13]

In China, 3TC is still unaffordable – at more than US$ 1,600 per patient per year - due to GSK's monopoly rights on the drug.

No company produces a child-friendly low dosage pill, and adapted dosages, for example 75 mg tablets, are urgently required. It was only in 2007 that GSK scored their adult tablet to facilitate the use in children. Some fixed-dose combination formulations for children containing 3TC have been developed by generic companies and should reach the market very soon.

NELFINAVIR (NFV)

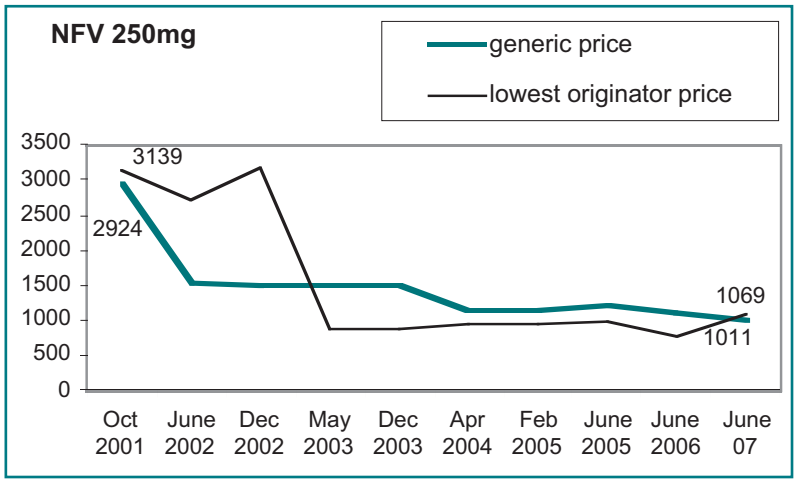
General information

- Therapeutic class: HIV-1 and HIV-2 protease inhibitor (PI)
- Indicated only for second-line in adults, adolescents and children (WHO 2006 guidelines)[2]
- Originator company, and product brand name: Roche, Viracept
- First approval by US Food and Drug Administration (FDA): 14th March 1997
- Included in the WHO Model List of Essential Medicines (EML)[14]
- World sales of originator product: US$ 259 million in 2004[16]
- Agouron Pharmaceuticals Inc. developed nelfinavir, in collaboration with the pharmaceutical division of Japan Tobacco Inc. In Europe and a few other countries outside the United States, Agouron/Pfizer has licensed Roche to market nelfinavir[28] Patents on nelfinavir are due to expire in 2014.

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	Roche		Aurobindo	Cipla	Hetero
		1st category	2nd category			
Eligibility restrictions		See table 2		None	None	None
NFV 250 mg tablets	10	**1069 (0.293)**	**2201 (0.470)**	1379 (0.420)	1486 (0.407)	1011 (0.277)
NFV 50 mg/g oral powder	24 g	**1927 (0.220/g)**	**2234 (0.255/g)**			



Evolution of the lowest price quoted for eligible developing countries
As of June 2007, there was no WHO prequalified generic source of NFV. The lowest available generic price is therefore given here.

Spotlight on access issues:

NFV is the only PI that does not require boosting with ritonavir (RTV). Although this makes it a less potent option when compared with a boosted PI,[29] the fact that it can be used without RTV means that using a NFV based regimen also comes without the refrigeration requirement that is a major limitation associated with RTV.

This therefore makes the drug an attractive option for some developing countries. In 2006, 23 countries reported transactions in WHO GPRM.[13]

Nevertheless, a large pill burden and the high price of NFV make it a less preferable option. In addition, the use of NFV in children is extremely complex, due to the significant amounts of powder that have to be taken on a daily basis (12 g of powder twice a day for a 10 kg child). Not only is this formulation ill-adapted, but its price remains prohibitive.

In June 2007, Roche recalled all batches of NFV due to the presence of a contaminate. As a result, WHO has temporally suspended the product from the prequalification list.[42]

There is no generic production of adapted paediatric formulations.

NEVIRAPINE (NVP)

General information

- Therapeutic class: HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI)
- Indicated for first- and second-line, for adults, adolescents and children (WHO 2006 guidelines)[2]
- Originator company and product brand name: Boehringer-Ingelheim (BI) Viramune
- First approval by US Food and Drug Administration (FDA): 21st June 1996
- Included in the WHO Model List of Essential Medicines (EML)[14]
- World sales of originator product: 2006 US$ 370 million,[30] 2005 US$ 386 million,[31] 2004 US $ 378 million[32]
- Patents on the nevirapine molecule are due to expire in 2010 in most countries, but BI also holds patents on the syrup formulation of nevirapine, which could run until 2018.

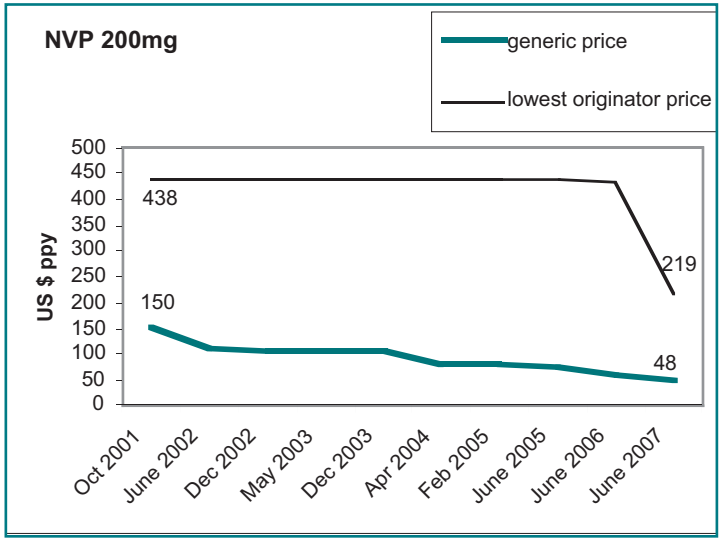
Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	BI		Aspen	Aurobindo	Cipla (CF)	Hetero	Ranbaxy	Strides	Matrix (CF)
Eligibility restrictions		Category 1	Category 2		None	None	None	None	None	None
NVP 200 mg tablets	2	**219 (0.300)**	**438 (0.600)**	**XX**	**51 (0.070)**	**55 (0.075)**	**48 (0.660)**	**52 (0.071)**	**50 (0.070)**	54 (0.074)
NVP 10 mg / ml	20 ml	**380 (0.052/ml)**	**533 (0.073/ml)**		**95 (0.013/ml)**	131 (0.018/ml)				
NVP granules 25 mg	--								(2.50)	
NVP granules 50 mg	--								(3.00)	

XX For prices on this product please contact Aspen directly

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.



Evolution of the lowest price quoted for eligible developing countries since 2001

As of June 2007, there are eight WHO prequalified generic sources of NVP. The lowest available WHO prequalified generic price is therefore given here.

Spotlight on access issues:

Until May 2007, the price of Boehringer-Ingelheim's 200 mg NVP tablets had remained unchanged since the first publication of this report in 2001. On 15th May 2007, BI announced a price reduction of 50%. However, this is arguably too little too late, as even after the price reduction, the five generic versions prequalified by WHO are still more than four times cheaper than BI's NVP.

Despite these prequalified generics, the BI product is still being bought in many developing countries. In 2006, 25% of countries reporting transactions in WHO GPRM were still purchasing the BI product. This included countries such as Tanzania, Nigeria, Uganda and Kenya.[13]

Crucially, BI did not grant a price reduction on the one formulation where a price drop would have had considerable impact: for the NVP 10 mg/ml suspension used for children.

BI applied for a patent on the syrup formulation of NVP, which if granted, would hamper future generic competition. Patient groups opposed the granting of this patent before the Indian patent office on 9th May 2006. The final decision was still pending at the time of publication

Some fixed-dose combination tablet formulations containing NVP for children have been developed by generic companies and will be soon on the market.

RITONAVIR (r or RTV)

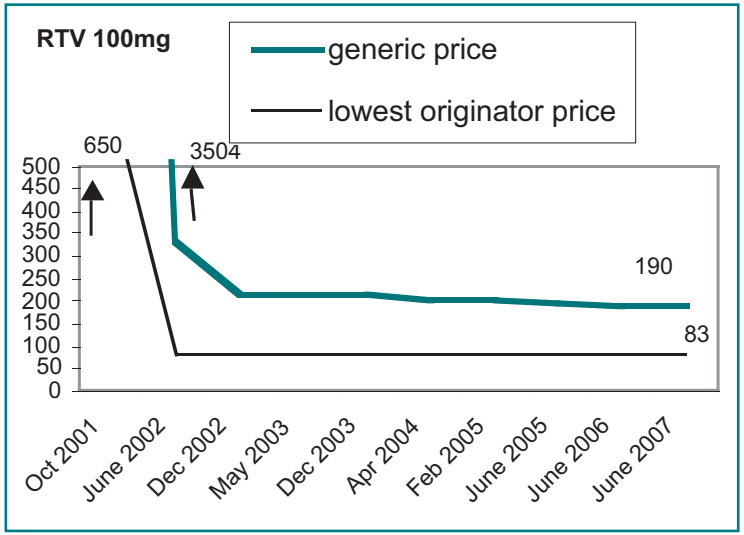
General information

- Therapeutic class: HIV-1 and HIV-2 protease inhibitor (PI)
- Indicated for second-line as a booster, for adults, adolescents and children (WHO 2006 guidelines)[2]
- Originator company, and product brand name: Abbott Laboratories, Norvir
- First approval by US Food and Drug Administration (FDA): March 1996 for the oral solution and 29th June 1999 for capsules
- Included in the WHO Model List of Essential Medicines (EML)[14]
- World sales of originator product: 2004 US$ 194 million, 2003 US$ 93 million, 2002 US$ 122 million.[36]

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose used as booster	Abbott	Aurobindo	Cipla	Hetero	Strides
Eligibility restrictions		See table 2	None	None	None	None
100 mg capsule	2	**83 (0.114)**	336 (0.460)	313 (0.429)	190 (0.260)	365 (0.500)
80 mg/ml oral solution	--	**(0.093/ml)**				



Evolution of the lowest price quoted for eligible developing countries since 2001

As of June 2007, there was no WHO prequalified generic source of ritonavir. The lowest available generic price is therefore given here.

The price of ritonavir, both originator and generic, fell dramatically in 2001.

Spotlight on access issues:

RTV is of crucial importance for scaling up, as all protease inhibitors with the exception of NFV, must be boosted with this drug. The importance of the drug is all the clearer at the time of going to press, following the recall of all batches of NFV from Roche in June 2007.[42]

Abbott has developed a heat-stable fixed-dose combination of RTV combined with LPV. Crucially though, the heat-stable version of ritonavir alone is not yet available. Manufacturing this formulation is urgently needed, as it would free other PIs such as ATZ, of refrigeration constraints when they need to be combined with RTV. Generic firms are working on the development of RTV heat-stable tablets.

Abbott has applied for various patents on improved formulations on RTV, which renders the extent of future generic competition unclear. Oppositions have been filed to these derivative patents in India. The outcome of these oppositions in India will have consequences on the extent of generic competition and any price decrease that can be expected from the arrival of competition.

There is a need for WHO prequalification of generic versions of RTV, in particular for middle-income countries which do not have access to Abbott's lowest price.

SAQUINAVIR (SQV)

General information

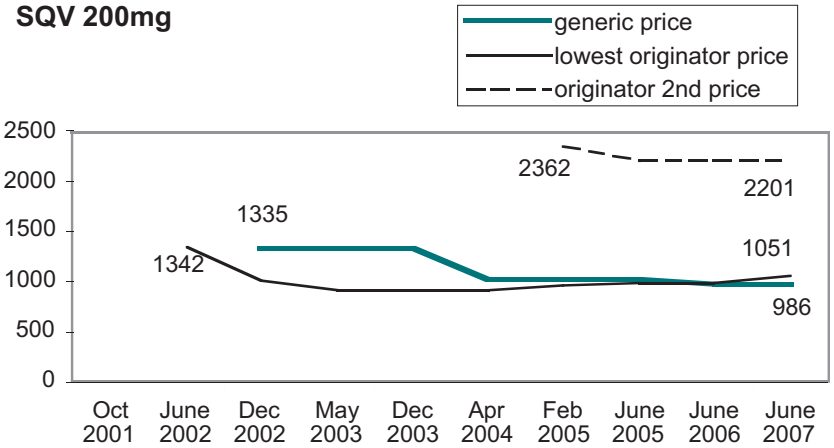
- Therapeutic class: HIV-1 and HIV-2 protease inhibitor (PI)
- Indicated for second-line, to be used boosted by ritonavir, for adults, adolescents and children. (WHO 2006 guidelines)[2]
- Originator company, and product brand name: Roche, Invirase
- First approval by US Food and Drug Administration (FDA): December 1995
- Included in the WHO Model List of Essential Medicines (EML).[14]

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	Roche		Cipla	Hetero
		1st category	2nd category		
Eligibility restrictions		See table 2		None	None
SQV 200 mg hard capsules	10*	**1051 (0.288)**	**2201 (0.603)**	1825 (0.500)	986 (0.270)
SQV 500 mg tablets	4*	**968 (0.663)**	**2205 (1.51)**		

* The dose of SQV must be boosted with RTV 100 mg twice a day [2]



Evolution of the lowest price quoted for eligible developing countries since 2001

As of June 2007, there was no WHO prequalified generic source of saquinavir.

The lowest available generic price is therefore given here.

Spotlight on access issues:

SQV capsules are very difficult to administer, as they need to be boosted with ritonavir and come with a high pill burden (ten capsules a day). However, since 2004, Roche has been marketing in the USA a new 500 mg tablet version of SQV. This formulation reduces the pill burden from ten to four tablets, but is not widely marketed in developing countries. Nevertheless, the product is still recommended by WHO.

Seven countries reported transactions in 2006 in WHO GPRM, all for the originator product. However, only Bulgaria reported a transaction for the newer 500 mg tablet - at a price of US$ 4,000 ppy. [13]

The high price of SQV and the need for boosting with RTV continue to be a barrier. Competition between producers remains severely limited, as its use is fairly limited.

STAVUDINE (d4T)

General information

- Therapeutic class: HIV-1 and HIV-2 nucleoside reverse transcriptase inhibitor (NRTI)
- Indicated for first-line, for adults, adolescents and children (WHO 2006 guidelines)[2]
- In 2006, WHO updated its treatment guidelines to recommend a reduction in the dose of d4T from 40 mg to 30 mg, for all weight categories of patients[43]
- Originator company, and product brand name: Bristol-Myers Squibb (BMS), Zerit
- First approval by US Food and Drug Administration (FDA): December 1994
- Included in the WHO Model List of Essential Medicines (EML)[14]
- World sales of originator product: 2006 US$ 155 million,[17] 2005 US$ 216 million, 2004 US$ 272 million and 2003 US$ 354 million[21]
- Stavudine was the result of US public sector research. It was originally synthesised by the Michigan Cancer Foundation in 1966 on a grant from the National Cancer Institute. Researchers from Yale University first discovered its activity against HIV/AIDS and filed the patent for this specific indication in the USA in December 1986. Yale licensed its marketing and distribution rights to BMS in 1988.[22]

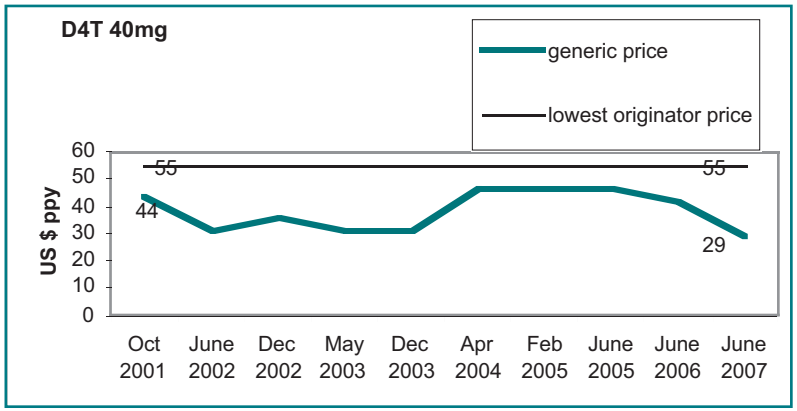
Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	BMS		Aspen (CF)	Aurobindo	Cipla (CF)	Hetero (CF)	Matrix (CF)	Ranbaxy (CF)	Strides (CF)
		1st category	2nd category							
Eligibility restrictions		See table 2		See table 2	None	None	None	None	None	None
15 mg capsule	--	**(0.082)**	**(0.093)**		**(0.032)**	(0.048)		(0.032)		
20 mg capsule	--	**(0.094)**	**(0.089)**	**xx**	**(0.034)**	(0.050)		(0.034)		
30 mg capsule	2	**48 (0.066)**	**65 (0.089)**	**xx**	**28 (0.039)**	39 (0.053)	20(0.027)	**28 (0.039)**	**28 (0.039)**	**31 (0.042)**
40 mg capsule	2	**55 (0.075)**	**65 (0.089)**	**xx**	**29 (0.040)**	42 (0.057)	24 (0.033)	**29 (0.040)**	**34 (0.047)**	**33 (0.045)**
1 mg / ml powder for syrup	20 ml	**51 (0.007/ml)**	**58 (0.008/ml)**		**73 (0.010/ml)**	146 (0.020/ml)				
5 mg granules										(2.00)
10 mg granules										(2.50)

XX For prices on these products please contact Aspen directly

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.



Evolution of the lowest price quoted for eligible developing countries since 2001: As of June 2007, there are four WHO prequalified generic sources of d4T. The lowest available WHO prequalified generic price is therefore given here.

Spotlight on access issues:

Bristol-Myers Squibb has no policy for middle-income countries, and prices are negotiated on a case-by-case basis. The new criteria chosen by BMS to establish eligibility for discounted prices aims to protect certain markets, and imposes a premium (over 25% more expensive) that applies even to countries as poor as Mozambique.

Despite the existence of many WHO prequalified generics, in 2006 some countries recorded transactions of the BMS product in WHO GPRM at elevated prices. Morocco, Thailand, Georgia and Bulgaria for example purchased the originator drug at US$ 284, US$ 810, US$ 1,314 and US$ 2,965 ppy respectively. [13]

The price of BMS's paediatric formulation has decreased significantly since 2005. This product has limitations however, as it is supplied as a powder, requiring reconstitution and once reconstituted must be refrigerated.

TENOFOVIR DISOPROXIL FUMARATE (TDF)

General information

- Therapeutic class: HIV-1 nucleotide reverse transcriptase inhibitor (NtRTI)
- Indicated for first- and second-line, for adults and adolescents (WHO 2006 guidelines)[2]
- Originator company, and product brand name: Gilead, Viread
- First approval by US Food and Drug Administration (FDA): October 2001
- Included in the WHO Model List of Essential Medicines (EML)[14]
- World sales of originator product: 2006 US$ 689 million, 2005 US$ 778 million, 2004 US$ 783 million[24]
- Although tenofovir was discovered and patented in 1985, Gilead later applied for additional patents on a new form of the drug, tenofovir disoproxil fumarate. These later patents are due to expire in 2018.[33]

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	Gilead	Aspen	Cipla (CF)		Hetero	Matrix (CF)
Eligibility restrictions		See table 2	See table 2	See table 2		None	None
				Category 1	Category 2		
TDF 300 mg tablets	1	**207 (0.567)**	XX	195 (0.534)	340 (0.932)	268 (0.733)	199 (0.546)

XX For prices on this product please contact Aspen directly.

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.

Spotlight on access issues:

The use of TDF is likely to increase as it is now part of the WHO recommended first-line treatment. The addition of TDF to first-line regimens will have a substantial impact on the budgets of AIDS programmes. Previously recommended d4T based first-line regimens now cost as low as US$ 100 per patient per year (see the product card for the triple FDC containing 3TC/d4T/NVP). In Sub-Saharan African and other countries eligible for Gilead's lowest price for TDF, the use of the new first-line regimen will increase the cost of treating a patient for a year by four to six times. The impact will be even more dramatic in countries that are excluded from the lowest prices.

Some middle-income countries, such as Brazil, nevertheless possess negotiating capacity with Gilead, and can threaten to issue compulsory licenses allowing local production or importation of the drug. As a result, Gilead recently agreed to halve the price from US$ 2,766 to US$ 1,380 per patient per year in Brazil. his new price - at almost seven times the price of the Gilead offers to countries in the Access Program - remains extremely inflated. The lack of progress on the registration of the drug is a further problem. Indeed TDF is barely available in developing countries at all. As of June 2007, Gilead's TDF was registered in only 25 of the 97 countries that Gilead deems eligible for its preferential prices.[34] TDF is not registered in either Zimbabwe or Malawi for instance, where HIV/AIDS prevalence exceeds 20% and 14% respectively.

Competition between generics and originators for TDF is now underway, as generic products have already been marketed in India for several months. But the future of such generic competition will depend on the patent status of TDF in India. Gilead patent applications are currently under examination at the Indian patent office. Indian patient groups opposed the granting of this patent on 9th May 2006 [35].

As a result of this opposition, Gilead has offered voluntary licenses to many Indian manufacturers in a move that was widely welcomed. It must be stressed however that there are certain key limitations to these agreements. Firstly, Indian manufacturers that signed the license cannot sell the product all over the developing world, as the terms of the license limit the production and export of generic versions to LDCs and a few developing countries only. Big markets such as China or Brazil are for example specifically excluded. Indian licensees are also prevented from selling the active pharmaceutical ingredient outside India.

Secondly, most of the Indian generic manufacturers did not need any technical support from Gilead to make generic versions. All they needed was the assurance that Gilead would not use patent rights to stop them from producing and exporting in countries where the product was needed. Finally, and perhaps most crucially, it is important to remember that Gilead had not been granted a patent in India and therefore did not hold any IP rights there when the voluntary licensing agreements were concluded - nor does it at the time of going to press. Gilead's offer of voluntary licenses can therefore be seen as a pre-emptive attempt to retain control over the marketing and selling of TDF in certain key markets, when the future patent status of TDF in India is still undetermined.

Crucially, TDF has not yet been tested in children, despite urgent needs.

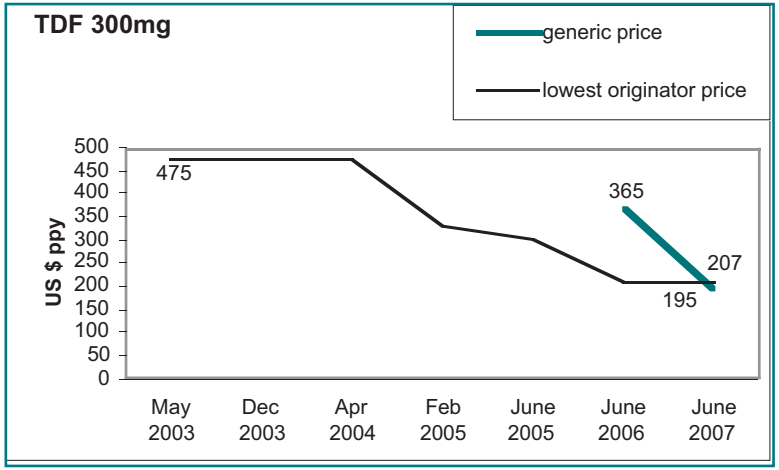


Chart 1: Evolution of the lowest price quoted for eligible developing countries since 2001
As of June 2007, there was no WHO prequalified generic source of TDF. The lowest available generic price is therefore given here.

ZIDOVUDINE (AZT, ZDV)

General information

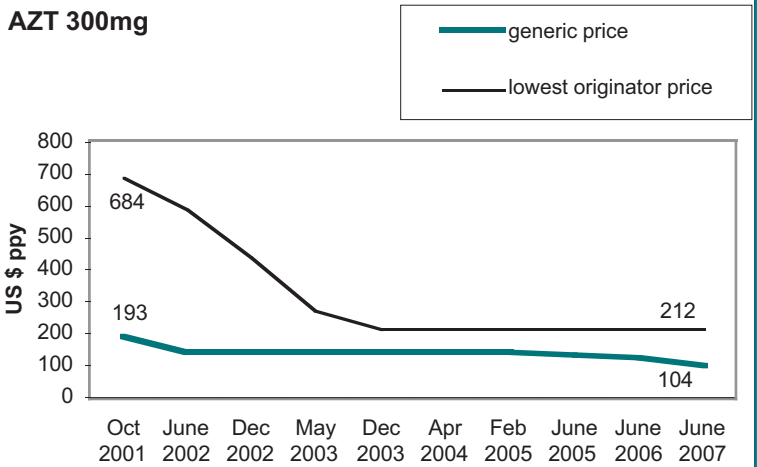
- Therapeutic class: HIV-1 and HIV-2 nucleoside reverse transcriptase inhibitor (NRTI)
- Indicated for first- and second-line, for adults, adolescents and children (WHO 2006 guidelines)[2]
- Originator company, and product brand name: GlaxoSmithKline (GSK), Retrovir
- First approval by US Food and Drug Administration (FDA): March 1987
- Included in the WHO Model List of Essential Medicines (EML)[14]
- World sales of originator product: 2005 US$ 84 million, 2004 US$ 80 million[26]
- Zidovudine was first discovered in 1964 as an anti-cancer medicine. The US National Institutes of Health did the majority of the research that showed the drug's effectiveness as an antiretroviral. Nevertheless, Glaxo-Wellcome obtained a patent for zidovudine for the treatment of AIDS and brought the drug onto the market in 1987 as one of the most expensive ever sold. Patents have expired in most countries now.

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	GSK	Aurobindo	Cipla (CF)	Hetero	Matrix (CF)	Ranbaxy	Strides
Eligibility restrictions		See table 2	None	None	None	None	None	
AZT 300 mg tabs	2	**212 (0.290)**	**120 (0.165)**	**104 (0.142)**	110 (0.150)	**110 (0.150)**	**115 (0.157)**	
AZT 100 mg caps	--	**(0.158)**	**(0.110)**	**(0.075)**				
AZT 250 mg caps	--	**(0.332)**						
AZT 10 mg/ml syrup	20 ml	**263 (0.036/ml)**	**95 (0.013/ml)**	**102 (0.014/ml)**				
AZT 25 mg granules	--							(2.85)
AZT 50 mg granules	--							(3.35)

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.



Evolution of the lowest price quoted for eligible developing countries since 2001

As of June 2007, there are five WHO prequalified generic sources of AZT 300 mg. The lowest available WHO prequalified generic price is therefore given here.

Spotlight on access issues:

Despite the existence of generic competition and the availability of WHO prequalified products, some developing countries such as Kenya and Zimbabwe, were in 2006 still purchasing the originator version of AZT. Countries have reported to the WHO GPRM that they were purchasing GSK products at prices between US$ 212 and US$ 241 (almost double the generic price).[13]

ABACAVIR/LAMIVUDINE (ABC/3TC)

General information

- Therapeutic class: 2 NRTIs in a double fixed-dose combination, for HIV-1 and HIV-2
- Indicated for first-line, for adults, adolescents and children (WHO 2006 guidelines)[2]
- Originator company, and product brand name: GlaxoSmithKline (GSK), Kivexa (in the EU), Epzicom (in the USA)
- First approval by US Food and Drug Administration (FDA): August 2004
- The WHO Expert Committee on the Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations[14]
- World sales of originator product: 2006 US$ 475 million, 2005 US$ 233 million.[26]

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	GSK	Cipla
Eligibility restrictions		See table 2	None
ABC/3TC 600/300 mg	1	**678 (1.858)**	256 (0.700)

Spotlight on access issues:

To date, no transactions have been reported in the WHO GPRM database.

GSK only very recently quoted a specific price for this double fixed-dose combination for developing countries. Generic production is very recent.

LAMIVUDINE/STAVUDINE (3TC/d4T)

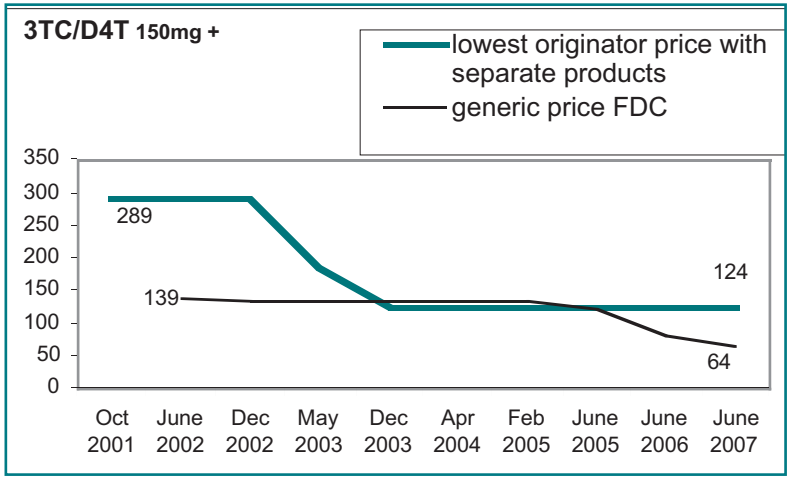
General information

- Therapeutic class: 2 NRTIs in double fixed-dose combination, for HIV-1 and HIV-2
- Indicated for first-line, for adults, adolescents and children (WHO 2006 guidelines)[2]
- WHO updated the 2006 guidelines to recommend a reduction in dose of d4T 40 mg to d4T 30 mg for all weight categories of patients[43]
- The WHO Expert Committee on the Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations[14]
- Generic manufacturers in India where none of the individual medicines are under patent developed the product. It is not available from originator companies.

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	Aurobindo	Cipla	Hetero	Matrix	Ranbaxy	Strides
Eligibility restrictions		None	None	None	None	None	None
3TC/d4T 150mg/30mg tablet	2	72 (0.099)	**64 (0.088)**	91 (0.125)	61 (0.083)	**73 (0.100)**	61 (0.083)
3TC/d4T 150mg/40mg tablet	2	74 (0.101)	**67 (0.092)**	93 (0.127))	64 (0.088)	**79 (0.108)**	**63 (0.087)**



Evolution of the lowest price quoted for eligible developing countries since 2001

As of June 2007, there are two WHO prequalified generic sources of 3TC/d4T. The lowest available WHO prequalified generic price is therefore given here. As there is no originator FDC, the price used is the combination of the two single products.

The first generic to be WHO prequalified was from Strides in February 2005. Prices of generic drugs have been decreasing since that date.

Spotlight on access issues:

Although this fixed-dose combination is included in the WHO recommendations for children, there are currently no adapted formulations available. Some generic manufacturers are however working on developing this FDC for children, to complement their triple FDC for children.

With the recent change in WHO recommendations concerning the dose of d4T, products using d4T 40 mg should gradually disappear.

LOPINAVIR/RITONAVIR (LPV/r)

General information

- Therapeutic class: boosted Protease Inhibitor (PI) in double fixed-dose combination, for HIV-1 and HIV-2
- Indicated for second-line for adults, adolescents and children (WHO 2006 guidelines)[2]
- First approval by US Food and Drug Administration (FDA): soft-gel capsules were approved in September 2000. Heat-stable tablets were approved in October 2005.
- Originator company, and product brand name: Abbott Laboratories, Kaletra, Aluvia
- Included in the WHO Model List of Essential Medicines (EML) - only soft-gel capsules[14]
- World sales of originator product: LPV/r is the most commonly used PI in the USA, representing 34% of total PI prescriptions. In four years, from 2001 to 2004, sales amounted to US$ 2.5 billion (US$ 292 million in 2001, US$ 551 million in 2002, US$ 754 million in 2003 and US$ 897 million in 2004).[36] Cumulative sales are estimated to reach US$ 7 billion over the years 2001 to 2008[36]
- Abbott patents on soft-gel capsules are due to expire in 2018. Patents were also filed to protect the heat-stable tablets, which if granted, could run until 2024.

Price information:

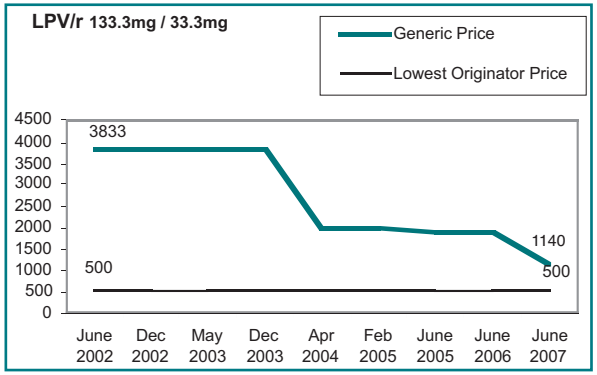
Table 1: Prices in US$ quoted by companies for eligible developing countries

		Abbott		Cipla	Hetero	Matrix (CF)
Eligibility restrictions	Daily dose	Category 1	Category 2	None	None	None
		See table 2				
LPV/r 133 / 33 mg soft gel capsule	6	**500 (0.228)**	**1000 (0.457)**	1338 (0.611)	1140 (0.520)	
LPV/r 200 / 50 mg tablet (heat-stable)	4	**500 (0.342)**	**1000 (0.685)**			1034 (0.708)
LPV/r 80 + 20 mg / ml oral solution	4 ml	**200 (0.137/ml)**	**400 (0.274/ml)**			

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.

Spotlight on access issues:

Abbott has developed a new formulation of the LPV/r that is heat-stable. The new formulation presents advantages over the older soft gel capsules: it has a lower pill count (reducing the burden from six to four pills per day), there is no need for refrigeration, and there are no dietary restrictions.
Its availability remains severely limited in developing countries however. The LPV/r heat stable tablet is only registered in 13 out of the 68 countries who can access the US $500 ppy price.[37] It is only after Médecins Sans Frontières (MSF) in early 2006 publicly placed an order for LPV/r heat stable tablets, supported by a petition letter signed by more than 300 scientists and organisations, that Abbott allowed the drug to be delivered to MSF programmes in African countries where it is not registered. Initially Abbott declined to fill the orders placed for MSF projects in Guatemala or Thailand. As a result of public pressure, Abbott finally announced a price for middle-income countries.
Due to the impossibility of obtaining the product at an affordable price, Thailand made use of the flexibilities of the TRIPS Agreement and issued a compulsory license in early 2007 to import and produce LPV/r in its older, soft gel capsules formulation. Abbott retaliated by withdrawing the applications for registration for all their new medicines in Thailand, including the newer LPV/r heat-stable tablets. By refusing to register these drugs and thereby restricting access to life-saving drugs in Thailand, Abbott's actions have attracted the condemnation of many, including MSF and patient groups.[38]
In Brazil, where this product is under patent, the cost of LPV/r alone took up 27% of the National AIDS Programme budget in 2005. After repeated negotiations with the company, Abbott eventually reduced the price to US$ 1,380 ppy for the older soft-gel version and US$ 1,518 ppy for the heat-stable tablets.[23] After Thailand issued a compulsory license, Abbott further reduced the price for middle-income countries, including Brazil, to US$ 1,000.
The Clinton Foundation's HIV/AIDS Initiative, after negotiation with generic manufacturers, has recently announced a price of US$ 695 for the LPV/r heat-stable tablet for countries in their consortium.[11] This is a positive indication that the price of the generic formulations will continue to drop as the market grows. This is already 30% below the new reduced price for middle-income countries offered by Abbott. However, the availability of these more affordable generic versions will depend on the upcoming patent decisions in India.
Indeed, generic competition from Indian sources, which would be expected to drive prices down as demand increases, is under threat. Abbott has applied for patents on the combination and on improved formulations of the individual drugs in India, which, if granted would hamper production of generic sources. Indian patient groups have opposed the grant of these patents before the Indian patent offices. The final decisions were still pending at the time of publication.
The majority of transactions recorded in 2006 in the WHO GPRM were for LPV/r 133.3/33.3 mg soft-gel capsules. Only three countries (Uganda, Zambia and Mozambique) reported transactions of the new heat-stable 200/50 mg tablet. Many countries reported paying more than 10 times Abbott's lowest offer for the soft-gel capsules (e.g. Jordan US$ 5,212 ppy and Honduras US$ 7,775 ppy).[13]
The paediatric formulation of LPV/r is a liquid that requires refrigeration. Adapted formulations for children are urgently needed.



Evolution of the lowest quoted price for eligible developing countries since 2001 As of June 2007, there was no WHO prequalified generic source of lopinavir/ritonavir. The lowest available generic price is therefore given here.

TENOFOVIR DISOPROXIL FUMARATE/ EMTRICITABINE (TDF/FTC)

General information

- Therapeutic class: one NtRTI + one NRTI in double fixed-dose combination, for HIV-1
- Indicated for first-line, for adults and adolescents (WHO 2006 guidelines)[2]
- Originator company, and product brand name: Gilead, Truvada
- First approval by US Food and Drug Administration (FDA): August 2004
- Included in the WHO Model List of Essential Medicines (EML) [14]
- The WHO Expert Committee on the Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations [14]
- World sales of originator product: 2006 US$ 1,194 million, 2005 US$ 568 million, 2004 US$ 68 million[24]
- Patent holders of both TDF and FTC have agreed to waive their right to a royalty on sales within Gilead's Access Program.

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	Gilead	Aspen	Matrix (CF)
Eligibility restrictions		See table 2	See table 2	None
TDF/FTC 300/200 mg tablets	1	**319 (0.875)**	xx	274 (0.750)

XX For prices on this product please contact Aspen directly.

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.

Spotlight on access issues:

As of June 2007, this combination is registered in only 20 of the 97 countries eligible within Gilead's Access Program. [34]

In 2006, only four countries reported transactions in WHO GPRM with the majority accessing Gilead's access price, although Armenia reported paying US$ 561. [13]

The final patent status of TDF in India will have implications on the availability of generic versions of this FDC (see TDF product card).

TENOFOVIR DISOPROXIL FUMARATE/ LAMIVUDINE (TDF/3TC)

General information

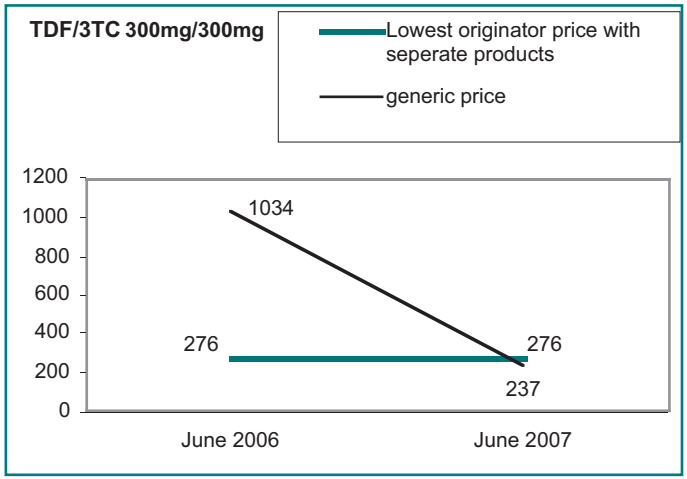
- Therapeutic class: NtRTI + NRTI in double fixed-dose combination, for HIV-1
- Indicated for first-line, for adults and adolescents (2006 WHO guidelines)[2]
- Included in the WHO Model List of Essential Medicines (EML) [14]
- The WHO Expert Committee on the Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations [14]
- Only generic companies manufacture this product but its final availability will depend on the pending patent decision of TDF in India. It is not available in Western countries because of various patents on TDF and 3TC.

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	Matrix (CF)
Eligibility restrictions		None
TDF/3TC 300/300 mg tablets	1	237 (0.650)

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.



Evolution of the lowest quoted price for eligible developing countries since 2001

As of June 2007, there was no WHO prequalified product. The lowest available generic price is therefore given here.

Spotlight on access issues:

This combination is likely to be widely used in developing countries as a backbone in first and second line regimes, even more so than the originator combination of TDF/FTC.[2] This is for two reasons. Firstly, the combination contains 3TC instead of FTC. 3TC is equally effective and safe but comes with fewer patent restrictions and is available at cheaper prices. Secondly, the fact that generic companies already produce this combination is likely to have an impact on the price as competition develops. Gilead patent applications on TDF are however pending in India, threatening the future production of this FDC.

The Clinton Foundation's HIV/AIDS Initiative, after negotiation with generic manufacturers, has recently announced a price of US$ 179 for this combination for countries in their consortium. This is a positive indication that the price of the generic formulations will continue to drop as the market grows. [11]

ZIDOVUDINE/LAMIVUDINE (AZT/3TC)

General information

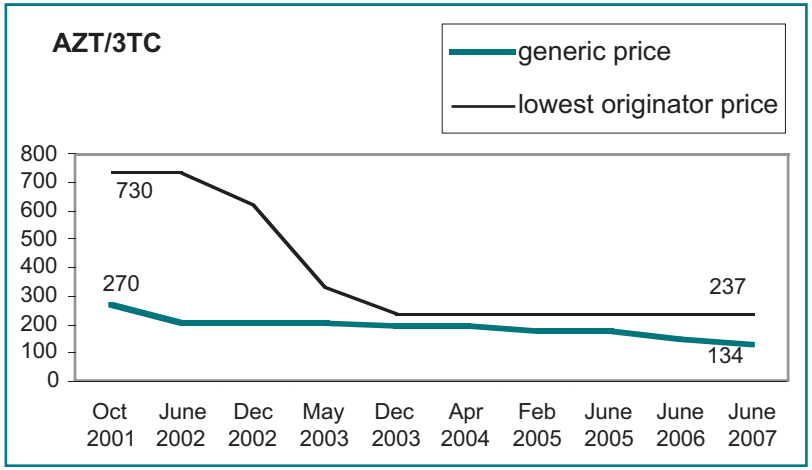
- Therapeutic class: 2 NRTI in double fixed-dose combination, for HIV-1 and HIV-2
- Indicated for first- and second-line for adults and adolescents, and only for first-line in children (WHO 2006 guidelines) [2]
- Originator company, and product brand name: GlaxoSmithKline (GSK), Combivir
- First approval by US Food and Drug Administration (FDA): September 1997
- Included in the WHO Model List of Essential Medicines (EML) [14]
- The WHO Expert Committee on the Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations [14]
- World sales of the originator: 2006 US$ 1,042 million, 2005 US$ 1,150 million, 2004 US$ 1,125 million [15]
- Patent status: GSK announced the withdrawal of all patents and patent applications for this combination in tablet form in all countries of the world on 9th August 2006 [50] Patent rights may still exist on the 3TC alone however.

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	GSK	Aspen	Aurobindo	Cipla (CF)	Hetero	Matrix (CF)	Ranbaxy	Strides
Eligibility restrictions		See table 2	See table 2	None	None	None	None	None	None
AZT/3TC 300 / 150 mg	2	**237 (0.325)**	XX	**140 (0.192)**	**134 (0.183)**	**161 (0.220)**	128 (0.175)	**140 (0.192)**	**270 (0.233)**

XX For prices on this product please contact the company directly
(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.



Evolution of the lowest price quoted for eligible developing countries since 2001
As of June 2007, there are five WHO prequalified generic sources of AZT/3TC. The lowest available WHO prequalified generic price is therefore given here.

Competition among WHO prequalified sources continues, and has led to a steady decrease in prices.

Spotlight on access issues:

Competition between originator and generics exists for adult formulations. Indian sources of the generic product came under threat in 2006 however when GSK applied for a patent on the combination. Civil society in India opposed the patent application on 30th March 2006. [39] In August 2006, GSK withdrew the patent application in India in response to this opposition. [46]

Despite GSK withdrawal of all patents related to the combination, generic versions of the FDC are still not available in some countries because of GSK's remaining rights on 3TC. In China for example, only the originator product is available at US$ 2,876 ppy because of GSK's exclusive rights on 3TC alone.

WHO GPRM 2006 data show that the majority of countries reported purchasing the generic products, although some countries, such as Algeria and Cameroon still paid prices over US$ 200. Countries like Russia and Jordan reported purchases of the GSK product as high as US$ 1,248 and US$ 2,694 respectively. [13]

To date, no formulation adapted for children is marketed. This is urgently needed. GSK have recently scored their adult AZT/3TC product to ease the use in children, but there is still no paediatric strength of this product available.

LAMIVUDINE/STAVUDINE/ NEVIRAPINE (3TC/d4T/NVP)

General information

- Therapeutic class: two NRTI + one NNRTI in triple fixed-dose combination, for HIV-1
- Indicated for first-line, for adults, adolescents and children (WHO 2006 guidelines) [2]
- WHO updated the 2006 guidelines to recommend a reduction in dose of d4T for all weight categories of patients, from 40 mg to 30 mg [43]
- Included in the WHO Model List of Essential Medicines (EML) - only the d4T 30 mg presentation [14]
- The WHO Expert Committee on the Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations [14]
- Only generic companies manufacture the combination; it is not available in Western countries because of various patents on 3TC, d4T and NVP. If these medicines had been under patent in India, this important FDC may never have been developed.

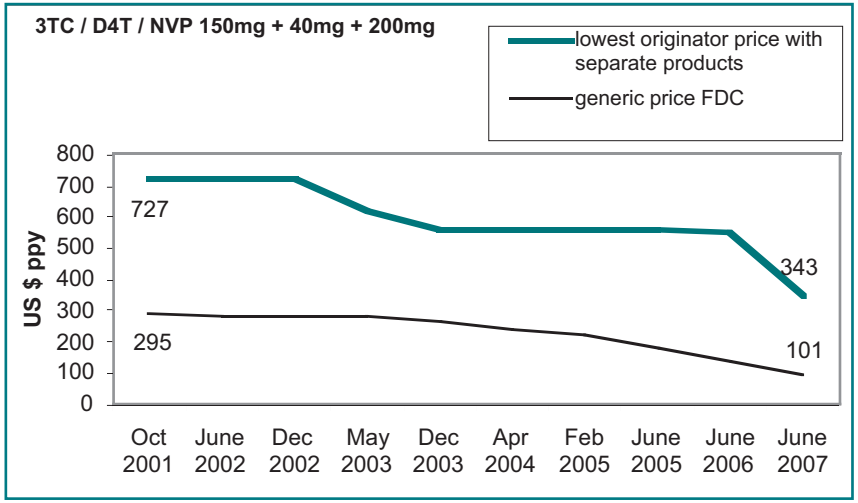
Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	Aurobindo	Cipla (CF)	Hetero (CF)	Matrix (CF)	Ranbaxy (CF)	Strides
Eligibility restrictions		None	None	None	None	None	None
30 / 6 / 50 mg dispersible tablets	4*		158 (0.108)				
60 / 12 / 100 mg dispersible tablets	2*		91 (0.125)				
20 / 5 / 35 mg dispersible tablets	5*					104 (0.057)	
40 / 10 / 70 mg dispersible tablets	2.5*					88 (0.096)	
150 / 30 / 200 mg tablets	2	139 (0.190)	**132 (0.181)**	**101 (0.138)**	119 (0.163)	**99 (0.135)**	121 (0.166)
150 / 40 / 200 mg tablets	2	146 (0.200)	**140 (0.192)**	**104 (0.142)**	128 (0.175)	**101 (0.139)**	125 (0.171)

*WHO has developed recommendations for dosage for different weight categories for the paediatric FDC - see spotlight on access issues for more details. [44]

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.



Evolution of the lowest price quoted for eligible developing countries since 2001

As of June 2007, there are three WHO prequalified generic sources of 3TC/d4T/NVP. The lowest available WHO prequalified generic price is therefore given here. As there is no originator FDC, the price used is the combination of the three single products. Competition among WHO prequalified sources continues, and has led to a steady decrease in prices.

Spotlight on access issues:

This is still the most commonly prescribed therapy in resource-limited settings for first-line treatment in adults. With the recent change in WHO recommendations concerning the dose of d4T, products using d4T 40 mg should gradually disappear.

Some generic manufacturers have now produced paediatric triple fixed-dose combinations. This is an important breakthrough, greatly facilitating the treatment of children.

Unfortunately, WHO recommendations on an ideal FDC for children came too late, and none of the products currently marketed follow the WHO guidelines. In order to address this problem, dosing tables were developed by an expert committee to give clear guidance on how to administer the current formulations.

None of the existing paediatric products are prequalified. The WHO Prequalification project must prioritise the assessment of these products.

TENOFOVIR DISOPROXIL FUMARATE/EMTRICITABINE/ EFAVIRENZ (TDF/FTC/EFV)

General information

- Therapeutic class: 1 NtRTI + 1 NRTI + 1 NNRTI in a triple fixed-dose combination, for HIV-1
- Indicated for first-line for adults (WHO 2006 guidelines) [2]
- Originator company, and product brand name: Gilead and BMS/Merck, Atripla
- Included in the WHO Model List of Essential Medicines (EML) [14]
- First approval by US Food and Drug Administration (FDA): July 2006
- The WHO Expert Committee on the Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations [14]
- World sales of the originator: In 2006, US$ 205 million. [24]

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	Gilead/BMS/Merck		Matrix (CF)
Eligibility restrictions		Category 1	Category 2	None
		See table 2	See table 2	
TDF/FTC/EFV 300/200/600 mg tablets	1	613 (1.68)	1033 (2.83)	487(1.333)

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.

Spotlight on access issues:

This is the first one-pill-a-day FDC, which makes it well adapted to resource-poor settings. This combination will probably become one of the most recommended first-line therapies, as it is well tolerated and delays the emergence of resistance, although it cannot be used in women of childbearing age.

Some generic manufacturers have started production of this FDC. Gilead patent applications are currently under examination at the Indian patent office, however. Indian patient groups opposed the granting of TDF patent in India in May 2006. [46]

The Clinton Foundation's HIV/AIDS Initiative, after negotiation with generic manufacturers, has recently announced a price of US$ 385 for this combination for countries in their consortium. This is a positive indication that the price of the generic formulations will continue to drop as the market grows. [11]

TENOFOVIR DISOPROXIL FUMARATE / LAMIVUDINE / EFAVIRENZ (TDF/3TC/EFV)

General information

- Therapeutic class: 1 NtRTI + 1 NRTI + 1 NNRTI in a triple fixed-dose combination, for HIV-1
- Indicated for first-line for adults (WHO 2006 guidelines) [2]
- Included in the WHO Model List of Essential Medicines (EML) [14]
- The WHO Expert Committee on the Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations [14]
- The product is developed only by generic manufacturers and is not available in Western countries because of various patents on TDF, 3TC and EFV

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	Matrix (CF)
Eligibility restrictions		
TDF/3TC/EFV 300/150/600mg tablets (FDC)	1	426 (1.167)

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.

Spotlight on access issues:

This combination is likely to be widely used in developing countries, even more so than the originator combination of TDF/FTC/EFV. This is for two reasons. Firstly, the combination contains 3TC instead of FTC. 3TC is equally effective and safe but comes with fewer patent restrictions and is available at cheaper prices. Secondly, the fact that this combination is already produced by generic companies is likely to have an impact on the price as competition develops. Gilead patent applications on TDF are however pending in India, threatening the future production of this FDC.

The Clinton Foundation's HIV/AIDS Initiative, after negotiation with generic manufacturers, has recently announced a price of US$ 339 for this combination for countries in their consortium. This is a positive indication that the price of the generic formulations will continue to drop as the market grows. [11]

ZIDOVUDINE/LAMIVUDINE/ ABACAVIR (AZT/3TC/ABC)

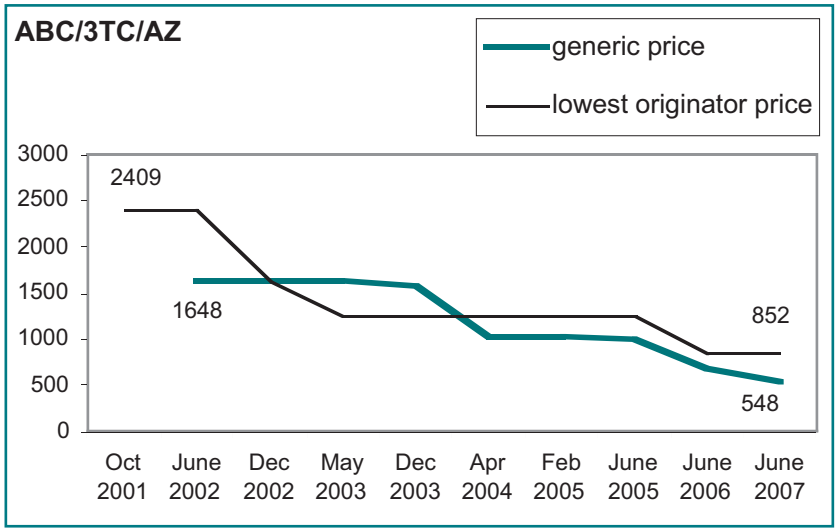
General information

- Therapeutic class: three NRTI in triple fixed-dose combination, for HIV-1 and -2
- Indicated for first-line, for adults, adolescents and children (WHO 2006 guidelines) [2]
- The WHO Expert Committee on the Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations [14]
- Originator company, and product brand name: GlaxoSmithKline (GSK), Trizivir
- First approval by US Food and Drug Administration (FDA): November 2000
- World sales of originator product: 2006 US$ 529 million, 2005 US$ 598 million, 2004 US$ 635 million. [26]

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	GSK	Aurobindo	Cipla	Hetero	Matrix	Ranbaxy
Eligibility restrictions		See table 2	None	None	None	None	None
AZT/3TC/ABC 300/150/300 mg (FDC)	2	**852 (1.167)**		548 (0.750)	730 (1.000)	548 (0.750)	639 (0.875)
AZT/3TC 300/150 mg +ABC 300mg (Co-Pack)	1 kit (4 tabs)		**548 (1.50)**				



Evolution of the lowest price quoted for eligible developing countries since 2001

As of June 2007, there was no WHO prequalified generic source of an FDC containing AZT/3TC/ABC.

The lowest available generic price is therefore given here.

Spotlight on access issues:

This FDC was the first triple formulation developed by an originator company to be made available in Western countries, and is therefore one of the most commonly prescribed regimens. The market remains very small in developing countries, however. Indeed only three countries reported transactions to WHO GPRM in 2006 (Madagascar, Côte d'Ivoire and the Central African Republic). [13]

The fixed-dose combination is still very expensive compared to other triple first-line FDCs, notably because of the high price of abacavir.

ZIDOVUDINE/LAMIVUDINE/ NEVIRAPINE (AZT/3TC/NVP)

General information

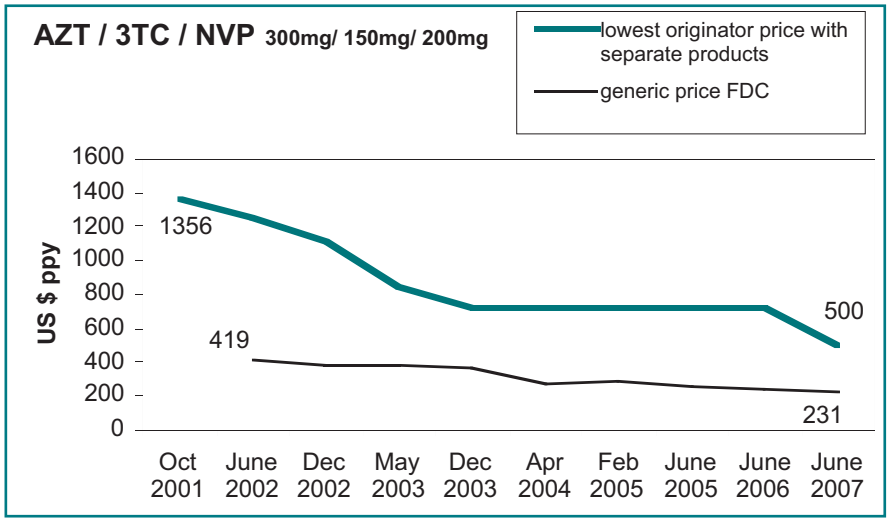
- Therapeutic class: two NRTI + one NNRTI in triple fixed-dose combination, for HIV-1
- vIndicated for first-line, for adults, adolescents and children (WHO 2006 guidelines) [2]
- Included in the WHO Model List of Essential Medicines (EML) [14]
- The WHO Expert Committee on the Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations [14]
- Only generic companies manufacture the combination; it is not available in Western countries because of various patent rights on AZT, 3TC and NVP.

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	Aspen	Aurobindo	Cipla (CF)	Hetero	Matrix (CF)	Ranbaxy	Strides
Eligibility restrictions		See table 2	None	None	None	None	None	None
AZT/3TC/NVP 150/300/200mg (FDC)	2		**231 (0.317)**	**231 (0.317)**	194 (0.266)	199 (0.273)	223 (0.306)	
AZT/3TC 150/300mg + NVP 200mg (Co-Pack)	1 kit (4 tabs)	**XX**						**225 (0.616)**

XX For prices on this product please contact Aspen directly
(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See Annex 10 for details.



Evolution of the lowest price quoted for eligible developing countries since 2001

As of June 2007, there are two WHO prequalified generic sources of AZT/3TC/NVP FDC. The lowest available WHO prequalified generic price is therefore given here.
As there is no originator FDC, the price used is the combination of the three single products.

Spotlight on access issues:

The price of this triple FDC is still a barrier for use and for scaling up purposes, especially when compared with other triple first-line FDCs.

Today, there are no paediatric formulations available for this FDC, although it is recommended by WHO for first-line children treatment.

LAMIVUDINE/STAVUDINE + EFAVIRENZ (3TC/d4T+EFV)

General information

- Therapeutic class: two NRTI + one NNRTI in a co-blister, for HIV-1
- Indicated for first-line, for adults, adolescents and children (WHO 2006 guidelines) [2]
- The WHO Expert Committee on the Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations [14]
- Only generic companies manufacture the combination; it is not available in Western countries because of various patents rights on 3TC, d4T and EFV.

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Daily dose	Cipla	Ranbaxy
Eligibility restrictions		None	None
3TC/d4T+EFV 150 / 30 + 600 mg daily co-blister	1 kit (3 tabs)	274 (0.750)	345 (0.945)
3TC/d4T+EFV 150 / 40 + 600 mg daily co-blister	1 kit (3 tabs)	280 (0.767)	358 (0.980)

ZIDOVUDINE/LAMIVUDINE + EFAVIRENZ (AZT/3TC + EFV)

General information

- Therapeutic class: two NRTI +one NNRTI in a co-blister, for HIV-1
- Indicated for first-line, for adults, adolescents and children (WHO 2006 guidelines [2])
- The WHO Expert Committee on the Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations [17]
- Only generic companies develop this product; it is not available in Western countries because of various patents on AZT, 3TC and EFV

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Dose	Aurobindo	Cipla	Ranbaxy	Strides
Eligibility restrictions		None	None	None	None
AZT/3TC +EFV 150/300 + 600 mg daily co-blister	1 kit(3 tabs)	**410 (1.125)**	347 (0.950)	434 (1.190)	**420 1.150)**

PMTCT: NEVIRAPINE + ZIDOVUDINE (NVP+AZT)

General information

- Therapeutic class: one NNRTI + one NRTI in a co-blister, for HIV-1
- Indicated for prevention of mother to child transmission [47]
- Only generic companies manufacture the combination; it is not available in Western countries because of various patents rights on NVP and AZT.

Price information:

Table 1: Prices in US$ quoted by companies for eligible developing countries

	Dose	Strides
Eligibility restrictions		None
NVP 6 mg granules + AZT 16 mg granules	1 + 14	2.50
NVP 6 mg granules + AZT 16 mg granules	1 + 56	4.70

Table 2: Conditions of offer by company

Company	Eligibility (countries)	Eligibility (bodies)	Additional comments	Delivery of goods
Abbott	Category 1 countries All African countries and all Least Developed Countries (as defined by UN) outside of Africa Category 2 countries All Low income countries (excluding African countries and LDC countries) plus all lower middle income countries See Annex 6 for more details	Category 1 countries Organisations providing sound, sustainable care, including, but not limited to governments, NGOs, UN organisations, private employers, hospitals and clinics Category 2 countries Governments and programs fully-funded by governments, UN Systems organisations, NGOs and other not-for-profit institutional providers of HIV treatment.		FOB
Aspen	Sub-Sahara Africa including Mauritius, Seychelles, Madagascar for all products except Viread and Truvada For Viread and Truvada - entire African continent	Governments, NGOs and other partners including private and such organisations that are able to run programmes in a responsible, sustainable and medically sound manner	Delivery terms: 90-120 days No minimum order unless any special labelling is required.	Quote ex works. Deliver CIF as per client request - freight charges to consignees account. Payment by telegraphic transfer
Aurobindo	No reported restrictions	NGOs and governmental organisations	Prices available for above 500,000 units for tablet packs and above 10,000 units for oral solutions. Delivery of goods 4-6 weeks from the date of confirmed orders.	Payment by letter of credit FOB Hyderabad (India)
Bristol-Myers Squibb	First category of countries: Sub-Saharan African countries (except southern African countries) plus countries classified as low-income by the World Bank (except Korea, Kyrgyzstan, Moldova and Uzbekistan). Second category of countries: Southern African countries See annex 5 for more details. For other developing countries, prices are negotiated on a case-by-case basis with BMS local representatives	Both private and public sector organisations that are able to provide effective, sustainable and medically sound care and treatment of HIV/AIDS	Category 1 countries are invoiced in US $, Category 2 countries are invoiced in South African Rand	CIP incoterm
Boehringer-Ingelheim	Category 1. All LDCs, all low income countries and all Africa Category 2 All middle income countries not covered under category 1	Governments, NGOs and other partners who can guarantee that the programme is run in a responsible manner		CIF

Company	Eligibility (countries)	Eligibility (bodies)	Additional comments	Delivery of goods
Cipla	For products with differential pricing Category 1 Low Human Development Index countries Category 2 Medium Human Development Index countries For products with no differential pricing there is no reported restrictions but higher prices have been negotiated separately for 10 Latin American countries	No restrictions	No quantity related conditions Prices for larger quantities are negotiable	FOB Mumbai (India) or CIF - Freight charges separately on actual
Gilead	98 countries including all African states and 44 additional countries classified as low-income by the World Bank. See Annex 7 for more details For other developing countries, prices are negotiated on a case by case basis	Organisations that provide HIV treatment in the 98 countries covered by the Gilead Access Program. For organisations in Africa enquiries should be directed to Ansie Savrda (asavrda@aspenpharma.com) For other countries application instructions are available at www.gileadaccess.org	The programme is managed through Gilead International Access Operations and Gilead`s local distribution partners. Please note that local taxes, tariffs, and limited distributor mark-ups may be added to the ex-factory prices.	Shipping terms vary by local distributor
GlaxoSmithKline	Least Developed Countries (LDCs) plus sub-Saharan Africa All Country Coordination Mechanisms (CCM) projects fully financed by the Global Fund to Fight AIDS, TB and Malaria, as well as projects funded by PEPFAR. For other low and middle-income countries, public sector prices are negotiated on a case-by-case basis, either bilaterally or through GSK's Accelerating Access Initiative	Governments, aid organisations, charities, UN agencies, other not-for-profit organisations and international procurement agencies In sub-Saharan Africa, employers offering HIV/AIDS care and treatment directly to their staff through workplace clinics or similar arrangements	Supply Agreement required (For NGOs requiring fewer than ten patient packs per month, this requirement may be waived) All organisations must supply the preferentially priced products on a not-for-profit basis.	CIP
Hetero Drugs Ltd	No reported restrictions	Private sector, public sector and NGOs	Prices may be negotiated on individual basis according commercial terms	FOB Mumbai (India)
Matrix	No reported restrictions except Belarus, Cuba, Democratic Republic of Congo, Iran, Liberia, Sudan and Syria for which prior approval from Mylan Labs Inc is required	No restrictions	None	Ex-works Nashik, India or as specified by customers
Merck & Co. Inc	*First category of countries:* Low Human Development Index (HDI) countries plus medium HDI countries with adult HIV prevalence of 1% or greater	Governments, international organisations, NGOs, private sector organisations (e.g. employers, hospitals and insurers)	Merck & Co. Inc may under certain circumstances supply ARVs to patients through retail pharmacies	CIP

Company	Eligibility (counries)	Eligibility (bodies)	Additional comments	Delivery of goods
	Second category of countries: Medium HDI countries with adult HIV prevalence less than 1%			
Ranbaxy	No reported restrictions, but higher prices were negotiated separately for ten Latin American countries	NGOs and governments or programmes supported by them	Confirmed letter of credit or advance payment preferred for new customers	FOB Delhi (India)
Roche	*First category of countries:* All countries in sub-Saharan Africa and all countries classified as Least Developed Countries by the United Nations *Second category of countries:* Low-income countries and lower middle-income countries, as classified by the World Bank.	Governments, non-profit institutional providers of HIV care, NGOs	CAD (Cash Against Documents) 30 days at sight. Minimum order and delivery amount per shipment is CHF 10,000 (US$ 8,179)	FCA Basel airport (Switzerland) or CIP airport of destination
Strides Arcolab Ltd	No reported restrictions	Governments, non-profit institutional providers of HIV treatment, NGOs	Payment by signed letter of credit	FOB Bangalore (India)

Notes:

The conditions detailed in the table above were those quoted directly by the companies. Definitions of eligibility vary from company to company. Each originator company establishes different restrictions to their offer of reduced prices, and classifies countries according to different categories. Some companies resort to Least Developed Countries (LDC) criteria developed by the United Nations, others to the UN Development Programme's Human Development Index (UNDP HDI), and others still to World Bank classifications concerning country income.

This lack of uniformity leads to significant differences in the eligibility of a country for different products. For instance, some countries are considered Least Developed Countries by the United Nations, but are classified as having medium development by UNDP. These include Bangladesh, Cambodia, Laos and Sudan. Six other LDCs do not appear in the UNDP HDI rankings at all – these include Liberia and Somalia.

Furthermore, many developing countries are left out of the differential pricing scheme altogether. These include Bolivia, Nicaragua, and Ukraine for the UNDP classification, and China, Honduras and Sri Lanka for the World Bank classification.

For full details please refer to annexes 1-8.

Table 3: Summary of prices in US$ quoted by companies for eligible developing countries

Prices are quoted as per patient year followed in brackets by the smallest unit price.

ABC	**Daily dose**	**Aurobindo**	**Cipla**	**GSK**	**Hetero**	**Matrix**	**Ranbaxy**		
300 mg tablet	2	**429 (0.587)**	**456 (0.625)**	**636 (0.871)**	548 (0.750)	439 (0.602)	473 (0.648)		
20 mg / ml oral solution	10 ml	**310 (0.085)**	420 (0.115)	**380 (0.104)**					
ATV		**BMS**	**BMS**						
		Cat 1	Cat 2						
150 mg	2	353 (0.484)	425 (0.582)						
200 mg		. (0.602)	. (0.732)						
ddI		**Aurobindo**	**BMS**	**BMS**	**Cipla**	**Ranbaxy**			
			Cat 1	Cat 2					
25 mg tablet	5		**212 (0.116)**	**416 (0.228)**	. (0.063)				
50 mg tablet			**. (0.158)**	**. (0.288)**	. (0.079)				
100 mg tablet	4	**234 (0.160)**	**310 (0.212)**	**352 (0.241)**	171 (0.117)	321 (0.220)			
150 mg tablet		**. (0.235)**	**. (0.308)**	**. (0.334)**	. (0.167)				
200 mg tablet		**. (0.315)**	**. (0.425)**		. (0.232)	. (0.210)			
125 mg EC capsule	1								
250 mg EC capsule	1	127 (0.350)	**223 (0.611)**	**239 (0.655)**	103 (0.283)	156 (0.427)			
400 mg EC capsule	1	208 (0.570)	**288 (0.789)**	**309 (0.846)**	132 (0.363)	248 (0.679)			
2g powder for reconstitution	12 ml	47 (2.160/2g)	**276 (12.59/2g)**	**293(13.496/2g)**					
EFV		**Aurobindo**	**Cipla**	**Hetero**	**Matrix**	**Merck**	**Merck**	**Ranbaxy**	**Strides**
						Cat 1	Cat 2		
50 mg capsule		**. (0.100)**				**. (0.120)**	**. (0.210)**		
100 mg capsule		**. (0.185)**							
200 mg capsule	3	**233 (0.267)**	226 (0.206)	219 (0.200)		**394 (0.360)**	**821 (0.750)**	**210 (0.192)**	219 (0.200)
600 mg tablet	1	**201 (0.550)**	**218 (0.597)**	201 (0.55)	187 (0.512)	**237 (0.65)**	**657 (1.80)**	**185 (0.506)**	**219 (0.600)**
30 mg / ml suspension		. (0.069 / ml)				**. (0.094 / ml)**	**. (0.151 / ml)**		
FTC									
200 mg capsule susp									
IDV		**Aurobindo**	**Cipla**	**Merck**	**Merck**	**Ranbaxy**			
				Cat 1	Cat 2				
400mg cap	4	432 (0.296)	321 (0.220)	**400 (0.274)**	**686 (0.470)**	639 (0.292)			

3TC	Daily dose	Aurobindo	Cipla	GSK	Hetero	Matrix	Ranbaxy	Strides	
150 mg tab	2	**47 (0.064)**	**51 (0.070)**	**69 (0.095)**	**53 (0.073)**	**49 (0.067)**	**43 (0.059)**	**46 (0.063)**	
300 mg tab	1	**57 (0.155)**	55 (0.150)				66 (0.180)		
10 mg / ml suspension	10 ml	**44 (0.012/ml)**	**66 (0.018/ ml)**	**102 (0.028/ml)**					
25 mg granules								. (2.20)	
50 mg granules								. (2.70)	
NFV		**Aurobindo**	**Cipla**	**Hetero**	**Roche**	**Roche**			
					Cat 1	Cat 2			
200 mg tab	10	1379 (0.420)	1496 (0.407)	1011 (0.277)	1069 (0.293)	2201 (0.603)			
50 mg / g oral powder	24 g				1927 (0.220/g))	2234 (0.255/g)			
NVP		**Aurobindo**	**Boehringer**	**Boehringer**	**Cipla**	**Hetero**	**Matrix**	**Ranbaxy**	**Strides**
			Cat 1	Cat 2					
200 mg tab	2	**51 (0.070)**	**219 (0.300)**	**438 (0.600)**	**55 (0.075)**	**48 (0.066)**	54 (0.074)	**52 (0.071)**	**50 (0.070)**
10 mg / ml suspension	20 ml	**95 (0.013)**	**380 (0.052/ml)**	**533 (0.073/ml)**	131 (0.018/ml)				
25 mg granules									. (2.50)
50 mg granules									. (3.00)
RTV		**Abbott**	**Aurobindo**	**Cipla**	**Hetero**	**Strides**			
100 mg caps	2	**83 (0.114)**	336 (0.460)	313 (0.429)	190 (0.260)	365 (0.500)			
80 mg / ml oral solution		**0.093/ml)**							
SQV		**Cipla**	**Hetero**	**Roche**	**Roche**				
				Cat 1	Cat 2				
200 mg hard caps	10	1825 (0.500)	996 (0.270)	**1051 (0.288)**	**2201 (0.603)**				
500 mg tabs	4			**968 (0.663)**	**2205 (1.51)**				
d4T		**Aurobindo**	**BMS**	**BMS**	**Cipla**	**Hetero**	**Matrix**	**Ranbaxy**	**Strides**
			Cat 1	Cat 2					
15 mg caps		**. (0.032)**	**. (0.082)**	**. (0.093)**	. (0.048)				
20 mg caps		**. (0.034)**	**. (0.094)**	**. (0.089)**	. (0.050)				
30 mg caps	2	**28 (0.039)**	**48 (0.066)**	**65 (0.089)**	39 (0.053)	20 (0.027)	**31 (0.042)**	**28 (0.039)**	**31 (0.042)**
40 mg caps	2	**29 (0.040)**	**55 (0.075)**	**65 (0.089)**	42 (0.057)	24 (0.033)	**34 (0.046)**	**34 (0.047)**	**33 (0.045)**
1 mg / ml powder for susp	20 ml	**73 (0.010/ml)**	**51 (0.007/ml)**	**58 (0.008/ml)**	146 (0.020/ml)				
5 mg granules									. (2.00)
10 mg granules									. (2.50)
TDF		**Cipla**	**Cipla**	**Gilead**	**Hetero**	**Matrix**			
		Cat 1	Cat 2						
300 mg tab	1	195 (0.534)	340 (0.932)	**207 (0.567)**	268 (0.733)	199 (0.546)			

AZT	Daily dose	Aurobindo	Cipla	GSK	Hetero	Matrix	Ranbaxy	Strides	
300 mg tab	2	**120 (0.165)**	**104 (0.142)**	**212 (0.290**	110 (0.150)	**110 (0.150)**	**115 (0.157)**		
100 mg caps		**. (0.110)**	**. (0.075)**	**. (0.158)**					
250 mg caps				**. (0.332)**					
10 mg / ml suspension	20ml	**95 (0.013/ml)**	**102 (0.014/ml)**	**263(0.036/ml)**					
25 mg granules								. (2.85)	
50 mg granules								. (3.36)	
ABC/3TC		**Cipla**	**GSK**						
300 mg / 600 mg tab	1	256 (0.700)	**678 (1.858)**						
3TC/d4T		**Aurobindo**	**Cipla**	**Hetero**	**Matrix**	**Ranbaxy**	**Strides**		
150 mg / 30 mg tab	2	72 (0.099)	**64 (0.088)**	91 (0.125)	73 (0.100)	**61 (0.083)**	61 (0.083)		
150 mg / 40 mg tab	2	74 (0.101)	**67 (0.092)**	93 (0.127)	79 (0.108)	**64 (0.088)**	**63 (0.087)**		
LPV/r		**Abbott**	**Abbott**	**Cipla**	**Hetero**	**Matrix**			
		Cat 1	Cat 2						
133 mg / 33 mg soft gel caps	6	**500 (0.228)**	**1000 (0.457)**	1338 (0.611)	1140 (0.520)				
200 mg / 50 mg tab	4	**500 (0.342)**	**1000 (0.457)**			1034 (0.708)			
80 mg / 20 mg / ml solution	4ml	**200 (0.137/ml)**	**400 (0.274/ml)**						
TDF/FTC		**Gilead**	**Matrix**						
300 mg/ 200 mg tab	1	**319 (0.875)**	274 (0.750)						
TDF/3TC		**Matrix**							
300 mg / 300 mg tab	1	237 (0.650)							
AZT/3TC		**Aurobindo**	**Cipla**	**GSK**	**Hetero**	**Matrix**	**Ranbaxy**	**Strides**	
300 mg / 150 mg tab	2	**140 (0.192)**	**134 (0.183)**	**237 (0.325)**	161 (0.220)	152 (0.208)	**140 (0.192)**	**170 (0.233)**	
3Tc/d4T/NVP		**Aurobindo**	**Cipla**	**Hetero**	**Matrix**	**Ranbaxy**	**Strides**		
30mg/ 6mg/ 50mg disp tab	4		158 (0.108)						
60mg/ 12mg/ 100mg disp tab	2		91 (0.125)						
20mg/ 5mg/ 35mg disp tab	5					104 (0.057)			
40mg/ 10mg/ 70mg disp tab	2.5					88 (0.096)			
150mg/ 30mg/ 200mg tab	2	139 (0.190)	**132 (0.181)**	**101 (0.138)**	119 (0.163)	**99 (0.135)**	121 (0.166)		
150mg/ 40mg/ 200mg tab	2	146 (0.200)	**140 (0.192)**	**104 (0.142)**	128 (0.175)	**101 (0.139)**	125 (0.171)		
TDF/FTC/EFV		**Matrix**	**Gilead/BMS/Merck**	**Gilead/BMS/Merck**					
			Cat 1	Cat 2					
300mg/ 200mg/ 600mg tab	1	487 (1.333)	613 (1.68)	1033 (2.83)					

TDF/3TC/EFV	Daily dose	Matrix							
300mg/300mg/600mg tab (FDC)	1	426 (1.167)							
AZT/3TC/ABC		**Aurobindo**	**Cipla**	**GSK**	**Hetero**	**Matrix**	**Ranbaxy**		
300mg/150mg/300mg tab (FDC)	2		548 (0.750)	852 (1.167)	730 (1.000)	548 (0.750)	639 (0.875)		
300mg/150mg + 300mg Co-pack	1 kit (4 tabs)	548 (1.500)							
AZT/3TC/NVP		**Aurobindo**	**Cipla**	**Hetero**	**Matrix**	**Ranbaxy**	**Strides**		
300mg/150mg/200mg tab (FDC)	2	**231 (0.317)**	231 (0.317)	194 (0.296)	199 (0.273)	223 (0.306)			
300mg/150mg+200mg Co-pack	1 kit (4 tabs)						**225 (0.616)**		
3TC/d4T + EFV (Co-blister)		**Cipla**	**Ranbaxy**						
150mg/ 30mg + 600mg	1 kit (3 tabs)	274 (0.750)	345 (0.945)						
150mg/ 40mg + 600mg	1 kit (3 tabs)	280 (0.767)	358 (0.980)						
AZT/3TC + EFV (Co-blister)		**Aurobindo**	**Cipla**	**Ranbaxy**	**Strides**				
150mg/ 300mg + 600mg	1 kit (3 tabs)	410 (1.125)	347 (0.950)	434 (1.190)	420 (1.15)				
NVP + AZT (Co-pack)		**Strides**							
6mg + 16mg granules	1 + 14	. (2.50)							
6mg + 16mg granules	1 + 56	. (4.70)							

Annexes

Annex 1: Least Developed Countries (LDCs)

Source: United Nations
http://www.un.org/special-rep/ohrlls/ldc/list.htm

Fifty countries are currently designated by the United Nations as least developed countries (LDCs).

Afghanistan; Angola; Bangladesh; Benin; Bhutan; Burkina Faso; Burundi; Cambodia; Cape Verde; Central African Republic; Chad; Comoros; Congo (Democratic Republic); Djibouti; Equatorial Guinea; Eritrea; Ethiopia; Gambia; Guinea; Guinea-Bissau; Haiti; Kiribati; Lao PDR; Lesotho; Liberia; Madagascar; Malawi; Maldives; Mali; Mauritania; Mozambique; Myanmar; Nepal; Niger; Rwanda; Samoa; São Tomé and Principe; Senegal; Sierra Leone; Solomon Islands; Somalia; Sudan; Timor-Leste; Togo; Tuvalu; Uganda; Tanzania; Vanuatu; Yemen; Zambia.

Annex 2: Human Development Index (HDI)

Source: United Nations Development Programme (UNDP)
http://hdr.undp.org/hdr2006/statistics/documents/hdi2004.pdf

The Human Development Index is published annually as a part of UNDP's annual Human Development Report.

Low human development:
Angola; Benin; Burkina Faso; Burundi;, Central African Republic; Chad; Congo (Democratic Republic); Côte d'Ivoire; Djibouti; Eritrea; Ethiopia; Gambia; Guinea; Guinea-Bissau; Haiti; Kenya; Lesotho; Malawi; Mali; Mauritania; Mozambique; Niger; Nigeria; Rwanda; Senegal; Sierra Leone; Tanzania; Togo;Yemen; Zambia; Zimbabwe..

Medium human development:
Albania; Algeria; Armenia; Azerbaijan; Bangladesh; Belarus; Belize; Bhutan; Bolivia; Botswana; Brazil; Cambodia; Cameroon; Cape Verde; China; Colombia; Comoros; Congo; Dominica; Dominican Republic; Ecuador; Egypt; El Salvador; Equatorial Guinea; Fiji; Gabon; Georgia; Ghana; Grenada; Guatemala; Guyana; Honduras; India; Indonesia; Iran; Jamaica; Jordan; Kazakhstan; Kyrgyzstan; Lao PDR; Lebanon; Libya; Macedonia; Madagascar; Maldives; Moldova; Mongolia; Morocco; Myanmar; Namibia; Nepal; Nicaragua; Pakistan; Palestinian Territories; Papua New Guinea; Paraguay; Peru; Philippines; Russian Federation; St. Lucia; St. Vincent and the Grenadines; Samoa; São Tomé and Principe; Saudi Arabia; Solomon Islands; South Africa; Sri Lanka; Sudan; Suriname; Swaziland; Syrian Arab Republic; Tajikistan; Thailand; Timor-Leste; Tunisia; Turkey; Turkmenistan; Uganda; Ukraine; Uzbekistan; Vanuatu; Venezuela; Viet Nam;

Annex 3: Sub-Saharan countries

Source: World Bank country classification
http://web.worldbank.org/WBSITE/EXTERNAL/DATASTATISTICS/0,,contentMDK:20421402~pagePK:64133150~piPK:64133175~theSitePK:239419,00.html#Sub_Saharan_Africa

Angola; Benin; Botswana; Burkina Faso; Burundi; Cameroon; Cape Verde; Central African Republic; Chad; Comoros; Congo; Congo (Democratic Republic); Côte d'Ivoire; Equatorial Guinea; Eritrea; Ethiopia; Gabon; Gambia; Ghana; Guinea; Guinea-Bissau; Kenya; Lesotho; Liberia; Madagascar; Malawi; Mali; Mauritania; Mauritius; Mayotte; Mozambique; Namibia; Niger; Nigeria; Rwanda; São Tomé and Principe; Senegal; Seychelles; Sierra Leone; Somalia;

South Africa; Sudan; Swaziland; Tanzania; Togo; Uganda; Zambia; Zimbabwe.

Annex 4: World Bank classification of economies

Source: World Bank
http://web.worldbank.org/WBSITE/EXTERNAL/DATASTATISTICS/0,,contentMDK:20421402~pagePK:64133150~piPK:64133175~theSitePK:239419,00.html

The list is updated every year on 1st July. This version is from 2006.

Low-income economies:
Afghanistan; Bangladesh; Benin; Bhutan; Burkina Faso; Burundi; Cambodia; Central African Republic; Chad; Comoros; Congo (Democratic Republic); Côte d'Ivoire; Eritrea; Ethiopia; Gambia; Ghana; Guinea; Guinea-Bissau; Haiti; India; Kenya; Korea (Democratic Republic); Kyrgyzstan; Lao PDR; Liberia; Madagascar; Malawi; Mali; Mauritania; Mongolia; Mozambique; Myanmar; Nepal; Niger; Nigeria; Pakistan; Papua New Guinea; Rwanda; São Tomé and Principe; Senegal; Sierra Leone; Solomon Islands; Somalia; Sudan; Tajikistan; Tanzania; Timor-Leste; Togo; Uganda; Uzbekistan; Viet Nam; Yemen; Zambia; Zimbabwe.

Lower middle-income economies:
Albania; Algeria; Angola; Armenia; Azerbaijan; Belarus; Bolivia; Bosnia and Herzegovina; Brazil; Bulgaria; Cameroon; Cape Verde; China; Colombia; Congo; Cuba; Djibouti; Dominican Republic; Ecuador; Egypt; El Salvador; Fiji; Georgia; Guatemala; Guyana; Honduras; Indonesia; Iran; Iraq; Jamaica; Jordan; Kazakhstan; Kiribati; Lesotho; Macedonia; Maldives; Marshall Islands; Micronesia; Moldova; Morocco; Namibia; Nicaragua; Paraguay; Peru; Philippines; Samoa; Serbia and Montenegro; Sri Lanka; Suriname; Swaziland; Syria; Thailand; Tonga; Tunisia; Turkmenistan; Ukraine; Vanuatu; West Bank and Gaza.

Upper middle-income economies:
American Samoa; Argentina; Barbados; Belize; Botswana; Chile; Costa Rica; Croatia; Czech Republic; Dominica; Equatorial Guinea; Estonia; Gabon; Grenada; Hungary; Latvia; Lebanon; Libya; Lithuania; Malaysia; Mauritius; Mayotte; Mexico; Northern Mariana Islands; Oman; Palau; Panama; Poland; Romania; Russian Federation; Seychelles; Slovakia; South Africa; St. Kitts and Nevis; St. Lucia; St. Vincent and the Grenadines; Trinidad and Tobago; Turkey; Uruguay; Venezuela.

Annex 5: Bristol-Myers Squibb eligible countries

Countries eligible for 1st price category:
Afghanistan; Angola; Bangladesh; Benin; Bhutan; Burkina Faso; Burundi; Cambodia; Cameroon; Cape Verde; Central African Republic; Chad; Comoros; Congo; Congo (Democratic Republic); Côte d'Ivoire; Djibouti; Equatorial Guinea; Eritrea; Ethiopia; Gabon; Gambia; Ghana; Guinea; Guinea-Bissau; Haiti; India; Kenya; Lao PDR; Liberia; Madagascar; Mali; Mauritania; Mauritius; Mongolia; Myanmar; Nepal; Nicaragua; Niger; Nigeria; Pakistan; Papua New Guinea; Rwanda; São Tomé and Principe; Senegal; Seychelles; Sierra Leone; Solomon Islands; Somalia; Sudan; Tanzania; Timor-Leste; Togo; Tuvalu; Uganda; Viet Nam; Yemen.

Countries eligible for 2nd price category (Southern African countries):
Botswana; Lesotho; Malawi; Mozambique; Namibia; South Africa; Swaziland; Zambia; Zimbabwe.

Annex 6: Abbott eligible countries

Source: Abbott's Access to HIV Care Program
http://www.abbott.com/static/content/document/aids_care.pdf

1st Category countries: Africa and LDC (as defined by UN)
Afghanistan; Algeria; Angola; Bangladesh; Benin; Bhutan; Botswana; Burkina Faso; Burundi; Cambodia; Cameroon; Cape Verde; Central African Republic; Chad; Comoros; Congo-Brazzaville; Côte d'Ivoire; Dem Rep of Congo; Djibouti; East Timor; Egypt; Equatorial Guinea; Eritrea; Ethiopia; Gabon; Gambia; Ghana; Guinea; Guinea-Bissau; Haiti; Kiribati; Kenya; Laos; Lesotho; Liberia; Libya; Madagascar; Malawi; Maldives; Mali; Mauritania; Mauritius; Morocco; Mozambique; Myanmar; Namibia; Nepal; Niger; Nigeria; Rwanda; Samoa; São Tomé and Principe; Senegal; Seychelles; Sierra Leone; Solomon Islands; Somalia; South Africa; Sudan; Swaziland; Tanzania;; Togo; Tunisia; Tuvalu; Uganda; Vanuatu; Yemen; Zambia; Zimbabwe.

2nd category countries Low Income economies (excluding Africa and the LDC as defined by the UN)
India, Kyrgyzstan, Mongolia, Pakistan, Papua New Guinea, Tajikistan, Uzbekistan, Vietnam

Lower Middle Income economies (excluding Africa and the LDC as defined by the UN)
Albania, Armenia, Azerbaijan, Belarus, Bolivia, Bosnia and Herzegovina, Brazil, China, Colombia, Dominican Republic, Ecuador, El Salvador, Fiji, Georgia, Guatemala, Guyana, Honduras, Indonesia, Jamaica, Jordan, Kazakhstan, Marshall Islands, Micronesia, Moldova, Nicaragua, Paraguay, Peru, Philippines, Serbia and Montenegro, Sri Lanka, Suriname, Syria, Thailand, The FYR-Macedonia, Tonga, Turkmenistan, Ukraine

Annex 7: Gilead eligible countries

Source: Gilead Access Program
http://www.gileadaccess.org/wt/page/countries

Afghanistan; Algeria; Angola; Antigua and Barbuda; Bahamas; Bangladesh; Barbados; Belize; Benin; Bhutan; Bolivia; Botswana; Burkina Faso; Burundi; Cambodia; Cameroon; Cape Verde; Central African Republic; Chad; Comoros; Congo; Congo (Democratic Republic); Côte d'Ivoire; Djibouti; Dominica; Dominican Republic; Egypt; Equatorial Guinea; Eritrea; Ethiopia; Gabon; Gambia; Ghana; Grenada; Guatemala; Guinea; Guinea-Bissau; Guyana; Haiti; Honduras; Indonesia; Jamaica; Kenya; Kiribati; Kyrgyzstan; Laos; Lesotho; Liberia; Libya; Madagascar; Malawi; Maldives; Mali; Mauritania; Mauritius; Moldova; Mongolia; Morocco; Mozambique; Myanmar; Namibia; Nepal; Nicaragua; Niger; Nigeria; Pakistan; Papua; New Guinea; Rwanda; St. Kitts and Nevis; St. Lucia ; St. Vincent and the Grenadines; Samoa; São Tomé and Principe; Senegal; Seychelles; Sierra Leone; Solomon Islands; Somalia; South Africa; Sudan; Suriname; Swaziland; Syria; Tajikistan; Tanzania; Timor-Leste; Togo; Trinidad and Tobago; Tunisia; Tuvalu; Uganda; Ukraine; Uzbekistan; Vanuatu; Viet Nam; Yemen; Zambia; Zimbabwe.

Annex 8: Suggested resources for further information:

For documentation on prices quoted by companies:
- Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries, 8th edition, June 2005, Médecins Sans Frontières http://www.accessmed-msf.org/documents/untanglingtheweb%208.pdf
- Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS (June 2005) http://www.who.int/medicines/areas/access/med_prices_hiv_aids/en/index.html-
Global HIV/Aids Epidemic Selection of Antiretroviral Medications Provided under U.S. Emergency Plan Is Limited, January 2005: http://pdf.dec.org/pdf_docs/Pcaab266.pdf

For documentation on prices reported by countries:
- WHO, AMDS, Global Price Reporting Mechanism for ARVs in Developing Countries
http://www.who.int/3by5/amds/price/hdd/
- The Global Fund Price Reporting Mechanism
http://www.theglobalfund.org/en/funds_raised/price_reporting/default.asp and
- Management Sciences for Health (MSH) International Drug Price Indicator Guide
http://erc.msh.org/mainpage.cfm?file=1.0.htm&id=1&temptitle=Introduction&module=DMP&language=English#top
- WHO AFRO region Essential Medicines Price Indicator
http://www.who.int/medicines/publications/afro-essential_med_price_indicator_nocover.pdf

For documentation on patents:
- "Determining the patent status of essential medicines in developing countries", Health Economies and Drugs, EDM Series No. 17, UNAIDS/WHO/MSF, 2004
- HIV/AIDS medicines and related supplies: Contemporary context and procurement. Technical guide. Chapter 2 and Annex B. World Bank, Washington, DC, 2004
http://siteresources.worldbank.org/INTPROCUREMENT/Resources/Technical-Guide-HIV-AIDS.pdf
"Drug patents under the spotlight. Sharing practical knowledge about pharmaceutical patents" MSF, June 2004

For documentation on quality:
- Prequalification project managed by the World Health Organization (WHO)
http://mednet3.who.int/prequal/
- US Food and Drug Administration (FDA) tentative approval
http://www.fda.gov/cder/ogd/approvals/

Other useful websites referenced in this document:
- International Dispensary Association (IDA) price indicator
http://www.idafoundation.org
- US Food and Drug Administration orange book
http://www.fda.gov/cder/ob/
- Catalogue of US Food and Drug Administration approved products, products documentation
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/
- WHO registration
http://ftp.who.int/htm/AMDS/drugsdatabase.pdf
- WHO HIV treatment guidelines for adults and adolescents
WHO Antiretroviral Therapy for HIV Infection in Adults and Adolescents in Resource-Limited Settings: Towards Universal Access: Recommendations for a public health approach 2006 version (in press). WHO Geneva 2006.
- WHO HIV treatment guidelines for Children
Antiretroviral therapy of HIV infection in infants and children in resource-limited settings: towards universal access: Recommendations for a public health approach 2006 (in press) WHO Geneva 2006.
- UNICEF website for procurement
- Biotechnology/Pharmaceuticals HIV/AIDS Industry Report - April 2005
http://www.aethlonmedical.com/pdfs/IndustryReport.pdf
- Clinton Foundation
http://www.clintonfoundation.org/
http://www.clintonfoundation.org/pdf/chai-arv-price-list-050807.pdf
- Access Campaign web site
http://www.accessmed-msf.org/

Annex 9: Company contacts

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Annex 10: The Clinton Foundation ARV list

CLINTON FOUNDATION

ANTIRETROVIRAL (ARV) PRICE LIST

The Clinton Foundation HIV/AIDS Initiative (CHAI) supports national governments to expand high-quality care and treatment to people living with HIV/AIDS. CHAI offers reduced prices for antiretrovirals (ARVs) to members of its Procurement Consortium.

SUPPLIERS & PRODUCTS

CHAI has agreements with seven manufacturers of ARV formulations, active pharmaceutical ingredients and/or pharmaceutical intermediates: Aspen Pharmacare, Cipla, Hetero Drugs, Matrix Laboratories, Mchem Pharma Group, Ranbaxy and Strides Arcolab. It also has commercial contracts with other suppliers of pediatric formulations. The ARVs included in CHAI's pricing agreements are: abacavir (ABC), didanosine (DDI), efavirenz (EFV), emtricitabine (FTC), lamivudine (3TC), lopinavir/ritonavir (LPV/r), nevirapine (NVP), stavudine (d4T), tenofovir (TDF) and zidovudine (AZT).

TERMS & CONDITIONS

Prices listed below are available to countries participating in the CHAI Procurement Consortium, which currently includes 66 nations. These prices apply to procurements using funding from local governments, the Global Fund and/or UNITAID which are conducted to support public care and treatment programs. Products should be purchased directly from partner suppliers or through procurement agents representing the aforementioned programs and funding sources. For pediatric formulations, some products (as indicated in the list) are available on the basis of CHAI acting as the procurement or sourcing agent. Access to CHAI prices assumes prompt payment following the shipment of orders. Requests to suppliers and/or tenders should reference membership in the CHAI Procurement Consortium but need not be restricted to CHAI partners.

PRICES

CHAI prices represent ceilings at or below which partner manufacturers – or CHAI itself, in the case of indicated pediatric formulations – will supply the specified products. Prices listed below are "Free on Board" (FOB) from the point of export, i.e. they do not include shipping and handling charges. Prices per year for pediatric formulations assume a 10 kg child.

QUALITY

CHAI is committed to the sustainable supply of high-quality ARVs, consistent with the specifications of dossiers approved by the World Health Organization (WHO) or a stringent regulatory authority such as the U.S. FDA. In the list below, footnotes specify the applicable quality standard for each formulation: (1) Listed by the WHO Prequalification Programme; (2) Approved by the U.S FDA; (3) Submitted to the WHO and/or FDA for review; (4) Pending submission to the WHO and/or FDA and manufactured at a facility compliant with Good Manufacturing Practice (GMP).

ADULT PRODUCT		Ceiling Price			Supplier					
Name and strength	Packaging	Per year	Per pack	Per pill	Aspen	Cipla	Hetero	Matrix	Ranbaxy	Strides
ABC (300mg)	HDPE bottle 60 tablets	$ 331	$ 27.58	$ 0.46				✓[1,2]		
ddI (250mg) [enteric-coated]	HDPE bottle 30 capsules	$ 156	$ 12.97	$ 0.43					✓[3]	
ddI (400mg) [enteric-coated]	HDPE bottle 30 capsules	$ 248	$ 20.65	$ 0.69					✓[3]	
EFV (200mg)	HDPE bottle 90 capsules	$ 240	$ 19.80	$ 0.22		✓[4]			✓[1]	✓[3]
EFV (600mg)	HDPE bottle 30 tablets	$ 164	$ 13.67	$ 0.46		✓[1,2]		✓[3]		
3TC+d4T+NVP (150/30/200mg)	HDPE bottle 60 tablets	$ 132	$ 10.80	$ 0.18		✓[1,2]	✓[1]	✓[3]	✓[1]	
3TC+d4T+NVP (150/40/200mg)	HDPE bottle 60 tablets	$ 140	$ 11.40	$ 0.19		✓[1,2]	✓[1]	✓[3]	✓[1]	
3TC+AZT+NVP (150/300/200mg)	HDPE bottle 60 tablets	$ 174	$ 14.50	$ 0.24		✓[1,2]		✓[4]		
3TC+AZT (150/300mg)	HDPE bottle 60 tablets	$ 129	$ 10.75	$ 0.18		✓[1,2]		✓[3]		
3TC (150mg)	HDPE bottle 60 tablets	$ 36	$ 3.00	$ 0.05		✓[1]		✓[1,2]		
3TC (300mg)	HDPE bottle 30 tablets	$ 36	$ 3.00	$ 0.10		✓[1]				
LPV/r (200/50mg) [heat-stable]	HDPE bottle 120 tablets	$ 695	$ 57.92	$ 0.48				✓[3]		
NVP (200mg)	HDPE bottle 60 tablets	$ 45	$ 3.75	$ 0.06		✓[1,2]		✓[3]		
d4T (30mg)	HDPE bottle 60 capsules	$ 36	$ 3.00	$ 0.05	✓[1]	✓[3]	✓[3]	✓[1,2]	✓[1]	✓[1,2]
d4T (40mg)	HDPE bottle 60 capsules	$ 45	$ 3.60	$ 0.06	✓[1]	✓[3]	✓[3]	✓[1,2]	✓[1]	✓[1,2]
TDF (300mg)	HDPE bottle 30 tablets	$ 149	$ 12.42	$ 0.41		✓[3]		✓[3]		
TDF+3TC (300/300mg)	HDPE bottle 30 tablets	$ 179	$ 14.92	$ 0.50		✓[4]		✓[3]		
TDF+FTC (300/200mg)	HDPE bottle 30 tablets	$ 225	$ 18.75	$ 0.63		✓[4]		✓[4]		
TDF+3TC+EFV (300/300/600mg)	HDPE bottle 30 tablets	$ 339	$ 28.25	$ 0.94				✓[4]		
TDF+FTC+EFV (300/200/600mg)	HDPE bottle 30 tablets	$ 385	$ 32.08	$ 1.07				✓[4]		
AZT (300mg)	HDPE bottle 60 tablets	$ 96	$ 8.00	$ 0.13		✓[1]		✓[3]		

PEDIATRIC PRODUCT		Ceiling Price			Supplier		
Name and strength	Packaging	Per year	Per pack	Per pill/ml	Via CHAI	Cipla	Ranbaxy
ABC (20mg/ml)	HDPE bottle 240ml	$ 210	$ 17.50	$ 0.073	✓[1,2]	✓[4]	
ddI (2g or 10mg/ml)	HDPE bottle 200ml	$ 72	$ 4.00	$ 0.020	✓[1,2]		
ddI (25mg)	HDPE bottle 60 tablets	$ 12	$ 0.50	$ 0.008		✓[4]	
ddI (50mg)	HDPE bottle 60 tablets	$ 12	$ 1.00	$ 0.017		✓[4]	
ddI (100mg)	HDPE bottle 60 tablets	$ 187	$ 7.80	$ 0.130	✓[1,2]	✓[4]	
ddI (150mg)	HDPE bottle 60 tablets	$ 211	$ 11.70	$ 0.195	✓[1,2]	✓[4]	
ddI (200mg)	HDPE bottle 60 tablets	$ 187	$ 15.60	$ 0.260	✓[1,2]	✓[4]	
EFV (50mg)	HDPE bottle 30 tablets	$ 30	$ 2.49	$ 0.083	✓[1,2]		
3TC+d4T+NVP (20/5/35mg)	HDPE bottle 60 tablets	$ 63	$ 2.70	$ 0.045			✓[3]
3TC+d4T+NVP (40/10/70mg)	HDPE bottle 60 tablets		$ 5.25	$ 0.088			✓[3]
3TC+d4T+NVP (30/6/50mg)	HDPE bottle 60 tablets	$ 54	$ 2.24	$ 0.037		✓[3]	
3TC+d4T+NVP (60/12/100mg)	HDPE bottle 60 tablets		$ 4.49	$ 0.075		✓[3]	
3TC (50mg/5ml)	HDPE bottle 240ml	$ 22	$ 1.80	$ 0.008	✓[1,2]	✓[1,2]	
NVP (50mg/5ml)	HDPE bottle 240ml	$ 44	$ 1.95	$ 0.008	✓[1,2]	✓[3]	
d4T (1mg/ml)	HDPE bottle 200ml	$ 49	$ 1.35	$ 0.007	✓[1,2]	✓[4]	
d4T (15mg)	HDPE bottle 60 capsules	$ 9	$ 1.50	$ 0.025	✓[1,2]	✓[4]	
d4T (20mg)	HDPE bottle 60 capsules	$ 11	$ 1.80	$ 0.030	✓[1,2]	✓[4]	
AZT (50mg/5ml)	HDPE bottle 240ml	$ 64	$ 2.15	$ 0.009	✓[1,2]	✓[1]	
AZT (100mg)	HDPE bottle 100 capsules	$ 39	$ 5.43	$ 0.054	✓[1,2]	✓[1]	
Cotrimoxazole (240mg/5ml)	HDPE bottle 60ml	$ 8	$ 0.21	$ 0.004		✓	
Cotrimoxazole (480mg)	HDPE bottle 100 tablets	$ 5	$ 0.70	$ 0.007		✓	

Notes & References

[1] To consult previous editions, please see www.accessmed-msf.org
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Glossary

3TC lamivudine; nucleoside analogue reverse transcriptase inhibitor

ABC abacavir; nucleoside analogue reverse transcriptase inhibitor

AIDS Acquired Immune Deficiency Syndrome

ARV Antiretroviral drug

ATV atazanavir; protease inhibitor

BI Boehringer-Ingelheim

BMS Bristol-Myers Squibb

CIF "Cost Insurance and Freight". A commercial term (incoterm) meaning that the seller delivers once the goods pass the ship's rail in the port of shipment. The seller must pay the costs and freight necessary to bring the goods to the named port of destination BUT the risk of loss or damage to the goods, as well as any additional costs due to events occurring after the time of delivery, are transferred from the seller to the buyer.

CIP "Carriage and Insurance paid to...". A commercial term (incoterm) meaning that the seller delivers the goods to the carrier nominated by him, but the seller must in addition pay the cost of carriage necessary to bring the goods to the named destination. This means that the buyer bears all the risks and any additional costs occurring after the goods have been delivered. However, in CIP the seller also has to procure insurance against the buyer's risk of loss of or damage to the goods during carriage. Consequently, the seller contracts for insurance and pays the insurance premium.

d4T stavudine; nucleoside analogue reverse transcriptase inhibitor

ddI didanosine; nucleoside analogue reverse transcriptase inhibitor

DDU "Delivered duty unpaid". A commercial term (incoterm) meaning that the seller delivers the goods to the buyer, not cleared for import, and not unloaded from any arriving means of transport at the named place of destination. The seller has to bear the costs and risks involved in shipping the goods, other than, where applicable, any 'duty' (which includes the responsibility for the risks of the carrying out of the customs formalities, and the payment of formalities, customs duties, taxes and other charges) for import in the country of destination. Such 'duty' has to be borne by the buyer as well as any costs and risks caused by his failure to clear the goods for the import time.

EC enteric-coated

EML Essential Medicines List. First published by WHO in 1977, it serves to identify a list of medicines, which provide safe and effective treatment for infectious and chronic diseases affecting the vast majority of the world's population. The 12th Updated List was published in April 2002 and includes twelve antiretrovirals.

EFV or **EFZ** efavirenz; non-nucleoside analogue reverse transcriptase inhibitor

EXW "Ex-works". A commercial term (incoterm) meaning that the seller delivers when he places the goods at the disposal of the buyer at the seller's premises or another named place (i.e. works, factory, warehouse etc.) not cleared for export and not loaded on any collecting vehicle.

FOB "Free on board". A commercial (incoterm) term meaning that the seller delivers when the goods pass the ship's rail at the named port of shipment. This means that the buyer has to bear all costs and risks of loss or damage to the goods from that point. The FOB term requires the seller to clear the goods for export.

FDC fixed-dose combination - several drugs combined in a single pill

FTC emtricitabine; nucleoside analogue reverse transcriptase inhibitor

Generic drug According to WHO, a pharmaceutical product usually intended to be interchangeable with the originator product, which is usually manufactured without a license from the originator company.

GPRM WHO Global Price Reporting Mechanism is a database containing prices paid by UNICEF, the International Dispensary Association (IDA), Management Sciences for Health (MSH)/Deliver, and the Global Fund to Fight AIDS, Tuberculosis and Malaria.

GSK GlaxoSmithKline

HDI Human Development Index. A summary composite index, compile by UNDP, that measures a country's average achievements in three basic aspects of human development: longevity (or life expectancy at birth), knowledge (or adult literacy rate and enrolment in education), and a decent standard of living (gross domestic product per capita).

HIV Human Immunodeficiency Virus

IDV indinavir; protease inhibitor

LDCs Least Developed Countries, according to United Nations classification

LPV/r Lopinavir/ritonavir; boosted protease inhibitor

MSD Merck Sharp & Dome (Merck & Co., Inc.)

MSF Médecins Sans Frontières

NDRA National Drug Regulatory Authority

NGO Non-Governmental Organisation

NFV nelfinavir; protease inhibitor

NNRTI Non-Nucleoside Reverse Transcriptase Inhibitor

NRTI Nucleoside Analogue Reverse Transcriptase Inhibitor

NtRTI Nucleotide Reverse Transcriptase Inhibitor

NVP nevirapine; non-nucleoside analogue reverse transcriptase inhibitor

OAPI Organisation Africaine de la Propriété Intellectuelle, African Intellectual Property Organisation, whose member states are Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Gabon, Guinea, Guinea-Bissau, Equatorial Guinea, Mali, Mauritania, Niger, Senegal, Togo.

PEPFAR President's Emergency Plan for AIDS Relief, a United States programme to fight HIV/AIDS in developing countries

PI protease inhibitor

PLWHA People Living With HIV/AIDS

PMTCT Prevention of Mother-to-Child Transmission

ppy per patient per year

R&D Research and Development

RTV ritonavir, protease inhibitor

r low-dose ritonavir, used as a booster

SQV saquinavir; protease inhibitor

TDF tenofovir disoproxil fumarate; nucleotide reverse transcriptase inhibitor

TRIPS Trade-Related aspects of Intellectual Property Rights

UNAIDS United Nations Joint Cosponsored Programme on HIV/AIDS, created in 1996, to lead, strengthen and support an expanded response to the HIV/AIDS epidemic. The six original cosponsors are UNICEF, UNDP, UNFPA, UNESCO, WHO and the World Bank. UNDCP joined in April 1999.

UNDP United Nations Development Programme

US FDA United States Food and Drug Administration

VL Voluntary license

WHO World Health Organization

WHO GPRM WHO Global Price Reporting Mechanism

WTO World Trade Organization

ZDV zidovudine; nucleoside analogue reverse transcriptase inhibitor

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