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General background and objectives

Lack of clear information on pharmaceutical prices on the international market is a significant barrier to improving access to essential medicines in developing countries. The situation is particularly complex in the case of antiretrovirals (ARVs).

The data in this guide on ARV prices offered by originator companies and some generic companies in low- and middle-income countries are meant to inform buyers. This information is intended for use by government and non-profit procurement agencies, as well as other bulk purchasers of ARVs, including health facilities and NGOs.

This document is meant to be used in tandem with the report of *Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS Drugs and Diagnostics of Acceptable Quality*, a project initiated by WHO and developed in collaboration with other United Nations Organisations (UNAIDS, UNICEF, UNFPA). Drugs on this list are commonly referred to as 'pre-qualified'. This pilot project evaluates pharmaceutical products according to WHO recommended

standards of quality and compliance with Good Manufacturing Practices. It is part of an ongoing process that will expand as the participation of suppliers increases. It is important to note this list of 'pre-qualified' drugs is not exhaustive and exclusion from the list does not mean that a drug has not been approved by one or more national drug regulatory authorities. In fact all generic drugs included in this pricing guide have at least been cleared for marketing in their countries of origin.

The most up-to-date list of 'pre-qualified' products/suppliers of HIV-related medicines can be found on the WHO and other UN-collaborating agencies^[1].

Pricing information on other essential drugs and diagnostics used for HIV/AIDS can be found in the 3rd edition of the report *Sources and Prices of Selected Drugs and Diagnostics for People Living with HIV/AIDS* May 2002^[2].

This is the third edition of, *Accessing Antiretrovirals: Untangling the Web of Price Reductions for Developing Countries*, the first and second editions were published in October 2001 and June 2002 respectively^[3].

This third edition provides:

- **updated information** on prices for eligible countries, including both price per unit and price per patient per year
- **updated information and clarifications** on the conditions and restrictions applying to these offers
- **new information** on paediatric formulations

Methodology

In order to obtain accurate information on discounted price offers by both originator and generic companies, we repeated the methodology of the first two editions. Companies were re-contacted and asked to verify their offers. The list of generic producers included in this report is by no means exhaustive^[4].

Manufacturers were asked to provide the following information:

- drug, dosage and pharmaceutical form
- price per unit (or daily dose) of different price offers
- restrictions that apply to the offers, including:
 - i. country eligibility
 - ii. potential beneficiaries of the offer
 - iii. additional comments on conditions or procedures, such as quantity restrictions, how to access

discounts, bureaucratic procedures such as memoranda of understanding or special agreement

- iv. delivery of goods in relation to payment (FOB, CIF etc.)^[5]

For products for which complete information was available, the annual cost of therapy was calculated according to the dosing schedules reported in WHO *Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach*^[6] or the Centres for Disease Control and Prevention (CDC) *Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents*, by the Panel on Clinical Practices for the Treatment of HIV, 2002^[7].

All prices are quoted in US dollars and conversions were made on the day the price was received.

All prices were checked and verified by companies.

It is important to note that these prices may not correspond to end-user prices (prices to patients), which may be further influenced by other factors such as national distribution and handling charges, mark-up rates, and national and/or import and sales taxes. Information concerning the patent status of ARVs was not included in the present analysis, and will differ between countries. Some information about patent status of ARVs in some countries can be found in *Patent Situation of HIV/AIDS related drugs in 80 countries, WHO/UNAIDS, 2000*^[8].

Inclusion in the report does not constitute pre-qualification or approval by MSF. National regulatory authorities are ultimately responsible for approving use of a given drug from a given manufacturer. WHO pre-qualified drugs are indicated with an asterisk (*).

Limitations of the current system

The lack of a uniform preferential pricing system has resulted in each company defining a unique series of terms and criteria. For instance, whereas Merck & Co., Inc. takes into account criteria related to resources (Gross Domestic Product and the Human Development Index) and epidemiology (HIV/AIDS prevalence) to determine national eligibility (theoretically, nearly 120 countries benefit from this offer), GlaxoSmithKline (GSK) uses the classification of Least Developed Countries and the geographical classification of sub-Saharan countries (theoretically, nearly 63 countries benefit from this offer).

Most of the originator companies do not have a clear policy for countries outside sub-Saharan Africa, or those which are not classified by UNCTAD as Least Developed Countries. For example, Bristol-Myers Squibb (BMS) applies discounts to wholesale and retail purchasers in sub-Saharan Africa (theoretically, 48 countries benefit from this offer) but not in Central America.

Even when a given country is eligible, all institutions within the country may

not be eligible for reduced prices. Again, eligibility is currently at the companies' discretion.

In actual practice, MSF has observed that the most powerful downward pressure on prices has been a system of equity pricing. Equity pricing is composed of a series of simultaneous strategies: a) stimulating generic competition; b) differential pricing or voluntary licensing of proprietary products; and c) readiness on the part of national governments to override patents by issuing compulsory licenses according to existing safeguards when affordable prices are not offered for patented products (*Interpretation of TRIPS agreement safeguards according to the Doha declaration of Nov 2001*^[9]).

Although generic competition is a critical factor in reducing prices (see Graph on page 5, where the prices trend of a sample ARV triple therapy combination is shown over the period May 2000-December 2002), it cannot be a stand alone strategy as newer drugs may not be available in generic form. There is an urgent need to develop a more systematic, transparent approach to differential pricing of originator products in addition to stimulating generic competition.

The challenge of paediatric formulations

Children living with HIV/AIDS are one of the most neglected populations: paediatric formulations are lacking and/or formulations do not meet children's needs (unpleasant tasting syrup, tablets too big to swallow, need to refrigerate some products, unbreakable tablets).

A 'classic' paediatric solution such as a syrup is not always the most appropriate in resource-limited settings. Better options include low dosage capsules which can be opened and mixed with food or low dosage dispersible tablets. The lack of fixed-dose combinations for pediatric use is a particular challenge for physicians and care-givers.

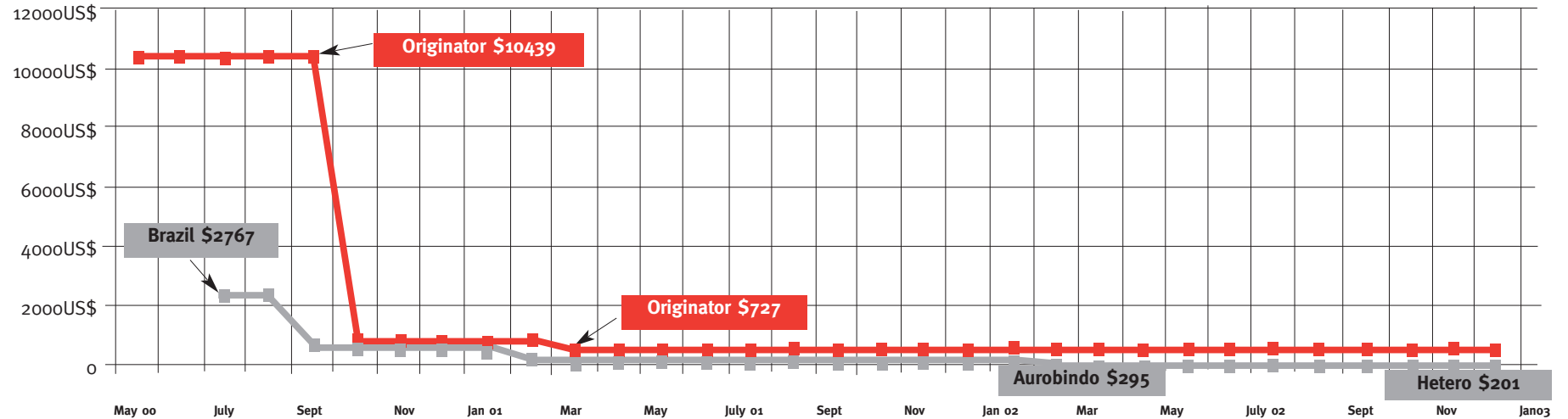
This edition introduces best price offers for paediatric formulations^[10].

The Effects of Generic Competition

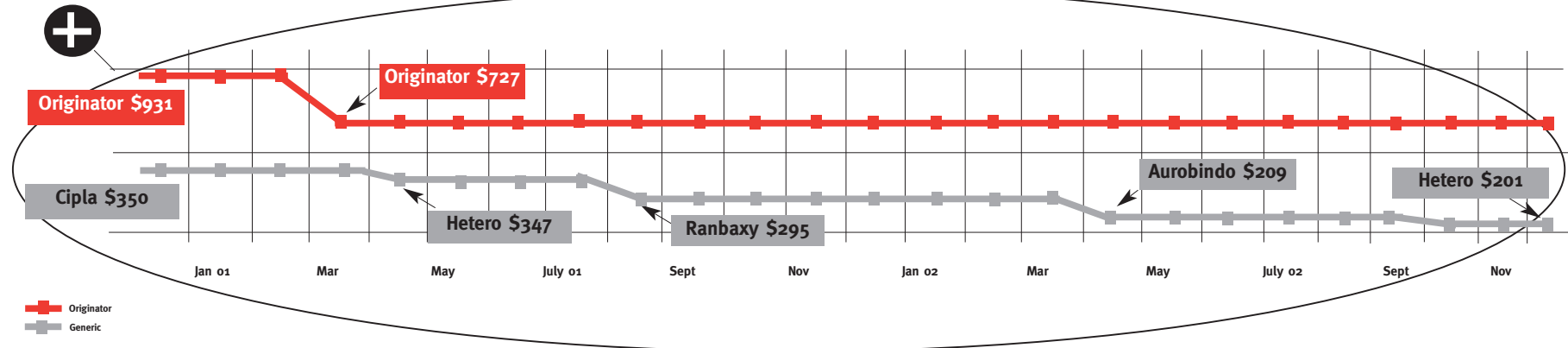
Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year.

Generic competition has shown to be the most effective means of lowering drug prices. During the last two years, originator companies have often responded to generic competition.

May 2000-Dec 2002



January 2000-Dec 2002



Guide to reading and using tables

Quality: This document strictly relates to prices: products from specific manufacturers have not necessarily been assessed for quality standards. Therefore, procurement agencies should follow their own procedure in this respect.

Prices: table 1 shows the best price offers of some generic manufacturers and originator producers for each antiretroviral drug, including fixed-dose combinations. Figures within brackets indicate price in US\$ per unit (capsules, tablets etc.). Prices per patient per year have been calculated according to daily doses given either in WHO guidelines or in CDC guidelines (for those products not recommended in WHO guidelines). Prices can be used as a reference with suppliers.

Restrictions: tables 2a and 2b show restrictions imposed by generic and originator companies and provide indications about the availability of offers in individual countries. There is no uniform differential pricing system and each company sets geographical limits to their programmes.

Access: since ARVs are not always registered and/or available in “selected countries”, many offers from pharmaceutical companies may remain “theoretical” until the companies are challenged to follow through on their offers.

Please refer to Annexes 1, 2 and 4 for updated country classification by UNCTAD (Least Developed Countries), UNDP (Human Development Index) and World Bank (Low income Countries). Annex 3 lists sub-Saharan countries.

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

Table 1a – Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

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

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

Products on the WHO list of Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS drugs and diagnostics of acceptable quality (edition of 9 September 2002) have an asterisk (*) next to the price.

Best prices are in **bold & underlined**.

Incoterms vary according to manufacturers.

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

NRTI (Abbreviation)	abacavir (ABC)	didanosine (ddl)	lamivudine (3TC)	lamivudine (3TC)	stavudine (d4T)	zidovudine (ZDV or AZT)
Strength (mg)	300	100 (\$)	150	300	40	300
Trade name in Europe/US	Ziagen® (GSK)	Videx® (BMS)	Epivir® (GSK)		Zerit® (BMS)	Retrovir® (GSK)
Daily dose	2	4	2	1	2	2
BMS (US) (US)		310* (0.212/unit)			55* (0.075/unit)	
GSK (UK)	986* (1.350/unit)		234* (0.320/unit)			438* (0.600/unit)
Aurobindo (India)		197 (0.135/unit)	66 (0.090/unit)		31 (0.043/unit)	140 (0.192/unit)
Cipla (India)	821 (1.125/unit)	426 (0.292/unit)	126 (0.172/unit)	124 (0.340/unit)	53 (0.072/unit)	198* (0.271/unit)
GPO (Thailand)		650 (0.445/unit)	163 (0.223/unit)		73 (0.100/unit)	277 (0.380/unit)
Hetero (India)	1325 (1.815/unit)	185 (0.127/unit)	65 (0.089/unit)		31 (0.042/unit)	175 (0.240/unit)
Ranbaxy (India)			100* (0.137/unit)		47 (0.064/unit)	180* (0.246/unit)
Combinopharm (Spain)						365 (0.500/unit)

(\$) BMS sells ddl (Videx®) in other doses (per mg price remains the same)

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

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

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

Products on the WHO list of Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS drugs and diagnostics of acceptable quality (edition of 9 September 2002) have an asterisk (*) next to the price.

Best prices are in **bold & underlined**.

Incoterms vary according to manufacturers.

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

NNRTI (Abbreviation)	efavirenz (EFV)	efavirenz (EFV)	nevirapine (NVP)
Strength (mg)	200	600	200
Trade name in Europe/US	Stocrin® (Merck & Co., Inc.)(**)	Stocrin® (Merck & Co., Inc.)(**)	Viramune® (Boehringer-Ingelheim)
Daily dose	3	1	2
Boehringer-Ingelheim (Germany)			438 (0.600/unit)
Merck & Co., Inc. (US)	500 (0.457/unit)	<u>346.75 (0.950/unit)</u>	
Aurobindo (India)	<u>438 (0.400/unit)</u>		112 (0.153/unit)
Cipla (India)	462 (0.422/unit)	462 (1.267/unit)	208* (0.285/unit)
GPO (Thailand)			244 (0.334/unit)
Hetero (India)	574 (0.500/unit)		<u>105 (0.144/unit)</u>
Ranbaxy (India)		578 (1.583/unit)	166* (0.228/unit)

(**) Known as Sustiva® (BMS) in developed countries.

Table 1c - Protease Inhibitors (PIs)

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

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

Products on the WHO list of Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS drugs and diagnostics of acceptable quality (edition of 9 September 2002) have an asterisk (*) next to the price.

Best prices are in **bold & underlined**.

Incoterms vary according to manufacturers.

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

For Roche, prices are given in Swiss Francs and were converted in US\$ (1 CHF = 0.69 US\$ on 14 November 2002).

PI (Abbreviation)	indinavir (IDV)	nelfinavir (NFV)	ritonavir (r)	saquinavir hard gel capsules (SQV hgc)	saquinavir soft gel capsules (SQV sgc)
Strength (mg)	400	250	100	200	200
Trade name in Europe/US	Crixivan® (Merck & Co., Inc.)	Viracept® (Roche)	Norvir® (Abbott)	Invirase® (Roche)	Fortovase® (Roche)
Daily dose	4 (**)	10 (***)	2 (§)	10 (#)	10 (#)
Abbott (US)			<u>83*</u> <u>(0.114/unit)</u>		
Merck & Co., Inc. (US)	400 (0.274/unit)				
Roche (US)		3172 (0.869/unit)		<u>1008</u> <u>(0.276/unit)</u>	<u>1573*</u> <u>(0.431/unit)</u>
Aurobindo (India)	393 (0.269/unit)	1533 (0.420/unit)	336 (0.460/unit)		
Cipla (India)	406 (0.278/unit)	2026 (0.555/unit)	1084 (1.485/unit)		
Hetero (India)	<u>387</u> <u>(0.265/unit)</u>	<u>1500</u> <u>(0.411/unit)</u>	219 (0.300/unit)	1335 (0.366/unit)	
Ranbaxy (India)	467 (0.320/unit)				

(**) The daily dose referred to is 800mg IDV twice daily with ritonavir 100mg twice daily as booster. This dose is not indicated in the manufacturer's label.

(***) The daily dose referred to is 1250 mg twice daily although In developed countries the dosage of 9 tablets is frequently used.

(§) The daily dose referred to is 100mg twice daily, for use as booster medication. This dose is not indicated in the manufacturer's label.

(#) According to the WHO, SQV should be used with ritonavir as a booster (1000 mg SQV plus 100 mg ritonavir twice daily); when combined with ritonavir either the soft gel capsules or the hard gel capsules can be used.

Table 1d – Fixed Dose Combinations (FDCs)

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

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

Combination	lopinavir+ ritonavir (LPV/r)	3TC+d4T	3TC+d4T	ZDV+3TC	ZDV+3TC NVP	ABC+3TC+ZDV	3TC+d4T+ NVP	3TC+d4T+ NVP
Strength (mg)	133.3 + 33.3	150 + 30	150 + 40	300+150	300 + 150 + 200	300+150+300	150 +30+200	150 +40+200
Therapeutic class(es)	PI	NRTI	NRTI	NRTI	NRTI + NNRTI	NRTI	NRTIs + NNRTI	NRTI + NNRTI
Trade name in Europe/US	Kaletra® (Abbott)			Combivir® (GSK)		Trizivir® (GSK)		
Daily dose	6	2	2	2	2	2	2	2
Abbott (US)	500* (0.228/unit)							
GSK (UK)				621* (0.850/unit)		1624* (2.225/unit)		
Aurobindo (India)				204 (0.280/unit)				
Cipla (India)		162 (0.222/unit)	172 (0.236/unit)	292 (0.400/unit)	418 (0.573/unit)		304 (0.417/unit)	304 (0.417/unit)
GPO (Thailand)				407 (0.558/unit)			325 (0.445/unit)	358 (0.490/unit)
Hetero (India)	3833 (1.750/unit)	135 (0.185/unit)	141 (0.193/unit)	276 (0.378/unit)	383 (0.525/unit)	1648 (2.258/unit)	281 (0.385/unit)	286 (0.392/unit)
Ranbaxy (India)		125* (0.171/unit)	135 (0.185/unit)	265* (0.363/unit)			285 (0.390/unit)	292 (0.400/unit)

Products on the WHO list of Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS drugs and diagnostics of acceptable quality (edition of 9 September 2002) have an asterisk (*) next to the price. Best prices are in **bold & underlined**. Incoterms vary according to manufacturers.

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

Table 1e – Paediatric Formulations

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

ARV (Abbreviation)	Company (trade name)	Strength/Dosage form	Presentation	Price per pack	Additional information
Zidovudine	GSK (Retrovir®)	10mg/ml oral solution	200ml	US\$ 7.90*	Cost per day as indicated by the manufacturer (average paediatric dosage based on 25kg average weight): US\$ 1.58
	Cipla (Zidovir®)	50mg/5ml oral solution	100ml	US\$ 1.53*	
	GPO (Antivir®)	10mg/ml syrup	60ml	US\$ 1.17	
	Combinopharm	50mg/5ml oral solution	200ml	US\$ 4.20	
Lamivudine	GSK (Epivir®)	10mg/ml oral solution	240ml	US\$ 7.45*	Cost per day as indicated by the manufacturer (average paediatric dosage based on 25kg average weight): US\$ 0.62
	Cipla (Lamivir®)	10mg/ml oral solution	100ml	US\$ 2.00*	
	GPO (Lamivir®)	10mg/ml syrup	60ml	US\$ 1.40	
Didanosine	BMS (Videx®)	powder: 2g of active principle sold as a bottle for re-constitution with water and with antacids		US\$ 16.61 (16.61 Euro) (**)	Sold in local currency in Southern Africa – Rand and East Africa - shillings. Sold in Euro to West African countries.
Abacavir	GSK (Ziagen®)	20mg/ml oral solution	240ml	US\$ 34.80*	Cost per day as indicated by manufacturer: 2.90US\$
Stavudine	BMS (Zerit®)	1mg/ml powder for syrup	200ml	US\$ 10.71 (10.71 Euro)(**)	Sold in local currency in Southern Africa - Rand and East Africa - shillings. Sold in Euro to West African countries.
	BMS (Zerit®)	20mg capsules	Blister pack of 56	tbc	
	GPO (Stavir®)	15mg capsules	Box of 60	US\$ 3.50	0.058 US\$/capsule
	GPO (Stavir®)	20mg capsules	Box of 60	US\$ 4.20	0.070 US\$/capsule
Nevirapine	BI (Viramune®)	10mg/ml suspension	240ml	US\$ 17.50	
	Cipla (Nevimune®)	50mg/5ml suspension	100ml & 25ml (PMTCT)	US\$ 2.45 & US\$ 2.00 (PMTCT)	PMTCT dose: 25ml
Ritonavir	Abbott (Norvir®)	80mg/ml oral solution	450ml(5x90ml)	US\$ 41.67*	
Ritonavir + lopinavir	Abbott (Kaletra®)	20mg + 80mg/ml oral solution	300ml(5x60ml)	US\$ 41.67*	
Nelfinavir	Roche (Viracept®)	50mg/g, powder for suspension	144g	US\$ 15.87 (23.00 CHF) (**)	

(**) on 14 November 2002, 1 Euro = 1.00 US\$ and 1 CHF = 0.69 US\$. Products on the WHO list of Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS drugs and diagnostics of acceptable quality (edition of 9 September 2002) have an asterisk (*) next to the price. Incoterms vary according to manufacturers.

Table 2 Originator companies' ARV offers and restrictions for developing countries

Table 2a Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

Product	Company	Eligibility (countries)	Eligibility (body)	Price (US\$ per year and per unit)	Additional comments	Delivery of goods ^[5]
abacavir (Ziagen®)	GlaxoSmithKline	Least Developed Countries (LDCs) plus sub-Saharan Africa All projects fully financed by the Global Fund to fight AIDS, TB and Malaria <i>(For middle income developing countries public sector prices negotiated on a case-by-case basis or bilaterally or through the AAI)</i>	Governments, aid organisations, UN agencies, other not-for profit organisations and international purchase funds such as the Global Fund to fight AIDS, TB and Malaria In sub-Saharan Africa employers there who offer HIV/AIDS care and treatment directly to their staff through workplace clinics or similar arrangements are also eligible All organisations must supply the preferentially priced products on a not for profit basis	US\$ 986/year 1.350/unit	Supply Agreement required (For NGOs requiring less than 10 patient packs per month, this requirement may be waived)	CIP
didanosine (Videx®)	Bristol-Myers Squibb Co.	Sub-Saharan Africa <i>(For other developing countries, prices negotiated on a case by case basis)</i>	Both private and public sector organisations that are able to provide effective, sustainable and medically sound care and treatment of HIV/AIDS are eligible	US\$ 310/year US\$ 0.212/unit Lower tablet dosages prices in line with this offer		DDU to government purchasing entities
lamivudine (Epivir®)	GlaxoSmithKline	LDCs plus sub-Saharan Africa All projects fully financed by the Global Fund to fight AIDS, TB and Malaria	Governments, aid organisations, charities, international, UN agencies, other not-for-profit organisations and international purchase funds such as the Global Fund to fight AIDS, TB and Malaria	US\$ 234/year US\$ 0.320/unit	Supply Agreement required (For NGOs requiring less than 10 patient packs per month, this requirement may be waived)	CIP

Product	Company	Eligibility (countries)	Eligibility (body)	Price (US\$ per year and per unit)	Additional comments	Delivery of goods ¹⁵
		<p>All projects fully financed by the Global Fund to fight AIDS, TB and Malaria</p> <p><i>(For middle income developing countries public sector prices negotiated on a case-by-case basis or bilaterally or through the AAI)</i></p>	<p>In sub-Saharan Africa employers there who offer HIV/AIDS care and treatment directly to their staff through workplace clinics or similar arrangements are also eligible</p> <p>All organisations must supply the preferentially priced products on a not for profit basis</p>			
stavudine (Zerit®)	Bristol-Myers Squibb Co.	<p>Sub-Saharan Africa</p> <p><i>(For other developing countries, prices negotiated on a case by case basis)</i></p>	<p>Both private and public sector organisations that are able to provide effective, sustainable and medically sound care and treatment of HIV/AIDS are eligible</p>	<p>US\$ 55/year (US\$0.075/unit)</p> <p>Lower capsule dosages priced in line with this offer.</p>		DDU to government purchasing entities
zidovudine (Retrovir®)	GlaxoSmithKline	<p>LDCs plus sub-Saharan Africa</p> <p>All projects fully financed by the Global Fund to fight AIDS, TB and Malaria</p> <p><i>(For middle income developing countries public sector prices negotiated on a case-by-case basis or bilaterally or through the AAI)</i></p>	<p>Governments, aid organisations, charities, international, UN agencies, other not-for-profit organisations and international purchase funds such as the Global Fund to fight AIDS, TB and Malaria</p> <p>In sub-Saharan Africa, employers there who offer HIV/AIDS care and treatment directly to their staff through workplace clinics or similar arrangements are also eligible</p> <p>All organisations must supply the preferentially priced products on a not for profit basis</p>	<p>US\$ 438/year (US\$ 0.600/unit)</p>	<p>Supply Agreement required</p> <p>(For NGOs requiring less than 10 patients packs per month, this requirement may be waived)</p>	CIP

Table 2b Non-Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

Product	Company	Eligibility (countries)	Eligibility (body)	Price (US\$ per year and per unit)	Additional comments	Delivery of goods ^[5]
efavirenz (Stocrin®)	Merck & Co., Inc.	Low Human Development Index (HDI) countries plus medium HDI countries with adult HIV prevalence of 1% or greater	Governments, international organisations, NGOs, private sector organisations (e.g. employers, hospitals and insurers) Merck & Co., Inc. does not rule out supplying ARVs to patients through retail pharmacies	200mg capsule: US\$ 500/year (US\$ 0.457/unit) 600mg tablet: US\$ 346.75/year (US\$ 0.950/unit)	Although Romania does not fall under these categories it also benefits from these prices.	CIF
efavirenz (Stocrin®)	Merck & Co., Inc.	Medium HDI countries with adult HIV prevalence less than 1%	Governments, international organisations, NGOs, private sector organisations (e.g. employers, hospitals and insurers). Merck & Co., Inc. does not rule out supplying ARVs to patients through retail pharmacies	200mg capsule: US\$ 920/year (US\$ 0.840/unit) 600mg tablet: US\$ 767/year (US\$ 2.10/unit)		CIF
nevirapine (Viramune®)	Boehringer Ingelheim	All World Bank low-income countries and sub-Saharan Africa <i>(Other countries on a case-by-case basis)</i>	Governments, NGOs and other partners who can guarantee that the programme is run in a responsible manner.	US\$ 438/year (US\$ 0.600/unit)		CIF

Table 2c Protease Inhibitors (PIs)

Product	Company	Eligibility (countries)	Eligibility (body)	Price (US\$ per year and per unit)	Additional comments	Delivery of goods ^[5]
indinavir (Crixivan®)	Merck & Co., Inc.	Low Human Development Index (HDI) countries plus medium HDI countries with adult HIV prevalence of 1% or greater	Governments, international organisations, NGOs, private sector organisations (e.g. employers, hospitals and insurers) Merck & Co., Inc. does not rule out supplying ARVs to patients through retail pharmacies	US\$ 400/year (US\$ 0.274/unit)	Although Romania does not fall under these categories it also benefits from these prices.	CIF
indinavir (Crixivan®)	Merck & Co., Inc.	Medium HDI countries with adult HIV prevalence less than 1%	Governments, international organisations, NGOs, private sector organisations (e.g. employers, hospitals and insurers) Merck & Co., Inc. does not rule out supplying ARVs to patients through retail pharmacies	US\$ 686/year (US\$ 0.470/unit)		CIF
nelfinavir (Viracept®)	Roche	LDCs plus sub-Saharan Africa	Governments, NGOs, Private sector employers	Bottle of 270 tablets: CHF 340.00 (US\$ 234.60) US\$ 3172/year (US\$ 0.869/unit)		FOB (must be shipped from Switzerland)
ritonavir (Norvir®)	Abbott	All African countries and the LDCs outside of Africa	Governments, NGOs, UN system organisations, and other national and international health institutions	“Booster dose”: US\$ 83/year (US\$ 0.114/unit)		FOB
saquinavir (Fortovase®) soft gel capsules	Roche	LDCs plus sub-Saharan Africa	Governments, NGOs, private sector employers	Bottle of 180 capsules: CHF 112.50 (US\$ 77.63) About US\$ 1573/year (US\$ 0.431/unit)		FOB (must be shipped from Switzerland)
saquinavir (Invirase®) hard gel capsules	Roche	LDCs plus sub-Saharan Africa	Governments, NGOs, private sector employers	Bottle of 270 capsules: CHF 108 (US\$ 74.52) US\$ 1008/year (US\$ 0.276/unit)		FOB (must be shipped from Switzerland)

Table 2d Fixed Dose Combinations

Product	Company	Eligibility (countries)	Eligibility (body)	Price (US\$ per year and per unit)	Additional comments	Delivery of goods ⁵¹
lopinavir/ritonavir (Kaletra®)	Abbott	All African countries and the Least Developed Countries (LDCs) outside of Africa	Governments, NGOs, UN system organisations, and other national and international health institutions	US\$ 500/year (0.228/unit)		FOB
3TC + ZDV (Combivir®)	GlaxoSmithKline	LDCs plus sub-Saharan Africa All projects fully financed by the Global Fund to fight AIDS, TB and Malaria <i>(For middle income developing countries public sector prices negotiated on a case-by-case basis bilaterally or through the AAI)</i>	Governments, aid organisations, charities, international, UN agencies, other not-for-profit organisations and international purchase funds such as the Global Fund to fight AIDS, TB & Malaria. In sub-Saharan Africa, employers there who offer HIV/AIDS care and treatment directly to their staff through workplace clinics or similar arrangements are also eligible. All organisations must supply the preferentially priced products on a not for profit basis.	US\$ 621/year (US\$ 0.850/unit)	Supply Agreement required (For NGOs requiring less than 10 patients packs per month, this requirement may be waived)	CIP
abacavir + 3TC + ZDV (Trizivir®)	GlaxoSmithKline	LDCs plus sub-Saharan Africa All projects fully financed by the Global Fund to fight AIDS, TB and Malaria <i>(For middle income developing countries public sector prices negotiated on a case-by-case basis bilaterally or through the AAI)</i>	Governments, aid organisations, charities, international, UN agencies, other not-for-profit organisations and international purchase funds such as the Global Fund to fight AIDS, TB & Malaria. In sub-Saharan Africa, employers there who offer HIV/AIDS care and treatment directly to their staff through workplace clinics or similar arrangements are also eligible. All organisations must supply the preferentially priced products on a not for profit basis.	US\$ 1624/year (US\$ 2.225 /unit)	Supply Agreement required (For NGOs requiring less than 10 patients packs per month, this requirement may be waived)	CIP

Table 2e Selected generic companies' ARV offers and restrictions for developing countries

All companies were invited to verify their offers during November 2002.

Company	Eligibility (countries)	Eligibility (body)	Price (US\$ per year and per unit)	Additional comments	Delivery of goods ⁵¹
Aurobindo	No restriction	NGOs and Governmental Organizations	See Table 1	Prices available for at least 1,000,000 units for each product per single shipment Payment by letter of credit	FOB Hyderabad (India)
Cipla	No restriction	NGOs and Governmental Organizations	See Table 1	Payment at the confirmation of the order Only available directly through Cipla HQ Mumbai	FOB Mumbai (India)
GPO	No restriction	Not-for-profit organizations and governments	See Table 1	Payment by signed letter of credit	FOB Bangkok (Thailand)
Hetero	No restriction	Private sector, Public sector and NGO's	See Table 1	Prices could be negotiated on individual basis according commercial terms	FOB Mumbai (India)
Ranbaxy	No restriction	NGO's and Governments or Programs supported by them	Prices given in Table 1 apply to orders for a minimum of 1.5 million units. Different prices are offered for smaller quantities (500 000 or 1 million units)	Signed letter of credit	FOB Delhi/Mumbai (India)
Combinopharm	No restriction	No restriction	See Table 1	Delivery terms 120 days. No minimum order required unless any special labelling is required (standard labelling is in Spanish): order of a complete batch. Pack of 60 or 300 capsules available for ZDV	FOB Barcelona (Spain)

Other generic manufacturers producing ARVs exist but are not included in this summary of offers⁴¹.

Annexes

Annex 1: Least Developed Countries (LDCs)

Forty-nine countries are currently designated least developed countries (LDCs). The list is reviewed every three years. Source:

<http://www.unctad.org/Templates/WebFlyer.asp?intItemID=2161&lang=1>

Afghanistan; Angola; Bangladesh; Benin; Bhutan; Burkina Faso; Burundi; Cambodia; Cape Verde; Central African Republic; Chad; Comoros; Democratic Republic of Congo; Djibouti; Equatorial Guinea; Eritrea; Ethiopia; Gambia; Guinea; Guinea Bissau; Haiti; Kiribati; Lao People's Democratic Republic; Lesotho; Liberia; Madagascar; Malawi; Maldives; Mali; Mauritania; Mozambique; Myanmar; Nepal; Niger; Rwanda; Samoa, Sao Tome and Principe; Senegal; Sierra Leone; Solomon Islands; Somalia; Sudan; Togo; Tuvalu; Uganda; United Republic of Tanzania; Vanuatu; Yemen; Zambia.

Annex 2: Human Development Index (HDI)

Source: Human Development Report 2002, Making new technologies work for human development UNDP. For full list of Human Development Index ranking see <http://www.undp.org/hdr2002/back.pdf>

Medium human development

Albania; Algeria; Armenia; Azerbaijan; Belarus; Belize; Bolivia; Botswana; Brazil; Bulgaria; Cambodia; Cameroon; Cape Verde; China; Colombia; Comoros; Congo; Cuba; Dominica; Dominican Republic; Ecuador; Egypt; El Salvador; Equatorial Guinea; Fiji; Gabon; Georgia; Grenada; Ghana; Guatemala; Guyana; Honduras; India; Indonesia; Iran (Islamic Rep. of); Jamaica; Jordan; Kazakhstan; Kenya; Kyrgyzstan; Lebanon; Lesotho; Libyan Arab Jamahiriya; Macedonia (TFYR); Malaysia; Maldives; Mauritius; Mexico; Moldova (Rep. of); Mongolia; Morocco; Myanmar; Namibia; Nicaragua; Oman; Panama; Papua New Guinea; Paraguay; Peru; Philippines; Romania; Russian Federation; Saint Lucia; Saint Vincent & the Grenadines; Samoa (Western); São Tomé & Príncipe; Saudi Arabia; Solomon Islands; South Africa; Sri Lanka; Suriname; Swaziland; Syrian Arab Republic; Tajikistan; Thailand;

Tunisia; Turkey; Turkmenistan; Ukraine; Uzbekistan; Vanuatu; Venezuela; Viet Nam; Zimbabwe.

Low human development

Angola; Bangladesh; Benin; Bhutan; Burkina Faso; Burundi; Central African Republic; Chad; Congo (Dem. Rep. of the); Côte d'Ivoire; Djibouti; Eritrea; Ethiopia; Gambia; Guinea; Guinea-Bissau; Haiti; Lao People's Dem. Rep.; Madagascar Malawi; Mali; Mauritania; Mozambique; Nepal; Niger; Nigeria; Pakistan; Rwanda; Senegal; Sierra Leone; Sudan; Tanzania (U. Rep. of); Togo; Uganda; Yemen; Zambia.

Annex 3: Sub-Saharan countries

Source: <http://www.worldbank.org/data/databytopic/CLASS.XLS> (July 2002)

Angola; Benin; Botswana; Burkina Faso; Burundi; Cameroon; Cape Verde; Central African Republic; Chad; Comoros; Congo (Dem. Rep.); Congo (Rep.); Côte d'Ivoire; Equatorial Guinea; Eritrea; Ethiopia; Gabon; Gambia; Ghana; Guinea; Guinea-Bissau; Kenya; Lesotho; Liberia; Madagascar; Malawi; Mali; Mauritania; Mauritius; Mayotte; Mozambique; Namibia; Niger; Nigeria; Rwanda; São Tomé and Príncipe; Senegal; Seychelles; Sierra Leone; Somalia; South Africa; Sudan; Swaziland; Tanzania; Togo; Uganda; Zambia; Zimbabwe.

Annex 4: World Bank low-income countries

Source: <http://www.worldbank.org/data/databytopic/CLASS.XLS> (July 2002)

Afghanistan; Angola; Armenia; Azerbaijan; Bangladesh; Benin; Bhutan; Burkina Faso; Burundi; Cambodia; Cameroon; Central African Republic; Chad; Comoros; Congo (Dem. Rep.); Congo (Rep.); Côte d'Ivoire; Eritrea; Ethiopia; Gambia; Georgia; Ghana; Guinea; Guinea-Bissau; Haiti; India; Indonesia; Kenya; Korea, Dem. Rep.; Kyrgyz Republic; Lao PDR; Lesotho; Liberia; Madagascar; Malawi; Mali; Mauritania; Moldova; Mongolia; Mozambique; Myanmar; Nepal; Nicaragua; Niger; Nigeria; Pakistan; Rwanda; São Tomé and Príncipe; Senegal; Sierra Leone; Solomon Islands; Somalia; Sudan; Tajikistan; Tanzania; Togo; Uganda; Ukraine; Uzbekistan; Vietnam; Yemen (Rep.); Zambia; Zimbabwe.

Annex 5: Company contacts

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Glossary and abbreviations^[11]

3TC lamivudine (Epivir®); nucleoside analogue reverse transcriptase Inhibitor

AAI United Nations Accelerating Access Initiative; Accelerated Access emerged out of the partnership initiated in May 2000 between the UN (UNFPA, UNICEF, WHO, the World Bank and UNAIDS Secretariat) and five pharmaceutical companies (Boehringer-Ingelheim GmbH, Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co., Inc., and F. Hoffmann-La Roche Ltd (Roche); Abbott Laboratories Ltd. joined the initiative later) to increase access to HIV/AIDS care, treatment and support. AAI plays a role in facilitating price negotiations between developing country governments and ‘originator’ drug companies that are participating in the AAI.

ABC abacavir (Ziagen®); nucleoside analogue reverse transcriptase inhibitor

AIDS Acquired Immune Deficiency Syndrome

ARVs Antiretroviral drugs

BMS Bristol-Myers Squibb

CDC Centres for Disease Control and Prevention

CIF^{ISI} ‘Cost Insurance and Freight’ means that the seller delivers when the goods pass the ship’s rail in the port of shipment. The seller must pay the costs and freight necessary to bring the goods to the named port of destination BUT the risk of loss or damage to the goods, as well as any additional costs due to events occurring after the time of delivery, are transferred from the seller to the buyer.

CIP^{ISI} ‘Carriage and Insurance paid to...’ means that the seller delivers the goods to the carrier nominated by him but the seller must in addition pay the cost of carriage necessary to bring the goods to the named destination. This means that the buyer bears all the risks and any additional costs occurring after the goods have been so delivered. However, in CIP the seller also has to procure insurance against the buyer’s risk of loss of or damage to the goods during the carriage. Consequently, the seller contracts for insurance and pays the insurance premium.

d4T stavudine (Zerit®); nucleoside analogue reverse transcriptase inhibitor

ddI didanosine (Videx®); nucleoside analogue reverse transcriptase inhibitor

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

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

EFV efavirenz (Stocrin®); non-nucleoside analogue reverse transcriptase inhibitor

EXW⁵¹ 'Ex-works' means that the seller delivers when he places the goods at the disposal of the buyer at the seller's premises or another named place (i.e. works, factory, warehouse etc.) not cleared for export and not loaded on any collecting vehicle.

FOB⁵¹ 'Free on board' means that the seller delivers when the goods pass the ship's rail at the named port of shipment. This means that the buyer has to bear all costs and risks of loss or damage to the goods from that point. The FOB term requires the seller to clear the goods for export.

Generic drug According to WHO, a pharmaceutical product usually intended to be interchangeable with the innovator product, which is usually manufactured without a license from the innovator company. Generic products may be marketed either under a non-proprietary or approved name rather than a proprietary name.

GPO Governmental Pharmaceutical Organization (Thailand)

GSK GlaxoSmithKline

HIV Human Immunodeficiency Virus

IDV indinavir (Crixivan®); protease inhibitor

LDCs Least Developed Countries, according to United Nations classification

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

MSF Médecins Sans Frontières

NGO Non Governmental Organization

NFV nelfinavir (Viracept®); protease inhibitor

NNRTI Non-Nucleoside Reverse Transcriptase Inhibitor

NRTI Nucleoside Analogue Reverse Transcriptase Inhibitor

NVP nevirapine (Viramune®); non-nucleoside analogue reverse transcriptase inhibitor

PMTCT Prevention of Mother-To-Child Transmission

r ritonavir (Norvir®), low dose ritonavir used as a booster; protease inhibitor

SQV hgc saquinavir hard gel capsules (Invirase®); protease inhibitor

SQV sgc saquinavir soft gel capsules (Fortovase®); protease inhibitor

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

UNDP United Nations Development Programme

UNFPA United Nations Population Fund

UNICEF United Nations Children's Fund

WHO World Health Organization

ZDV zidovudine (Retrovir®); nucleoside analogue reverse transcriptase inhibitor

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<http://www.who.int/medicines/library/par/hivrelateddocs/sourcesandpricesmay.doc>
- [3] Accessing ARVs: Untangling the Web of Price Reductions for Developing Countries, first edition, October 2001 and second edition, June 2002
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http://www.who.int/HIV_AIDS/CARE/ScalingUp_Guidelines_Final021002.pdf
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<http://www.hivatis.org>
- [8] Patent Situation of HIV/AIDS related drugs in 80 countries, WHO/UNAIDS, 2000
<http://www.who.int/medicines/library/par/hivrelateddocs/patentshivdrugs.pdf>
- [9] More information about the World Trade Organisation (WTO) Agreement on Trade-related aspects of intellectual property rights (TRIPS) can be found at
http://www.wto.org/english/tratop_e/trips_e/trips_e.htm. The full declaration is also available on the WTO site.
- [10] For more information on paediatric treatment in resource-limited settings see WHO Guidelines “Scaling Up Antiretroviral Therapy in Resource-Limited Settings” (June 2002)
- [11] Abbreviations for the ARVs are taken from the WHO draft guidelines “Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health approach”
http://www.who.int/HIV_AIDS/HIV_AIDS_Care/ARV_Draft_April_2002.pdf

company
price
reliability
countries
reductions
reductions

Untangling the web of price reductions:

a pricing guide for the purchase of ARVs for developing countries



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