Access to Antiretroviral Therapy in Uganda
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Executive Summary

Recent (2002) estimates place the number of HIV-infected Ugandans at between 1.5 and 2 million. According to the United Nations AIDS Programme (UNAIDS), between 5,000 and 10,000 HIV-infected people are currently on antiretroviral therapy, which includes patients on both branded and generic drugs. In an effort to increase access to antiretrovirals (ARVs) and to improve the quality of care and treatment of HIV-infected patients, the United Nations has introduced two initiatives in Uganda: the Drug Access Initiative (DAI) in 1998 and the Accelerating Access Initiative (AAI) in 2000. The latter emerged out of an agreement in May 2000 between the UN and five pharmaceutical companies to rapidly increase access to ARVs in developing countries, primarily through price reductions.

Significant price reductions, however, were not observed in Uganda until the importation of generic ARVs in October 2000 by the Joint Clinical Research Centre (JCRC). JCRC is the largest provider of ARVs in Uganda (it dispenses approximately 40-70 per cent of all ARVs administered, both branded and generic), and has approximately 3,400 active patients. In 2001, shortly after generics were introduced, the number of patients accessing ARVs at JCRC increased from 962 to 3,000; this represented an increase of 200 per cent. All but one of the generic ARVs currently imported have recently been registered with the Ugandan Drug Authority. Prior to registration, JCRC imported the drugs on a provisional import permit, which it still uses to import Triomune, a generic combination product made by Indian pharmaceuticals company Cipla.

Médecins sans Frontières – France (MSF-F), a medical and relief NGO, is also importing generic ARVs for patients registered in its pilot HAART (Highly Active Antiretroviral Therapy) Programme in the northwestern town of Arua.

Legislation and international agreements also affect access to medicines. Uganda, like other members of the World Trade Organisation, is obliged under the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement to protect all categories of intellectual property, including pharmaceuticals. In an attempt to comply with TRIPS, the Ugandan Law Reform Committee has drafted an Industrial Property Bill (IP Bill). Some argue that the Bill is premature, as Uganda has until 2006 to comply with TRIPS.

The proposed IP Bill does not take advantage of the 2016 extension to patent pharmaceuticals provided by the Doha Declaration. It does, however, potentially provide other important safeguards, such as compulsory licensing, government use, and Article 30 exceptions. Critics of the Bill say it is confusing and the terms it uses need further clarification to take full advantage of the Doha Declaration. This is especially true with regard to compulsory licensing.

In conclusion, while access to ARVs has increased, mainly due to price reductions led by the importation of generics, the great majority of HIV-infected Ugandans still cannot afford to pay for therapy. The least expensive triple-drug regimen available in Uganda, generic Triomune, costs US$40 per month. This can represent 30 to 90 per cent of an average monthly income of $50-$150 in Kampala. In rural areas incomes are much lower. Other HAART combinations – especially those involving a protease inhibitor-based regimen – are even costlier.

In order to increase access to ARVs (whether branded or generic), a stronger government commitment to providing access to treatment is required. The government and the international community should encourage further price reductions through generic competition and through the adoption of intellectual property rights that maximise the use of the Doha Declaration, including the extension of the grace period to 2016. The international community should enhance the generic production of ARVs for export, enabling countries such as Uganda, which has limited manufacturing capacity of its own, to import generics from other countries.

The government should also increase investment in health services, including the provision of technical training to health workers and the expansion of geographical access, with support from donors, including the Global Fund on AIDS, Tuberculosis and Malaria.

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Abbreviations

AAI = Accelerating Access Initiative
ACP = Aids Control Programme
AIDS = Acquired Immune Deficiency Syndrome
ARIPO = African Regional Industrial Property Organisation
ART = Antiretroviral therapy
ARVs = Antiretrovirals
BI = Boehringer Ingelheim
BMS = Bristol-Myers Squibb
DAI = Drug Access Initiative
GFATM = Global Fund on AIDS, Tuberculosis and Malaria
GSK = GlaxoSmithKline
HAART = Highly Active Antiretroviral Therapy
HEPS = Health Promoting and Social Development Coalition
HIV = Human Immune Deficiency Virus
IP = Industrial Property
JCRC = Joint Clinical Research Centre
MU = Makerere University
MOH = Ministry of Health
MSD = Merck Sharp & Dohme
MSF-F =Médecins sans Frontières – France
NDA = National Drug Authority
NGO = Non-governmental organisation
OI = Opportunistic infection
PI = Protease inhibitor
STD = Sexually transmitted disease
TRIPS = Trade Related Aspects of Intellectual Property Rights Agreement
UN = United Nations
UNAIDS = United Nations AIDS Programme
USAID = United States Agency for International Development
WHO = World Health Organisation
WTO = World Trade Organisation

1. Introduction

The dramatic decrease in morbidity and mortality seen in resource-rich settings due to the introduction of HIV antiretroviral therapies has not been experienced in developing countries. Even though resource-poor countries account for over 90 per cent of HIV infection worldwide, relatively few have access to treatment with ARVs. The principal barrier to access is the high cost of treatment in relation to per capita incomes and public health expenditures. People make great sacrifices in order to provide life-saving therapy to HIV-infected family members. Cost not only affects initial access but adherence to treatment as well. Incomplete adherence or limited treatment will provide little benefit to the patient, yet places exceptional burdens on the family income. It may also encourage drug resistance.

This research is an attempt to understand the current situation in Uganda in terms of access to ARVs. It describes what role generic alternatives to branded ARVs have played in reducing prices and increasing access to antiretroviral therapies (ART). In addition, it reviews the laws governing pharmaceutical patents in Uganda, as well as the newly proposed Industrial Property Bill 2002 (IP Bill). Finally, the thoughts and comments of some HIV-infected patients regarding affordability of medications are also included.

2. Methods

This document is a collection of data gathered from three principal sources:

A) Informal discussions with representatives of the following:
   a. Five HIV/AIDS treatment centres in greater Kampala:
      - Joint Clinical Research Centre (JCRC)
      - St. Francis Nsambya Hospital
      - Mulago Hospital
      - Mildmay Centre
      - Mengo Hospital
   b. UNAIDS
   c. Ugandan Ministry of Health
   d. Medical Access Uganda Limited
   e. Representatives of pharmaceutical companies:
      - Star Pharmaceutical (MSD, BMS)
      - Shurik Limited (Cipla)
      - Surgipharm (BI, GSK, although GSK provides drugs directly to treatment centres from Kenya)
      - House and McGeorge Laborex (F. Hoffman-La Roche)
   f. Ugandan AIDS Control Programme
   g. National Drug Authority
   h. Registrar of patents
   i. Ugandan patent lawyer
   j. Médecins sans Frontières – France (MSF-F)

B) Review of documents and articles prepared by relevant groups, including Ministry of Health, NGOs, UNAIDS, WHO, WTO, MSF, ARIPO. The proposed IP Bill, National Drug Policy and current patent laws were also reviewed.

C) Interviews with patients accessing ARVs.

3. UNAIDS HIV/AIDS Drug Initiatives in Uganda

Two United Nations (UN)-sponsored initiatives were introduced in an effort to increase access to ARVs and improve the quality of care and treatment for HIV-infected patients in Uganda: the Drug Access Initiative and the Accelerating Access Initiative.

3.1. Drug Access Initiative (DAI)

In November 1997, UNAIDS launched the Drug Access Initiative (DAI) in Uganda, a two-year pilot programme which operated between June 1998 and July 2000. The goal of the DAI was to 'create the proper environment and induce relevant changes in health care delivery systems to improve access to HIV/AIDS drugs'. A National Advisory Board was appointed by the Ministry of Health (MOH) to oversee the implementation of the initiative. In addition, a non-profit, autonomous organisation, Medical Access Uganda Limited, was established and given responsibility for the procurement and distribution of ARVs, supplied by participating pharmaceutical companies at subsidised prices.

Although pharmaceutical companies did offer some price reductions for certain ARVs, the price of treatment was still out of reach for the great majority of HIV/AIDS patients in Uganda. UNAIDS found the approximate cost of treatment was $1,000 per month for brand-name drugs before the introduction of generic equivalents.

An evaluation of the pilot phase of the DAI was conducted by UNAIDS in collaboration with other partner institutions in August 2000. The evaluation found that a total of 912 HIV/AIDS patients accessed antiretroviral therapy during the two-year pilot phase. These patients were seen at five UNAIDS-accredited centres of excellence in Kampala. The accredited centres were:

- JCRC
- St. Francis Nsambya Hospital
- Mildmay Clinic
- Mulago Hospital
- Mengo Hospital.

According to Dr. Cissy Kityo, Deputy Director of JCRC (Research and Clinical) – the largest provider of ARVs in Uganda, and the first centre to gain UNAIDS accreditation – the significant accomplishments of the DAI were: 1) to bring ARVs to a central location, via Medical Access Uganda Ltd; 2) to train health care workers; and 3) to build a basic infrastructure. However, the programme fell short of improving access through significant price reductions.

3.2. Accelerating Access Initiative (AAI)

The AAI emerged out of a partnership formed between the UN and five pharmaceutical companies and was intended to rapidly increase access to ARVs in selected developing countries through significant price reductions. The five companies to sign a Joint Statement of Intent in May 2002, thereby initiating the partnership, were Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck and Hoffman-La Roche. The new initiative used the data already collected by the DAI and expanded its scope.

However, the agreement initiating the AAI did not provide any guidelines for relations between the pharmaceutical corporations and the developing countries. The former have thus taken their negotiations directly to governments or providers of health services, on a country-by-country, drug-by-drug, bilateral basis. In Uganda, it is unclear what agreements were made between the pharmaceutical companies and the government. The researchers were unable to access the documents delineating the agreement, and there is uncertainty regarding its stipulations and provisions.

As a result of the AAI, UNAIDS has provided technical support and training to an additional nine treatment centres, increasing the number of accredited centres of excellence in Uganda to 14 (10 in Kampala and four in other major towns). The following centres are supplied with ARVs by Medical Access Uganda Limited, with the exception of Victoria Medical Centre, which does not dispense them:

1. Joint Medical Research Centre (JCRC)*
2. St. Francis Nsambya Hospital
3. Mildmay Clinic
4. Mulago Hospital
5. Mengo Hospital
6. Bank of Uganda Clinic
7. Case Clinic
8. Africa Air Rescue
9. International Medical Centre
10. Victoria Medical Centre
11. Mbarara Regional Hospital*
12. Masaka Regional Hospital
13. Kabale Regional Hospital
14. Gulu Regional Hospital

*These centres are also accessing generic ARVs from Cipla (the Indian generic company), imported by JCRC.

4. Prices and Access to Antiretroviral Therapy in Uganda

The Sexually Transmitted Diseases/AIDS Control Programme (STD/ACP) Unit of the Ugandan Ministry of Health estimates that, as of December 1999, there were 1,438,000 people living with HIV/AIDS in Uganda, a country with a total population of 22 million. Recent (2002) estimates

place the number of HIV-infected Ugandans at between 1.5 and 2 million. According to UNAIDS, between 5,000 and 10,000 HIV-infected persons are currently on antiretroviral therapies, including patients on generic as well as branded drugs.

4.1. Description of Coverage at Five Treatment Centres in Kampala

As previously mentioned, JCRC is the largest provider of ARVs in Uganda. With 8,000 patients currently registered and approximately 3,400 on HAART (Highly Active Antiretroviral Therapy) regimens, JCRC dispenses roughly 40-70 per cent of all ARVs in Uganda.

JCRC was created in 1990 with USAID funding in an effort to provide quality treatment and care for HIV/AIDS patients. It is a joint project of the Ministry of Defence (the largest stakeholder), the Ministry of Health and Makerere Medical School. Although it is an offshoot of government ministries, JCRC functions as an autonomous, semi-private entity.

Unlike JCRC, other centres focus primarily on treating opportunistic infections (OIs) and providing palliative care to HIV/AIDS patients. The majority of patients registered at these centres cannot afford ARV therapy (either branded or the less expensive generic alternatives). Table 1 below shows the number of persons registered and the number currently on ARVs at five sample treatment centres in Kampala. These treatment centres were the initial UNAIDS-accredited centres of excellence.

Table 1: Coverage at Five Treatment Centres in Kampala – June 2002

Treatment Centre	Approximate number of patients registered	Approximate number of patients on HAART
JCRC (non-profit)	8,000	3,400
Nsambya Hospital (non-profit)*	13,000	450
Mildmay Centre (non-profit – collaboration between MOH and Mildmay International)	4,204	130
Mulago Hospital (public)**	17,000 (since 1990)	0
Mengo Hospital (public and private wing)	10,000 (since early 1990s)	0 (dispensed during DAI pilot phase only; restarted dispensing in July 2002)

* Outpatients not included
** Patients seen at private wing not included

The above data indicates that the number of patients accessing ARVs is very low in comparison with the number registered at each clinic. In the case of Mulago Hospital, for example, the majority of patients are not even informed about ARV treatment options, as the costly nature of these makes them inaccessible. Dr. Moses Kamya, Co-Director of the HIV clinic, says, 'Why should we tell patients about ARVs when they will not be able to buy them? It will just make them more depressed.' The few that do inquire about ARVs are commonly referred to JCRC, the

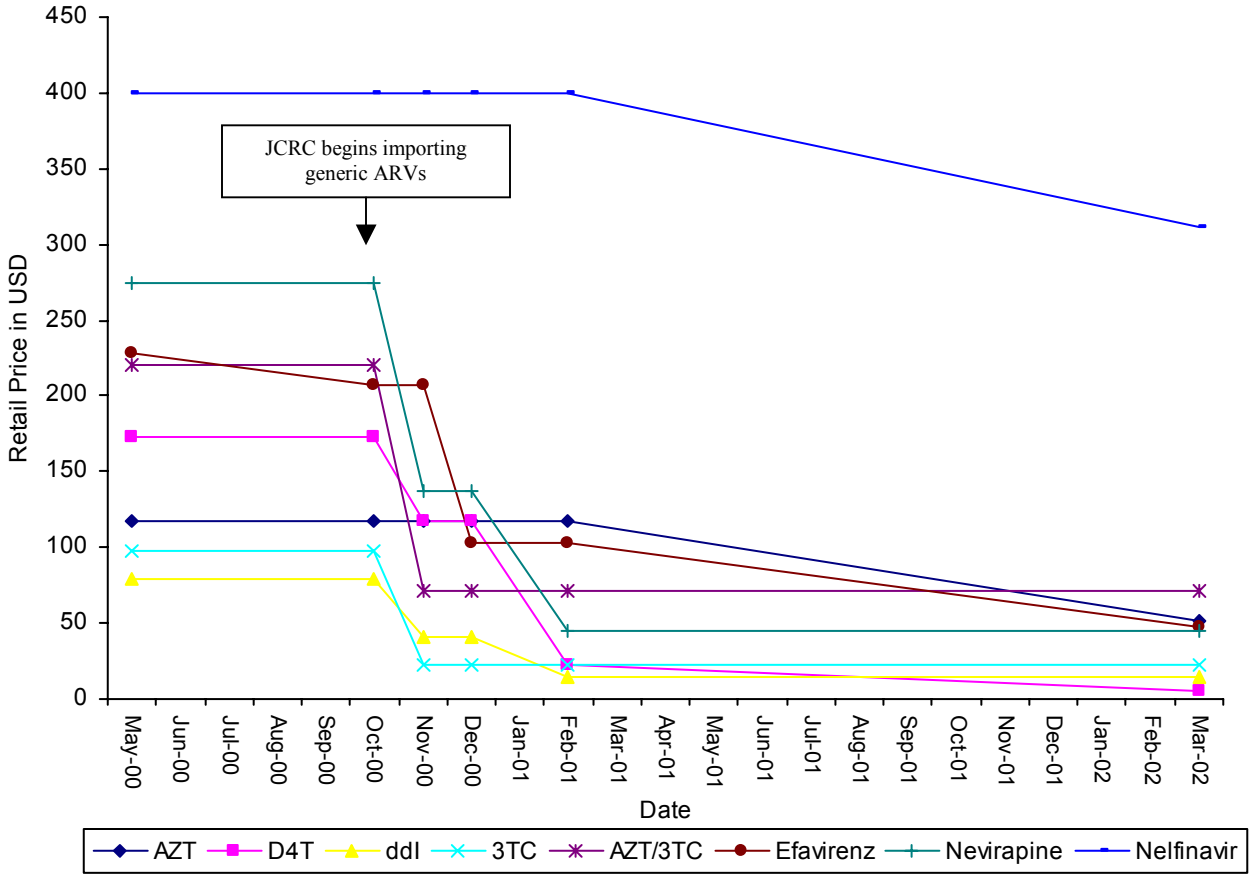
Mildmay Centre or to a private doctor. When we approached Dr. Kamya to discuss access to ARVs in Uganda, he correctly pointed out that at Mulago Hospital the discussion would most certainly have to focus on lack of access.

4.2. Importation of Generic ARVs: Price Reductions and Increased Coverage

Although the agreement to reduce ARV prices for developing countries was signed in May 2000, the most significant reductions in prices for branded ARVs coincided with the importation of generics from Cipla (the WHO-accredited Indian generics manufacturer) by JCRC in October 2000 (See Figure 1). This was allowed because JCRC is considered a non-profit-making research organisation. Technically speaking, JCRC was breaking the patent law but the drugs were registered with the National Drug Authority (NDA), which does not deal with IPR issues, and the importation went unchallenged.

Medical Access Uganda Limited, however, believes the price reduction of ARVs was due to 'the goodwill of the pharmaceutical companies', adding that 'all but Hoffman-La Roche are offering ARVs at not-for-profit prices'. However, Figure 1 establishes a strong link between the importation of generics and branded price reductions.

Figure 1: Chronology of Prices for Selected Brand ARV's
May-2000 to March-2002



Initially, the importation of generic ARVs faced several obstacles; most importantly, they were not registered with the NDA. Researchers were told that the first shipments of generics were met at the airport by Dr. Peter Mugyenyi, Director of JCRC, who 'forced' the authorities to release the drugs. Later, JCRC was able to import generic versions of ARVs using a provisional import permit, issued on an emergency basis. Since then, Cipla has been granted registration for five generic ARVs in Uganda (see section 6: Legislation Relating to Pharmaceuticals in Uganda). JCRC still imports the generic Triomune using the provisional permit. It is worth noting that JCRC performed quality research on the generic ARVs it proposed to import, in order to ensure drug quality.

The following table (Table 2) shows the number of patients on ARV therapy at JCRC, from 1996 to date.

Table 2: Number of Patients Accessing ARVs at JCRC per Year

Year	Number of patients accessing ARVs (both branded and generic) at JCRC
1996	93
1997	237
1998	614
1999	1,017
2000	962
2001	3,000
2002	3,400

With the importation of generic drugs, JCRC increased its coverage from 962 patients on ARV therapy in 2000 to 3,000 in 2001. This represents a 200 per cent increase in the numbers of patients taking HAART at one treatment centre alone. In addition, the price reductions of ARVs that followed shortly after generics were accepted in Uganda allowed JCRC to expand its treatment, using both branded and generic drug combinations. Price reductions also permitted patients to significantly improve adherence to their treatment regimen, which is expected to reduce the risk of HIV drug resistance.

JCRC started providing Mbarara Regional Hospital with generic ARVs in October 2001. Up until March 2002, JCRC dispensed approximately 2,500 doses of generic ARVs to Mbarara, including Triomune (3TC + D4T + Nevirapine), 3TC, D4T and Duovir (3TC + AZT). JCRC also provides technical support, supervision and training to Mbarara Hospital, as well as to three other regional hospitals.

After the initial steep price reductions of October 2000, the prices of certain branded, as well as generic ARVs, have gradually decreased. Table 3 below compares the prices of selected branded and generic ARVs. The price of protease inhibitors (Nelfinavir, Indinavir and Kaletra) remains

high compared with other drug classes. The generic versions of Nelfinavir and Efavirenz are not imported by JCRC, and hence the quoted prices for the generic equivalents of these drugs do not reflect real prices in the treatment centres.

Table 3: Comparison of Lowest Retail Prices in Uganda For Selected Branded and Generic Antiretrovirals

Prices are in US$ for a One-Month Treatment Supply

Generic Drug Name (Dosage)	Chronology of Prices				
	May – Sept 2000	January – February 2001		March – April 2002	
	Brand	Brand	Generic	Brand	Generic
NRTIs					
AZT (300 mg)	117	117	–	51	23
AZT (100 mg)	81	81	55	30	55
D4T (40 mg)	173	23	332	6	5
D4T (20 mg)	160	15	–	5	–
3TC (150 mg)	98	22	28	22	17
AZT+3TC (300/150 mg) (Combivir or Duovir)	220	71	68	71	35
ddI (100 mg)	79	14	–	14	–
ddI (25 mg)	20	8	–	8	–
Abacavir (300 mg)	266	266	–	127	–
NNRTIs					
Efavirenz (200 mg)	207	104	–	48	–
Nevirapine (200 mg)	273	45	Feb 01 = 127 Aug 01 = 25	45	25
PIs					
Nelfinavir (250 mg)	400	400	–	311	–
Indinavir (400 mg)	289	96	–	57	–
Lopinavir/Ritonavir (133.3/33.3 mg)			–	62	–

NRTIs = Nucleoside Reverse Transcriptase Inhibitors
NNRTIs = Non-Nucleoside Reverse Transcriptase Inhibitors
PIs = Protease Inhibitors

Notes:

- Generics were introduced in Uganda in October 2000.
- Branded retail prices are those suggested by Medical Access Uganda Ltd; generic retail prices are those offered by JCRC.
- Generic Efavirenz and Nelfinavir are not imported by JCRC and therefore the prices given here are not the prices available in Uganda. Generic Nelfinavir is available commercially through the local Cipla representative (Shurik) to private patients, rather than through the accredited centres.
- MSF-F has negotiated a price of $177/month/patient for Viracept (Nelfinavir) from Roche. The NGO will provide ARVs free of charge to patients enrolled in its HAART pilot project in Arua.

Although JCRC currently purchases the majority of branded ARVs from Medical Access, it also negotiates specific discounts for certain brands directly from the pharmaceutical companies (e.g. Efavirenz from Merck Sharp & Dohme). Its goal is to provide quality HAART to patients who need it at the least expensive price, which should be the goal of all providers.

Médecins sans Frontières (MSF) has also started importing generic ARVs from Cipla. MSF-F is initiating a HAART pilot project in the district of Arua, in northwestern Uganda. The project, which aims to enroll 20 new patients per month, provides ARV therapy free of charge. The HAART regimen proposed by MSF-F will use a combination of branded and generic ARVs. MSF- has managed to negotiate a discounted price for Nelfinavir (Viracept) of $177 per month directly from Hoffman-La Roche. Medical Access's suggested retail price for Viracept is US$311 per month. One would expect that Medical Access, UNAIDS or the Ugandan government would be able to negotiate a comparable price for the same drug.

Although generic ARVs are dispensed, there is a lack of information among providers with regards to their availability and efficacy. Many providers (e.g. Mildmay Centre) were unaware that certain generic ARVs are now registered with the NDA. Other providers did not know that generic ARVs are of high quality and efficacy, with the result that some doctors dissuade their patients from taking them.

Nevertheless, Dr. Cissy Kityo, Deputy Director of JCRC, believes that increased competition through the importation of generics is imperative to increasing access. She says, 'Over half of our patients would stop treatment if we were unable to import generics.'

4.3. Common ARV Combinations, Prices and Affordability

The least expensive ARV combination available in Uganda is a generic triple combination from Cipla called Triomune. Triomune therapy costs $40 per month and is a combination of 3TC + D4T + Nevirapine. JCRC estimates that 700 of its patients are currently taking Triomune. However, this treatment option may not suit all patients – some may require regimens that are more expensive, especially those containing protease inhibitors (PIs), such as Efavirenz.

A combination therapy consisting of Duovir + Efavirenz, however, at $83 per month costs twice as much as the Triomune regimen. By substituting Duovir with branded Combivir, the cost increases to $119 per month. Combinations with a PI such as Nelfinavir can cost from $330 to $381 per month, clearly out of reach for the majority of Ugandans.

The following tables (Tables 4 and 5) show the most common HAART combinations dispensed in Uganda, at their lowest retail prices.

Table 4: Most Common HAART Combinations Dispensed in Uganda
At Lowest Retail Prices
Prices are in US$ for a One-Month Treatment Supply

	ARV Combinations	+ Nevirapine (200 mg)		+ Efavirenz (200 mg)		+ Nelfinavir (250 mg)	
		Brand	Generic	Brand	Generic	Brand	Generic
1)	Combivir (brand) (AZT 300mg + 3TC 150mg)	116	96	119	–	381	–
	Duovir (generic) (AZT 300mg + 3TC 150mg)	80	60	83	–	346	–
2)	D4T 40mg + 3TC 150mg (brand)	72	52	75	–	338	–
	D4T 40mg + 3TC 150mg (generic)	52	47	69	–	332	–
3)	D4T 40mg + ddI 100mg (brand)	65	45	68	–	339	–
	D4T 40mg (generic) + ddI 100mg (brand)	64	44	67	–	330	–
4)	Triomune (generic) (D4T 40mg + 3TC 150mg + Nevirapine 200mg)	40 Lowest-priced HAART available in Uganda					

Notes:

- Branded retail prices are those suggested by Medical Access; generic retail prices are those offered by JCRC.
- Generic Efavirenz and Nelfinavir are not imported by JCRC; and therefore the prices given here are not the prices available in Uganda. Generic Nelfinavir is available commercially through the local Cipla representative (Shurik) to private patients, rather than through the accredited centres.
- Although rarely used at treatment centres due to their high cost, combinations with the PI Nelfinavir are included, since MSF-F imports Viracept (Nelfinavir) at a price negotiated with Roche of $177/month/patient for use in its HAART pilot project in Arua.

Table 5: Other HAART Combinations at Lowest Retail Prices in Uganda

Prices are in US$ for a One-Month Treatment Supply

	NRTI Combinations	+ Indinavir (400 mg)		+ Kaletra (133.3/33.3 mg)	
		Brand	Generic	Brand	Generic
1)	Combivir (brand) (AZT 300mg + 3TC 150mg)	128	–	133	–
	Duovir (generic) (AZT 300mg +3TC150mg)	93	–	98	–
2)	D4T 40mg + 3TC 150mg (brand)	114	–	119	–
	D4T 40mg + 3TC 150mg (generic)	85	–	89	–
3)	D4T 40mg + ddI 100mg (brand)	77		82	–
	D4T 40mg (generic) + ddI 100mg (brand)	76	–	81	–

The following monthly salaries of the 'average' Ugandan (in US$) make it quite clear that only the very well off can comfortably afford to access ARVs without having to sacrifice critical family needs.

- $55 to $138 for a cleaner, housekeeper, guard, farmer, or merchant at a market
- $152 for a teacher
- $276 for a nurse, health worker, or civil servant.

In addition, people 'up-country' (those living in villages outside of the capital) are completely excluded from ARV treatment.

In some instances, patients are assisted by their employers in paying for therapy. Companies such as the *New Vision* (a local newspaper), Bank of Uganda, Standard Chartered Bank, Shell and other international corporations subsidise all or part of ARV treatment for their employees. This practice is, however, rare and the majority of patients struggle to pay for ARV treatment themselves, with the help of their families and friends. Dr. Charles Kabuga of St. Francis Nsambya Hospital believes that employers are not doing enough to assist their employees in accessing treatment. He says, 'In general, employers have not stepped up to help their employees who need it.'

5. Additional Barriers to Access

The majority of providers and all patients interviewed (see section 7) agree that the principal barrier to accessing ARVs is still the price. In addition, there are other obstacles that are hindering access to these life-saving (prolonging) drugs. These include:

- the cost of monitoring (CD4 counts and viral load testing). The cost of monitoring and the treatment of OIs are additional burdens on the patient and limit access. At JCRC, for example, the cost of a CD4 test is approximately $14.50, and that of a viral load test $80. Other centres may be even more expensive.

- inadequately trained health workers. Although training of health workers has been provided through AAI (as well as other institutions such as JCRC), there is still a great need for capacity-building among providers, so that HAART can be administered properly.

- lack of appropriate infrastructure. Many centres do not have the capacity or infrastructure to perform the laboratory tests required for optimal monitoring of ARV therapies.

- inadequate distribution network and storage facilities. In order to increase geographical access to ARVs, a more efficient distribution and storage system is needed. Medical Access, for example – which currently undertakes procurement for the 14 centres of excellence – has only two employees. The National Medical Stores, which distribute other medicines throughout the country, are also insufficiently equipped to provide the necessary storage and distribution network.

- insufficient voluntary and confidential testing. Many people are not tested. Even if they are, and find that they are HIV-positive, they will not go for treatment until they become very sick. There is still a stigma attached to HIV/AIDS. Those who become infected are somehow considered 'bad' or 'reckless'. This is in spite of the government's highly praised HIV/AIDS campaign, which focuses primarily on prevention.

6. Legislation Relating to Pharmaceuticals in Uganda

The National Drug Policy (NDP) and patent laws are significant in governing the availability of pharmaceuticals and related products in Uganda. The National Drug Authority (NDA) controls access to pharmaceuticals by regulating the registration of drugs imported or manufactured in the country. Patent laws, on the other hand, affect access when exclusive rights are sought by patent holders, thereby potentially hindering access to cheaper, generic versions.

This section will briefly describe the NDP, Uganda's current patent laws, and the newly proposed Industrial Property Bill 2002 (IP Bill), as they relate to pharmaceuticals.

6.1. National Drug Policy (NDP) and Authority Statute

The NDP and Authority Statute 1993 are implemented by the NDA, Uganda's drug regulatory agency. The NDA has a responsibility to ensure the availability of safe, efficacious and cost-effective drugs. Drugs registered under this statute can be imported or supplied by the pharmaceutical sector. As Table 6 shows, 32 formulations (including six generic dose forms) of 13 ARV drug types were registered with the NDA between 1998 and May 2002.

Table 6: Registration and Patent Status of ARVs Available in Uganda

Drug name	Other name	Manufacturer	Registration	Patent
1. NRTIs				
Retrovir	AZT	GSK	+	+
Zidovir*	AZT	Cipla	+	
Zerit	d4T	BMS	+	
Stavir	d4T	Cipla	+	
Epivir	3TC	GSK	+	+
Lamivir	3TC	Cipla	+	
Videx	DdI	BMS	+	
Hivid	DdC	Roche		
Ziagen	Abacavir, ABC	GSK	+	+
Combivir	AZT/3TC	GSK	+	+
Duovir	AZT/3TC	Cipla	+	
Trizivir**	AZT/3TC/ABC	GSK	+	**
Triomune	d4T/3TC/Nevirapine	Cipla		
2. NNRTIs				
Viramune	Nevirapine	BI	+	+
Nevimune	Nevirapine	Cipla	+	
Rescriptor	Delavirdine	Aguoron		
Stocrin	Efavirenz	MSD	+	
3. PIs				
Invirase/Fortorase	Saquinavir	Roche		
Norvir	Ritonavir	Abbott	+	
Crixivan	Indinavir	MSD	+	
Viracept	Nelfniavir	Agourom		
Agenerase	Amprenavir	GSK		+
Kaletra	Lopniavir/Ritonavir	Abbott	+	

GSK = GlaxoSmithkline; BMS = Bristol Myers Squibb; Roche = F. Hoffman-La Roche; BI –=Boehringer Ingelheim; MSD = Merck Sharp & Dohme.
* Zidovir is formulated as a tablet, while Retrovir is formulated as a capsule.
** A patent application was filed for Trizivir, with Uganda as a designated state. (ARIPO)

Five of the ARVs had generic equivalents registered as of May 2002; all are manufactured in India by Cipla. The innovator brands of these generics are, however, patented in Uganda. Therefore, the importation of generic versions constitutes an infringement of patent rights, although no lawsuits have yet been filed to this effect.

Fifteen further generic ARV registration applications have been filed with the NDA, indicating a strong desire on the part of other generic manufacturers to register generic ARVs. The NDA has stringent regulations regarding the registration of generic ARVs. It requires a dossier to be submitted containing the comparative bio-availability or bio-equivalence of a generic formulation in relation to innovator products, together with product-specific Good Manufacturing Practice (GMP) reports and certificates.

Unregistered drugs can also be imported into Uganda, under Section 9 (4) of the NDP and Authority Statute.[1] This special permission, however, only applies to innovator branded drugs, or proprietary drugs. Generic ARVs from Cipla have been an exception because the WHO recognises the company as a manufacturer of ARVs having an acceptable quality. Although ARVs from Cipla have since been registered, prior to registration their importation under Section 9 (4) was agreed partly because the only importer – JCRC – was a research-based health facility. JCRC also has a procurement policy that aims at obtaining the most cost-effective ARVs.

6.2 Current Patent Laws in Uganda

Strong patent protection in a developing country such as Uganda is promoted as a way to attract foreign investment and to protect local inventions. These benefits, however, have been slow to manifest themselves in Uganda, due to the costs of production, the lack of a raw materials industry and an absence of research and development capacity. Thus, more than 95 per cent of drugs consumed in the country are imported (33 per cent from India alone), of which 80 per cent are generics (according to the National Drug Register, December 2001). Patents on pharmaceuticals (such as ARVs), can be used to prevent the importation of cheaper essential medicines and local manufacture of similar products.

Currently, patents in Uganda may be granted at three levels: national (Patents Statute 1991), regional (African Regional Industrial Property Organisation), or international (Patents (Amendment) Bill 2002).

National level:
The current patent law in Uganda at the national level is the Patents Statute 1991. The patent regulations 1993, made under Section 47, are for the better implementation of the statute. Under the current patent law, product and process patents have been granted for pharmaceuticals[2]. A patent granted under this statute has effect for 15 years, but is subject to a five-year extension on request by the owner (Section 32 (1), (2)). The maximum duration of protection is therefore 20 years.

[1] '…. Notwithstanding section 3 (section 9 (3) – mentioned above), any drug not appearing on the National Formulary (NDA) may be imported and sold after authorisation by the National Drug Authority to meet emergency or extraordinary circumstances.'

[2] Section 8 '…. Invention means a solution to a specific technological problem and may be or may relate to a product or process.' Novelty, inventive step and industrial applicability are requirements for patentability, section 9. These criteria, however, are not rigorous when considered in light of a patent that improves access to medicines in a Lesser Developed Country (LDC).

In the current patent law, under Section 31, compulsory licenses may be granted[3]. Provisions are also present for government use under Section 30, although there are currently no provisions for parallel importation. Seven ARVs have been patented in Uganda under the current patent laws.

Regional level

The African Regional Industrial Property Organisation (ARIPO) office – established under the Lusaka Agreement of ninth December 1976 – may grant patents in accordance with the Harare protocol on patents and industrial designs (10 December 1982), naming Uganda as a designated state (both under the current patent law and the proposed IP Bill). ARIPO patents can have effect in up to 14 African countries.

The ARIPO regional patent system has been used quite frequently to obtain patents for HIV-related products in Uganda. This is demonstrated by the 61 valid ARIPO patent applications relating to HIV filed between 1989 and December 2001. They encompass a wide range of claims, including those for products that can be considered experimental. A patent application for Trizivir (ALT + 3TC + ABC) has been filed with ARIPO (see Table 6).

International level

The Patents (Amendment) Bill 2002 is an attempt by Uganda to enter into a patent agreement at the international level. The Patent (Amendment) Bill 2000, although only tabled in Parliament and therefore not yet official, seeks to enable the filing of international patents under the Patent Cooperation Treaty (PCT), when Uganda is a designated state.

6.3. The Proposed Industrial Property Bill 2002 (IP Bill)

Uganda, like other WTO members, is obliged under the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement to protect all categories of intellectual property, including pharmaceuticals. In an attempt to comply with TRIPS, an IP Bill was drafted by the Law Reform Commission (created by the Ministry of Justice and Constitutional Affairs) and funded by USAID, which also provided a consultant to assist in the deliberations. Other stakeholders, including NGOs (i.e. Oxfam, MSF), the private sector, and other professional bodies, had some input in the discussions.

Although the proposed IP Bill is still a draft document, if tabled and enacted, it will mean that Uganda has not taken advantage of the 2006 transition period, the extension to TRIPS compliance granted to less developed countries. NGOs and others propose that Uganda should not hurry to implement its obligations but rather learn from the 'best practices' of other countries, as it has been granted the time to do.

[3] Compulsory licenses may be granted by a judicial process, four years after the filing of an application or three years after the grant of a patent. Conditions for the grant of compulsory licenses relate to non-working of the patented invention in Uganda, the inhibition thereof by importation, or the refusal to grant voluntary licenses for its working. They can also be granted if domestic demand is not reasonably met. Although 'working' is not explicitly defined under this section, under section 32 the invention is considered 'worked' if it is used to a reasonable scale, although this excludes importation.

In addition, Uganda is under no obligation to patent pharmaceutical products until 2016, as per the Declaration on the TRIPS agreement and Public Health (Doha Declaration). The proposed IP Bill, however, does not provide for this extension.

The Bill does take advantage of certain safeguards and provisions of the Doha Declaration. However, the Coalition for Health Promotion and Social Development (HEPS-Uganda) considers some of the Bill's language and terminology confusing. HEPS suggests that there should be more deliberation, including a better definition of terms and a clarification of confusing language. Other critics believe that the IP Bill is significantly more stringent in some cases than even TRIPS, and could benefit from a thorough re-examination and redraft.

The safeguards and provisions included in Uganda's IP Bill are the following:

Compulsory licensing (CL)

Compulsory licensing enables Government to give permission to an authorised person (company agency or other party) to supply a patented drug in the market without the consent of the patent holder. The Bill places restrictions on the use of CL which are more stringent than TRIPS itself, as illustrated below.

Under the IP Bill, compulsory licenses may be granted by judicial process under Section 59, four years after the filing of an application or three years after the grant of a patent, whichever comes first. Licenses may be granted if the local market is not supplied on 'reasonable' terms or when a drug, patented later, cannot be supplied or 'worked' without infringing on rights from a drug patented earlier. The terms 'reasonable' and 'worked' are not explicitly defined, and it is not clear whether the latter includes the importation of drugs.

In addition, the party requesting the compulsory license, under the proposed Bill, should have initially tried to obtain a contract license from the patent owner and must satisfy the court that the problem for which the license was granted will be satisfactorily resolved (though this is not required in the case of an urgent or emergency situation). Complying with these terms may be difficult for persons who seek compulsory licenses, but do not have the capacity to meet the obligations: i.e. manufacturing a drug in quantities sufficient to meet local demand.

It is also argued that limiting the authorisation of a compulsory license to a judicial process may not be appropriate for pharmaceuticals, since a more expeditious method may be required.

Furthermore, compulsory licensing for the manufacture of pharmaceutical products will be useful only if there is a local capacity to produce them. There is no capacity yet to produce ARVs in Uganda that meet the regulatory criteria, and the need for bio-equivalence studies makes this even more costly. Nevertheless, certain local manufacturers have shown interest in importing the necessary equipment and acquiring the required capacity if the Bill is passed.

Because the proposed Bill is in line with Article 31f of the TRIPS Agreement, compulsory licenses are intended predominantly for supply of the domestic market. This may create problems with access to new medicines when producers (e.g. India) comply with TRIPS and

become unable to produce generics for export to other countries (e.g. Uganda), since the local manufacturing capacity of Uganda is still weak.

Government use

Under section 67, the Bill enables the Government to authorise any party other than the patent holder, on its behalf, to import, manufacture, supply or utilise a drug, without the authority of the patent holder. The Government may make an order allowing Government use in at least two circumstances: 1) public interest, in particular health and national security; and 2) when the registrar of patents determines that the exploitation of the patent is not competitive. It is not clear however, whether the second instance refers to an anti-competitive situation.

Although it is argued that the Government use provisions are not explicitly phrased, and in some instances contradictory, the authorisation process does not require a lengthy or complicated procedure.

Article 30 exceptions

Exceptions are provided for in the proposed Bill (Section 45.1), as allowed under Article 30 of the TRIPS agreement. This section of the IP Bill restricts rights under the patent to industrial and commercial purposes and permits acts carried out for the purpose of research. These exceptions include the following:

- Parallel importation. This allows for a patented drug to be imported from a third country where the price is lower. Parallel importation is currently practised widely in countries of the European Union, where prices for the same medicines vary considerably among the member states. The IP Bill (Section 45.2), limits this exception to drugs imported into Uganda by the patent owner, or with their express consent. This limitation may hinder access to drugs, as it will be illegal for anyone to import any medicines from a third country without the agreement of the patent owner.

- The Bolar exception. The Bolar early-working exception permits research and the performance of tests necessary to obtain regulatory approvals and registration of a generic product, before the expiration term of the patent. This exception can be useful for domestic pharmaceutical manufacturers as they develop a capacity to produce generic equivalents, which frequently increases the availability of affordable drugs. Although mentioned in the IP Bill, however, this exception is not clearly stated.

Other sections also need further clarification. For example, Section 10 of the draft Bill considers an invention '…. patentable if it is new, involves an inventive step or is a new use'. 'New use' with respect to pharmaceuticals could mean a second use. Whether this fits the criteria for patentability is subject to debate. Furthermore, although member states are obliged under Articles 27.1 and 28 of the TRIPS Agreement to grant product or process patents, protection of 'new uses' is not mandatory. Careful consideration of its implications is therefore necessary.

This issue is further complicated because the Ugandan patent registry is presently not well equipped to assess patent applications or examine claims for pharmaceuticals. The legal and administrative framework to process patents is not in place. The registrar of patents believes that

there is a lack of sufficient knowledge in patent-related issues, as expressed in her statement: 'We have the office, but we don't have the equipment and facilities to examine the claims, so we send them to ARIPO. These industrial property issues are new, they were not taught at that time, [and] I wish they could be incorporated at Makerere (University)…'.

The proposed IP Bill is still in the draft stage. Further deliberations and parliamentary reviews are still needed before it becomes law.

6.4. Government Status with Regards to the Doha Declaration

It was difficult for the researchers to assess the government's stance with regards to the IP Bill and the Doha Declaration. This is due to the fact that government departments have different concerns. The Ministry of Health, for example, supports measures to reduce the prices of ARVs in the interests of universal access, together with a complete interpretation of the Doha Declaration on the TRIPS and Public Health. However, the Ministry of Tourism, Trade and Industry believe that the Doha Declaration should be implemented fully. A representative from the latter adds, 'The declaration on patents and medicines (the Doha Declaration) gives countries leeway to access essential medicines… Uganda should not be left out.'

On the one hand, the Law Reform Commission (Ministry of Justice) and some members of the private sector are keen to have comprehensive patent laws with reference to TRIPS, favouring free trade and recouping research and development costs. On the other hand, civil society organisations have criticised this stance, stating that the Bill is influenced by United States interests, through the connection with USAID.

In conclusion, there is no clear government stance on the Doha Declaration. Some criticise President Yoweri Museveni's government for not adopting a more transparent policy with regards to the Declaration and Uganda's proposed IP Bill.

7. Interviews with Patients Accessing Antiretrovirals

The researchers interviewed a total of nine patients at two treatment centres in Kampala: JCRC and St. Francis Nsambya Hospital. All of the patients interviewed were on a HAART regimen, with either branded or generic drugs (in the case of patients seen at JCRC). The names are pseudonyms because many preferred to remain anonymous.

The median age of the patients interviewed was 38 (range 30-62 years). Six of the nine were male, and their median monthly income was $249 (range $83-$718). The majority of patients paid for treatment themselves, with the help of family pooling. In one case, the employer contributed by paying for 50 per cent of the treatment. This arrangement, however, is rare and most patients struggle to buy their treatment each month. Many buy on a bi-weekly basis, because a monthly dose is too costly. Most have to sacrifice other family needs in order to pay for treatment – including sending their children to private schools and buying food items such as chicken, milk, and butter. As one patient put it, 'My children now go to bad (public) schools'; this sentiment was shared by others interviewed.

Except for one, all the patients are married and all have at least four children. In one case the spouse has also been diagnosed with HIV and the family can only afford to pay for treatment for one. Since the man is most commonly the economic provider for the family, it is he who is chosen to receive treatment. Other spouses have not yet been tested as they have not fallen ill. As one man said, 'My wife doesn't have the courage to go for the test.'

Most patients are spending 50 per cent or more of their monthly income on ARVs. Many are not aware of generic options available at lower costs, or their doctors have dissuaded them from taking generic ARVs, because of their own lack of awareness of the availability and quality of generics. Others who are taking generic ARVs don't know the difference; they only know that they are on an expensive medicine that they must take every month in order to survive.

Even the least expensive HAART regimen available is expensive for the majority of patients, and they all have to be 'creative' in finding ways to pay for both treatment and basic family needs. One of the interviewees summed up what appeared to be a consensus: 'It is difficult for us… but many people up-country (those who live in the villages) can't even afford to buy a Panadol (pain reliever).' The following are five of the interviews conducted.

James: A police officer struggling to pay for ARVs and 'keep his family going'

James is a police officer in Kampala. He is 38 years old and is originally from Bushenyi District. In August 2000, James fell sick with tuberculosis and was diagnosed with HIV in December of the same year. He managed to get money together to start a HAART regimen the following month.

James is seen at St. Francis Nsambya Hospital and has been on Combivir (ATC + AZT) + Stocrin (Efavirenz) since he started his treatment regimen. At the beginning, he paid $247 per month for ARV therapy. Since then, prices have gone down and he now pays approximately half of that ($127). This amount, however, is still more than his monthly salary of $83. Luckily, James's wife also works, as a saleslady in a shop, and contributes $138 to the family's monthly income. James also has investments, which help him pay for his treatment, as well as for the tests (CD4 and viral load). He doesn't test as often as he should, due to lack of funds. He usually buys his medication bi-weekly, as gathering the necessary money can be a problem. 'I have to constantly struggle to get the money and keep the family going. It's a tug-of-war,' he says. He adds that $17 would be a more affordable price for him to pay. This would represent 7.5 per cent of his total monthly income.

Since he started treatment, James can no longer send his five children to private schools. He states, 'My children are now going to bad schools. I feel embarrassed because of my medicines and the burden on my family. I often feel that I should leave the medicines.' James has heard about 'copies' of medicines (generics) that are supposed to be cheaper, but his doctor has advised him that the quality is sub-standard. He asks me about these cheaper medicines, if they are good, and where he can buy them. It is apparent that James lacks information regarding his treatment options.

James's health has improved since he began taking ARVs. He says, 'I am OK. I do not have any serious problems, only simple illnesses such as body weakness. At least I am not a gone case.' Although his wife has not been tested because 'she does not have the courage to take the test', she has not fallen ill. James knows of other people on ARVs who are selling their properties to pay for treatment. Still others have fallen ill but don't get tested, for fear of the results. He adds that many people continue to keep their condition a secret because they are embarrassed.

When asked what can be done to help people with HIV/AIDS, he replies that there should be a project for government employees, 'a project for getting medicines at a cheaper cost. It should be funded by the government.' Also, he believes, people with HIV should not lose their jobs when they have to miss work due to illness.

Charles: A civil servant recently diagnosed with HIV, along with his wife

Charles is seen at St. Francis Nsambya Hospital. He was diagnosed with HIV in December 2001 and started taking ARVs in February 2002. Charles is 36 years old and is a civil servant from Jinja, not far from Kampala. He makes approximately $276 per month.

Charles is on a Zerit (D4T) + Epivir (3TC) + Stocrin (Efavirenz) combination. He pays approximately $80 a month for his treatment. This represents about 30 per cent of his monthly income. He is married with children and his wife has also recently been diagnosed with HIV. His wife does not work outside the home and now Charles must begin paying for her treatment as well.

Although he knows other people with HIV for whose ARV treatment the government pays, his district will not pay for him because technically he can still 'afford' to pay for himself. Charles does pay for himself, but with a lot of difficulty. He says, 'I must continue to pay or I will die.' His children still attend private schools because he asks family members and colleagues to assist with school fees. He adds, 'My wish is for my children to continue in private schools but I do know if this will be possible.'

A more affordable price for Charles to pay would be $28 per month, approximately 35 per cent of what he is currently paying. This reduction would also allow him to pay for his wife, without sacrificing other family needs.

'Many people with HIV keep it a secret because they fear the stigma attached to HIV+ people,' he says. 'If you are diagnosed with HIV you are a reject in society. You are considered reckless with your life.'

When asked about generics, Charles looks at me, puzzled. I explain that they are less expensive versions of the medicines he is taking. 'Where are these generics from?' he asks. 'They are from India.' 'Oh, forget it… those are not good,' he says as he gets up, indicating that the interview has concluded.

Violet: A shopkeeper who receives help from her sister in London to pay for her ARV treatment

Violet is a 42-year-old shopkeeper with four children. Her husband is not around, for reasons she does not want to disclose. She was diagnosed with HIV in 1998 and began HAART almost immediately. She is being treated at St. Francis Nsambya Hospital. Her monthly income varies, as it depends on the business her small clothes shop generates. She estimates that she spends approximately half of her income on her ARV treatment.

Violet is on a HAART regimen that includes Nelfinavir, and her treatment is thus more expensive. Her sister, who is a nurse in London, pays for over 50 per cent of her monthly treatment, which can cost up to $330 per month. Her sister also sometimes manages to get Nelfinavir from sources in England, at a reduced price or as a donation. Just two years ago, Violet was paying more than $500 per month – with the help of her sister – for the same regimen. Although the $110 that Violet pays monthly is just about affordable, she says, 'I must still find a way to pay for everything for myself and my children. I could not pay if my sister did not help me.'

When asked about a more affordable price for her and others like her in Kampala, Violet states that $28 would be a fair price. She believes, however, that people from the villages should receive free ARVs. 'In the villages, people don't have money,' she says.

Since she started treatment, Violet is no longer sick. She can work and she is happy. 'Before, I was very sick and now I am fine,' she says. Violet knows other people taking ARVs, but does not know how they are paying for their therapy. She also knows others who need the treatment but cannot afford it. 'If the prices are lower maybe they can buy, but free is the best,' she concludes.

Agnes: A woman who lost her husband to AIDS and whose children do not know that she is also HIV-infected

Agnes is a secretary by profession but currently runs a car accessories shop together with her brother. She lost her husband to AIDS about six years ago, around the time that she was diagnosed with HIV. She is 45 years old and has five children. Her business makes her about $277 per month, of which $165 (over 50 per cent) goes to pay for her monthly doses of ARVs. She says that this amount is too expensive and she could comfortably pay no more than $55 per month.

Agnes is on a HAART regimen (she could not recall the names of her drugs or whether they were generic or brand) prescribed by JCRC. She used to be on another drug regimen that made her stomach hurt. She now 'feels good on these drugs'. Her doctor says there are some cheaper drugs but they could make her feel weak, so she prefers to continue with her current combination.

To pay for her children's school fees, Agnes rents out part of her house. 'I pray to God that the tenants stay in my house,' she says. 'My children do not know that I am sick. I want them to go to a good school and I do not want them to know that I could die if I do not have my medicines.'

Although it would seem that Agnes is managing for now, she cannot keep money in the bank or save for her and her children's future. She still, however, feels fortunate that she can afford to pay for her treatment. 'At least I can afford to pay. Some people cannot afford to pay and they will die,' she comments. Agnes's brother is also HIV-infected. Although he is also on a HAART regimen, he is very sick. She says that perhaps he cannot pay for 'better medicines'. A second brother is helping him pay, she adds.

Agnes believes her risk factor for acquiring HIV was the multiple blood transfusions she received during childbirth in the early 1980s. She adds, 'Many women have suffered from these transfusions.'

John: A local fisherman, married with eight children

John is a local fisherman, married with eight children. He has been suffering from stomach problems since 1995. He finally took a blood test in 2001 and was diagnosed with HIV. He began ARV therapy that same year.

John is treated at JCRC with a regimen consisting of AZT + 3TC (most likely generic Duovir) + Efavirenz. His treatment costs $88 per month. This is approximately 30 per cent of his $276 monthly income. His wife does not work and he has no other income. He pays for the treatment himself, with no help from family or friends. From his monthly income John must pay for everything, including food, school fees, household items, medicines to treat OIs, and laboratory tests.

Since he started ARV therapy, John has felt much better. He can work and provide for his family. John's wife has also recently been diagnosed with HIV. Unfortunately, John states, 'I do not have the money to pay for both.' If he pays for his wife, his children cannot go to school, and 'they will not have a future.' If he stops taking the ARVs and his wife starts instead, he will die. 'What will happen to my family?' he asks sadly.

Like many others, John says a more affordable price would be $28 per month. This would allow both John and his wife to access treatment. John believes that the government should help those in need by cutting the price of ARVs.

8. Limitations to the Study

This study faced several limitations, which were predominantly concerned with accessing quantitative data regarding coverage and sales of ARVs. These limitations included the following:

- There is not a centrally controlled distribution system of ARVs in place. Pharmaceutical companies, as well as their local representatives, sell to providers directly (i.e. Medical Access, pharmacies, and treatment centres). In some cases, patients access ARVs over the counter with a prescription from a private physician. Still others receive medicines from abroad. In addition, JCRC and MSF import generics directly from Cipla and in some cases go to the pharmaceutical companies directly, thereby bypassing Medical Access and local representatives.

- UNAIDS has not attempted to track the increased accessibility of ARVs as a result of the AAI, and therefore there are no comprehensive evaluations or monitoring reports of the initiative.

- Pharmaceutical company representatives would not disclose sales figures. One firm said, '…this is classified information'.

- Medical Access Uganda Limited's computer system 'crashed' and was 'down' for two weeks while the researchers were collecting data. Apparently, this made it impossible to access the organisation's sales figures to treatment centres. Medical Access claims to 'control 80 per cent of the ARV market in Uganda'. Unfortunately we were unable to verify this claim.

- Patients may be registered – while not necessarily accessing ARVs – at more than one treatment centre, thereby creating duplication.

- Treatment centres may not always keep updated quantitative data on their patients, or on quantities of ARVs dispensed.

- Time constraints made it impossible to obtain information from all treatment centres in Kampala, or those in other parts of the country.

- JCRC dispenses ARV drug combinations that combine branded and generic compounds; its database was not set up to differentiate between the two until very recently.

- Interpretation of the IP Bill may differ according to the reader (which is why clearer language and further definition of terms is suggested).

9. Conclusions

In conclusion, the study shows that access to ARVs has increased, due mainly to price reductions led by the importation of generics. However, the great majority of HIV-infected Ugandans still cannot afford to pay for therapy. The least expensive triple-drug regimen available in Uganda, Triomune, costs $40 per month. The cheapest HAART therapy would represent 30-90 per cent of a monthly income of $50-$150 – the average income of a housekeeper, guard, shopkeeper, teacher, or policeman in Kampala. Other HAART combinations, especially those with a PI-based regimen, are even more costly.

The government has no framework or programme in place that focuses on access and distribution of ARVs. The AIDS Control Programme (ACP) of the MOH primarily focuses on prevention, research, and collecting and distributing statistics. A representative of the ACP added that the government's application to receive US$7 million from the Global Fund on AIDS, Tuberculosis and Malaria (GFATM) has been successful. This will bring the total funds available for HIV-related drug treatments (ARV and treatment of OIs) to US$17 million. However, it is not clear how the government will make these funds available to the population in need.

Along with securing price reductions and finding alternative sources of funding, access to ARV therapy in Uganda is faced with several challenges, including:

- providing adequate technical training for treatment centres and health workers;
- expanding geographical and equitable access of ARVs and quality HIV care that includes monitoring;
- ensuring patent laws that provide safeguards for essential medicines; and
- creating awareness regarding generic versions of ARVs through professional education, community training programmes and the media.

The work of the Government of Uganda on the HIV epidemic, particularly in terms of prevention through education, has been justly praised by the international public health community. Now it is time to take the next step, offering hope to those people already infected with this virus, who are suffering despair and death. A framework or plan at the government level for accessing ARVs will be a first step in providing life-saving therapy to a greater majority of HIV-infected people.

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