Untangling the web of price reductions:
A Pricing Guide for the Purchase of ARVs for Developing Countries

9th Edition

July 2006 (Revised)
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**Untangling the Web of Price Reductions**
BACKGROUND

This is the ninth edition of "Untangling the Web of Price Reductions: A Guide for the Purchase of ARVs for Developing Countries." The report was first published by Médecins Sans Frontières (MSF) in October 2001 in response to the lack of transparent and reliable information about prices of pharmaceutical products on the international market—a factor which significantly hampers 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 antiretroviral drugs. It is not intended to be a guide for the purchase of ARVs for ARVs.

In the absence of competition, pharmaceutical companies may charge prohibitive prices. This is particularly the case for the most recent ARVs, including those recommended in the 2006 WHO treatment guidelines for both first- and second-line medications. Since the first edition of "Untangling," the effects of generic competition have been significant in driving prices down.

Graph 1 provides a good illustration of how prices charged by originator manufacturers have fallen as generic competitors enter the market. This graph shows the lowest world prices charged per patient per year for three ARVs: efavirenz, zidovudine, and lamivudine.

Graph 2 illustrates that for the lowest world prices per patient per year, the effects of generic competition have been significant. This graph shows the lowest world prices charged per patient per year for three ARVs: efavirenz, zidovudine, and lamivudine.
Untangling the Web of Price Reductions

Graph 2: Average weighted prices paid in 2005, reported to WHO GPRM for second-line ARVs in low- and middle-income countries, compared with first-line regimens

- Note: the price of US$ 132 quoted ... companies. In this graph, US$ 144 is the 2005 average weighted price reported to WHO GPRM as actually paid by countries.

In the absence of competition, the price of treatment based on these second-generation ARVs is currently extremely high.

Improved first-line treatment

Whereas most of the regimens previously recommended included stavudine (d4T) or zidovudine (AZT), the 2006 WHO treatment guidelines include second-generation ARVs for both first- and second-line treatment. In the absence of competition, the price of treatment based on these second-generation ARVs is currently extremely high.

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 treatment for an adult for one year in a developing country from US$ 132 (with the triple fixed-dose combination 3TC/d4T/NVP) to:

- at the very least, US$ 321, which is two and a half times more. This assumes that Gilead’s advertised differential prices for TDF can be obtained, and that countries choose to purchase the cheapest WHO-prequalified generics for 3TC and NVP.

- up to US$ 708, which is almost five and a half times more. This assumes the originator’s advertised differential prices can be obtained for all three drugs. If they cannot be obtained, the price would be higher still.

Scaling up treatment to one million people with this improved regimen would therefore imply an extra financial burden of between US$ 189 million and US$ 576 million.

Second-line treatment

It is estimated that 5-10% of a patient cohort in a given year will need to move from first- to second-line treatment. Data from an MSF project in South Africa shows that 16.7% of patients were on a second-line regimen after 48 months.

As more and more patients will need to move to second-line regimens, the impact of these prices on the financial sustainability of AIDS programmes is devastating. Switching one-tenth of patients in a given country in Africa to a second-generation ARV regimen after 48 months would double the price paid in low-income countries, compared with WHO GPRM for the previous generation.

Patent barriers

Although least-developed countries, such as India, are a major source of WHO-prequalified generic antiretrovirals, with significant manufacturing capacity, January 2005’s decision by the World Trade Organization (WTO) to end its在过渡期 (10Y.P) 2000-2005, 2010-2015, this period ended in 2006. The new WHO guidelines have addressed this change, by:

- Mechanism (GPRM database): WHO-GPRM price reporting, according to the combination, second-line regimens, and the WHO average weighted price paid in low-income countries.
- Graph 2: Illustrates this change, by the costs of drugs for the national budget.

The price paid for TDF can be double the price paid in low-income countries, compared with the previous generation. While the price of TDF is almost five and a half times more, this assumes that Gilead’s advertised differential prices for TDF can be obtained, and that countries choose to purchase the cheapest WHO-GPRM price-reporting price paid in low-income countries, where the accompanying fixed-dose ARV combination (EFV/NVP) is less expensive than the fixed-dose combination (ABC/3TC/NVP).

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which were required to introduce new pharmaceutical patent legislation. 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. India was therefore required to change its patent legislation in 2005. The new 2005 Indian Patents Act does not affect medicines that were invented before 1995. To examine the thousands of pending patent applications, and patents on key AIDS medicines may subsequently 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 continue to produce, and market 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 it compulsory to produce, and market, the medicine at an affordable price.

These TRIPS flexibilities, however, remain underused. Least Developed Countries still continue to purchase unnecessarily expensive originator products, when cheaper generic versions are available. The Doha Declaration was a milestone in its affirmation of the primacy of public health interests in the application of intellectual property rights protection. Member States of the World Trade Organization classified as "Least Developed" are authorised, under paragraph 7 of the Doha Declaration, to not recognise, and the public health interests in the production of new medicine, but generic versions were granted a license allowing the production of new medicine. member States of the World Trade Organization (WTO) of the Agreement to apply. WTO members are therefore required to introduce new

Some recent examples include:

■ Purchases of nevirapine 200 mg illustrated in the WHO Global Price Reporting Mechanism (GPRM) summary report issued in March 2006 [4], which shows how "low-income countries paid on average US$ 219 per patient-year (even more than middle-income countries, at US$ 112) as 40.5% of medicines were still under patent in Kenya and in other several low-income countries or regions such as Malawi, Uganda, Zambia, Zimbabwe and most francophone African countries."■ Purchases of older ARVs such as lamivudine/zidovudine, for which GPRM data shows that many countries purchased the originator product at prices ranging from more than US$ 270 in South Africa or Sudan, to US$ 60 per patient per year in Kenya and in other several low-income countries. The public health interests in the production of new medicine may be subordinated by purchase of patented pharmaceuticals, and patents on key AIDS applications, and patents on key AIDS pharmaceuticals, with "reasonable" costs, and increase the production of new medicine, but generic versions were granted a license allowing the production of new medicine. member States of the World Trade Organization (WTO) of the Agreement to apply. WTO members are therefore required to introduce new

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Untangling the Web of Price Reductions and using generic versions of medicines under patent protection through the granting of a compulsory licence or government use. Countries should proactively make use of these provisions and donor countries and agencies should actively encourage countries to use the TRIPS safeguards to ensure that already scarce resources are not wasted on the purchase of overpriced products.

Graph 3 below shows how middle-income countries are paying extra-high prices for ARVs. Without competition, the price of ARVs is prohibitive, and limitations imposed by companies to accessing the lowest price lead to huge discrepancies among developing countries with a sort of mixed criteria, the mean that it is a country can have some middle-income countries with up to nine times more, for new ARVs such as LPV/r in low-income countries, and even up to nine times more, for second generation ARVs is prohibitive, and countries with highest prevalence of ARVs.

Box 2: Limiting the Scope of patentability

Graph 2, and Graph 3 below both show how middle-income countries are paying extra-high prices for ARVs.

Graph 3: Brand and country premium: example of prices paid by developing countries for ARVs

WHO GPRM Average prices paid in 2005

<table>
<thead>
<tr>
<th>Brand</th>
<th>Low-income countries</th>
<th>Middle-income countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>3TC+d4T(30)+NVP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3TC+AZT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EFV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABC 300mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ddl EC 400mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TDF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RTV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LPV/r</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Average prices paid by low-income countries:

- 3TC+d4T(30)+NVP: $5000
- 3TC+AZT: $4500
- EFV: $4000
- ABC 300mg: $3500
- ddl EC 400mg: $3000
- TDF: $2500
- RTV: $2000
- LPV/r: $1500

Average prices paid by middle-income countries:

- 3TC+d4T(30)+NVP: $5000
- 3TC+AZT: $4500
- EFV: $4000
- ABC 300mg: $3500
- ddl EC 400mg: $3000
- TDF: $2500
- RTV: $2000
- LPV/r: $1500

Most originator companies offer their most discounted prices only to a certain group of countries, usually Least Developed Countries and sub-Saharan Africa. There are two issues here: the marketing and registration of products, and complexity of companies' access programmes.

Box 2: Limiting the scope of patentability

On a more positive note, the Indian Patents Act includes key provisions to ensure that patents are not used to extend monopolies on medicines artificially at the expense of the public. Firstly, a provision allows a citizen of India to oppose a patent before it is granted. This is known as the ‘opposition period’. Secondly, if a patent is granted, a citizen of India may challenge the validity of the patent in court. These are known as ‘nullity action’. If a patent is declared invalid, the company loses its monopoly and other companies can produce the same product.

Government use

The government of a compulsory licence or where an essential public interest is claimed, can purchase the product for the public at a low price, without licence fees.

Without competition from other companies, the price of new ARVs is prohibitive, and limitations imposed by companies to accessing the lowest price lead to huge discrepancies among developing countries with the highest prevalence of ARVs. In all Africa, the highest prevalence rate is found in South African countries, and this is reflected in the prices charged by originator companies. Most of the originator companies establish a country premium, thereby excluding patients in some developing countries.

When originator companies apply discounted prices on ARVs, each has different eligibility criteria, which is a considerable source of confusion for purchasers. Most originator companies offer their most discounted prices only to a certain group of countries, usually Least Developed Countries and sub-Saharan Africa. These prices are most discounted prices only to a certain group of countries, usually Least Developed Countries and sub-Saharan Africa. These prices are:

- Merck: offers differential prices for their products to all Global Fund grantees.
- GlaxoSmithKline: offers differential prices for their products to all Global Fund grantees.
- Gilead: has established its own list of eligible countries with a sort of mixed criteria, including some middle-income countries. When ARVs were introduced, Gilead’s list was much shorter, and only included countries with high HIV prevalence rates. As ARVs became more available, Gilead expanded its list of eligible countries. Gilead offers differential prices for their products to all Global Fund grantees.
- Pharmacia: offers differential prices for their products to all Global Fund grantees.

There are two issues here: the marketing and registration of products, and complexity of companies’ access programmes. The marketing and registration of products, and complexity of companies’ access programmes.
Marketing and registration

Registration of a medicine allows it to be marketed in a country after evaluation of the product dossier by the relevant authorities. This process involves several steps: submission of the dossier, evaluation by the regulatory authority, and approval. Once a medicine is registered, it can be sold only in the country where it has been registered. Applications must come from manufacturers or their representatives in each country.

Nevertheless, some companies continue to ignore the marketing and registration of their products. This is particularly true for some of the newer ARVs, which are still being introduced into the market. Many companies are not registering their products in all countries, even in those with high prevalence of HIV/AIDS.

The consequences of not registering a drug are obvious in terms of access. For example, Gilead's TDF is registered in thirteen of the 97 countries that have reported cases of HIV/AIDS. The problem is compounded by the fact that National Drug Regulatory Authorities' procedures for registering the products are often slow, even in countries that are considered to be in the same region, such as Sub-Saharan Africa. This can delay the availability of the drug in these countries.

MSF's experience purchasing TDF directly from manufacturers has shown that obtaining such authorizations to import non-registered drugs can be extremely complex and time-consuming. The process involves extensive paperwork, which can take months or even years, depending on the procedures of the relevant authorities.

The pace of registration of ARVs, including generic formulations as they become available, is of critical importance. It is strongly recommended for public health, based on WHO guidance, that new products of relevant interest for resource-limited settings be placed in prequalification, allowing for faster approval and distribution.

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Pharmaceutical companies are not investing enough resources in the development of appropriate paediatric formulations, since it is a small market and new formulations are not seen as a priority in wealthier countries, where prevention of mother-to-child transmission is largely successful.

A limited number of generic paediatric triple fixed-dose combinations are currently reaching the market, however, and pressure should be put on these manufacturers to develop disease-appropriate products, since these are not always available to children. 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. WHO should give clear recommendations to manufacturers on dosages for children, and work proactively to ensure that these are followed by generic manufacturers.

PATENTS

Past campaigns to challenge the use of patents have been ill-focused and have failed. Cipla and Ranbaxy are developing formulations of 3TC/d4T/NVP at different dosages. WHO should ensure that these measures are followed by generic manufacturers and that the appropriate fixed-dose combinations are developed.

FINAL CONSIDERATIONS

According to UNAIDS, an estimated 250,000 to 350,000 deaths were averted in 2005 because of expanded access to antiretrovirals. Of these, more than 90% were children. These deaths are the result of delays in accessing paediatric medicines, which are still not available in many countries and are often unavailable to those who need them. Patients should no longer be a barrier to accessing antiretrovirals.

The completion of the paediatric formulations needed to help manufacturers speed up the development of new formulations is crucial. Support should be given to help manufacturers develop and manufacture these products, by outlining the requirements needed for the WHO prequalification project and encouraging the development of paediatric formulations.
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 18th May 2006.

All originator companies marketing ARVs were included in the survey. But the list of generic producers is by no means exhaustive. Indeed, only those generic companies having at least one antiretroviral prequalified by WHO 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.

- 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). Prices quoted by all generic companies, plus 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 US General Accountability Office, these differences do not undermine their essential comparability.

- 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. But occasionally generic companies may negotiate prices different from those quoted here.

- The Clinton HIV/AIDS Initiative 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 five ARVs manufacturers to lower the prices of 20 ARV formulations. When these prices differ significantly from those quoted in the survey by companies, they are mentioned in the product card.

- 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)
Untangling the Web of Price Reductions

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. The lowest price per patient is considered for the graph. If no generic is WHO prequalified yet, the lowest possible price is taken into account.

Chart 2: Transaction prices of ARVs purchased in developing countries as compiled by WHO GPRM 2005-2006

This chart gives examples of transaction prices of ARVs purchased in some developing countries, as compiled by WHO/AHIS Global Price Reporting Mechanism (GPRM) and other global mechanisms. This chart does not represent the price paid by consumers, with which might be higher (due to, e.g., transport cost). The chart represents the transaction price as quoted to the GPRM.

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 assisting informed decision-making. Each country level section includes the problems and obstacles that may be encountered when trying to gain access to a product, and at the best price.

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 appendices.

How to read the product cards?

General Information:

For each of the ARVs’ general information on the history of the product and development of their price, please refer to table 2 and the list of countries for each category given in the appendices. For paediatric treatments, prices are calculated for a 20 kg child using WHO treatment guidelines. This is an estimate since the weight of a child increases during any given year. It was not possible to calculate the dose for a 20 kg child in this scenario, so the smallest unit is included in brackets.

Table 1: Prices quoted by companies for eligible developing countries

For each category, the annual cost of treatment per patient (cpp) 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.

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July 2006 (Revised)
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):** [17]
- **World sales of originator product:** US$ 290 million in 2004 [19]

**Price information:**

<table>
<thead>
<tr>
<th>Month</th>
<th>lowest originator price</th>
<th>generic price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct 01</td>
<td>636 (0.871)</td>
<td>none</td>
</tr>
<tr>
<td>Jan 02</td>
<td>394 (0.597)</td>
<td>668 (0.975)</td>
</tr>
<tr>
<td>Dec 02</td>
<td>394 (0.597)</td>
<td>696 (1.032)</td>
</tr>
<tr>
<td>May 03</td>
<td>394 (0.597)</td>
<td>696 (1.032)</td>
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<td>696 (1.032)</td>
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<td>Apr 04</td>
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<td>Feb 05</td>
<td>2628 (4.009)</td>
<td>564 (0.810)</td>
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<td>Jun 05</td>
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<td>511 (0.770)</td>
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<tr>
<td>Jun 06</td>
<td>511 (0.770)</td>
<td>564 (0.810)</td>
</tr>
</tbody>
</table>

Note: the Clinton Foundation has agreed with Cipla to sell ABC 300 mg at US$ 447 per patient per year in countries included in their program since 2002.

**Chart 1:** Evolution of the lowest price quoted for eligible developing countries since 2001

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

<table>
<thead>
<tr>
<th>Eligibility restrictions</th>
<th>ABC 300 mg tablets</th>
<th>ABC 300 mg oral solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>336 mg (0.517)</td>
<td>336 mg (0.517)</td>
<td>604 (0.924)</td>
</tr>
<tr>
<td>772 mg (0.695)</td>
<td>496 mg (0.862)</td>
<td>696 (1.032)</td>
</tr>
<tr>
<td>549 mg (0.870)</td>
<td>696 (1.032)</td>
<td>1387 (2.071)</td>
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<td>2628 (4.009)</td>
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<td>727 mg (0.975)</td>
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<td>949 mg (1.475)</td>
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<td>none</td>
</tr>
<tr>
<td>394 mg (0.597)</td>
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<tr>
<td>564 mg (0.810)</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>696 mg (1.032)</td>
<td>daily dose 650 mg</td>
<td>650 mg (1.032)</td>
</tr>
<tr>
<td>696 mg (1.032)</td>
<td>696 mg (1.032)</td>
<td>1387 (2.071)</td>
</tr>
<tr>
<td>1387 mg (2.071)</td>
<td>1387 mg (2.071)</td>
<td>2628 (4.009)</td>
</tr>
<tr>
<td>2628 mg (4.009)</td>
<td>2628 mg (4.009)</td>
<td>564 (0.810)</td>
</tr>
</tbody>
</table>

**Spotlight on access issues:**

There is a need for greater competition between manufacturers to reduce prices further. The current lowest price for the originator product, at US$ 636, is almost five times the price of the triple FDC used in most first-line regimens today.

In addition, because of GSK's eligibility restrictions, only eligible Indian producers of abacavir that are not funded by the Global Fund, have no access to the lowest price for the GSK product.

Although the abacavir molecule was developed in the 1980's, GSK applied for patents in 1997 on abacavir sulphate. This may hamper generic competition. If the Indian patent office grants a patent, Indian manufacturers may lose their products from the market, unless they can make use of the automatic licensing provisions of the 2005 India Patents Act (see introduction). Indian NGOs and manufacturers may, however, seek to oppose the granting of this patent in India.

Abacavir was included as part of first-line NRTI backbone in most recent WHO recommendations for paediatric treatment. no company has yet developed a child-friendly version.

Although abacavir was included as part of first-line NRTI backbone in most recent WHO recommendations for paediatric treatment, no company has yet developed a child-friendly version.

**Eligibility restrictions**

- ABC 300 mg tablets
- ABC 20 mg/ml oral solution

- Daily dose: 650 mg
- 650 mg (1.032)
- 1387 mg (2.071)
- 2628 mg (4.009)
- 336 mg (0.517)
- 564 mg (0.810)
- 696 mg (1.032)
- 772 mg (0.695)
- 949 mg (1.475)
- 496 mg (0.862)
- 549 mg (0.870)
**Spotlight on access issues:**

Atazanavir is one of the three protease inhibitors recommended by WHO for second-line treatment and is the most patient-friendly PI as its administration requires an intake of only two 150mg pills a day. But its price, at more than US$6,125 per adult patient per year in rich markets, is prohibitive for developing countries. Moreover, it must be combined with ritonavir as a booster so the final cost when compared with other PIs is prohibitive.

The Indian Government is willing to grant compulsory licenses to Indian manufacturers of all PIs for governmental use, but, the process is complex and time-consuming. Moreover, if the patent is rejected by the Indian patent office or if India's National Drug Authority issues a compulsory license, the original manufacturer may still file an opposition to the patent application.

**World sales of originator product:**
- ATZ is one of the three PIs recommended by WHO for second-line treatment, and is the most patient-friendly PI as its administration requires an intake of only two 150mg pills a day.
- ATZ is not included in the WHO Model List of Essential Medicines.

**First approval by US Food and Drug Administration (FDA):**
- 20th June 2003

**Patent protection:**
- ATZ was patented in 1997 in many countries, including India, but the patent is challenging in India's National Drug Authority.
- ATZ was patented in India in 1997, but the Indian government is willing to grant compulsory licenses to Indian manufacturers for governmental use.

**General Information:**

**ATZ (Atazanavir):**
- Therapeutic class: HIV-1 protease inhibitor
- Administered as an oral suspension or tablet
- Indicated for adults and adolescents with WHO stage 4 disease
- Combination therapy with ritonavir as a booster
- Available in 150 mg tablets for oral administration
- Renal clearance is not affected by ATZ
- No drug interactions with ATZ

**Product information:**
- Bristol-Myers Squibb (BMS)
- Brand name: Reyataz
- Marketed in many countries

**Access issues:**
- Legislation in many countries: India
- Challenges in obtaining patent protection
- Prohibitive cost for developing countries
Untangling the Web of Price Reductions

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

**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)**
- **Originator company, and product brand name:** Bristol-Myers Squibb (BMS), Videx
- **First approval by US Food and Drug Administration (FDA):** October 1991 for chewable tablets; October 2000 for enteric-coated tablets
- **Included in the WHO Model List of Essential Medicines (EML)**
- **World sales of originator product:** US$ 274 million in 2004 (in 1999, the figure was already US$ 205 million)
- **Didanosine was developed by the National Institutes of Health (NIH), a US government research institute, which then licensed the drug to Bristol-Myers Squibb, in exchange for a 5 to 6% royalty on sales**
- **NIH basic patents on didanosine are supposed to expire in the US in 2006-2007, but BMS holds patents on improved formulations, which run until 2012 and 2018.**

**Spotlight on access issues:**
- The Bristol-Myers Squibb list of eligible countries is too limited, as it only includes 66 countries, and the product is not always available in the countries defined as eligible. Additionally, BMS has no pricing policy for middle-income countries. For instance, according to the WHO GPRM database in 2005, in El Salvador, where there is no competition, purchasers paid US$ 1,533 per patient per year for the originator 100 mg formulation (five times the price fixed by BMS in eligible countries). In neighboring Honduras, where there is competition between the originator and generic alternatives, the same report lists the price charged by BMS at US$ 429 per patient per year.

**Chart 1: Evolution of the lowest price quoted for developing countries since 2001**

As of June 2006, there was no WHO prequalified generic source of didanosine 400 mg. The lowest available generic price is therefore given here.

In the absence of strong competition, originator prices have not changed in the last five years.

**Chart 2: Evolution of the lowest price quoted for developing countries since 2001**

Price reductions:

<table>
<thead>
<tr>
<th>ddI 400 mg EC</th>
<th>lowest originator price</th>
<th>lowest generic price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current price</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>2001 (US$)</td>
<td>709</td>
<td>2002 (US$)</td>
</tr>
<tr>
<td>2002 (US$)</td>
<td>575</td>
<td>2003 (US$)</td>
</tr>
<tr>
<td>2003 (US$)</td>
<td>333</td>
<td>2004 (US$)</td>
</tr>
<tr>
<td>2004 (US$)</td>
<td>223</td>
<td>2005 (US$)</td>
</tr>
<tr>
<td>2005 (US$)</td>
<td>140</td>
<td>2006 (US$)</td>
</tr>
</tbody>
</table>

**Spotlight on access issues:**

- In the absence of strong competition, originator prices have not changed in the last five years.

**Table 2: Eligibility restrictions for Didanosine (ddI)**

<table>
<thead>
<tr>
<th>Eligibility restrictions</th>
<th>Price information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randhay</td>
<td>See table 2</td>
</tr>
<tr>
<td>Hetere</td>
<td>See table 2</td>
</tr>
<tr>
<td>Chipa</td>
<td>See table 2</td>
</tr>
<tr>
<td>Angola</td>
<td>Amyva</td>
</tr>
<tr>
<td>Vietnam</td>
<td>BMS</td>
</tr>
<tr>
<td>Burundi</td>
<td>Swiss</td>
</tr>
<tr>
<td>Nicaragua</td>
<td>Swiss</td>
</tr>
<tr>
<td>Armenia</td>
<td>Swiss</td>
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<tr>
<td>Azerbaijan</td>
<td>Swiss</td>
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<tr>
<td>Australia</td>
<td>Swiss</td>
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<td>Belarus</td>
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<td>Swiss</td>
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<td>Hungary</td>
<td>Swiss</td>
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<td>Iceland</td>
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<td>India</td>
<td>Swiss</td>
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<td>Swiss</td>
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<td>Ireland</td>
<td>Swiss</td>
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<td>Kazakhstan</td>
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<td>Panama</td>
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<td>Peru</td>
<td>Swiss</td>
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<td>Philippines</td>
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<td>Poland</td>
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<td>Portugal</td>
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<td>Romania</td>
<td>Swiss</td>
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<tr>
<td>Russia</td>
<td>Swiss</td>
</tr>
<tr>
<td>Saint Vincent and the Grenadines</td>
<td>Swiss</td>
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<tr>
<td>Senegal</td>
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<td>Slovakia</td>
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<td>Spain</td>
<td>Swiss</td>
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<td>Sri Lanka</td>
<td>Swiss</td>
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<td>Suriname</td>
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<td>Syria</td>
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<td>Taiwan</td>
<td>Swiss</td>
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<tr>
<td>Thailand</td>
<td>Swiss</td>
</tr>
<tr>
<td>Trinidad and Tobago</td>
<td>Swiss</td>
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<td>Turkey</td>
<td>Swiss</td>
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<td>Tunisia</td>
<td>Swiss</td>
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<td>Ukraine</td>
<td>Swiss</td>
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<tr>
<td>United Arab Emirates</td>
<td>Swiss</td>
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<tr>
<td>United Kingdom</td>
<td>Swiss</td>
</tr>
<tr>
<td>Uruguay</td>
<td>Swiss</td>
</tr>
<tr>
<td>Venezuela</td>
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<td>Vietnam</td>
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<tr>
<td>Yemen</td>
<td>Swiss</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>Swiss</td>
</tr>
</tbody>
</table>
Untangling the Web of Price Reductions

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) [17]
• World sales of originator product: US$ 621 million in 2004 [19]. In 2004, EFV was the most prescribed ARV in the US, representing 65% of all NNRTIs prescriptions.

Efavirenz was developed by Dupont Pharma and is now marketed by BMS. Merck has the marketing license in several countries.

Spotlight on access issues:

Efavirenz is a key drug for first-line treatment. Although EFV has been marketed for a considerable period already, its price is still very high. Alone, it is priced at more than twice the price of the most widely used triple (stavudine, lamivudine and efavirenz).

There is an urgent need to have fixed-dose combinations including efavirenz that could simplify the new WHO recommended treatment.

The price of the lowest WHO prequalified generic of EFV is given here.

The price of the lowest WHO prequalified generic of EFV is given here.

<table>
<thead>
<tr>
<th>Country</th>
<th>EFV 50 mg capsule</th>
<th>EFV 200 mg capsule</th>
<th>EFV 600 mg tablet</th>
<th>EFV 30 mg/ml suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aurobindo</td>
<td>394 (0.360)</td>
<td>277 (0.760)</td>
<td>309 (0.094)</td>
<td>394 (0.360)</td>
</tr>
<tr>
<td>Merck</td>
<td>821 (0.750)</td>
<td>697 (1.910)</td>
<td>496 (0.151)</td>
<td>821 (0.750)</td>
</tr>
<tr>
<td>Cipla</td>
<td>462 (0.109)</td>
<td>299 (0.820)</td>
<td>227 (0.069)</td>
<td>292 (0.267)</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>217 (0.597)</td>
<td>217 (0.597)</td>
<td>217 (0.597)</td>
<td>217 (0.597)</td>
</tr>
<tr>
<td>Strides</td>
<td>920 (0.092)</td>
<td>920 (0.092)</td>
<td>920 (0.092)</td>
<td>920 (0.092)</td>
</tr>
</tbody>
</table>

Note: the Clinton Foundation has agreed with Aspen, Cipla, Ranbaxy, and Strides to sell EFV 600 mg at the price of US$ 600, and EFV 200 mg at the price of US$ 240 per patient per year.


daily

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

Eligibility restrictions

- None
- None
- See table 2
- Any 2
- Mtrk
- Daily
- None, None, None, None

General Information

Efavirenz (EFV)
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
- World sales of originator product: US$ 75.6 million in 2004
- Not included in the WHO Model List of Essential Medicines (EML[2])
- 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[28].
- Patents on the basic molecule are due to expire in 2010-2011[28].

Spotlight on access issues:

Emtricitabine is neither registered nor marketed in developing countries, but is available co-formulated with TDF when making the choice. It should be taken into account that there are potential intellectual property issues that could affect this product in countries in need, while its older therapeutic equivalent, lamivudine (which has the same indications and profile), could be free of such restrictions.

[17] WHO Model List of Essential Medicines
[26] US$ 10 million in 2003 (in five months)
[27] US$ 57.6 million in 2004
Untangling the Web of Price Reductions

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 [17]
- World sales of originator product: US$ 549 million in 2004 [19] and more than US$ 500 million each year for last nine years [29].
- Patent status: the patent holder is IAF Biochem International SA (Canada). Various litigations have taken place with the rights, as research was undertaken by others including a Yale University scientist. GSK pays a 14% royalty to the Canadian firm [30].

Spotlight on access issues:

Lamivudine is a product in high demand, whose price has substantially decreased. There are, as of June 2006, five generic versions prequalified by WHO. In 2005, most countries reported to the WHO GPRM having paid the lowest price, whether for the generic or the originator product.

Some transactions, however, were reported at double the price, or more, for example in Swaziland - with Cipla's product, or in Thailand - with GPO's product.

In China, lamivudine is still unaffordable at US$ 1,977 per patient per year due to GSK monopoly rights on the drug.

Eligibility restrictions

<table>
<thead>
<tr>
<th>Combination</th>
<th>3TC 150 mg tablet</th>
<th>3TC 300 mg tablet</th>
<th>3TC 10 mg/ml oral solution and dry syrup</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Eligibility restrictions</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>Hello</td>
<td>GSK</td>
<td>Daily</td>
</tr>
<tr>
<td>Hetero</td>
<td>See Table 2</td>
<td>See Table 2</td>
<td>See Table 2</td>
</tr>
<tr>
<td>Aspin Medical Group</td>
<td>US$ 0.009 per unit (ml)</td>
<td>US$ 0.020 per unit (ml)</td>
<td>US$ 0.150 per unit (ml)</td>
</tr>
</tbody>
</table>

Note: The Clinton Foundation has agreed with Cipla to sell abacavir 50 mg / 5 ml at US$ 0.009 per unit (ml) in countries included in their portfolio.

Eligibility restrictions (GSK, 2006):

- For children (WHO 2006 guidelines), indicated for AIDS-related complex and oral candidiasis, and for initiating any ART
- For children (WHO 2006 guidelines), indicated for HIV-1 and HIV-2

Table 2: Prices in US$ quoted by companies for eligible developing countries:

<table>
<thead>
<tr>
<th>Company</th>
<th>3TC (300 mg)</th>
<th>3TC (150 mg)</th>
<th>3TC (300 mg)</th>
<th>3TC (10 mg/ml)</th>
<th>3TC (150 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aurobindo</td>
<td>69 (0.095)</td>
<td>None</td>
<td>69 (0.095)</td>
<td>None</td>
<td>54 (0.075)</td>
</tr>
<tr>
<td>GSK</td>
<td>69 (0.095)</td>
<td>None</td>
<td>50 (0.017)</td>
<td>56 (0.155)</td>
<td>58 (0.020)</td>
</tr>
<tr>
<td>Aspen</td>
<td>54 (0.070)</td>
<td>51 (0.073)</td>
<td>51 (0.070)</td>
<td>54 (0.150)</td>
<td>52 (0.018)</td>
</tr>
<tr>
<td>Cipla</td>
<td>53 (0.073)</td>
<td>53 (0.073)</td>
<td>66 (0.18)</td>
<td>66 (0.090)</td>
<td>66 (0.18)</td>
</tr>
<tr>
<td>Hetero</td>
<td>None</td>
<td>None</td>
<td>69 (0.095)</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Chart 1: Evolution of the lowest price quoted for eligible developing countries since 2001.

Table 3: Prices in US$ quoted by companies for eligible developing countries:
Médecins Sans Frontières • www.accessmed-msf.org • July 2006 (Revised)

Untangling the Web of Price Reductions

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 [17]
• World sales of originator product: US$ 259 million in 2004 [19]

- Nelfinavir was developed by Agouron Pharmaceuticals Inc. 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 [31]. Patents on nelfinavir are due to expire in 2014.

Spotlight on access issues:

The use of nelfinavir in children is extremely complex due to the significant amounts of powder that have to be taken on a daily basis (12 g/12 kg), making adherence a challenge. The use of powders in children is associated with a high risk of medication errors, and the powder formulation results in a high number of complaints and medication-related adverse events.

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

<table>
<thead>
<tr>
<th>Country</th>
<th>Original price</th>
<th>Lowest originator price US$ ppy</th>
<th>Lowest generic price US$ ppy</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>683 (0.208)</td>
<td>469 (0.142)</td>
<td>683 (0.208)</td>
</tr>
<tr>
<td>China</td>
<td>2,300 (0.680)</td>
<td>2,300 (0.680)</td>
<td>2,300 (0.680)</td>
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<tr>
<td>Brazil</td>
<td>696 (0.208)</td>
<td>696 (0.208)</td>
<td>696 (0.208)</td>
</tr>
<tr>
<td>Mexico</td>
<td>896 (0.260)</td>
<td>896 (0.260)</td>
<td>896 (0.260)</td>
</tr>
<tr>
<td>South Africa</td>
<td>1,543 (0.470)</td>
<td>1,543 (0.470)</td>
<td>1,543 (0.470)</td>
</tr>
</tbody>
</table>

Price Information:

- NFV 250 mg tablets
- NFV 625 mg tablets
- NFV 50 mg/g oral powder

Table 2: Price in US$ quoted by companies for eligible developing countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Eligibility restrictions</th>
<th>Power of 250 mg (mg/4)</th>
<th>Power of 625 mg (mg/4)</th>
<th>Power of 50 mg/g (mg/4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>None</td>
<td>696 (0.208)</td>
<td>696 (0.208)</td>
<td>696 (0.208)</td>
</tr>
<tr>
<td>China</td>
<td>None</td>
<td>2,300 (0.680)</td>
<td>2,300 (0.680)</td>
<td>2,300 (0.680)</td>
</tr>
<tr>
<td>Brazil</td>
<td>None</td>
<td>696 (0.208)</td>
<td>696 (0.208)</td>
<td>696 (0.208)</td>
</tr>
<tr>
<td>Mexico</td>
<td>None</td>
<td>896 (0.260)</td>
<td>896 (0.260)</td>
<td>896 (0.260)</td>
</tr>
<tr>
<td>South Africa</td>
<td>None</td>
<td>1,543 (0.470)</td>
<td>1,543 (0.470)</td>
<td>1,543 (0.470)</td>
</tr>
</tbody>
</table>

Spotlight on access issues continues...

- The lowest generic prices for NFV are given here (see "how to read the product cards" box). For the treatment of children, procurement prices reported in 2005 to the WHO GPRM were always higher than the price announced by the company—more than twice in Guatemala, for example.
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) [17]
- World sales of originator product in 2004: US$ 282 million [33]
- 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.

Spotlight on access issues:

Offered at a special price of US$ 4.07 per patient-year to 95% of developing countries, the price of US$ 44.72 per patient-year to the remaining 5% of the market. BI licenses generic producers to manufacture nevirapine, but only four of these companies in India and Africa currently produce the drug. The price of nevirapine for children has been finalized at US$ 0.078 per day.

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

<table>
<thead>
<tr>
<th>Company</th>
<th>NVP 200 mg tablets</th>
<th>NVP 10 mg/ml or 50 mg/5 ml suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aurobindo</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>BI</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Aspen under VL</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Cipla</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Hetero</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Strides</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Note: the Clinton Foundation has agreed with Cipla to sell NVP 50 mg/ml at US$ 0.009 per unit (ml) in countries included in their list.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The lowest WHO prequalified generic price for NVP is given here. In five years, the generic price, which from the outset was already much lower than the originator price, has been halved, while the originator price has increased. The brand premium for NVP, which was already high, is now even higher.

The chart shows the evolution of the lowest price quoted for eligible developing countries since 2001.

The lowest WHO prequalified generic price is given here. In five years, the generic price, which from the outset was already much lower than the originator price, has been halved, while the originator price has increased. The brand premium for NVP, which was already high, is now even higher.

The table shows prices in US$ quoted by companies for eligible developing countries. The lowest originator price is compared to the lowest prequalified generic price.
**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)** [17]

**Price information:**
- Table 1: Prices in US$ quoted by companies for eligible developing countries
- Chart 1: Evolution of the lowest price quoted for eligible developing countries since 2001

**Spotlight on access issues:**
- RTV is of crucial importance for scaling up and management of second-line treatment, as all protease inhibitors must be boosted with this drug.
- Abbott has developed a heat-stable fixed-dose combination of RTV combined with lopinavir, but the heat-stable RTV alone is not commercialised yet. Manufacturing this formulation is crucial, in order to make other PIs, such as atazanavir, free of refrigeration constraints when used together.

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

<table>
<thead>
<tr>
<th>Country</th>
<th>Eligibility restrictions</th>
<th>Solution 1</th>
<th>Solution 2</th>
<th>Solution 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aurobindo</td>
<td>None</td>
<td>39 (0.006)</td>
<td>39 (0.006)</td>
<td>39 (0.006)</td>
</tr>
<tr>
<td>Abbott</td>
<td>Daily dose needed</td>
<td>34 (0.009)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hetero</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Cipla</td>
<td>Abortion</td>
<td>2 (0.001)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strides</td>
<td>None</td>
<td>83 (0.013)</td>
<td>83 (0.013)</td>
<td>83 (0.013)</td>
</tr>
</tbody>
</table>

**Note:** The daily dose referred to is 100 mg twice daily, use as booster medication.

**Chart 1:** Evolution of the lowest price quoted for eligible developing countries since 2001
- The lowest originator price is 2.3 times lower than the generic price in 2001.
- The price of the originator drug decreases and stabilizes gradually in 2002.
- After June 2006, there was no WHO prequalified generic source of RTV.

**General Information**

**Ritonavir (r or RTV)**

**Price Information:**

<table>
<thead>
<tr>
<th>Country</th>
<th>Eligibility restrictions</th>
<th>Solution 1</th>
<th>Solution 2</th>
<th>Solution 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aurobindo</td>
<td>None</td>
<td>39 (0.006)</td>
<td>39 (0.006)</td>
<td>39 (0.006)</td>
</tr>
<tr>
<td>Abbott</td>
<td>Daily dose needed</td>
<td>34 (0.009)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hetero</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Cipla</td>
<td>Abortion</td>
<td>2 (0.001)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strides</td>
<td>None</td>
<td>83 (0.013)</td>
<td>83 (0.013)</td>
<td>83 (0.013)</td>
</tr>
</tbody>
</table>

**Note:** The daily dose referred to is 100 mg twice daily, use as booster medication.
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)
• 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)
• As of June 2006, there was no WHO prequalified generic source of saquinavir. The lowest available generic price is therefore given here.

Spotlight on access issues:

Saquinavir is very difficult to administer due to a high pill burden. Its use is very limited, as its use is very reduced.

Since 2004, Roche has been marketing in the US a new version of saquinavir in a tablet of 500 mg. This formulation reduces the pill burden.

As with other protease inhibitors, its high price continues to be a barrier. Solid competition and economies of scale among producers are severely limited, as its use is very reduced.

Very few transactions were reported during the last year to the WHO GPRM. As with other protease inhibitors, the product is still recommended by WHO. Its high price continues to be a barrier. Solid competition and economies of scale among producers are severely limited, as its use is very reduced.

Since 2004, Roche has been marketing in the US a new version of saquinavir in a tablet of 500 mg. This formulation reduces the pill burden.

Spotlight on access issues:

Saquinavir is very difficult to administer due to a high pill burden. Its use is very limited, as its use is very reduced.

Since 2004, Roche has been marketing in the US a new version of saquinavir in a tablet of 500 mg. This formulation reduces the pill burden.

Spotlight on access issues:

Saquinavir is very difficult to administer due to a high pill burden. Its use is very limited, as its use is very reduced.

Since 2004, Roche has been marketing in the US a new version of saquinavir in a tablet of 500 mg. This formulation reduces the pill burden.
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])
- 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) [17]

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. In 1984, the key stavudine patent filed in the US in 1979 was licensed to Yale University. In 1988, Yale licensed its marketing and distribution rights to BMS in 1988.

Price information:

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

<table>
<thead>
<tr>
<th>Country</th>
<th>15 mg capsule</th>
<th>20 mg capsule</th>
<th>30 mg capsule</th>
<th>40 mg capsule</th>
<th>1 mg/ml powder for solution (syrup)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspen</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VL from BMS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>See table 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: The Clinton Foundation has agreed with Cipla to sell 1 ml at US$0.017 per unit (ml) in countries included in their consortium.

The lowest WHO-prequalified generic price for all is given here:

Chart 1: Evolution of the lowest price quoted for eligible developing countries since 2001:

The lowest WHO prequalified generic price for stavudine is given here.
Untangling the Web of Price Reductions

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
• Not included in the WHO Model List of Essential Medicines [17]
• World sales of originator product: today, TDF is the most commonly prescribed branded ARV in the US, with sales climbing to US$ 783 million in 2004, representing a 38% increase over the previous year [27].

Although tenofovir was discovered and patented in the USA 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 [26].

TDF 300 mg tablets

<table>
<thead>
<tr>
<th>Daily dose</th>
<th>Eligibility restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zidovudine</td>
<td>None</td>
</tr>
<tr>
<td>Hetero</td>
<td>See table 2</td>
</tr>
<tr>
<td>Cipla</td>
<td>Daily dose</td>
</tr>
<tr>
<td>Gilead</td>
<td>Eligible</td>
</tr>
</tbody>
</table>

Price Information:

Table 2: Prices in US$ quoted by companies for eligible developing countries:

<table>
<thead>
<tr>
<th>Country</th>
<th>Price (US$ ppy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>365</td>
</tr>
<tr>
<td>India</td>
<td>365 (2.667)</td>
</tr>
<tr>
<td>Cipla</td>
<td>207 (0.567)</td>
</tr>
</tbody>
</table>

The use of tenofovir disoproxil fumarate is likely to increase as it is now part of the WHO recommended first-line treatment. The addition of TDF to these regimens will have a substantial impact on the durability of AIDS treatments. First-line regimens will no longer contain 3TC, which is associated with the development of resistance to other ARVs. The use of tenofovir disoproxil fumarate is likely to increase as it is now part of the WHO recommended first-line treatment. The addition of TDF to these regimens will have a substantial impact on the durability of AIDS treatments. First-line regimens will no longer contain 3TC, which is associated with the development of resistance to other ARVs.
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)
- 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)
- World sales of originator product: GB£ 43 million in 2004; down from US$ 476 million in 1997

Zidovudine was first discovered in 1964 as an anti-cancer medicine. Most of the research that showed the drug’s effectiveness as an antiretroviral was done by the US military in the early 1980s. The drug was first made commercially available in 1987 by GlaxoSmithKline, bringing the drug onto the market in 1987 as one of the most expensive products ever sold.

GlaxoSmithKline’s patents on AZT expired in September 2005 in the USA and several generic versions of the drug are therefore available on the US market. Patents in other countries are due to expire in 2006.

In January 2006, GSK announced a shortage of AZT, (almost double the usual price), frustrating efforts to get the WHO prequalified products at prices below US$ 2.41.

In 2005, despite the existence of generic competition and the availability of WHO prequalified products, many countries, including Least Developed Countries such as Haiti or Cambodia, continued to purchase GSK products at prices between US$ 212 and US$ 241 (almost double the generic price).

In January 2006, GSK announced a shortage of AZT.

The lowest WHO prequalified generic price for zidovudine is given here.

**Chart 1: Evolution of the lowest price quoted for eligible developing countries since 2001**

The lowest WHO prequalified generic price for zidovudine is given here.

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

<table>
<thead>
<tr>
<th>Eligibility restrictions</th>
<th>103</th>
<th>205 (0.035)</th>
<th>215 (0.036)</th>
<th>212 (0.036)</th>
<th>259 (0.038)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligibility restrictions</td>
<td>193 (0.035)</td>
<td>193 (0.035)</td>
<td>212 (0.036)</td>
<td>212 (0.036)</td>
<td>212 (0.036)</td>
</tr>
<tr>
<td>Eligibility restrictions</td>
<td>212 (0.036)</td>
<td>212 (0.036)</td>
<td>212 (0.036)</td>
<td>212 (0.036)</td>
<td>212 (0.036)</td>
</tr>
<tr>
<td>Eligibility restrictions</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
</tr>
<tr>
<td>Eligibility restrictions</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
</tr>
<tr>
<td>Eligibility restrictions</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
</tr>
<tr>
<td>Eligibility restrictions</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
<td>101 (0.036)</td>
</tr>
</tbody>
</table>

Note: The Clinton Foundation has agreed with Cipla to sell AZT 50 mg/ml at US$ 0.011 per unit (ml) in countries included in their consortium.

Table 2: Prices in US$ quoted by companies for developing countries:

<table>
<thead>
<tr>
<th>Company</th>
<th>Price Information:</th>
<th>Price Information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aurobindo GSK</td>
<td>Daily dose GSK</td>
<td>Eligibility restrictions</td>
</tr>
<tr>
<td>Aspen under GSK</td>
<td>10 mg/ml syrup and 10 mg/ml oral</td>
<td>See table 2</td>
</tr>
<tr>
<td>Cipla</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Hetero</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>None</td>
<td>See table 2</td>
<td>See table 2</td>
</tr>
</tbody>
</table>

Note: the Clinton Foundation has agreed with Cipla to sell AZT 50 mg/ml at US$ 0.011 per unit (ml) in countries included in their consortium.

**General Information**

- Included in the WHO Model List of Essential Medicines (EML)
- Approved by the US Food and Drug Administration (FDA) on 27 May 1987
- GSK: Global anti-retroviral treatment (GART) network
- Available from the GSK and WHO 2006 guidelines for the treatment of AIDS, brought the drug onto the market in 1987 as one of the most expensive products ever sold.

In January 2006, GSK announced a shortage of AZT.
ABACAVIR/LAMIVUDINE (ABC/3TC)

**General information**
- Therapeutic class: double fixed-dose combination, for HIV-1 and HIV-2 (NRTIs)
- Indicated for first-line, for adults, adolescents and children (WHO 2006 guidelines [2])
- Originator company, and product brand name: GlaxoSmithKline (GSK), Kivexa
- 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 [17].
- World sales of originator product: GSK estimates that sales will reach $490 million in 2009.

**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.

<table>
<thead>
<tr>
<th>Price Information: ABC 600 / 3TC 300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>555 (0.700) 678 (1.858)</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>Eligibility restrictions</td>
</tr>
<tr>
<td>Daily dose 6SK</td>
</tr>
<tr>
<td>See table 2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2: Prices in US$ quoted by companies for eligible developing countries:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC 600 / 3TC 300 mg</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>Eligibility restrictions</td>
</tr>
<tr>
<td>Daily dose 6SK</td>
</tr>
<tr>
<td>See table 2</td>
</tr>
</tbody>
</table>

**Table 2:** Prices in US$ quoted by companies for eligible developing countries:
- ABACAVIR/LAMIVUDINE (ABC/3TC)
- Therapeutic class: double fixed-dose combination, for HIV-1 and HIV-2 (NRTIs)
- Indicated for first-line, for adults, adolescents and children (WHO 2006 guidelines [2])
- Originator company, and product brand name: GlaxoSmithKline (GSK), Kivexa
- 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 [17].
- World sales of originator product: GSK estimates that sales will reach $490 million in 2009.

**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)**
- 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.
- The product is developed only by generic manufacturers and is not available in Western countries because of various patents on 3TC and d4T.

### Price information:

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

<table>
<thead>
<tr>
<th>Price Information:</th>
<th>3TC/44T 40 mg</th>
<th>3TC/44T 40 mg</th>
<th>3TC/44T 40 mg</th>
<th>3TC/44T 40 mg</th>
<th>3TC/44T 40 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hetero</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Atripla</td>
<td>Daily</td>
<td>Daily</td>
<td>Daily</td>
<td>Daily</td>
<td>Daily</td>
</tr>
<tr>
<td>Cipla</td>
<td>Daily</td>
<td>Daily</td>
<td>Daily</td>
<td>Daily</td>
<td>Daily</td>
</tr>
<tr>
<td>Strides</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td><strong>Price range (US$)</strong></td>
<td>64 (0.088)</td>
<td>67 (0.092)</td>
<td>73 (0.100)</td>
<td>74 (0.101)</td>
<td>73 (0.100)</td>
</tr>
</tbody>
</table>

**Table 2: Prices in US$ quoted by companies for eligible developing countries:**

<table>
<thead>
<tr>
<th>Price Information:</th>
<th>3TC/44T 40 mg</th>
<th>3TC/44T 40 mg</th>
<th>3TC/44T 40 mg</th>
<th>3TC/44T 40 mg</th>
<th>3TC/44T 40 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hetero</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Atripla</td>
<td>Daily</td>
<td>Daily</td>
<td>Daily</td>
<td>Daily</td>
<td>Daily</td>
</tr>
<tr>
<td>Cipla</td>
<td>Daily</td>
<td>Daily</td>
<td>Daily</td>
<td>Daily</td>
<td>Daily</td>
</tr>
<tr>
<td>Strides</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td><strong>Price range (US$)</strong></td>
<td>80 (0.110)</td>
<td>87 (0.120)</td>
<td>64 (0.088)</td>
<td>67 (0.092)</td>
<td>73 (0.100)</td>
</tr>
</tbody>
</table>

**Spotlight on access issues:**
- Although included in the WHO recommendations for children, to date there are no adapted formulations available.
- The lowest prequalified generic price for 3TC/d4T is given here.

**Chart 1: Evolution of the lowest priced product for eligible developing countries since 2001**

- The chart illustrates the evolution of the lowest prequalified generic price for 3TC/d4T since February 2005.
- Prices of generic drugs have been decreasing since that date.
- The first generic to be WHO prequalified was from Strides in February 2005.
- The lowest WHO prequalified generic price for 3TC/d4T is given here.
- Combined, the lowest price of originator products, only available separately instead of FDCs, reaches US$ 124.
Untangling the Web of Price Reductions

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

• Included in the WHO Model List of Essential Medicines (EML) [17]

• World sales of originator product: LPV/r is the most commonly used PI in the US, 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) [34]. Cumulative sales are estimated to reach US$ 7 billion over the years 2001 to 2008 [34].

• Abbott patents on soft gel capsules are due to expire in the USA in 2018. Patents were also filed to protect the heat-stable tablets, which are to run until 2024.

Spotlight on access issues:

As of June 2006, there was no WHO prequalified generic source of lopinavir/ritonavir. The lowest available generic price is therefore considered for the graph.

Only originator sales were reported to the WHO GPRM in 2005. In countries excluded from Abbott's list of eligible countries, such as some Middle Eastern countries, the product is available but not approved for sale or distribution under the local law.

Abbott developed a new formulation of the LPV/r FDC, but it is not made available in developing countries. Crucially, the new formulation has great advantages for these resource-poor settings: 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. Nevertheless, Abbott has not filed for registration in developing countries, except for South Africa. It is only after Médecins Sans Frontières (MSF) publicly placed an order, 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. But as of July 2006, the company declined to fill orders placed for Elsewhere.

Abbott is expected to make the new formulation available in Africa by the first quarter of 2007. However, there is no assurance that the new formulation will be made available in developing countries. In Brazil, where this product is under patent, the cost of it alone used to take up 27% of the National AIDS Programme budget. After strong negotiations with the company, the price was recently further reduced to US$ 1,518 for the heat-stable tablets [25].

Further, current generic competition, which would be expected to drive prices down as demand increases, is under threat. Abbott has applied for patents on both combinations in India (soft gel capsules and more recent heat-stable tablets). Opposition to the grant of Indian patents on the combination is needed.

In Brazil, where this product is under patent, the cost of it alone used to take up 27% of the National AIDS Programme budget. After strong negotiations with the company, the price was recently further reduced to US$ 1,518 for the heat-stable tablets [25].

In June 2004, Abbott told MSF that the product would be marketed there by October 2004, but as of June 2006, it was still not available. Moreover, current generic competition, which would be expected to drive prices down as demand increases, is under threat. Abbott has applied for patents on both combinations in India (soft gel capsules and more recent heat-stable tablets). Opposition to the grant of Indian patents on the combination is needed.
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
• 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]

World sales of originator product: TDF/FTC was launched in August 2004 and reached US$ 66 million, meaning an increase of sales of 735% within six months (sales already exceeded US$ 70 million in 2005). Sales of the product is developed only by generic companies but its final availability will depend on the patent status of TDF in India and the availability of the fixed-dose combination.

• Patent holders of both TDF and FTC have agreed to waive their right to the royalties for sales within Gilead’s Access Program[28].

Spotlight on access issues:

As of February 2006, this combination was registered in only four developing countries. The published offered price is therefore meaningless.

Purchases reported to the WHO GPRM are so far extremely limited, and can be found only among countries eligible for the lowest Gilead price (only three transactions reported).

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

Price information:

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

<table>
<thead>
<tr>
<th>Eligibility restrictions</th>
<th>TDF/FTC</th>
<th>300 + 300 mg tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily dose</td>
<td>Gilead</td>
<td>319 (0.875)</td>
</tr>
<tr>
<td>Cipla</td>
<td>Cipla</td>
<td>None</td>
</tr>
</tbody>
</table>

TENOFOVIR DISOPROXIL FUMARATE/LAMIVUDINE (TDF/3TC)

General information

• Therapeutic class: NtRTI + NRTI in double fixed-dose combination, HIV-1
• Indicated for first-line, for adults and adolescents (2006 WHO 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]

• The product is developed only by generic companies but its final availability will depend on the patent status of TDF in India. It is not available in Western countries because of various patents on TDF and FTC.

• Pending holders of both TDF and FTC have agreed to waive their right to the royalties for sales within Gilead’s Access Program.

Price information:

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

<table>
<thead>
<tr>
<th>Eligibility restrictions</th>
<th>TDF/3TC</th>
<th>300 + 300 mg tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily dose</td>
<td>Cipla</td>
<td>1,034 (2.833)</td>
</tr>
<tr>
<td>See table 2</td>
<td>Cipla</td>
<td>None</td>
</tr>
</tbody>
</table>

Cipla: Product card; TDF (see TDF)
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
• 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.

Spotlight on access issues:

Competition between originator and generics exist for adult formulations but Indian generic versions of the medicine are currently under examination by the Indian patent office. PLWHA opposed the grant of this patent in India on 30th March 2006 [41]. If the Indian patent office grants the patent, Indian generic manufacturers will only be able to continue producing the medicine under the “automatic licensing” provisions of the patent and may have to pay a “reasonable royalty” to GSK, which may increase the price of the combination in India.

In some countries, generic versions of the FDC are not available because of GSK patent rights. In China, only the originator product is available at US$ 593 because of GSK exclusive rights on 3TC alone.

In Honduras, the government only decided to procure from a generic source after GSK’s shortage of AZT in January 2006.

In some countries, “B GN” versions of the FDC are not available because of generic price of the combination (see introduction).

To date, no formulation adapted for children is marketed and it is urgently needed.

Eligibility restrictions

A child weighing under 15 kg should be treated with AZT 300 mg and 3TC 150 mg once daily.

Price Information:

<table>
<thead>
<tr>
<th>Eligibility</th>
<th>AZT 300 mg</th>
<th>3TC 150 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligible</td>
<td>130</td>
<td>70</td>
</tr>
<tr>
<td>None</td>
<td>160</td>
<td>90</td>
</tr>
<tr>
<td>Strides</td>
<td>160</td>
<td>90</td>
</tr>
<tr>
<td>NDAI</td>
<td>160</td>
<td>90</td>
</tr>
<tr>
<td>Average</td>
<td>170</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 2: Prices in US$ quoted by companies for eligible developing countries:
Untangling the Web of Price Reductions

**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)**
- 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.
- The product is developed only by generic companies; 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.

**Spotlight on access issues:**

- Over the last five years, generic competition has shown to be the most effective means of lowering drug prices. Prices are still decreasing, with a combined average price of USD 95.
- Three commonly prescribed therapies in Africa are 3TC/d4T/NVP combined triple fixed-dose combination.
- This is still the most commonly prescribed therapy in Africa. It is not available in developing 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.
- The product is developed only by generic companies. Its approval and launch in the market have been delayed because of various patents on 3TC, d4T and NVP.
- A limited number of generic paediatric triple fixed-dose combinations are currently reaching the market. But WHO must urgently give clear guidance on the best dosages for children.
- Resource-limited settings for HIV treatment in Africa.
- Eligibility restrictions

**Price Information:**

<table>
<thead>
<tr>
<th>Country</th>
<th>Price Information</th>
<th>150 / 40 / 200 mg</th>
<th>30 / 6 / 50 mg</th>
<th>60 / 12 / 100 mg</th>
<th>20 / 5 / 35 mg</th>
<th>40 / 10 / 70 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aurobindo</td>
<td>None</td>
<td>138 (0.190)</td>
<td>80 (0.055)</td>
<td>79 (0.108)</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Cipla</td>
<td>None</td>
<td>146 (0.200)</td>
<td>91 (0.125)</td>
<td>153 (0.210)</td>
<td>153 (0.210)</td>
<td>146 (0.200)</td>
</tr>
<tr>
<td>Hetero</td>
<td>None</td>
<td>140 (0.192)</td>
<td>146 (0.200)</td>
<td>153 (0.210)</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>None</td>
<td>143 (0.195)</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Strides</td>
<td>None</td>
<td>146 (0.200)</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**Price trends**

- Chart 1: Evolution of the lowest price quoted for eligible developing countries since 2001
- Over the last five years, generic competition has shown to be the most effective means of lowering drug prices. Prices are still decreasing, with a combined average price of USD 95.
- Three commonly prescribed therapies in Africa are 3TC/d4T/NVP combined triple fixed-dose combination.
- This is still the most commonly prescribed therapy in Africa. It is not available in developing 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.
- The product is developed only by generic companies. Its approval and launch in the market have been delayed because of various patents on 3TC, d4T and NVP.
- A limited number of generic paediatric triple fixed-dose combinations are currently reaching the market. But WHO must urgently give clear guidance on the best dosages for children.
- Resource-limited settings for HIV treatment in Africa.
- Eligibility restrictions

**Table 1: Prices in USD quoted by companies for eligible developing countries:**

<table>
<thead>
<tr>
<th>Country</th>
<th>Price Information</th>
<th>150 / 40 / 200 mg</th>
<th>30 / 6 / 50 mg</th>
<th>60 / 12 / 100 mg</th>
<th>20 / 5 / 35 mg</th>
<th>40 / 10 / 70 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aurobindo</td>
<td>None</td>
<td>138 (0.190)</td>
<td>80 (0.055)</td>
<td>79 (0.108)</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Cipla</td>
<td>None</td>
<td>146 (0.200)</td>
<td>91 (0.125)</td>
<td>153 (0.210)</td>
<td>153 (0.210)</td>
<td>146 (0.200)</td>
</tr>
<tr>
<td>Hetero</td>
<td>None</td>
<td>140 (0.192)</td>
<td>146 (0.200)</td>
<td>153 (0.210)</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>None</td>
<td>143 (0.195)</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Strides</td>
<td>None</td>
<td>146 (0.200)</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**General Information**

**NEVIRAPINE (NVP)**

**LAMIVUDINE/STAVUDINE/STAVUDINE**
**Untangling the Web of Price Reductions**

**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 infection.
- **Indicated for:** First-line for adults (WHO 2006 guidelines).
- **Originator company, and product brand name:** Gilead and BMS/Merck, Atripla.
- **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.**
- **Generic versions are being developed in India, and the approximate market launch could be expected before the end of 2006 in India.**
- **To date, there has been no announcement as to what the price for this FDC will be or any indication of a registration timeline.**
- **If the patent is granted on TDF, any generic production could be blocked, or severely restricted, until the patent expires, which could be as late as 2018.**

**Spotlight on access issues:**

- This is the first one-pill-a-day FDC, which makes it well adapted to resource-poor settings.
- As it is well tolerated and delays the emergence of resistance, but it cannot be used in women of childbearing age.
- This combination will probably become one of the most recommended first-line therapies.
- This combination will probably become one of the most recommended first-line therapies.
- The WHO recommends fixed-dose combinations for NNRTI in a triple fixed-dose combination, for treatment-naive HIV-1 infected adults.
Médecins Sans Frontières
www.accessmed-msf.org
July 2006 (Revised)

Untangling the Web of Price Reductions

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.

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: US$ 602 million in 2004 [19].

Spotlight on access issues:

- This FDC is the only triple formulation available in Western countries. It is hence one of the most commonly prescribed regimens, but the market is very small in developing countries.
- The FDC is still very expensive compared to other triple first-line FDCs, notably because of the high price of abacavir.

Chart 1: Evolution of the lowest price quoted for eligible developing countries since 2001

As of June 2006, there was no WHO prequalified generic source of AZT/3TC/ABC.

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

<table>
<thead>
<tr>
<th>Eligibility restrictions</th>
<th>AZT/3TC/ABC</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.75 (0.75/0.75)</td>
<td>2409</td>
</tr>
<tr>
<td>0.75 (1.75/1.75)</td>
<td>2502</td>
</tr>
<tr>
<td>0.75 (2.0/1.75)</td>
<td>2602</td>
</tr>
<tr>
<td>0.75 (2.0/2.0)</td>
<td>2709</td>
</tr>
</tbody>
</table>

* Eligibility restrictions for AZT/3TC/ABC: See table 2
* US$ per 100 mg tablet
* Indicated for adults for triple first-line regimen
* The generic class: these NRTIs in triple fixed-dose combinations

**General Information**

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

**Price Information:**

- **AZT/3TC/ABC**
- **ZIDOVUDINE/LAMIVUDINE**
- **ABACAVIR**
Untangling the Web of Price Reductions

ZIDOVUDINE/LAMIVUDINE/NEVIRAPINE (AZT/3TC/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])
• 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.

Spotlight on access issues:

The price of this triple FDC is still a barrier for use and for scaling up programmes, 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.

Price information:

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

<table>
<thead>
<tr>
<th>Tablet</th>
<th>Daily dose</th>
<th>Aspen (under VL)</th>
<th>GSK and BI</th>
<th>Cipla</th>
<th>Aurobindo</th>
<th>Hetero</th>
<th>Ranbaxy</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 / 150 / 200 mg</td>
<td>2</td>
<td>308 (0.422)</td>
<td><em>co-blister, not FDC</em></td>
<td>257 (0.352)</td>
<td>231 (0.317)</td>
<td>263 (0.360)</td>
<td>255 (0.350)</td>
</tr>
</tbody>
</table>

Note: the Clinton Foundation has agreed with Cipla, Hetero and Ranbaxy for a price of US$ 239 per patient per year in countries of their consortium.

Chart 1: Evolution of the lowest price quoted for eligible developing countries since 2001

AZT/3TC/NVP

The lowest WHO prequalified generic price for AZT/3TC/NVP is considered here. Generic products have led to a decrease in prices, especially when compared with originator products marketed separately and not in FDCs.

Eligibility restrictions

- z 300 / 150 / 200 mg
- Eligibility restrictions
- See table 2

Table 2: Eligibility restrictions for triple first-line combination for HIV-1

<table>
<thead>
<tr>
<th>Country</th>
<th>Eligibility restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZS (0.350)</td>
<td>None</td>
</tr>
<tr>
<td>ZS (0.350)</td>
<td>None</td>
</tr>
<tr>
<td>ZS (0.350)</td>
<td>None</td>
</tr>
<tr>
<td>ZS (0.350)</td>
<td>None</td>
</tr>
<tr>
<td>ZS (0.350)</td>
<td>None</td>
</tr>
</tbody>
</table>

General Information

NEVIRAPINE/LAMIVUDINE/ZIDOVUDINE

Price Information:
## LAMIVUDINE/STAVUDINE + EFAVirenZ

### 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)**
- **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**
- This product is developed only by generic companies; it is not available in Western countries because of various patents on AZT, 3TC and EFV.

### Eligibility Restrictions
- Eligibility restrictions - Daily dose
- Aurobindo
- Cipla
- Ranbaxy

### Price Information

<table>
<thead>
<tr>
<th>Company</th>
<th>Price in US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aurobindo</td>
<td>274 (0.750)</td>
</tr>
<tr>
<td>Cipla</td>
<td>280 (0.767)</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>365 (1.000)</td>
</tr>
</tbody>
</table>

---

## ZIDOVUDINE/LAMIVUDINE + EFAVirenZ

### 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)

### Eligibility Restrictions
- Eligibility restrictions - Daily dose
- Aurobindo
- Cipla
- Ranbaxy

### Price Information

<table>
<thead>
<tr>
<th>Company</th>
<th>Price in US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aurobindo</td>
<td>451 (1.237)</td>
</tr>
<tr>
<td>Cipla</td>
<td>347 (0.950)</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>457 (1.250)</td>
</tr>
</tbody>
</table>
Table 2: Conditions of offer by company

<table>
<thead>
<tr>
<th>Company</th>
<th>Eligibility (countries)</th>
<th>Delivery of goods</th>
<th>Additional comments</th>
<th>Eligibility (countries)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott</td>
<td>For all countries classified as low-income by the World Bank (except South Africa, Russia, and Belarus). For other developing countries, prices are negotiated on a case-by-case basis.</td>
<td>FOB Mumbai (India) with CIF. Freight charges separately on CIF.</td>
<td>NGOs and governmental organisations. NGS and other partners</td>
<td>All African states and LCs outside of Africa.</td>
</tr>
<tr>
<td>Aspen</td>
<td>Eligible on a case-by-case basis. Specific agreements are negotiated with individual governments and NGOs.</td>
<td>CIP to French-speaking Africa. FOB to English-speaking Africa.</td>
<td>No reported restrictions</td>
<td>All countries classified by the World Bank as low-income. We negotiate separately on a case-by-case basis.</td>
</tr>
<tr>
<td>Boehringer-Ingelheim</td>
<td>Eligible on a case-by-case basis. Specific agreements are negotiated with individual governments on a case by case basis.</td>
<td>FOB Hyderabad (India).</td>
<td>No reported restrictions</td>
<td>Boehringer-Ingelheim</td>
</tr>
<tr>
<td>Cipla</td>
<td>Eligible on a case-by-case basis. Specific agreements are negotiated with individual governments and NGOs.</td>
<td>CIP to French-speaking Africa. FOB to English-speaking Africa.</td>
<td>No reported restrictions</td>
<td>Cipla</td>
</tr>
<tr>
<td>Gilead</td>
<td>For all countries classified as low-income by the World Bank and sub-Saharan Africa. For other developing countries, prices are negotiated on a case-by-case basis.</td>
<td>FOB Mumbai (India) with CIF. Freight charges separately on CIF.</td>
<td>No reported restrictions</td>
<td>Gilead</td>
</tr>
</tbody>
</table>

---

Application instructions are subject to Government approval. The programme is managed through Gilead’s Access Program (GAP). In African countries where the drugs are approved, information on eligibility and how to access the programme is managed through Gilead’s Access Program. In African countries where the drugs are approved, information on eligibility and how to access the programme is managed through Gilead’s Access Program.
<table>
<thead>
<tr>
<th>Company</th>
<th>Eligibility (countries)</th>
<th>Additional comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>GlaxoSmithKline</td>
<td></td>
<td>Government non-profit institutions, HICs, public sector, and NGOs</td>
</tr>
<tr>
<td>Hetero Drugs Ltd</td>
<td>Least Developed Countries plus sub-Saharan Africa</td>
<td>No reported restrictions, but higher prices were negotiated separately for Latin American countries</td>
</tr>
<tr>
<td>Merck &amp; Co. Inc</td>
<td>Low Human Development Index (HDI) countries plus medium HDI countries with adult HIV prevalence 1% or greater</td>
<td>No reported restrictions, but higher prices were negotiated separately for Latin American countries</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>Least Developed Countries</td>
<td>No reported restrictions</td>
</tr>
<tr>
<td>Roche</td>
<td>All countries in sub-Saharan Africa and all countries classified as Least Developed Countries by the United Nations</td>
<td>No reported restrictions</td>
</tr>
<tr>
<td>Strides Arcolab Ltd</td>
<td>Low Human Development Index (HDI) countries plus medium HDI countries with adult HIV prevalence 1% or greater</td>
<td>No reported restrictions</td>
</tr>
</tbody>
</table>

Notes:
The conditions detailed in the table above were those quoted directly by the companies. Definitions of eligibility vary among companies. Each 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, while others still use World Bank classifications concerning country income.

This lack of uniformity leads to significant differences in the eligibility of a country for different products. For example, six countries in the UNDP HDI rankings 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

The price for adult formulations is the yearly price per patient. The price for paediatric formulations is the price for the smallest unit available. Products that were WHO prequalified as of July 2006 are listed in bold.

<table>
<thead>
<tr>
<th>Product</th>
<th>Originator lowest offer / originator second price when specified</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>abacavir</strong></td>
<td></td>
</tr>
<tr>
<td>- 300 mg tablet</td>
<td>Strides</td>
</tr>
<tr>
<td>- 20 mg / ml oral solution</td>
<td>Strides</td>
</tr>
<tr>
<td><strong>atazanavir</strong></td>
<td></td>
</tr>
<tr>
<td>- 150 mg</td>
<td>Strides</td>
</tr>
<tr>
<td><strong>didanosine</strong></td>
<td></td>
</tr>
<tr>
<td>- 25 mg tablet</td>
<td>Strides</td>
</tr>
<tr>
<td>- 50 mg tablet</td>
<td>Strides</td>
</tr>
<tr>
<td>- 100 mg tablet</td>
<td>Strides</td>
</tr>
<tr>
<td>- 200 mg tablet</td>
<td>Strides</td>
</tr>
<tr>
<td><strong>emtricitabine</strong></td>
<td></td>
</tr>
<tr>
<td>- 0.05 mg / ml powder for syrup</td>
<td>Strides</td>
</tr>
<tr>
<td><strong>generic offers</strong></td>
<td></td>
</tr>
<tr>
<td><strong>single formulations</strong></td>
<td></td>
</tr>
<tr>
<td><strong>GSK</strong></td>
<td>BMS</td>
</tr>
<tr>
<td>- 0.104 / ml</td>
<td>- n/a</td>
</tr>
<tr>
<td><strong>BMS</strong></td>
<td>GSK</td>
</tr>
<tr>
<td>- 0.213 / cap</td>
<td>- 0.116 / 0.213 / cap</td>
</tr>
<tr>
<td><strong>Merck</strong></td>
<td>Gilead</td>
</tr>
<tr>
<td>- 0.094 / 0.151 / ml</td>
<td>- n/a</td>
</tr>
<tr>
<td><strong>Gilead</strong></td>
<td>Roche</td>
</tr>
<tr>
<td>- 0.028 / ml</td>
<td>- 0.039 / ml</td>
</tr>
<tr>
<td><strong>Roche</strong></td>
<td>Boehringer</td>
</tr>
<tr>
<td>- 0.017 / ml</td>
<td>- 0.054 / cap</td>
</tr>
<tr>
<td><strong>Boehringer</strong></td>
<td>Abbott</td>
</tr>
<tr>
<td>- 0.056 / cap</td>
<td>- 0.056 / cap</td>
</tr>
</tbody>
</table>

*Table 3: Summary of prices in US$ quoted by companies for eligible developing countries*
### Double Fixed-Dose Combination in Co-blister

<table>
<thead>
<tr>
<th>Product</th>
<th>Originator</th>
<th>Lowest Offer/Originator Second Price When Specified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strides</td>
<td>Ranbaxy</td>
<td>0.055 / tab / 0.108 / tab</td>
</tr>
<tr>
<td></td>
<td>Strides</td>
<td>0.014 / ml / 0.015 / ml</td>
</tr>
<tr>
<td></td>
<td>Hetero</td>
<td>0.028 / ml / 0.036 / ml</td>
</tr>
<tr>
<td></td>
<td>Aspen</td>
<td>0.201 / cap / 0.205 / cap</td>
</tr>
<tr>
<td></td>
<td>Cipla</td>
<td>0.075 / cap / 0.075 / cap</td>
</tr>
<tr>
<td></td>
<td>Aurobindo</td>
<td>0.158 / cap / 0.197 / cap</td>
</tr>
<tr>
<td></td>
<td>Gilead</td>
<td>0.158 / cap / 0.197 / cap</td>
</tr>
<tr>
<td></td>
<td>GSK</td>
<td>0.158 / cap / 0.197 / cap</td>
</tr>
<tr>
<td></td>
<td>Abbott</td>
<td>0.139 / ml / 0.197 / cap</td>
</tr>
</tbody>
</table>

### Single Formulations

<table>
<thead>
<tr>
<th>Product</th>
<th>Originator</th>
<th>Lowest Offer/Originator Second Price When Specified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strides</td>
<td>Ranbaxy</td>
<td>0.055 / tab / 0.108 / tab</td>
</tr>
<tr>
<td></td>
<td>Strides</td>
<td>0.014 / ml / 0.015 / ml</td>
</tr>
<tr>
<td></td>
<td>Hetero</td>
<td>0.028 / ml / 0.036 / ml</td>
</tr>
<tr>
<td></td>
<td>Aspen</td>
<td>0.201 / cap / 0.205 / cap</td>
</tr>
<tr>
<td></td>
<td>Cipla</td>
<td>0.075 / cap / 0.075 / cap</td>
</tr>
<tr>
<td></td>
<td>Aurobindo</td>
<td>0.158 / cap / 0.197 / cap</td>
</tr>
<tr>
<td></td>
<td>Gilead</td>
<td>0.158 / cap / 0.197 / cap</td>
</tr>
<tr>
<td></td>
<td>GSK</td>
<td>0.158 / cap / 0.197 / cap</td>
</tr>
<tr>
<td></td>
<td>Abbott</td>
<td>0.139 / ml / 0.197 / cap</td>
</tr>
</tbody>
</table>

**Note:** The table above includes both generic offers and double fixed-dose combinations in co-blister. The originator lowest offer and originator second price are indicated when specified.
Annex 2: Human Development Index (HDI)


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; Cameroon, Central African Republic; Chad; Congo (Democratic Republic); Côte d’Ivoire; Democratic Republic of the Congo; Equatorial Guinea; Eritrea; Ethiopia; Guinea-Bissau; Haiti; Honduras; Kongo; Lesotho; Liberia; Madagascar; Malawi; Mali; Mauritania; Mozambique; Niger; Nigeria; Rwanda; Senegal; Sierra Leone; Swaziland; Tanzania; Yemen; Zambia.

Medium human development: Albania; Angola; Antigua and Barbuda; Armenia; Azerbaijan; Bangladesh; Belarus; Belize; Bhutan; Bolivia; Bosnia and Herzegovina; Botswana; Burkina Faso; Burundi; Central African Republic; Chad; Colombia; Comoros; Congo; Costa Rica; Côte d’Ivoire; Cuba; Djibouti; Dominica; Dominican Republic; Georgia; Ghana; Grenada; Guatemala; Guyana; Honduras; India; Indonesia; Iran; Jamaica; Jordan; Kazakhstan; Kyrgyzstan; Lao PDR; Latvia; Lesotho; Liechtenstein; Lithuania; Luxembourg; Malawi; Malta; Malaysia; Maldives; Mauritius; Morocco; Mozambique; Namibia; Nepal; Nicaragua; Oman; Pakistan; Panama; Paraguay; Peru; Philippines; Portugal; Qatar; Republic of Korea; Saint Vincent and the Grenadines; Samoa; Sao Tome and Principe; Senegal; Serbia and Montenegro; Seychelles; Sierra Leone; Somalia; South Sudan; Sri Lanka; Suriname; Swaziland; Syria; Tajikistan; Tanzania; Thailand; Togo; Trinidad and Tobago; Tunisia; Turkey; Turkmenistan; Uganda; Ukraine; United Kingdom; United States of America; Uruguay; Uzbekistan; Vanuatu; Venezuela; Viet Nam; Yemen; Zambia.

Annex 3: Least Developed Countries (LDCs)


Fifty countries are currently designated by the United Nations as least developed countries (LDCs). The list is scheduled for review in 2006.

Afghanistan; Angola; Bangladesh; Benin; Bhutan; Burkina Faso; Burundi; Cambodia; Cape Verde; Central African Republic; Chad; Comoros; Congo; Côte d’Ivoire; Djibouti; Dominica; Ethiopia; Madagascar; Malawi; Maldives; Mauritania; Mozambique; Niger; Nigeria; Pakistan; Panama; Paraguay; Peru; Philippines; Senegal; Sierra Leone; Solomon Islands; Somalia; Sudan; Swaziland; Togo; Uganda; United Republic of Tanzania; Uganda; Yemen; Zambia.

Annex 4: Sub-Saharan countries


Angola; Benin; Botswana; Burkina Faso; Burundi; Cameroon; Cape Verde; Central African Republic; Chad; Comoros; Congo; Côte d’Ivoire; Djibouti; Dominica; Ethiopia; Madagascar; Malawi; Maldives; Mauritania; Mozambique; Niger; Nigeria; Pakistan; Panama; Paraguay; Peru; Philippines; Senegal; Somalia; South Sudan; Tanzania; Togo; Uganda; United Republic of Tanzania; United States of America; Uzbekistan; Vanuatu; Yemen; Zambia.
Annex 4: World Bank classification of economies

**Lower-income economies:**
- Afghanistan; Bangladesh; Bhutan; Comoros; Cote d’Ivoire; Gambia; Guinea; Lesotho; Lao People’s Democratic Republic; Malawi; Mauritania; Mozambique; Niger; Pakistan; Papua New Guinea; Nepal; United Republic of Tanzania; Sierra Leone; Somalia; Swaziland; Timor-Leste; Togo; Yemen; Zaire.

**Lower-middle-income economies:**
- Albania; Algeria; Armenia; Azerbaijan; Benin; Botswana; Burkina Faso; Burundi; Cambodia; Cameroon; Cape Verde; Central African Republic; Comoros; Cote d’Ivoire; Djibouti; Ethiopia; Gabon; Georgia; Guinea; Madagascar; Malawi; Mali; Mozambique; Namibia; Niger; Rwanda; Saint Lucia; São Tomé and Príncipe; Senegal; Sierra Leone; Sudan; Togo; Tonga; Togo; Uganda; Zambia; Zimbabwe.

**Upper-middle-income economies:**
- Argentina; Armenia; Azerbaijan; Barbados; Benin; Botswana; Cape Verde; Central African Republic; Chad; Comoros; Cote d’Ivoire; Djibouti; Eritrea; Ethiopia; Gabon; Gambia; Ghana; Guinea-Bissau; Lesotho; Malawi; Mauritania; Mozambique; Niger; Nigeria; Senegal; Seychelles; Sierra Leone; Somalia; South Africa; Sudan; Swaziland; Tanzania; Togo; Uganda; Zambia; Zimbabwe.

**High-income economies:**
- Austria; Belgium; Canada; Denmark; Estonia; Finland; France; Germany; Greece; Iceland; Ireland; Italy; Japan; Luxembourg; Netherlands; New Zealand; Norway; Portugal; Spain; Sweden; Switzerland; United Kingdom; United States; Australia; Austria; Belgium; Canada; Denmark; Estonia; Finland; France; Germany; Greece; Iceland; Ireland; Italy; Japan; Luxembourg; Netherlands; New Zealand; Norway; Portugal; Spain; Sweden; Switzerland; United Kingdom; United States; Australia; Brazil; China; Japan; South Korea; Russia; Singapore; South Africa; Taiwan; Turkey; United Arab Emirates; United Kingdom; United States; Australia; Brazil; China; Japan; South Korea; Russia; Singapore; South Africa; Taiwan; Turkey; United Arab Emirates; United Kingdom; United States; Australia; Brazil; China; Japan; South Korea; Russia; Singapore; South Africa; Taiwan; Turkey; United Arab Emirates; United Kingdom; United States.

Annex 5: Global Fund recipient countries

Countries eligible for 1st price category:
- Afghanistan; Angola; Bangladesh; Benin; Bhutan; Burkina Faso; Burundi; Cambodia; Cameroon; Cape Verde; Central African Republic; Chad; Comoros; Cote d’Ivoire; Djibouti; Eritrea; Ethiopia; Gabon; Gambia; Guinea; Haiti; Lesotho; Madagascar; Malawi; Mauritania; Mozambique; Namibia; Niger; Rwanda; Seychelles; Sierra Leone; Somalia; South Africa; Sudan; Tanzania; Togo; Uganda; Viet Nam; Zimbabwe.

Countries eligible for Southern African prices:
- Botswana; Lesotho; Malawi; Mozambique; Namibia; South Africa; Swaziland; Zambia; Zimbabwe.

Annex 6: 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; Cote d’Ivoire; Djibouti; Eritrea; Ethiopia; Gabon; Gambia; Guinea; Haiti; Lesotho; Madagascar; Malawi; Mauritania; Mozambique; Namibia; Niger; Rwanda; Seychelles; Sierra Leone; Somalia; South Africa; Sudan; Tanzania; Togo; Uganda; Viet Nam; Yemen.

Countries eligible for Southern African prices:
- Botswana; Lesotho; Malawi; Mozambique; Namibia; South Africa; Swaziland.
Untangling the Web of Price Reductions

Annex 7: Abbott eligible countries
Afghanistan; Algeria; Angola; Bangladesh; Benin; Bhutan; Botswana; Burkina Faso; Burundi; Cambodia; Cameroon; Cape Verde; Central African Republic; Chad; Comoros; Congo; Côte d’Ivoire; Djibouti; Egypt; Equatorial Guinea; Eritrea; Ethiopia; Gabon; Gambia; Ghana; Guinea; Guinea-Bissau; Haiti; Honduras; India; Indonesia; Iraq; Jordan; Kenya; Kyrgyzstan; Lao People’s Democratic Republic; Lesotho; Libya; Madagascar; Malawi; Maldives; Mali; Mauritania; Mauritius; Morocco; Myanmar; Nepal; Niger; Nigeria; Oman; Pakistan; Panama; Papua New Guinea; Paraguay; Peru; Philippines; Poland; Portugal; Rwanda; Saint Lucia; Saudi Arabia; Senegal; Somalia; South Africa; Sri Lanka; Sudan; Swaziland; Tanzania; Thailand; Togo; Tunisia; Turkey; Uganda; United Arab Emirates; Vanuatu; Yemen; Zambia; Zimbabwe.

Annex 8: Gilead eligible countries
Source: Gilead Access Program http://www.gileadaccess.org
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; Côte d’Ivoire; Djibouti; Egypt; Equatorial Guinea; Eritrea; Ethiopia; Gabon; Gambia; Ghana; Guinea; Guinea-Bissau; Haiti; Honduras; India; Indonesia; Iraq; Jordan; Kenya; Kyrgyzstan; Lao People’s Democratic Republic; Lesotho; Libya; Madagascar; Malawi; Maldives; Mali; Mauritania; Mauritius; Morocco; Myanmar; Nepal; Niger; Nigeria; Oman; Pakistan; Panama; Papua New Guinea; Paraguay; Peru; Philippines; Poland; Portugal; Rwanda; Saint Lucia; Saudi Arabia; Senegal; Somalia; South Africa; Sri Lanka; Sudan; Swaziland; Tanzania; Thailand; Togo; Tunisia; Turkey; Uganda; United Arab Emirates; Vanuatu; Yemen; Zambia; Zimbabwe.

Annex 9: Suggested resources for further information:
For documentation on prices quoted by companies:
- Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS (June 2005) http://mednet2.who.int/sourcesprices/sources.pdf
- Global HIV/AIDS epidemic: Selection of antiretroviral medications provided under the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) June 2005: http://iptc.fi/15604
- Global HIV/AIDS epidemic: Selection of antiretroviral medications provided under the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) June 2005: http://iptc.fi/15604

For documentation on prices reported by countries:
- WHO, AMIS, Global Price Reporting Mechanism for ARVs in Developing Countries http://www.who.int/3by5/amis/price/hdd/
- WHO, AMIS, Global Price Reporting Mechanism for ARVs in Developing Countries

For documentation on patents:
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:
- White List for ARV Procurement, 5th June 2005, Clinton Foundation
  http://www.clintonfoundation.org/pdf/060505-white-list-for-arv-procurement.pdf
- WHO AFRO region Essential Medicines Price Indicator
- International Dispensary Association (IDA) price indicator
  http://www.idafoundation.org
- US Food and Drug Administration approved products, product documentation
  http://www.accessdata.fda.gov/scripts/cder/drugsatfda/
- WHO HIV treatment guidelines for adults and adolescents
  http://www.who.int/hiv/pub/guidelines/adults/en/

Annex 1: Company contacts

**Abbott**:  
E-mail: victor.vijayakumar@abbot.com  
Web site: www.abbot.com  
Tel: +91 40 2304 4070  
Fax: +91 40 2304 4058

**Aurobindo Pharma Ltd**:  
Mr. A. Vijaykumar  
Head - Anti Retrovirals Project  
Tel: +91 40 2304 4070  
Fax: +91 40 2304 4058

**Aspen**:  
Vivian Victor Viljoen - Senior Executive  
E-mail: viljoenv@aspenpharma.com  
Web site: www.aspenpharma.com  
Tel: +27 11 239 6551  
Fax: +27 11 239 6573

**AXIOS International**:  
Project Manager Access to HIV Care Programme  
P.O. Box 6924  
Tel: +256 75 693 756  
Fax: +256 41 543 021

**Bristol-Myers Squibb**:  
Pause:  
Tel: +49 6132 77-92701  
Fax: +49 6132 77-3929  
Website: www.bms.de

**Boehringer-Ingelheim**:  
Helmut Leuchten  
CD Marketing Prescription Medicines  
Head of CDept. HIV  
Tel: +49 6132 77-8486  
Fax: +49 6132 77-3829

**Biotechnology/Pharmaceuticals HIV/AIDS Industry Report - April 2005**:  

**Clinton Foundation**:  
http://www.clintonfoundation.org/

**Access Campaign web site**:  
http://www.accessmed-msf.org/
Untangling the Web of Price Reductions

Cipla Ltd:
Mr. Sanjeev Gupte, General Manager-Exports
Mr. Shailesh Pednekar, Executive-Exports, Cipla Limited
Tel: +91 22 23021397 (Direct) 23095521 23092891
Fax: +91 22 23070013/23070393/23070385
E-mail: exports@cipla.com and ciplaexp@cipla.com

Gilead:
Gilead Access Program: Deborah Ovadia, Gilead Access Program Manager
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, California 94404 USA
Tel: +1-650-574-3000, Option #1
Fax: +1-650-522-5870
E-mail: ARVaccess@gilead.com
Website: www.gileadaccess.org

Corporate Contact:
Sheryl Meredith, International Operations, Gilead Sciences
333 Lakeside Drive
Foster City, California 94404 USA
Tel: +1-650-522-5505
E-mail: smeredith@gilead.com

GlaxoSmithKline:
Isabelle Girault, Director, Government Affairs
HIV & AIDS
Tel: +44 (0) 20 8047 5488
Fax: +44 (0) 20 8047 6957
E-mail: isabelle.s.girault@gsk.com

Hetero Drugs Limited:
"Hetero House", H.No.:8-3-166/7/1, Erragadda, Hyderabad - 500 018, India
Tel: +91-40-23704923 / 24
Tel (Direct): +91-40-23818029
Fax: +91-40-23186357
E-mail: msreddy@heterodrugs.com

Merck & Co. Inc:
Brenda D. Colatrella, Executive Director, HIV Policy & External Affairs, Human Health Intercontinental
Merck & Co., Inc.
One Merck Drive (W2A-56)
Whitehouse Station, NJ 08889-0000 USA
Tel: +1-908-423-2047
Fax: +1-908-735-1839
E-mail: brenda_colatrella@merck.com

Ranbaxy:
Mr. Sandeep Juneja, Ranbaxy Laboratories Limited
Tel: +91 124 518 59 06 (Direct) or +91 124 513 50 00
Fax: +91 124 516 60 35
E-mail: sandeep.juneja@ranbaxy.com

Roche:
For information regarding quotations and deliveries to customers contact:
Hanspeter Wälchli, Logistics Sales International Customers Dept.
PTGS-I 4303 Kaiseraugst, Switzerland
Tel: +41 61 688 1060
Fax: +41 61 687 1526
E-mail: hanspeter.waelchli@roche.com

Strides Arcolab Ltd:
Mrs. Aloka Sengupta, Assistant Vice President - AIDS/Tuberculosis/Malaria
Strides House, Bilekahalli
Bannerghatta Road
Bangalore 560 076, India
Tel: +91-80-57580748
Fax: +91-80-57580747
E-mail: aloka.sengupta@stridesarco.com
Untangling the Web of Price Reductions

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


[4] Pharmaceutical patents and the TRIPSagreement


[8] WHO Global Price Reporting Mechanismdata base


[11] Examples of other generic manufacturersknown to be producing one or more ARVs,but not included in this survey are: ... Sources and Prices of selected medicinesand diagnostics for people living withHIV/AIDS, June 2005

[12] Incoterms definitions, InternationalChamber of commerce, see http://www.iccwbo.org/index_incoterms.asap


[14] Australian Ex Works  price


[21] Brazilian government’s websites www.aids.gov.br


[26] Please, note that there was an errorincalculations of this price in the 8th edition of"Untangling the web of price reductions",MSF, June 2005, www.accessmed-msf.org


[31] WHO puts abortifacients on it’s essentialdrug listhttp://bmj.bmjournals.com/cgi/content/full/331/7508/68-c


[33] http://www.pharmafield.co.uk/asp/article.asp?id=320&source=1

[34] CNN Money article, 7th June 2005

Untangling the Web of Price Reductions

Glossary

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 risk of damage to the goods during carriage. Consequently, the seller contracts for insurance and pays the insurance premium.

DDT 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 when the goods pass the ship's rail at the named place of destination. The seller has to bear the costs and risks of loss or damage to the goods from that point. The seller also has to clear the goods for export, and any additional costs due to events occurring after the time of delivery, are transferred from the seller to the buyer.

EEC Center of the customs formalities, the point of duty payment or customs clearance. The term is used in the Community to mean that the goods are delivered to the buyer at the Community border, the usual point of destination, and all the formalities for import, including customs duties, taxes and other charges, are payable and have been paid by the seller.

EEX "Ex-works". A commercial (incoterm) term meaning that the seller delivers when he places the goods at the disposal of the buyer at the place (e.g. works, factory, warehouse) named in the sales contract, or another named place (i.e. works, factory, warehouse etc.) but not cleared for export and not loaded on any collecting vehicle. The seller is not cleared for export and not unloaded from any transportation means.

EFOB "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. The costs and risks of loss or damage to the goods from that point are transferred from the seller to the buyer as well as any additional costs due to events occurring after the time of delivery. The FOB term requires the seller to clear the goods for export.

EFCF "Cost Insurance and Freight". A commercial (incoterm) term meaning that the seller delivers once the goods pass the ship's rail in the port of shipment. The seller has to bear the costs and risks of loss or damage to the goods during carriage, and any additional costs due to events occurring after the time of delivery, are transferred from the seller to the buyer.

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

EMT essential medicines list. First published in 1977 by WHO in collaboration with other United Nations agencies. The list was updated in 1993 and is intended to guide the selection of essential medicines for inclusion in the medicines burden in developing countries. The list includes over 300 medicines, which are divided into six categories based on their use and effect, and includes about 100 critical medicines, each of which is recommended for use in multiple disease areas. The list is updated every three years and is intended to help governments and international organizations prioritize the selection of essential medicines for programs.

EMTAD essential medicines list. First published in 1996 by WHO in collaboration with other United Nations agencies. The list was updated in 1999 and is intended to guide the selection of essential medicines for inclusion in the medicines burden in developing countries. The list includes over 300 medicines, which are divided into six categories based on their use and effect, and includes about 100 critical medicines, each of which is recommended for use in multiple disease areas. The list is updated every three years and is intended to help governments and international organizations prioritize the selection of essential medicines for programs.

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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.

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.

GlaxoSmithKline (GSK) is a human immunodeficiency virus (HIV) drug company.

Human Development Index (HDI) is a summary composite index compiled by UNDP that measures a country’s average achievements in three basic aspects of human development: a long and healthy life (life expectancy at birth), knowledge (education and skills), and a decent standard of living (per capita income).

Least Developed Countries (LDCs) are a group of countries that are considered to be the poorest in the world.

Lopinavir/ritonavir; boosted protease inhibitor

Médecins Sans Frontières •

National Drug Regulatory Authority (NDDA)

Non-Perinatal/Non-HIV/AIDS

Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)

Non-Governmental Organization (NGO)

Organization for Economic Co-operation and Development (OECD)

OPEC: Organization of Petroleum Exporting Countries

People Living With HIV/AIDS (PLHWA)

Prevention of Mother-to-Child Transmission (PMTCT)

Price Reductions Reporting Mechanism (PRRR)

Protease Inhibitor (PI)

Research and Development (R&D)

Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Trade-Related Intellectual Property Rights (TRIPs)

United Nations Educational, Scientific and Cultural Organization (UNESCO)

United Nations Development Programme (UNDP)

United Nations Joint Programme on HIV/AIDS (UNAIDS)

United Nations Office on Drugs and Crime (UNODC)

Voluntary license