

Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS

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WHO/Department of Essential Health Technologies:
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Information on HIV/AIDS diagnostic support, HIV test kit
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Information on HIV/AIDS and substance abuse is available
from www.who.int/substance_abuse

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Glossary

AIDS¹ Acquired Immune Deficiency Syndrome – the late stage of HIV disease. AIDS involves the loss of function of the immune system as CD4 cells are infected and destroyed, allowing the body to succumb to opportunistic infections (e.g., *Pneumocystis jiroveci* Pneumonia (PCP), toxoplasmosis) that are generally not pathogenic in people with intact immune systems.

CE CE Marking on a product indicates that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislations.

CIF² Cost Insurance and Freight – (...named port of destination) the seller delivers when the goods pass the ship's rail in the port of shipment. The seller must pay the cost of freight if 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. This term can be used only for sea or inland waterway transport.

COF Consejo General de Colegios Oficiales de Farmacéuticos (General Spanish Council of Pharmacists and Pharmaceutical Associations) – Spanish organization of Pharmaceutical Colleges, which represents all colleges in the national and international forum, develops norms, rules, and professional policy, and acts as the interlocutor with Spanish Ministries.

Diagnostics Laboratory tests used in the diagnosis of infection.

ELISA Enzyme-linked immunosorbent assay – HIV antibody test which requires a machine to measure color change in test wells.

Endemic¹ The continuous presence of a disease in a geographic location, community or population.

Epidemic¹ An outbreak of a disease within a population. See also pandemic.

EXW² Ex-works – (... named place) the seller's only responsibility is to make the goods available at the seller's premises, i.e., the works or factory. The seller is not responsible for loading the goods on the vehicle provided by the buyer unless otherwise agreed. The buyer bears

the full costs and risk involved in transporting the goods from there to the desired destination. Ex-works represents the minimum obligation of the seller.

FCA (nearest port)² Free Carrier – (... named place) This term has been designed to meet the requirements of multimodal transport, such as container or roll-on, roll-off traffic by trailers and ferries. It is based on the same name principle as F.O.B. (free on board), except the seller fulfils its obligations when the goods are delivered to the custody of the carrier at the named place. If no precise place can be named at the time of the contract of sale, the parties should refer to the place where the carrier should take the goods into its charge. The risk of loss or damage to the goods is transferred from the seller to the buyer.

FOB² Free-on-board – (... named port of shipment) Under 'F.O.B' the goods are placed on board the ship by the seller at a port of shipment named in the sales agreement. The risk of loss of or damage to the goods is transferred to the buyer when the goods pass the ship's rail (i.e., off the dock and placed on the ship). The seller pays the cost of loading the goods.

Generic medicine³ The term 'generic product' has somewhat different meaning in different jurisdictions. In many technical documents, use of this term is avoided, and the term 'multisource pharmaceutical product' is used instead. In this document, where the term generic medicine is used, it means a pharmaceutical product intended to be interchangeable with the originator product, which is manufactured without a license from the originator company and marketed after expiry of patent or other exclusivity rights where these have previously existed. Generic products may be marketed either under the non-proprietary approved name or under a new brand (proprietary) name. They may sometimes be marketed in dosage forms and/or strengths different from those of the originator products.

¹ AIDS Education Global Information System.

² International Chamber of Commerce.

³ *Quality Assurance of Pharmaceuticals. A compendium of guidelines and related materials, Volume 1.* WHO, Geneva, 1997.

GMP Good Manufacturing Practice

HAART Highly Active Antiretroviral Therapy. The use of 3 or more antiretroviral compounds in the management of HIV disease.

HDI Human Development Index

HIV Human Immunodeficiency Virus – a slow-acting retrovirus of the lentivirus family, believed to be the sole or primary cause of AIDS. HIV is transmitted sexually, through blood or vertically (from mother to child). There are 2 known types: HIV-1 and HIV-2.

HIV Test kit There are 3 main types of test for detecting the presence of HIV antibodies: simple/rapid tests, ELISA tests, and confirmatory tests.

Innovator pharmaceutical product A product which was first authorized for marketing (usually as a patented product) on the basis of documentation of efficacy, safety and quality (according to requirements at the time of the authorization).

International Drug Price Indicator Guide 2004 A joint publication by the World Health Organization and Management Sciences for Health (MSH). Provides a spectrum of prices from non-profit drug suppliers, procurement agencies, and ministries of health, based on their current catalogs or price lists.

ITC International Trade Centre – technical cooperation agency of the United Nations Conference on Trade and Development (UNCTAD) and the World Trade Organization (WTO) for operational, enterprise-oriented aspects of trade development since 1964.

Manufacturing license Granted by national licensing authorities and gives authorization to manufacture a specific product in a specified manufacturing plant.

MSF Médecins Sans Frontières is an international humanitarian aid organization that provides emergency medical assistance to populations in danger in more than 80 countries, since 1971.

MSH Management Sciences for Health is a private, nonprofit educational and scientific organization. Since 1971, MSH has worked with its worldwide partners to improve the management of, and access to, public health services.

MTCT Mother-to-child transmission (of HIV)

Opportunistic infection¹ (OI) An illness caused by a microorganism that usually does not cause disease in persons with healthy immune systems, but which may cause serious illness when the immune system is suppressed. Common OIs in HIV positive people include *Pneumocystis jirovecii* Pneumonia (PCP), *Mycobacterium avium* complex (MAC) disease and cytomegalovirus (CMV) disease.

Palliative care² Pain and symptom management, and psycho-social support for persons living with a terminal illness, as well as for their families and caregivers.

Pandemic¹ A widespread disease outbreak affecting the population of an extensive area of the world. See also epidemic.

Patents A title granted by public authorities conferring time-limited exclusive rights for the exploitation of an invention upon the person who reveals this invention, furnishes a sufficiently clear and full description of it and is found to meet the legal requirements for such rights.

PEPFAR The President's Emergency Plan for AIDS Relief, announced in 2003, is a five-year, \$15 billion US initiative to turn the tide in combating the global HIV/AIDS pandemic.

Protease inhibitor (PI) Type of antiretroviral medicine

Proprietary medicines Medicines that are under patent.

Reverse transcriptase inhibitor Type of ARV medicine. Can be divided into two classes: Nucleoside Reverse Transcriptase Inhibitor (NRTI) and Non Nucleoside Reverse Transcriptase Inhibitor (NNRTI)

Simple/rapid test Can generally be carried out in 15 minutes and results are read with the naked eye. The tests are easy to use and require limited training and little or no equipment, making them particularly suitable for use in Voluntary Counselling and Testing (VCT) centres.

The Global Fund to Fight AIDS, TB, and Malaria (GFATM) Created in 2002, the Global Fund's purpose is to attract and disburse additional resources to prevent and treat AIDS, tuberculosis (TB) and malaria. As a partnership between governments, civil society, the private sector and affected communities, the Global Fund represents a new approach to international health financing.

The World Bank Group Established in 1944, it is one of the world's largest sources of development assistance. In fiscal year 2004, the institution provided more than US\$20.1 billion in loans to its client countries.

TRIPS³ Agreement on Trade Related Aspects of Intellectual Property Rights

UNAIDS The Joint United Nations Programme on HIV/AIDS advocates for accelerated, comprehensive and coordinated global action on the epidemic. The Programme brings together the efforts and resources of ten UN system organizations to help the world prevent new HIV infections, care for those already infected, and mitigate

¹ AIDS Education Global Information System.

² Council on palliative care, Canada.

³ <http://www.wto.org>

the impact of the epidemic. The ten UNAIDS cosponsoring organizations are: Office of the United Nations High Commissioner for Refugees (UNHCR), United Nations Children's Fund (UNICEF), World Food Programme (WFP), United Nations Development Programme (UNDP), United Nations Population Fund (UNFPA), United Nations Office on Drugs and Crime (UNODC), International Labour Organization (ILO), United Nations Educational, Scientific and Cultural Organization (UNESCO), the World Health Organization (WHO) and the World Bank.

UNCTAD United Nations Conference on Trade and Development, established in 1964, aims at the development-friendly integration of developing countries into the world economy. It is the focal point within the United Nations for the integrated treatment of trade and development and the interrelated issues in the areas of finance, technology, investment and sustainable development.

UNFPA United Nations Population Fund – began operations in 1969. It is the largest international source of population assistance. About a quarter of all population assistance from donor nations to developing countries is channelled through UNFPA.

UNICEF With its strong presence in 157 countries and territories, the United Nations Children's Fund (UNICEF) is the world's leading advocate for children. Its action, guided by children's rights, focuses on giving children the best start in life (including through immunization), promoting girls' education, fighting HIV/AIDS and protecting children.

WHO World Health Organization – Founded in 1948, the World Health Organization acts as the directing and coordinating authorities in international health work. WHO promotes technical cooperation for health among nations, carries out programmes to control and eradicate disease and strives to improve the quality of human life. It is governed by 192 Member States and operates through its headquarters in Geneva and six regional offices and 141 country offices.

WIPO World Intellectual Property Organization – Founded in 1970, WIPO administers 23 international treaties dealing with different aspects of intellectual property protection.

WTO World Trade Organization – succeeded the General Agreement on Tariffs and Trade (GATT), first signed in 1947 by 23 countries and aimed at protecting and regulating international trade. WTO now has 147 members, three quarters of which are developing or least developed countries.

1. Introduction

1.1 Background

Antiretroviral therapy, prevention and treatment of opportunistic infections and cancers, as well as palliative care are important elements of HIV/AIDS care and support. HIV/AIDS care hence requires a wide range of essential medicines. If available, these effective medicines can prevent, treat, or help manage HIV/AIDS and most of the common HIV-related diseases.

It is estimated that 1 million people who require antiretroviral (ARV) medicines now have access to these medicines through various national and international treatment programmes.¹ This represents 15% of the nearly 6.5 million people living with HIV/AIDS (People Living with HIV/AIDS) needing treatment in developing and transitional countries as of 2005.

The high price of many of the HIV-related medicines and diagnostics offered by common suppliers – especially antiretroviral and anti-cancer medicines – is one of the main barriers to their availability and affordability in developing countries.

There are several other important barriers, including a lack of the basic components required for care, treatment, and support of people living with HIV/AIDS, such as sufficient numbers of trained staff in health facilities; availability of laboratory equipment and supplies; sufficient funding; efficient pharmaceutical supply and distribution services; strong political will and government commitment. Demand forecasting and supply planning in countries remains inadequate, which may also lead to erratic supply. Wider availability of information on prices of medicines and diagnostic tools can help those responsible for procurement make better decisions.

Since 2000, prices of important first-line ARVs have fallen considerably. This trend is attributable to a cumulation of factors including advocacy, competition from generic manufacturers, sustained public pressure, corporate responsiveness, and the growing political attention paid to the AIDS epidemic. In addition, originator and generic companies began announcing lower prices for the benefit of the poorest countries or those where HIV prevalence is highest.²

Furthermore, the availability of additional funding from financing mechanisms such as the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM) and The President's Emergency

Plan for AIDS Relief (PEPFAR) has led to increased volumes of medicine purchases.

In addition to the data found in this report the AIDS Medicines and Diagnostics Service (AMDS) has, within the “3by5” framework, published reports on the regulatory status of antiretroviral drugs,³ and sources and prices of Active Pharmaceutical Ingredients (API).⁴ The GFATM has also set up the Price Reporting Mechanism (PRM),⁵ a tool used to gather information about product prices, product quality and supplier performance.

1.2 Aim

This report provides market information that can be used by agencies wishing to procure HIV/AIDS medicines and diagnostics, and may serve as the basis for negotiating affordable prices.

The data provided by the manufacturers highlight the multiplicity of suppliers and the variation in price of some essential HIV/AIDS-related medicines on the international market. Without this information, there is a risk that low-income countries may be paying more than necessary to obtain HIV/AIDS-related medicines and diagnostics. Price variations are highlighted through the tables in chapter 5 of this report, as well as in Annex 4.

1.3 Target audience

This report is intended for use primarily by national procurement agencies in resource-limited countries that lack easily accessible information on sources and prices of medicines and diagnostics. It may also be useful to others involved in the procurement of medicines and diagnostics, such as not-for-profit organizations, distributors, importers and whole-

¹ See: WHO/UNAIDS, “3 by 5” Progress report, Dec 2004, <http://www.who.int/3by5/progressreport05/en/>

² HIV prevalence status of countries see www.who.int/emc-hiv/fact_sheets/All_countries.html

³ See: <http://ftp.who.int/htm/AMDS/drugsdatabase.pdf>

⁴ See: <http://www.who.int/3by5/amds/en/API.pdf>

⁵ See: <http://web.theglobalfund.org/prm/index.jsp>

salers or public health professionals interested in current price levels of medicines and diagnostics for people living with HIV/AIDS.

1.4 Generating the report

This is the sixth in a series of annual reports commenced in 1999, providing information on sources and prices of medicines and diagnostics commonly required by people living with HIV/AIDS, but difficult to obtain locally due to a small number of producers, the lack of distribution channels, or high prices. The information in this report is based on surveys that we expect will be continued and the report updated and made available regularly.

A survey was carried out between December 2004 and January 2005. The responses of 76 manufacturers in 28 different countries, 39% of which had not previously participated in the survey, as well as those manufacturers whose HIV test kits have been successfully evaluated by WHO (see Chapter 3) formed the basis of this report. The number of manufacturers reached has greatly increased since the first survey in 1999 as more resources became available. Manufacturers that participated in previous surveys, those held in various databases, and those belonging to national pharmaceutical associations were contacted for voluntary participation and completion of a questionnaire.

The UNAIDS Secretariat, UNICEF, MSF, and WHO have worked jointly to conduct this price survey and have compiled the results into a comprehensive publication, whilst respecting the manufacturers' requests for confidentiality in relation to their individual pricing information.

It must be pointed out that the companies included in this report have been screened only through the completeness of the requested documents they have provided, such as the questionnaire, a national GMP certificate, and associated documents relating to the company and their products. Inclusion in this report does not necessarily constitute pre-qualification or endorsement of any sort by UNICEF, WHO, UNAIDS or MSF. Only those products identified in Annex 2B in bold and with an asterisk (*) have (at the time of publication of this document) been found to meet WHO recommended standards through the ongoing Pre-qualification Project (see Chapter 4).

1.4.1 Additional requests for expressions of interest

From the recent survey, we have been unable to obtain price information on the following dosage forms of medicines due to lack of response from manufacturers.

Medicine name (INN)	Dosage Form
ivermectin	scored tablet, 6 mg
cefixime	powder for injection, 250 mg (as sodium salt)
chloramphenicol	oily suspension for injection, 0.5 g/ml (as sodium succinate) in 2-ml ampoule; oral suspension, 150 mg/5 ml (as palmitate)
clarithromycin	oral suspension, 125 mg/5 ml
erythromycin	powder for injection, 500 mg (as lactobionate) in vial
metronidazole	suppository, 500 mg
rifabutin	capsule, 150 mg
silver nitrate	solution (eye drops), 1%
sulfadiazine	injection, 250 mg (sodium salt) in 4-ml ampoule
sulfamethoxazole+ trimethoprim	injection, 80+16 mg/ml in 10-ml ampoule
amphotericin B	IV infusion, powder for reconstitution 50 mg vial; liposomal IV infusion, 5 mg/ml in vial; powder for injection, 50 mg in vial
fluconazole	oral suspension, 50 mg/5 ml
itraconazole	oral solution, 10 mg/ml
ketoconazole	oral suspension, 100 mg/5 ml
tinidazole	tablet, 2 g
cidofovir	IV infusion, 75 mg/ml in 5-ml vial
famciclovir	tablet, 125 mg; tablet, 250 mg; tablet, 500 mg
foscarnet sodium	IV infusion, 24 mg/ml
ganciclovir	capsule, 250 mg; capsule, 500 mg
imiquimod	cream, 5%
podofilox	cream, 0.15%, 5 g tube; solution or gel, 0.5%
podophyllum resin	solution, 10–25%
valacyclovir	tablet, 500 mg
valganciclovir	tablet, 450 mg
atazanavir (ATV)	capsule, 200 mg
didanosine (ddI)	unbuffered enteric coated capsule, 125 mg
emtricitabine (FTC)	capsule, 200 mg
indinavir (IDV)	capsule, 333 mg (as sulphate)
lamivudine (3TC)	tablet, 300 mg

Medicine name (INN)	Dosage Form
lopinavir+ritonavir (LPV/r)	capsule, 133.3+33.3 mg ; oral solution, 400 mg+100 mg/5 ml
saquinavir (SQV)	soft gel capsule, 200 mg
tenofovir (TDF)	tablet, 300 mg
ABC+3TC	tablet, 600+150 mg
FTC+TDF	tablet, 200+300 mg
calcium folinate (leucovorin)	injection, 3 mg/ml in 10-ml ampoule
liposomal doxorubicine HCl	conc. for IV infusion, 2 mg/ml in vial
levomepromazine	tablet, 25 mg
buprenorphine	sublingual tablet, 2 mg (hydrochloride); sublingual tablet, 8 mg (hydrochloride)
methadone HCl	oral solution, 10 mg/5 ml; powder for oral concentrate, 10 mg/ml; powder for oral concentrate, 5 mg/ml; tablet, 5 mg
morphine	oral solution, 10 mg/5 ml (sulfate or HCl); tablet, modified release, 10 mg (sulfate)
pethidine	tablet, 100 mg
prochlorperazine	tablet, 10 mg
docusate sodium	capsule, 100 mg; paediatric oral solution, 12.5 mg/5 ml

We would therefore welcome expressions of interest from manufacturers of medicines on this list.

1.5 Format of this report

This report has thus far been published in hard-copy format only. However, owing to the additional information provided in this 2005 edition (e.g. registration status of medicines by country) certain parts of the report are available only the CD-ROM attached to the inside back cover. A web site is also currently under development, which will house a searchable version of this report, as well as in-country registration information that will be regularly updated. It will also contain direct links to other relevant on-line resources and tools.

1.6 Theme of the report: Paediatric formulations and diagnostics

The estimated number of children living with HIV worldwide was over 2.2 million for 2004. In the same year, 640,000 children under the age of 15 were newly infected with HIV.¹ Approximately 50% of children with HIV die before the age of two. Unfortunately, children with AIDS are dying needlessly

because of a lack of suitable medicines and diagnostic tools.² Simplified methods of treating AIDS in adults are increasingly becoming available to patients in developing countries, more so within the past year. In many treatment programmes in developing countries, adult patients are now able to take a single pill, twice daily, as triple fixed-dose combination (FDC) formulations are available at a lower price than other less adapted formulations. Similar options are not yet available in paediatric doses. Moreover, it can cost over 6 times more to treat a child compared with an adult. Most of the currently available paediatric ARV formulations require children to take frequent doses of unpalatable syrups, many of which need cold chain storage, have limited shelf life and stability once opened, and are very costly. Chapter 3 of this publication looks more closely at the constraints in treating children with AIDS and urges manufacturers to strengthen their efforts in producing appropriate paediatric formulations.

1.7 How to use this report

1.7.1 Information on prices

Chapter 5 provides prices of medicines and diagnostic tests based on data obtained from the survey. Official UN exchange rates for the month of January 2005 were used to convert local currencies into US dollars. The prices you will find listed in section 5.1 are provided as statistical ranges explained below.

The distribution and range of prices indicate what a purchaser should expect to pay when planning procurement. Section 5.2 provides prices of HIV test kits as given by the manufacturers at the time of the WHO evaluation. UN negotiated prices for selected HIV/AIDS diagnostics may be obtained from UNICEF and WHO for those eligible to procure under the UN system.³

Annex 4 contains the latest version of the MSF bi-annual publication *Untangling the Web of Price Reductions: a Pricing Guide for the Purchase of ARVs for Developing Countries*.

Most of the prices in this report are ex-works (EXW) or Free Carrier (FCA). They do not include added costs such as freight, insurance, import duties or taxes. For this reason the prices in this report cannot be compared with final consumer prices. Many countries continue to impose considerable import duties, tariffs and taxes on the price of essential medicines.⁴ In addition, wholesale and retail mark-ups vary from one coun-

¹ See http://www.unaids.org/wad2004/EPI_1204_pdf_en/EpiUpdate04_en.pdf

² More information can be found at <http://www.who.int/3by5/paediatric/en/>

³ See http://www.who.int/diagnostics_laboratory/procurement/en/hiv_bulk_flyer_EN.pdf

⁴ See *Policy and Programming Options for Reducing the Procurement Costs of Essential Medicines in Developing Countries*, Levinson L, Boston University School of Public Health, 2003.

(a)	(b)		(c)				(d)		
Therapeutic category	Manufacturer		Indicative prices, US\$				List prices, US\$		
	NO. OF MANUFACTURERS	NO. OF COUNTRIES	UNIT	MAX	MIN	MEDIAN	25TH PERC	BRAZIL	SPAIN

try to another. As a result, the EXW price is often less than half the end-price to the consumer.

The above structure is used for reporting the price information:

(a) **Therapeutic category** (according to the WHO Model List of Essential Medicines)

(b) The **number of manufacturers** that provided an indicative price and the number of countries they represent

(c) The **indicative price unit**

The price quoted relates to the unit described. For example, if the unit is “tablet” the price quoted is for one single tablet.

max

The maximum price listed represents the highest price among products in this category, with no differentiation between originator or generic products.

min

The minimum price listed represents the lowest price among products in this category, with no differentiation between originator or generic products.

median

The median price is the middle price, or when there is an even number of prices listed, it is the mean of the two middle numbers. This means that half the prices quoted are above this median price, and the other half are below it.

25th perc

The 25th percentile is the value point representing the first quartile of quoted prices in ascending order. It is used to give some indication of the dispersion of prices for a given product.

For example, if four suppliers were identified as manufacturing cefixime paediatric oral suspension, 100 mg/5 ml, and the 25th percentile is US\$ 0.023 per ml of suspension: one out of the four (a quarter) manufacturers surveyed offer a price equal to or less than US\$ 0.023.

(d) The List prices are used to indicate the difference in price, if any, between a developing and a developed country. Brazilian and Spanish prices are selected to give a point of comparison with current market prices in a developing and a developed country with considerable manufacturing capacity.

Brazilian list price

The Brazilian list price included in this report represents the minimum price payable by Brazilian health institutions, between 01/01/2004 and 01/01/2005, for the product and is taken from the Brazilian databank of health purchases (refer to <http://bpreco.saude.gov.br/pls/BPREFD/consulta.inicio>). Where the entry reads ‘none’, this indicates no purchase has been made for that product, and therefore no minimum price is available.

Spanish list price

This EXW price has been calculated by applying the regulated margins to the consumer price as published by The General Spanish Council of Pharmacists and Pharmaceutical Associations (www.portalfarma.com). It should be noted that Spanish list prices are generally considered the lowest in Europe. In most cases, the indicative prices listed in the report are a fraction of the comparative prices in the Spanish list.

1.7.2 Information on sources

Lists of manufacturers, their contact information, and the HIV/AIDS-related medicines and diagnostics they manufacture are given in Chapter 6. Annex 2B lists the sources identified in the survey for each of these medicines.

1.7.3 Selection of medicines and diagnostics

This report includes antiretroviral medicines, medicines used to treat a range of opportunistic infections, medicines for use in palliative care, medicines for the treatment of AIDS-related cancers, and medicines for the management of opioid dependence. It also provides information on a range of test kits available for diagnosis of HIV infection and for monitoring the efficacy of antiretroviral therapy.

The medicines included in the report were selected based on recommendations from available WHO treatment guidelines. The list is not intended to be exhaustive but to broadly cover the most commonly used medicines or medicine categories. The report also includes medicines not in WHO treatment guidelines as they may be helpful for the following reasons:

- Greater cost offset by greater safety, e.g. fluconazole instead of ketoconazole;
- Fewer unwanted adverse effects, e.g. alternatives to amitriptyline.

Paediatric formulations have been included wherever possible.

Antiretroviral therapy

This report includes information on the availability and price range of antiretroviral medicines for use in Highly Active Antiretroviral Therapy. In resource – poor settings, it is critical that these medicines are used in conjunction with WHO treatment guidelines intended to support and facilitate the proper management and scale-up of HAART in the years to come, by proposing a public health approach to achieve these goals.

The topics addressed in the treatment guidelines include when to start HAART, which antiretroviral regimens to start, reasons for changing ARVs, and what regimens to continue if treatment needs to be changed. They also address how treatment should be monitored, with specific reference to the side effects of ARVs, and make specific recommendations for certain categories of patients.

The recommended first-line ARV regimens in adults and adolescents consist of a thymidine analog nucleoside reverse transcriptase inhibitor (NRTI) [stavudine (d4T) or zidovudine (ZDV)], a thiacytidine NRTI [lamivudine (3TC)] and a non-nucleoside reverse transcriptase inhibitor (NNRTI) [nevirapine (NVP) or efavirenz (EFV)]. The full text of the treatment guidelines can

be found at: http://www.who.int/3by5/publications/documents/arv_guidelines/en/

Antituberculosis medicines

This report does not include data on sources and prices of medicines for first-line treatment of tuberculosis (TB) as this information is available on the website of the International Price Indicator Guide 2004¹ or of the Global Drug Facility.² In addition, further information on sources of first-line tuberculosis medicines is available through the prequalification of TB medicines.³

Further resources for information on TB can be found in Annex 3, including links to the DOTS-plus for multidrug resistant TB website and the prequalification of TB medicines.

1.8 Medicine donations and price offers

Public pressure, advocacy, competition from generic manufacturers and initiatives from pharmaceutical companies have led to reduced prices of some HIV-related medicines in developing countries. There is no systematic approach to setting prices for developing countries. Each company determines its own eligibility criteria for countries, sectors and institutions that may benefit from a reduced price. Manufacturers of innovator products do not generally offer across-the-border discounts, and low- and middle-income countries have to pay close to full price for a number ARVs. In most cases, only those countries which come under UNCTAD's least-developed country category benefit from such discounts. Some companies offer donations of medicines for specific indications such as to prevent mother-to-child transmission of HIV, or to treat certain opportunistic infections affecting People Living with HIV/AIDSs. These donations are not monitored and hence their scope and success is not known yet.

The prices quoted in Chapter 5 of this report do not necessarily reflect all agreements that may have been negotiated with individual countries. Information on price offers for ARVs publicly announced by pharmaceutical manufacturers, including information on countries eligible for the offers and other conditions, can be found in the MSF report *Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries* (see Annex 4). Apart from providing prices of ARVs as offered by originator companies and selected generic companies, it highlights the lack of standardization among different companies on eligibility, and terms

¹ *The International Price Indicator Guide 2004* is a joint publication of WHO and Management Sciences for Health. For more information refer to Annex 4, Websites: Drug Prices.

² See <http://www.stoptb.org/GDF/drugsupply/drugs.available.html>

³ See <http://mednet3.who.int/prequal/>

and conditions of price offers. For example, some companies use UNCTAD classification (Least Developed Countries), or the World Bank classification (Low Income/ Middle Income Countries) or a combination of UNDP classification (Human Development Index) and UNAIDS prevalence data.

1.9 Additional methods of price reduction

In addition to generic competition and advocacy for reduced pricing in line with the purchasing power of countries, other important options for price reduction which may be considered by governments include compulsory licensing, government use licences and parallel importation¹ in accordance with the provisions in the TRIPS Agreement.

As agreed by the WTO Ministerial Conference in 2001, Least Developed Countries (LDCs) are not obliged to grant or enforce pharmaceutical product patents until at least 2016.² LDCs can make use or avail themselves of this provision to purchase medicines at the lowest prices on the world market. As of January 2005, non-LDC Members of the WTO must be fully TRIPS-compliant and provide patent protection for pharmaceuticals. See Annex 3 for details and references on the impact of these changes. A briefing note is also available on the MSF website.³

Additional information on the TRIPS Agreement, please see the joint WHO/UNAIDS/MSF report: Determining the patent status of essential medicines in developing countries.

The Global Fund to Fight AIDS, Tuberculosis and Malaria “encourages recipients to comply with national laws and applicable international obligations in the field of intellectual property including the flexibilities provided in the TRIPS agreement and referred to in the Doha Declaration in a manner that achieves the lowest possible price for products of assured quality.”⁴

Other measures may include reducing or eliminating import duties and taxes. As data clearly demonstrate, these factors can severely distort the prices patients will pay for medicines compared with the price at which they were sold by the manufacturer. Increasing demand through pooled procurement may also be an option for purchasers to explore.

Countries could also take advantage of programs such as The Clinton Foundation HIV/AIDS Initiative which has negotiated price ceilings with generic suppliers for some single-, double-, and triple-combination ARVs as well as diagnostic equipment. Governments are required to first sign a memorandum of understanding with The Clinton Foundation, in order to obtain the lower prices for these products and services. The Foundation has also set up two new programmes to help expand AIDS care and treatment to children and to people living in rural areas.⁵

¹ As described in chapter 2 of *HIV/AIDS Medicines and Related Supplies: Contemporary Context and Procurement*. The World Bank, Washington, D.C., 2004.

² Doha Declaration on the TRIPS agreement and Public Health, paragraphs 6 & 7.

³ See: <http://www.accessmed-msf.org/prod/>

⁴ The Global Fund to Fight AIDS, Tuberculosis and Malaria, Report of the Third Board Meeting, GF/B4/2, page 25, para 10 (a).

⁵ <http://www.clintonfoundation.org/041105-nr-cf-hs-ai-pr-treatment-for-ten-thousand-children.htm>

2. Price information projects

2.1 Medicine Prices: a new approach to measurement

The Medicines Prices project¹ has developed technical guidance for a standard approach to the measurement of the prices people pay for key medicines. Availability and retail prices are recorded for a core list of 30 widely used medicines in their originator brand and lowest-priced generic versions. Supplementary lists with different medicines can be tailored to meet local needs using the same method. The method described also assesses availability in the different sectors and for different medicines as well as assessing affordability for the treatment of common conditions.

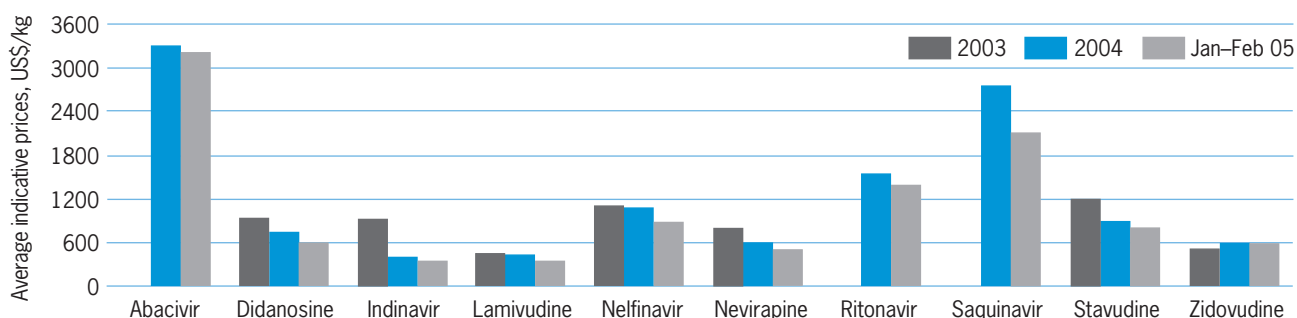
Price information is collected for procurement prices and at a sample set of pharmacies in public, private and one other sector which can be defined to fit local conditions (eg. NGO agencies, faith-based or other charity organizations, or other types of not for profit service providers). The method uses

2.2 Price monitoring of pharmaceutical starting materials

The Market News Service (MNS) of the International Trade Centre UNCTAD/WTO provides detailed price and market information on selected primary and semi-processed products of particular interest to developing countries and economies in transition, including a monthly report *Pharmaceutical Starting Materials of Essential Medicines*. The report is an information source with the sole aim of improving market transparency and encouraging price and quality competition for the benefit of all market players. It covers the main trading centres in Europe and Asia and draws information from a network of price information providers.

The prices of active pharmaceutical ingredients used in manufacturing antiretrovirals have been significantly reduced during the last two years as shown in figure 1.

FIGURE 1. Price trends for various active pharmaceutical ingredients used in manufacturing antiretroviral medicines



median prices provided by Management Sciences for Health (MSH) for the core medicines as a benchmark and the Excel spreadsheet provided helps calculate price ratios for each medicine to the MSH 'reference' price. The spreadsheet programme also analyzes the input data to generate standard report tables. The HAI website contains an open-access repository of data from studies undertaken so far, national and regional reports and a synthesis of results from the various studies.

As part of its effort to provide information to improve market transparency, MNS reports are now directly available on-line through ITC's market analysis tool, Product Map, www.p-maps.org, a subscription-based service. Subscribers from LDCs, WHO Regional and Country Offices receive the report via E-mail and printed copies free-of-charge. Sub-Saharan African users now have free access to the MNS reports through www.p-maps.org. The Product Map on Pharmaceuticals combines quantitative market information in relation to international trade statistics and macroeconomic indicators, qualitative market intelligence – such as market briefs and published market studies – and networking links to key market players in the Pharmaceuticals industry.

¹ <http://www.who.int/medicines/library/prices.shtml>;
<http://www.haiweb.org/medicineprices/>

3. Paediatric formulations and diagnostics

There are many challenges in the provision of ARV treatment for children infected with HIV, many of them not exclusive to HIV infection. To address some of these issues, UNICEF and WHO co-hosted a technical consultation in November 2004.¹ It was widely recognised that children can and should be treated with existing formulations. Prices of currently available paediatric formulations can be found in Chapter 5. In addition, some generic companies are in the process of developing paediatric FDCs, and WHO is working on the preparation of clear treatment guidelines.

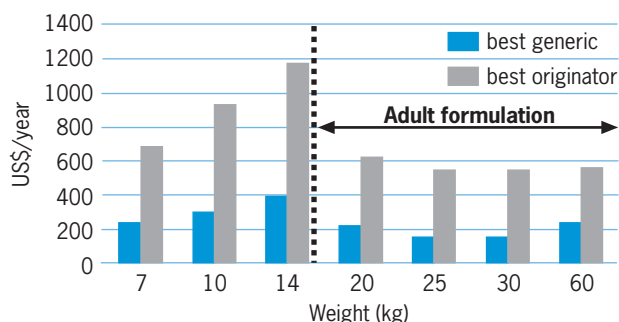


FIGURE 2. Grandmother with her grandchild at an MSF project clinic in Khayelitsha, South Africa. The medicines on the table are the monthly treatment for the children. Many practitioners are obliged to use liquids for children as better adapted paediatric formulations are unavailable. This means huge volumes of formulations that are difficult to manage and transport. In addition, the price normally increases considerably. Photo: MSF

The following chart shows the evolution in price of a treatment regimen consisting of the three ARVs, stavudine/lamivudine/nevirapine (d4T/3TC/NVP). The price falls when treatment is switched to a single adult formulation (above 14 kg). In most cases, however, these adult formulations are unsuitable for children. For instance, lamivudine, as marketed by most of the manufactures, is not scored, which makes it difficult to break accurately in half. Additionally, the use of adult formulations makes it difficult to adjust the dose for

¹ Please visit the WHO website for the full report: <http://www.who.int/3by5/en/finalreport.pdf>

FIGURE 3. Evolution on price for pediatric treatment (d4T+3TC+NVP) according to the weight



children. Furthermore, the price is always as high as treating adults using FDCs.

Recommendations for paediatric ARVs required in resource-poor settings

Syrups and solutions should be reserved for infants weighing <10–12kg. Where possible, sachets granules, or dispersible tablets would be preferred.

Liquid formulations:

- Should be stable at room temperature; have small dose/volume; have a long shelf life at high humidity and temperature
- Be available in suitable dosage forms to provide appropriate dose ranges by 2–3kg weight band for smallest infants.
- Be packaged to provide for 28–30 treatment days
- Have suitable masking of unpleasant taste (e.g. AZT)

Solid formulations

- For use as soon as a child can swallow (usually for children weighing >10kg)
- Be available in suitable dosage forms to provide appropriate dose ranges by 2–3kg weight band for smaller infants and by 10kg weight band for older ones:
 - Crushable, granulate or dispersible tablets
 - Stable product with longer shelf life at high room temperatures and humidity
 - Scored tablets
 - Have suitable masking of bad taste
 - Innovative delivery systems for reduced dose frequency

The early diagnosis of infants born to HIV-seropositive mothers is difficult as traditional HIV serological tests cannot be used with certainty before the age of 12–18 months owing to interference with maternal HIV antibodies. Earlier detection of HIV infection is possible after 6–12 weeks by using either DNA or RNA nucleic-acid-based technologies, which detect parts of the virus instead of antibodies against HIV. However, these technologies are technically sophisticated, and require excellent laboratory facilities and expensive equipment not commonly available in resource-limited settings.

In some countries an alternative approach could be to collect a blood or plasma sample on filter paper and send it for centralized testing. Once infants have been diagnosed as being

infected with HIV and requiring ARV therapy, the challenge is to monitor the effectiveness of the treatment regimen. The measurement of CD4 percentages is quite feasible when using flow cytometry. However, most of the smaller CD4 technologies, which are more appropriate for use in resource-limited settings, do not yet have a protocol for measuring CD4 percentages or their application has not yet been validated. Manufacturers of CD4 technologies are aware of this issue and efforts are being made to resolve it. The lack of appropriate diagnostic tools to diagnose HIV infection early in infants and to monitor the efficacy of ARV treatment for paediatrics hampers the roll out of care and support to this patient group.

4. Access to quality HIV/AIDS medicines and diagnostics

4.1 Prequalification project¹

This project evaluates pharmaceutical products according to WHO recommended standards of safety, efficacy and quality and compliance with good manufacturing practices (GMP), as well as good clinical practices (GCP). The prequalification process follows a standard procedure developed through WHO's Expert Committee on Specifications for Pharmaceutical Preparations. A medicine is added to the list of prequalified products only when the products and manufacturing sites are found to meet the required standards. A list of HIV-related products/manufacturers that have been found acceptable, in principle, for procurement by UN agencies is available on the web sites of collaborating UN agencies, such as UNICEF, UNFPA and the UNAIDS Secretariat.

As of January 2005, 285 product dossiers for various products and dosage forms from over 40 manufacturers were received: only 85 of these products, from 26 manufacturing sites have been listed as prequalified products. The products evaluated are ARVs (including fixed dose combinations), and medicines for the treatment of opportunistic infections and cancers. A list of products evaluated under this project is regularly updated through the websites of collaborating UN agencies.

This report provides pricing information and does not prequalify any products. Every effort has been made to ensure the accuracy of the price information presented and screening of the products included in this survey has been carried out as indicated on page 2. However, this screening in no way constitutes an in-depth review of product quality, safety or efficacy. Products that have been prequalified are marked in Annex 2B of this report in bold and with an asterisk (*). The information contained in Annex 2B is, however, subject to change and should therefore be verified before a decision on procurement is taken. Products not included in the list of prequalified products should, in relation to purchase, be subject to prequalification review as indicated in the WHO General Procedure for Prequalification of Suppliers of Pharmaceutical Products. Manufacturers are encouraged to apply for WHO prequalification for their HIV-related products. In scaling up access to ARVs, it is not only the quantity of medicines that is important, but also their quality.

¹ <http://mednet3.who.int/prequal/default.shtml>

4.2 Product registration

In order to guide procurement, governments must ensure they have well-functioning national drug regulatory authorities (DRAs) with a clear mandate and legal authority, appropriate organizational structure, adequate number of qualified staff, sufficient resources and a sustainable financing mechanism. The primary objective of DRAs is to safeguard public health by ensuring that all medicines circulating in the markets meet appropriate standards of safety, quality and efficacy. Safety aspects cover potential or actual harmful effects; quality relates to development and manufacture of products; and efficacy is a measure of the beneficial effect of the medicine on patients. To assist procurement agencies with regulatory aspects of medicines, Annex 2A (see attached CD-ROM) provides information on countries in which products listed in this report are currently registered. This information is provided by manufacturing companies and is subject to change. Any updates in information will be placed on partner websites. To improve the accuracy of this publication, DRAs are strongly encouraged to submit any known changes or corrections to the data provided to: UNICEF Supply Division in Copenhagen, Denmark, e-mail supply@unicef.org, fax +45 35 269421.

4.3 Diagnostics

In parallel to the scale-up efforts and roll-out programmes of ARVs in countries with limited resources there is an increased demand for HIV/AIDS related diagnostics and laboratory support. Access to appropriate and cost-effective diagnostics can make a difference. HIV tests are crucial tools for ensuring blood safety, gathering surveillance data and to identify individuals infected with HIV. Qualitative nucleic acid-based tests, such as DNA or RNA PCR, or alternative methods, such as heat denaturated p24 antigen, are key in early detection of HIV infection in infants born to HIV positive mothers. Diagnostic technologies, measuring CD4 counts and to a lesser extent viral load tests are important for making decisions about when to start, substitute, switch or stop ARV treatment.

A wide range of tests that can be used for the above-mentioned purposes is available in the global market and many more tests are under development. Yet their quality, affordability and suitability for use in settings with limited resources need to be assessed and validated.

The Department of Essential Health Technologies at WHO provides information to Member States on the quality and operational characteristics of diagnostics for HIV prevention, care and treatment. As part of this effort, several types of diagnostic equipment and assays have already been assessed or are scheduled for an evaluation.

In general the evaluation process consists of five steps: (1) WHO receives a request from a manufacturer or the request is initiated by WHO; (2) WHO reviews independent data on performance generated in trials, and reviews existing certifications, such as FDA approval or CE mark). (3) An original equipment manufacturer (OEM) investigation is pursued. OEM represents the repackaging of an assay sourced from a single manufacturer under a different label that does not involve alterations in the production of the assay components. (4) Assay and/or equipment performance is evaluated at WHO collaborating centers around the world. (5) The data from each stage of the evaluation is analyzed, and the information is disseminated.

Slightly different approaches are used for the validation process, depending on the technologies assessed.

HIV serology: Evaluation of HIV serological assays, relies on a well characterized WHO reference panel of specimens, and a standardized algorithm. Minimal performance criteria have been established in terms of: sensitivity [$>99\%$ for rapid, 100% for ELISA]; specificity [$>98\%$]; inter-reader variability [$<4\%$]; seroconversion sensitivity. The clarity of the test kit insert, the labeling of the component of the kit and the easy of the test procedure are also assessed.

CD4 technologies: The validation of CD4 technologies are conducted in several sites according to one protocol. Specimens are collected in a prospective manner and a certain number of control specimens are included in the assessment, the results are compared to gold standard methods. Performance criteria include: accuracy; linearity, reproducibility/precision; inter/intra run variability and technician variability.

Viral load: The assessment of the viral load assays includes the sensitivity to the various HIV subtypes, reproducibility/precision and accuracy. Data are compared to gold standard methods for these assays. The ExaVir v2.0 (Cavidi) and the Retina Rainbow assay (Primagen) are currently under evaluation.

The main focus of WHO is on diagnostics and equipment appropriate for use in resource-limited settings. Assays that have been successfully evaluated are eligible to tender for bulk procurement through the UN. The one year procurement agreements made with companies by WHO cover the other UN organizations (e.g. UNAIDS, UNDP, UNFPA, UNICEF, World Bank etc). Hence, access to quality diagnostics at reasonable cost are made available to Member States.

Please note that this and additional information is regularly updated and available on the WHO website at www.who.int/diagnostics_laboratory (follow the links to Diagnostics, HIV or Bulk Procurement Scheme, HIV). More information related to diagnostics is provided in Annex 1A and 1B of this document.

5. Prices of medicines and diagnostics

5.1 Medicines

TABLE 1. ANTI-INFECTIVE MEDICINES

	Manufacturer		unit	Indicative price, US\$				List prices, US\$	
	No. of manufacturers	No. of countries		max	min	median	25th perc	Brazil	Spain
Anthelmintics – Antifilarials									
crotamiton									
cream/lotion 10%	1	1	ml	0.010	0.010	0.010	0.010	n/a	0.877
ivermectin									
scored tablet, 3 mg	1	1	tablet	0.530	0.530	0.530	0.530	n/a	n/a
scored tablet, 6 mg*	—	—	tablet	—	—	—	—	n/a	n/a
lindane									
cream, lotion or powder, 0.3%	1	1	gram	0.122	0.122	0.122	0.122	n/a	n/a
permethrin									
cream, 5%	1	1	gram	0.152	0.152	0.152	0.152	n/a	0.175
lotion, 1%	1	1	ml	0.019	0.019	0.019	0.019	n/a	n/a
Anthelmintics – Intestinal anthelmintics									
albendazole									
chewable tablet, 400 mg	13	8	tablet	0.420	0.007	0.045	0.022	0.048	0.929
Antibacterials, beta lactam medicines									
benzathine benzylpenicillin									
powder for injection, 1.44 g (=2.4 million IU) in 5-ml vial	3	3	vial	1.300	0.170	0.278	0.224	n/a	n/a
benzylpenicillin									
powder for injection, 3 g (=5 million IU) (as sodium or potassium salt) in vial	3	2	vial	1.200	0.180	0.350	0.265	0.619	1.284
powder for injection, 600 mg (=1 million IU) (as sodium or potassium salt) in vial	2	2	vial	0.200	0.146	0.173	0.160	n/a	1.765
cefixime									
paediatric oral suspension, 100 mg/5 ml	2	2	ml	0.163	0.034	0.098	0.066	n/a	0.075
paediatric oral suspension, 40 mg/5 ml	1	1	ml	0.098	0.098	0.098	0.098	n/a	n/a
powder for injection, 250 mg (as sodium salt)*	—	—	vial	—	—	—	—	n/a	n/a
tablet, 200 mg	5	4	tablet	0.975	0.186	0.343	0.291	n/a	0.749
tablet, 400 mg	2	2	tablet	0.400	0.165	0.283	0.224	n/a	1.373

* No price information; n/a – not available.

	Manufacturer		unit	Indicative price, US\$				List prices, US\$	
	No. of manufacturers	No. of countries		max	min	median	25th perc	Brazil	Spain
ceftriaxone									
powder for injection, 1 g (as sodium salt) in vial	18	10	1 g vial	4.613	0.109	1.170	0.900	0.687	6.237
powder for injection, 250 mg (as sodium salt) in vial	13	7	vial	2.917	0.270	0.700	0.470	n/a	1.840
powder for injection, 500 mg (as sodium salt) in vial	14	10	vial	3.664	0.085	0.800	0.700	n/a	3.462
procaine benzylpenicillin									
powder for injection, 1 g (=1 million IU) in vial	1	1	vial	0.134	0.134	0.134	0.134	n/a	n/a
powder for injection, 3 g (=3 million IU) in vial	2	2	vial	0.240	0.144	0.192	0.168	n/a	n/a
Antibacterials, others									
azithromycin									
oral suspension, 200 mg/5 ml (dihydrate)	4	2	ml	0.133	0.040	0.042	0.040	0.078	0.226
tablet/capsule, 250 mg (dihydrate)	7	3	tablet/ capsule	0.890	0.117	0.152	0.121	n/a	n/a
tablet/capsule, 500 mg (dihydrate)	7	4	tablet/ capsule	2.714	0.247	0.667	0.275	0.447	2.175
capreomycin¹									
powder for injection, 1 g in vial	1	1	1 g vial	5.000	5.000	5.000	5.000	n/a	2.074
chloramphenicol									
capsule, 250 mg	3	3	capsule	0.028	0.014	0.020	0.017	n/a	n/a
oily suspension for injection, 0.5 g/ml (as sodium succinate) in 2-ml ampoule*	—	—	ampoule	—	—	—	—	n/a	n/a
oral suspension, 150 mg/5 ml (as palmitate)*	—	—	ml	—	—	—	—	n/a	n/a
powder for injection, 1 g (sodium succinate) in vial	5	3	1 g vial	1.440	0.175	0.280	0.231	0.371	n/a
ciprofloxacin									
tablet, 250 mg (as hydrochloride)	25	14	tablet	0.658	0.008	0.028	0.020	0.048	0.151
tablet, 500 mg (as hydrochloride)	24	12	tablet	1.289	0.013	0.044	0.034	0.058	0.295
clarithromycin									
oral suspension, 125 mg/5 ml*	—	—	ml	—	—	—	—	n/a	0.061
powder for injection, 500 mg	1	1	vial	0.700	0.700	0.700	0.700	n/a	11.105
tablet, 250 mg	14	9	tablet	0.472	0.105	0.160	0.133	0.296	0.582
clindamycin									
capsule, 150 mg	4	4	capsule	0.113	0.033	0.058	0.035	0.660	0.131
cream, 2% (as phosphate)	1	1	gram	0.125	0.125	0.125	0.125	n/a	n/a
injection, 150 mg/ml (as phosphate) in 2-ml ampoule	1	1	ampoule	2.008	2.008	2.008	2.008	0.464	1.206
cycloserine¹									
capsule, 250 mg	1	1	capsule	0.466	0.466	0.466	0.466	n/a	n/a
doxycycline									
capsule/tablet, 100 mg (hydrochloride)	12	6	capsule/ tablet	0.025	0.008	0.016	0.014	0.052	0.090

* No price information; n/a – not available.

¹ Please visit <http://www.stoptb.org/gdf/> for a comprehensive list of TB medicines and pricing strategies

	Manufacturer		unit	Indicative price, US\$				List prices, US\$	
	No. of manufacturers	No. of countries		max	min	median	25th perc	Brazil	Spain
erythromycin									
powder for injection, 500 mg (as lactobionate) in vial*	—	—	vial	—	—	—	—	n/a	n/a
powder for oral suspension, 125 mg (as stearate or ethylsuccinate)	8	7	ml	0.977	0.006	0.011	0.009	0.010	n/a
tablet/capsule, 250 mg (as stearate or ethylsuccinate)	15	8	tablet/capsule	0.049	0.021	0.030	0.025	n/a	n/a
tablet/capsule, 500 mg (as stearate or ethylsuccinate)	12	7	tablet/capsule	0.090	0.043	0.051	0.047	0.099	0.162
gentamicin									
injection, 10 mg/ml (as sulfate) in 2-ml vial	1	1	vial	0.109	0.109	0.109	0.109	0.072	0.357
injection, 40 mg/ml (as sulfate) in 2-ml vial	4	3	vial	0.370	0.058	0.118	0.101	0.065	0.402
metronidazole									
injection, 500 mg in 100-ml vial	6	5	vial	2.880	0.570	0.700	0.651	0.189	2.434
oral suspension, 200 mg (as benzoate)/5 ml	6	5	ml	0.008	0.003	0.005	0.004	n/a	n/a
suppository, 1 g	1	1	suppository	0.450	0.450	0.450	0.450	n/a	n/a
suppository, 500 mg*	—	—	suppository	—	—	—	—	n/a	n/a
tablet, 200 mg	7	6	tablet	0.011	0.003	0.007	0.005	n/a	n/a
tablet, 500 mg	6	6	tablet	0.093	0.009	0.022	0.019	n/a	n/a
vaginal gel, 0.75%	1	1	gram	0.025	0.025	0.025	0.025	n/a	0.108
ofloxacin									
IV infusion, 2 mg/ml (hydrochloride)	2	2	ml	0.032	0.012	0.022	0.017	n/a	n/a
tablet, 200 mg	11	7	tablet	0.713	0.024	0.063	0.044	n/a	0.412
tablet, 400 mg	7	4	tablet	0.158	0.062	0.120	0.097	1.014	n/a
rifabutin									
capsule, 150 mg*	—	—	capsule	—	—	—	—	n/a	2.118
silver nitrate									
solution (eye drops), 1%*	—	—	ml	—	—	—	—	n/a	n/a
spectinomycin									
powder for injection, 2 g (as hydrochloride) in vial	1	1	vial	4.000	4.000	4.000	4.000	n/a	n/a
sulfadiazine									
injection, 250 mg (sodium salt) in 4-ml ampoule*	—	—	ampoule	—	—	—	—	n/a	n/a
tablet, 500 mg	3	3	tablet	0.324	0.041	0.149	0.095	0.018	0.060
sulfamethoxazole+trimethoprim									
injection, 80+16 mg/ml in 10-ml ampoule*	—	—	ampoule	—	—	—	—	n/a	n/a
oral suspension, 200+40 mg/5 ml	15	9	ml	0.149	0.003	0.005	0.003	0.002	0.012
tablet, 100+20 mg	7	5	tablet	0.015	0.001	0.007	0.004	n/a	0.021
tablet, 400+80 mg	21	13	tablet	0.027	0.005	0.010	0.008	0.016	0.039
tablet, 800+160 mg	13	8	tablet	0.066	0.011	0.018	0.014	0.069	0.098

* No price information; n/a – not available.

	Manufacturer		unit	Indicative price, US\$				List prices, US\$	
	No. of manufacturers	No. of countries		max	min	median	25th perc	Brazil	Spain
Antifungal medicines									
amphotericin B									
IV infusion, powder for reconstitution 50 mg vial*	—	—	vial	—	—	—	—	n/a	133.166
liposomal IV infusion, 5 mg/ml in vial*	—	—	vial	—	—	—	—	n/a	0.584
powder for injection, 50 mg in vial	2	2	vial	9.000	3.664	6.332	4.998	2.426	1.910
clotrimazole									
cream, 1%	13	11	gram	0.133	0.009	0.026	0.016	0.653	1.194
pessary, 500 mg	2	2	pessary	0.600	0.400	0.500	0.450	n/a	1.619
fluconazole									
capsule, 150 mg	10	7	capsule	1.300	0.028	0.225	0.066	0.151	3.438
capsule, 200 mg	8	6	capsule	1.406	0.036	0.233	0.170	n/a	4.590
capsule, 50 mg	7	5	capsule	0.500	0.043	0.163	0.094	n/a	1.143
injection, 2 mg/ml in ampoule	4	3	ml	0.046	0.008	0.039	0.027	0.014	0.049
oral suspension, 50 mg/5 ml*	—	—	ml	—	—	—	—	n/a	0.234
itraconazole									
capsule, 100 mg	4	4	capsule	0.550	0.132	0.406	0.266	0.292	0.806
oral solution, 10 mg/ml*	—	—	ml	—	—	—	—	n/a	0.968
ketoconazole									
cream, 2%	7	7	gram	2.510	0.016	0.024	0.020	n/a	2.335
oral suspension, 100 mg/5 ml*	—	—	ml	—	—	—	—	n/a	n/a
tablet, 200 mg	13	10	tablet	0.188	0.006	0.040	0.032	n/a	0.426
miconazole									
cream/ointment 2% (as nitrate) 15 g tube	5	4	tube	0.700	0.258	0.455	0.380	n/a	n/a
cream/ointment 2% (as nitrate) 20 g tube	4	4	tube	1.357	0.200	0.545	0.410	n/a	n/a
cream/ointment 2% (as nitrate) 30 g tube	8	4	tube	0.980	0.026	0.490	0.438	0.618	1.918
cream/ointment 2% (as nitrate) 40 g tube	1	1	tube	0.669	0.669	0.669	0.669	n/a	1.792
nystatin									
lozenge, 100,000 IU	1	1	lozenge	0.030	0.030	0.030	0.030	n/a	n/a
pessary, 100,000 IU	6	5	pessary	0.030	0.019	0.024	0.022	n/a	0.093
tablet, 100,000 IU	4	3	tablet	0.025	0.017	0.023	0.020	n/a	n/a
tablet, 500,000 IU	9	6	tablet	0.075	0.028	0.040	0.036	n/a	0.061
Antiprotozoal medicines									
pentamidine									
powder for injection, 200 mg (isetionate) in vial	1	1	vial	9.000	9.000	9.000	9.000	n/a	n/a
powder for injection, 300 mg (isetionate) in vial	3	3	vial	48.400	5.020	24.700	14.860	36.948	7.039

* No price information; n/a – not available.

	Manufacturer		unit	Indicative price, US\$				List prices, US\$	
	No. of manufacturers	No. of countries		max	min	median	25th perc	Brazil	Spain
pyrimethamine									
tablet, 25 mg	2	2	tablet	0.187	0.050	0.119	0.084	0.017	0.062
tinidazole									
tablet, 2 g*	—	—	tablet	—	—	—	—	n/a	n/a
tablet, 500 mg	4	3	tablet	0.058	0.012	0.016	0.014	n/a	0.663
Antiviral medicines									
aciclovir									
cream, 5%	5	4	gram	0.936	0.026	0.102	0.041	0.409	1.048
powder for injection, 250 mg (as sodium salt)	7	5	vial	14.286	0.170	2.000	1.882	1.457	4.133
tablet, 200 mg	16	12	tablet	0.435	0.025	0.045	0.031	0.086	0.576
tablet, 400 mg	11	6	tablet	0.350	0.048	0.086	0.059	n/a	n/a
tablet, 800 mg	10	6	tablet	1.370	0.098	0.366	0.180	n/a	1.818
cidofovir									
IV infusion, 75 mg/ml in 5-ml vial*	—	—	vial	—	—	—	—	n/a	117.572
famciclovir									
tablet, 125 mg*	—	—	tablet	—	—	—	—	n/a	2.349
tablet, 250 mg*	—	—	tablet	—	—	—	—	n/a	4.744
tablet, 500 mg*	—	—	tablet	—	—	—	—	n/a	n/a
foscarnet sodium									
IV infusion, 24 mg/ml*	—	—	ml	—	—	—	—	n/a	0.122
ganciclovir									
capsule, 250 mg*	—	—	capsule	—	—	—	—	n/a	n/a
capsule, 500 mg*	—	—	capsule	—	—	—	—	n/a	n/a
powder for IV infusion, 500 mg in vial	1	1	vial	42.520	42.520	42.520	42.520	17.337	19.990
imiquimod									
cream, 5%*	—	—	gram	—	—	—	—	n/a	n/a
podofilox									
cream, 0.15%, 5 g tube*	—	—	tube	—	—	—	—	n/a	13.036
solution or gel, 0.5%*	—	—	ml	—	—	—	—	n/a	8.379
podophyllum resin									
solution, 10 – 25%*	—	—	ml	—	—	—	—	n/a	n/a
valacyclovir									
tablet, 500 mg*	—	—	tablet	—	—	—	—	n/a	1.745
valganciclovir									
tablet, 450 mg*	—	—	tablet	—	—	—	—	n/a	21.630

* No price information; n/a – not available.

Antiviral medicines – Antiretrovirals	Manufacturer		unit	Indicative price, US\$				List prices, US\$	
	No. of manufacturers	No. of countries		max	min	median	25th perc	Brazil	Spain
abacavir (ABC)									
syrup, 20 mg/ml	1	1	ml	0.131	0.131	0.131	0.131	n/a	0.253
tablet, 300 mg	3	3	tablet	2.962	1.018	1.215	1.116	n/a	3.914
atazanavir (ATV)									
capsule, 200 mg*	—	—	capsule	—	—	—	—	n/a	7.500
didanosine (ddI)									
buffered chewable tablet, 100 mg	5	4	tablet	0.271	0.024	0.191	0.165	0.317	1.097
buffered chewable tablet, 25 mg	3	3	tablet	0.117	0.090	0.103	0.097	n/a	0.274
buffered chewable tablet, 50 mg	2	2	tablet	0.158	0.136	0.147	0.141	n/a	0.622
syrup, 2 g	1	1	ml	0.088	0.088	0.088	0.088	n/a	21.949 (bottle)
unbuffered enteric coated capsule, 125 mg*	—	—	capsule	—	—	—	—	n/a	1.623
unbuffered enteric coated capsule, 250 mg	3	3	capsule	0.557	0.430	0.543	0.486	n/a	3.432
unbuffered enteric coated capsule, 400 mg	2	2	capsule	0.764	0.543	0.653	0.598	n/a	5.401
efavirenz (EFZ)									
capsule, 100 mg	2	2	capsule	1.001	0.231	0.616	0.424	n/a	1.450
capsule, 200 mg	5	4	capsule	0.463	0.188	0.421	0.399	n/a	2.982
capsule, 50 mg	1	1	capsule	0.116	0.116	0.116	0.116	n/a	0.725
oral solution, 150 mg/5 ml	1	1	ml	0.094	0.094	0.094	0.094	n/a	n/a
tablet, 600 mg	5	3	tablet	1.312	0.950	1.189	1.003	2.182	9.165
emtricitabine (FTC)									
capsule, 200 mg*	—	—	capsule	—	—	—	—	n/a	n/a
indinavir (IDV)									
capsule, 200 mg (as sulphate)	2	2	capsule	0.170	0.137	0.153	0.145	n/a	0.754
capsule, 333 mg (as sulphate)*	—	—	capsule	—	—	—	—	n/a	n/a
capsule, 400 mg (as sulphate)	5	4	capsule	1.058	0.002	0.294	0.274	0.404	1.509
lamivudine (3TC)									
oral solution, 50 mg/5 ml	3	3	ml	0.028	0.021	0.025	0.023	0.035	0.032
tablet, 150 mg	10	6	capsule/ tablet	0.398	0.094	0.118	0.097	0.237	2.476
tablet, 300 mg*	—	—	capsule/ tablet	—	—	—	—	n/a	4.952
lopinavir+ritonavir (LPV/r)									
capsule, 133.3+33.3 mg*	—	—	capsule	—	—	—	—	n/a	2.087
oral solution, 400 mg+100 mg/5 ml*	—	—	ml	—	—	—	—	n/a	1.252
nelfinavir (NFV)									
oral powder, 50 mg/g	1	1	gram	0.243	0.243	0.243	0.243	n/a	0.354
tablet, 250 mg	4	4	tablet	0.921	0.290	0.480	0.405	0.611	1.132

* No price information; n/a – not available.

	Manufacturer		unit	Indicative price, US\$				List prices, US\$	
	No. of manufacturers	No. of countries		max	min	median	25th perc	Brazil	Spain
nevirapine (NVP)									
syrup, 50 mg/5 ml	4	3	ml	0.073	0.013	0.018	0.014	0.143	0.171
tablet, 200 mg	9	6	tablet	3.306	0.122	0.195	0.171	n/a	4.336
saquinavir (SQV)									
hard gel capsule, 200 mg	1	1	capsule	0.294	0.294	0.294	0.294	n/a	1.036
soft gel capsule, 200 mg*	—	—	capsule	—	—	—	—	n/a	0.733
stavudine (d4T)									
capsule, 15 mg	1	1	capsule	0.058	0.058	0.058	0.058	n/a	2.089
capsule, 20 mg	3	3	capsule	0.094	0.056	0.070	0.063	n/a	2.167
capsule, 30 mg	9	6	capsule	1.345	0.043	0.068	0.056	0.093	2.267
capsule, 40 mg	10	7	capsule	1.427	0.055	0.075	0.065	0.182	2.343
syrup, 1 mg/ml	2	2	ml	0.048	0.011	0.029	0.020	n/a	0.095
tenofovir (TDF)									
tablet, 300 mg*	—	—	tablet	—	—	—	—	n/a	9.970
zalcitabine (ddC)									
tablet, 0.375 mg	1	1	tablet	0.251	0.251	0.251	0.251	n/a	n/a
tablet, 0.75 mg	2	2	tablet	0.865	0.425	0.645	0.535	n/a	1.393
zidovudine (AZT or ZDV)									
oral solution, 50 mg/5 ml	6	5	ml	0.300	0.016	0.025	0.021	0.015	0.060
solution for IV infusion/injection, 10 mg/ml in 20-ml vial	2	2	vial	41.000	5.000	23.000	14.000	1.443	6.474
tablet/capsule, 100 mg	9	8	capsule/ tablet	0.617	0.076	0.140	0.115	0.114	0.659
tablet/capsule, 250 mg	5	5	capsule/ tablet	1.450	0.315	0.360	0.332	n/a	1.643
tablet/capsule, 300 mg	10	6	tablet/ capsule	0.475	0.005	0.250	0.218	n/a	1.972
Antiviral medicines – Antiretrovirals (combinations)									
3TC+AZT									
tablet, 150+300 mg	9	6	tablet	2.951	0.007	0.313	0.271	0.471	5.014
3TC+d4T									
tablet, 150+30 mg	3	2	tablet	0.174	0.107	0.158	0.139	n/a	n/a
tablet, 150+40 mg	5	2	tablet	0.267	0.117	0.175	0.159	n/a	n/a
3TC+d4T+NVP									
tablet, 150+30+200 mg	7	4	tablet	0.650	0.237	0.317	0.264	n/a	n/a
tablet, 150+40+200 mg	7	4	tablet	0.650	0.246	0.358	0.289	n/a	n/a
ABC+3TC									
tablet, 600+150 mg*	—	—	tablet	—	—	—	—	n/a	n/a

* No price information; n/a – not available.

	Manufacturer		unit	Indicative price, US\$				List prices, US\$	
	No. of manufacturers	No. of countries		max	min	median	25th perc	Brazil	Spain
ABC+3TC+ZDV									
tablet, 300+150+300 mg	2	2	tablet	1.700	1.683	1.692	1.687	n/a	8.414
AZT+3TC+NVP									
tablet, 300+150+200 mg	2	2	tablet	0.500	0.452	0.476	0.464	n/a	n/a
FTC+TDF									
tablet, 200+300 mg*	—	—	tablet	—	—	—	—	n/a	n/a

TABLE 2. ANTINEOPLASTIC MEDICINES

Cytotoxic medicines	Manufacturer		unit	Indicative price, US\$				List prices, US\$	
	No. of manufacturers	No. of countries		max	min	median	25th perc	Brazil	Spain
bleomycin									
powder for injection, 15 mg (as sulfate) in vial	5	4	vial	21.000	12.429	20.000	18.000	22.515	11.158
calcium folinate (leucovorin)									
injection, 3 mg/ml in 10-ml ampoule*	—	—	ampoule	—	—	—	—	n/a	n/a
tablet, 15 mg	4	4	tablet	3.799	0.014	1.047	0.328	n/a	0.582
doxorubicine HCl									
powder for injection, 10 mg in 5-ml vial	6	4	vial	25.780	2.940	4.591	3.375	3.196	5.836
powder for injection, 50 mg in 25-ml vial	5	4	vial	120.760	10.660	18.159	15.000	14.739	23.008
etoposide									
capsule, 100 mg	1	1	capsule	10.000	10.000	10.000	10.000	n/a	9.264
injection, 20 mg/ml in 5-ml ampoule	7	5	ampoule	33.921	1.723	6.000	3.857	2.921	6.607
liposomal doxorubicine HCl									
conc. for IV infusion, 2 mg/ml in vial*	—	—	vial	—	—	—	—	n/a	38.192
methotrexate									
injection, 25 mg/ml (as sodium salt) in 2-ml vial	3	3	vial	18.100	1.400	1.800	1.600	2.062	1.443
powder for injection, 50 mg (as sodium salt) in 2-ml vial	3	3	vial	4.310	2.000	3.360	2.680	n/a	2.989
tablet, 2.5 mg	5	4	tablet	0.188	0.034	0.070	0.065	n/a	0.043
vinblastine									
powder for injection, 10 mg (sulfate) in 10-ml vial	4	3	vial	14.260	1.400	5.254	3.281	11.684	5.170
vincristine									
powder for injection, 1 mg (sulfate) in 1-ml vial	3	2	vial	2.000	1.550	1.600	1.573	2.405	4.024
powder for injection, 5 mg (sulfate) in vial	1	1	vial	4.500	4.500	4.500	4.500	2.405	8.118
vinorelbine									
injection concentrate, 10 mg/ml in vial	2	2	ml	23.230	19.500	21.365	20.433	143.086	16.201

* No price information; n/a – not available.

TABLE 3. PSYCHOTHERAPEUTIC MEDICINES

Medicines used in depressive disorders	Manufacturer		unit	Indicative price, US\$				List prices, US\$	
	No. of manufacturers	No. of countries		max	min	median	25th perc	Brazil	Spain
amitriptyline									
tablet, 25 mg (as hydrochloride)	5	5	tablet	0.078	0.003	0.007	0.004	0.010	0.026
fluoxetine									
tablet, 20 mg	8	6	tablet	0.626	0.015	0.073	0.044	0.034	0.329
Medicines used in generalized anxiety and sleep disorders									
diazepam									
injection, 5 mg/ml in 2-ml ampoule	5	5	ampoule	0.298	0.090	0.120	0.110	n/a	n/a
tablet, 5 mg	6	6	tablet	0.020	0.002	0.004	0.003	n/a	0.016
lorazepam									
injection, 4 mg/ml in 1-ml ampoule	1	1	ampoule	0.008	0.008	0.008	0.008	n/a	n/a
tablet, 1 mg	2	2	tablet	0.047	0.006	0.027	0.016	n/a	0.022
methotrimepazine/levomepromazine									
powder for injection, 10 mg (sulfate) in 10-ml vial	2	2	tablet	0.108	0.033	0.070	0.052	n/a	0.229
tablet, 25 mg*	—	—	tablet	—	—	—	—	0.038	0.047
Medicines used in substance dependence programmes									
methadone HCl									
oral solution, 10 mg/5 ml*	—	—	ml	—	—	—	—	n/a	n/a
oral solution, 5 mg/5 ml	1	1	ml	0.020	0.020	0.020	0.020	n/a	n/a
powder for oral concentrate, 10 mg/ml*	—	—	ml	—	—	—	—	n/a	n/a
powder for oral concentrate, 5 mg/ml*	—	—	ml	—	—	—	—	n/a	n/a
tablet, 5 mg*	—	—	tablet	—	—	—	—	n/a	0.044
buprenorphine									
sublingual tablet, 2 mg (hydrochloride)*	—	—	tablet	—	—	—	—	n/a	0.280
sublingual tablet, 8 mg (hydrochloride)*	—	—	tablet	—	—	—	—	n/a	n/a
naltrexone HCl									
tablet, 50 mg	2	2	tablet	1.388	0.969	1.178	1.074	n/a	1.911

TABLE 4. ANALGESICS

Opioid analgesics	Manufacturer		unit	Indicative price, US\$				List prices, US\$	
	No. of manufacturers	No. of countries		max	min	median	25th perc	Brazil	Spain
codeine									
tablet, 30 mg (phosphate)	3	3	tablet	0.062	0.033	0.036	0.034	0.232	0.079
morphine									
injection, 10 mg/ml (sulfate or HCl), in 1-ml ampoule	2	2	ampoule	0.439	0.307	0.373	0.340	0.495	0.240
oral solution, 10 mg/5 ml (sulfate or HCl)*	—	—	ml	—	—	—	—	n/a	0.130
tablet, modified release, 10 mg (sulfate)*	—	—	tablet	—	—	—	—	n/a	0.123

* No price information; n/a – not available.

	Manufacturer		unit	Indicative price, US\$				List prices, US\$	
	No. of manufacturers	No. of countries		max	min	median	25th perc	Brazil	Spain
pethidine									
injection, 50 mg/ml (hydrochloride) in 1-ml ampoule	2	2	ampoule	0.390	0.360	0.375	0.368	0.344	n/a
injection, 50 mg/ml (hydrochloride) in 2-ml ampoule	4	4	ampoule	0.600	0.374	0.476	0.401	n/a	0.666
tablet, 100 mg*	—	—	tablet	—	—	—	—	n/a	n/a
tablet, 50 mg	1	1	tablet	0.130	0.130	0.130	0.130	n/a	n/a

TABLE 5. GASTROINTESTINAL MEDICINES

Antacids and other antiulcer medicines	Manufacturer		unit	Indicative price, US\$				List prices, US\$	
	No. of manufacturers	No. of countries		max	min	median	25th perc	Brazil	Spain
omeprazole									
capsule, 10 mg	4	4	capsule	0.339	0.015	0.057	0.041	0.028	0.086
capsule, 20 mg	21	12	capsule	0.368	0.011	0.075	0.021	0.034	0.168
capsule, 40 mg	3	3	capsule	0.601	0.140	0.563	0.143	n/a	0.372
powder for injection, 40 mg (as sodium salt) in vial	1	1	vial	3.000	3.000	3.000	3.000	1.371	7.282
powder for IV infusion, 40 mg (as sodium salt) in vial	1	1	vial	3.000	3.000	3.000	3.000	n/a	n/a
Antiemetic medicines									
dimenhydrinate									
tablet, 50 mg	5	5	tablet	0.041	0.005	0.009	0.008	n/a	0.199
metoclopramide									
injection 5 mg/ml in 2-ml ampoule	6	3	ampoule	0.200	0.041	0.103	0.065	0.062	0.171
tablet, 10 mg (as hydrochloride)	6	6	tablet	0.072	0.004	0.008	0.005	0.005	0.038
prochlorperazine									
injection, 12.5 mg/ml	1	1	ml	0.359	0.359	0.359	0.359	n/a	n/a
tablet, 10 mg*	—	—	tablet	—	—	—	—	n/a	n/a
tablet, 5 mg	1	1	tablet	0.008	0.008	0.008	0.008	n/a	n/a
promethazine									
elixir or syrup, 5 mg/5 ml (HCl)	3	3	ml	0.008	0.005	0.006	0.005	n/a	n/a
injection, 25 mg/ml (hydrochloride) in 2-ml ampoule	3	3	ampoule	0.200	0.176	0.188	0.182	n/a	n/a
tablet, 10 mg	1	1	tablet	0.008	0.008	0.008	0.008	n/a	n/a
tablet, 25 mg	3	3	tablet	0.010	0.004	0.008	0.006	n/a	n/a
Laxatives									
docusate sodium									
capsule, 100 mg*	—	—	capsule	—	—	—	—	n/a	0.063
paediatric oral solution, 12.5 mg/5 ml*	—	—	ml	—	—	—	—	n/a	n/a
senna									
capsule, 7.5 mg	1	1	capsule	0.017	0.017	0.017	0.017	n/a	n/a

* No price information; n/a – not available.

5.2 HIV Test Kits – Simple/Rapid, EIA and Confirmatory Assays¹

SIMPLE/RAPID TEST KITS

Assay Name (Manufacturer)	Company Order Code*	Test per Kit	Shelf Life/ Storage Temp (°C)	HIV Type ²	Assay Type/ Antigen Type	Sample Type	Equip- ment ³	WHO Report ⁴	Indicative Price ⁵
Advanced Quality™ Rapid HIV Test (InTec Products)	ITP02002- TC40	40	18 months/ 2°–30°	HIV 1+2	lateral flow/ recombinant proteins	serum/ plasma whole blood	G	12 & 16	US\$0.80– \$1.20
Bionor HIV-1&2 (Bionor)		40 200	6 months/ 2°–8°C	HIV 1+2	magnetic beads/ synthetic peptides	serum/ plasma whole blood	C,D,E,G Bionor Testing Station (US\$1000)	11	US\$2.50
Capillus™ HIV-1/HIV-2 (Trinity Biotech)	6048G	100	9 months/ 2°–8°	HIV 1+2	agglutination/ recombinant proteins	serum/ plasma whole blood	G	12	US\$2.20
Determine™ HIV-1/2 Serum/Plasma Assay (Abbott Diagnostics)	7D23-13	100	6–9 months/ 2°–30°	HIV 1+2	lateral flow/ recombinant protein, synthetic peptide	serum/ plasma whole blood	D,G	12	US\$1.20
Determine™ HIV-1/2 Whole Blood Assay (Abbott Diagnostics)	7D23-33	100							
Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) (Shanghai Kehua)	KHR-02	50	15 months/ 4°–30°	HIV 1+2	lateral flow/ recombinant protein, synthetic peptide	serum/ plasma whole blood	D,G	14	US\$0.60
DoubleCheck HIV 1&2 (Organics)	60332000	40	15 months/ 4°–8°	HIV 1+2	lateral flow/ recombinant proteins, synthetic peptides	serum/plasma	G	11	US\$2.00
First Response™ HIV 1-2-0 Card Test (Premier Medical Corp)	I05FRC30	30	15 months/ 2°–30°	HIV 1+2	lateral flow/ recombinant proteins	serum/plasma whole blood	D,G	12	US\$1.15
Genedia® HIV 1/2 Rapid 3.0 (Green Cross Medical Science)	F3302	30	14 months/ 2°–30°	HIV1 1+2	lateral flow/ recombinant proteins	serum/plasma whole blood	D,G	14	US\$0.93– 1.15
Genie II HIV-1/HIV-2 (Bio-Rad Laboratories)	72323	40	12 months/ 2°–8°	HIV 1+2	lateral flow/ recombinant proteins, synthetic peptides	serum/plasma	D, G	14	US\$2.55
HIV 1/2 Stat-Pak (Chembio Diagnostics)	HIV101 HIV133	20 Bulk	18 months/ 8°–30°	HIV 1+2	lateral flow/ synthetic peptides	serum/plasma whole blood	G	14 & 16	US\$1.45
HIV 1/2 Stat-Pak Dipstick (Chembio Diagnostics)	HIV301 HIV333	20 Bulk	18 months/ 8°–30°	HIV 1+2	lateral flow dipstick/ synthetic peptides	serum/plasma whole blood	C,G	16	US\$1.15
HIV Tridot (J Mitra & Co)	IR130050 IR130100 IR130200	50 100 200	10 months/ 4°–8°	HIV 1 HIV 2	flow through/ recombinant proteins	serum/plasma	G	11	US\$2.00

* Company order code may vary from country to country

¹ This is a list of HIV test kits evaluated by WHO and which are still commercially available. Therefore, the list may include test kits not currently on the UN Bulk Procurement Scheme.

² Assays denoted as HIV 1 HIV 2 are capable of discrimination between HIV-1 and HIV-2, those denoted HIV 1+2 are not capable of discrimination

³ Equipment Requirements – A: ELISA reader, B: ELISA washer, C: Consumables, D: Pipette, E: Power supply, F: For large volume testing more than 40 samples daily, G: For small volume testing 1 to 40 samples daily

⁴ Report numbers in *italics* are currently in publication

⁵ Indicative pricing only, price stated by the company in original WHO test kit evaluation

Assay Name (Manufacturer)	Company Order Code*	Test per Kit	Shelf Life/ Storage Temp (°C)	HIV Type ¹	Assay Type/ Antigen Type	Sample Type	Equip- ment ²	WHO Report ³	Indicative Price ⁴
ImmunoComb® II BiSpot HIV 1 & 2 (Orgenics)	60432002	36	15 months/ 4°–8°	HIV 1 HIV 2	dipstick/ synthetic peptides	serum/plasma	D,G	9	US\$1.70
Instant Chek™ HIV 1+2 Rapid Test (EY Laboratories)	8-1003-40 8-1003-100	40 100	16 months/ 4°–25°	HIV 1+2	lateral flow/ recombinant protein	serum/plasma whole blood	G	14	US\$1.00
OraQuick® HIV-1/2 - Rapid HIV-1/2 Antibody Test (OraSure Technologies)	5X4-0012 5X4-0010	100 500	8 months/ 2°–30°	HIV 1+2	lateral flow/ synthetic peptides	serum/plasma whole blood oral fluid	G	14 & 18	US\$4.00
Retrocheck HIV (Qualpro Diagnostics) also marketed Core™ HIV 1&2 (Core Diagnostics)	40501050 40501100	50 100	24 months/ 4°–30°	HIV 1+21	lateral flow/ recombinant protein, synthetic peptides	serum/plasma whole blood	G	16	US\$0.75 US\$0.70
SD BIOLINE HIV-1/2 3.0 (Standard Diagnostics)	03FK10	30	16 months/ 2°–30°	HIV 1 HIV 2	lateral flow/ recombinant proteins	serum/plasma whole blood	D,G	14	US\$1.10
Serocard HIV (Trinity Biotech)	1200100	40	15 months/ 2°–8°	HIV 1+2	lateral flow/ synthetic peptides	serum/plasma whole blood	G	11	US\$4.00
Serodia® HIV (Fujirebio)	224557 224564	100 220	12 months/ 2°–10°	HIV 1	agglutination/ recombinant proteins	serum/plasma	C,D,G	1	US\$0.88
Serodia® HIV-1/2 (Fujirebio)	220658 226063	100 220	12 months/ 2°–10°	HIV 1+2	agglutination/ recombinant proteins	serum/plasma	C,D,G	8	US\$2.80
Uni-Gold™ HIV-1/HIV-2 (Trinity Biotech)	1206502	20	9 months/ 2°–27°	HIV 1+2	lateral flow/ recombinant proteins	serum/plasma whole blood	G	12	US\$2.34

EIA TEST KITS

Assay Name (Manufacturer)	Company Order Code*	Test per Kit	Shelf Life/ Storage Temp (°C)	HIV Type ¹	Antigen Type/ Wavelength	Sample Type	Equip- ment ²	WHO Report ³	Indicative Price ⁴
Anti-HIV 1+2 Antibodies ELISA Diagnostics Kit (Shanghai Kehua)	KH-T-10	96	5 months/ 2°–8°	HIV 1+2	recombinant proteins, synthetic peptides/ 450/620nm	serum/ plasma	A,B,C,D,E,F	17	US\$0.27
Enzygnost Anti-HIV 1/2 Plus (Dade Behring) Reagent Kit	OQFK135 OQFK215 OUVP175	192 960	12 months/ 2°–8°	HIV 1+2 O	recombinant proteins/ 450/650nm	serum/ plasma	A,B,C,D,E,F	11	US\$1.00 Gratis
Genedia® HIV Ag-Ab ELISA (Green Cross)	D1305	480	15 months 2°–8°	HIV 1+2 O HIV Ag	recombinant proteins synthetic peptides monoclonal antibody/ 450/620nm	serum/ plasma	A,B,C,D,E,F	15	US\$0.35

* Company order code may vary from country to country

¹ Assays denoted as HIV 1 HIV 2 are capable of discrimination between HIV-1 and HIV-2, those denoted HIV 1+2 are not capable of discrimination

² Equipment Requirements – A: ELISA reader, B: ELISA washer, C: Consumables, D: Pipette, E: Power supply, F: For large volume testing more than 40 samples daily, G: For small volume testing 1 to 40 samples daily

³ Report numbers in *italics* are currently in publication

⁴ Indicative pricing only, price stated by the company in original WHO test kit evaluation

Assay Name (Manufacturer)	Company Order Code*	Test per Kit	Shelf Life/ Storage Temp (°C)	HIV Type ¹	Antigen Type/ Wavelength	Sample Type	Equip- ment ²	WHO Report ³	Indicative Price ⁴
Genscreen® Plus HIV Ag-Ab (BioRad Laboratories)	72375 72376	96 480	9 months/ 2°–8°	HIV 1+2 O HIV Ag	recombinant proteins synthetic peptides monoclonal antibody/ 450/620nm	serum/ plasma	A,B,C,D,E,F	15	US\$0.35
HIV EIA (AniLabsystems OY)	6111011 6111012 6111013	96 480 960	12 months/ 4°–8°	HIV 1+2	synthetic peptides/ 450nm	serum/ plasma	A,B,C,D,E,F	10	US\$0.60
IMx HIV-1/HIV-2 3rd generation Plus (Abbott Diagnostics)		100	3 months/ 2°–8°	HIV 1+2	recombinant proteins synthetic peptides	serum/ plasma	A,B,C,D,E,F IMx Instru- mentation	11	US\$3.00
Murex HIV Ag/Ab Combination (Abbott/Murex)	L/N7G79-01 L/N7G79-02	96 480	6 months/ 2°–8°	HIV 1+2 O HIV Ag	recombinant proteins synthetic peptides, monoclonal antibody/ 450/620nm	serum/ plasma	A,B,C,D,E,F	15	US\$1.20 US\$0.80
UBI HIV 1/2 EIA (United Biomedical Inc)	680328	192	14 months/ 2°–8°	HIV 1+2	synthetic peptides/ 492 492/620-690	serum/ plasma	A,B,C,D,E,F	9	US\$1.00
Vironostika Uni-Form II plus O (bioMérieux bv)	284017 284018	192 576	12 months/ 2°–8°	HIV 1+2 O	recombinant proteins synthetic peptides/ 450/620nm	serum/ plasma	A,B,C,D,E,F	11	US\$1.50
Vironostika® HIV Uni-Form II Ag/Ab (bioMérieux bv)	285046 285047	192 576	9 months/ 2°–8°	HIV 1+2 O HIV Ag	recombinant proteins synthetic peptides, monoclonal antibody/ 450/620nm	serum/ plasma	A,B,C,D,E,F	15	US\$1.48

CONFIRMATORY TEST KITS

Assay Name (Manufacturer)	Company Order Code*	Test per Kit	Shelf Life/ Storage Temp (°C)	HIV Type ¹	Assay Type/ Antigen Type	Sample Type	Equip- ment ²	WHO Report ³	Indicative Price ⁴
Genelabs Diagnostics HIV BLOT 2.2 (M P Biomedicals Asia Pacific)	11031-036	36	15 months/ 2°–8°	HIV 1 HIV 2	Western blot/ viral lysate, synthetic peptide	serum/plasma	C,D,E	N/A	US\$10.97
INNO-LIA™ HIV I/II SCORE (Innogenetics)	80540	20	?/ 2°–8°	HIV 1 HIV 2	line immunoassay/ recombinant proteins, synthetic peptides	serum/plasma	C, D, E	N/A	€15.50
PEPTH-LAV 1-2 (Bio-Rad Laboratories)	72253	10	9 months/ 2°–8°	HIV 1 HIV 2	line immunoassay/ synthetic peptides	serum/plasma	C, D, E	N/A	€15.00
NEW LAV BLOT I (Bio-Rad Laboratories)	72251	18	9 months/ 2°–8°	HIV 1	Western blot/ viral lysate	serum/plasma	D, E	N/A	€13.00
NEW LAV BLOT II (Bio-Rad Laboratories)	72252	18	9 months/ 2°–8°	HIV 2	Western blot/ viral lysate	serum/plasma	D, E	N/A	€13.00

* Company order code may vary from country to country

¹ Assays denoted as HIV 1 HIV 2 are capable of discrimination between HIV-1 and HIV-2, those denoted HIV 1+2 are not capable of discrimination

² Equipment Requirements – A: ELISA reader, B: ELISA washer, C: Consumables, D: Pipette, E: Power supply, F: For large volume testing more than 40 samples daily, G: For small volume testing 1 to 40 samples daily

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⁴ Indicative pricing only, price stated by the company in original WHO test kit evaluation

N/A – Not applicable

6. List of manufacturers – medicines and diagnostics

6.1 Manufacturers of medicines

Manufacturer	Address	Telephone	Fax	Email/Website	Products
Alembic Ltd.	Alembic Road, Vadodara 551455, Vadodara, India	+91 265 2284074	+91 265 228 0331	navneetbattu@alembic.co.in www.alembic.com	azithromycin, benzathine benzylpenicillin, benzylpenicillin, ceftriaxone, ciprofloxacin, clarithromycin, erythromycin, orteprazole, procaine benzylpenicillin
Alpharma	Jl. Raya Bogor km 28 P.O. Box 1044 JAT 13710 Jakarta, Indonesia	+62 21 871 0311	+62 21 871 0044	herny.prasetya@alpharma.no www.alpharma.no	ciprofloxacin, clarithromycin, diazepam, metoclopramide, metronidazole, sulfamethoxazole+trimethoprim
Apex Drug House	28, Mahendra Mansion, Babu Genu Road, 400002, Mumbai, India	+91 22 2207 7266	+91 22 2208 6900	apex19@vsnl.com www.apexdrugshindia.com	albendazole, azithromycin, benzathine benzylpenicillin, benzylpenicillin, ceftriaxone, chloramphenicol, ciprofloxacin, clotrimazole, doxycycline, erythromycin, fluconazole, gentamicin, ketoconazole, metoclopramide, metronidazole, miconazole, orteprazole, sulfamethoxazole+trimethoprim, tinidazole
Aristo Pharmaceuticals Ltd.	23-A Shah Industrial Estate, Off Veera Desai Road, Andheri West, 400053, Mumbai, India	+91 22 2673 0001	+91 22 2673 4792	aristoexp@vsnl.net www.aristopharma.org	ceftriaxone, ciprofloxacin, doxycycline, metronidazole, ofloxacin, orteprazole, sulfamethoxazole+trimethoprim
Artesan Pharma GmbH & Co.	Osterbrooksweg, 15, 22869, Schenefeld, Germany	+49 4054 2270	+49 4054 2283	j.ahlers@pharma-aid.de www.pharma-aid.de	albendazole, erythromycin, ketoconazole, nystatin, promethazine, sulfamethoxazole+trimethoprim
Aventis Intercontinental	20, Avenue Raymond Aron/Tri E1/360, 92165, Antony Cedex, France	+33 155 717 637	+33 155 717 447	sandrine.girardot@aventis.com www.sanofi-aventis.com	benzathine benzylpenicillin, bleomycin, cefixime, methotrexate, methotrimepazine/levomepromazine, metronidazole, ofloxacin, pentamidine
B. Braun Biotech International GmbH	Schwarzenberger Weg 73-79, 3508, Melsungen, Germany	+49 5661 713900	+49 5661 713702	joerg.griesel@bbraun.com www.BBraun.com	metronidazole
Bayer Healthcare AG	Pharma Division, 42096, Wuppertal, Germany	+49 202 36 5869	+49 202 36 5880	michaela.oxfort@ bayerhealthcare.com www.bayerhealthcare.com	ciprofloxacin
Beltapharm SpA	Via Stelvio, 66, 20095, Cusano Milanino, Italy	+39 02 66401216	+39 02 6196714	f.pansera@beltapharm.com www.beltapharm.com	albendazole, erythromycin, ketoconazole, metronidazole, miconazole, nystatin, promethazine, sulfamethoxazole+trimethoprim
Bilim Pharmaceutical Ind.	Avazaga Koyu Yolu No:6, 34398, Maslak, Turkey	+90 212 365 15 00	+90 212 2869472	info@bilimpharma.com www.bilimpharma.com	cefixime, ceftriaxone, clarithromycin, clindamycin, fluconazole, ketoconazole
Biologici Italia Laboratories SRL	Via Cavour 41-43, 20026, Novate Milanese, Italy	+39 0 235 48 451	+39 0 235 42 956	info@biitalia.com www.biologici.com	aciclovir

Manufacturer	Address	Telephone	Fax	Email/Website	Products
Boehringer Ingelheim GmbH	Binger Straße 173, 55216, Ingelheim am Rhein, Germany	+49 6132 77 0	+49 6132 77 3000	claryh@ ing.boehringer-ingelheim.com www.boehringer-ingelheim.com	nevirapine (NVP)
Bristol-Myers Squibb (Africa Export Division)	3 Rue Joseph Monier BP 325, 92506 Rueil-Malmaison Cedex, France	+33 158 83 60 00	+33 158 83 6565	marie-astrid.mercier@bms.com	didanosine (ddl), stavudine (d4T)
Cadila Pharmaceuticals Ltd.	Cadila Corporate Campus Sarkhej – Dholka Road, Bhat, 382 210, Ahmedabad, India	+91 27 1822 5001	+91 2718 225035	website@cadilapharma.co.in www.cadilapharma.co.in	aciclovir, albendazole, azithromycin, ceftriaxone, ciprofloxacin, erythromycin, fluconazole, fluoxetine, omeprazole, sulfamethoxazole+trimethoprim, tinidazole
Cibro	563 Songtao Road, B107, 201203, Shanghai, China	+86 21 50808516	+86 21 50804208	info@cibropharm.com www.cibropharm.com	aciclovir, ciprofloxacin, metronidazole, sulfamethoxazole+trimethoprim
Cipla Ltd.	289, Belasis Road, Mumbai Central, 547649, Mumbai, India	+91 22 2302 1397	+91 22 2307 0013	ciplaexp@cipla.com www.cipla.com	3TC/AZT, 3TC/d4T, 3TC/d4T/NVP, abacavir (ABC), aciclovir, albendazole, azithromycin, AZT/3TC/NVP, bleomycin, cefixime, ceftriaxone, ciprofloxacin, clotrimazole, didanosine (ddl), doxorubicine HCl, doxycycline, efavirenz (EFZ), erythromycin, etoposide, fluconazole, indinavir (IDV), lamivudine (3TC), methotrexate, metronidazole, miconazole, nelfinavir (NFV), nevirapine (NVP), nystatin, ofloxacin, omeprazole, stavudine (d4T), sulfamethoxazole+trimethoprim, vinblastine, vincristine, zidovudine (AZT or ZDV)
CLARIS Lifesciences Ltd.	Corporate Towers, Near Parimal Crossing, Ellisbridge, 555015, Ahmedabad, India	+91 79 656 3331	+91 79 656 5879	claris@clarislifesciences.com www.clarislifesciences.com	ceftriaxone, fluconazole, metoclopramide, metronidazole, ofloxacin
Combino Pharm, S.L.	Carrer Fructuós Gelabert, 6-8 Edificio Conata 2, 08970, Sant Joan Despi, Spain	+34 93 480 8833	+34 93 480 8832	info@combino-pharm.es www.combino-pharm.es	aciclovir, amphotericin B, ceftriaxone, clindamycin, fluoxetine, pentamidine, zidovudine (AZT or ZDV)
Cosmos Limited	P.O. Box 41433 Rangwe Road, Off Lunga Lungu Road Nairobi Industrial Area, 100, Nairobi, Kenya	+2542 550 700	+2542 550 680	cosmositd@form-net.com	3TC/AZT, 3TC/d4T, 3TC/d4T/NVP, aciclovir, albendazole, amitriptyline, azithromycin, chloramphenicol, ciprofloxacin, clotrimazole, codeine, diazepam, doxycycline, efavirenz (EFZ), erythromycin, fluconazole, ketoconazole, lamivudine (3TC), metoclopramide, metronidazole, miconazole, nevirapine (NVP), nystatin, omeprazole, promethazine, pyrimethamine, senna, stavudine (d4T), sulfamethoxazole+trimethoprim, tinidazole, zidovudine (AZT or ZDV)
Ecobi Farmaceutici S.a.s.	Via Enrico Bazzano, 26, 16019, Ronco Scrivia, Italy	+39 010 935 280	+39 010 935 0679	ecobi@aleph.it www.ecobi.com	aciclovir, calcium folinate (leucovorin), miconazole, sulfadiazine, sulfamethoxazole+trimethoprim

Manufacturer	Address	Telephone	Fax	Email/Website	Products
Emcure Pharmaceuticals Limited	Emcure House, T-184, M.I.D.C. Bhosari, 411026, Pune, India	+91 20 30610000	+91 20 30610200	exports@emcure.co.in www.emcure.co.in	3TC/AZI, 3TC/d4T, 3TC/d4T/NVP, albendazole, AZI/3TC/NVP, cefixime, ceftriaxone, ciprofloxacin, clarithromycin, clotrimazole, didanosine (ddl), efavirenz (EFZ), lamivudine (3TC), nevirapine (NVP), omeprazole, stavudine (d4T), sulfamethoxazole+trimethoprim, zidovudine (AZI or ZDV)
F. Hoffmann-La Roche Ltd.	Pharma International, CH-4070, Basel, Switzerland	+41 61 688 9291	+41 61 688 2778	maria.vigneau@roche.com www.roche-hiv.com	nelfinavir (NFV), saquinavir (SQV)
FDC Ltd.	142-48, S.V. Road, Jogeshwariii (W), 400102, Mumbai, India	+91 22 678 0652	+91 22 678 0967	rs@fdcxport.com www.fdcindia.com	aciclovir, azithromycin, ciprofloxacin, doxycycline, fluconazole, metronidazole, ofloxacin, sulfamethoxazole+trimethoprim
Genepharm SA	18th Km. Marathon Ave., 15351, Pallini, Greece	+30 210 6039336/8	+30 210 6039402	info@genepharm.gr www.genepharm.gr	cefixime, ceftriaxone, ciprofloxacin, clarithromycin, clindamycin, doxycycline, fluconazole, ketoconazole, ofloxacin
GlaxoSmithKline Export Ltd.	GSK House, 980 Great West Road, TW8 9GS, Brentford, UK	+44 20 8047 5000	+44 20 8047 6957	isabelle.s.girault@gsk.com www.gsk.com	3TC/AZI, abacavir (ABC), ABC/3TC/ZDV, lamivudine (3TC), zidovudine (AZI or ZDV)
Grupo Reig Jofre	Gran Capitan 10, 08970, San Joan Despi, Spain	+34 93 480 67 15	+34 93 480 67 21	rfexport@reigjofre.com www.reigjofre.com	aciclovir, ceftriaxone, fluconazole, sulfadiazine
Heyl Chemisch.- pharmazeutische Fabrik GmbH & Co KG	Goerzallee 253, 14167, Berlin, Germany	+49 30 816 9617	+49 30 817 4049	info@hey-berlin.de www.heyberlin.de	sulfadiazine
Human Pharmaceutical Works Co. Ltd.	Tancsics Mihály út 82, 2100, Godollo, Hungary	+36 28 532 103	+36 28 420 594	pallos@human.hu www.human.hu	metronidazole
Instituto Quimioterapico S.A.(IQFARMA)	Avenida Santa Rosa 350, 43 Santa Anita, Peru	+51 362 0210	+51 362 0210	iqfarma@terra.com.pe	aciclovir, amitriptyline, ciprofloxacin, clotrimazole, dimenhydrinate, erythromycin, fluconazole, itraconazole, ketoconazole, metoclopramide, metronidazole, omeprazole, sulfamethoxazole+trimethoprim
Intas Pharmaceuticals Ltd	2nd floor, Chinubhai Centre, Ashram Road, 554923, Ahmedabad, India	+91 79 2657 6655	+91 79 2657 8862	alkesh_shah@intaspharma.com www.intaspharma.com	albendazole, amitriptyline, ciprofloxacin, clarithromycin, diazepam, doxorubicine HCl, doxycycline, erythromycin, etoposide, fluconazole, fluoxetine, itraconazole, ketoconazole, lamivudine (3TC), methotrexate, metoclopramide, naltrexone HCl, ofloxacin, omeprazole, sulfamethoxazole+trimethoprim, tinidazole, vincristine
Korea United Pharm. Inc.	154-8, Nonhyun-Dong Kangnam-Ku, 135010, Seoul, Republic of Korea	+82 2 512 9982	+82 2 512 0144	trade@kup.co.kr www.kup.co.kr	aciclovir, albendazole, bleomycin, calcium folinate (leucovorin), cefixime, ceftriaxone, ciprofloxacin, clarithromycin, clindamycin, clotrimazole, diazepam, doxorubicine HCl, doxycycline, etoposide, fluconazole, fluoxetine, itraconazole, ketoconazole, methotrexate, metronidazole, ofloxacin, omeprazole, vinblastine, vincristine

Manufacturer	Address	Telephone	Fax	Email/Website	Products
Lab. Filaxis International S.A.	Panama 2121, B1640DKC, Martinez, Argentina	+54 11 4513 8009	+54 11 4513 8004	liliana.b.mendez@filaxis.com www.filaxis.com	3TC/AZT, abacavir (ABC), aciclovir, calcium folinate (leucovorin), didanosine (ddl), doxorubicine HCl, efavirenz (EFZ), etoposide, ganciclovir, indinavir (IDV), lamivudine (3TC), methotrexate, nelfinavir (NFV), nevirapine (NVP), pentamidine, stavudine (d4T), zalcitabine, zidovudine (ddC), zidovudine (AZT or ZDV)
Lab. Renaudin	125, Bureaux de la Colline, F-92213, Saint-Cloud Cedex, France	+33 1 4112 0382	+33 1 4112 0377	fpetit@labo-renaudin.com www.labo-renaudin.com	diazepam, metoclopramide, morphine, pethidine, promethazine
Laboratorios Andrómaco S.A.	Avenida Quilín, 5273, Peñalolén, Chile	+56 2510 8500	+56 2510 8502	info@andromaco.cl www.andromaco.cl	omeprazole
Laboratorios Cinfa S.A.	Olaz-Chipi, 10 Poligono Areta, E-31620, Huarte, Pamplona, Spain	+34 948 33 51 02	+34 948 33 03 67	bsanado@cinfa.com www.cinfa.com	aciclovir, azithromycin, ciprofloxacin, dimenhydrinate, fluoxetine, omeprazole
Laboratorios Juventus S.A.	Julián Camarillo, 37, 28037, Madrid, Spain	+34 91 375 22 00	+34 91 375 22 33	exporte@juventus.es www.juventus.es	azithromycin, ciprofloxacin, clarithromycin, omeprazole
Lachifarma, SRL	S.S. 16 Zona Industriale Zollino, 73010, Zollino (LE), Italy	+39 0836 600 661	+39 0836 600 662	info@lachifarma.com www.lachifarma.com	albendazole, erythromycin, ketoconazole, miconazole, naltrexone HCl, sulfamethoxazole+trimethoprim
Lilly España	Av. de la Industria 30, E-28108, Alcobendas, Spain	+34 91 663 5028	+34 91 623 3391	hernandez_vicente@lilly.com www.lilly.es	fluoxetine
Lisapharma	Via Licinio 11, 22036, Erba, Italy	+39 031 641257	+39 031 644 182	lisapharm@lisapharma.it www.lisapharma.it	aciclovir, ceftriaxone, fluoxetine
Lomapharm, Rudolf Lohmann GmbH KG	Langes Feld 5, 31860, Emmerthal, Germany	+49 5155 63200	+49 5155 63256	i.wilpert@lomapharm.de www.lomapharm.de	codeine, diazepam, dimenhydrinate, erythromycin, lorazepam, metoclopramide, metronidazole, nystatin, sulfamethoxazole+trimethoprim
Martindale Pharmaceuticals Ltd.	Hubert Road, CM14 4LZ, Brentwood, UK	+44 1277 266 600	+44 1277 266 688	matt.bartlett@martindalepharma.co.uk www.martindalepharma.co.uk	methadone HCl, morphine, pethidine
Medac GmbH, International Operations	Theaterstraße 6, D-22880, Wedel, Germany	+49 4103 8006 145	+49 4103 8006 153	d.rehder@medac.de www.medac.de	calcium folinate (leucovorin), doxorubicine HCl, etoposide
Mepha Ltd	Dornacherstrasse 114, CH-4147, Aesch, Switzerland	+41 61 705 4219	+41 61 705 4338	stefan.muehl@mepha.ch www.mepha.com	ceftriaxone, ciprofloxacin, omeprazole
Merck & Co., Inc.	One Merck Drive, P.O. Box 100, NJ 08889-0100, Whitehouse Station, USA	+1 908 423 1000	+1 908 735 1839	samir_khail@merck.com www.merck.com	efavirenz (EFZ), indinavir (IDV), ivermectin

Manufacturer	Address	Telephone	Fax	Email/Website	Products
Neon Antibiotics PVT. Ltd.	146A, Damji Shamji Industrial Complex, M. Caves Road, 28 Mahal Ind. Estate, Mahakali Caves Road, 400 093, Andheri (East), India	+91 22 2687 5366	+91 22 2687 3502	neon@bom1.vsnl.net.in www.neongroup.com	aciclovir, amphotericin B, bleomycin, capreomycin, doxorubicine HCJ, etoposide, methotrexate, omeprazole, pentamidine, spectinomycin, vinblastine, vincristine, vinorelbine
Nippon Kayaku	Tokyo Fujimi Bldg, 11-2, Fujimi 1 chome, Chiyoda-ku, 102-8172, Tokyo, Japan	+81 3 3237 5072	+81 3 3237 5093	kouho@nipponkayaku.co.jp www.nipponkayaku.co.jp	bleomycin, etoposide
Nuevas Tecnologías Farmaceuticas	Alfonso XII, 22, 4 dcha., 28014, Madrid, Spain	+34 91 531 02 17	+34 91 531 96 48	axis@correo.interlink.es	3TC/AZT, 3TC/d4T/NVP, aciclovir, albendazole, ciprofloxacin, clarithromycin, clindamycin, didanosine (ddl), doxycycline, efavirenz (EFZ), erythromycin, fluconazole, indinavir (IDV), ketoconazole, lamivudine (3TC), ofloxacin, omeprazole, stavudine (d4T), sulfamethoxazole+trimethoprim, zidovudine (AZT or ZDV)
Ovelle Limited	Coe's Road, Dundalk, Ireland	+353 42 9332 304	+353 42 9332 008	igardiner@ovelle.ie www.ovelle.ie	clotrimazole, ketoconazole, miconazole, permethrin
Pharmadrug	Saseler Chausee 191a, 22393, Hamburg, Germany	+49 40 601 79 37	+49 40 601 63 58	info@pharmadrug.de www.pharmadrug.de	aciclovir, clotrimazole, cycloserine, doxycycline, erythromycin, ketoconazole, methotrimopazine / levomepromazine, miconazole, nystatin, pethidine, prochlorperazine
Pharmathen Pharmaceuticals S.A.	6, Dervenakion str., 153 51, Pallini, Greece	+30 210 666567	+30 210 6666749	info@pharmathen.gr www.pharmathen.gr	ceftriaxone, ciprofloxacin, fluconazole, fluoxetine, lorazepam, omeprazole
Protein S.A. DE C.V. (Apotex)	Damas 120, 3900, Mexico D.F, Mexico	+52 5554829035	+52 5554829002	rjimenez@apotex.com.mx www.apotex.com.mx	aciclovir, ciprofloxacin, didanosine (ddl), dimenhydrinate, fluoxetine, ketoconazole, metoclopramide, miconazole, nystatin, omeprazole, stavudine (d4T), sulfamethoxazole+trimethoprim, zalcitabine (ddC), zidovudine (AZT or ZDV)
Purna Pharmaceuticals NV	K.M.O. Zone "Pullaar", Rijksweg 17, 2870, Puurs, Belgium	+32 388 60085	+32 388 62538	info@purna.be www.purna.be	clotrimazole, erythromycin, ketoconazole, metronidazole, miconazole, promethazine, sulfamethoxazole+trimethoprim
Ranbaxy Laboratories Ltd	13th Floor, 6 Devika Towers, 6 Nehru Place, 110 019, New Delhi, India	+91 11 2600 21 20	+91 11 2600 21 21	sandeep.juneja@ranbaxy.com www.ranbaxy.com	3TC/AZT, 3TC/d4T, 3TC/d4T/NVP, abacavir (ABC), ABC/3TC/ZDV, aciclovir, ceftriaxone, ciprofloxacin, clarithromycin, didanosine (ddl), efavirenz (EFZ), indinavir (IDV), lamivudine (3TC), nevirapine (NVP), ofloxacin, stavudine (d4T), zidovudine (AZT or ZDV)
Remedica Ltd.	Acharnon Street, Ypsonas Industrial Estate, PO Box 51706, CY-3508, Limassol, Cyprus	+357 25 553000	+357 25 390192	remedica@cytanet.com.cy www.remedica.com.cy	aciclovir, albendazole, amitriptyline, cefixime, ciprofloxacin, clarithromycin, clotrimazole, codeine, diazepam, doxycycline, erythromycin, fluconazole, fluoxetine, ketoconazole, lorazepam, methotrexate, metoclopramide, metronidazole, nystatin, ofloxacin, omeprazole, prochlorperazine, promethazine, senna, sulfamethoxazole+trimethoprim, tinidazole

Manufacturer	Address	Telephone	Fax	Email/Website	Products
Rotexmedica	Bunsenstrasse 4, Postfach 1266, 22946, Trittau, Germany	+49 41 548620	+49 41 54862155	orange@rotexmedica.com www.rotexmedica.com	diazepam, gentamicin, metronidazole
Samchully Pharm. Co., Ltd.	947-7, Daechi-Dong, Gangnam-Gu, 135-735, Seoul, Republic of Korea	+82 2 527 6300	+82 2 561 6006	shkim@samchullypharm.com www.samchullypharm.com	aciclovir, stavudine (d4T), zidovudine (AZT or ZDV)
Sanavita Aktiengesellschaft & Co.	Am Bahnhof 1-3, 59368, Werne, Germany	+49 2389 79720	+49 2389 797259	thea.dadrich@sanavita.net www.sanavita.net	benzathine benzylpenicillin, benzylpenicillin, chloramphenicol, doxycycline, erythromycin, gentamicin, nystatin, procaine benzylpenicillin, sulfamethoxazole+trimethoprim
Shanghai Desano Biopharmaceutical Co., Ltd	No. 78, 887 Zuchongzhi Road, Zhangjiang Hitech Park, Pudong, 201203, Shanghai, China	+86 21 50806118	+86 21 50806558	fanyi@desano.com www.desano.com	didanosine (ddl), nevirapine (NVP), stavudine (d4T)
Shiba Pharmaceuticals & Chemicals Mfg. Co. Ltd.	P.O. Box 4265, Seif Street, 9th Branch Bldg. No. 7, Sana'a, Republic of Yemen	+967 1 218 451/2/3	+967 1 218 454	shiba@y.net.ye	albendazole, azithromycin, chloramphenicol, ciprofloxacin, clindamycin, doxycycline, erythromycin, fluconazole, metronidazole, omeprazole, ofloxacin, promethazine, pyrimethamine, sulfamethoxazole+trimethoprim
SM Pharmaceuticals Sdn Bhd	Lot 88, Sungai Petani Industrial Estate, 8000, Sungai Petani, Malaysia	+604 4411801	+604 4411341	smformu@po.jaring.my	aciclovir, chloramphenicol, ciprofloxacin, clarithromycin, clotrimazole, crofamidol, diazepam, erythromycin, itraconazole, ketoconazole, nystatin, omeprazole, sulfamethoxazole+trimethoprim
Strides Arcolab Ltd.	Strides House, Bleikahalli Opp. IIMB, Bannerghatta Rd., 560 076, Bangalore, India	+91 80 6581 343	+91 80 6584 330	info@stridesarco.com www.stridesarco.com	3TC/AZT, 3TC/d4T, 3TC/d4T/NVP, albendazole, azithromycin, ceftriaxone, chloramphenicol, ciprofloxacin, clarithromycin, erythromycin, indinavir (IDV), ketoconazole, lamivudine (3TC), nevirapine (NVP), omeprazole, stavudine (d4T), sulfamethoxazole+trimethoprim, zidovudine (AZT or ZDV)
The Government Pharmaceutical Organization	75/1 Rama VI Rd., Ratchathewi, 547588, Bangkok, Thailand	+662 3548857	+662 3548858	sukhum@health.moph.go.th www.gpo.org.th	3TC/AZT, 3TC/d4T/NVP, amiktriptyline, clarithromycin, clotrimazole, dimenhydrinate, fluconazole, ketoconazole, lamivudine (3TC), metoclopramide, neftinavir (NFV), nevirapine (NVP), stavudine (d4T), sulfamethoxazole+trimethoprim, zidovudine (AZT or ZDV)
Vitafarma S.L.	Florida 29, 20120, Hernani, Spain	+34 943 335057	+34 943 335269	export@vitafarma.es	clotrimazole, miconazole
Warsaw Pharmaceutical Works Polfa, S.A.	Karolkova Street 22/24, 618354, Warsaw, Poland	+48 226 913 825	+48 226 913 827	zoi@polfawar.com.pl www.polfawar.com.pl	diazepam, morphine

6.2 Manufacturers of diagnostics¹

Manufacturer	Address	Telephone	Fax	Email/Website	Products
Abbott GmbH Diagnostika	Max-Planck-Ring 2, 65205 Wiesbaden, Germany	+49 6122 58 16 23	+49 6122 58 16 12	Kamlesh.kumar@abbott.com www.abbott.com	Determine™ HIV-1/2, Abbott HIV-1/HIV-2 gO EIA, IMx HIV-1/HIV-2 3rd generation Plus, Murex HIV Ag-Ab, Real Time HIV-1 3.0 Assay
AniLabsystems Ltd	Museokatu 13B 0100 Helsinki, Finland	+358 20 155 7520	+358 20 155 7521	www.anilabsystems.com	HIV EIA
Bayer (Diagnostics)	Werk Leverkusen; D-51368 Leverkusen, Germany	+49 641400 3448		www.bayer.com	Versant HIV-1 RNA 3.0 Assay
Beckman Coulter	22, Rue Juste Olivier, CH-1260 Nyon, Switzerland	+41 22 994 08 33	+41 22 994 34 67	www.beckmancoulter.com	Cyto-Spheres; CD4 reagents, EPICS XL Flow Cytometer, PointCare
BD (Becton Dickinson)	86, Eredebodegem-Dorp, B-9320 Eredebodegem, Belgium	+32 53 720 211	+3253 720 450	Jan_Stragier@europe.bd.com www.bd.com	FacsCalibur, FacsCount, CD4 reagents
BioMérieux S.A.	69280 Marcy-l'Étoile, France	+33 78 87 20 00	+33 78 87 20 90	jacqueslemius@eu.biomerieux.com www.biomerieux.com	Vironostika® HIV Uni-Form II plus O, Vironostika® HIV Uniform II Ag/Ab, Vidas Duo Quick, Vidas Duo Ultra, Nuclisens EasyQ HIV, Nuclisens HIV-1 QT
BIONOR A/S	P.O. Box 1868, N-3705 Skien, Norway	+47 35 53 84 88	+47 35 53 71 30	Gunnar.flaten@bionor.no www.bionor.no	Bionor HIV-1&2
Bio-Rad Laboratories	3, boulevard Raymond Poincaré, 92430 Marnes-la-Coquette, France	+33 1 47 95 60 00	+33 1 47 41 91 33	christine_heinen@bio-rad.com www.bio-rad.com	Genscreen HIV 1/2, Genscreen Plus HIV Ag/Ab, Genie II HIV-1/HIV-2, Pepti-LAV 1-2, New LAV BLOT I, New LAV BLOT II
Cavidi Tech AB	32 A, Dag Hammarskjöldsv., Uppsala Science Park, SE-751 83 Sweden	+461855 20 40	+46 18 55 20 41	info@cavidi.se www.cavidi.com	Exa Vir Load Quantitative HIV-RT
Chembio Diagnostics	3661 Horseblock Road Medford, NY 11765 USA	+1 631 924 1135	+1 631 924 6033	avi@chembio.com www.chembio.com	HIV 1/2 Stat-Pak, HIV 1/2 Stat-Pak Dipstick
Dade Behring Marburg GmbH	Postfach 1149, 35001 Marburg, Germany	+49 6421 39 4478	+49 6421 66064	Eckhardt_Petri@dadebehring.com www.dadebehring.com	Enzygnost® Anti-HIV 1/2 Plus
DYNAL BIOTECH AS	66, Avenue de Landshut (Centre de transfert de L.U.T.C.), F-60200 Compiègne, France	+33 3 44 23 45 95	+33 3 44 23 16 24	frcustserv@dynambiotech.com www.dynambiotech.com	Dynabeads T4-T8 quantification
EY Laboratories, Inc.	P.O. Box 1787, 107 N. Amphlett Blvd., San Mateo, CA 94401, USA	+1 650 342 3296	+1 650 342 2648	sales@eylabs.com www.eylabs.com	InstantCHEK™ HIV 1+2

¹ Please note: Product list gives an overview of most relevant products available. This list is not intended to be comprehensive, therefore additional information should be obtained from company websites where needed.

Manufacturer	Address	Telephone	Fax	Email/Website	Products
Fujirebio Inc.	19th floor, Shinjuku Daiichi Seimei Building, 7-1 Nishi-Shinjuku 2-Chome, Shinjuku-Ku, Tokyo 163-07, Japan	+81 3 3348 0947	+81 3 3342 6220	www.fujirebio.co.jp/english	Serodia® HIV-1/2
Genelabs Diagnostics (now M P Biomedicals Asia Pacific)	Halle de Frêt, P. O. Box 1015, 1215 Geneva 15 Airport, Switzerland	+41 22 788 1908	+41 22 788 1986	mnoore@mpbio.com www.genelabs.com.sg	Genelabs Diagnostics HIV-Blot 2.2
Green Cross Life Science Corporation	227-3, Gugal-hi, Giheung-eup, Yongin-shi, Kyonggi-do, Korea	+82 31 260 9300	+82 31 260 9491	suji2@greencross.com www.greencross.com	Genedia® HIV Ag-Ab; Genedia® HIV 1/2 Rapid 3.0
Guava Technologies	25801, Industrial Blvd., Hayward, CA 94545, USA	+1 510 576 1441	+1 510 576 1500	tbaumgartner@guavatechnologies.com www.guavatechnologies.com	EasyCD4
Innogenetics S.A.	Technologiepark 6, 9052 Ghent, Belgium	+32 9 329 1329	+32 9 329 1911	Roland_geers@innogenetics.be www.innogenetics.com	INNOLIA HIV Confirmation
InTec Products	332 Xinguang Rd, Xinyang Industry Area, Haicang, Xiamen, 361022 China	+86 592 68 07162	+86 592 6519159	jean_zhao@asintec.com www.intecasi.com	Advanced Quality™ Rapid HIV Test
J. Mitra & Co. Ltd	A-180, Okhla Industrial Area, Phase-1, New Delhi-110 020, India	+91 11 681 8971 +91 11 681 8973 +91 11 681 3995 +91 11 681 3989	+91 11 681 0945 +91 11 681 8970	jmitra@del2.vsnl.com.in	HIV TR-DOT
KHB Shanghai Kehua Bio-engineering Co. Ltd.	1189 N Qinzhou Road, Shanghai, 200233, People's Republic of China	+86 21 64851188 +86 21 64853370 +86 21 8203370	+86 21 64854051	cskhk@online.cn	Anti-HIV 1+2 antibodies ELISA diagnostic Kit; Diagnostic kit for HIV (1+2) Antibody (colloidal gold)
OraSure Technologies, Inc.	150 Webster Street, Bethlehem, PA 18015, USA	+1 610 882 1820	+1 610 882 1830	doxley@orasure.com www.orasure.com	OraQuick® HIV-1/2 - Rapid HIV-1/2 Antibody test
Orgenics Ltd.	P.O. Box 360, Yavne 70650, Israel	+972 8 9429212	+972 8 9438758	baruch@orgenics.co.il www.orgenics.com	Immunocomb® II Bispot HIV 1&2, HIV 1&2 DoubleCheck
Partec GmbH	32, Otto Hahn strasse, D-48161, Münster, Germany	+49 2534 8008-0	+49 2534 8008-90	info@partec.de www.partec.de	CyFlow Green, Cyflow Counter
Perkin Elmer Life Sciences	8, Imperiastraat, B 1930 Zaventem, Belgium	+39 335 8031579	+39 0331 376702	www.perkinelmer.com	HIV-1p24 Ultra ELISA , ELAST ELISA amplification system
Premier Medical Corporation	259, Amherst Avenue, Colonia, NJ 07067, USA	+1 732 815 0462	+1 530 869 7966	nileshmeta@verizon.net www.premiermedcorp.com	First Response™ HIV-1-2 O Card Test
Primagen	59, Meibergdreef, N-1105 BA Amsterdam, The Netherlands	+31 20 566 85 69	+31 20 566 9081	www.primagen.com	Retina Rainbow

Manufacturer	Address	Telephone	Fax	Email/Website	Products
Qualpro Diagnostics	88/89, Phase II C, Verna Industrial Estate, Verna, Goa, 403 722 India	+91 832 278 3140	+91 832 278 3139	qualpro@tulipgroup.com www.tulipgroup.com/Qualpro	Retrocheck HIV
Roche Diagnostics	116, Sandhofer strasse, D-68305 Mannheim, Germany	+49 621 759 87 85	+49 621 759 40 68	www.roche-diagnostics.com	Amplacor HIV-1 DNA assay version 1.5, Amplacor HIV-1 Monitor Test version 1.5, Taqman
Standard Diagnostics, Inc.	575-34 Pajang-dong, Jangan-ku, Suwon-si, Kyonggi-do, 440-290, Korea	+82 31 258 2994	+82 31 258 2995	johnkim@standardia.com www.standardia.com	SD BIOLINE HIV 1/2 3.0
Trinity Biotech plc	IDA Business Park, Bray, Co. Wicklow, Ireland	+353 1276 9800	+353 1276 9888	Tom.Lindsay@compuserve.com www.trinitybiotech.com	Capillus™ HIV-1/HIV-2, Uni-Gold™ HIV
United Biomedical Inc	25, Davids Drive, Hauppauge, NY 11788, USA	+1 516 273 2828	+1 516 273 1717	www.unitedbiomedical.com	UBI® HIV-1/2 EIA

ANNEX 1A

Summary of CD4+ T-cell enumeration technologies

FLOW CYTOMETRY			
Parameter	Double-platform ^a	Single-platform	
		Volumetric ^b	Bead-based ^c
Instruments	Flow cytometer	Flow cytometer	Flow cytometer
Manufacturers	Partec GmbH (Munster, Germany) Becton Dickinson (CA, USA) Coulter Corporation (FL, USA)	Partec GmbH (Munster, Germany) ^d Guava Technologies ^d (CA,USA)	Becton Dickinson (CA, USA) Coulter Corporation (FL, USA)
Cost of instrument (US\$)	20–95 000	20–70 000	20–95 000
Cost of reagents/test (US\$)	2–11	1–10	3–25
Specimen	Whole blood	Whole blood	Whole blood
Results	Absolute CD4 count Absolute CD8 count CD4% and CD8% among lymphocytes CD4/CD8 ratio B and NK cells are possible	Absolute CD4 count Absolute CD8 count CD4% and CD8% among lymphocytes CD4/CD8 ratio B and NK cells are possible	Absolute CD4 count Absolute CD8 count CD4% and CD8% among lymphocytes CD4/CD8 ratio B and NK cells are possible
Throughput (samples/day)	Up to 250	Up to 250	Up to 250
Advantages	One tube assay possible without QC problems EQA available	No need for extra beads or haematology analyser Protocols for aged samples available EQA available	No need for haematology analyser Protocols for aged samples available EQA available
Disadvantages	Requires the use of a haematology analyser More prone to clerical errors Fresh samples needed in order to obtain absolute counts	Internal QC for pipetting requires two tubes assay Instruments not yet proven in an independent multi centre study	Internal QC for pipetting requires two tubes assay Beads are expensive and require careful handling

B and NK cells – subsets of lymphocytes; QC – quality control; EQA – external quality assessment

^a Any flow cytometer from any of the three manufacturers can operate with this method to provide absolute counts. The results of flow cytometry are combined with those from haematology to calculate absolute counts.

^b Volumetric instruments have the inherent hardware property of measuring the volume of the sample, providing direct absolute counts without the use of haematology analysers or beads.

^c Any flow cytometer from any of the three manufacturers can operate with this method to provide absolute counts.

^d Instruments from these manufacturers, are being validated as volumetric absolute CD4 T cell counters by independent investigators in multicentre studies.

DEDICATED AND MANUAL ASSAYS

	Dedicated Technology			
	FACSCCount	CyFlow Counter	CyFlow SL	PointCare
Manufacturer	Becton Dickinson (CA, USA)	Partec GmbH (Munster, Germany)	Partec GmbH (Munster, Germany)	Beckman Coulter Inc. (CA, USA)
Instrumentation	Dedicated CD4 counter	Dedicated CD4 counter	Dedicated CD4 and CD4% counter	PointCare System
Assay principle	Flow cytometry	Flow cytometry	Flow cytometry	Flow cytometric detection of CD4+ T-cells
Detection system	Fluorochrome labelled anti-CD3, CD4 and CD8 MAb	Fluorochrome labeled, anti-CD4, (CD45, CD3, CD8) MAb	Fluorochrome labeled, anti-CD4 /anti CD45 MAbs, (CD3/CD4),(CD3CD8), (CD4/ CD8	Anti-CD4 MAb conjugated with colloidal gold particles
Specimen	Whole blood	Whole blood	Whole blood	Whole blood
Results	Absolute CD4 and CD8 count CD4/CD8 ratio CD4% and CD8% among T cells	Absolute CD4 count Absolute CD8 count Absolute CD3 count Absolute CD45 count	Absolute CD4 count Absolute CD45 count Absolute lymphocyte count CD4% among lymphocytes CD4% among T-lymphocytes	Absolute and % CD4 count WBC absolute count Absolute and % lymphocyte count
Correlation with flow cytometry^a (r value)	0.93–0.98 (several international studies)	0.92–0.99 (international studies ongoing)	0.95–0.99 (international studies ongoing)	0.95 and 0.97 (international studies ongoing)
Cost of instrument (US\$)	27 000	21 800	26 975	16 500
Cost of reagents/test (US\$)^c	5–20	2.26	2.26–3.23	5.5–7.8
Advantages	Automated, fewer steps, less human error, low biohazard risk Absolute CD4 and CD8 counts Quick results EQA available	Reagents available at low cost Equipment includes reagents for 1000 CD4 tests Quick results EQA available	Reagents available at low cost Equipment includes reagents for 200 CD4 % tests Quick results EQA available	Simple, no manual gating No manual sample preparation
Disadvantages	Reagent prices vary widely CD4% among lymphocytes not reported, can be calculated from haematology parameters	CD4% among lymphocytes not reported Limited data available	Limited data available	One sample processed at a time 17 min. No EQA available No published data available yet

MAb – monoclonal antibody; EQA – external quality assessment

^a The analysis of correlation using linear regression is not appropriate to study method comparison. Instead, the analysis of agreement should be performed. Unfortunately, few of the published studies has used this analysis to compare these methods with flow cytometry. Therefore, here the 'r' values are still reported.

^b Depending on if a light or fluorescence microscope is used.

^c Instrument costs may vary, reagent cost may decrease substantially in the near future.

MANUAL ASSAYS

	Manual Assays	
	Cyto-Spheres	Dynabeads
Manufacturer	Beckman Coulter (FL, USA)	Dynal AS (Oslo, Norway)
Instrumentation	Haemocytometer Light microscope	Magnet Haemocytometer Light or fluorescence microscope
Assay principle	Direct observation of bead-rosetted cells	Direct observation of immunocaptured cells
Detection system	Latex beads conjugated to anti-CD4 MAb	Magnetic beads conjugated to anti-CD4 and CD8 MAb
Specimen	Whole blood	Whole blood
Results	Absolute CD4 count	Absolute CD4 count Absolute CD8 count CD4/CD8 ratio
Correlation with flow cytometry^a (r value)	0.67–0.93 (several international studies)	0.94 and 0.96 (several international studies)
Cost of instrument (US\$)	2000	2–10 000 ^b
Cost of reagents/test (US\$)^c	4–8	3–5
Advantages	Simple and rapid	Simple and rapid Absolute CD4 and CD8 counts
Disadvantages	10 samples processed at a time Subjectivity in visual counting CD4% among lymphocytes or CD8 counts not reported No EQA available	6 samples processed at a time Subjectivity in visual counting CD4% among lymphocytes not reported No EQA available

MAb – monoclonal antibody; EQA – external quality assessment

^a The analysis of correlation using linear regression is not appropriate to study method comparison. Instead, the analysis of agreement should be performed. Unfortunately, few of the published studies has used this analysis to compare these methods with flow cytometry. Therefore, here the 'r' values are still reported.

^b Depending on if a light or fluorescence microscope is used.

^c Instrument costs may vary, reagent cost may decrease substantially in the near future

ANNEX 1B

Summary of main characteristics of viral load technologies

NUCLEIC ACID BASED				
COMPANY	ROCHE	ROCHE	ROCHE	ROCHE
Assay Name	AMPLICOR™ HIV-1 Monitor® Test v1.5	COBAS AMPLICOR™ HIV-1 Monitor® Test v1.5	TaqMan HIV-1 Monitor Test v1.5	AMPLICOR™ HIV-1 DNA Test v1.5*
Type of assay	RT-PCR, quantitative	RT-PCR, quantitative	Real-Time RT-PCR, quantitative	PCR, qualitative
Dynamic Range (copies/ml)	50–100,000 (UltraSensitive) 400–750,000 (Standard)	50–100,000 (UltraSensitive) 500–1,000,000 (Standard)	40–10 Million copies/ml (95% confidence)	N/A
Specimen Type	Plasma, Serum	Plasma, Serum	Plasma, Serum	Whole Blood, DBS
Specimen volume	200 µl (UltraSensitive) 500 µl (Standard)	500 µl (US, Manual Extraction) 750 µl (US, Automated Extraction) 200 µl (Std, Manual Extraction) 350 µl (Std, Automated Extraction)	500 µl (Manual Extraction) 1 ml (Automated Extraction)	200–500 µl
Area of HIV genome amplified	Gag	Gag	Gag	Gag
HIV-1 subtypes amplified	Group M, subtypes A–H	Group M, subtypes A–H	Group M, subtypes A–H	Group M, subtypes A–H
Time for result	7–8 hours	6–8 hours	5–6 hours	7–8 hours
Cost/test¹	\$ 17–35/test \$ 35–90/ test	\$ 17–35/test \$ 35–90/test	\$ 17–35/test \$ 35–90/test	\$ 10–15 / test \$ 15–30 / test
Number of samples/run	9–21	9–21	21–84 (COBAS TaqMan 48 or 96)	9–21
Equipment required²	Thermocycler, ELISA Reader/Washer, Microcentrifuge Not supplied by Roche Total approx \$25,000.	COBAS AMPLICOR (PCR) COBAS AmpliPrep – automated extraction (Optional)	COBAS TaqMan 48 or 96 COBAS AmpliPrep – automated extraction (Optional)	Thermocycler, ELISA Reader/Washer, Microcentrifuge Not supplied by Roche Total approx \$25,000.
Equipment cost (US\$)		COBAS AMPLICOR: \$35,000–45,000 AmpliPrep: \$80,000– 100,000	COBAS TaqMan 48 or 96: \$45,000–\$60,000/ \$120,000 AmpliPrep: \$80,000– \$100,000	

* Research use only

¹ Prices will vary considerably depending on quantities, infrastructure and support required plus special negotiations, first price bracket for the least developed countries.

² All assays require pipettes, vortex mixers (and refrigerator for all but Primagen).

NUCLEIC ACID BASED

COMPANY	ABBOTT	BAYER	BIOMÉRIEUX	PRIMAGEN
Assay Name	Abbott RealTime HIV-1	Versant® HIV-1 RNA 3.0 Assay	NucliSens EasyQ® HIV-1	Retina™ Rainbow
Type of assay	Real Time PCR	bDNA	RT-NASBA	NASBA
Dynamic Range (copies/ml)	40–10,000,000	75–500,000	50–3,000,000	500–50,000,000
Specimen Type	Plasma	Plasma	Plasma, Serum, Dried Blood Spots	Plasma, Serum, Whole Blood, Dried Fluid Spots
Specimen volume	200–500–1,000 µl	1,000–2,000 µl	10–2,000 µl	200 µl
Area of HIV genome amplified	Pol	Pol	Gag	LTR
HIV-1 subtypes amplified	Group M (subtypes A–G) and Group O	Group M (subtypes A–G)	All	All
Time for result	5 hours	22 hours	2.5–3 hours	1.5 hours
Cost/test¹	\$20–70	\$87	\$38–76	\$17–23
Number of samples/run	21–95 (+3 controls)	12–168	8–48	96
Equipment required²	M2000sp \$100,000 Or magnetic racks, plate cooler \$500	Bayer System 340 (bDNA Analyzer, Data Management Software, and computer system) Centrifuge Heatblock Waterbath Vacuum system	NucliSens miniMAG system or Nuclisens easyMAG system NucliSens EasyQ Analyser Strip centrifuge	RetinAlyser Heatblock Computer Centrifuge
Equipment cost (US\$)	M2000rt: \$50,250	\$10 000 + Bayer System Analyzer	\$63,000	\$23 000

NON NUCLEIC ACID BASED

COMPANY	CAVIDI	PERKIN ELMER
Assay Name	ExaVir™ Load Quantitative HIV-RT Load Kit	HIV-1 p24 Ultra ELISA ELAST ELISA amplification system
Type of Assay	Enzyme immunoassay for quantitation of Reverse Transcriptase activity	Enzyme immunoassay for quantitation of p24 antigen
Dynamic Range	750 – over 50,000 copies/ml	400 copies/ml
Specimen Type	Plasma	Plasma, Serum or Cell Culture Supernatant
Specimen Volume	1000 µl	100 µl
Area of HIV Genome Selected for Amplification	Reverse Transcriptase (RT) activity	p24 antigen
HIV-1 Subtypes Amplified	All, plus HIV-2	HIV-1
Time for Result	24 hours	6 hours
Cost/Test¹	\$13–15	\$10
Number of Samples/Run	30	96
Equipment required²	Incubator (33 °C), Freezer, ELISA Reader, Computer	Incubator, ELISA Reader, Refrigerator
Equipment cost (US\$)	\$9,000–\$10,000 (start up pack includes other necessary equipment and 3 kits)	\$7,000–\$9,000

¹ Prices vary considerably with quantities and special negotiations.

² All assays require pipettes, vortex mixers (and refrigerator for all but Primagen).

ANNEX 2B†

Sources of medicines

Prequalified sources of specific products are marked in bold with an asterisk

TABLE 1. ANTI-INFECTIVE MEDICINES

Anthelmintics – Antifilarials	Manufacturer
CROTAMITON	
cream/lotion 10%	SM Pharmaceuticals SDN BHD
IVERMECTIN	
scored tablet, 3 mg	Merck & Co., Inc.
LINDANE	
cream, lotion or powder, 0.3%	Ovelle Limited
PERMETHRIN	
cream, 5%	Ovelle Limited
lotion, 1%	Ovelle Limited
Anthelmintics – Intestinal anthelmintics	
albendazole	
chewable tablet, 400 mg	Apex Drug House, Artesan Pharma GmbH & Co. KG, Beltapharm SpA, Cadila Pharmaceuticals Ltd., Cipla Ltd., Cosmos Limited, Emcure Pharmaceuticals Limited, Korea United Pharm. Inc., Lachifarma, SRL, Nuevas Tecnologías Farmaceuticas, Remedica Ltd., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd., Strides Arcolab Ltd.
Antibacterials, beta lactam medicines	
benzathine benzylpenicillin	
powder for injection, 1.44 g (=2.4 million IU) in 5-ml vial	Alembic Ltd., Aventis Intercontinental, Sanavita Aktiengesellschaft & Co.
benzylpenicillin	
powder for injection, 3 g (=5 million IU) (as sodium or potassium salt) in vial	Alembic Ltd., Apex Drug House, Sanavita Aktiengesellschaft & Co.
powder for injection, 600 mg (=1 million IU) (as sodium or potassium salt) in vial	Apex Drug House, Sanavita Aktiengesellschaft & Co.
cefixime	
paediatric oral suspension, 100 mg/5 ml	Aventis Intercontinental, Bilim Pharmaceutical Ind.
paediatric oral suspension, 40 mg/ 5 ml	Aventis Intercontinental
tablet, 200 mg	Aventis Intercontinental, Cipla Ltd., Emcure Pharmaceuticals Limited, Korea United Pharm. Inc., Remedica Ltd.
tablet, 400 mg	Bilim Pharmaceutical Ind., Genepharm SA

† Annex 2A. Registration status of products included in the sources and prices survey on CD-ROM only.

ceftriaxone

powder for injection, 1 g (as sodium salt) in vial	Alembic Ltd., Apex Drug House, Aristo Pharmaceuticals Ltd., Bilim Pharmaceutical Ind., Cadila Pharmaceuticals Ltd., Cipla Ltd., CLARIS Lifesciences Ltd., Pharmaceutical Industry, Emcure Pharmaceuticals Limited, F. Hoffmann-La Roche Ltd.NPI, Genepharm SA, Grupo Reig Jofre, Korea United Pharm. Inc., Lisapharma, Mepha Ltd, Neon Laboratories Limited, Pharmathen Pharmaceuticals S.A., Ranbaxy Laboratories Ltd, Strides Arcolab Ltd.
powder for injection, 250 mg (as sodium salt) in vial	Aristo Pharmaceuticals Ltd., Cadila Pharmaceuticals Ltd., Cipla Ltd., CLARIS Lifesciences Ltd., Combino Pharm, S.L., Pharmaceutical Industry, Emcure Pharmaceuticals Limited, *F. Hoffmann-La Roche Ltd.NPI , Korea United Pharm. Inc., Mepha Ltd, Neon Laboratories Limited, Pharmathen Pharmaceuticals S.A., Ranbaxy Laboratories Ltd, Strides Arcolab Ltd.
powder for injection, 500 mg (as sodium salt) in vial	Aristo Pharmaceuticals Ltd., Bilim Pharmaceutical Ind., Cadila Pharmaceuticals Ltd., Cipla Ltd., CLARIS Lifesciences Ltd., Pharmaceutical Industry, Emcure Pharmaceuticals Limited, *F. Hoffmann-La Roche Ltd.NPI , Grupo Reig Jofre, Korea United Pharm. Inc., Lisapharma, Mepha Ltd, Neon Laboratories Limited, Pharmathen Pharmaceuticals S.A., Strides Arcolab Ltd.

procaine benzylpenicillin

powder for injection, 1 g (=1 million IU) in vial	Sanavita Aktiengesellschaft & Co.
powder for injection, 3 g (=3 million IU) in vial	Alembic Ltd., Sanavita Aktiengesellschaft & Co.

Antibacterials, others

azithromycin

oral suspension, 200 mg/5 ml (dihydrate)	Alembic Ltd., Cadila Pharmaceuticals Ltd., FDC Ltd., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
tablet/capsule, 250 mg (dihydrate)	Alembic Ltd., Cadila Pharmaceuticals Ltd., Cipla Ltd., Cosmos Limited, FDC Ltd., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd., Strides Arcolab Ltd.
tablet/capsule, 500 mg (dihydrate)	Alembic Ltd., Cadila Pharmaceuticals Ltd., Cosmos Limited, FDC Ltd., Laboratorios Cinfa S.A., Laboratorios Juventus S.A., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.

capreomycin

powder for injection, 1 g in vial	Neon Antibiotics PVT. Ltd.
chloramphenicol	
capsule, 250 mg	Apex Drug House, Cosmos Limited, Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
powder for injection, 1 g (sodium succinate) in vial	Apex Drug House, Neon Laboratories Limited, Sanavita Aktiengesellschaft & Co., SM Pharmaceuticals Sdn Bhd, Strides Arcolab Ltd.

ciprofloxacin

tablet, 250 mg (as hydrochloride)	Alembic Ltd., Alpharma, Apex Drug House, Bayer Healthcare AG, Cadila Pharmaceuticals Ltd., Cipro, *Cipla Ltd. , Cosmos Limited, Emcure Pharmaceuticals Limited, FDC Ltd., Genepharm SA, Instituto Quimioterapico S.A.(IQFARMA), Intas Pharmaceuticals Ltd, Korea United Pharm. Inc., *Laboratorios Cinfa S.A. , Laboratorios Juventus S.A., Mepha Ltd, Nuevas Tecnologías Farmaceuticas, Pharmathen Pharmaceuticals S.A., Protein S.A. DE C.V. (Apotex), *Ranbaxy Laboratories Ltd , Remedica Ltd., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd., SM Pharmaceuticals Sdn Bhd, Strides Arcolab Ltd.
tablet, 500 mg (as hydrochloride)	Alembic Ltd., Alpharma, Apex Drug House, Aristo Pharmaceuticals Ltd., Bayer Healthcare AG, Cadila Pharmaceuticals Ltd., *Cipla Ltd. , Cosmos Limited, Pharmaceutical Industry, Emcure Pharmaceuticals Limited, FDC Ltd., Instituto Quimioterapico S.A.(IQFARMA), Intas Pharmaceuticals Ltd, Korea United Pharm. Inc., *Laboratorios Cinfa S.A. , Laboratorios Juventus S.A., Mepha Ltd, Nuevas Tecnologías Farmaceuticas, Pharmathen Pharmaceuticals S.A., Protein S.A. DE C.V. (Apotex), *Ranbaxy Laboratories Ltd , Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd., SM Pharmaceuticals Sdn Bhd, Strides Arcolab Ltd.

clarithromycin

powder for injection, 500 mg	Strides Arcolab Ltd.
tablet, 250 mg	Alembic Ltd., Alpharma, Bilim Pharmaceutical Ind., Emcure Pharmaceuticals Limited, Genepharm SA, Intas Pharmaceuticals Ltd, Korea United Pharm. Inc., Laboratorios Juventus S.A., Nuevas Tecnologías Farmaceuticas, *Ranbaxy Laboratories Ltd , Remedica Ltd., SM Pharmaceuticals Sdn Bhd, Strides Arcolab Ltd., The Government Pharmaceutical Organization

clindamycin	
capsule, 150 mg	Bilim Pharmaceutical Ind., Korea United Pharm. Inc., Nuevas Tecnologías Farmaceuticas, Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
cream, 2% (as phosphate)	Genepharm SA
injection, 150 mg/ml (as phosphate) in 2-ml ampoule	Combino Pharm, S.L.
cycloserine	
capsule, 250 mg	Pharmadrug
doxycycline	
capsule/tablet, 100 mg (hydrochloride)	Apex Drug House, Aristo Pharmaceuticals Ltd., Cipla Ltd., Cosmos Limited, FDC Ltd., Intas Pharmaceuticals Ltd, Korea United Pharm. Inc., Nuevas Tecnologías Farmaceuticas, Pharmadrug, Remedica Ltd., Sanavita Aktiengesellschaft & Co., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
erythromycin	
powder for oral suspension, 125 mg (as stearate or ethylsuccinate)	Beltapharm SpA, Cosmos Limited, Instituto Quimioterapico S.A.(IQFARMA), Lachifarma, SRL, Pharmadrug, Purna Pharmaceuticals NV, Remedica Ltd., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
tablet/capsule, 250 mg (as stearate or ethylsuccinate)	Alembic Ltd., Artesan Pharma GmbH & Co. KG, Beltapharm SpA, Cadila Pharmaceuticals Ltd., Cipla Ltd., Cosmos Limited, Instituto Quimioterapico S.A.(IQFARMA), Intas Pharmaceuticals Ltd, Lachifarma, SRL, Lomapharm, Rudolf Lohmann GmbH KG, Remedica Ltd., Sanavita Aktiengesellschaft & Co., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd., SM Pharmaceuticals Sdn Bhd, Strides Arcolab Ltd.
tablet/capsule, 500 mg (as stearate or ethylsuccinate)	Alembic Ltd., Artesan Pharma GmbH & Co. KG, Cipla Ltd., Cosmos Limited, Instituto Quimioterapico S.A.(IQFARMA), Intas Pharmaceuticals Ltd, Lomapharm, Rudolf Lohmann GmbH KG, Nuevas Tecnologías Farmaceuticas, Remedica Ltd., Sanavita Aktiengesellschaft & Co., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd., Strides Arcolab Ltd.
gentamicin	
injection, 10 mg/ml (as sulfate) in 2-ml vial	Rotexmedica
injection, 40 mg/ml (as sulfate) in 2-ml vial	Apex Drug House, Neon Laboratories Limited, Rotexmedica, Sanavita Aktiengesellschaft & Co.
metronidazole	
injection, 500 mg in 100-ml vial	Aventis Intercontinental, B. Braun Biotech International GmbH, CLARIS Lifesciences Ltd., Pharmaceutical Industry, Human Pharmaceutical Works Co. Ltd., Rotexmedica
oral suspension, 200 mg (as benzoate)/5 ml	Beltapharm SpA, Cipla Ltd., Cosmos Limited, FDC Ltd., Purna Pharmaceuticals NV, Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
suppository, 1 g	Aventis Intercontinental
tablet, 200 mg	Apex Drug House, Aristo Pharmaceuticals Ltd., Cibro, Cosmos Limited, Lomapharm, Rudolf Lohmann GmbH KG, Remedica Ltd., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
tablet, 500 mg	Alpharma, Aventis Intercontinental, FDC Ltd., Instituto Quimioterapico S.A.(IQFARMA), Lomapharm, Rudolf Lohmann GmbH KG, Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
vaginal gel, 0.75%	Korea United Pharm. Inc.
ofloxacin	
IV infusion, 2 mg/ml (hydrochloride)	CLARIS Lifesciences Ltd., Genepharm SA
tablet, 200 mg	Aristo Pharmaceuticals Ltd., Aventis Intercontinental, Cipla Ltd., FDC Ltd., Genepharm SA, Intas Pharmaceuticals Ltd, Korea United Pharm. Inc., Nuevas Tecnologías Farmaceuticas, Ranbaxy Laboratories Ltd, Remedica Ltd., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
tablet, 400 mg	Aristo Pharmaceuticals Ltd., Cipla Ltd., FDC Ltd., Korea United Pharm. Inc., Ranbaxy Laboratories Ltd, Remedica Ltd., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
spectinomycin	
powder for injection, 2 g (as hydrochloride) in vial	Neon Antibiotics PVT. Ltd.

sulfadiazine	
tablet, 500 mg	*Doms Recordati ^{NPI} , Ecobi Farmaceutici S.a.s., Grupo Reig Jofre, Heyl Chemisch.-pharmazeutische Fabrik GmbH & Co KG
sulfamethoxazole+trimethoprim	
oral suspension, 200+40 mg/5 ml	Apex Drug House, Aristo Pharmaceuticals Ltd., Beltapharm SpA, Cadila Pharmaceuticals Ltd., Cipla Ltd., Cosmos Limited, Ecobi Farmaceutici S.a.s., Emcure Pharmaceuticals Limited, *F. Hoffmann-La Roche Ltd. ^{NPI} , Instituto Quimioterapico S.A.(IQFARMA), Lachifarma, SRL, Protein S.A. DE C.V. (Apotex), Purna Pharmaceuticals NV, Remedica Ltd., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd., SM Pharmaceuticals Sdn Bhd
tablet, 100+20 mg	Artesan Pharma GmbH & Co. KG, Cosmos Limited, Ecobi Farmaceutici S.a.s., FDC Ltd., Lachifarma, SRL, Lomapharm, Rudolf Lohmann GmbH KG, Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
tablet, 400+80 mg	Alpharma, Apex Drug House, Aristo Pharmaceuticals Ltd., Artesan Pharma GmbH & Co. KG, Cadila Pharmaceuticals Ltd., Cibro, Cosmos Limited, Ecobi Farmaceutici S.a.s., Emcure Pharmaceuticals Limited, *F. Hoffmann-La Roche Ltd. ^{NPI} , FDC Ltd., Instituto Quimioterapico S.A.(IQFARMA), Intas Pharmaceuticals Ltd, Lomapharm, Rudolf Lohmann GmbH KG, Nuevas Tecnologías Farmaceuticas, Protein S.A. DE C.V. (Apotex), Remedica Ltd., Sanavita Aktiengesellschaft & Co., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd., SM Pharmaceuticals Sdn Bhd, Strides Arcolab Ltd., The Government Pharmaceutical Organization
tablet, 800+160 mg	Alpharma, Apex Drug House, Aristo Pharmaceuticals Ltd., Cadila Pharmaceuticals Ltd., Cosmos Limited, Emcure Pharmaceuticals Limited, *F. Hoffmann-La Roche Ltd. ^{NPI} , FDC Ltd., Instituto Quimioterapico S.A.(IQFARMA), Nuevas Tecnologías Farmaceuticas, Protein S.A. DE C.V. (Apotex), Remedica Ltd., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd., Strides Arcolab Ltd.
Antifungal medicines	
amphotericin B	
powder for injection, 50 mg in vial	Combino Pharm, S.L., Neon Antibiotics PVT. Ltd.
clotrimazole	
cream, 1%	Apex Drug House, Cipla Ltd., Cosmos Limited, Emcure Pharmaceuticals Limited, Instituto Quimioterapico S.A.(IQFARMA), Korea United Pharm. Inc., Ovelle Limited, Pharmadrug, Purna Pharmaceuticals NV, Remedica Ltd., SM Pharmaceuticals Sdn Bhd, The Government Pharmaceutical Organization, Vitafarma S.L.
pessary, 500 mg	Korea United Pharm. Inc., Remedica Ltd.
fluconazole	
capsule, 150 mg	Bilim Pharmaceutical Ind., Cadila Pharmaceuticals Ltd., *Cipla Ltd., Cosmos Limited, FDC Ltd., Instituto Quimioterapico S.A.(IQFARMA), Intas Pharmaceuticals Ltd, Pharmathen Pharmaceuticals S.A., *Ranbaxy Laboratories Ltd ^{NPI} , Remedica Ltd., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
capsule, 200 mg	Cadila Pharmaceuticals Ltd., *Cipla Ltd., Cosmos Limited, FDC Ltd., Pharmathen Pharmaceuticals S.A., *Ranbaxy Laboratories Ltd ^{NPI} , Remedica Ltd., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd., The Government Pharmaceutical Organization
capsule, 50 mg	*Cipla Ltd., Cosmos Limited, FDC Ltd., Genepharm SA, Korea United Pharm. Inc., Nuevas Tecnologías Farmaceuticas, Pharmathen Pharmaceuticals S.A., *Ranbaxy Laboratories Ltd ^{NPI}
injection, 2 mg/ml in ampoule	CLARIS Lifesciences Ltd., Genepharm SA, Grupo Reig Jofre, Pharmathen Pharmaceuticals S.A.
itraconazole	
capsule, 100 mg	Instituto Quimioterapico S.A.(IQFARMA), Intas Pharmaceuticals Ltd, Korea United Pharm. Inc., SM Pharmaceuticals Sdn Bhd
ketoconazole	
cream, 2%	Apex Drug House, Genepharm SA, Instituto Quimioterapico S.A.(IQFARMA), Laboratorios Juventus S.A., Ovelle Limited, Protein S.A. DE C.V. (Apotex), Purna Pharmaceuticals NV
tablet, 200 mg	Artesan Pharma GmbH & Co. KG, Beltapharm SpA, Bilim Pharmaceutical Ind., Cosmos Limited, Intas Pharmaceuticals Ltd, Korea United Pharm. Inc., Lachifarma, SRL, Nuevas Tecnologías Farmaceuticas, Pharmadrug, Remedica Ltd., SM Pharmaceuticals Sdn Bhd, Strides Arcolab Ltd., The Government Pharmaceutical Organization

miconazole	
cream/ointment 2% (as nitrate) 15 g tube	Beltapharm SpA, Cipla Ltd., Cosmos Limited, Lachifarma, SRL, Purna Pharmaceuticals NV
cream/ointment 2% (as nitrate) 20 g tube	Apex Drug House, Ovelle Limited, Protein S.A. DE C.V. (Apotex), Purna Pharmaceuticals NV
cream/ointment 2% (as nitrate) 30 g tube	Beltapharm SpA, Ecobi Farmaceutici S.a.s., Lachifarma, SRL, Pharmadrug, Purna Pharmaceuticals NV, Vitafarma S.L.
cream/ointment 2% (as nitrate) 40 g tube	Purna Pharmaceuticals NV
nystatin	
lozenge, 100,000 IU	Cosmos Limited
pessary, 100,000 IU	Artesan Pharma GmbH & Co. KG, Beltapharm SpA, Cipla Ltd., Cosmos Limited, Pharmadrug, SM Pharmaceuticals Sdn Bhd
tablet, 100,000 IU	Artesan Pharma GmbH & Co. KG, Beltapharm SpA, Cipla Ltd., Lomapharm, Rudolf Lohmann GmbH KG
tablet, 500,000 IU	Artesan Pharma GmbH & Co. KG, Beltapharm SpA, Cipla Ltd., Cosmos Limited, Lomapharm, Rudolf Lohmann GmbH KG, Pharmadrug, Protein S.A. DE C.V. (Apotex), Remedica Ltd., Sanavita Aktiengesellschaft & Co.
Antiprotozoal medicines	
pentamidine	
powder for injection, 200 mg (isetionate) in vial	Neon Antibiotics PVT. Ltd.
powder for injection, 300 mg (isetionate) in vial	Aventis Intercontinental, Combino Pharm, S.L., Lab. Filaxis International S.A.
pyrimethamine	
tablet, 25 mg	Cosmos Limited, Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
tinidazole	
tablet, 500 mg	Cadila Pharmaceuticals Ltd., Cosmos Limited, Intas Pharmaceuticals Ltd, Remedica Ltd.
Antiviral medicines	
aciclovir	
cream, 5%	*Cipla Ltd. , Cosmos Limited, Ecobi Farmaceutici S.a.s., Instituto Quimioterapico S.A.(IQFARMA), Lisapharma
powder for injection, 250 mg (as sodium salt)	Biologici Italia Laboratories SRL, Combino Pharm, S.L., Grupo Reig Jofre, Korea United Pharm. Inc., Lab. Filaxis International S.A., Neon Antibiotics PVT. Ltd., Neon Laboratories Limited
tablet, 200 mg	Cadila Pharmaceuticals Ltd., Cipro, *Cipla Ltd. , Cosmos Limited, FDC Ltd., Instituto Quimioterapico S.A.(IQFARMA), Korea United Pharm. Inc., Lab. Filaxis International S.A., Lisapharma, Nuevas Tecnologías Farmaceuticas, Pharmadrug, Protein S.A. DE C.V. (Apotex), *Ranbaxy Laboratories Ltd. , Remedica Ltd., Samchully Pharm. Co., Ltd., SM Pharmaceuticals Sdn Bhd
tablet, 400 mg	Cadila Pharmaceuticals Ltd., *Cipla Ltd. , Ecobi Farmaceutici S.a.s., FDC Ltd., Instituto Quimioterapico S.A.(IQFARMA), Korea United Pharm. Inc., Lisapharma, *Ranbaxy Laboratories Ltd. , Remedica Ltd., Samchully Pharm. Co., Ltd., SM Pharmaceuticals Sdn Bhd
tablet, 800 mg	*Cipla Ltd. , Combino Pharm, S.L., Ecobi Farmaceutici S.a.s., FDC Ltd., Korea United Pharm. Inc., Lab. Filaxis International S.A., Laboratorios Cinfa S.A., Lisapharma, *Ranbaxy Laboratories Ltd. , Remedica Ltd.
ganciclovir	
powder for IV infusion, 500 mg in vial	*F. Hoffmann-La Roche Ltd. ^{NPI} , Lab. Filaxis International S.A.
Antiviral medicines – Antiretrovirals	
abacavir (ABC)	
syrup, 20 mg/ml	*GlaxoSmithKline Export Ltd.
tablet, 300 mg	Cipla Ltd., *GlaxoSmithKline Export Ltd. , Lab. Filaxis International S.A.

didanosine (ddI)	
buffered chewable tablet, 100 mg	*Bristol-Myers Squibb (Africa Export Division) , Cipla Ltd., Emcure Pharmaceuticals Limited, Nuevas Tecnologías Farmaceuticas, Protein S.A. DE C.V. (Apotex)
buffered chewable tablet, 25 mg	*Bristol-Myers Squibb (Africa Export Division) , Cipla Ltd., Protein S.A. DE C.V. (Apotex)
buffered chewable tablet, 50 mg	*Bristol-Myers Squibb (Africa Export Division) , Cipla Ltd.
syrup, 2 g	Bristol-Myers Squibb (Africa Export Division)
unbuffered enteric coated capsule, 250 mg	Bristol-Myers Squibb (Africa Export Division), Cipla Ltd., Shanghai Desano Biopharmaceutical Co., Ltd
unbuffered enteric coated capsule, 400 mg	Bristol-Myers Squibb (Africa Export Division), Cipla Ltd.
efavirenz (EFZ)	
capsule, 100 mg	Lab. Filaxis International S.A., Merck & Co., Inc.
capsule, 200 mg	Cipla Ltd., Cosmos Limited, Merck & Co., Inc., Nuevas Tecnologías Farmaceuticas, Ranbaxy Laboratories Ltd
capsule, 50 mg	Merck & Co., Inc.
oral solution, 150 mg/5 ml	Merck & Co., Inc.
tablet, 600 mg	Cipla Ltd., Cosmos Limited, Emcure Pharmaceuticals Limited, Merck & Co., Inc., Ranbaxy Laboratories Ltd
indinavir (IDV)	
capsule, 200 mg (as sulphate)	Cipla Ltd., Merck & Co., Inc.
capsule, 400 mg (as sulphate)	Cipla Ltd., Lab. Filaxis International S.A., Merck & Co., Inc., Nuevas Tecnologías Farmaceuticas, Strides Arcolab Ltd.
lamivudine (3TC)	
oral solution, 50 mg/5 ml	*Cipla Ltd., *GlaxoSmithKline Export Ltd. , The Government Pharmaceutical Organization
tablet, 150 mg	*Cipla Ltd. , Cosmos Limited, Emcure Pharmaceuticals Limited, *GlaxoSmithKline Export Ltd. , Intas Pharmaceuticals Ltd, Lab. Filaxis International S.A., Nuevas Tecnologías Farmaceuticas, Ranbaxy Laboratories Ltd, *Strides Arcolab Ltd. , The Government Pharmaceutical Organization
nelfinavir (NFV)	
oral powder, 50 mg/g	*F. Hoffmann-La Roche Ltd.
tablet, 250 mg	Cipla Ltd., *F. Hoffmann-La Roche Ltd. , Lab. Filaxis International S.A., The Government Pharmaceutical Organization
nevirapine (NVP)	
syrup, 50 mg/5 ml	*Boehringer Ingelheim GmbH , Cipla Ltd., Emcure Pharmaceuticals Limited, The Government Pharmaceutical Organization
tablet, 200 mg	*Boehringer Ingelheim GmbH , *Cipla Ltd. , Cosmos Limited, Emcure Pharmaceuticals Limited, *Hetero Drugs Ltd^{NPI} , Lab. Filaxis International S.A., Ranbaxy Laboratories Ltd, Shanghai Desano Biopharmaceutical Co., Ltd, *Strides Arcolab Ltd. , The Government Pharmaceutical Organization
saquinavir (SQV)	
hard gel capsule, 200 mg	*F. Hoffmann-La Roche Ltd.

stavudine (d4T)	
capsule, 15 mg	*Bristol-Myers Squibb (Africa Export Division) ^{NPI} , The Government Pharmaceutical Organization
capsule, 20 mg	*Bristol-Myers Squibb (Africa Export Division) , Shanghai Desano Biopharmaceutical Co., Ltd, The Government Pharmaceutical Organization
capsule, 30 mg	*Bristol-Myers Squibb (Africa Export Division) , Cipla Ltd., Cosmos Limited, Emcure Pharmaceuticals Limited, Lab. Filaxis International S.A., Nuevas Tecnologías Farmaceuticas, Ranbaxy Laboratories Ltd, Strides Arcolab Ltd., The Government Pharmaceutical Organization
capsule, 40 mg	*Bristol-Myers Squibb (Africa Export Division) , Cipla Ltd., Cosmos Limited, Emcure Pharmaceuticals Limited, Lab. Filaxis International S.A., Protein S.A. DE C.V. (Apotex), Ranbaxy Laboratories Ltd, Samchully Pharm. Co., Ltd., *Strides Arcolab Ltd. , The Government Pharmaceutical Organization
syrup, 1 mg/ml	Bristol-Myers Squibb (Africa Export Division), The Government Pharmaceutical Organization
zalcitabine (ddC)	
tablet, 0.375 mg	*F. Hoffmann-La Roche Ltd. ^{NPI} , Protein S.A. DE C.V. (Apotex)
tablet, 0.75 mg	*F. Hoffmann-La Roche Ltd. ^{NPI} , Lab. Filaxis International S.A., Protein S.A. DE C.V. (Apotex)
zidovudine (AZT or ZDV)	
oral solution, 50 mg/5 ml	*Cipla Ltd. , *Combino Pharm, S.L. , Emcure Pharmaceuticals Limited, *GlaxoSmithKline Export Ltd. , Lab. Filaxis International S.A., The Government Pharmaceutical Organization
solution for IV infusion/injection, 10 mg/ml in 20-ml vial	*GlaxoSmithKline Export Ltd. , Lab. Filaxis International S.A.
tablet/capsule, 100 mg	*Cipla Ltd. , *Combino Pharm, S.L. , Cosmos Limited, Emcure Pharmaceuticals Limited, *GlaxoSmithKline Export Ltd. , Lab. Filaxis International S.A., Protein S.A. DE C.V. (Apotex), Samchully Pharm. Co., Ltd., The Government Pharmaceutical Organization
tablet/capsule, 250 mg	*Combino Pharm, S.L. , *GlaxoSmithKline Export Ltd. , Lab. Filaxis International S.A., Protein S.A. DE C.V. (Apotex), Samchully Pharm. Co.
tablet/capsule, 300 mg	*Cipla Ltd. , *Combino Pharm, S.L. , Cosmos Limited, Emcure Pharmaceuticals Limited, *GlaxoSmithKline Export Ltd. , Nuevas Tecnologías Farmaceuticas, Ranbaxy Laboratories Ltd, Samchully Pharm. Co., Ltd., Strides Arcolab Ltd., The Government Pharmaceutical Organization
Antiviral medicines – Antiretrovirals (combinations)	
3TC+AZT	
tablet, 150+300 mg	*Cipla Ltd. , Cosmos Limited, Emcure Pharmaceuticals Limited, *GlaxoSmithKline Export Ltd. , Lab. Filaxis International S.A., Nuevas Tecnologías Farmaceuticas, Ranbaxy Laboratories Ltd, Strides Arcolab Ltd., The Government Pharmaceutical Organization
3TC+d4T	
tablet, 150+30 mg	Cosmos Limited, Emcure Pharmaceuticals Limited, Ranbaxy Laboratories Ltd
tablet, 150+40 mg	Cipla Ltd., Cosmos Limited, Emcure Pharmaceuticals Limited, Ranbaxy Laboratories Ltd, *Strides Arcolab Ltd.
3TC+d4T+NVP	
tablet, 150+30+200 mg	*Cipla Ltd. , Cosmos Limited, Emcure Pharmaceuticals Limited, Nuevas Tecnologías Farmaceuticas, Ranbaxy Laboratories Ltd, Strides Arcolab Ltd., The Government Pharmaceutical Organization
tablet, 150+40+200 mg	*Cipla Ltd. , Cosmos Limited, Emcure Pharmaceuticals Limited, Nuevas Tecnologías Farmaceuticas, Ranbaxy Laboratories Ltd, Strides Arcolab Ltd., The Government Pharmaceutical Organization
ABC+3TC+ZDV	
tablet, 300+150+300 mg	*GlaxoSmithKline Export Ltd. , Ranbaxy Laboratories Ltd
AZT+3TC+NVP	
tablet, 300+150+200 mg	Cipla Ltd., Emcure Pharmaceuticals Limited

TABLE 2. ANTINEOPLASTIC MEDICINES**Cytotoxic medicines**

bleomycin	
powder for injection, 15 mg (as sulfate) in vial	Aventis Intercontinental, Cipla Ltd., Korea United Pharm. Inc., Neon Antibiotics PVT. Ltd., Nippon Kayaku
calcium folinate (leucovorin)	
tablet, 15 mg	Ecobi Farmaceutici S.a.s., Korea United Pharm. Inc., Lab. Filaxis International S.A., Medac GmbH, International Operations
doxorubicine HCl	
powder for injection, 10 mg in 5-ml vial	Cipla Ltd., Intas Pharmaceuticals Ltd, Korea United Pharm. Inc., Lab. Filaxis International S.A., Medac GmbH, International Operations, Neon Antibiotics PVT. Ltd.
powder for injection, 50 mg in 25-ml vial	Cipla Ltd., Intas Pharmaceuticals Ltd, Korea United Pharm. Inc., Lab. Filaxis International S.A., Medac GmbH, International Operations, Neon Antibiotics PVT. Ltd.
etoposide	
capsule, 100 mg	Nippon Kayaku
injection, 20 mg/ml in 5-ml ampoule	Cipla Ltd., Intas Pharmaceuticals Ltd, Korea United Pharm. Inc., Lab. Filaxis International S.A., Medac GmbH, International Operations, Neon Antibiotics PVT. Ltd., Nippon Kayaku
methotrexate	
injection, 25 mg/ml (as sodium salt) in 2-ml vial	Aventis Intercontinental, Korea United Pharm. Inc., Neon Antibiotics PVT. Ltd.
powder for injection, 50 mg (as sodium salt) in 2-ml vial	Aventis Intercontinental, Lab. Filaxis International S.A., Neon Antibiotics PVT. Ltd.
tablet, 2.5 mg	Aventis Intercontinental, Cipla Ltd., Korea United Pharm. Inc., Neon Antibiotics PVT. Ltd., Remedica Ltd.
vinblastine	
powder for injection, 10 mg (sulfate) in 10-ml vial	*Cipla Ltd., Korea United Pharm. Inc., Lab. Filaxis International S.A., Neon Antibiotics PVT. Ltd.
vincristine	
powder for injection, 1 mg (sulfate) in 1-ml vial	*Cipla Ltd., Korea United Pharm. Inc., Neon Antibiotics PVT. Ltd.
powder for injection, 5 mg (sulfate) in vial	Korea United Pharm. Inc.
vinorelbine	
injection concentrate, 10 mg/ml in vial	Lab. Filaxis International S.A., Neon Antibiotics PVT. Ltd.

TABLE 3. PSYCHOTHERAPEUTIC MEDICINES**Medicines used in depressive disorders**

amitriptyline	
tablet, 25 mg (as hydrochloride)	Cosmos Limited, Instituto Quimioterapico S.A.(IQFARMA), Intas Pharmaceuticals Ltd, Remedica Ltd., The Government Pharmaceutical Organization
fluoxetine	
tablet, 20 mg	Cadila Pharmaceuticals Ltd., Combino Pharm, S.L., Korea United Pharm. Inc., Laboratorios Cinfa S.A., Lilly España, Lisapharma, Pharmathen Pharmaceuticals S.A., Remedica Ltd.

Medicines used in generalized anxiety and sleep disorders

diazepam	
injection, 5 mg/ml in 2-ml ampoule	F. Hoffmann-La Roche Ltd.NPI, Lab. Renaudin, Neon Laboratories Limited, Rotexmedica, SM Pharmaceuticals Sdn Bhd, Warsaw Pharmaceutical Works Polfa, S.A.
tablet, 5 mg	Alpharma, Cosmos Limited, F. Hoffmann-La Roche Ltd.NPI, Intas Pharmaceuticals Ltd, Korea United Pharm. Inc., Lomapharm, Rudolf Lohmann GmbH KG, Remedica Ltd.

lorazepam	
injection, 4 mg/ml in 1-ml ampoule	Remedica Ltd.
tablet, 1 mg	Lomapharm, Rudolf Lohmann GmbH KG, Pharmathen Pharmaceuticals S.A.
methotrimepazine/levomepromazine	
tablet, 25 mg	Aventis Intercontinental, Pharmadrug

TABLE 4. ANALGESICS

Medicines used in substance dependence

naltrexone HCl	
tablet, 50 mg	Intas Pharmaceuticals Ltd, Lachifarma, SRL

Opioid analgesics

codeine	
tablet, 30 mg (phosphate)	Cosmos Limited, Lomapharm, Rudolf Lohmann GmbH KG, Remedica Ltd.

methadone HCl	
oral solution, 5 mg/5 ml	Martindale Pharmaceuticals Ltd.

morphine	
injection, 10 mg/ml (sulfate or HCl), in 1-ml ampoule	Lab. Renaudin, Warsaw Pharmaceutical Works Polfa, S.A.

pethidine	
injection, 50 mg/ml (hydrochloride) in 1-ml ampoule	Martindale Pharmaceuticals Ltd., Neon Laboratories Limited
injection, 50 mg/ml (hydrochloride) in 2-ml ampoule	Lab. Renaudin, Martindale Pharmaceuticals Ltd., Neon Laboratories Limited, Pharmadrug
tablet, 50 mg	Martindale Pharmaceuticals Ltd.

TABLE 5. GASTROINTESTINAL MEDICINES

Antacids and other antiulcer medicines

omeprazole	
capsule, 10 mg	Cipla Ltd., Mepha Ltd, Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd., SM Pharmaceuticals Sdn Bhd
capsule, 20 mg	Alembic Ltd., Apex Drug House, Aristo Pharmaceuticals Ltd., Cadila Pharmaceuticals Ltd., Cipla Ltd., Cosmos Limited, Pharmaceutical Industry, Emcure Pharmaceuticals Limited, Instituto Quimioterapico S.A.(IQFARMA), Intas Pharmaceuticals Ltd, Korea United Pharm. Inc., Laboratorios Andr�maco S.A., Laboratorios Cinfa S.A., Laboratorios Juventus S.A., Mepha Ltd, Nuevas Tecnolog�as Farmaceuticas, Pharmathen Pharmaceuticals S.A., Protein S.A. DE C.V. (Apotex), Remedica Ltd., Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd., SM Pharmaceuticals Sdn Bhd, Strides Arcolab Ltd.
capsule, 40 mg	Laboratorios Andr�maco S.A., Mepha Ltd, Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
powder for injection, 40 mg (as sodium salt) in vial	Neon Antibiotics PVT. Ltd.
powder for IV infusion, 40 mg (as sodium salt) in vial	Neon Antibiotics PVT. Ltd.

Antiemetic medicines

dimenhydrinate	
tablet, 50 mg	Instituto Quimioterapico S.A.(IQFARMA), Laboratorios Cinfa S.A., Lomapharm, Rudolf Lohmann GmbH KG, Protein S.A. DE C.V. (Apotex), The Government Pharmaceutical Organization

metoclopramide

injection 5 mg/ml in 2-ml ampoule	Apex Drug House, CLARIS Lifesciences Ltd., Intas Pharmaceuticals Ltd, Lab. Renaudin, Neon Laboratories Limited, The Government Pharmaceutical Organization
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tablet, 10 mg (as hydrochloride)	Alpharma, Cosmos Limited, Instituto Quimioterapico S.A.(IQFARMA), Lomapharm, Rudolf Lohmann GmbH KG, Protein S.A. DE C.V. (Apotex), Remedica Ltd.
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prochlorperazine

injection, 12.5 mg/ml	Pharmadrug
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tablet, 5 mg	Remedica Ltd.
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promethazine

elixir or syrup, 5 mg/5 ml (HCl)	Beltapharm SpA, Purna Pharmaceuticals NV, Shiba Pharmaceuticals & Chemicals Mfg.Co.Ltd.
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injection, 25 mg/ml (hydrochloride) in 2-ml ampoule	Pharmaceutical Industry, Lab. Renaudin, Neon Laboratories Limited
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tablet, 10 mg	Remedica Ltd.
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tablet, 25 mg	Artesan Pharma GmbH & Co. KG, Cosmos Limited, Remedica Ltd.
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Laxatives**senna**

capsule, 7.5 mg	Cosmos Limited
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ANNEX 3

Further reading, reference and contacts

General – HIV/AIDS

- *Progress on global access to HIV antiretroviral therapy: an update on “3 by 5”, June 2005.* UNAIDS/WHO, Geneva, 2005.
- *Forecasting of antiretrovirals and diagnostics: Report of a WHO-UNICEF technical consultation.* WHO, Geneva, 2004.
- *Two pills a day saving lives: Fixed-dose combinations (FDCs) of antiretroviral drugs.* MSF, Geneva, 2004.
- *Treating 3 million by 2005: Making it happen.* UNAIDS/WHO, Geneva, 2003.
- *Human capacity-building plan for scaling up HIV/AIDS treatment.* WHO, Geneva, 2003.
- *A public health approach for scaling up antiretroviral (ARV) treatment. A toolkit for programme managers.* WHO, Geneva, 2003.
- *Handbook on access to HIV/AIDS-related treatment. A collection of information, tools and resources for NGOs, CBOs and PLWA groups.* Joint publication UNAIDS, WHO and International AIDS Alliance, Geneva, 2003.
- *Monitoring and evaluating of national ART programmes in the rapid scale-up to 3 by 5.* Draft document. WHO, Geneva, 2003.
- *Guidelines for surveillance of HIV drug resistance.* Draft document. WHO, Geneva, 2003.
- *A commitment to action for expanded access to HIV/AIDS treatment.* International HIV Treatment Access Coalition. WHO, Geneva, 2002 (WHO/HIV/2002.24).
- Berwick D. “We All Have AIDS”: The case for reducing the cost of HIV medicines to zero”. *British Medical Journal*, 2002, 324:214–218.

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- *The selection and use of essential medicines. Report of the WHO Expert Committee, 2005 (including the 14th Model List of Essential Medicines).* WHO, Geneva, 2005.
- *WHO Model Formulary 2004.* WHO, Geneva, 2004.

- *Guidelines for price discounts of single-source pharmaceuticals (interagency document).* WHO, Geneva, 2003. (WHO/EDM/PAR/2003.3).
- Levison L. *Policy and programming options for reducing the procurement costs of essential medication in developing countries.* Boston University School of Public Health, 2003.
- *Guidelines for drug donations (interagency document).* WHO, Geneva, 1999 (WHO/EDM/PAR/99.4).
- *Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies (interagency guidelines).* WHO, Geneva, 1999 (WHO/EDM/PAR/99.2).

Procurement guides

- *HIV/AIDS Medicines and related supplies: Contemporary context and procurement. Technical Guide.* World Bank, Washington, DC, 2004.
- *Surmounting challenges: Procurement of antiretroviral medicines in low- and middle-income countries.* WHO/MSF, Geneva, 2003.
- *Managing Drug Supply.* 2nd edition. WHO and Management Sciences for Health, Arlington, VA, 2003. <http://www.kpbooks.com/details.asp?title=Managing+Drug+Supply>
- WHO HIV test kit bulk procurement scheme. Flyer, 2002.
- *Operational principles for good pharmaceutical procurement (interagency document).* WHO, Geneva, 1999 (WHO/EDM/PAR/99.5).

Intellectual property rights and pharmaceuticals

- *HIV/AIDS medicines and related supplies: Contemporary context and procurement. Technical guide. Chapter 2 and Annex B.* World Bank, Washington, DC, 2004.
- *Determining the patent status of essential medicines in developing countries. Health economics and drugs.* EDM series number 17. WHO, Geneva, 2004 (WHO/EDM/PAR/2004.6).
- *Drug patents under the spotlight: sharing practical knowledge about pharmaceutical patents.* MSF, Geneva, 2004.

- *Globalization, patents and drugs. An annotated bibliography.* Health Economics and Drugs series number 9. WHO, Geneva, 2002 (EDM/PAR/2001.1).
- *Implications of the DOHA Declaration on the TRIPS Agreement and public health.* WHO, Geneva, 2002. (WHO/EDM/PAR/2002.3).
- *Network for monitoring the impact of globalization and TRIPS on access to medicines.* Health Economics and Drugs series number 11. WHO, Geneva, 2002 (WHO/EDM/PAR/2002.1).
- *Globalization, TRIPS and access to pharmaceuticals.* WHO Policy Perspectives on Medicines number 3. WHO, Geneva, 2001.
- *Patent situation of HIV/AIDS-related drugs in 80 countries.* UNAIDS/WHO, Geneva, 2000.
- *Globalization and access to drugs: Perspectives on the WTO/TRIPS Agreement.* Health Economics and Drugs Series number 7 (revised). WHO, Geneva, 1999 (WHO/DAP/98.9 Rev).
- *Integrated management of adolescent and adult illness (IMAI) modules.* WHO, Geneva, 2004 (WHO/CDS/IMAI/2004.1).
- *Saving mothers, saving families: The MTCT-Plus Initiative. Perspectives and practice in antiretroviral treatment.* Case study. WHO, Geneva, 2003.
- *Guidelines for the management of sexually transmitted infections.* WHO, Geneva, 2003.
- *Scaling up antiretroviral therapy in resource limited settings: Treatment guidelines for a public health approach.* WHO, Geneva, 2003.
- *Provision of antiretroviral therapy in resource-limited settings: A review of experience up to August 2003.* WHO and UK Department for International Development, 2003.
- *HIV/AIDS care and treatment: A clinical course for people caring for people living with HIV/AIDS.* Family Health International, Arlington, VA, 2003.
- *AIDS Palliative Care: UNAIDS.* Technical Update, October 2000.

Pricing strategies

- *Drug Price Information Services: What is WHO doing to improve drug price information?* WHO Information Sheet.
- *Medicine prices: a new approach to measurement.* WHO and Health Action International, Geneva, 2003 (WHO/EDM/PAR/2003.2).
- *Medicines prices: data base with survey results.* WHO and Health Action International: <http://www.haiweb.org/medicineprices/>
- *Cost-containment mechanisms for essential medicines, including antiretrovirals, in China.* WHO, Geneva, 2003 (WHO/EDM/PAR/2003.6).
- *Public-private roles in the pharmaceutical sector. Implications for equitable access and rational drug use.* WHO, Geneva, 1997 (WHO/DAP/97.12).
- *Alternative drug pricing policies in the Americas.* WHO, Geneva, 1995 (WHO/DAP/95.6).
- *Essential Drugs Monitor.* Number 33. WHO, Geneva, 2003.

Treatment guidelines

- *Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants.* WHO, Geneva, 2004.
- *Antiretroviral drugs and the prevention of mother-to-child transmission of HIV infection in resource-limited settings.* Draft document. WHO, Geneva, 2004.

Substance abuse

- *Evidence for action: Effectiveness of community-based outreach in preventing HIV/AIDS among injecting drug users.* WHO, Geneva, 2004.
- *Practices and context of pharmacotherapy of opioid dependence in Central and Eastern Europe.*
- *Training guide for HIV prevention outreach to injecting drug users.* Workshop Manual. WHO, Geneva, 2004.
- *Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention.* WHO/UNODC/UNAIDS position paper. WHO, Geneva, 2004.
- *Neuroscience of psychoactive substance use and dependence.*

HIV testing

- *HIV simple/rapid assays: operational characteristics.* Report 14. WHO/UNAIDS, Geneva, 2004.
- *Rapid HIV tests. Guidelines for use in HIV testing and counselling services in resource-constrained settings.* WHO, Geneva, 2004.
- *Increasing access to HIV testing and counselling. Report of a WHO Consultation, 19–21 November 2002.* WHO, Geneva, 2003.
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TB/HIV

- *Interim policy on collaborative TB/HIV activities.* WHO, Geneva, 2004 (WHO/HTM/TB/2004.330).
- *Guidelines for HIV surveillance among tuberculosis patients.* Second edition. WHO, Geneva, 2004 (WHO/HTM/TB/2004.339).
- *TB/HIV clinical manual.* WHO, Geneva, 2004 (WHO/HTM/TB/2004.329).

Websites

Partner sites

- **UNAIDS:** www.unaids.org
- **UNICEF:** www.unicef.org
- **WHO:** www.who.int
- **MSF:** www.msf.org

Other websites for information related to HIV/AIDS activities

- UNAIDS/WHO Global HIV/AIDS Online Database: <http://www.who.int/globalatlas/default.asp>
- The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM): <http://www.theglobalfund.org/en/>
- The President's Emergency Plan for AIDS Relief (PEPFAR): http://www.usaid.gov/our_work/global_health/aids/pepfar.html and on <http://www.avert.org>
- Clinton Foundation: <http://www.clintonfoundation.org/>
- AIDS Education Global Information System: <http://www.aegis.com>
- International HIV/AIDS Alliance: <http://www.aidsalliance.org/>
- John Snow Inc/DELIVER: <http://deliver.jsi.com>
- Management Sciences for Health: <http://www.msh.org/>

Other websites for information related to STI activities

- Sexually transmitted infections: http://www.who.int/topics/sexually_transmitted_infections/en/
- Sexually transmitted diseases and diagnostics initiative: http://www.who.int/std_diagnostics/

Other websites for information related to TB activities

- The Global TB Drug Facility: <http://www.stoptb.org/GDF/>
- DOTS-plus for multidrug resistant TB: <http://www.who.int/gtb/policyrd/DOTSpplus.htm>
- Stop TB Partnership: <http://www.stoptb.org>

Contacts

For further information about suppliers or products, please contact:

Sources of Medicines for HIV/AIDS Survey
Pharmaceutical and Micronutrients Team
UNICEF Supply Division
Fax: +45 35 269421
E-mail: supply@unicef.org

For further information on HIV test kit evaluation or the bulk procurement scheme, please contact:

Essential Health and Technologies (EHT)
World Health Organization
Fax +41 22 791 4836

For any comments on this document, or additional information that could be useful to this project, please complete the feedback form, Annex 5.

ANNEX 4

Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries

company
price
price
eligibility
countries
reductions
reductions

Untangling the web of price reductions:

a pricing guide for the purchase of ARVs for developing countries

8th Edition

June 2005

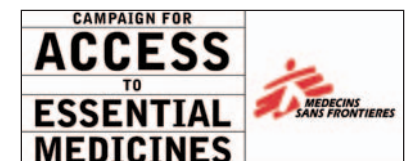


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1. General background and objectives

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.

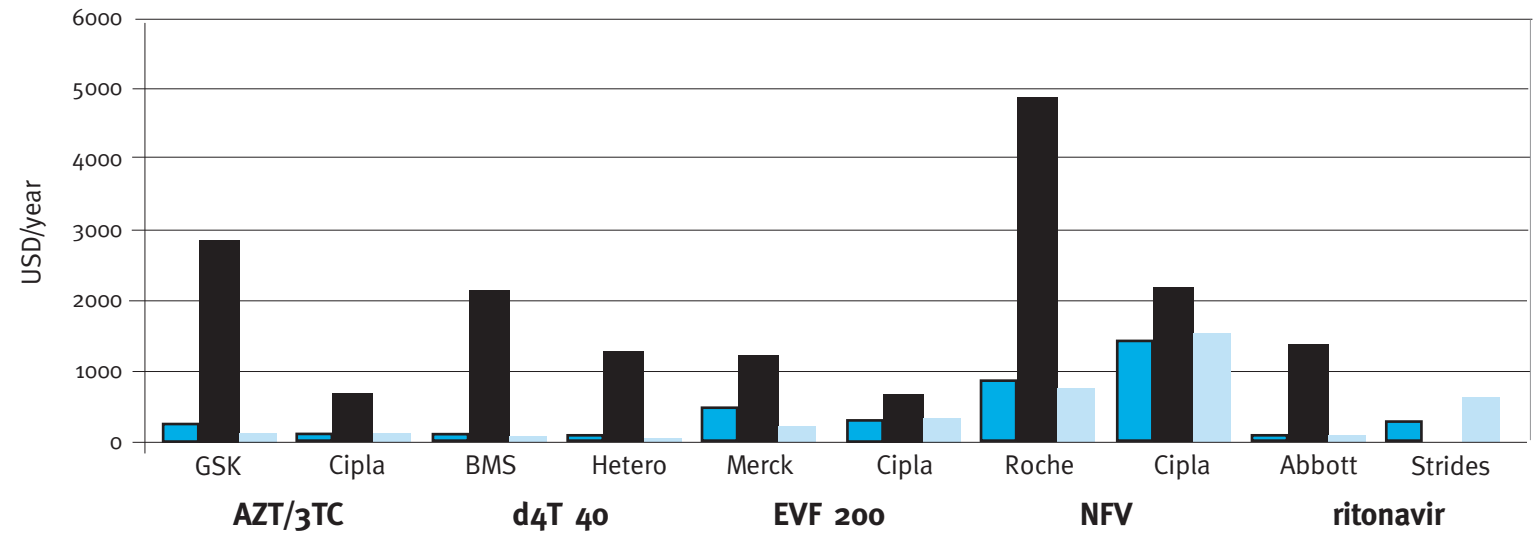
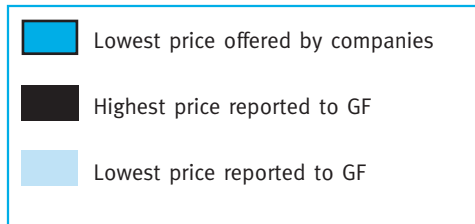
Despite the exemptions and the existence of specific second category prices for some products, prices paid in middle-income countries are still much higher than the offers published in this report (graph 1).

- 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.

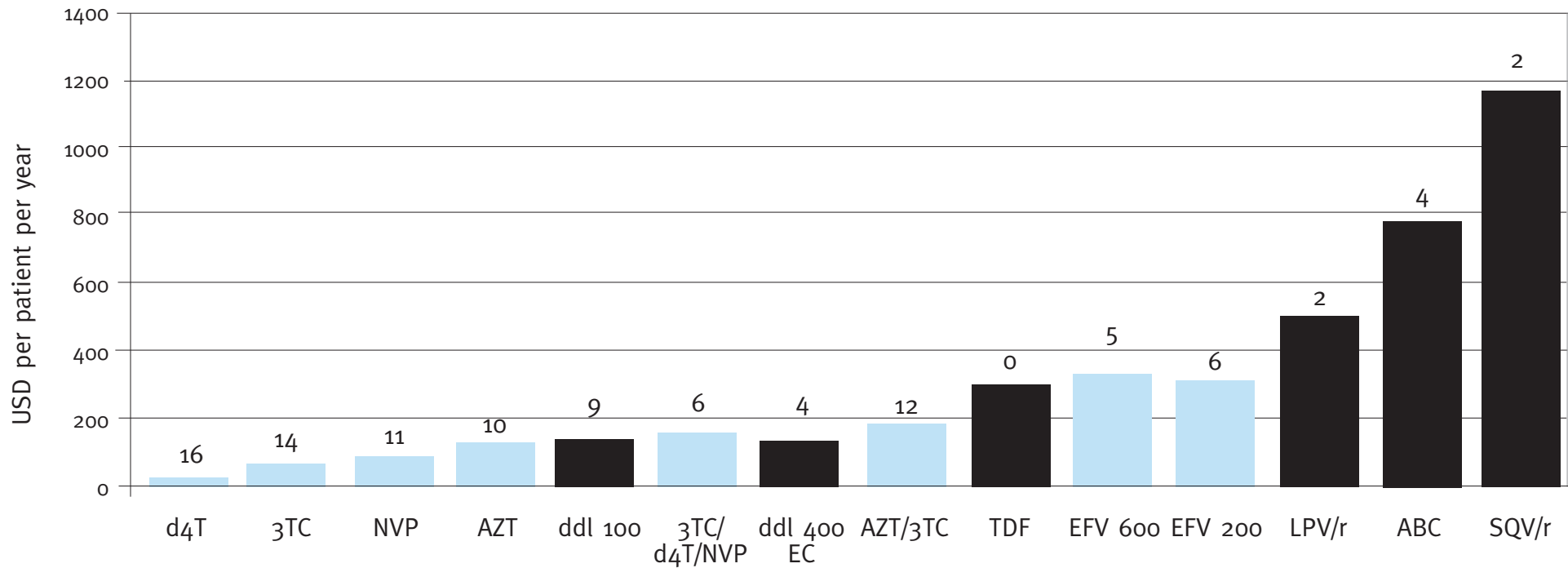
Comparison between prices published in this report and prices reported by Global Fund

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.

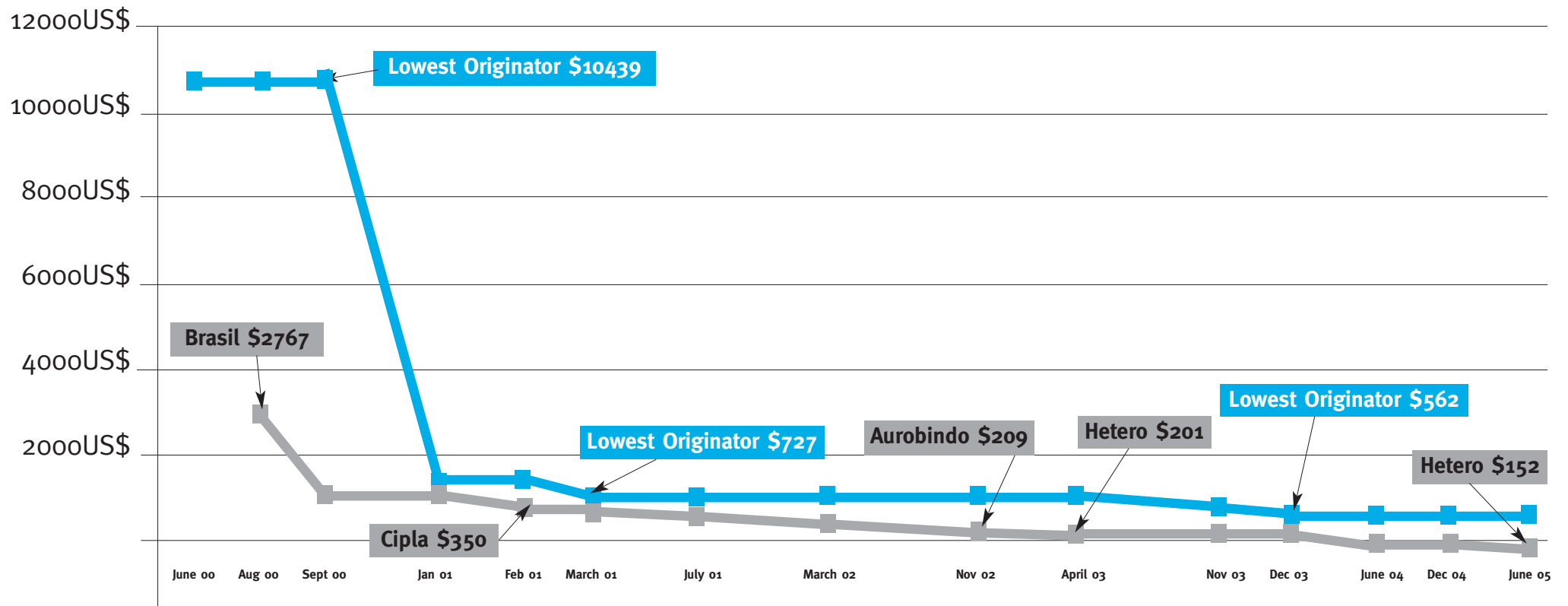
Prices of medicines recommended as 1st and 2nd line by WHO. June 2005



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

Abbott:

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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

Feedback, application and corrections form

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