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1. General background and objectives

This is the eighth edition of *Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries*. The report was first published by Médecins Sans Frontières (MSF) in October 2001^[1] in response to the lack of transparent and reliable information about prices of pharmaceutical products on the international market – a factor which significantly hampers access to essential medicines in developing countries. The situation is particularly complex in the case of antiretrovirals (ARVs). The purpose of this document is to provide information on prices and suppliers that will help purchasers make informed decisions when buying ARVs.

Since the first edition of “Untangling”, prices of some first-line ARVs have fallen significantly due to competition between multiple producers. However, not all countries are able to benefit from these lower prices because of patent barriers to accessing generic versions. Price and availability of newer ARVs are still significant obstacles to access to treatment. This report shows that the

prices of second-line drugs are six to twelve times¹ higher than those of older first-line treatments, in Least Developed Countries (LDCs) and sub-Saharan Africa. In the case of some of the second-line ARVs, it is lack of competition that has led to high prices (see graph 2). In some developing countries outside sub-Saharan Africa, the prices of both first- and second-line drugs mirror those charged in wealthy countries.

MSF has found that problems fall into three categories: 1) some single-source drugs are very expensive, 2) differential prices are not really available as advertised in developing countries because some companies do not register their products in poor countries, and 3) some companies do not offer discounted prices in middle-income countries.

Brazil is a good illustration of problems encountered in middle-income countries. Brazil currently spends 63% percent of its total ARV drug budget on three products (Abbott’s lopinavir/ritonavir, Gilead’s tenofovir and Merck’s efavirenz). In theory, a government such as Brazil’s can overcome this problem by using

compulsory licensing to override patents or intellectual property barriers. These mechanisms are in-built flexibilities of the World Trade Organization’s TRIPS Agreement and have been affirmed in the Doha Declaration on TRIPS and Public Health in 2001^[2].

Following the adoption of the Doha Declaration, Least Developed Countries (LDCs) are no longer obliged under the WTO rules to grant or enforce pharmaceutical product patents until at least 2016.

The use of these flexibilities and safeguards is particularly important since India, the biggest producer of generic drugs, is now obligated to grant patents on new pharmaceutical products. The new Indian Patents Act will not affect medicines that were invented before 1995. However, patent applications filed between 1995 and 2005 will be reviewed by Indian patent authorities and patents may subsequently be granted.

If a patent is granted, it will not stop a generic manufacturer from continuing to produce and market the drug in India if they have made a

“significant investment”, as the new Indian law stipulates an automatic licensing system which will allow for the continued production of the generic version if a “reasonable royalty” is paid. But when patents are granted for applications submitted after January 2005, only patent holders will have the right to produce these drugs unless India and other countries issue compulsory licenses to give others the right to produce, market and export the product^[3,4].

Treatment of HIV/AIDS in children deserves special attention: most companies produce syrups and oral solutions, which are ill-adapted for use in developing countries because caregivers have problems reconstituting syrups, as well as measuring and preserving them. Pharmaceutical companies are not investing enough resources in the development of paediatric formulations, since it is a small and risky market that is also of diminishing importance in Western countries^[5]. In addition to this, the price of liquid and solid drugs in paediatric formulations is higher than that of their adult equivalents. For instance, treating a child weighing 10

¹ Comparison between the triple fixed-dose combination (3TC/d4T/NVP) and best available prices for WHO recommended 2nd line regimens. Only WHO prequalified products or products registered in highly regulated countries were compared.

kg for one year with stavudine, nevirapine and lamivudine can cost up to US\$816, while treating an adult with the same drugs costs US\$182.

This document complements the information in the pricing guide Sources and Prices of selected medicines and diagnostics for People

Prices listed are selling prices as quoted from the manufacturers and constitute an indication for procurement departments of eligible organisations. In any case, the prices listed here are not necessarily the same as the final prices paid by either patients or their health care providers. For example, in some countries there are local add-ons such as import taxes and distribution mark-ups that are not included in the comparisons. In addition, the information on prices in this report only relates to the price of medicines: it does not include other costs linked to antiretroviral treatment, such as diagnostics and monitoring.

This report is a pricing guide and does not include information about the quality of the products listed. But price should not be the only factor determining procurement decisions. Readers and purchasers wishing to obtain more information about drug quality are encouraged to consult “*Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS Drugs and Diagnostics of Acceptable Quality*” (known as WHO prequalification list), a project initiated by the World Health Organization (WHO) and developed in collaboration with other United Nations Organizations^[7]. This project evaluates pharmaceutical manufacturers and products according to WHO recommended standards of quality and compliance with Good Manufacturing Practices. It is part of an ongoing process that will expand as the participation of suppliers increases. Not all the products listed in this report have been prequalified by WHO, and only some of them are used by MSF in its own projects.

living with HIV/AIDS published by UNICEF/UNAIDS/WHO/MSF^[6].

Products included in the last edition of the WHO prequalification list (23rd edition, April 4th 2005) appear in **bold** in the tables. Please consult the WHO website (<http://mednet3.who.int/prequal/>) for the latest information.

2. Methodology

To obtain accurate information, MSF has contacted both originator and generic companies and asked them to provide the following information about the ARVs offered to developing countries: dosage and pharmaceutical form, price per unit (or daily dose), restrictions that apply to the offers (eligibility), and any additional specificity of the offers.

Products listed here have been approved for marketing at least in their countries of origin. The list of generic producers included in this report is by no means exhaustive^[8]. These companies were mostly chosen because they have publicly announced price offers to developing countries.

All prices are quoted in US dollars and conversions have been made on the day the price information was received using the currency converter site: www.oanda.com.

We acknowledge the difficulties and inaccuracies when establishing price comparisons across different countries and purchasers, and therefore recommend that these prices be considered in relative and not absolute terms.

Table 1: First and Second Category of Prices offered by manufacturers for the different countries (yearly and unit prices)

Generic companies do not apply any geographical restriction.

Most originator companies offer their discounted prices only to a certain group of countries, normally only to LDCs and sub-Saharan African countries. These prices are referred to as FIRST CATEGORY PRICES. See table 2 for details.

There are exceptions such as Gilead and Bristol-Myers Squibb that have recently, for example, extended their first category of price to some middle-income countries, or Merck, which applies first category prices also to medium human development index countries when the country's HIV prevalence is greater than 1%, or GlaxoSmithKline, which has offered their products for all Global Fund recipient countries.

Finally, companies like Merck and Roche offer a SECOND CATEGORY OF PRICES for middle-income countries (almost twice as much as the first category price). When these second

category prices exist, they have been included in the table.

Prices are rounded up to the third decimal for unit price and to the nearest whole number for yearly price per patient.

Prices quoted by the different companies are not always directly comparable since companies use different trade terms (incoterms^[9]). Prices quoted by Roche, all generic companies, Abbott and Gilead are so-called “FCA” or “FOB” prices which means that transport, international freight and insurance costs are not included; the other companies mentioned in this report do include freight and insurance in their prices. Despite this fact, in this edition the prices have not been adjusted, following the methodology used in the US General Accountability Office (GAO) report^[10].

For all paediatric treatments, prices are calculated for a 10 kg child using WHO treatment guidelines. This is an estimate since the weight of a child increases during any given year. The annual cost of treatment has been calculated according to WHO

dosing schedules^[11] multiplying the unit price (price of e.g. one tablet or capsule) by the number of units required for the daily dose and by 365 days in a year. Price is then presented in USD/year, and in brackets, the price per smallest unit is quoted.

The price of products prequalified by WHO are based on the 23rd edition of the WHO prequalification list (April 4th 2005) and appear in bold. Please consult the latest WHO prequalification list for more details regarding manufacturing sites.

Table 2: Conditions of offer by company

Conditions applying to each company’s offer were quoted directly by companies.

There is no uniformity concerning geographical restrictions to the offers but rather each originator company establishes different limits to their offer for different categories of countries (annex 1-4). Some companies use UNCTAD (Least Developed Countries) criteria, others the UNDP Human Development index, and yet others the World Bank classification.

There are significant differences between categories used by companies. For instance, 15 countries are considered Least Developed Countries (LDCs) by UNCTAD, but are placed in the medium level by UNDP. These include Bangladesh, Cambodia, Laos and Sudan. Six other LDCs do not appear in the UNDP classification at all, including Democratic Republic of Congo, Liberia and Somalia.

Furthermore, many developing countries are left out of the differential pricing scheme altogether. These include Bolivia, Nicaragua, Thailand, Ukraine and Vietnam for the UNDP classification, China, Honduras and Sri Lanka for the World Bank classification, and all Latin American countries except Haiti for the UNCTAD classification.

3. Analysing the limitations of current offers: are products getting to patients in need?

3.1. Availability in countries?

The products listed in this report are not always available in every country. There are several reasons for this:

Even when price reductions have been announced, the products are not necessarily marketed in all the eligible countries

- MSF projects have experienced this situation in many cases, even in the poorest nations such as Mozambique or Cambodia, where some ARVs coming from originator companies must be bought in neighbouring countries with all the additional expenses and investment in human and administrative resources that this implies.

Registration of products is a major problem

- Companies have varying policies on product registration. Some companies offer discounted prices but do not register their products in specified countries. This practice makes the discounted price unattainable for everyone except those that have the possibility of asking for special authorisation from the Ministry of Health.
- National Drug Regulatory Authorities’ procedures for registering the products are sometimes slow, even if companies do everything necessary to get approval.

- The investment needed to import drugs that are not registered is enormous. MSF has had to request special authorisation for Merck's efavirenz, GSK's abacavir, Abbott's lopinavir/ritonavir, Cipla's lamivudine/stavudine/nevirapine or Gilead's tenofovir in several countries, such as Cambodia, Uganda, Guatemala, Honduras, Laos or Ethiopia.

The channel chosen by the companies to distribute the products priced at lower price is too complex.

- For example, to benefit from the differential price from Abbott's products, the orders must be placed with Axios, an Irish NGO that works as intermediary. According to our staff, this is a burdensome procedure even for MSF procurement centers.
- Roche's products have to be ordered from Basel, and paid in Swiss francs, which is in practice difficult for procurement centres in developing countries.

3.2. At what price?

Even when the product is available on the market, prices quoted by manufacturers for this report may not represent the actual price for the following reasons:

- Excessive mark-ups by company local representatives in some countries;
- Lack of interest from companies to invest in exporting their products to small markets, for instance, generic companies in Latin America. In these cases, prices are often higher than those announced internationally by the companies;
- Lack of monitoring by responsible entities and donors of the prices paid by the different programmes for the same product;
- In countries outside sub-Saharan Africa and not classified as LDCs, prices can be as high as they are in Western countries, despite the fact that large numbers of people in these countries live below the poverty line. Generic companies have no geographical limits, but they do have quantity-related conditions in certain cases.

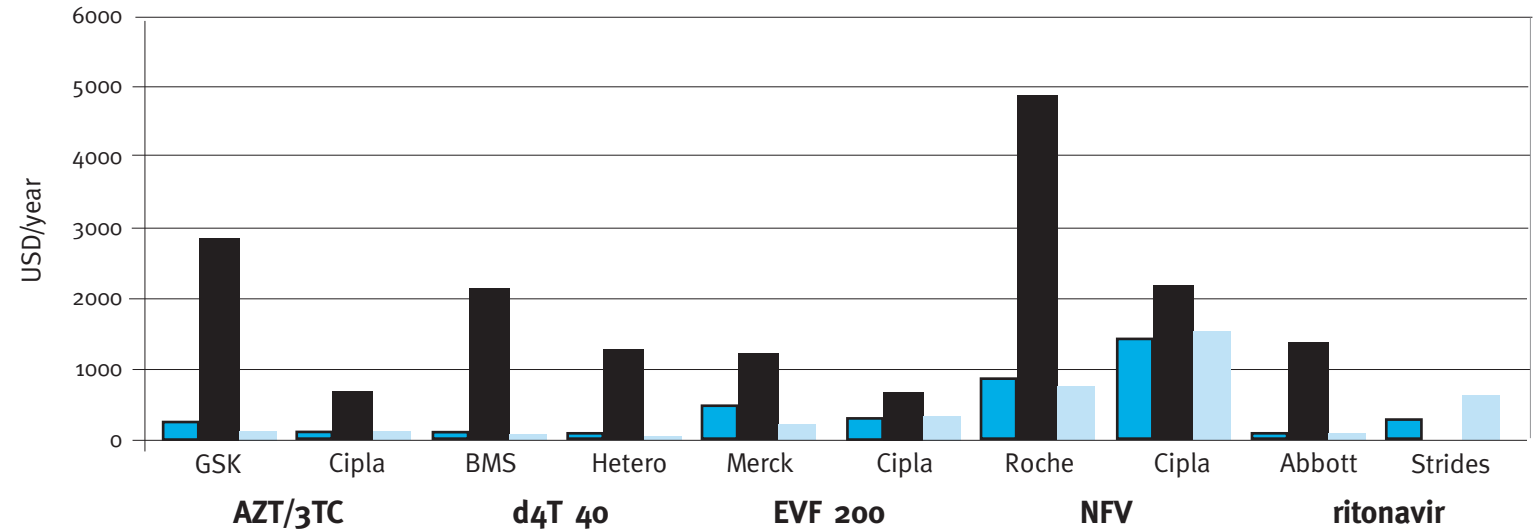
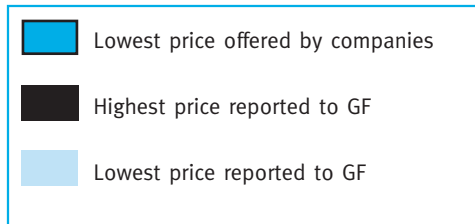
Despite the exemptions and the existence of specific second category prices for some products, prices paid in middle-income countries are still much higher than the offers published in this report (graph 1).

- A good example of pricing problems is China, a non-LDC, non-African country, with an estimated one million people infected with HIV. There are very few generic products in the country, mainly due to intellectual property restrictions. Originator products are expensive and not always marketed in all dosages. For instance, stavudine from BMS is only marketed at the dosage of 20 mg. This makes it very difficult to treat children and doubles the pill burden for adults. Other important ARVs like lopinavir/ritonavir from Abbott are offered to MSF projects at US\$ 5,000 per year – this is ten times more than the price for developing countries.
- Other middle-income countries, such as Ecuador or Georgia, pay unacceptably high prices for some products. For instance, Guatemala is paying US\$ 2,500 per year for GSK's abacavir. The lack of competition for these new drugs lies behind high prices and lack of availability in the market.

For reasons described above, the current “differential pricing” practice cannot alone be considered the solution for increasing access to all needed ARVs worldwide. Access to life-saving medicines by the poorest populations should not depend on the goodwill of private companies. Making drugs affordable and available is a government responsibility. Where the political will exists, people pay less for their drugs and more people have access to them. International institutions and governments must work together to ensure that poor populations systematically benefit from lower prices which can be attained when sourcing from all available quality manufacturers.

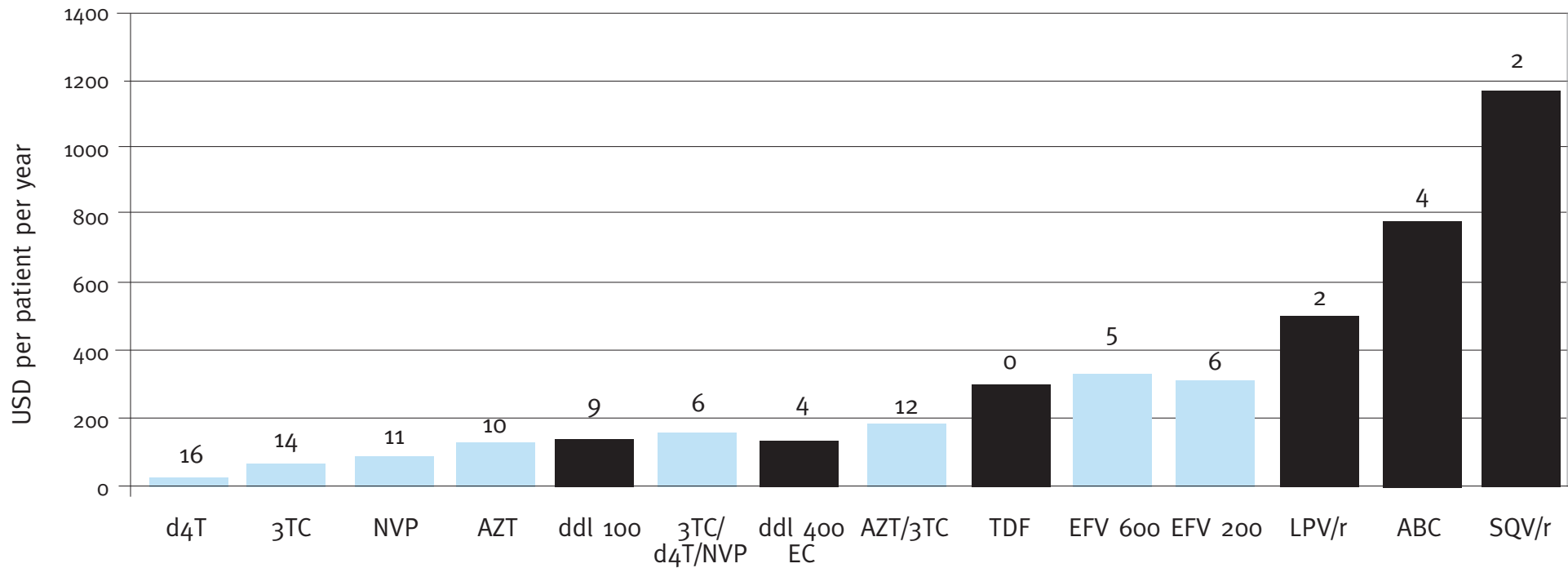
Comparison between prices published in this report and prices reported by Global Fund

Graph 1: The chart shows the differences in prices paid in different countries. Although prices paid by the poorest countries are indeed very close to the prices announced by companies, prices paid in middle-income countries are far too high compared with the offers. This is particularly true for most prices of the originator products applicable in middle-income countries.



Source: Global Fund Price reporting Mechanism. The GF pricing reporting site was consulted from June 6th to June 14th 2005^[12], taking the minimum and the maximum reported prices from 2004 onwards. Minimum prices correspond with orders made by sub-Saharan African countries or LDCs outside Africa. Maximum prices correspond to non-African, non-LDC recipient countries.

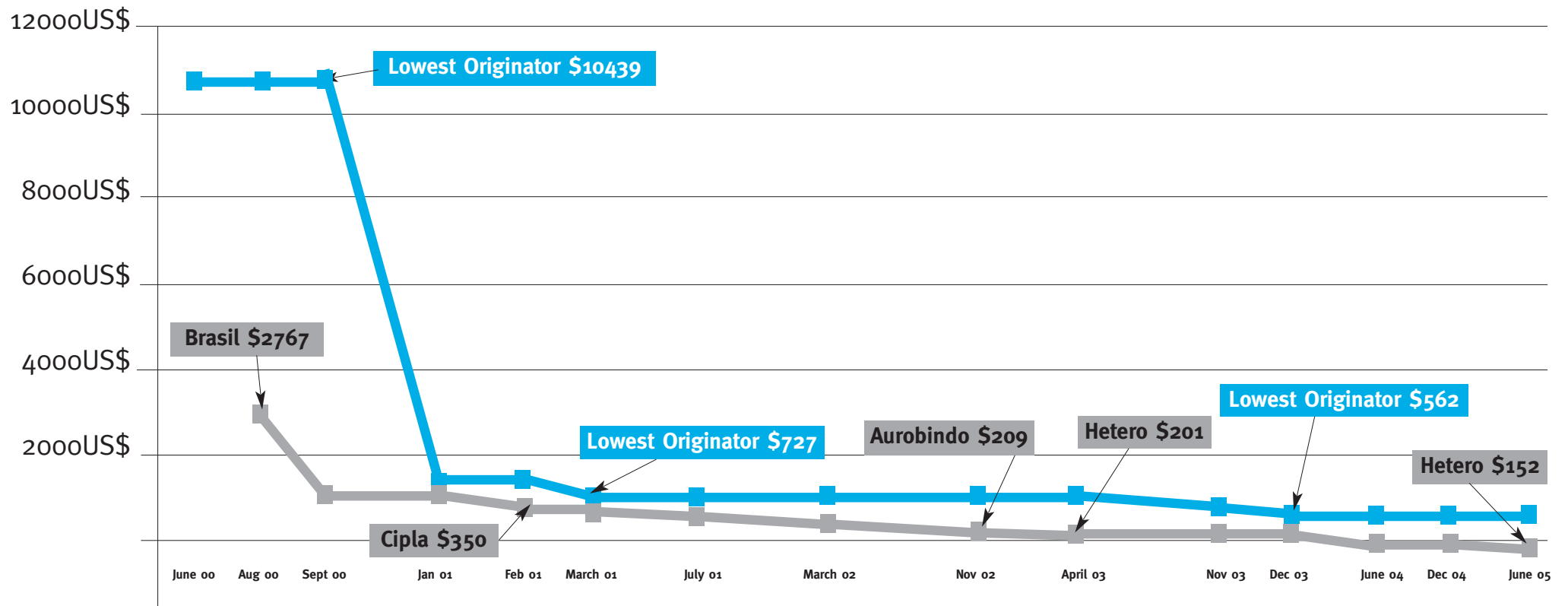
Prices of medicines recommended as 1st and 2nd line by WHO. June 2005



Graph 2: The chart shows the best prices for most drugs used in WHO recommended 1st (shaded bars) and 2nd line (solid bars) drugs. Prices indicated in the graph are the lowest amongst all surveyed manufacturers for this report. The figure over the columns shows the number of producers included in this report and having answered to Sources and Prices survey (*Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS*, UNICEF-UNAIDS-WHO-MSF, June 2004). There are other reasons lying behind the high prices of some ARVs that are not included in this graph.

The Effects of Generic Competition

May 2000-June 2005



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 four years, originator companies have often responded to generic competition.

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

[2] HIV/AIDS medicines and related supplies: Contemporary context and procurement. Technical guide. Chapter 2 and Annex B. World Bank, Washington, DC, 2004
<http://siteresources.worldbank.org/INT/PROCUREMENT/Resources/Technical-Guide-HIV-AIDS.pdf>

[3] “Determining the patent status of essential medicines in developing countries”, Health Economics and Drugs, EDM Series No. 17, UNAIDS/WHO/MSF, 2004

[4] “Drug patents under the spotlight. Sharing practical knowledge about pharmaceutical patents” MSF, June 2004

[5] Pediatric HIV/AIDS Factsheet, MSF, June 2005, www.accessmed-msf.org

[6] “Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS”. A joint UNICEF, UNAIDS Secretariat, WHO, MSF project. May 2004 (WHO/EDM/PAR/2003.2).
<http://www.who.int/medicines/organization/par/ipc/sources-prices.pdf>

[7] *Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS drugs and diagnostics of acceptable quality, 23rd edition 4 April 2005.*
<http://www.who.int/medicines/organization/qsm/activities/pilotproc/pilotproc.shtml>

[8] Other generic manufacturers known to be producing one or more ARVs but not included in this document are: Richmond Laboratorios, Panalab, Filaxis (Argentina); Pharmaquick (Benin); Far Manguinhos, FURP, Lapefe, Laob, Iquego, IVB (Brazil); Apotex, Novopharm (Canada); Shanghai Desano Biopharmaceutical company, Northeast General Pharmaceutical Factory (China); Biogen (Colombia); Stein (Costa Rica); Zydus Cadila Healthcare, SunPharma, EAS-SURG, Mac Leods, IPCA (India); LG Chemicals, Samchully, Korea United Pharm Inc. (Korea); Protein, Pisa (Mexico); Andromaco (Spain); Aspen (South Africa); T.O. Chemecal (Thailand); Laboratorio Dosa S.A. (US), Varichem (Zimbabwe). This list is not exhaustive.

[9] Incoterms are standard trade definitions most commonly used in international sales contracts, as

published by the International Chamber of Commerce, http://www.iccwbo.org/index_incoterm_s.asp

[10] “GAO Rept to Congressional Requesters. GLOBAL HIV/AIDS EPIDEMIC. Selection of Antiretroviral Medications Provided under U.S. Emergency Plan is Limited”, page 24, GAO, January 2005.”In some cases a manufacturer’s prices include costs that other manufacturers do not include – such as shipping and insurance charges. We note where these differences exist, and have determined that they do not undermine the essential comparability of the prices presented in our report”

[11] Scaling up antiretroviral therapy in resource-limited settings: Treatment guidelines for a public health approach, WHO, 2003 Revision.
http://www.who.int/hiv/pub/prev_care/en/ARVGuidelinesRevised2003.pdf

[12] Global Fund Price Reporting Mechanism.
<http://www.theglobalfund.org/en/>

Table 1: 1st and 2nd category of prices offered by manufacturers for the different countries (yearly and unit prices)

	Unit								
abacavir		Cipla	GSK 1st categ	GSK 2nd categ	Hetero Drugs Ltd	Ranbaxy			
300mg, tablet	tab	584 (0.8)	887 (1.215)	n/a	773 (1.058)	664 (0.91)			
20mg/ml, oral solution	ml	292 (0.1)	382 (0.131)	n/a					
didanosine		Aurobindo 1st categ	BMS 1st categ	BMS 2nd categ	Cipla	Hetero Drugs Ltd	Ranbaxy		
100mg, tablets	tab	197 (0.135)	310 (0.212)	n/a	234 (0.16)	280 (0.192)	321 (0.22)		
250mg, enterocoated caps	cap		198 (0.543)	n/a	106 (0.29)		146 (0.4)		
400mg, enteric-coated caps	cap		279 (0.764)	n/a	142 (0.39)		219 (0.6)		
2g powder for reconstitution with water and with antacids	g	39 (2.160)	133 (7.370)	n/a					
efavirenz		Aurobindo	Cipla	Hetero Drugs Ltd	Merck 1st categ	Merck 2nd categ	Ranbaxy		
50mg	cap				169 (0.116)	311 (0.113)			
200mg	cap	438 (0.4)	372 (0.34)	316 (0.289)	500 (0.457)	920 (0.840)	405 (0.37)		
600mg	tab	472 (1.292)	347 (0.95)	355 (0.917)	347 (0.95)	766 (2.1)	358 (1.17)		
30mg/ml suspension	ml	227 (0.069)			309 (0.094)	496 (0.151)			
emtricitabine		Gilead 1st categ	Gilead 2nd categ						
200mg	cap	n/a	n/a						
indinavir		Aurobindo	Cipla	Hetero Drugs Ltd	Merck 1st categ	Merck 2nd categ	Ranbaxy	Strides	
400mg	cap	432 (0.296)	321 (0.220)	217 (0.149)	400 (0.274)	686 (0.470)	336 (0.23)	453 (0.31)	
lamivudine		Aurobindo	Cipla	GSK 1st categ	GSK 2nd categ	GPO	Hetero Drugs Ltd	Ranbaxy	Strides
150mg	tab	66 (0.09)	73 (0.1)	69 (0.095)	n/a	171 (0.234)	53 (0.073)	69 (0.095)	73 (0.10)
300mg	tab		85 (0.233)	n/a	n/a			69 (0.19)	
10mg/ml oral solution and syrup and dry syrup	ml	61 (0.021)	58 (0.02)	82 (0.028)	n/a	76 (0.026)			
lamivudine + efavirenz + didanosine		Cipla							
150+600+250 (EC)	3 cap	766 (2.1)							
150+600+400 (EC)	3 cap	839 (2.3)							

	Unit								
lamivudine/zidovudine/ abacavir		GSK 1st categ	GSK 2nd categ	Hetero Drugs Ltd	Ranbaxy				
300 + 150 + 300mg	tab	1241 (1.7)	n/a	992 (1.358)	1095 (1.5)				
lamivudine/stavudine		Aurobindo	Cipla	Hetero Drugs Ltd	Ranbaxy	Strides			
150 + 30mg	tab	72 (0.099)	79 (0.108)	74 (0.101)	124 (0.17)	113 (0.155)			
150 + 40mg	tab	80 (0.109)	85 (0.117)	81 (0.111)	131 (0.18)	120 (0.165)			
lamivudine/stavudine/ nevirapine		Aurobindo	Cipla	GPO	Hetero Drugs Ltd	Ranbaxy	Strides		
150 + 30 + 200mg	tab	144 (0.198)	175 (0.24)	341 (0.467)	147 (0.201)	219 (0.3)	168 (0.23)		
150 + 40 + 200mg	tab	152 (0.208)	182 (0.25)	375 (0.514)	161 (0.221)	234 (0.32)	175 (0.24)		
lamivudine/zidovudine		Aurobindo	Cipla	GSK 1st categ	GSK 2nd categ	GPO	Hetero Drugs Ltd	Ranbaxy	Strides
150 + 300mg	tab	204 (0.28)	182 (0.25)	237 (0.325)	n/a	426 (0.584)	190 (0.260)	197 (0.27)	204 (0.280)
lamivudine/zidovudine/ nevirapine		Aurobindo	Cipla	Hetero Drugs Ltd	Ranbaxy				
150 + 300 + 200mg	tab	257 (0.352)	255 (0.35)	281 (0.385)	292 (0.4)				
lopinavir/ritonavir		Abbott 1st categ	Abbott 2nd categ	Hetero Drugs Ltd					
133.3 + 33.3mg	cap	500 (0.228)	n/a	1898 (0.867)					
80 + 20mg/ml oral solution	ml	152 (0.139)	n/a						
nelfinavir		Aurobindo	Cipla	GPO	Hetero Drugs Ltd	Roche 1st categ	Roche 2nd categ		
250mg (3)	tab	1533 (0.42)	1423 (0.39)	1599 (0.438)	1217 (0.333)	978 (0.268)	2211 (0.606)		
50mg/g oral powder	g					1962 (0.224)	2243 (0.256)		
nevirapine		Aurobindo	Boehringer 1st categ	Boehringer 2nd categ	Cipla	GPO	Hetero Drugs Ltd	Ranbaxy	Strides
200mg	tab	112 (0.153)	438 (0.6)	n/a	73 (0.1)	255 (0.35)	77 (0.106)	84 (0.115)	80 (0.11)
10mg/ml suspension	ml	411 (0.075)	400 (0.073)	n/a	137 (0.025)	82 (0.015)			
ritonavir		Abbott 1st categ	Abbott 2nd categ	Aurobindo	Cipla	Hetero Drugs Ltd	Strides		
100mg	cap	83 (0.114)	n/a	336 (0.46)	339 (0.464)	196 (0.269)	438 (0.6)		
80mg/ml oral solution	ml	79 (0.93)	n/a						

	Unit								
saquinavir		Hetero Drugs Ltd	Roche 1st categ	Roche 2nd categ					
hard caps 200mg (5)	cap	1022 (0.28)	989 (0.271)	1327 (0.606)					
stavudine		Aurobindo	BMS 1st categ	BMS 2nd categ	Cipla	GPO	Hetero Drugs Ltd	Ranbaxy	Strides
15mg	cap		n/a	n/a	0.04	0.058			
20mg	cap		0.094	n/a	0.045	0.07			
30mg	cap	14 (0.019)	48 (0.066)	n/a	36 (0.05)	60 (0.082)	21 (0.029)	36 (0.049)	35 (0.048)
40mg	cap	31 (0.043)	55 (0.075)	n/a	39 (0.054)	77 (0.105)	25 (0.035)	47 (0.064)	46 (0.063)
1mg/ml powder for syrup	ml		358 (0.048)	n/a	153 (0.021)	80 (0.011)			
5mg/ml powder for syrup	ml					23 (0.016)			
tenofovir disoproxil fumarate		Gilead 1st categ	Gilead 2nd categ						
300mg	tab	301 (0.824)	n/a						
tenofovir disoproxil fumarate/emtricitabine		Gilead 1st categ	Gilead 2nd categ						
300 + 200mg	tab	362 (0.991)	n/a						
zidovudine		Aurobindo	Cipla	Combino Pharm	GSK 1st categ	GSK 2nd categ	GPO	Hetero Drugs Ltd	Ranbaxy
100mg	cap				241 (0.33)	n/a			
250mg	cap				117 (0.16)	n/a			
300mg	tab	140 (0.192)	131 (0.18)	285 (0.39)	212 (0.29)	n/a	277 (0.38)	134 (0.183)	161 (0.22)
10mg/ml syrup and 50mg/5ml oral solution	ml		93 (0.015)	130 (0.021)	223 (0.036)	n/a	130 (0.021)		

n/a = discounted price not available.

Price of products pre-qualified by WHO (23rd edition of WHO Pre-Qualified List) appear in **bold**.

BMS sells ddl in other doses (per mg price remains the same).

The daily dose referred to is 800mg IDV twice daily with ritonavir 100mg twice daily as booster as recommended by WHO. The prescribing information given by the manufacturer is 800mg three times daily (price US\$ 600/year).

The daily dose referred to is 1250 mg twice daily although the dosage of 9 tablets (3 tablets three times a day) can also be used.

Cipla PMTCT a 0.080 ml en envase de 25 ml.

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

Saquinavir should be used in combination with low-dose ritonavir as Saquinavir/Ritonavir 1000mg/100mg twice daily.

Not possible to use stavudine 15 mg capsule for 15 kg patient.

Not possible to use zidovudine 100 mg capsule for 15 kg patient.

GPO, has AZT at 0.021 in 60 ml bottle.

According to WHO treatment guidelines, the pediatric dosage of NVP is 120 to 200 mg/m²/dose, twice daily. For these calculations we considered 160mg/m².

According to WHO treatment guidelines, the pediatric dosage of NFV is 55 to 65 mg/m²/dose, twice daily. For these calculations we considered 60mg/m².

Gilead 1st category price applies to some middle-income countries. See Table 2 for conditions.

Table 2: Summary table for conditions

Company	Eligibility (countries)	Eligibility (body)	Additional comments	Delivery of goods ⁽⁶⁾
Abbott	All African countries and LDCs outside of Africa	Governments, NGOs, UN system organizations and other national and international health institutions		FOB
Aurobindo	No restriction	NGOs and Governmental Organizations	Prices available for at least 1,000,000 units for each product per single shipment.	Payment by letter of credit. FOB Hyderabad (India)
BMS	Sub-Saharan Africa, Haiti, Mauritius, Cambodia, Vietnam <i>(For other developing countries, prices negotiated on a case by case basis with BMS local market representative.)</i>	Both private and public sector organizations that are able to provide effective, sustainable and medically sound care and treatment of HIV/AIDS are eligible.		DDU to French Speaking Africa and CIF incoterm for English Speaking Africa (Kenya, Uganda, Tanzania, Ethiopia, Nigeria, Ghana, Eritrea)
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.		CIF
Cipla	No restriction	No restriction	No quantity related conditions. Prices are as per table 1 however for larger quantities the prices are negotiable.	FOB Mumbai (India) or CIF – Freight charges separately on actual.
Combino Pharm	No restriction	No restriction	Delivery terms 120 days. No minimum order required unless any special labeling is required (standard labeling is in Spanish): order of a complete batch. Pack of 60 or 300 capsules available for ZDV.	FOB Barcelona (Spain)
Gilead	95 nations including all of Africa and 15 other UN-designated 'least developed' countries.	Organizations that provide HIV treatment in the 68 countries covered by the Gilead Global Access programme will be able to receive Viread at the access price. Applications will go through a review process.	Gilead works with several distributors in Africa to facilitate low cost local distribution channels.	FOB
GlaxoSmithKline	Least Developed Countries (LDCs) plus sub-Saharan Africa. All projects fully financed by the Global Fund to fight AIDS, TB and Malaria as well as projects funded by PEPFAR.	Governments, aid organizations, charities, UN agencies, other not-for-profit organizations and international procurement agencies.	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. In sub-Saharan Africa employers there who offer HIV/AIDS care and treatment directly to their staff	CIP

Company	Eligibility (countries)	Eligibility (body)	Additional comments	Delivery of goods ^[6]
	<i>(For middle income developing countries public sector prices negotiated on a case-by-case basis bilaterally through the AAI).</i>		through workplace clinics or similar arrangements are also eligible. All organizations must supply the preferentially priced products on a not for profit basis. Supply Agreement required (For NGOs requiring less than 10 patient packs per month, this requirement may be waived). The manufacturer recommends that 'prescribers must ensure that patients are fully informed regarding hypersensitivity reaction to abacavir. Patients developing signs or symptoms must contact their doctor immediately for advice.'	
GPO	No restriction	Not-for-profit organizations and governments	Payment by signed letter of credit.	FOB Bangkok (Thailand)
Hetero Drugs Ltd	No restriction	Private sector, public sector and NGOs	Prices could be negotiated on individual basis according commercial terms.	FOB Mumbai (India)
Merck & Co. Inc	First category of countries: Low Human Development Index (HDI) countries plus medium HDI countries with adult HIV prevalence of 1% or greater ¹⁰ . Second category of countries: Medium HDI countries with adult HIV prevalence less than 1% ¹⁰ .	Governments, international organizations, NGOs, private sector organizations (e.g. employers, hospitals and insurers).	Merck & Co. Inc does not rule out supplying ARVs to patients through retail pharmacies. Although Romania does not fall under these categories it also benefits from these prices due to a government commitment to a programme of universal access.	CIP
Ranbaxy	No restriction	NGOs and Governments or Programs supported by them	Confirmed letter of credit or advance payment preferred for new customers	FOB Delhi/Mumbai (India)
Roche	First category of countries: All countries in sub-Saharan Africa and all UN defined Least Developed Countries Second category of countries: Low income countries and lower middle income countries – as classified by the World Bank.	Governments, Non Profit Institutional Providers of HIV care, NGOs.	CAD (Cash Against Documents) 30 days at sight. Minimum order and delivery amount per shipment is CHF 10,000 (US\$ 8,179)	FCA Basel (CH),
Strides Arcolab Ltd	No restriction	Governments, non profit institutional providers of HIV treatment, NGOs	Payment by signed letter of credit	FOB Bangalore (India)

Annexes

Annex 1: Least Developed Countries (LDCs)

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

Fifty countries are currently designated least developed countries (LDCs). The list is reviewed every three years.

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; Timor-Leste; Togo; Tuvalu; Uganda; United Republic of Tanzania; Vanuatu; Yemen; Zambia.

Annex 2: Human Development Index (HDI)

Source: *Human Development Report 2004, Cultural Liberty in Today's*

Diverse World, UNDP, 2004. For full list of Human Development Index ranking see:
http://hdr.undp.org/docs/statistics/indices/index_tables.pdf

Low human development

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

Medium human development

Albania; Algeria; Armenia; Azerbaijan; Bangladesh; Belarus; Belize; Bhutan; Bolivia; Bosnia and Herzegovina; Botswana; Brazil; Bulgaria; Cambodia; Cameroon; Cape Verde; China; Colombia; Comoros; Dominica; Dominican Republic; Ecuador; Egypt; El Salvador; Equatorial Guinea; Fiji; Gabon; Georgia; Ghana; Grenada; Guatemala; Guyana; Honduras; India; Indonesia; Iran (Islamic Rep. of); Jamaica; Jordan; Kazakhstan; Kyrgyzstan; Lao People's Dem. Rep;

Lebanon; Libyan Arab Jamahiriya; Macedonia (TFYR); Malaysia; Maldives; Mauritius; Moldova (Rep. of); Mongolia; Morocco; Myanmar; Namibia; Nepal; Nicaragua; Occupied Palestinian Territories; Oman; Panama; Papua New Guinea; Paraguay; Peru; Philippines; Romania; Russian Federation; Saint Lucia; Saint.Vincent and the Grenadines; Samoa (Western); São Tomé & Príncipe; Saudi Arabia; Solomon Islands; South Africa; Sri Lanka; Sudan; Suriname; Swaziland; Syrian Arab Republic; Tajikistan; Thailand; Tonga; Tunisia; Turkey; Turkmenistan; Ukraine; Uzbekistan; Vanuatu; Venezuela; Viet Nam.

Annex 3: Sub-Saharan countries

Source: World Bank (May 2005)
http://www.worldbank.org/data/countryclass/classgroups.htm#Sub_Saharan_Africa

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 economies

Source: World Bank (May 2005)
<http://www.worldbank.org/data/countryclass/classgroups.htm>

Low-income economies

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

Uzbekistan; Vietnam; Yemen (Rep.), Zambia; Zimbabwe.

Lower-middle-income economies

Albania; Algeria; Armenia; Azerbaijan; Belarus; Bolivia; Bosnia and Herzegovina; Brazil; Bulgaria; Cape Verde; China; Colombia; Cuba; Djibouti; Dominican Republic; Ecuador; Egypt, Arab Rep.; El Salvador; Fiji; Georgia; Guatemala; Guyana; Honduras; Indonesia; Iran, Islamic Rep.; Iraq; Jamaica; Jordan; Kazakhstan; Kiribati; Macedonia, FYR; Maldives; Marshall Islands; Micronesia, Fed. Sts.; Morocco; Namibia; Paraguay; Peru; Philippines; Romania; Russian Federation; Samoa; Serbia and Montenegro; South Africa; Sri Lanka; Suriname; Swaziland; Syrian Arab Republic; Thailand; Tonga; Tunisia; Turkey; Turkmenistan; Ukraine; Vanuatu; West Bank and Gaza.

Upper-middle-income economies

American Samoa; Antigua and Barbuda; Argentina; Barbados; Belize; Botswana; Chile; Costa Rica; Croatia; Czech Republic; Dominica; Estonia; Gabon; Grenada; Hungary; Latvia; Lebanon; Libya; Lithuania; Malaysia; Mauritius; Mayotte; Mexico; Northern Mariana Islands;

Oman; Palau; Panama; Poland; Saudi Arabia; Seychelles; Slovak Republic; St. Kitts and Nevis; St. Lucia; St. Vincent and the Grenadines; Trinidad and Tobago; Uruguay; Venezuela, RB.

Annex 5: Company contacts

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Bristol-Myers Squibb Co:

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Southern Africa:

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Glossary

3TC lamivudine; nucleoside analogue reverse transcriptase Inhibitor

ABC abacavir; 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^[10] ‘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^[10] ‘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; nucleoside analogue reverse transcriptase inhibitor

ddl didanosine; nucleoside analogue reverse transcriptase inhibitor

DDU^[10] ‘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 or EFZ efavirenz; non-nucleoside analogue reverse transcriptase inhibitor

EXW^[10] ‘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.

FOB^[10] ‘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 originator product, which is usually manufactured without a license from the originator company.

GPO The Government Pharmaceutical Organization (Thailand)

GSK GlaxoSmithKline

HIV Human Immunodeficiency Virus

IDV indinavir; 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; protease inhibitor

NNRTI Non-Nucleoside Reverse Transcriptase Inhibitor

NRTI Nucleoside Analogue Reverse Transcriptase Inhibitor

NtRTI Nucleotide Reverse Transcriptase Inhibitor

NVP nevirapine; non-nucleoside analogue reverse transcriptase inhibitor

PMTCT Prevention of Mother-To-Child Transmission

r low dose ritonavir used as a booster; protease inhibitor

SQV hgc saquinavir hard gel capsules; protease inhibitor

SQV sgc saquinavir soft gel capsules; protease inhibitor

TDF tenofovir; nucleotide reverse transcriptase 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

WHO World Health Organization

ZDV zidovudine; nucleoside analogue reverse transcriptase inhibitor

