

Untangling the Web of Price Reductions:

a Pricing Guide for the Purchase of ARVs for Developing Countries

June 2002 2nd edition

Campaign for Access to Essential Medecines

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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 are designed to assist buyers in making informed decisions and negotiating affordable prices, by providing them with ARV prices offered by originator companies and some generic companies in low- and middle-income countries. It 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 pricing guide 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). This pilot project evaluates pharmaceutical products according to WHO recommended standards of quality and compliance with Good Manufacturing Practices. It is the beginning of an ongoing process that will expand as the participation of suppliers increase.

A list of suppliers whose HIV-related medicines have already been validated for procurement is now available on the websites of collaborating UN agencies.

Pricing information on other essential drugs and diagnostics needed for HIV/AIDS can be found in the 4th edition of the report "Sources and Prices of Selected Drugs and Diagnostics for People Living with HIV/AIDS"².

Information on prices offered by some generic and originator companies, including conditions and restrictions, was first published in the first edition of this document, "Accessing Antiretrovirals: Untangling the Web of Price Reductions for Developing Countries", in October 2001³.

This second edition provides:

- updated information on sample prices for low- and middle-income countries, including new fixed-dose drug combinations.
- updated information on the conditions and restrictions applying to these offers.

Methodology

In order to obtain accurate information on discounted price offers by both originator and generic companies, we repeated the methodology used for the first edition. Companies were re-contacted and asked to verify their offers. In addition, we contacted companies that had communicated new offers since October 2001⁴.

Manufacturers were asked to provide information on the following:

- 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's "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines

for a Public Health Approach"⁶ or the 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, April 13th, 2001⁷.

Prices quoted and currency conversion rate used were established on the date the offer was made.

All prices were checked and confirmed by the companies making the offers.

It is important to note that these prices do not correspond to end-user (patient) prices, which can be influenced by other factors such as transport costs, handling charges, national mark-up rates, national and/or import and sales taxes (if applicable) and national health policies.

Inclusion in the report does not constitute pre-qualification or approval of any sort by MSF. National regulatory authorities are ultimately responsible for approving use of a given drug from a given manufacturer.

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, 2000⁸.

Limitations of the current system

The lack of a uniform pricing system has resulted in each company defining a unique series of terms and criteria. For instance, whereas Merck & Co., Inc. uses the Human Development Index and prevalence of HIV to determine national eligibility, GlaxoSmith-Kline (GSK) uses the classification of least developed countries and the geographical classification of sub-Saharan countries.

Most of the originator companies do not have a clear policy for countries outside sub-Saharan Africa, or 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 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, prices have only dramatically decreased in countries where

an equity pricing policy is in place. Equity pricing is composed of a series of simultaneous strategies: a) stimulating generic competition; b) differential pricing or voluntary licensing of proprietary products; c) readiness on the part of national governments to override patents when affordable prices are not offered for patented products; and d) regional or international bulk procurement.

Although generic competition is a critical factor in reducing prices (see Graph 1, where the prices trend of a sample ARV triple therapy combination is shown over the period May 2000-April 2002), it cannot stand alone as a strategy. There is an urgent need to develop a more systematic, transparent approach to differential pricing of originator products combined with increased access to generic products. This system can only be developed by a UN affiliated organisation with the mandate to address health and economic issues, such as the WHO or UNDP. In order for countries to administer care programmes that maximise the usefulness of existing therapies, they will need access to all the ARVs on the Essential Medicines List⁹. This is far from the current reality.

Snapshot of eligibility requirements

(for more detailed information see table 2)

Abbott: governments, non-governmental organisations (NGOs), UN system organisations, and other national and international health institutions

BMS: both private and public sector organisations that are able to provide effective, sustainable and medically sound care and treatment to HIV/AIDS patients

Boehringer Ingelheim: governments, NGOs and other partners who can guarantee that the programme is run in a responsible manner

GSK: governments, aid organisations, charities, international and UN agencies and international purchase funds

Merck & Co., Inc.: governments, international organisations, NGOs, and private sector organisations

Roche: governments, NGOs, private sector employers **Aurobindo:** NGOs, and governmental organisations **Cipla:** NGOs and governmental organisations

GPO: Not-for-profit organisations and governments **Hetero:** private sector, public sector and NGOs

Ranbaxy: NGOs and governments or programmes supported by them

Note to readers:

In order to collect further and updated information on prices available in different countries and to different bodies, MSF encourages international organisations, governments and other purchasers to share information. Please send any relevant information to: access@geneva.msf.org or by fax: +41 22 849 84 04. Any information collected by December 15th, 2002, will be used to prepare the next update of this document.

The Effects of Generic Competition

Sample of ARV triple-combination:

Lowest world prices per patient per year

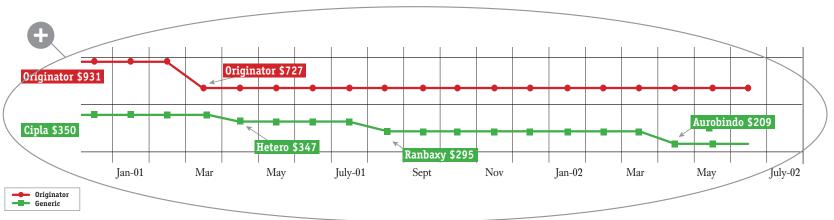
(stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP))

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 2001 - July 2002



January 2001 - July 2002



Guide to reading and using tables

Table 1 shows the best price offers of some generic manufacturers and originator producers for each antiretroviral drug, including fixed-dose combinations. Products are classified by therapeutic class. This table provides indicator prices, and can be used as a reference for negotiations with suppliers. As explained above, these offers do not apply to all developing countries or to all institutions in a given country, but are subject to a series of restrictions and limitations.

Table 2 shows restrictions imposed by generic and originator companies. This table provides indications about availability of offers in individual countries. However, because of lack of agreement on terms and the ambiguous nature of some offers, it is not always clear whether a certain type of institution is eligible for a given level of discount in a given country.

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

This document is also available in French and Spanish at www.accessmed-msf.org

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

Table 1a - Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

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

(*) Zalcitabine was not included in the 12th Edition of the WHO Essential Medicines List^o. For daily dose, "Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents", by the Panel on Clinical Practices for the Treatment of HIV, 2001, was taken as reference document⁷.

Prices are shown in US\$ per adult patient per year. For details on conditions please refer to Table 2. Unless otherwise noted prices are FOB for generic Manufacturers, and at least CIF for originator companies. All prices in other currencies than dollars were converted at the rate in force when the offer was made. Prices are rounded up to whole numbers for easier comparison. Annual costs are calculated according to the daily doses given in the WHO document "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 20026. Suppliers have not necessarily been assessed for quality standards, procurement agencies should follow their own procedures in this respect.

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

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

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

Prices are shown in US\$ per adult patient per year. For details on conditions please refer to Table 2. Unless otherwise noted prices are FOB for generic Manufacturers, and at least CIF for originator companies. All prices in other currencies than dollars were converted at the rate in force when the offer was made. Prices are rounded up to whole numbers for easier comparison. Annual costs are calculated according to the daily doses given in the WHO document "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 2002. Suppliers have not necessarily been assessed for quality standards, procurement agencies should follow their own procedures in this respect.

Table 1c - Protease Inhibitors (PIs)

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

- (*) Amprenavir was not included in the 12th Edition of the WHO Essential Medicines List ⁹. For daily dose, "Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents", by the Panel on Clinical Practices for the Treatment of HIV, 2001, is used as a reference.⁷
- (**) Please note that "Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents", by the Panel on Clinical Practices for the Treatment of HIV, 2001, is used as a reference. According to the WHO document "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 20026, IDV should be used combination with ritonavir as a booster (800mg IDV plus 100mg ritonavir twice daily): it will be included in the next edition.
- (***) The daily dose is 1250 mg twice daily (both "Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents", by the Panel on Clinical Practices for the Treatment of HIV, 2001 and WHO document "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 2002).^{7,6}
- (1) The daily dose is 100mg twice daily, for use as booster medication (see "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 2002, and the WHO Essential Medicine List, 12th Edition, April 2002).
- (#) Saquinavir is also available as hard-gel formulation from both Roche and generic manufacturers.
- (##) Please note that according to the WHO document "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 20026, 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.

Prices are shown in US\$ per adult patient per year. For details on conditions please refer to Table 2. Unless otherwise noted prices are FOB for generic Manufacturers, and at least CIF for originator companies. All prices in other currencies than dollars were converted at the rate in force when the offer was made. Prices are rounded up to whole numbers for easier comparison. Unless differently stated, annual costs are calculated according to the daily doses given in the WHO document "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 20026. Suppliers have not necessarily been assessed for quality standards, procurement agencies should follow their own procedures in this respect.

Table 1d: Fixed Dose Combinations (FDCs)

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

Prices are shown in US\$ per adult patient per year. For details on conditions please refer to Table 2. Unless otherwise noted prices are FOB for generic Manufacturers, and at least CIF for originator companies. All prices in other currencies than dollars were converted at the rate in force when the offer was made. Prices are rounded up to whole numbers for easier comparison. Annual costs are calculated according to the daily doses given in the WHO document "Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach", 22nd April 2002°. Suppliers have not necessarily been assessed for quality standards, procurement agencies should follow their own procedures in this respect.

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

Product	Company (for all company contacts see annex 4)	Eligibility (countries)	Eligibility (body)	Price (US\$ per year and per day)	Additional Comments	Delivery of goods ⁵
abacavir (Ziagen®) NRTI	GlaxoSmithKline	Least Developed Countries (LDCs) plus sub-Saharan Africa For middle income developing countries public sector prices negotiated on a case-by-case basis or bilaterally or through the AAI	Governments, aid organisations, charities, international and UN agencies and international purchase funds. In sub-Saharan Africa offer only available to employers who can deliver care and treatment directly to their staff. All organisations must supply the preferentially priced products on a not for profit basis.	US\$ 1387/year (US\$ 3.80/day)	See Annexes 1 and 3 Supply Agreement required	CIF
abacavir + 3TC + ZDV (Trizivir®) NRTI	GlaxoSmithKline	LDCs plus sub-Saharan Africa For middle income developing countries public sector prices negotiated on a case-by-case basis or bilaterally or through the AAI	same as GSK above	US\$ 2409/year (US\$ 6.60/day)	See Annexes 1 and 3 Supply Agreement required	CIF
amprenavir (Agenerase®) PI	GlaxoSmithKline	LDCs plus sub-Saharan Africa For middle income developing countries public sector prices negotiated on a case-by-case basis or bilaterally or through the AAI	same as GSK above	US\$ 3176/year (US\$ 8.70/day)	See Annexes 1 and 3 Supply Agreement required	CIF
didanosine (Videx®) NRTI	Bristol-Myers Squibb Co.	sub-Saharan Africa	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\$ 0.85/day – average daily dose of 400mg) Lower tablet dosages prices in line with this offer	As of May 15, 2002, the public sector in Senegal, Benin, Ivory Coast, Rwanda, Gabon, Chad, Republic of Congo, Mali, Cameroon, Togo, Burundi, Guinea and Burkina Faso have availed themselves of this offer. Numerous organisations in the private sector (including NGOs, private employers, retail pharmacies) or Uganda, Tanzania, Kenya, Zimbabwe, Namibia, South Africa, Botswana, Lesotho, Zambia, Swaziland, Malawi and Mozambique have also availed themselves to this offer.	DDU to government purchasing entities

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

Product	Company (for all company contacts see annex 4)	Eligibility (countries)	Eligibility (body)	Price (US\$ per year and per day)	Additional Comments	Delivery of goods ⁵
didanosine (Videx®) NRTI	Bristol-Myers Squibb Co.	Developing countries outside of sub-Saharan Africa	same as BMS above	Price determined in consultation on a case by case basis	BMS advocates the reduction of distribution costs (import duties, taxes, wholesaler and retailer mark-ups, etc.) as much as possible.	DDU to govern- ment purchasing entities
efavirenz (Stocrin®) NNRTI	Merck & Co., Inc.	Low Human Development Index (HDI) countries plus medium HDI countries with adult HIV prevalence of 1% or greater 10	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\$ 500/year (US\$ 1.37/day)	Although Romania does not fall under these categories it also benefits from these prices. See Annex 2	CIF
efavirenz (Stocrin®) NNRTI	Merck & Co., Inc.	Medium HDI countries with adult HIV prevalence less than $1\%^{10}$	same as Merck & Co., Inc. above	US\$ 920/year (US\$ 2.52/day)	See Annex 2	CIF
indinavir (Crixivan®) PI	Merck & Co., Inc.	Low Human Development Index (HDI) countries plus medium HDI countries with adult HIV prevalence of 1% or greater 10	same as Merck & Co., Inc. above	US\$ 600/year (US\$ 1.64/day)	Although Romania does not fall under these categories it also benefits from these prices. See Annex 2	CIF
indinavir (Crixivan®) PI	Merck & Co., Inc.	Medium HDI countries with adult HIV prevalence less than $1\%^{10}$	same as Merck & Co., Inc. above	US\$ 1029/year (US\$2.82/day)	See Annex 2	CIF
lamivudine (Epivir®/3TC) NRTI	GlaxoSmithKline	LDCs plus sub-Saharan Africa For middle income developing countries public sector prices negotiated on a case-by-case basis whether unilaterally or through the AAI	same as GSK above	US\$ 234/year (US\$ 0.64/day)	See Annexes 1 and 3 Supply Agreement required	CIF

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

Product	Company (for all company contacts see annex 4)	Eligibility (countries)	Eligibility (body)	Price (US\$ per year and per day)	Additional Comments	Delivery of goods 5
nelfinavir (Viracept®) PI Tab 250mg	Roche	LDCs plus sub-Saharan Africa	Governments, NGOs, Private sector employers	Bottle of 270 tab- lets: US\$ 200.00 (CHF 340.00) US\$ 2704/year (US\$ 7.41/day) for 1250mg twice daily regimen	See Annexes 1 and 3	CIF
nevirapine (Viramune®) NNRTI	Boehringer Ingelheim	sub-Saharan Africa plus other countries on a case-by-case basis	Governments, NGOs and other partners who can guarantee that the programme is run in a responsible manner	US\$ 438/year (US\$ 1.20/day)	See Annex 3	CIF Price may vary in view of possible import taxes
nevirapine (Viramune®) NNRTI	Boehringer Ingelheim	Developing countries as defined by the World Bank Classification of Economies (Low-income and Lower-middle-income econo- mies) plus all other sub-Saharan countries	same as Boehringer Ingelheim above	For the duration of 5 years (2000-2005) a donation for use in preventing mother-to-child transmission only	See Annex 3	CIF
lopinavir/ ritonavir (Kaletra®) PI	Abbott	Africa plus Afghanistan, Bangladesh, Bhutan, Cambodia, Cape Verde, Haiti, Kiribati, Lao People's Dem. Rep., Maldives, Myanmar, Nepal, Samoa, Solomon Islands, Tuvalu, Vanuatu, Yemen	Governments, NGOs, UN system organisations, and other national and international health institutions	US\$500/year		Prices do not include the cost of shipping, insurance, etc.
ritonavir (Norvir®) PI	Abbott	Africa plus Afghanistan, Bangladesh, Bhutan, Cambodia, Cape Verde, Haiti, Kiribati, Lao People's Dem. Rep., Maldives, Myanmar, Nepal, Samoa, Solomon Islands, Tuvalu, Vanuatu, Yemen	same as Abbott above	"Booster dose": US\$ 83/year (US\$ 0.23/day)		Prices do not include the cost of shipping, insurance, etc.

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

Product	Company (for all company contacts see annex 4)	Eligibility (countries)	Eligibility (body)	Price (US\$ per year and per day)	Additional Comments	Delivery of goods ⁵
saquinavir (Fortovase®) PI Caps 200 mg	Roche	LDCs plus sub-Saharan Africa	Governments, NGOs, private sector employers	Bottle of 180 capsules: US\$ 66.18 (CHF 112.50) US\$ 1342/year (US\$ 3.68/day) for daily dose 1000mg twice daily to be boostered with ritonavir 100mg twice daily	See Annexes 1	CIF
stavudine (Zerit®) NRTI	Bristol-Myers Squibb Co.	sub-Saharan Africa	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\$ 55/year (US\$ 0.15/day) based on an average daily dose of 80mg Lower capsule dosages priced inline with this offer.	As of may 15, 2002, the public sector in Senegal, Benin, Ivory Coast, Rwanda, Gabon, Chad, Republic of Congo, Mali, Cameroon, Togo, Burundi, Guinea and Burkina Faso have availed themselves of this offer. Numerous organisations in the private sector (including NGOs, communities of faith, private employers, retail pharmacies) or Uganda, Tanzania, Kenya, Zimbabwe, Namibia, South Africa, Botswana, Lesotho, Zambia, Swaziland, Malawi and Mozambique have also availed themselves to this offer.	DDU to govern- ment purchasing entities
stavudine (Zerit®) NRTI	Bristol-Myers Squibb Co.	Developing countries outside of sub-Saharan Africa	same as BMS above	Price determined in consultation with on a case by case basis		DDU to government purchasing entities

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

Product	Company (for all company contacts see annex 4)	Eligibility (countries)	Eligibility (body)	Price (US\$ per year and per day)	Additional Comments	Delivery of goods ⁵
zalcitabine (Hivid®) NRTI	Roche	LDCs plus sub-Saharan Africa	same as Roche above	Cost per pack of 100 tablets is US\$ 14.70 (CHF 25.00) US\$ 161/year (daily treatment cost of US\$ 0.44/day)	See Annexes 1	CIP
zidovudine (Retrovir®) NRTI	GlaxoSmithKline	LDCs plus sub-Saharan Africa For middle income developing countries public sector prices negotiated on a case-by-case basis whether unilaterally or through the AAI	same as GSK above	US\$ 584/year (US\$ 1.60/day)	See Annexes 1 and 3 Supply Agreement required	CIF
zidovudine + lamivudine (Combivir®) NRTI	GlaxoSmithKline	LDCs plus sub-Saharan Africa For middle income developing countries public sector prices negotiated on a case-by-case basis whether unilaterally or through the AAI	same as GSK above	US\$ 730/year (US\$ 2.00/day)	See Annexes 1 and 3 Supply Agreement required	CIF

Table 2b) Generic companies' ARV offers and restrictions for developing countries

Company (for all company contacts see annex 4)	Eligibility (countries)	Eligibility (body)	Price (US\$ per year and per day)	Additional Comments	Delivery of goods ⁵
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	FOB
GP0	No restriction	NGOs and Governmental Organizations	See Table 1		FOB Bangkok (Thailand)
Hetero	No restriction	NGOs and Governmental Organizations	See Table 1	Prices could be negotiated on individual basis according commercial terms	FOB Mumbai (India)
Ranbaxy	No restriction	NGOs and Governmental Organizations	Prices given in table 1 apply to orders for a minimum of 5000 patients. Different prices are offered for smaller quantities (1000, 1000-5000, patients)	Sign Letter of Credit	FOB Delhi/ Mumbai (India)

6. Annexes

Annex 1

Least Developed Countries (LDCs)

Source: http://www.unctad.org/en/ pub/ldcprofiles2001.en.htm

Afghanistan Angola Bangladesh Benin Bhutan Burkina Faso

Burundi Cambodia Cape Verde

Central African Republic

Chad Comoros

Democratic Republic of Congo

Diibouti

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

(*) In early 2001, following the triennial review of the list of LDCs, Senegal was placed in the category, bringing the total to 49.

Annex 2

Belize

Brazil

Human Development Index

Source: Human Development Report 2001, Making new technologies work for human development UNDP

For full list of Human Development

Index ranking see http://

www.undp.org/hdr2001/back.pdf

Medium human development

Kenva Albania Kyrgyzstan Algeria Latvia Armenia Lebanon Azerbaijan Lesotho Belarus Libyan Arab Jamahiriya

Macedonia, TFYR Bolivia Malaysia Botswana Maldives

Mauritius Bulgaria Mexico Moldova, Rep. of Cambodia

Cameroon Mongolia Morocco Cape Verde China Myanmar Namibia Colombia Comoros Nicaragua Congo Oman Dominican Republic Panama

Ecuador Papua New Guinea

Egypt Paraguay El Salvador Peru Equatorial Guinea **Philippines**

Fiji Gabon Georgia Ghana

Romania Russian Federation Samoa (Western) Saudi Arabia South Africa

Guatemala

Guyana

India

Honduras

Indonesia

Jamaica

Kazakhstan

Iordan

Iran, Islamic Rep. of

Sri Lanka Suriname Swaziland

Syrian Arab Republic

Tajikistan Thailand

Trinidad and Tobago

Tunisia Turkey Turkmenistan Ukraine

Uzbekistan 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

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
Ethiopia
Gabon
Gambia, The
Ghana
Guinea
Guinea
Guinea-Bissau

Kenya Lesotho Liberia Madagascar Mali Mauritania Mauritius Mayotte Mozambique Namibia Niger Nigeria

Malawi

São Tomé and Principe

Senegal Seychelles Sierra Leone Somalia South Africa Sudan

Rwanda

Swaziland Tanzania Togo Uganda Zambia Zimbabwe

Annex 4

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Glossary and abbreviations11

3TC lamivudine (Epivir®); nucleoside analogue reverse transcriptase inhibitor AAI¹² 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

APV amprenavir (Agenerase®); protease inhibitor

ARVs Antiretroviral drugs **BMS** Bristol-Myers Squibb

CIF⁵ "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.

CIP⁵ "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 ddC zalcitabine (Hivid®); nucleoside analogue reverse transcriptase inhibitor **ddI** didanosine (Videx®); nucleoside analogue reverse transcriptase inhibitor **DDU**⁵ "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.

EML⁹ 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 **EXW**⁵ "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.

FOB⁵ "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 & Dohme (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

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 UNCTAD United Nations Conference on Trade and Development

UNESCO United Nations Educational, Scientific and Cultural Organisation **UNDCP** United Nations International Drud Control Programme

Endnotes

¹ Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS drugs and diagnostics of acceptable quality, First Edition 20th March 2002 http://www.who.int/medicines/organization/qsm/activities/pilotproc/pilotproc.shtml

² Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS. Joint UNICEF, UNAIDS Secretariat, WHO/HTP, MSF project. May 2001. Fourth edition currently under preparation 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 available on the website http://www.accessmed-msf.org

⁴ Other generic manufacturers producing ARVs exist but are not included in this summary of offers. Generic manufacturers known to be producing one or more ARVs are: Richmond Laboratorios, Panalab (Argentina); Pharmaquick (Benin); Far Manguinhos, FURP, Lapefe, Laob, Iquego, IVB (Brazil); Apotex, Novopharm (Canada); Biogen (Colombia); Stein (Costa Rica); Zydus Cadila Healthcare, SunPharma, (India); LG Chemicals, Samchully (Korea); Protein, Pisa (Mexico); Combinopharm, Andromaco (Spain); T.O. Chemecal (Thailand); Filaxis (Uruguay).

⁵ Incoterms 2000 http://www.iccwbo.org/index_incoterms.asp

⁶ Scaling-up Antiretroviral therapy in Resource Limited Settings: Guidelines for a Public Health approach. Document still in development, Draft 22nd April 2002 http://www.who.int/HIV_AIDS/HIV_AIDS_Care/ARV_Draft_April_2002.pdf

⁷ Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents, by the Panel on Clinical Practices for the Treatment of HIV, April 13th, 2001 http://www.hivatis.org

⁸ Patent Situation of HIV/AIDS related drugs in 80 countries, WHO/UNAIDS, 2000

http://who.int/medicines/library/par/hivrelateddocs/patentshivdrugs.pdf

⁹ WHO Model List of Essential Drugs (EDL), lastly updated 22nd April 2002 http://www.who.int/medicines/organization/par/edl/infedlmain.shtml

¹⁰ To find the HIV prevalence status of countries see http://www.unaids.org/epidemic_update/

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

¹² Accelerating Access Initiative, information on participating countries and updates http://www.unaids.org/acc_access/