

# Missing the Target #5:

*Improving AIDS Drug Access and  
Advancing Health Care for All*



**International Treatment Preparedness Coalition (ITPC)**

*December 2007*

**The International Treatment Preparedness Coalition (ITPC)** was born out of the International Treatment Preparedness Summit that took place in Cape Town, South Africa in March 2003. That meeting brought together for the first time community-based HIV treatment activists and educators from over 60 countries.

Since the Summit, ITPC has grown to include more than 1,000 activists from over 125 countries and has emerged as a leading civil society coalition on treatment preparedness and access issues.

**All ITPC treatment reports are available online at  
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## TABLE OF CONTENTS

Acknowledgements.....	i
Acronyms and Abbreviations.....	iii
Executive Summary.....	1
The Global Response.....	7
Country Special Issue Reports.....	12
• The real cost of free treatment: China .....	13
• Remaining work in a successful program: Dominican Republic....	15
• Delivering services amidst turmoil: Zimbabwe.....	20
• Making marginalized groups a priority: Russia.....	28
• The deadly impact of stigma: Kenya.....	30
• Waiting for second-line ART over?: India.....	34
• Linking nutrition and treatment: Cameroon.....	37
• A district-by-district survey: Zambia.....	42
• Addressing serious human resource needs: Cambodia.....	46
Drug Registration Barriers and Logjams.....	49
ARV Procurement, Registration, and Stock-Outs.....	59
Argentina, Belize, Cambodia, China, Dominican Republic, India, Malawi, Morocco, Nigeria, Philippines, Russia, Uganda, Zambia, Zimbabwe	
Short Summary.....	105
Pakistan.....	106

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## ACRONYMS AND ABBREVIATIONS

The following acronyms and abbreviations may be found in this report:

AMDS = AIDS Medicines and Diagnostics Service (WHO)  
ARV = antiretroviral  
ART = antiretroviral treatment  
CCM = Country Coordinating Mechanism (Global Fund)  
FDA = US Food and Drug Administration  
FDC = fixed-dose combination  
FTA = free trade agreement  
Global Fund = Global Fund to Fight AIDS, Tuberculosis and Malaria  
GMP = good manufacturing practice  
GPRM = Global Price Reporting Mechanism  
IDU = injecting drug user  
IGWG = Intergovernmental Working Group (WHO)  
IP = intellectual property  
IPR = intellectual property rights  
ITPC = International Treatment Preparedness Coalition  
MoH = Ministry of Health  
MSF = Médecins Sans Frontières  
MSM = men who have sex with men  
NACO = National AIDS Control Organization (India)  
NAP = National AIDS Program  
NGO = non-governmental organization  
NNRTI = non-nucleoside reverse transcriptase inhibitors  
NRTI = nucleoside reverse transcriptase inhibitors  
OI = opportunistic infection  
PAHO = Pan American Health Organization  
PEPFAR = US President's Emergency Program for AIDS Relief  
PI = protease inhibitor  
PICT = provider-initiated counseling and testing  
PLWHA = people living with HIV and AIDS  
PMTCT = prevention of mother-to-child transmission  
PR = Principal Recipient (Global Fund)  
SCMS = Supply Chain Management System  
STD = sexually transmitted disease  
STI = sexually transmitted infection  
SW = sex worker  
TB = tuberculosis  
TRIPS = trade-related aspects of intellectual property rights (through the WTO)  
UNAIDS = Joint United Nations Programme on HIV/AIDS  
UNICEF = United Nations Children's Fund  
USAID = US Agency for International Development  
UN = United Nations  
UNGASS = United Nations General Assembly Special Session  
VCT = voluntary counseling and testing  
WHO = World Health Organization  
WTO = World Trade Organization

## DRUG NAMES

With limited exceptions, all HIV medicines referred to in this document are listed by their generic name. Other versions of their names are included on occasion, however, including when it is necessary to specifically indicate brand names. The HIV medicines referred to in this report are listed below in alphabetical order by generic name. Linked to each medicine are commonly used alternative versions and relevant brand names.

abacavir = ABC

atazanavir = ATV

darunavir

didanosine = ddl

efavirenz = EFV

emtricitabine = FTC

enfuvirtide = T-20

indinavir = IND/IDV

(note: indinavir boosted with ritonavir is often listed as IDV/r)

fosamprenavir

lamivudine = 3TC

lopinavir/ritonavir = LPV/r (brand names: Kaletra, Aluvia)

nelfinavir = NLF (brand name: Viracept)

nevirapine = NVP

ritonavir = r

saquinavir = SQV

stavudine = d4T

tenofovir = TDF

tipranavir

zidovudine = AZT

Multi-drug combinations referred to by brand names:

Atripla = efavirenz (EFV) + tenofovir (TDF) + emtricitabine (FTC)

Combivir or Duovir = zidovudine (AZT) + lamivudine (3TC)

Triomune or Stalanev = stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP)

Truvada = tenofovir (TDF) + emtricitabine (FTC)

## DOLLAR FIGURES

Unless specified otherwise, all figures marked in "\$" are US dollar amounts.

## Executive Summary

At the G8 meeting in Gleneagles in 2005 and again at the United Nations UNGASS session in 2006, world leaders promised to come as close as possible to providing universal access to AIDS treatment and prevention by 2010. Estimates of HIV incidence and prevalence will change, but by any account, today several million people in desperate need of AIDS treatment do not have access to it. And at the current pace of growth in treatment delivery, several million will not have access by the end of 2010. Broken promises will mean millions of deaths.

Scale up of AIDS treatment is driving unprecedented expansion of health delivery and, in the process, identifying critical challenges to health systems as well as practical solutions to address them. This report identifies many ways in which governments and global agencies must act to correct systems essential to delivery of health. In the area of antiretroviral drug access—a special focus of this report—our research found that in many countries drug registration, procurement, and supply management systems are inadequate, drug stock-outs are common, and most people are not being treated with ARV regimens that are consistent with recent WHO recommendations for improved first-line and standardized second-line treatment combinations.

On-the-ground research by civil society advocates from 17 countries also reveals the close interconnection of AIDS services with other health and social supports. The lessons for successful AIDS treatment are true for all health services: appropriate delivery includes adequate nutrition, clean water, trained health workers, accessible health clinics, integration of prevention and treatment, and free provision of drugs, diagnostic and monitoring tests, and other commodities.

Mobilization around AIDS has raised new resources, built consumer-engagement in providing health care, marshaled enduring public support, and promoted the development of results-oriented approaches to global health. Building on these foundations should be a central strategy in developing comprehensive systems of health care. In Haiti and Rwanda, for example, providers are demonstrating how to deliver AIDS treatment as part of a comprehensive program that includes HIV prevention and a wide range of health services.<sup>1 2 3</sup>

We cannot allow responses to AIDS and other chronic health issues to become bogged down in simplistic dichotomies: prevention vs. treatment; horizontal vs. vertical programming; disease-specific funding vs. strong health systems. There is only one appropriate approach: We must do everything, better, for more people, and in an increasingly coherent way.

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<sup>1</sup> Global Fund to Fight AIDS, Tuberculosis and Malaria. Partners in Impact: Results Report. 2007: 36. <http://80.80.227.97/en/files/about/replenishment/oslo/Progress%20Report.pdf>

<sup>2</sup> Farmer, P, From “Marvelous Momentum” to Health Care for All, January 23, 2007, [www.foreignaffairs.org/special/global\\_health/farmer](http://www.foreignaffairs.org/special/global_health/farmer)

<sup>3</sup> Partners in Health. Rwanda scales up PIH model as national rural health system. October 2007. [www.pih.org/inforesources/news/Rwanda\\_Scale-up.html](http://www.pih.org/inforesources/news/Rwanda_Scale-up.html)



In this fifth installment of the *Missing the Target* report series, we are broadening and deepening our approach to monitoring AIDS service delivery in heavily affected countries. Seventeen teams (from Eastern Europe, Africa, Asia, and Latin America) participated in the development of this report. And we are beginning the process of expanding the focus of the report series to incorporate more of the inextricably interwoven aspects of ending AIDS, including HIV prevention, TB services, and support services.

### **Scaling up AIDS services**

In the first section of MTT5, nine country teams provide first-hand reports on central issues related to AIDS service scale-up in their countries. Each demonstrates that increasing access to AIDS treatment brings not only better life and new hope, but also shines light on challenges and effective approaches to a spectrum of health, poverty, and human rights issues.

*The goal of getting AIDS treatment to more and more people is working, saving millions of lives, and transforming people's relationship to health services around the world.*

- The *Missing the Target* team in Cambodia found that low salaries, inadequate training and other issues have led to a serious human resources shortfall
- Cameroon describes how lack of nutritional resources has emerged as a determining factor in delivering care
- In China, a close analysis reveals that multiple charges for AIDS-related health services exist, even in the context of a “free” ARV program
- In the Dominican Republic, there is an increasing level of ARV coverage but the government must now address poorly supported public hospitals and limited access to specialized care
- In India, the national AIDS authority has just announced a long awaited second-line therapy plan; much greater attention is needed to marginalized populations
- In Kenya, the report team documents the devastating impact of stigma and discrimination on health service delivery
- The Russia team reviews the deadly combination of poverty, powerlessness and social discrimination among marginalized groups
- In Zambia, a district-by-district survey identifies multiple and variable barriers to care, including limited access to diagnostic tests, poor nutrition, and long travel times to clinics

- The Zimbabwe team documents advances in service delivery that have been accomplished in the midst of national political and economic turmoil but finds continuing challenges such as fake ARVs and lack of access to clean water

### **Focus on drug access**

In part two of this report, “ARV Procurement, Registration, and Stock-Outs”, 14 national teams review drug access issues, and find that global and national processes for AIDS drug registration are burdened by inefficiencies, duplications, delay, and, in some instances, corruption. In many cases key ARVs, particularly newer and second-line therapies, are not yet registered in high impact countries – an administrative roadblock that puts lifesaving care out of reach for hundreds of thousands of people.

While specifics vary by country, our research reveals that high prices, patent barriers, registration barriers, and misinformation among policy makers and clinicians mean that many countries are using AIDS treatment combinations that are not preferred according to WHO guidelines, such as fixed-dose combinations of stavudine (d4T)+lamivudine (3TC)+nevirapine (NVP). In China there is still wide use of didanosine (ddI)+stavudine (d4T)+ nevirapine (NVP), another combination not recommended by WHO. Drug stock-outs in government-run treatment centers are common in several countries, and they often prompt drug sharing, and with it the potential for the development of resistance, as well as impoverishment as people who are forced to pay out of pocket for medicines in the private sector.

- In Argentina, high cost and restrictions on some drugs impede access to some second-line and other medicines
- In Belize, human resources shortfalls, price increases and inadequate quality assurance plague drug delivery
- In Cambodia, expanded access to drug resistance and viral load testing is needed, as is increased attention to drug quality
- In China, access to second-line therapy is extremely limited, new WHO treatment guidelines on improved first-line treatment have not been widely implemented and patents on key medicines are preventing cost-cutting generic competition
- In the Dominican Republic, new intellectual property laws and patent enforcement by Merck are leading to higher prices and limited access to some key drugs
- In India, drug stock-outs are reported across the country, particularly where IDUs require treatment regimens that are not hepatotoxic

- In Malawi, a chronic shortage of health care workers is a major impediment to drug access; while there are no ARV stock-outs, other important drugs are often unavailable
- In Morocco, new intellectual property laws threaten the provision of AIDS treatment
- In Nigeria, despite a rapid scale up of ARV treatment and a free treatment policy, treatment sites are not easily accessible in many parts of the country, and CD4 and other tests are still being offered at a fee in several locations
- In the Philippines, treatment is not yet accessible to all, there is a healthcare worker shortage and diagnostic testing access is limited
- In Russia, ARV stock-outs are a severe and ongoing problem
- In Uganda, stock-outs are commonplace, and limited support and care services undermine drug access
- In Zambia, there is concern that AIDS drug access depends on the work of NGOs and the government is not sufficiently engaged
- In Zimbabwe, stock-outs are frequent and the increasingly unfriendly general policy environment remains a cause for concern

### **Recommendations**

The report makes a number of concrete recommendations to the key players who are responsible for making near universal access to AIDS treatment a reality by 2010:

- **WHO, UNAIDS and other UN technical agencies:**
  - WHO needs to take the lead to educate countries about changes to standard first- and second-line treatment regimens. This will increase country demand and help contribute to price reductions.
  - UN technical agencies must clearly and publicly communicate changes in WHO ARV drug guidelines and provide technical support and guidance to countries to help implement the changes.
  - WHO must be much more active and visible as the arbiter in setting norms on the use and availability of life-saving medicines, for example through reinvigorating the AIDS Medicine and Diagnostic Service (AMDS) and through eliminating bottlenecks and increasing support for the WHO prequalification program.
  - WHO must reinvigorate the operational urgency of the “3 by 5 Initiative.” Given its focus on building primary care services, WHO should lead global efforts to simultaneously expand AIDS services while strengthening broader care systems.

- UN agencies should provide increased technical and political support to help create political and policy space for governments to overcome patent barriers through use of public health flexibilities in international trade law.
- WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) provides a critical opportunity for much-needed leadership from UN agencies, as well as national governments, to increase access to affordable medicines through a clear international strategy and plan of action.

#### ■ **The Global Fund:**

- The Global Fund should encourage countries to switch from outdated and non-optimal AIDS treatment regimens to improved treatment combinations, and develop a plan to support countries making the switch.
- The Global Fund should ensure its grantees are procuring medicines at preferential prices, such as those secured through UNITAID's partnership with the Clinton Foundation (announced May 2007).
- The Global Fund should act in cases where countries are reporting paying high prices for medicines through the Price Reporting Mechanism by diagnosing the problem and working with partners such as UNITAID to ensure procurement at lowest cost.
- The Fund should proactively support grantees in identifying and correcting procurement bottlenecks and strengthening national procurement systems for ARVs and other medicines.

#### ■ **Bilateral donors including PEPFAR:**

- Bilateral programs should work with national treatment programs, community organizations, PLWHA and other partners to support national efforts to switch to optimized first-line treatment. Budgetary allocations should reflect at least the initial increases in costs for optimized first-line treatment.
- PEPFAR and other bilateral donors should work with countries to achieve agreed benchmarks for increasing the national capacity of countries in procurement and supply management.

#### ■ **UNITAID:**

The international drug purchase facility should work aggressively to support initiatives to increase competition and further reduce the price of new standardized treatment regimens, such as fixed dose combinations of tenofovir (TDF) + lamivudine (3TC) + efavirenz (EFV), as well as generic versions of heat-stable lopinavir+ritonavir (LPV/r) and other ritonavir-boosted protease inhibitors such as atazanavir (ATV).

■ **Drug companies:**

Pharmaceutical companies must act with enlightened self-interest to expand access to their products by ceasing to intimidate countries that use flexibilities in trade law and, where appropriate, by establishing voluntary licensing arrangements to encourage local production. Both innovator and generic drug companies must work to register their products much more expeditiously where people are in urgent need of treatment.

■ **National governments:**

Governments must build local and regional regulatory capacity to assure the quality, safety, and efficacy of medicines and make use of options to accelerate access to drugs, including reliance on the WHO drug prequalification process. National governments must show political will to increase access to affordable medicines by using flexibilities in international trade rules established by the Doha Declaration on TRIPS and Public Health.

The *Missing the Target* reports illustrate many connections between access to AIDS treatment and wider health and social support issues. In countries such as the Dominican Republic, which we've followed across five reports, problems get solved, new problems emerge and, over time, the number of people getting ARVs (and staying alive) increases. Continuing monitoring and civil society pressuring plays a major role in this improvement.

Natural disaster and political and economic upheavals (for example, in Zimbabwe) can set-back but do not have to stop the momentum of increasing access to treatment. The goal of getting AIDS treatment to more and more people is working, saving millions of lives, and transforming people's relationship to health services around the world.

## The Global Response

The response to AIDS is threatened by today's global debate pitting disease-specific "vertical" programs against "horizontal" health systems development. The on-the-ground research from 17 heavily impacted countries in this report argues against absolutes on these issues. *Missing the Target* country reports document how the mobilization around AIDS is driving health systems advancement in countries on every continent, and they also reveal the need for improvements in broader systems of care and services to meet the needs of PLWHA and the communities in which they live.

In every country included in this report, AIDS treatment access has expanded markedly in the last several years, demonstrating the powerful combination of increased resources, consumer-driven community mobilization, and an outcomes focus by governments, external donors and providers. In Zimbabwe, one of the most troubled nations in the world, the effort to deliver AIDS care has saved many thousands of lives and the reach of AIDS-related services is steadily increasing even as political disarray continues.

Yet in every country covered here, AIDS treatment scale up is also revealing fundamental challenges in meeting the health care needs of communities. In Cameroon, insufficient nutrition makes it difficult for people to benefit from AIDS treatment and the crisis in human resources undermines service provision.

In Kenya, pervasive and ongoing stigma against PLWHA discourages people from seeking treatment and leads to actual denial of lifesaving care. In Zambia, a district-by-district review documents multiple challenges such as lengthy travel times to clinics and lack of access to diagnostic tests. In the Dominican Republic, a lucky few receive top quality care while AIDS services through the public health system remain inadequate. In Russia and Zimbabwe, women, children and marginalized populations including sex workers and men who have sex with men are often shut out of health services because of stigma, discrimination, and poverty.

Addressing each of these issues will have benefits far beyond provision of AIDS care. But losing a focus on AIDS in global health will endanger the gains made thus far, undermining consumer engagement, outcomes orientation, and public support.

This report's special focus on drug pricing, registration, and supply point to the urgent need for leadership and coordination from global health agencies, including the World Health Organization, UNAIDS, and the Global Fund. These lessons apply

*...losing a focus on AIDS in global health will endanger the gains made thus far, undermining consumer engagement, outcomes orientation, and public support.*

to all health commodities including AIDS treatment, and they indicate the multiple opportunities to utilize guidance, pressure, leadership and funding to improve health policy and health delivery in countries.

## FOCUS ON COUNTRY DRUG ACCESS RESEARCH

### **New options for first-line treatment**

Because of the risk of significant long-term toxicities associated with stavudine (d4T), such as peripheral neuropathy, lactic acidosis, and lipodystrophy, WHO now recommends other NRTIs than d4T for first-line therapy, either zidovudine (AZT) or tenofovir (TDF), combined with [lamivudine (3TC) or emtricitabine (FTC)] plus the NNRTI [efavirenz (EFV) or nevirapine (NVP)] as preferred triple-combination first-line therapy.

WHO's new recommendations ("Antiretroviral therapy for HIV infection in adults and adolescents: recommendations for a public health approach," 2006 revision<sup>1</sup>) for optimized first-line therapy have not yet been widely implemented by countries. Stavudine (d4T), about which there are toxicity and tolerability concerns, is still in wide use in many national programs for first-line treatment (for example: India, Uganda, China, Malawi). Few countries are currently using tenofovir as an option for first-line treatment (of the countries in this sample, only Morocco and Zambia report tenofovir as a possible option for first-line treatment). The improved first-line treatment combination of tenofovir (TDF) + lamivudine (3TC) + efavirenz (EFV) recommended by WHO is significantly more expensive than the current most widely used first-line combinations in the countries surveyed.

The new first-line treatment protocols proposed by WHO are based on increased efficacy, longer durability, and improved tolerability, as well as the need to maintain alternative second-line and salvage therapies. Although the new therapies are more expensive in the short run, according to the Clinton Foundation the price disparities will decrease as generic companies produce at efficient economies of scale and the costs of active pharmaceutical ingredients fall.

The new regimens are likely to be more cost effective in the long run because: (1) they are more effective in suppressing HIV, resulting in CD4 T-cell rebound and lower viral load which reduces risk of transmission; (2) they are more durable because of their resistance profiles meaning that there will be cost savings on monitoring resistance and on delaying the start of even more expensive second-line therapies; and (3) they are more tolerable, meaning that there are fewer adverse side effects. This reduces both costs of side effect treatment and of switching therapies and will undoubtedly enhance patient adherence to treatment.

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<sup>1</sup> <http://www.who.int/hiv/pub/guidelines/adult/en/index.html>

Price should not be a barrier when there is the opportunity to provide a significantly improved drug regimen. In addition, costs must be reduced over time through the entry of multiple manufacturers and through increased volume of demand. We also need a revision in calculations of the cost of scaling up access to treatment so that countries do not have to choose between rationing first-line treatment with a more expensive regimen or continuing to use a cheaper combination with more toxic side effects. People living with HIV/AIDS and civil society should be involved with debate over the trade offs and in the decision making process at country level.

In China, the lack of fixed-dose combinations (FDCs) for first-line treatment and the slow introduction of lamivudine (3TC) as part of the national free ARV program has sometimes resulted in non-standard combinations being used, such as such as didanosine (ddl) + stavudine (d4T) + nevirapine (NVP) (not recommended due to excess toxicity). This situation arose because of GlaxoSmithKline's patent monopoly on 3TC in China and the high price the company charged; it remains a problem because of the Chinese government's reluctance to approve generic FDCs containing 3TC, even after the Glaxo patent expired in October 2006.

The high price of efavirenz reported in the Dominican Republic and China, this time due to a patent monopoly by Merck, is a barrier to access. Identifying ways to introduce competition and lower prices, such as through compulsory licensing for efavirenz, 3TC, and other products, should be an important priority.

### **Second-line treatment**

The revised WHO guidelines also contain new preferred options for standardized second-line treatment built around a ritonavir-boosted protease inhibitor such as heat-stable lopinavir/ritonavir (LPV/r) or atazanavir/ritonavir (ATV/r). (The price of ATV/r is eventually expected to be 40-60% less than LPV/r, according to the Clinton Foundation). Currently, high prices, patent barriers, and registration delays all complicate access to such products.

For most countries in this sample, tenofovir and abacavir (where available) are only used for second-line treatment.

### **Recommendations:**

The new WHO guidelines for optimized first-line treatment and standardized second-line treatment will be a useful tool for improving treatment safety and quality, but also for increasing demand for certain preferred but underutilized medicines, providing an incentive to generic manufacturers to increase production and reduce prices for these drugs. Until then, because of high prices, patent barriers, lack of competition, registration barriers, and lack of information about options among policy makers, clinicians, and people living with HIV/AIDS, many countries are likely to continue using sub-optimal combinations.



- **WHO and UNAIDS:** On a national and regional basis, clearly and publicly communicate the changes in the guidelines to national programs, civil society organizations, people living with HIV/AIDS and other stakeholders, and provide technical support and guidance to countries to implement the changes. Aggressive public leadership from WHO could lead to significant uptake of its treatment guidelines.
- **The Global Fund:** As a major funding institution with the potential to act strategically in the market, the Global Fund should develop a simple plan to facilitate and encourage countries to switch to improved first-line combinations. Lower prices should follow increased uptake.
- **UNITAID:** Work aggressively to support initiatives to increase competition and further reduce the price of improved first-line treatment as well as protease inhibitors for second-line treatment.
- **Bilateral donors:** PEPFAR and other donors should work with national treatment programs, community organizations, people living with HIV/AIDS and other partners to support efforts by countries to switch to optimized first-line treatment. PEPFAR reauthorization should allow the program to greatly expand utilization of newer first-line regimens. Again, as the market for these drugs increases, costs should decrease.

### **Pricing and patent issues for first- and second-line medicines**

A major barrier preventing countries from rolling out optimized first-line treatment and standardized second-line therapy has been the significantly higher cost of the newer fixed dose combinations as well as the high cost of heat stable lopinavir/ritonavir (LPV/r).

As we've seen with the examples of China and Dominican Republic, Merck's patent monopoly prevents generic efavirenz and FDCs containing efavirenz from being procured. Merck's price for its combination regimen is two to three times higher than prices for generic equivalents negotiated by the Clinton Foundation (TDF/3TC/EFV for \$339 per patient per year), which are still ten times higher than stavudine/lamivudine combinations.

In the Dominican Republic, delays in registering Abbott's heat-stable lopinavir/ritonavir kept the only practical formulation of this critical medicine out of reach until October 2007.

### **Recommendations:**

- WHO and UNAIDS and other UN technical agencies (including the United Nations Development Programme): Country governments need technical and political support to overcome patent barriers where they exist through use of TRIPS flexibilities.

- The Global Fund and UNITAID: The Fund's potential market share should be leveraged with UNITAID's ability to negotiate price reductions with generic manufacturers. This will help ensure Global Fund resources are spread further, to more people in need of treatment as countries switch to improved combinations of drugs. The Global Fund must accelerate efforts to monitor prices paid for medicines by grantees through its Global Price Reporting Mechanism, and increase efforts to respond with corrective action if and when countries are found to be paying too high a price for medicines.

### **Stock-outs and supply management**

For several countries in this report (Uganda, Zimbabwe, China, India, Russia) medicine stock-outs are commonplace. In Uganda, for example, only two out of seven clinics surveyed had not experienced stock-outs in the previous 60 days. Stock-outs have led to drug sharing in some places, increasing risk for drug resistance and impoverishment as people are forced to pay out of pocket for medicines on the private market when supplies are interrupted in public clinics.

#### **Recommendations:**

Countries urgently need increased capacity and support from technical normative agencies as well as other technical partners such as the Clinton Foundation, Management Sciences for Health, and others, to increase the strength of their national procurement and supply management systems. Countries need to create systems that assure the availability of sufficient buffer stock at all times, assure adequate planning so that drug supplies do not expire, and reduce and eliminate dangerously long wait times. Transparency in issuing procurement tenders should become standard practice.

When countries do face a crisis, there should be national, regional, as well as international mechanisms that can be used to resolve stock-outs of ARVs with emergency supplies.

- PEPFAR and other bilateral donors should be setting benchmarks for increasing the national capacity of countries in procurement and supply management, and should be establishing dates when it will transfer procurement and supply management responsibilities associated with PEPFAR programs to countries. PEPFAR should be reporting regularly to the public on the prices paid for medicines purchased with PEPFAR funds, not only by countries participating in the Procurement and Supply Chain Management System.
- The Global Fund should proactively support grantees in identifying and correcting drug procurement bottlenecks, emphasizing core principles such as increasing national capacity, and ensuring that procurement systems are strengthened across the health sector (not only for ARV procurement).

# COUNTRY SPECIAL ISSUE REPORTS



## The real cost of free treatment

*By anonymous Missing the Target team*

China announced a “free” AIDS treatment program in late 2003, but in fact there are a number of ART-related costs that must be borne by patients. The only part of the treatment that is truly “free” is the ARVs themselves. Diagnostic tests, treatments for OIs, and most other related costs often must be paid by patients themselves. Substantial discrepancies in service delivery exist from province to province, and even among different cities in the same province, because each distinct area has flexibility (and the burden) to manage its own treatment program. Based on a number of sources around China, costs that generally must be paid by patients include:

- Western blot confirmation test (\$50 to \$80 for an individual test);
- CD4 tests (usually required twice a year, with costs ranging from \$10 to \$25 each time);
- regular diagnostic tests (required a minimum of twice a year, such tests include blood count, liver function, and other tests; costs about \$30 a year);
- viral load tests, when available (about \$150); and
- OI treatment (cost and frequency varies greatly, with an approximate range of \$150 to \$4,200 per year).

It is important to acknowledge that some cities and provinces have eliminated some of these charges for PLWHA. For example, the city of Guangzhou has allocated approximately 7,000 yuan (\$940) a year per person to cover inpatient costs; Guangxi province recently stopped charging for the Western blot confirmation and initial CD4 tests; and many areas have significantly reduced the price of CD4 tests. However, there is no uniform national policy, and the cost of OI treatments is generally prohibitively high. In many areas, hospitals are under heavy financial pressure to produce revenue, and as a result they seek to earn high profits from both tests and OI treatments for PLWHA.

In a study carried out by Médecins Sans Frontières (MSF) based on its own clinic experience in Guangxi and Hubei provinces, the actual amount that each patient had to spend on OI treatments ranged from about \$45 to more than \$8,000 annually, with a mean of \$928 (“Cost of Care”, MSF, August 2006). While this data is from only two sites, PLWHA in other provinces report spending similar amounts on OI treatments, diagnostic tests and follow-up, transportation to and from

treatment sites, and other treatments (such as “liver protecting” Chinese medicine, which is sold by many doctors and hospitals). There has been no systematic nationwide assessment of the impact that these costs have on accessibility of services, but given the low incomes of most PLWHA in China and near complete lack of insurance coverage, the impact is likely to be large. For many rural PLWHA, where annual incomes average only 2,936 yuan (\$392) [National Bureau of Statistics, China Statistical Yearbook, 2005], even \$50 or \$100 in hospital charges can represent a major barrier to accessing treatment.

In addition, PLWHA who are not legally resident in a city are generally not eligible to receive free treatment there. This is a particularly major barrier because an estimated 10 percent or more of the entire Chinese population can be classified as “migrants”. In the city of Chongqing, more than 45 percent of PLWHA were found to be “non-local” [Chongqing Times, 26 December 2005]; theoretically, they would need to return to their home towns or villages to receive free or subsidized treatment.

### **Recommendations**

The following steps are recommended to help improve access to free treatment for a greater number of PLWHA in China:

- create a transparent system for providing reduced-cost and free treatment services, with clear pricing policies;
- create widely publicized monitoring mechanisms to prevent hospitals from profiting on what should be “free and reduced price” treatment; and
- eliminate residency restrictions so PLWHA can get free ARV treatment and related services where they actually live.

## Remaining work for a successful program

By Eugene Schiff and Felix Reyes



### Overview of HIV treatment and care

One thousand people have been able to newly access ART over the past six months in the Dominican Republic. According to government statistics, by August 31, there were now close to 7,300 people receiving ART at approximately 60 sites throughout the country. The Global Fund is currently fully subsidizing the purchase of all ARVs distributed at these sites, in coordination with the MoH's HIV/AIDS Program.

Despite these significant improvements, major gaps and challenges remain. In particular, many public hospitals are still poorly equipped to provide quality care for PLWHA. Our field research revealed inefficient logistics systems, stifling bureaucracy, and a lack of urgency to resolve problems and ensure universal access to quality care. A recent report by the Pan American Health Organization calculated that 49.3 percent of all PLWHA needing treatment in the Dominican Republic were receiving antiretroviral medicines at the end of 2006. However, the same report estimated 19,190 PLWHA had died of AIDS between 2004 and 2006. Relative coverage may soon get even worse, since even using the lowest current estimate of HIV prevalence for the country (1.1 percent), as many as 7,000 additional HIV-positive people in the country now need ART in 2007, and at least a similar number may require medicines each additional year in the future.

### Findings in the field

In preparing this report, the authors interviewed more than 25 individuals, including doctors, PLWHA, counselors, government officials, NGO staff, and representatives of international agencies. They also visited a dozen clinics and hospitals in September and October 2007<sup>1</sup>.

As observed during site visits, ARV medicines, particularly for first-line drugs, are more widely and consistently available than ever before. Except for two hospitals, which needed but still lacked ARV drugs as of late September 2007 (Boca Chica and San Pedro de Marcoris), health workers reported ARV drugs were available without

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<sup>1</sup> The facilities visited included Hospital Luis Aybar, Hospital Robert Reid, IDEV, Centro Sanitario, Hospital de San Cristobal, Hospital de Puerto Plata, CEPROSH, Hospital MUSA de San Pedro de Marcoris, Maternidad de San Andres Boca Chica, and Maternidad de Los Mina.

limitations in most of the treatment sites visited. However, many health facilities lacked essential medicines for OIs and other basic supplies. For example, at the largest children's hospital in the country, where hundreds of HIV-positive children receive care, health workers acknowledged that they lacked cotrimoxazole, an important and inexpensive drug for preventing and treating some OIs.

The government has not prioritized public sector treatment access in high prevalence areas with considerable resources and massive development from tourism. For example, the public hospital in Boca Chica, a tourist resort located half an hour from Santo Domingo, lacked in-patient care of any kind. The hospital's new "comprehensive care" outpatient unit for HIV/AIDS lacked supplies of test kits and was unable to offer free HIV testing, including for pregnant women and TB patients. ARVs were also unavailable and PLWHA had to travel to Santo Domingo to obtain CD4 tests. Only a few medicines for treating OIs were observed in a nearly empty storage cabinet.

Meanwhile, PLWHA in Puerto Plata, another resort area, are able to access ARVs but must travel several hours to larger cities for CD4 and viral load tests, making it difficult to access appropriate care. Those who cannot afford transportation often forgo or delay these important monitoring tests. A similar situation limits access to diagnostics and proper care in other areas of the country as well.

Effective coordination is not always visible between the public and non-governmental sectors. For instance, NGO clinics (many of which are providing ART to significantly greater numbers of PLWHA than the public sector) still must refer PLWHA who are sick (such as those with TB and other OIs or significant health problems) back to the public sector (or to expensive private facilities) for hospitalization and specialized care. Anecdotal reports from several doctors, activists, and patients indicated that specialized care is often impossible to access. Cases were reported of PLWHA being denied essential medical procedures, including surgery, hospitalization, lab tests, and kidney dialysis—often because they were HIV-positive and unable to pay for potentially lifesaving procedures in the private sector.

### **HIV treatment for children**

In several areas of the country, the Clinton Foundation has been focusing, often with the support of religious and community-based groups, on providing ARVs for children. The Foundation's initiative is important, because it has offered training, pediatric treatment combinations, and increased access to testing and specialized care for children with HIV, particularly in areas where the MoH had been slow to act.

However, there are already real concerns about the sustainability and the need for better coordination with some of these programs. In one project implemented at the Maternidad de Los Mina in Santo Domingo, HIV-positive children were able

to access rapid tests and receive ARVs—yet thousands of pregnant women at the same site must wait several days for their test results. Although their children can get care in the public hospital in Los Mina, HIV-positive parents are forced to obtain their own medicines from separate sites in other parts the city. This is a major inconvenience for patients and families and highly inefficient from a comprehensive public health perspective.

A similar dichotomy exists in Boca Chica, where extensive services are now being offered to a small number of people by the Clinton Foundation at private Catholic health clinics, standing in sharp contrast to the limited services available to a much larger number of patients, who are mostly poor, at the nearby municipal public hospital. Improved coordination between the new pediatric and adult treatment sites sponsored by the Clinton Foundation and other NGOs is needed to better integrate these services with public hospitals, which is where the majority of pregnant women seek antenatal care, and where most Dominicans end up when they are sick.

### **Access to treatment among vulnerable groups**

Theoretically, HIV/AIDS treatment and care is available to anyone who needs it in the Dominican Republic. In practice however, for many individuals, for a variety of reasons, accessing care and receiving medicines remains difficult if not impossible. This is particularly true among prisoners, men who have sex with men (MSM), injecting drug users (IDUs), Haitian migrants, people living in rural areas, and the poor, who remain among the least likely to have access to ART and other vital HIV prevention and care services.

Little if any progress has been made in extending ART access to HIV-positive people in prisons in the Dominican Republic. According to data provided by the National AIDS Program, only one of seventy inmates identified as HIV-positive was receiving ART in two large jails covered by the Global Fund and the National HIV/AIDS Treatment Program. It is unclear how many of those identified, or how many prisoners nationwide in other jails also need treatment, but the number is likely greater than one. For example, provincial health workers reported they were unable to obtain assistance to provide support for HIV-positive inmates needing treatment in one of the many jails where no official treatment program exists. This indicated that while in some cases there is capacity and leadership on the ground to help bring counseling, testing, and ART to prisoners needing these services, authorities have yet to coordinate, prioritize, and finance such efforts.

Staff at Amigos Siempre Amigos, an NGO that has long engaged in advocacy, prevention, and defense of human rights of sexual minorities in the Dominican Republic, noted that despite some improvements, it remains difficult to obtain appropriate support in many treatment sites. They noted that there is still a need



## DOMINICAN REPUBLIC

for health workers who are non-judgmental, non-discriminatory, and able to offer specialized counseling, physical examinations, and treatment for HIV and STDs for MSM. As a result of real and perceived discrimination, some sexual minorities, particularly transgendered individuals, delay seeking care and treatment.

The situation is similar among the large numbers of Haitians living in the Dominican Republic, particularly undocumented workers and those who speak little Spanish. They are among the poorest and most exploited groups in Dominican society. With hundreds of thousands of undocumented workers, there are few reliable statistics or studies indicating the current HIV prevalence rate (or changes over time) among Haitian migrants living and working in the Dominican Republic. PLWHA at the community level reported that while access to treatment among this population has improved, services remain limited and many Haitian migrants continue to die in their communities from AIDS and other preventable diseases, without ever obtaining ARV medicines and other needed health services.

There still has been no genuine recognition of, or proactive intervention to address the growing number of HIV-positive IDUs in the Dominican Republic. Hundreds if not thousands of IDUs on the street and in prisons remain at risk for contracting and spreading HIV. They not only face difficulties in accessing treatment for HIV, TB, and hepatitis C, but also rarely have access to vital harm reduction services such as clean needles and substitution therapy. Persistent obstacles to HIV-positive IDUs' access to ART include assumptions by health care workers that drug users cannot and will not adhere to treatment, and laws and policies that place harsh criminal penalties on drug use and drug users. Such policies drive users underground, thereby further restricting their willingness and ability to access appropriate health care.

### **Access to essential diagnostic tests**

Due to a recent massive recall of one defective brand of rapid HIV tests, there has been a shortage of tests at many sites nationwide in August and September 2007. Beyond this hopefully temporary crisis, there is insufficient will on the part of authorities to improve inefficient systems to provide better access to HIV tests. Access to free HIV tests, which the government has been promising for years, remains scattered and insufficient.

“Counseling” ironically often serves as a barrier to rapid, anonymous, and free HIV testing throughout the public sector. Due to inefficient laboratory and counseling systems, pregnant women are routinely asked to wait hours to be tested and then must return several days later for the results of the “rapid” tests, which in theory can be delivered within an hour. Thousands of pregnant women and others never return for their test results and are thus lost to follow-up.

## DOMINICAN REPUBLIC

In Santo Domingo and throughout the country, lack of access to viral load tests continues to be a problem. There is no clear national protocol for the use of viral load tests. Guidelines and access to viral load tests vary widely from doctor to doctor and clinic to clinic. In numerous sites, even when tests were ordered based on urgent clinical considerations, doctors and PLWHA reported that it sometimes took three to four months or more to receive results, delays which can prove fatal. Authorities noted that these delays are due to poor logistics, insufficient lab capacity (which is supposedly being corrected with the purchase of new equipment), and high costs (at over \$50 per test) for reagents.

We also encountered increasing numbers of physicians and PLWHA stressing the need for drug resistance testing. Resistance tests are available in nearly every major city in the US and also an increasing number of countries in Latin America, but are still lacking in the Dominican Republic. Samples must be sent abroad for testing; however, the \$400 cost is prohibitive.

According to one government official, reagents for each CD4 test (which are generally provided free of charge to PLWHA), cost the government and the Global Fund project approximately \$30. This is almost six times more than the cost of test reagents available through international suppliers. Even a few local, privately run labs in the Dominican Republic charge less than \$30 to perform a CD4 test. The high cost of the reagents is significant given that CD4 tests are recommended at least twice a year for the nearly 20,000 PLWHA registered in clinical follow-up or taking ARVs. Unfortunately, the lack of transparency within government agencies makes it extremely difficult for all stakeholders—including civil society and patients—to obtain access to critical information about the negotiations and details of the contracts that set the prices. This is not only true for CD4 tests but also in the planning and procurement for the purchase of first- and second-line ARVs.



## **Delivering services amidst turmoil**

*By Matilda Moyo, Carol Mubaira, and Martha Tholanah*

Zimbabwe has reported a steady decline in adult HIV prevalence, currently estimated at 15.6 percent in the 15–49 year age group, compared to 18.1 percent last year.<sup>1</sup> Dr David Parirenyatwa, the Health and Child Welfare Minister, noted that although this was a significant decline, the figure was still too high and there was still a lot of work to be done, as more than 2,214 people die of AIDS-related illnesses, including TB, on a weekly basis.

Although the country has made considerable progress towards improving access to AIDS treatment in 2007, even with significant changes, including scrapping user fees for patients on the government treatment program and introducing provider-initiated counseling and testing (PICT), access to treatment still remains a major challenge, especially for the poor majority.

Among the negative developments that continue to hamper adequate access to treatment for PLWHA are the sale of fake ARVs, the consequences of policies such as price controls, and the popularization of a new herbal remedy called “Gundamiti,” the promoters of which claim it reverses the symptoms of HIV.

Similarly, the overall economic environment has continued to deteriorate, thereby reducing the number of patients who can afford private sector care, and concurrently increasing demand for the over-subscribed government program. Inflation, currently at over 8,000 percent, has pushed basic commodities, including ARVs, further beyond the reach of most people. The government treatment program, which had been catering to vulnerable groups such as women and children, has temporarily halted taking on new patients.

### **Major improvements in treatment delivery**

Despite the challenges the country faces, it is important to acknowledge the incremental gains that have been made toward improving treatment access to PLWHA. By the end of October 2007, 91,000<sup>2</sup> PLWHA in Zimbabwe were on

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<sup>1</sup> Minister of Health and Child Welfare, Dr. David Parirenyatwa, at the launch of the new HIV prevalence estimates, the Ante-Natal Care (ANC) Survey 2006, and the Zimbabwe Demographic Health Survey (ZDHS+) 2005-06 on October 31, 2007.

<sup>2</sup> Ibid.

## ZIMBABWE

treatment, representing 35 percent of the 260,000 in need of ART and 75.1 percent of government's target to treat 120,000 by year-end. Of these, 7,000 are children, representing 23 percent of the 30,000 children in need of ART. This is a slight improvement from a total 82,000 people on treatment in July 2007 and 4,794 children at end of March 2007. WHO estimates, however, place the number of those in need of treatment at 321,000.<sup>3</sup>

The total number of PLWHA in Zimbabwe is estimated at 1.3 million, of whom 132,938 are children below the age of 14 and 651,402 are women.<sup>4</sup>

The treatment access data includes individuals served by government and church-run mission hospitals and private sector programs. While the bulk of patients are covered through 81 public and mission health facilities, it is estimated that the number of private patients has declined from 10,000 in July to 6,000 due to various factors such as the unavailability of drugs caused by government policies and inflation, which has escalated the cost of treatment.

Between July and October 2007, significant changes aimed at improving ARV treatment delivery took place in Zimbabwe. These included decisions by the Ministry of Health and Child Welfare (MoH&CW) to eliminate user fees for patients on the government treatment program, and a shift from voluntary counseling and testing (VCT) to provider-initiated counseling and testing (PICT).

However, although the elimination of user fees was a welcomed step, the move had limited impact because it was done without addressing barriers such as the cost of diagnostic tests and transportation. Transport costs have continued to soar in the prevailing hyper-inflationary environment, making it difficult for patients to visit health institutions to collect drugs and receive medical attention. In some areas, patients fail to visit for as many as three months in a row while trying to raise money for transport to the nearest health center. Such gaps in treatment availability may result in patients developing resistance to some ARVs.

Meanwhile, patients must also pay for diagnostic tests. On average, for example, one CD4 test costs Z\$22 million while a liver function test costs Z\$21 million, which was the average civil servant's monthly salary in October. Attempts are being made to reduce the cost of diagnostics. "We are working on modalities so that diagnostics are rationalized to make them free," Dr. Parirenyatwa said.

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<sup>3</sup> WHO 2006

<sup>4</sup> Ibid.

## Access to treatment for vulnerable groups

### Adolescents

Although Zimbabwe has made great strides in providing treatment for adults and children, there is a growing number of infected adolescents who were either born with HIV or contracted it after birth. This group has been largely neglected because they neither fall within treatment programs targeted at adults nor those for children. At the same time, there seems to be no immediate, deliberate plan to ensure that they get access to treatment. Members of this group do not have consistent access to diagnostics and are not in a position to fund their own treatment. As a result, the few adolescents who are on treatment programs are only diagnosed after suffering from opportunistic infections.<sup>5</sup>

### Women

Although women comprise the larger share of PLWHA, they are less likely to have access to ART. Rural women, due to biting poverty and lack of information, are in a worse situation than their urban counterparts. According to research on HIV-positive women's health, three-quarters of all women on treatment were from urban areas—yet the majority of those in need live in rural areas. Many of those in rural areas or with limited resources have opted to manage their symptoms with herbal treatments.<sup>6</sup>

### Prisoners

Another highly neglected but vulnerable group is the prison population. Of an estimated 20,000 prisoners, some 4,000 are likely to be infected and are susceptible to both HIV and TB. With no sero-prevalence survey or statistics on HIV in prisons, experts warn that the country could be sitting on a time bomb.<sup>7</sup>

## Major setbacks in treatment delivery

### Influx of fake ARV drugs

In September 2007, it emerged that counterfeit and adulterated ARVs had flooded flea markets and hair salons, where they were being sold at low prices. The prohibitive cost of ARVs and, in some cases, unavailability at private pharmacies fuelled the illegal market.

In addition, a syndicate of unscrupulous business people resorted to hoarding and repackaging painkillers. They sold these pills as ARVs to unsuspecting patients through flea markets and private homes<sup>8</sup>, capitalizing on the desperation of people and unavailability of treatment.

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<sup>5</sup> Discussion with Dr. Rashida Ferrand

<sup>6</sup> ZWRCN research

<sup>7</sup> Dr. Mugurungi

<sup>8</sup> The Sunday Mail, October 28 2007.

## ZIMBABWE

According to the Medicines Control Authority of Zimbabwe (MCAZ), individual drug importers had also flooded the local market with ARVs, which were being sold from unlicensed locations. This raised concerns by MCAZ that some drugs might have been subjected to inappropriate and hazardous storage conditions, thereby affecting their quality and effectiveness, which would put patients at risk for developing drug resistance. Calls by government officials to only purchase drugs from authorized selling points proved futile because patients have limited options due to shortages and the high cost of drugs.

### Price controls

In an attempt to rein in galloping inflation, the government in July 2007 froze the price of most goods retroactive to their price a few weeks earlier. Businesses, including pharmacies, were forced to reduce their prices, in some instances by up to 50 percent.

The subsequent effect was an acute shortage of goods as customers hoarded products and businesses stopped restocking. Most goods however, became available on the parallel market through unauthorized dealers at extremely high prices. The prohibitive cost of ARVs and, in some cases, unavailability at private pharmacies fuelled the illegal market for the life-prolonging drugs.

Although the controls were lifted in the pharmaceutical industry in October 2007, businesses were still suffering from the consequences of the decision. Companies that sold their products at imposed low prices were having difficulties raising money to restock products that had to be procured at higher new prices. By end of October, most pharmacies still had empty shelves and were not sure when operations would normalize. This also affected availability of food, a vital support for those on treatment.

Furthermore, pharmacies could not import ARVs directly due to protracted foreign currency shortages.

### Water shortages

Zimbabwe is experiencing erratic water supplies. This situation is particularly problematic in the country's second largest city, Bulawayo, which has been severely affected by drought. This is worsened by mismanagement of water resources by the Zimbabwe National Water Authority (ZINWA), which has taken over water administration from local authorities.

Some residents have gone as long as three months without safe tap water and are sometimes forced to resort to unhygienic wells. AIDS patients under home-based care have been severely affected and are at risk of contracting other illnesses associated with poor hygiene, such as diarrhea. Cases of cholera and diarrhea have been recently reported.

Limited treatment literacy

PLWHA continued to fall victim to false information due to limited treatment literacy. This is worsened by conflicting messages about unproven remedies such as Gundamiti.

Given its limited resources, the government has appealed for civil society support in conducting treatment literacy. However, civil society has accused the government of implementing policies that hinder its operations. For example, the government recently centralized the disbursement of foreign currency for local organizations, including NGOs.

“It now takes up to two weeks to access your own money from your foreign currency account because of the centralization; how can NGOs operate in an environment with such prohibitive policies?” asked Moses Mutyasira, director of the Zimbabwe Network of Positive Youth. He called on government to revise its policies and mend bridges with civil society in order to facilitate a multi-sectoral approach toward ensuring universal access to treatment.

Limited government resources

Partly because of targeted sanctions, Zimbabwe has experienced a flight of donors and lacks credit facilities. As a result, the country has to operate on a cash basis. The problem is further exacerbated by a lack of significant donor funding: According to the MoH&CW, per capita donor spending is \$10 per person, compared with \$200 to \$400 for people in the southern African region.<sup>9</sup>

Despite committing 15 percent of the national budget toward health, in compliance with the Abuja declaration of 2001, health institutions remained under-funded and continued to deteriorate, while failing to play their role effectively. This has occurred even though 70 percent of the national health budget currently goes to hospitals for equipment, drugs and other essential supplies, leaving very little for treatment.<sup>10</sup>

Global Fund rigidity

Global Fund programs have been negatively affected by high staff turnover. This results from challenges such as workers going for months without salaries due to delays in disbursement.

Although Zimbabwe has a sufficient supply of pediatric and second-line treatments, they are not reaching PLWHA due to Global Fund bureaucracy, such as the institution’s insistence on zoning systems and that the medicines be distributed solely through its programs. The rigidity of the Global Fund affects implementation, and there is need for greater flexibility.<sup>11</sup>

<sup>9</sup> Interview with Dr. Owen Mugerungi, Head of AIDS and TB Unit in the MoH&CW.

<sup>10</sup> Presentation by Dr. Peter Iliff at the International Federation of Health and Human Rights Organisations (IFHHRO) Annual Conference. Harare, October 24–26, 2007.

<sup>11</sup> Interview with Dr. Owen Mugerungi, Head of AIDS and TB Unit, MoH&CW.

Zimbabwe's application for the Global Fund's 7th round was turned down although the reasons are not yet clear.

### Human resources shortfalls

Zimbabwe has experienced a flight of qualified health personnel as a direct result of its economic challenges. Fifty percent of all health posts are vacant<sup>12</sup>, thereby negatively impacting the health delivery system.

Chief among the causes for the high attrition rate are low salaries and poor working conditions. Furthermore, lack of incentives, night duty, transport allowances, and housing loans have driven medical personnel to neighboring countries where their work is more rewarding. Although training programs are offered, they serve to make personnel more marketable, and they leave the country as soon as they receive additional training.

The situation is worse in rural areas, where one or two doctors are expected to cover vast geographic areas with limited resources.

To curb the impact of the brain drain, government, municipalities, and some NGOs have trained community health workers. These caregivers have become a vital resource at the community level. The caregivers mostly are dealing with counseling and home-based care due to the high prevalence of HIV and chronic diseases. The community health workers function according to the prevalence of diseases in the community.

### Stigma and discrimination

Although medical personnel deny the existence of stigma, they have been accused of being the worst discriminators against PLWHA.

"There is free treatment for all regardless of one's race or gender. We operate on a first-come-first-served basis and this is made possible through the use of a waiting list. The only problem is that, at first people did not want to be seen entering or leaving the OI clinic; however with time they adjusted," a nurse from Mpilo hospital said during an interview.

However, interviewees argued that medical personnel were major culprits in discriminating against PLWHA, particularly among the youth who were accused of loose morals when they sought medical attention for HIV-related ailments. This has deterred patients, particularly youth, from seeking assistance from medical personnel.

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<sup>12</sup> Presentation by Dr. Peter Iliff at the International Federation of Health and Human Rights Organisations (IFHHRO) Annual Conference. Harare, October 24–26, 2007.



## Promises made by country leaders regarding AIDS treatment

- In October 2006, the Reserve Bank Governor, Dr. Gideon Gono, pledged to avail \$1 million for ART on a monthly basis. This has not been done, but would go a long way in enabling the local pharmaceutical industry to meet demand. Meanwhile, the situation in Zimbabwe has worsened, with local pharmaceutical companies failing both to import drugs and to procure raw materials to manufacture ARVs locally.<sup>13</sup>
- Although the government has noble intentions and sets annual treatment targets, it has repeatedly failed to meet them. In 2005, government pledged to place 110,000 people on treatment, but only managed to add 27,000. In 2006, 56,000 were placed on treatment. This year's target is 120,000, less than 50% of the 260,000 people in need of ART, and as of October 2007 it seemed apparent it would not be reached. Many observers worry that that the government is scaling down treatment efforts by aiming low.
- The health minister, Dr. David Parirenyatwa, in July 2007 pledged to ensure that diagnostics would be available free of charge as part of ensuring greater access to treatment for PLWHA on the government program. As of October 2007, however, that important step had not been implemented.

## Recommendations

### ■ Civil society

- Assist with aspects of ensuring access to treatment, e.g., treatment literacy provision to communities.

### ■ Health ministry

- Develop standardized guidelines for adolescent treatment.
- Find more creative ways to retain trained personnel.
- Fulfill the promise to avail diagnostics to patients on the government program free of charge.

### ■ Global Fund/multilateral agencies

- Countries are the drivers of these programs. Thus the Global Fund should be more flexible in respecting the country's strategic decisions as long as they are justified and approved by the CCM.
- Timely disbursement of Global Fund monies is essential to enable smooth operations.

### ■ Reserve Bank of Zimbabwe

- Allocate foreign currency for purchase of ARVs and support local ARV production on a monthly basis as promised.
- Decentralize administration of foreign currency accounts run by NGOs.

## ■ **National government**

- Address macro-economic fundamentals as a point of departure in solving most of the social and political challenges that ultimately affect health delivery and subsequently treatment access.
- Through ZINWA, urgently address the water situation, including ensuring availability and quality.
- Improve relations with other countries, multilateral agencies, and international donors to ensure increased funding and support.
- Provide a friendlier policy environment and work with civil society and other partners, rather than isolate and treat them with suspicion.

## ■ **International community**

- Support Zimbabwe to fight HIV from a humanitarian perspective.
- Improve relations with the government of Zimbabwe

## ■ **All stakeholders**

- Conduct a massive joint campaign to deter people from buying ARVs from unregistered selling points and encourage them to purchase their drugs only from registered pharmacies, clinics, and hospitals.
- Conduct treatment literacy so that patients do not turn to unproven remedies.
- Train communities and service providers who live and work with HIV-positive adolescents on counseling and communication skills.
- Increase access to testing and care for adolescents, including dedicated facilities that address their unique challenges within HIV services.
- Develop sustainable joint initiatives to train and retain health professionals.

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<sup>13</sup> Speech by Reserve Bank of Zimbabwe (RBZ) governor, Dr. Gideon Gono at the Harare Central Hospital School of Nursing and Midwifery graduation ceremony, 27 October 2006.

## Making marginalized groups a priority

By Sergey Kovalevsky, Anastasia Agafonova,  
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Eurasian Harm Reduction Network (EHRN)



### Access to services for marginalized groups

Poverty, powerlessness, and social discrimination continue to exacerbate the health problems of marginalized groups in Russia. Injection drug users (IDUs), sex workers (SW), men who have sex with men (MSM), prisoners, and migrants have poor access to health care resources and services. These individuals are particularly vulnerable to HIV infection, and face stigma and discrimination throughout society, including in the workplace and in medical institutions. While national funds for HIV increased substantially over the last years, funding for evidence-based prevention programs still mainly relies on international funding.

#### MSM

MSM tend to remain invisible and meet significant opposition when they become vocal. Although highly vulnerable to HIV infection, MSM are not targeted by prevention activities of government and national projects, which may be taken as evidence that the government is not concerned with the welfare of this population. Recently, some officials have begun discussing the idea of criminal punishment for homosexual behavior, and some government representatives have become increasingly aggressive about homosexual issues.

#### IDU

In Russia, despite the fact that as many as 85% of PLWHA are IDUs, active drug users still face significant barriers to accessing HIV treatment and care. Treatment uptake among IDUs has been low and rates of cessation of treatment are high. Addiction treatment is not accessible and substitution therapies proven to support treatment adherence among IDUs are still illegal. Few IDUs have access to harm reduction services. Though some good models of providing integrated care exist in Russia (in which TB, HIV, drug addiction, psychological support, and harm reduction are offered), they are rare. Stigma, discrimination, and punitive rather than medical approaches to drug-related harm, continues to deter many drug users from accessing care.

#### Sex Workers

Sex workers in Russia face a multitude of vulnerability factors. Some studies suggest that HIV prevalence among sex workers is quite high -- as much as 15% in Moscow and 48% in St. Petersburg among street-based sex workers. Sex workers are often at risk from both sexual and injection-related transmission. Many are migrants and face additional difficulties accessing health care services. There are very few programs specifically targeting sex workers with outreach and client-oriented services. Russia does not yet have a union or network of sex workers.

### Migrants

Russia, with the second largest immigrant population in the world, has a growing number of labor migrants who face heightened vulnerability to HIV and hindered access to care. Migrants, especially those without documentation, face difficulties accessing medical care as most HIV care facilities provide care only to those with an official residence permit. Neither prevention nor treatment services are adapted to the language and cultural needs of migrants. The threat of deportation serves to deter migrants from accessing medical services. According to Russian law, foreign citizens living with infectious diseases must be deported to their home countries; however this does not always occur. In 2007, 1,189 foreign people and non-citizens crossing the border were identified as HIV-positive, according to data from the Russian Federation Federal Service for Surveillance on Consumer Rights Protection and Human Welfare, and 223 were deported.

### Prisoners

Russia has one of the world's highest rates of incarceration, with the majority of people in the prison system serving time on charges related to illegal drugs. Of 808,000 prisoners in the system in September of 2005, 37,000 were living with HIV, so nearly 5% of the prison population is HIV-positive.<sup>1</sup> Studies have shown that drug use continues in prison and that people are actually more likely to share injection equipment in prison than outside due to the difficulty of acquiring syringes. Risk-taking sexual behavior and sexual violence inside prisons are also reported. Though some health promotion programs exist in prisons, syringes are not distributed and condoms very rarely.

## **Recommendations**

- Scale up existing model programs for linking testing, prevention, treatment care, and support services and integrate these services with TB, hepatitis, addiction and other services.
- The scope, coverage, and quality of evidence-based and user-friendly prevention programs targeting vulnerable populations should be improved, as should the incorporation of case-finding initiatives within them to improve treatment uptake.
- Improve access to non-discriminatory voluntary testing and counseling services with special attention to protection of confidentiality and privacy.
- Social support, including peer counseling and case management, should be designed to increase treatment uptake by vulnerable groups.
- Prevention and treatment programs should address the social exclusion that often leads to marginalization and vulnerability.
- National funds for prevention should be increased substantially, focusing on evidence-based policies and approaches that are integrated with treatment programs.

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<sup>1</sup> Transatlantic Partners Against AIDS (TPAA). Right to Health: Prevention and Treatment of HIV-infection among Most At-Risk Populations. Informational Bulletin No 3(5). December 2006.



## **The deadly impact of stigma**

*By Elizabeth Owiti, Healthpartners; and  
James Kamau, Kenya Treatment Access Movement (KETAM)*

Although the campaign for increased access to HIV/AIDS medicines has improved distribution of ARV drugs, most people with HIV/AIDS in Kenya still do not seek treatment, and many die of treatable infections such as TB. It is therefore important to ask what factors bar demand for treatment in Kenya, and what role stigma and discrimination play in determining treatment access.

To address these questions a literature review was conducted and a brief qualitative survey was undertaken involving Kenyans living with HIV/AIDS, health care workers, and key informants. Our results reveal that stigma and discrimination are prevalent in Kenya in many forms, and affect people differently depending on socio-economic status.

### **HIV and AIDS-related stigma**

In Kenya, the general population, including many medical personnel, is not well informed about HIV and AIDS. In the public eye, HIV and AIDS are commonly associated with socially-censured sexual behaviors that are often viewed as the responsibility of the individual. AIDS is understood to be incurable, degenerative, often disfiguring, and associated with an “undesirable death.” It is often incorrectly thought to be highly contagious and a threat to the community at large. All of these fears are used to justify marginalization of PLWHA, thus further entrenching deeply rooted prejudices.

### **Causes of stigma and discrimination**

Our survey shows that stigma around HIV and AIDS persists because ideas about the disease are deeply enmeshed with social, personal, cultural, and religious beliefs, as well as fears about sex and death, two taboo issues not traditionally discussed in most communities.

#### Knowledge and fears

Most Kenyans understand the basic facts of HIV prevention and transmission. However, our study found that there is a lack of in-depth knowledge, which feeds fears about casual transmission. Many respondents did not understand the difference between HIV and AIDS, how the HIV disease progresses, or how long one can live with HIV before progressing to AIDS. Many respondents believed that

a person with HIV will die very quickly, if not immediately. People with certain illnesses (such as TB and herpes zoster) are usually believed to have HIV, therefore are also stigmatized. Furthermore, some respondents did not believe that OIs are treatable or curable, and others equated TB with AIDS. Cultural perceptions, such as a belief that disease is caused by witchcraft, has also increased fears. Some respondents expressed fear of physical contact with those infected.

Respondents also expressed a strong fear of painful, certain death. Given this profound fear, people said they tended to limit their contact with PLWHA.

### Sex and morality

Because HIV is mainly sexually transmitted in Kenya—and because it is associated with promiscuity—HIV/AIDS is not thought of like other diseases. Studies reveal a common belief that people with HIV acquired it through sexual activity that is not socially sanctioned or goes against religious teachings. Hence, having HIV is considered to be a result of “deviant behavior,” and PLWHA are regarded as adulterers, prostitutes, and generally immoral or shameful. Therefore, PLWHA are blamed and stigmatized as irresponsible persons. Sex and HIV infection are also often associated with sin, with some people saying that HIV is a punishment from God for sexual sins committed by humanity at large, and individuals in particular. Those who get HIV are supposed to have sinned, while following strict religious strictures is believed to ward off illness.

### **The context of stigma**

This study also found socioeconomic status, gender, and age also influence the stigma experienced by PLWHA and affect a person’s ability to cope with the stigma. The rich are believed to become infected because of promiscuous lives and their ability to buy sex from prostitutes, while the poor— especially women— are viewed to have become infected due to abject poverty that forces them to accept risky sexual activities to earn a living. It is also believed that youth are at a higher risk for HIV infection due to their irresponsible and active sexual lives, and they are typically blamed for becoming infected through promiscuous, immoral, and “improper” behavior.

### Gender

Women have a higher risk of infection than men, both for physiological reasons and due to environmental factors such as sexual violence. However, men may also be considered to be at higher risk than women due to men’s polygamous or promiscuous sexual lives; in Kenya, the culture allows men to be polygamous. Both men and women are stigmatized if infected by HIV, but stigma directed toward women is typically stronger.

The impact of HIV/AIDS on women is overall more acute, and HIV-positive women are treated very differently from men. In Kenya, women are economically, culturally,

and socially disadvantaged, lacking equal access to treatment, financial support, and education. In a number of societies, women are mistakenly perceived as the main transmitters of STDs. Together with traditional beliefs about sex, blood, and the transmission of other diseases, these perceptions provide a basis for the further stigmatization of women within the context of HIV and AIDS. Men are likely to be “excused” for the behavior that resulted in their infection, whereas women are not.

## **Manifestations of stigma**

### Stigma towards PLWHA

This study found that PLWHA are treated differently, gossiped about, deprived of their identity and roles, and often denied their own resources.

The most common forms of differential treatment are physical or social exclusion from the family and community, which may also include denial of care and support by the family, community, and health system. Those infected sleep separately, use separate beddings and linen, and at times use separate utensils. Social exclusion usually manifests itself as the reduction of daily social interaction with family and neighbors, and exclusion from family and community events.

Gossip—and the fear of gossip—is pervasive. PLWHA are talked about negatively, and this may be the most common and feared manifestation of stigma. Gossip has a greater impact on women than men as women usually have a greater dependence on social networks. The targets of gossip also lose their identity and social roles, as they are considered to have no future and are no longer productive. Stigma and discrimination also manifests through loss of access to resources and livelihood. Workplace stigma may result in job loss when the HIV-positive person is laid off, and HIV-positive business and trades people are likely to lose customers. Worse yet, an HIV-positive person may lose his or her property rights within the family, and HIV-positive women may lose their inheritance.

### The internal stigma

PLWHA were also found to internalize the stigma. The feelings of helplessness and that death is imminent can be debilitating. PLWHA may internalize the guilt and blame for being HIV-positive and accept their inferior status in society. Psychologically affected by stigma, they can become despondent and lose hope, and may isolate or separate themselves and even give up on previous life aspirations. This form of stigma is devastating because it bars people who already know their status from seeking care and treatment, and also prevents those with advanced stages of AIDS from seeking care.

*“If I’m tested and found to be HIV-positive, I will commit suicide.”*

—A person with late-stage AIDS, who has since died of complications due to AIDS.

### Families

In Kenya, families are the primary caregivers for sick members. Some families provide adequate care for members with HIV/AIDS; however, not all family responses are supportive. HIV-positive family members are sometimes stigmatized and discriminated against within the home. There is also mounting evidence that women are more likely to be badly treated than children and men.

### Employment

Several employers use the supposed risk of transmitting HIV, the cost of health care management, and work absenteeism to terminate or refuse employment to PLWHA. Our study also found that PLWHA who are open about their infection status at work may experience discrimination by others. Pre-employment and annual screening and medical checkups are performed by many companies in Kenya, and those found HIV-positive risk being laid off.

### Health care

Even at the health care centers, PLWHA are not spared stigmatization. Many reports reveal the extent to which people are discriminated against by health care systems. Studies reveal withheld treatment, non-attendance of hospital staff to patients, HIV testing without consent, lack of confidentiality, and denial of hospital facilities and medicines. Also fuelling such responses are ignorance and lack of knowledge about HIV transmission among medical professionals.

### **The way forward**

HIV/AIDS-related stigma and discrimination remain enormous barriers to effectively fighting the epidemic. Fear of discrimination often prevents people from seeking treatment for HIV/AIDS or from admitting their status publicly. People with (or suspected of having) HIV/AIDS may be turned away from health care services and employment, or refused entry to foreign countries. In some cases, they may be evicted from their homes by their families and rejected by their friends and colleagues. The stigma attached to HIV/AIDS can extend into the next generation, placing an emotional burden on those left behind.

Internal stigma and denial go hand-in-hand with discrimination, with many people continuing to deny that HIV/AIDS exists in their communities. Combating the stigma and discrimination against people who are affected by HIV/AIDS is as important as developing the medical advances for preventing and controlling the global epidemic.

A more enabling environment needs to be created that increases the visibility of PLWHA until they are seen as a “normal” part of any society. The task is to confront the impact of fear-based messages and biased social attitudes in order to reduce the stigma and discrimination faced by PLWHA.

Finally, an aggressive treatment education campaign is needed, especially in the rural part of Kenya, to help reduce internal stigma as an impediment to the demand for testing, treatment, and care.



## Waiting for second-line ART over?

By Abraham KK, Celina D'Costa, Murali Shunmugam, Venkatesan Chakrapani, Indian Network for People living with HIV (INP+)



According to estimates from India's National AIDS Control Organization (NACO), about 2.47 million individuals in India were living with HIV at the end of 2006, the third highest number in the world by country.<sup>1</sup> At the end of August 2007, a total of 100,572 PLWHA—56,999 men, 32,038 women, 6,721 children, and 128 Hijras (transgender individuals who identify as women)—were receiving treatment through the 127 ART centers supported by NACO. An additional 4,686 PLWHA were receiving ART outside of the core public sector program. Global Fund assistance is directly responsible for ART provision to some 75,538 PLWHA through the public sector and 2,207 in a separate program.

Targets set at the end of the third phase of the National AIDS Control Programme (NACP-3) are for 300,000 adults and 40,000 children to be on ART in the public sector by the end of 2012. The interim target, which has already been achieved, was to have 100,000 adults on ART through the public sector by the end of 2007.

### Status of previous key recommendations to NACO

1. Develop a plan to provide second-line ARVs through the national ART program

#### *Follow-up:*

Currently, all PLWHA (including children) in the national program are provided only first-line ARVs; second-line ARVs are not currently available in the national program. The director-general of NACO has announced that NACO would start providing second-line ARVs once the treatment access target of 100,000 is reached. That target was reached by August 2007. During a meeting that month, NACO's technical resource group on ART discussed the technical and operational issues related to introduction of second-line ARVs in the national ART program. As of October 2007, however, no concrete plan had been developed or made available. Just before the release of the report, NACO has announced that second-line ART will be introduced in the national ART program in a phased manner. However, the details of the phased scale-up plan is still not publicly released.

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<sup>1</sup> International Institute for Population Sciences (IIPS) and Macro International. National Family Health Survey (NFHS-3), India: Key Findings. Mumbai: IIPS. 2007. [http://www.nfhsindia.org/nfhs3\\_national\\_report.html](http://www.nfhsindia.org/nfhs3_national_report.html)

## 2. Provide pediatric formulations for ART

### *Follow-up:*

Based on NACO's revised estimates, about 70,000 children are living with HIV in India, and pediatric ARVs are available in all the currently functional (a total of 127) government ART centers. National pediatric ART and dosing guidelines are being followed at these centers. The current goal is provide ART to 40,000 children by 2012.

The national pediatric ART program is supported by the Clinton Foundation. In an e-mail communication to this report's authors, the Foundation said that it did not have any plans for supporting second-line regimens for children living with HIV in India.

Additional challenges for the pediatric program include whether and how to disclose the HIV status of children; explaining to the children why they need to take their medications (ART) on a regular basis; and a lack of trained counselors to provide counseling on treatment adherence in children.

## 3. Develop a policy to ensure equity in ART access to members of vulnerable groups

### *Follow-up:*

No information is yet available on how many MSM, IDUs, and sex workers—all members of vulnerable groups—are receiving ART through the national program. However, the numbers are likely to be very low because of actual or perceived discrimination. In an October 2007 e-mail communication, NACO's national ART program officer mentioned that specific information regarding vulnerable groups' ART access might be available at individual centers, but that the centers did not report such data to NACO.

Currently there is no national action plan for equity in ART access that is designed to ensure that marginalized populations living with HIV are not excluded from the national ART program.

## 4. Establish enough ART centers across the country to help facilitate universal access

### *Follow-up:*

NACO's target is to have at least 188 public sector ART centers by December 2007, up significantly from the total of 127 at the end of August 2007. In an e-mail communication to the Indian Network for People Living with HIV (INP+), a NACO official mentioned that 16 additional ART centers will have become functional by the end of October and 31 more ART centers are soon to be established.

**ARV shortages in national ART centers:**

In an e-mail communication to INP+, a NACO staff member mentioned that “there had been low stock-outs [ARV shortages] in the last six months” and that when shortages occur in any center there is a system designed to facilitate immediate replenishment from another ART center. The NACO staff member also mentioned that it is developing a mechanism for supply chain management of ARVs and setting up a dedicated team for the same endeavor. Despite these claims, stock-outs have been noted by activists in several regions of India, and the response to a shortage has caused particular problems in the state of Manipur (see the report on shortages in Manipur in the Drug Access section).

## Linking nutrition and treatment

By Wendi Losha Bernadette and Dr. Oliver Birnso Verbe



### Current situation

Between March and June 2007, the number of adults on ART in Cameroon increased by nearly 25 percent, from 29,198 to 37,081<sup>1</sup>. That surge followed the government's declaration that ARVs would be dispensed free of charge to all in clinical need. The subsequent sharp rise in ART access indicates that provision of free ARVs plays an important role in scaling up ART uptake.

However, despite recent improvements, more than half of those who need ART in Cameroon have yet to start treatment. The situation was particularly dire for children. Just 1,360 children were on ART at the end of June 2007, a number that represented about 13.7 percent of the 9,953 children considered eligible for ART.

### Cross-section by age of PLWHA on ART

Age	0-15	16-19	20-24	25-29	30-34	35-39	40-45	45+
%	3.7%	2.4%	7.9%	15.1%	20.2%	19.7%	15.3%	15.7%

Source: National AIDS Control Committee's Central Technical Group Report (June 2007)

The main barriers to treatment access and uptake are the high cost of diagnostic tests (about \$42 per person on average for a CD4 count test, and \$68 per person for viral load analysis, for example); the lack of affordable and convenient transportation to treatment centers; and lack of awareness about the availability of free ART or where to obtain it.

Another persistent problem is that many patients start ART only after they become extremely ill. In such cases, ART should be accompanied by treatment for OIs or the acute illness, and supplemented with adequate nutrition and treatment for drug side effects, if necessary. Yet OI medications are costly and some patients go untreated if they cannot afford them. Nutritional support rarely exists, especially for the poorest patients, and many health providers are not trained to manage or mitigate drug side effects and toxicity. As a result, the average survival rate of individuals on ART in Cameroon is just 12 months.

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<sup>1</sup> National AIDS Control Committee Progress Report No. 7. August 2007.

## CAMEROON

Access to PMTCT services in public health institutions has had shortcomings for a number of reasons. Many pregnant women do not attend antenatal clinics in general, which means that they are rarely if ever offered the opportunity to be tested for HIV. And since results are not usually given the same day, a significant number of those who are tested do not return to obtain them.

Some steps have been taken to improve PMTCT uptake and access. For example, a more comprehensive program to integrate PMTCT into antenatal care was established by the Cameroon Baptist Convention Health Board, a faith-based organization in Kumbo-Nso, in 2000. It currently reaches 6 out of 10 provinces in Cameroon and includes remote villages. Village health workers and birth attendants have been trained to implement the program<sup>2</sup>.

### **Research objectives and methodology**

The objectives of our research were to identify obstacles to scaling up HIV/AIDS treatment and prevention in Cameroon and to propose solutions for mitigating barriers to efficient health care system development.

Data was collected using an ITPC template developed for in-country research. Official data was obtained from government agencies, and the research team interviewed people living with HIV and AIDS (PLWHA), civil society representatives (including community-based advocates), medical practitioners, pharmacists, government officials, international organizations, and funders.

### **Nutrition**

Although Cameroon is rich in agricultural land and grows a wide range of food produce, a majority of the population does not consume a balanced diet, mainly because they lack information about the importance of nutrition. A nutrition literacy program could help prolong and improve the quality of life for PLWHA in Cameroon. Better access to nutrition may also contribute to improved outcomes for those on ART.<sup>3</sup>

*“It is evident that proper nutrition builds tissue damaged by HIV, OIs, and the ARVs themselves. No doubt, many patients on ART either skip doses or completely abandon treatment when there is no food to eat.”*

— Dr. Oliver Birnsó Verbe, medical practitioner in Cameroon

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<sup>2</sup> Welty, T.K.; Bulterys, M.; Welty, E. ; et. al. “Integrating Prevention of Mother-to-Child HIV Transmission Into Routine Antenatal Care: The Key to Program Expansion in Cameroon. JAIDS: Journal of Acquired Immune Deficiency Syndromes. 40(4): 486-493. December 1, 2005.

<sup>3</sup> Dr. Palmer Denis, Mbingo Baptist Hospital.

## CAMEROON

Most people living with advanced HIV are in poor health, are economically impoverished, and cannot afford proper nutrition. Nutritional access concerns were expressed by PLWHA we encountered in the field. When asked to be interviewed, a treatment adherent living with HIV/AIDS told us:

*"I am not interested in what you may want to ask me for now since I have not eaten. I need to cook, eat, and take my drugs."*

A member of a support group had this to say:

*"I cannot attend support group meetings any more because I have to toil all day long just to have food on my table. I will attend support group meetings only if I am assured that meals will be provided in meetings."*

### **National AIDS Control Committee**

Based on the National Health Strategic Plan, the MoH determines the National AIDS Control Committee's policies. In addition to providing direct support through the public sector, the committee through its provincial technical groups also funds local NGOs involved in HIV prevention and care.

The MoH coordinates HIV/AIDS program activities, including drug procurement and treatment. The government receives significant external support for these activities, including from the Global Fund and the Clinton Foundation.

Incompetence and corruption have plagued the program at times. Data collection has been poor at the provincial technical group level. A recent external evaluation by donors revealed gross mismanagement, a finding that led to the temporary suspension of funding for local HIV prevention, sensitization, and support/care activities. Also, some members of provincial technical groups formed their own local NGOs and funded them; they have yet to provide evidence of any meaningful HIV-related activity. Reports have also surfaced of provincial technical group members requesting kick-backs from NGOs before funding their activities. The overall result of these problems has been poorly executed projects in the field.

### **Limited civil society capacity**

There is a great need to build the capacities of civil society advocates to assess and monitor government policies, financial management, and HIV/AIDS and health service delivery. A case in point: Civil society and PLWHA have only limited involvement in the Global Fund process in Cameroon. The MoH, which serves as the Principal Recipient, dominates the Global Fund CCM by controlling membership, setting agendas, and deciding meeting times and venues without consultation. There is no effective control regarding the PR's use of Global Fund assistance intended to improve the country's HIV/AIDS response.

## **Lack of health care personnel**

On average, there is only one doctor available to serve every 5,000 PLWHA in Cameroon. Physicians receive relatively low salaries and must deal with poor working conditions. Most doctors are inadequately trained on HIV/AIDS, especially with respect to nutrition, counseling, and drug side effects. The doctors' inefficiency and lack of adequate incentives is further compounded by overwhelming workloads. Between May 2007 (when access to ART was declared free of charge) and September 2007, treatment centers in Bamenda, Douala, and Yaoundé witnessed more than double the number of PLWHA coming for services.

Reports have surfaced about unscrupulous behavior on the part of some health care personnel in the public sector. For example, some patients have been told that they must pay for ARVs, even though the medicines are supposed to be provided free of charge.

The government plans to recruit over 30,000 health care workers over 15 years to address the personnel shortfall and to be able to fulfill WHO standards in the future. It is unclear how successful these efforts will be, given how slowly the government has moved to initiate them. Currently the government is recruiting community health workers through public and private health institutions as well as local NGOs.

## **Treatment for OIs**

OIs are a particular problem in Cameroon because most people are reluctant to be tested for HIV, due to stigma associated with HIV and AIDS. People often get tested only when suffering from at least one OI, which indicates significant HIV progression. Also, patients are required to pay for all drugs to treat OIs, including prophylactic medicines such as cotrimoxazole. This places a high financial burden on many HIV-positive individuals, some of whom forego necessary treatment because they cannot afford the medicines.

## **Diagnostic tests**

Patients are required to pay for all HIV diagnostic tests. The cost for a standard HIV test ranges from \$1 in public facilities to \$4 in most private health institutions. Only pregnant women and children below the age of five can receive HIV tests free of charge through the public sector.

Meanwhile, individual CD4 count and organ function tests cost about \$42, with a single viral load analysis priced at about \$68. Unsurprisingly, such costs are beyond the reach of most Cameroonians. Those that can afford them often find it difficult to access such tests anyway. Many of the more than 100 treatment centers do not have the necessary equipment to offer CD4 count tests, and viral load analysis is

## CAMEROON

only available in the capital, Yaoundé, and the largest city, Douala. Such limitations offer ample evidence that treatment monitoring is substandard and problematic.

### **Marginalized groups**

The Bororo Fulanis and the pygmies in the rural areas of Cameroon are the most vulnerable of the country's more than 250 ethnic groups in terms of HIV-related health risks. Most of them are not aware of HIV and AIDS, let alone the availability of free ART. They also tend to live far from treatment centers, which adds yet another barrier to ART scale up for these Cameroonians.

Sex between men is a crime in Cameroon; even talking about it is taboo. Men who have sex with men (MSM) therefore hide their actions from most people in their lives, even though doing so may place themselves and others (including wives) at risk for HIV. Socially difficult yet vital steps should be taken to reach out to these individuals and offer them non-discriminatory education, care, and treatment. Sex workers also face widespread stigma. They constitute a major at-risk group and should be catered for more extensively and thoroughly. Sex workers are a common sight on the streets of most big cities, namely Yaoundé, Douala, Bamenda, and Limbe, yet they are usually denied access to appropriate services.

### **Recommendations**

The following actions and activities would help improve the response to HIV/AIDS in Cameroon:

- Educate PLWHA on the importance of good nutrition and adherence to treatment.
- Involve civil society representatives from the entire country on the Global Fund CCM.
- Establish a permanent country office for the CCM.
- Donors and civil society organizations should implement programs to more strictly control and monitor the government's use of the funds for HIV/AIDS.
- Greater efforts must be made to inform rural residents and members of marginalized groups as to the existence of free ART.
- Government entities at all levels should implement initiatives designed to reach out to and provide appropriate care to members of marginalized groups. Such efforts are likely to help reduce HIV-related stigma and discrimination as well.



## **A district-by-district survey**

*By Felix Mwanza and Paul Kasonkomona*



### **Challenges to access to treatment and related services**

#### Methodology

This research examines access to treatment and care in Zambia through stakeholders' consultations, focus group discussions, interviews with key informants, and empowerment forums. Findings were analyzed from the perspectives of gender, rural versus urban settings, and human rights.

#### Lessons learnt

The government often fails to consult with grass roots and rural partners; funding organizations and urban-based partners have a greater voice in shaping government responses. The exclusion of rural partners from government decision-making may be part of a strategy to disempower and limit the political strength of this sector of society.

Eighty percent of the Zambian population is poor and life is not easy for them, particularly so when HIV and AIDS are added to existing challenges. Access to health care is difficult. Long travel times to and from health care facilities are common; charges for services such as diagnostics and transport costs are a burden; poor nutrition, illiteracy levels in general, and treatment illiteracy in particular inhibit demand for services; unskilled health care providers, counselors, and community health care workers hamper the quality of care; and unregulated claims by traditional healers and advertising of fake cures by opportunists further victimize people in desperate situations.

New formulations of ARV drugs are not widely dispensed and patients find it difficult to access them even in places where they are available. Patients have little say in deciding which drugs they are prescribed. The lack of essential drugs to treat OIs is another great challenge.

Patients commonly encounter poor attitudes and lack of respect by health care providers, which makes people reluctant to engage with these services. People may arrive at 5:00 AM and stand in long queues only to be attended to at 4:00 in the afternoon. This is demoralizing for women who might be required to travel 2-3 hours to reach home.

## Findings in particular provinces

### Luapula Province

#### NCHELENGE DISTRICT

The Nchelenge district has one major provider of ART services, MSF Holland, which earlier this year indicated it would pull out of the country. This has caused much uncertainty for people on ART and for people considering enrolling on an ART program, since they are not sure about the sustainability of the program.

Sources at the MSF office said they are acting under an agreement with the government to hand over ART service provision at the end of 2008. The government has not informed the national or local PLWHA what plans have been made, and PLWHA remain unsure what will happen after MSF leaves.

Long distances to the nearest ART centers are a major problem, with many people unable to access treatment when needed. Missed appointments are common and many patients have dropped out of the program.

### North-Western Province

#### SOLWEZI DISTRICT

Solwezi district, a mining region undergoing an economic boom with the opening of new mines throughout the province, faces many challenges. People from all over the country arrive in Solwezi in search of jobs and there has been a huge influx of commercial sex workers. This district borders the Democratic Republic of Congo and has also seen a flow of refugees and illegal immigrants coming into Zambia. Due to similarities in tribes these people have sometimes enrolled themselves in the ART programs, increasing the burden on the health care system. Our findings show that the population has outgrown the capacity of the ART services. There is great need for implementers to double their capacity as many people in need of these services experience problems in accessing them. Solwezi is semi-rural, and many people need to travel long distances to reach the nearest ART center.

#### MWINILUNGA DISTRICT

Mwinilunga district borders Angola and is mostly rural and remote. Long distances, poor nutrition, low treatment literacy levels, lack of diagnostics, and stigma and discrimination by unskilled counselors who are believed to divulge the results of people who go for VCT are some of the challenges to accessing treatment in Mwinilunga.

# ZAMBIA

## Eastern Province

### MAMBWE DISTRICT

Complaints from respondents in Mambwe highlighted the lack of CD4 count testing equipment (available only at the Kamoto Seventh Day Adventist (SDA) Mission Hospital) out of the nine antiretroviral treatment centers in the district. Reagents for chemistry and hematology for laboratory analysis, as well as the continued shortage of qualified health personnel to handle the clinical responsibilities, were other concerns cited. Similar concerns were raised for Katete, Nyimba, Petauke/Sinda, Chama, Chadiza, and Lundazi districts.

Lack of money for ART clients to pay for transport to Kamoto SDA Mission ART center was another handicap cited.

### CHAMA DISTRICT

Only the Chama District Hospital out of a total of 10 district-based health government centers is providing ART. Some ART clients are forced to travel up to 750 kilometres (600 miles) to reach the District Hospital for ART services. Many more are forced to make way through the lion, leopard, and hyena-haunted North Luangwa Game Reserve—either on foot for weeks or by wrecked bicycles—to reach the ill-equipped District Hospital ART Centre. Several travelers are said to have been mauled by lions, while some crossing the crocodile-swarmed Luangwa River met the same fate from human-feasting crocodiles.

Chama district experiences floods every rainy season as it lies below the Muchinga Escarpments and receives the Mozambican torrential rains. This renders the journey to the District Hospital ART Center a seasonal one. Defaults and failure to acquire medication have become a common phenomenon, with the majority of ART clients rendered impoverished due to rains and floods, which limits adequate food supplements to support their ART uptake.

### CHADIZA DISTRICT

The District AIDS Task Force Coordinating Advisor (DACA) for Chadiza district was reported to have vehemently refused to carry a batch of ARVs from Chipata General Hospital to Chadiza after she was pleaded with to do so by a group of persons living with HIV and AIDS as she was driving her official vehicle from the Hospital to Chadiza. The DACA was reported to have met the group at Chipata General Hospital, where, through the hospital management, they requested her assistance in delivering the drugs to the local district hospital as they had no other transport alternatives. She refused, saying that was not what she had traveled to Chipata for, and furiously drove off, forcing the support group members to hire a private van to deliver the drugs a few days later.

## ZAMBIA

The DACA for Chadiza District was also reported to have severed contacts with support groups of PLWHA within the district, and was said to have rejected project proposals handed to her office for funding from various donors including PEPFAR and CRAIDS.

Two of the 13 health centers in the district are providing ART, but there is no CD4 count testing machinery in the district and clients must travel to Chipata General Hospital for such services. Some blood samples being sent from Chadiza District Hospital to Chipata for CD4 count testing were reported to be lost, misplaced, or clotted.

Another problem of great concern raised by support group members from the district involved inmates from an open air prison who have used proceeds from the vegetables, tomatoes, and other perishable crops they were growing and selling from the open air prison garden, to accumulate money and have unprotected sex with women. Cases of pregnancies involving inmates have rocked the area surrounding the open air prison; a situation they said was increasing HIV prevalence rates.

### KATETE DISTRICT

Long distances from far-flung rural villages that must be traveled to reach the ART center at the District Hospital, and congestion at the center from an increasing number of clients, were cited as problems PLWHA in the district experienced. The District Hospital is the only center offering ART out of a total of 18 health centers in the district, and there is a lack of literacy information materials on HIV/AIDS and ART. Cases of sharing ARVs amongst clients from far away places awaiting their appointment was said to be very common, and some counselors based at the local district hospital were said to have identified clients on similar drugs who were later asked to share.

### CHIPATA DISTRICT

Congestion was reported at the three health centers out of 40 in the provincial headquarters that offer ART services. The CD4 count testing equipment constantly breaks down and clients have to seek such services from Mwami Seventh Day Adventist (SDA) Mission Hospital, where they have to pay K48,000 for such services. The New Start Center Network has been providing ART through Mwami Mission Hospital. HIV testing reagents were also out of stock for months.

### PETAUKE DISTRICT

Four functional health centers out of a total of 28 are providing ART services in the district. Long distances must be traveled by clients living in far-off places, most of whom are rural dwellers with few or no sources of income. Many people have discontinued treatment due to these challenges and others.



## Addressing serious human resource needs

by Mony Pen

In 2006, there were 44 health facilities offering ART and treatments for OIs in 19 provinces in Cambodia. Of those sites, four were providing care for OIs only and 19 were providing pediatric care. According to figures from December 2006, a total of 20,131 individuals, including 18,344 adults and 1,787 children, were receiving ART.

The ART program is run by the MoH's National Center for HIV/AIDS and STD Control. The Cambodian government has committed to expand the program nationwide—a challenging goal given the relatively poor state of the health system. One major problem is that human resources are unevenly distributed. Nearly 85 percent of Cambodians live in rural areas, but only 13 percent of health professionals live in those areas. Few incentives exist to encourage health care workers to take positions in rural regions where service delivery is, in general, much more difficult and shortages of supplies much more common.

Salaries account for just 10 percent of MoH expenditures, a proportion that ranks it among the lowest in the world. Within a decade, socio-economical inequalities have increased, corruption has become rampant, and the gap between rural and urban areas (mostly Phnom Penh) has widened. Moreover, the Ministry of Economy and Finance's ability to manage health care funds is hampered by the fact that its systems are not fully computerized. Partly for that reason, resources are often chronically late or insufficient when finally disbursed to public health facilities. In terms of health and development, the government's overall strategy, in agreement with external donors, is to improve the equity and accessibility of essential health services and to rebuild confidence in the public health sector. The public health sector is perceived to be of such poor quality that many Cambodian opt to pay for private sector services, even though they can theoretically receive such services free of charge through the public system. Those who cannot afford private sector fees often prefer to receive care (usually provided free of charge) at clinics run by NGOs. Corruption within the public system also creates barriers. Although services are supposed to be free in the public sector, patients are regularly asked or expected to pay money under the table for various services. For example, most patients at government clinics must pay at least 1,000 riel (US\$0.25) for CD4 counts and much more for viral load tests (US\$25). Supply shortages have also forced some public-system patients to buy medicines from outside sources.

Many health care workers are inadequately trained. As a result, patients are often treated poorly, which contributes to high levels of stigma and discrimination toward PLWHA in health care settings and in general. The following account of unacceptable behavior was provided to the report's authors by an observer: Yesterday I was waiting outside the counseling room for my shift. A doctor called a patient's name, but unfortunately that person had already left for home. The doctor started yelling and threw the patient's profile to the floor and kicked it. Everyone in the room felt very uncomfortable.

Health care workers are also greatly overworked, which also may contribute to their inability or disinclination to offer high quality care. One observer noted the following in a discussion with the report's authors:

*"I am working as a peer counselor. In my hospital we have provided treatment to more than 4,000 patients. There are only six doctors here (three in the morning, and three in the afternoon) providing medical counseling and care, and each of them must see 20 to 30 patients a day. Many of the patients have significant problems that require lengthy examinations and consideration. I think it is difficult for the doctors to provide good service to all patients due to their workload."*

### **Other treatment and care limitations**

The MoH is trying to implement a new health system policy based on regional care. For example, patients are now required to obtain treatment in their own province; they cannot access public sector care in other provinces. As part of that shift, the government is planning to require many internal migrants receiving care in Phnom Penh to return to their home provinces for treatment services.

This new system has both positive and negative implications. On the one hand, it may help spread more extensive and higher quality health care across the country, as long as adequate numbers of personnel are available. On the other hand, many people seek care elsewhere because they do not trust their local health facilities. They may have had negative experiences in obtaining appropriate care locally; some, too, may go elsewhere to avoid stigma and discrimination in their home communities. Removing these obstacles will be a difficult challenge for public health officials. One patient's account touches on many of the issues involved:

*"I come from the Svay Rieng province. We have an ART clinic, but I do not want to visit the clinic there because I was told the clinic is new and that doctors are poorly skilled regarding treatment. Also, I do not want my neighbor to find out about my HIV status. I wanted to go to Phnom Penh, the capital city, but I was rejected. They said they could not receive any more new patients because they had no space...only those from the city could go to clinics there. I do not know what to do now."*

## Recommendations

As noted throughout this analysis, public health efforts to provide care to PLWHA in Cambodia are constrained by inadequate health care infrastructure, shortages of trained workers, limited access to free diagnostics, and HIV-related stigma and discrimination. However, international donors and national stakeholders have been far too timid in responding to these persistent problems, claiming that respect for cultural norms necessitates proceeding slowly and incrementally. Improvements will continue to be limited unless these attitudes change and more aggressive steps are taken to develop new plans and strategies.

Until now, there have been no efficient programs to respond to these issues. Therefore, we would like to appeal to the Cambodian government and civil society to take urgent action on the following points:

- Revise and strengthen the health care infrastructure, policies, and systems, with an emphasis on providing equivalent human resources in both urban and rural areas and improved salaries for health care workers.
- As a step toward increasing capacity as soon as possible, it may be necessary to implement while training, which is a quicker way to improve the situation than waiting until training is completed.
- The enforcement of HIV/AIDS medical ethics needs to be enhanced within the health care setting.
- Civil society, including PLWHA organizations, must become stronger and united to effectively communicate their demands.

# DRUG REGISTRATION BARRIERS & LOGJAMS

*By Brook K. Baker, Health GAP*

In order for people living with HIV/AIDS to access lifesaving medicines and to be relatively assured that the medicines they are receiving are safe, effective, and of good quality, antiretroviral and OI medicines must be evaluated by competent authorities. The global and national architecture for this regulatory process is extraordinarily complex and, as the country reports indicate, the process is fraught with disharmonies, inefficiencies, duplications, delays, and in some instances, corruption.

This section of the report highlights the multiple areas of concern that can be classified within the following broad categories:

- Lack of incentive mechanisms or regulatory systems that encourage or compel innovator companies to promptly register their medicines for use in smaller and poorer countries with resulting long delays in access to newer medicines;
- Lack of sufficient incentive mechanisms, technical assistance, or other measures that encourage or compel generic companies to promptly register their therapeutic equivalents for use in smaller and poorer countries;
- Absence of fast-track registration procedures in most countries to permit expedited registration of medicines that have been accepted by the WHO Prequalification Programme or registered by a stringent regulatory authority in another country;
- Absence of efficient special authorization procedures that allow automatic marketing of important medicines that have been accepted by the WHO Prequalification Programme or registered by a stringent regulatory authority in another country while the formal registration process is being completed;
- Insufficient capacity, inefficiency, high fees, and occasional corruption in national drug regulatory authorities that create delays and disincentives to both innovators and producers of generic equivalents;
- Insufficient capacity and delays in the WHO prequalification system that result in delayed registration of newer medicines;
- Duplication of effort by the United States Food and Drug Administration (FDA) and the “fast-track” tentative approval system required by the President’s Emergency Plan for AIDS Relief (PEPFAR), which does not allow purchase of medicines accepted by the WHO Prequalification Programme;



- Data exclusivity and registration/patent linkage rules, which in their most absolute form can prevent registration of follow-on generic products;
- Lack of post-approval quality assurance mechanisms and lack of efficient supervision of the marketing of medicine to prevent the use of substandard or counterfeit medicines<sup>1</sup>; and
- Lack of a global, up-to-date, accessible registry on registration status of HIV/AIDS medicines.

In addressing these myriad problems, both international and national authorities bear responsibility to expedite and rationalize the assessment and registration of lifesaving medicines. In this regard, this section of the report considers the performance of key international institutions, including WHO, UNITAID, PEPFAR, the Clinton Foundation, and others, to highlight areas of progress and further work to be done. In addition, this chapter highlights key regulatory reforms needed at the local level to ensure that PLWHA receive good quality medicines.

### **The perverse registration practices of innovator pharmaceutical companies**

The current regulatory regime for country-by-country registration of medicines provides few if any incentives or requirements for drug companies to register new medicines in a particular market other than the purely profit-driven motive of whether registration will be worth the time, effort, and money (Morocco, China). As the report from Morocco states, drug companies do not register their new HIV/AIDS medicines in smaller markets or in countries with small numbers of PLWHA. Accordingly, the country reports indicate that atazanavir (ATV), tenofovir (TDF), emtricitabine (FTC), lopinavir (LPV), ritonavir (r), and efavirenz + emtricitabine + tenofovir (Atripla), some of the most important, newer first- and second-line medicines, are currently not registered separately or as appropriate combinations, in most countries.<sup>2</sup>

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<sup>1</sup> The term “counterfeit medicine” does not apply to legitimate generic equivalents of innovator drugs, but is limited to medicines that are deliberately and fraudulently mislabeled, that often do not contain any or the correct amounts of active ingredients and excipients claimed, and that are therefore dangerous and/or ineffective for patients.

<sup>2</sup> Abbott claims that its Kaletra capsule has been registered in 118 countries, and that it has filed for registration in 135 countries for Aluvia tablets and had obtained 89 approvals as of June 2007. Abbott claims it will seek to register Aluvia in over 150 countries. Just this November, Gilead posted country-by-country registration status of TDF (tenofovir - Viread®) and TDF/FTC (tenofovir/emtricitabine - Truvada®) in its International Access Operations. See [http://www.gilead.com/pdf/GAP\\_Registration\\_Status.pdf](http://www.gilead.com/pdf/GAP_Registration_Status.pdf). As of November 13, 2007, TDF had been approved in 43 countries, been filed in another 35, but not filed in 51; TDF/FTC has been approved in 36 countries, filed in 34, and pending submission in 59. It should clearly become an industry standard that companies list country-by-country registration status on a publicly accessible website.

Country	ATV	R	LPV/r LPV/r (HS)	TDF	FTC	TDF/ FTC	TDF/ FTC/ EFV
Argentina		Y		Y	Y		
Belize				Y	Y		
Cameroon							
Cambodia				Y			
China		Y	Y/N		Y		
Dominican Republic	Y	Y	Y/N	Y			
India	Y			Y			
Malawi				Y		Y*	
Morocco		Y					
Philippines				Y	Y		
Russia		Y	Y				
Uganda		Y		Y	Y*	Y*	
Zambia		Y		Y	Y	Y*	Y
Zimbabwe		Y			Y		

\* This registration information comes from the Gilead website.

Although innovator companies complain of slow and complicated processes to justify their delay, these same companies will register their bigger-selling products much more quickly. The fact that drug companies suffer no adverse consequences of delaying or staggering registration of lifesaving medicines is deeply problematic and must be addressed both through international norms and national law.

Paradoxically, some of the same companies that issue big publicity announcements on their developing-country access programs thereafter drag their heels in terms of actually registering their medicines in-country. Gilead is one of the most infamous companies in this regard, having announced a large-scale access program for tenofovir (TDF), emtricitabine (FTC), and Truvada (TDF + FTC) in 2005, but having done little to actually register their product until 2007.<sup>3</sup>

In a more egregious case, Abbott has used registration as a cudgel by withdrawing a registration application for heat stable lopinavir/ritonavir (LPV/r) from the Thai Food and Drug Administration in retaliation for Thailand having issued a lawful compulsory license. Although Abbott is acting relatively expeditiously in registering

<sup>3</sup> Part of this problem was caused by Aspen Pharmacare which undertook to register Gilead's products in Access Countries but made no serious effort to do so.

LPV/r in developing countries, it is simply outrageous that drug companies can not only delay registration with impunity, but that they can use registration delays or withdrawals to retaliate against lawful use of TRIPS-compliant flexibilities. Fortunately, Thai activists have filed a competition complaint to Thai authorities challenging the product withdrawal.

It is important to note that at the same time that they are delaying their market entry, drug companies benefit from their pre-existing patent rights that give them rights to exclude competitors (China). This is where local working rules in compulsory licensing schemes can play a role: failure to register the product and to satisfy the local market within a certain period of time can be an independent justification for issuing a compulsory license.

### **Delayed registration by generic companies**

Generic companies are also required to register their therapeutically equivalent products before marketing them, but they too frequently prioritize registration applications based on market incentives, e.g., the size of the PLWHA community and whether international donors are supporting treatment access. Because generic companies work on smaller margins, inefficient and costly registration processes are doubly problematic. For this reason, the newly WHO prequalified and FDA-approved triple fixed-dose pediatric formulation from Cipla is not widely available (e.g., Uganda). In the same token, although 142 ARVs have been WHO prequalified to date—the vast majority of them generics, to the best of our knowledge—most of these products have not been separately registered in most developing country markets, reducing competition and potential availability of alternative sources of supply.

Global institutions are playing an insufficient role in expediting generic registration with three exceptions. The most proactive entity is the WHO Prequalification Programme, which has granted prequalification to 142 ARVs and multiple OI drugs since it was launched in 2001. However, even if a generic company navigates prequalification, it must still file separate registration applications in each developing country where it wants to do business. In addition, the Clinton Foundation has worked behind the scenes to assist generic companies in its consortium to prosecute successful registration applications in Clinton Foundation buying countries (Clinton Foundation consultation, Sept. 15, 2007). Finally, the U.S. Supply Chain Management System has been proactive in seeking to expedite registration of FDA-approved products.

However, in general, international institutions, including WHO and regional organizations like the Southern African Development Community (SADC), have done little to harmonize and streamline the registration process for generic producers, to provide technical assistance in filing registration applications, or to provide reliable market incentives for generic producers to take the risk of product

development and registration. Likewise, generic producers have invested too little to build their own regulatory competence. All too often, the prequalification and registration files filed by generic companies are incomplete, delaying the prequalification and registration process (WHO Prequalification Programme, status of product dossiers; Uganda).

### **Lack of fast-track registration procedures**

Argentina is an example of a country that has done a lot to streamline and expedite follow-on registration processes. As described in its country report, both innovator drugs and generic equivalents can be registered in Argentina via reliance on the fact of prior registration elsewhere. If prior registration has been granted by a stringent regulatory authority, then Argentina will permit registration automatically upon presentation of a Certificate of Pharmaceutical Product. Alternatively, if the registration has only been granted from an average authority, it must follow the ordinary process (product, technical information, and labeling information and drug monograph) plus it must submit a Certificate of Pharmaceutical Product from the registering authority.

However, the Argentina country report does not specify what happens in the event of WHO prequalification. Thus an even better process, like that used in Belize and Malawi, would allow fast-track registration of WHO prequalified products and/or of products registered elsewhere by a stringent regulatory authority. Given weak regulatory capacity in many developing countries and problems of delay, it would make sense for countries to modify their legislative and regulatory regime in order to permit such regulatory reliance (Zimbabwe, China).

Regulatory reliance of this form is slightly different than the normal process that applies to a follow-on generic equivalent. In this case, assuming that the originator product has already been registered, and thus proved its safety and efficacy, all that the follow-on producer must establish is the requisite degree of therapeutic equivalence, often based on evidence of bioequivalence, and the quality of the manufacturing process, often based on GMP certification. It behooves countries to adopt clear and efficient guidelines permitting prompt registration of generic equivalents, even if they have not yet been WHO prequalified or registered elsewhere by a stringent regulatory authority (China), so long as there is adequate evidence of bioequivalence, GMP, stability, and other data appropriate for abbreviated approvals. In this regard, WHO has provided some international technical assistance, especially on the tricky issue of registering fixed-dose combination (FDC) equivalents to otherwise separately sold products. However, registration of FDCs remains problematic in some countries (China).

Both regular and fast-track registration of generic equivalents might be delayed, however, if a country has improvidently adopted data exclusivity (a rule preventing a drug regulatory authority from referencing or relying on an innovator's registration

data or even on the fact of prior registration in order to establish the safety and efficacy of the follow-on product). Cambodia was forced to adopt five years of data exclusivity by the US in its WTO ascension agreement and China has been forced to adopt six years. Likewise, the Dominican Republic has been forced to accept five years of data exclusivity as part of the US-CAFTA-DR, which also included a linkage provision restricting registration of patented products.

### **Inefficiencies in special authorization procedures**

Frequently, ARV treatment programs in developing countries need to make certain medicines available to their patients even before they have been registered either by an innovator or generic producer. In many such cases, there is not much question that the product is safe and efficacious because it is already registered and in broad use elsewhere, both in developed and developing countries, and because it has therefore already gone through comparable regulatory processes to establish safety, efficacy, and quality. When the product is not yet approved, there needs to be an easy-to-use temporary authorization process, which unfortunately is often cumbersome and burdensome for both the producer and the treatment provider (Morocco, China). Accordingly, in addition to relying on WHO prequalification or registration by a stringent regulatory authority for expedited registration/marketing-approval, countries could use the fact of prequalification or registration to automatically grant special authorization for marketing and use prior to final registration.

### **Lack of regulatory capacity, inefficiencies, and corruption in national drug registration**

Poor countries suffer in general from a lack of regulatory capacity, which extends to the highly technical field of drug registration. Although some of the problems of incapacity could be solved through forms of regional cooperation (see Belize report describing quality assurance work done in Jamaica), WHO has had little success to date in organizing regional cooperation despite years of trying to do so. However, incapacity is not the only problem – registration processes are often complex, slow, and costly (China, Morocco, Zimbabwe, and Uganda) which not only delays registration but actually deters companies from even attempting to register their products (China, Morocco). Complexities come in multiple forms; not only do paperwork requirements differ, but in some instances there are translation barriers and costs, including translation of required product labels (Dominican Republic). In terms of costs, not only are initial filing fees high, but in some instances there are annual renewal fees (Zimbabwe), the non-payment of which can lead to product deregistration (Uganda). Some companies get around the delays by resorting to corruption, a danger exacerbated by low pay and lack of transparency within the registration authority. China experienced a major scandal in 2007 when the director of the China Food and Drug Administration was convicted for having sold registration rights to unqualified manufacturers.

## **Capacity issues and delays in the WHO Prequalification Programme**

As stated previously, the WHO Prequalification Programme is one of the bright lights in the global registration architecture, but it is far from perfect (Malawi). According to the WHO website, the WHO List of Prequalified Medicinal Products lists “medicinal products used for HIV/AIDS, tuberculosis, malaria and other diseases, and for reproductive health, which have been assessed as part of the WHO Prequalification Programme and found to be acceptable, in principle, for procurement by UN agencies.” The Programme focuses on products that are vital to treatment of the specified diseases. Prequalification of medicines requires evaluation of data relating to quality, safety, and efficacy and inspection of the relevant manufacturing and clinical sites. Alternatively, some products approved by a stringent regulatory authority, like the US FDA, are referenced on the WHO list. The list is updated regularly and the dossier and facility inspection are conducted by highly qualified technical experts seconded from other drug regulatory authorities.<sup>4</sup> The Programme activities are unusually transparent, and it discloses both products approved, a list of dossiers awaiting approval, and detailed non-proprietary information in its Public Inspection Reports.

The major problem at the Programme is insufficient capacity resulting in delays in prequalification. Although 142 ARVs have been approved, earlier approvals took many months (e.g. Cipla’s Lamivir [generic lamivudine (3TC)]: 19 months; Aspen’s stavudine [d4T]: 22 months; Strides’ lamivudine [3TC]/ stavudine [d4T]: 15 months); fortunately the process has speeded up since. Many of the more recent, quicker approvals have been for medicines that had already been assessed by stringent regulatory authorities. Despite this more streamlined process and the growing familiarity of manufacturers with WHO prequalification, there are still 174 products awaiting approval as of October 29, 2007, including several important generic equivalents of Atripla (EFV + TDF + FTC), heat-stable Kaletra (LPV/r), tenofovir (TDF), and Truvada (TDF + FTC).

Fortunately, UNITAID committed \$1 million to WHO Prequalification in 2006 and is expected to contribute an additional \$6 million for 2007. Unfortunately, even this amount is insufficient to rapidly reduce the backlog of pending files.

### **Duplication in the US FDA “fast-track” approval system**

The US fast-track approval system was set up within the US FDA to grant tentative approval for purposes of purchases with funds made available by the President’s Emergency Plan for AIDS Relief (PEPFAR). AIDS activists had major criticisms of the fast-track procedures when they were set up because they seemed unduly

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<sup>4</sup> Including: Argentina, Bangladesh, Brazil, Canada, China, Cuba, Denmark, Estonia, Ethiopia, Finland, France, Germany, Hungary, India, Italy, Latvia, Malaysia, Mexico, Netherlands, Pakistan, Philippines, South Africa, Spain, Sweden, Switzerland, Tanzania, Uganda, United States of America, and Zimbabwe.

duplicative of equivalent efforts already set up at the WHO Prequalification Programme, and because they would inevitably delay entry of generic products. The concerns about delay remain valid today and have been a topic in the Institute of Medicine's review of PEPFAR, which recommended that the US rely on WHO prequalification instead<sup>5</sup>. However, the FDA has now approved 52 separate products manufactured by multiple generic producers, the vast majority of them Indian companies.

A little-known provision in the US fast track system is that the FDA cannot consider generic applications for products that are still protected by data exclusivity rules in the US. This requirement effectively bars FDA tentative approval for generic versions of the newest medicines, e.g. integrase inhibitors, which in turn delays generic entry and its resulting lower prices. This lacuna in the US fast-track system is a major impediment to procurement of cheaper generics by PEPFAR.

**Data exclusivity and registration/patent linkage rules** (which in their most absolute form can prevent registration of follow-on generic products)

As discussed at length in the Dominican Republic and China reports, data exclusivity rules can have an extremely negative effect on the registration of generic equivalents in countries burdened by such rules. In an absolute form, data exclusivity of five years (Morocco and the Dominican Republic) or of six years (China) could completely preclude registration of a follow-on product that cannot submit independent clinical trial data. Likewise, an absolute form of patent-registration linkage could prevent a drug regulatory authority from registering a generic product whenever a patent holder claims a patent on the product. Under such absolute rules, even if a country were to grant a compulsory license permitting a generic company to bypass the patent, marketing approval and distribution of the product might actually be prevented.

Obviously, countries should avoid adopting TRIPS-plus rules like data exclusivity and patent-registration linkage. However, even if they have done so, they should insist on using trade agreement side letters and recent trade policy changes in Congress to insist that data exclusivity and linkage provisions can be overridden in order to protect public health and to promote medicines for all.

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<sup>5</sup> From the Institute of Medicine's PEPFAR Implementation: Progress and Promise (2007): "[T]he U.S. Global AIDS Coordinator should work to support World Health Organization (WHO) prequalification as the accepted global standard for assuring the quality of generic medications. Specifically, the Coordinator should provide an analysis of WHO prequalification that determines whether it can adequately assure the quality of generic antiretroviral medications for purchase under PEPFAR. If the analysis shows that WHO prequalification needs strengthening to provide a sufficient guarantee of quality for PEPFAR, the U.S. Global AIDS Initiative should work with other donors to support strengthening of the process, and work to transition from U.S. Food and Drug Administration approval to WHO prequalification as rapidly as feasible." (5.2)

## **Lack of post-approval quality assurance and regulation of medicines**

Some countries report that the drug regulatory system in their country is simply too lax, resulting in a lack of government accountability. In other contexts, the problem is not all-pervasive, but is instead limited to weaknesses in post-approval quality assurance (Belize). Although there are some examples of regional cooperation in quality assurance (Belize) or of procurement agents providing such services on a contract basis (Nigeria/Axios) and as part of a bilateral initiative (US SCMS), in general quality assurance programs seem weak. Given the critical importance of ensuring that people receive good quality medicines, major efforts should be undertaken at the multilateral, regional, and national level to prevent formal and informal marketing of counterfeits and substandard, expired, or degraded medicines. Developing countries should commit substantially more of their existing regulatory capacity to quality assurance, and people living with HIV/AIDS should receive more treatment literacy on the danger of obtaining medicines from unofficial sources.

It is important to note that the US and its key trading partners— including Canada, the European Union (with its 27 Member States), Japan, Korea, Mexico, New Zealand, and Switzerland— have started negotiations on an Anti-Counterfeiting Trade Agreement<sup>6</sup>. Although counterfeiting and substandard medicines are certainly an important issue for developing countries, there are reasons to suspect that the motivation for this new focus on counterfeits is at least partially to attack the quality of generic production and to seek even stronger IPR-enforcement, border-control, product-tracing, and anti-diversion measures in future trade agreements.

## **Lack of a global, up-to-date, accessible registry on registration status of HIV/AIDS medicines**

As is true with patents, there is an appalling lack of transparency on a global scale concerning the registration status of ARVs and OI medicines. With rare exceptions, innovator drug companies don't list up-to-date registration status on publicly accessible websites—nor for that matter do generic producers. Likewise, governments are often non-transparent, although Uganda is an exception, since it publishes a national drug-registration list on a monthly basis. It is unsurprising that ITPC researchers had such a hard time accessing ARV registration data in their home countries and that, even at this date, civil society does not have access to verified information.

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<sup>6</sup> Office of the US Trade Representative. "Ambassador Schwab Announces U.S. Will Seek New Trade Agreement to Fight Fakes." October 23, 2007. [http://www.ustr.gov/Document\\_Library/Press\\_Releases/2007/October/Ambassador\\_Schwab\\_Announces\\_US\\_Will\\_Seek\\_New\\_Trade\\_Agreement\\_to\\_Fight\\_Fakes.html?ht=](http://www.ustr.gov/Document_Library/Press_Releases/2007/October/Ambassador_Schwab_Announces_US_Will_Seek_New_Trade_Agreement_to_Fight_Fakes.html?ht=)



WHO undertook to collect and update such information through its AIDS Medicines and Diagnostic Services (AMDS) mechanism to operate “as a clearing house, collecting and disseminating strategic information. Prices, availability and regulatory status of anti-retroviral medicines, technical information of HIV diagnostics and condoms, are made available to those who need them through the AMDS website and by other means of communication.” In particular AMDS promised, concerning registration and quality assurance to provide “[g]lobal guidance and information on regulatory matters and registration status of ARVs; strengthening drug regulatory agencies in dealing with ARVs (registration, inspection, importation, local production and combination products).”

There is little evidence that the AMDS has accomplished this task. It last updated registration status on its website over two years ago on October, 25, 2005. Accordingly, the data in that document is woefully incomplete. Although it is surely a question of resources and technical capacity, WHO should reinvigorate AMDS so that it can perform its information and technical assistance promises.

## **Conclusion**

The most troubling issue in the country reports is the absence of registration of key ARVs, especially newer and second-line therapies that are absolutely essential to lifesaving treatment. The picture that emerges from the tip-of-the-iceberg country reports on registration status reveals a product approval system in total disarray, with bits of operational coherence overwhelmed by the chaos of failed incentives, failed harmonization, and failed regulatory oversight, both nationally and internationally. It seems clear that WHO must do much more to fulfill its fiduciary obligation as the arbiter in international norms on rational use and widespread availability of lifesaving medicines. It seems clear as well that drug companies, innovator and generic, must take their responsibility to register their products much more seriously. Finally, national governments must do much better in amassing local and regional capacity to assure the quality, safety, and efficacy of medicines and to utilize the efficiencies that are available to them such as reliance on WHO prequalification and/or prior registration by stringent regulatory authorities. It turns out that the crisis of access to lifesaving medicines is a crisis of patent-related pricing, registration, and procurement/distribution. Attention to registration issues has lagged far behind and it is far past the time for economic interests and policymakers to rectify the mess that they have created.

# ARV PROCUREMENT, REGISTRATION, AND STOCK-OUTS

## Argentina

By Dr. María Lorena Di Giano



### Patent issues

With an eye on WTO requirements and policies, Argentina passed a new patent law in October 2000 that has direct implications on access to ARVs in the country. The law—which has been modified several times, most recently in December 2003—builds on some precedents established in previous statutes.

### Compulsory licenses

As allowed under the WTO's TRIPS agreement (from 2001), the patent law authorizes the government to override or ignore patents in the case of national health emergencies. In such situations, the government can issue a compulsory license to import lower-priced medicines and/or to manufacture generic versions of drugs previously under patent with a company. (As of October 2007, the government had not issued any compulsory licenses for HIV medicines. It should be noted that compulsory licensing is considered a drastic step by governments around the world. In the few places where such steps have been taken, including Brazil and Thailand, they followed extensive efforts to negotiate agreements with patent-holders to reduce the prices of branded medicines.)

### Exceptions to the patent law

The patent law also establishes that the National Institute of Industrial Property (funded by the finance and health ministries) can establish limited exceptions to patent rights, as long as they do not unduly affect the normal exploitation of patents, or infringe upon the legitimate interests of the patentee.

By agreeing on this provision, the legislature lost a valuable opportunity to use the freedom offered by TRIPS in the application of exceptions. For example, legislators could have incorporated mechanisms to promote the transfer of technology, prevent the abuse conferred by patent rights, or introduce the possible application of the "Bolar exception."<sup>1</sup> These are all instruments that promote the production and accelerated access of lower-cost generic medicines and stimulate price competition.

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<sup>1</sup> As per the WTO website, the "Bolar exception" is defined as such: "...Some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval—for example from public health authorities—without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the 'regulatory exception' or 'Bolar' provision." See [www.wto.int/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm](http://www.wto.int/english/tratop_e/trips_e/factsheet_pharm02_e.htm).

## **Parallel importing**

Relating to the depletion of intellectual property rights, Argentina adopts the principle of international exhaustion. This means that parallel importing is legal and acceptable. (Parallel import is the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a so-called parallel patent. Since some patented products are sold at different prices in different markets, the rationale for parallel importation is to enable the import of patented products from countries in which they are sold at lower prices into those countries where the same patented product is being sold at a higher price.)

## **Patent-holders' opposition**

National companies represent approximately 50 percent of the local drug market; most of them manufacture ARVs. These companies have historically built their competitiveness by introducing imitation drugs, simultaneously with the original drugs, that are manufactured by the innovative labs or their licensees. According to the information disclosed by press accounts, as of late 2005 the number of patents granted for pharmaceutical products and procedures was minimal. The National Institute of Industrial Property had granted 8 patents for products and 180 for procedures; combined, this covered 5 percent of the drugs marketed in the country.

Many multinational pharmaceutical companies are unhappy with this situation, claiming that their rights as internationally recognized patent-holders have been violated. Some have resorted to legal remedies to enforce their rights. For example, at the beginning of 2007, Bristol-Myers Squibb (BMS) filed a lawsuit demanding a ban on the production and marketing of didanosine by a domestic Argentinian company. The presiding judge ruled in the company's favor, essentially forcing the government to purchase the higher-priced version of the drug from BMS directly. The government in April 2007 warned that it would have difficulty covering such high costs. According to PLWHA organizations, doctors, and health center administrators, one result has been stock-outs of didanosine at major healthcare and treatment centers. This has placed great risks on the health of at least 1,800 beneficiaries of the National AIDS Program.

## **Improvements in governmental commitment**

In 2005, the Argentinian and Brazilian health ministries signed an agreement to establish a joint work program to strengthen the exchange information related to intellectual property in order to ensure better access to medicines and to work together to properly incorporate the flexibilities and safeguards of the TRIPS agreement. This commitment was complemented seven months later with the "South American Ministers Declaration on Intellectual Property, Access to Medicines and Health" signed by nine Latin American countries.

The signatory countries pledged to promote the effective implementation of the safeguards and flexibilities included in the TRIPS agreement and the WTO's 2001 Doha Declaration, notably parallel importing and (when necessary) issuing compulsory licenses. They also pledged to work together on the strengthening of international cooperation projects and strategic alliances related to access to ARVs and other important medicines.

## **Conclusion and recommendations**

Argentina has complied with the commitments established by the WTO, adapting its legislation to the minimal standards demanded by the TRIPS agreement and Doha Declaration. However, the government has not incorporated all of the advantages that the agreement offers, and it is not using the mechanisms, safeguards, and flexibilities that could encourage improvements in public health, particularly regarding access to HIV/AIDS treatment.

The decision to establish alliances and political commitments with countries in the region in order to adequately implement flexibilities related to intellectual property rights seems to be an important step. The results of such cooperation are not yet evident, however.

To improve the situation, it is necessary to immediately:

1. Begin a debate at the national level about the need for progress in implementing the flexibilities incorporated to the patent law related to HIV/AIDS and make decisions about it.
2. Improve regional cooperation efforts that provide a balance between the need for research and development, and the need for access to medicines for HIV/AIDS.
3. Promote the reform and regulation of the patent law, by the introduction of:
  - legal and administrative procedures that tend to help the effectiveness of the implementation of compulsory licenses, and clear rules to establish the specific fees corresponding to the patentees, in order to avoid unnecessary delays;
  - more operational mechanisms to prevent the abuse of patent rights and the extension of the periods of protection from new uses; and
  - safeguards and flexibilities related to patent rights, like the "Bolar" exception.

## Access to ARVs

No difficulties or anomalies related to the registration process have been detected regarding access to new ARVs in Argentina. However, some obstacles have been identified regarding actual provision of the drugs (unrelated to registration).<sup>2</sup> They include the following:

- There are some restrictions in the prescription of lopinavir/ritonavir (Kaletra, soft capsules and tablets), even though it has been included in the drug list from the National Aids Program (or VPNS, as per its Spanish acronym). The restrictions have occurred because the National Sanitary Authority classifies it as a lifesaving therapy only, which means it cannot be prescribed as initial therapy. Exceptions are made only for children and pregnant women who cannot tolerate nevirapine (NVP) or patients who do not respond well to any other drug.
- Emtricitabine (FTC) is not provided under the National Aids Program; it has been replaced by lamivudine (3TC) because, according to the program, FTC is three times more expensive. FTC is therefore only available through private medical services.
- Enfuvirtide (T-20), tipranavir, and darunavir are not included in the National AIDS Program. However, the Ministry of Social Development will make them available in exceptional situations if deemed medically necessary. The following process is used:
  1. The prescribing physician presents a clinical history that justifies the use of one or more of the drugs.
  2. The National AIDS Program then evaluates the prescription submission; program staff consult with an expert advisory committee if necessary.
  3. If the request is approved, a certification is given to the applicant.
  4. The request must be renewed every three months.

According to the National AIDS Program, about 50 patients were receiving regimens containing one or more of these drugs as of October 2007. Program staff added that it was not yet possible for the health ministry to acquire these drugs directly because of their high cost.

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<sup>2</sup> Information about all of these restrictions was provided by public health care workers and clients of the National AIDS Program and confirmed by the National Sanitary Authority.

## **Belize**

*By Caleb Orozco, United Belize Advocacy Movement*



As of the second quarter of 2007, the officially reported number of people living with HIV/AIDS in Belize totaled 4,035, but UNAIDS 2006 country profile estimates suggest the number infected could be 5,700, with only 31% getting ARV treatment. WHO report estimates of around 10,000 persons living with HIV/AIDS. Of 587 people accessing treatment, 529 were adults and 58 were children, 10 of whom were on second-line medications.

Access to essential medicines can be especially difficult in small countries such as Belize. Because quantities procured are relatively small, foreign pharmaceutical companies often consider such orders low priority and thus do not process them promptly, waiting for several orders to accumulate before filling them.

In December 2005, the Belize government sought to address this problem by arranging with the Pan American Health Organization (PAHO) to handle procurement for ARVs. PAHO orders bulk supplies to minimize costs for both producers and purchasers. PAHO and the government each make purchasing decisions based on the WHO's list of ARVs that have been prequalified for quality assurance.

In the current fiscal year, the overall budget for the Ministry of Health's National AIDS Program is about US\$573,000. Of that amount the budget for ARVs is about US\$230,000. Beyond this, the Global Fund covers part of the cost of medicines for OIs and sexually transmitted infections (STIs). The MoH has also received donations of specific ARVs and OI drugs from the neighboring Mexican state, Quintana Roo; the charity, Aid for AIDS, and the Pfizer pharmaceutical company; but it is not clear how donated ARVs are monitored for quality. Recently, the government added three new ARVs to the National Drug Formulary: tenofovir, fosamprenavir, and emtricitabine.

### **Diagnostic services**

Diagnostic services are available in both the public and private sectors. According to the national VCT coordinator, there are a total of seven facilities where HIV tests are offered. The MoH has sought to increase testing uptake through its "Know Your Status" campaign. Officials report that more than 15,000 people were tested for HIV from 2003 to the end of October 2007.

Viral load tests are available, but samples must be sent to Trinidad for analysis. The National AIDS Program anticipates acquiring a viral load machine through the PAN Caribbean Partnership against HIV/AIDS (PANCAP). The MoH purchased a CD4 count machine in March 2007 although it is uncertain if operators have as yet been trained in its use.

### **Challenges and obstacles**

Despite important steps forward in recent years in regard to increasing access to ARVs, significant challenges and obstacles persist. These include:

Drug stock-outs. There were reports in 2007 of shortages of particular medications. Government officials assert that such problems, if they exist, stem from inadequate forecasting or problems with delayed payments or delayed funding. Generally stock-outs are avoided by borrowing needed medications from neighboring countries.

Insufficient human resources. Health workers are unevenly distributed throughout the country. Moreover, there are far too few personnel who are adequately trained in HIV/AIDS care and treatment. This makes it difficult to ensure consistent service delivery, in particular for people in rural areas.

Price shocks and quality assurance. Belize does not produce medicines domestically. As such, it remains especially vulnerable to price hikes in ARVs and treatments for OIs and STIs. ARV medications purchased through PAHO's prequalified list of manufacturers have good quality assurance, but donated drugs remain vulnerable due to poor in-country quality control mechanisms.

Limited treatment uptake. As noted previously, more than 4,000 people in Belize were living with HIV as of August 2007. The number actually needing ART has not been ascertained as of the second quarter of 2007. Factors restricting greater access to treatment include widespread HIV-related stigma and discrimination, and infrastructure limitations, including lack of trained personnel. Individuals living in rural areas also find it difficult to obtain treatment and care because of costly and limited transportation options.

Sustainability concerns. Demand for treatment will likely increase in the future. It is unclear to what extent Belize will be able to pay for the increasing cost of ARVs, especially expensive second-line medications, after Global Fund support ends.



## Recommendations

The following recommendations are geared toward improving the short- and long-term situation in regard to access to treatment and other HIV-related services in Belize.

- The MoH's Planning Unit should address long-term tracking of human resources needs in HIV/AIDS and the health system overall. This can be assisted by implementing and/or upgrading computer systems to ensure more efficient planning and to better track health service delivery demands.
- There is a need to identify monitoring options to test the quality of donated drugs. This should be a coordinated effort of the health and foreign trade ministries, with a goal of expanding the capabilities of Belize in monitoring medication quality.
- There is a need to identify and design a proactive plan internally and externally to reduce stigma and discrimination so as to improve access to treatment for marginalized groups and for HIV-positive people in general. This effort must include a human rights agenda that is proactive and constructive. It should implement such a plan in consultation with partners including the Belize Family Life Association, the Pan American Social Marketing Organization (PASMO), United Belize Advocacy Movement (UNIBAM), and the media and affected populations directly.
- The National AIDS Commission in consultation with the MOH needs to develop a plan to ensure a sustainable supply of ARVs after the Global Fund grant ends in 2009. This plan should also take into account the likelihood that demand for treatment and care services will continue to increase. Mapping exercises can help establish reasonable estimates for both demand and supply.

## **Cambodia**

*by Mony Pen*



Only pharmacists or pharmaceutical companies registered with the Ministry of Commerce and authorized by the Ministries of Health and Agriculture, Forestry and Fisheries are eligible for license application and importation of pharmaceuticals and agricultural inputs. An import license from the MoH is required for the importation of pharmaceuticals and medical material including raw ingredients and finished products.

The drug registration process currently seems to work better in Cambodia in comparison with recent years because the MoH has announced that the drugs to be distributed officially in the country must be registered with WHO for prequalified assurance.

A local company, Cambodian Pharmaceutical Enterprise (CPE), produced cheap ARVs to meet the needs of local patients. However, its drugs did not meet WHO prequalification standards and thus were barred from the market. Access to tenofovir was limited in the wake of fall-out from a highly publicized and criticized clinical trial; however, that controversy has died down and the medicine is now more easily available. Recently, some key second-line therapies have been made newly available, including the heat-stabilized version of lopinavir/ritonavir (Aluvia) and a coated formulation of didanosine (ddl). New pediatric formulations are also expected to be available soon. However, very few Cambodian HIV patients have been tested for drug resistance or even tested for viral load due to high costs and no subsidies from the national program; therefore, only about 10 percent of ART treatment patients are on second-line therapies.

### **Drug stock-outs**

One of the hardest tasks for health experts is to predict and plan for the quantities of drugs needed. For economic reasons, excessively high stocks should be avoided. On the other hand, a shortage of necessary drugs is even worse because of the health consequences.

At present, it is difficult to assess how often stock-outs occur in Cambodia because of different reports from donors, the government, and health care providers. For instance, many donor and government staff report never experiencing stock-outs resulting from the structure of the drug delivery system. In contrast, some health care providers, especially at provincial levels, have complained about a shortage of necessary drugs and a poor system of drug transferring. They say they have had

to manage on their own in emergency situations, by “borrowing” medicines and supplies from other AIDS treatment clinics.

The Center for Medical Supplies (CMS) manages drug delivery in general, including for ARVs. The agency’s ability to meet its supply responsibilities is hindered at times by the inability of local health care staff to properly estimate drug needs. They ordinarily submit letters to the national program three months in advance to ask for drugs, but sometimes they underestimate or incorrectly predict the number of patients that will start or change treatments.

The bureaucracy surrounding Global Fund procedures and protocols also contributes to stock-outs. For example, the PR sometimes cannot process drug requests because it must wait for agreement and approval from the Global Fund. Such approval could take up to six months, and the delay is often extended because of other factors regarding tendering and shipping.

### Recommendations

- Assure the quality of pharmaceuticals:
  - Set up local—and independent, if possible—quality control laboratories.
  - Draft and distribute a manual on quality control laboratory management.
  - Improve regulatory controls and legislation, with particular attention paid to devising measures against counterfeited drugs.
  - Improve enforcement of laws and regulations.
  - Intensify the joint efforts of WHO and the pharmaceutical industry to assure quality.
  - Check expiry date: If no expiry date is given, one should be requested from the manufacturer or supplier. A file stating the expiry date should be used.
- The capacity of CMS staff on drug management and distribution issues should be improved.
- An enabling environment should be created to combat drug stock-out issues. This would entail the MoH providing a platform for local health providers to talk openly about the health system in the country context.
- The WHO must work harder to control and provide technical assistance on drug stock-out and quality issues.



## China

*By anonymous Missing the Target team*

### **Access to second-line drugs and pediatric treatment**

There is still extremely limited access to second-line ARVs in China. Government treatment authorities are in the process of slowly rewriting the national treatment guidelines to include second-line treatment; a rough draft of that document included lopinavir/ritonavir + tenofovir + lamivudine (LPV/r+TDF+3TC) as a standard second-line regimen. However, it is still impossible to purchase tenofovir in China because the medicine is not yet registered. The government plans to introduce free second-line treatment in three “pilot” provinces—Anhui, Henan, and Hubei—and officials have indicated that strict entry requirements will be imposed, including confirmation of drug resistance (MoH, July 2007). Treatment authorities say it is critical to impose such restrictions to ensure that second-line ARVs are only used by patients who truly need them, and so that doctors are properly trained and able to monitor patients on second-line treatment.

It is unclear if any arrangements have been made to allow individual patients or doctors outside of these three provinces to access second-line ARVs, or if they will have to wait until the results from the pilot sites are analyzed.

Access to second-line ARVs has not improved significantly since the publication in July 2007 of the previous *Missing the Target* report. It is not for lack of opportunities. Contacts within the government and among NGOs report, for example, that one major drug company (Gilead) in August 2007 submitted an application for tenofovir to be registered in China and that the company has expressed its willingness to cooperate with the Chinese government on an accelerated access program while awaiting regulatory approval. Such an arrangement would include the donation of tenofovir until regulatory approval is received, and subsequent purchase at the already agreed price of \$1 per person per day. Yet despite the urgent need for second-line treatment, government regulators were moving slowly (as of October 2007) to respond. The delay is especially problematic because the government’s plan to start providing second-line ARVs on a pilot basis in three provinces cannot proceed without tenofovir.

**Recommendations to increase access to second-line ARVs:**

- The government needs to speed up the approval process for tenofovir, possibly getting a temporary approval for the first six-month supply, and it should start rolling out second-line ART as soon as possible.
- Second-line ART entry requirements should not include resistance testing (genotyping) because such tests are not widely available in China and their absence will prevent most PLWHA from ever accessing second-line ARVs. Clinical and/or virological confirmation of resistance should be sufficient to start second-line treatment.
- Second-line ART should be made available nationally as long as patients meet entry requirements and a qualified doctor is monitoring the patient.
- Treatment education and (preferably) peer-led support and treatment counseling should be introduced in all treatment sites.
- The Chinese government should participate in UNITAID in order to access cheaper ARVs and to improve its negotiating position with multinational pharmaceuticals.

**Drug registration**

On paper, China has a clear system for new drug registration in place, with applications being managed by the State Food and Drug Administration (SFDA). In reality, this system is not working smoothly or quickly enough to ensure that newer and cheaper medicines enter the market. The slow pace of drug registration is a major barrier to the availability of effective and affordable ART in China. A number of systemic factors and related causes can be identified, including the following:

- The complex and slow processing of new drug applications by the SFDA has created long delays and at times convinced drug manufacturers that entry into the Chinese market is too cumbersome to be worth the time and money required.
- Regulatory agencies have refused to approve domestic applications for the production of fixed-dose combinations (FDCs) of first-line ARVs.
- For years, corruption has been a problem within drug registration agencies. In early 2007, a high-ranking official within the SFDA was arrested on corruption charges and subsequently executed. Other officials received jail sentences. The related investigations, and fears among SFDA staff of future criminal cases, have greatly slowed the processing of new drug registrations.

## CHINA

- The current process for registration of drug donations for unregistered ARVs or other essential medicines (such as FDCs for treatment of HIV and/or TB) is rigid and inflexible. Technically such donations are not permitted, but they have taken place on a case-by-case basis and only with special “waivers.”
- The requirement that companies submit production information along with clinical trial data has caused originator companies to delay or hesitate to register new ARVs. Originator companies say they fear that production information would be shared with local generic companies.
- Originator companies are not motivated to register and distribute their ARVs in China due to the small commercial market at present—only about 39,000 people were on ART as of October 2007, the vast majority of those on free first-line ARVs. In particular, many newer or more expensive ARVs never enter the China market (although some are registered to prevent generic production but not actually marketed in China).

In August 2007, new regulations for drug registration were issued. Despite the release of a draft version of the regulations and many suggestions made by NGOs working on treatment access, fundamental problems remain with the regulations that will impact the availability of newer or cheaper ARVs. Those problems include the following:

- There is a lack of clear “fast-track” approval procedures for medicines to treat HIV infection and other diseases.
- There is a lack of clear requirements for approval of generic medicines. In particular, there is lingering uncertainty as to whether clinical trials are necessary, or whether bioequivalence data only will suffice for such approval.
- Data exclusivity provisions go beyond TRIPS requirements, thereby creating barriers to timely registration of generic drugs. Especially considering the fact that originator companies often patent and register but fail to market newer drugs, use of this data in assessing generic ARVs is particularly important.

Faced with only a handful of ARVs to choose from, many patients and even treatment providers are forced to turn to personal contacts outside of China to secure newer or second-line ARVs. Medicines such as tenofovir and lopinavir/ritonavir have been carried in by hand from Africa and countries including India, the United States (mainly private donations), Hong Kong, and Thailand. However, there is no sustainable supply chain system in place in China.

## Stock-outs

While some stock-outs of ARVs have occurred, they have usually been localized (in one city or province), and information about such incidents is limited. It is therefore unclear how seriously shortages are impacting the national treatment program.

A centralized procurement and distribution system run by the national Centers for Disease Control (CDC) until mid-2006 allowed for rapid adjustments to cover stock-outs. However, that fallback guarantee at the national level ceased when procurement of ARVs was delegated to individual provinces in mid-2006. At the local (provincial or city) level, ARV shortages or stock-outs are more common. There was one well-known incident of stock-out of lamivudine in Guangzhou province in 2006. In response, patients were being switched instead to didanosine, but strong advocacy and action on the part of a local PLWHA group—including borrowing medicine from another site and communicating directly with Beijing authorities—ensured that the problem was quickly rectified.

It is likely, however, that the overall problem may be more serious than this incident suggests. PLWHA from different provinces have been told that certain ARVs, in particular efavirenz, are “not available,” and they have been forced to purchase their own supply. In late 2006, MSF reported that many shortages or stock-outs have occurred in sites where they work in China, with patients often resorting to purchasing the ARVs at market prices (which are much higher than the government’s procurement prices<sup>1</sup>).

### Recommendations to improve drug access

- Pursue compulsory licenses for generic versions of second-line ARVs, notably lamivudine (3TC) and efavirenz (EFV). WHO and relevant UN agencies should strengthen assistance to the Chinese government to do this, but the decision ultimately rests with the government.
- The Chinese government should urgently register FDCs of first-line ARVs and use these in the national treatment program.
- The Chinese government should speed up the new drug approval process to ensure timely access to newer and cheaper ARVs.

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<sup>1</sup> Reported market prices for ARVs included the following: lamivudine (3TC), 1,300 yuan (\$175) a month; and efavirenz, 619 yuan (\$83) a month. According to the MSF report, “a one-year supply of d4T (Chinese generic), 3TC (GSK), and nevirapine (Chinese generic) costs 18,000 yuan (\$2,400) at the market price.”

## **Dominican Republic**

*By Eugene Schiff and Felix Reyes*



### **ARV pricing and registration issues**

Following global trends, prices for many ARVs in the Dominican Republic have decreased in recent years. Yet surprisingly, the actual procurement receipts and official drug prices are extremely difficult to obtain. This is particularly noteworthy with regard to second-line medicines. It was impossible to ascertain the current number of PLWHA on such regimens or future epidemiologic and budget projections related to the procurement of second-line drugs despite repeated requests during interviews with authorities at the MoH (DIGECTSS), Principal Recipient (COPRESIDA), or the Procurement Agent (Clinton Foundation). The lack of transparency is perplexing considering that all ARVs distributed by the national program are purchased through the Global Fund, which requires the public posting of the prices and quantities of drugs procured using its funds.

Another factor raising the cost and limiting access to at least two drugs is the enforcement of patents. While most first-line drugs are sourced from generic suppliers, Merck has registered and is enforcing its patent for efavirenz (EFV). Even though Merck has lowered the price of efavirenz several times, local procurement experts noted that this important first-line drug still costs as much as two and a half times more from Merck than equivalent versions produced by generic companies. The generic versions cannot be purchased under current trade laws, however. The patent on efavirenz, in addition to the price set by Merck, and/or the lack of registration for the convenient fixed-dose combination containing efavirenz, tenofovir and emtricitabine (a combination branded as Atripla by Merck), has thus far served to keep Atripla or generic equivalents made by competitors from becoming available in the government treatment program in the Dominican Republic.

Patent-related restrictions may become an even greater concern in the future as more patients need second-line drugs. The branded versions of many second-line ARV drug combinations currently cost more than \$15,000 per year in the United States, and some drug companies have indicated they hope to enforce their drug's patents around the world. This could allow patent holders complete discretion in determining drug prices worldwide, preventing access to generic formulations of these newer drugs and blocking competition from additional suppliers which could reduce the costs of essential second-line lifesaving medicines the future.



## DOMINICAN REPUBLIC

Representatives of PLWHA networks reported that access to second-line medicines is already an urgent problem in the Dominican Republic. The problem may only get worse if current drug price differentials and restrictions on generic formulations persist.

It is worth considering the situation regarding Abbott Laboratories' Kaletra (lopinavir/ritonavir), an important second-line protease inhibitor. The company insists upon a tiered international-pricing policy for that drug, and it has long delayed the registration of its more effective heat-stable version (called Aluvia). As a result, as of September 2007 there was still not a single person in the Dominican Republic with access to Aluvia, although MoH authorities conveyed that the new drug had finally arrived in their warehouses and would be available soon. Even while delaying access to Aluvia and selling an even higher-priced version of the older Kaletra gel tabs, Abbott has been heavily marketing Aluvia in the Dominican Republic, particularly so in recent months. However, Aluvia costs more than \$80 per person per month, which is twice the price Abbott charges in neighboring Haiti, and is significantly more than the generic version, which is expected to become available next year. (It should be noted that in comparison, Aluvia costs as much as ten times more than some first-line drugs, which currently cost less than \$80 per year.) Atazanavir (ATV), which is marketed by Bristol Myers-Squibb, is currently the most expensive drug procured (in limited quantities) in the Dominican Republic. Access remains scarce and physicians noted that many who need the drug (due to side effects from Abbott's Kaletra) are unable to obtain it. Despite recent price reductions, atazanavir still costs about \$3,000 per year, thirty times more than some first-line drugs.

Another important issue with negative consequences vis-à-vis HIV/AIDS treatment access is that the Dominican government has refused to prioritize or invest its own resources in the purchase of antiretroviral treatment. Notably, it continues to exclude ARVs from the new national health insurance program. This means that all treatment programs are sustained almost exclusively by international donors (most prominently, the Global Fund). The government has not given any indication as to how—or even if—it plans to ensure that the treatment programs are sustainable after the Global Fund grant concludes in 2009.

## India

*By Abraham KK, Celina D'Costa, Bobby Jayanta, Murali Shunmugam, Dr. Venkatesan Chakrapani  
Indian Network for People living with HIV (INP+)*



### Stock-outs in Manipur

Stock-outs of ARVs have been reported by PLWHA activists from several different regions of India. However, the reasons behind the stock-outs and the follow-up actions taken are relatively unique in Manipur, a state in northeast India where, unlike the rest of the country, the HIV/AIDS epidemic is predominantly affecting injecting drug users (IDUs).

There are government-run ART centers in just five of Manipur's nine districts. PLWHA from the other four districts must travel six to eight hours to reach the nearest ART center. Even PLWHA living in a district that has a center face very long travel times. The hilly landscape makes travel even more difficult for many PLWHA. IDUs living with HIV/AIDS usually also have liver complications, often due to hepatitis-B and -C co-infections, as well as due to alcohol-related liver damage. In such cases, the ARV nevirapine (NVP) cannot be used; doctors in Manipur and elsewhere often prescribe an efavirenz (EFV)-based ART regimen instead.

In August 2007, acute shortages of efavirenz were reported in some ART centers in Manipur. The shortages occurred because only about 20 percent of the expected number of first-line regimens were allocated as efavirenz-based. The crisis led Bobby Jayanta, the general secretary of Manipur Network of People living with HIV (MNP+), and some other activists to approach the National AIDS Control Organization (NACO) and the Manipur State AIDS Control Society (SACS) to demand action to fix the problem. Manipur SACS's immediate short-term solution was to transfer efavirenz tablets from nearby ART centers to those experiencing efavirenz shortfalls. However, because of the shortage, PLWHA were only given enough efavirenz to last for 10 or 15 days (instead of a month's supply), a solution that necessitated traveling to ART centers twice or three times per month. In addition to the additional travel costs, many PLWHA had to bear accommodation costs since long distances meant overnight stays became necessary.

Thus, the short-term solution of transferring efavirenz from other ART centers in Manipur or from those in the neighboring state of Assam was not convenient or helpful for the affected PLWHA. Although no data have yet been obtained about the impact of the efavirenz shortfall on treatment adherence, it is thought that some

HIV-positive clients in Manipur were unable to comply with their treatment regimens because of the hassle and difficulties they faced in obtaining ART.

NACO, however, has not still increased the percentage of efavirenz allocated to Manipur's ART centers. It is imperative from a public health perspective, however, that such a crisis be avoided in the future. The following are among the possible long-term solutions that could be implemented to prevent future stock-outs:

1. Periodic estimation of the expected utilization of efavirenz-based regimens in Manipur is needed. This should be based on the past month's utilization pattern as well as projected needs for the upcoming few months. The allocation of efavirenz-based regimens should not be just a blanket allocation based on an assumption that 20 percent of first-line regimens need to be efavirenz-based. (Note: The need for efavirenz-based regimens in Manipur may be greater than 35 percent.)
2. In case of drug shortages, PLWHA who are getting ART (including efavirenz) from government ART centers should be permitted to buy ARVs from outside the system with a guarantee that their expenditures will be reimbursed. NACO should immediately adopt such a policy and ensure that it is understood and implemented across the country.

NACO has not yet officially released its 2007 ART (adult) guidelines, but is expected to soon. If these guidelines are accepted then the following will become priorities:

- train health care providers on the revised guidelines;
- procure and budget for the revised list of drugs; and
- prepare treatment education materials on the new drugs.

## Malawi

By Lot Nyirenda and Grace Bongololo



### Commonly used ARVs in Malawi

The four most commonly used ARV regimens in Malawi include tenofovir (TDF), efavirenz (EFV), lopinavir/ritonavir (LPV/r, as Kaletra capsules), and fixed-dose Triomune (stavudine [d4T]+ lamivudine [3TC]+ nevirapine [NVP]). These medicines are currently used for children and adults in first- and second-line regimens. Emtricitabine (FTC) and Atripla (a fixed-dose combination of efavirenz [EFV] + tenofovir [TDF] + emtricitabine [FTC]) are not used in Malawi. Ritonavir (r), meanwhile, is only available as part of FDCs.

According to the MoH<sup>1</sup>, the Triomune FDC is the usual first-line regimen. Alternative first-line regimens are available as well. One such alternative, consisting of zidovudine (AZT) + lamivudine (3TC) + nevirapine (NVP), is usually provided to patients who experience side effects stemming from stavudine (such as severe peripheral neuropathy, pancreatitis, and lactic acidosis/lipodystrophy syndrome). Patients who experience nevirapine-related side effects (such as skin reactions and hepatitis) may use yet another alternative first-line regimen: stavudine (d4T) + lamivudine (3TC) + efavirenz (EFV).

The available second-line regimen for adults consists of zidovudine (AZT) + lamivudine (3TC) + tenofovir (TDF) + lopinavir/ritonavir (LPV/r). Children, meanwhile, have access to didanosine (ddI) + abacavir (ABC) + lopinavir/ritonavir (LPV/r) as a second-line regimen.

### Cost of ARVs

The cost per patient per month of first-line regimens varies from \$12 (supplied by Hetero) to \$18 (supplied by Cipla). In addition, Cipla supplies all second-line regimens. Second-line regimens cost \$20 per patient per month.

### Drug procurement

The UN Children's Fund (UNICEF) has overseen procurement since Global Fund started supporting the roll-out of free ARVs in Malawi. The organization will no longer be the automatic choice in the future, however, in light of the exorbitant

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<sup>1</sup> As cited in the Ministry of Health's 2006 publication, "Treatment of AIDS: Guidelines for use of antiretroviral therapy in Malawi, 2nd edition."

prices it charges for handling drug procurement and distribution. Current plans call for the World Bank to advertise for a procurement entity and for a tendering process to follow.

There are official guidelines in Malawi as to which ARVs and combinations to prescribe. However, some private institutions are allowed to use different combinations as long as the drugs are certified by the Pharmacy, Medicines and Poisons Board, a government regulatory body.

### **Drug registration**

Malawi uses Global Fund money to purchase ARVs and all drugs used in public hospitals must be WHO-certified. This means that the procurement entity (currently UNICEF) cannot purchase and supply ARVs that have not passed WHO's prequalification process.

There have been problems related to this requirement. In 2004, for example, WHO de-listed some ARVs from Ranbaxy because of improper bioequivalence testing. That occurred after UNICEF had already purchased a large supply of the affected medicines. UNICEF subsequently was forced to identify an alternative supplier and chose Cipla—and then had to wait for nearly six months for the replacement medicines to arrive. Fortunately, at the time Malawi had just started rolling out the free ART program and only a small number of patients had initiated treatment. Since then, there have been no reports of service providers facing problems related to drug registration.

### **Originator vs. generic drugs**

Drugs from originator firms do not come as complete regimens in FDCs (Atripla, for example, is currently unavailable in Malawi). That means patients may need to take up to three separate tablets at a time. In contrast, several generic producers supply an entire three-drug regimen in a single tablet. Triomune, the most commonly prescribed first-line regimen in Malawi, is an FDC. Because they are easier to take, single-pill combinations are known to promote adherence and thus decrease the risk of developing resistance. They are also cheaper and facilitate easier stock and procurement management, two other important reasons they are widely recognized as a core element in efforts to scale up ART in developing countries.

Malawi's emphasis on using generic drugs has allowed more people to be on ART. It is estimated that if it were restricted to using originator drugs, Malawi could only have put around 25,000 people on ART by 2008. However, with generic drugs, at least 120,000 are currently on ART in Malawi. That is still short of meeting the total estimated need of about 170,000 individuals (as of October 2007), but it does appear that Malawi is on the right track.

## Stock-outs

According to an external report on Malawi's ART program in 2006<sup>2</sup>, all ART sites had adequate supplies of ARVs—three-month buffer stocks at each facility—except for the central hospitals, all of which had limited buffer stocks. However, stock-outs, ordering, and delivery problems were observed for other commodities relevant to HIV care and support, including cotrimoxazole, some medicines for OIs, and HIV test kits. The main reason for the problems is that unlike the ordering of ARVs, which has a strong supply chain, procurement of other HIV-related commodities lacks a comprehensive and coordinated approach. This situation has translated into a fragmented supply chain for these services. Some MoH officials, however, blame the Global Fund for such problems, arguing that they stem directly from delays in the transfer of funds from the Global Fund to UNICEF.

A recent sector-wide approach (SWAP) mid-term review<sup>3</sup> nevertheless found that while there were no stock-outs for ARVs, many other drugs were out of stock. According to the report, in February 2007 a total of 151 drug items were out of stock at one of the main medical supply facilities. The major reason for the stock-outs is inadequate capacity to procure goods and services. Ensuring that sufficient and appropriate drugs are continually in stock remains a perennial challenge for the MoH.

## Human resources

A chronic shortage of health care workers remains one of the key challenges facing the public health system in Malawi. The government has embarked on a number of programs to address the challenge, including those designed to improve pay and allowances; increase the number of hours worked by staff through use of the 'locum' (overtime); and relief systems. In relief systems, staff move from one place to another on a regular basis, which helps ensure that remote health centers are less severely understaffed.

The government is planning to allow nurses working in the national ART program to initiate treatment as well (in addition to doctors and other clinicians). The government has also hired at least 5,000 additional health surveillance assistants (HSAs), who are important elements in ensuring better links between health facilities and communities. Task-shifting efforts should however be implemented with utmost care to ensure that quality of services does not decline—especially for the poor, who are more likely to access services "shifted" to the lower-level personnel. Efforts should also be made to ensure that the task shifting initiative is an inclusive process. The Medical Council, Nurses and Midwifery Council, and other stakeholders should be involved directly in the process to ensure it is implemented smoothly.

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<sup>2</sup> Gilks C., Blose S., Carpenter B., et al. Report of the Malawi ART Programme External Review Team, Malawi Ministry of Health. September 15, 2006.

<sup>3</sup> Carlson et al (2007), Malawi Health SWAP Mid-term Review Summary Draft Report.

**Conclusion**

The shortage of human resources is the major challenge not only to the ART program but to the entire health sector. This ongoing problem threatens to limit the program's effectiveness even as the number of people receiving ART free of charge continues to rise. In addition, although more ART sites are being opened every year, ART services need to be further decentralized so that problems with transportation over long distance to health facilities are alleviated.

Stock-outs of other commodities relevant to HIV care and support also should be cause for concern to government as well as donors. Given that inadequate capacity is one of the major reasons for drug stock-outs, efforts should be made to build capacity to procure goods and services within the appropriate frameworks. Addressing the human resources challenges, including human resources in the procurement field, will go a long way toward ensuring that the gains Malawi has made so far are not lost.

## Morocco

By Othman Mellouk



Morocco has taken bold steps during recent years to improve access to medicines. This includes the introduction of a new health insurance scheme and promotion of the use of generic drugs. However, ensuring the sustainability of access to treatment and avoiding the negative impact of new intellectual property (IP) protections the country has recently adopted pose major challenges.

Before 2000, Morocco had no patent legislation concerning pharmaceuticals. This enabled the Moroccan pharmaceutical industry to flourish and develop into the second largest pharmaceutical industry in Africa, after South Africa. In 2000, the local pharmaceutical industry was able to cover 72.2 percent of national needs and sell generic medicines at 10 to 80 percent of the cost of the equivalent brand-name products. But as a member of the World Trade Organization (WTO), Morocco in 2005 amended its IP law to be in compliance with the WTO TRIPS agreement. While the TRIPS agreement and the WTO Doha Declaration allow countries to adopt safeguards to protect public health and access to medicines, the new Moroccan IP law did not take into consideration all of these possible protections. Under the new legislation, recourse to parallel import is not allowed, compulsory licences are subject to restrictions, and there is no mention of the Bolar provision (which reduces delay in the registration of generic drugs). Also excluded from the new law was mention of the August 30, 2003 WTO declaration allowing exportation of locally produced generic drugs. Lack of this provision inhibits generic production of ARVs, since the Moroccan market is too small to justify investment in ARV production unless there is also an export market.

Moreover, the Morocco-United States free trade agreement (FTA), signed in March 2004 and effective in January 2006, imposes additional intellectual property protections that constrain rights afforded by the WTO agreements. The FTA text dismantles the flexibilities reaffirmed by the WTO Doha Declaration on TRIPS and Public Health, such as compulsory licensing or parallel importation, and introduces rules that curtail Morocco's ability to take measures to reduce the cost of medicines:

- Extension of the patent term,
- Limitations on parallel imports of patented drugs,
- Data exclusivity, and
- Marketing authorization restrictions.



## MOROCCO

These rules, termed “TRIPS-plus” rules, because they go beyond TRIPS protections, risk the sustainability of Morocco’s HIV treatment program, considered a model in the Middle East and North Africa region. In the face of strong criticism from national and international civil society, the US and Morocco tried to resolve public health concerns by exchanging side-letters reaffirming that the obligations under the IP chapter “do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria and other epidemics, as well as circumstances of extreme urgency and national emergency.” However, these side-letters are not incorporated into the FTA and therefore do not override the strict IP provisions in the agreement that undermine access to medicines.

It is difficult to assess the impact of the reinforcement of IP protection on access to medicines in the country since no impact study has yet been carried out. But advocates for HIV treatment agree that progress made to date, especially regarding access to the new generation of ARVs and some key drugs for the treatment of OIs, will likely suffer a setback.

Lack of openness in the operation of the Moroccan patent office, and the difficulty for treatment advocates—and even the MoH—to know what is patented and what is not, pose additional challenges.

It seems likely that few multinational companies patented ARVs in the past, since there was little interest in the Moroccan HIV market prior to the success of the government HIV treatment program. But the situation is expected to change in the coming years, as the number of patents granted increases rapidly under the new IP law and the Morocco US-FTA. Even in the absence of patents on ARVs, the new IP rules have already dissuaded the introduction of generic drugs. For example, the national AIDS program has had an agreement with the Clinton Foundation since 2005 to buy generic drugs at lower prices than are available today, yet until now have never ordered a single pill for fear of infringing on the IP rules. The situation is different for drugs to treat OIs that have larger markets; however some of these drugs are already protected.

In view of these concerns, and in order to protect the rights of Moroccans to access essential medicines and ensure the sustainability of treatment to all PLWHA in the country, the government must:

- Conduct an independent impact assessment study of the new IP protection measures (TRIPS implementation and Morocco-US FTA) on access to medicines in general and to HIV/AIDS-related drugs in particular; and that the results of such a study be used as a basis for the revision of IP law in order to include all safeguards permitted by TRIPS and the Doha Declaration.

- Determine the patent status of all ARVs and drugs most commonly used for OIs and use compulsory licences when necessary to allow generic competition.
- Reactivate the partnership already signed between the national AIDS program and the Clinton Foundation that guarantees lower prices. This will introduce competition in the market.
- Put in place an advocacy strategy addressed to the Moroccan and the US government to use the side letter in order to protect access to medicines when necessary.

## ARV price comparisons

Morocco's national guidelines recommend for the following combinations for first-line treatment regimens: (zidovudine [AZT] or stavudine [d4T] or tenofovir [TDF] or abacavir [ABC]) + (lamivudine [3TC] or emtricitabine [FTC]) + (efavirenz [EFV] or nevirapine [NVP]). The most commonly used combinations are:

- zidovudine/ lamivudine/ efavirenz (AZT/3TC/EFV),
- zidovudine/ lamivudine/ indinavir + ritonavir (AZT/3TC/IDV+r), and
- stavudine/ lamivudine/ efavirenz (d4T/3TC/EFV).

Thus, most ARVs purchased by the National AIDS Program (NAP) are: zidovudine (AZT), lamivudine (3TC), efavirenz (EFV), stavudine (d4T), indinavir (IDV) and ritonavir (r). These drugs are either sourced from the originator companies or imported through Moroccan suppliers (Afric-Phar and Cooper Maroc) from Indian generic producers (Cipla and Ranbaxy).

Prices for these drugs Morocco in 2007, both generic and from the originator, are higher than median prices recommended by WHO for lower middle income countries, and higher than ceiling prices specified by the Clinton Foundation. Even if Morocco introduced generic drugs, this would not result in a real drop in prices. The local suppliers have created a new monopoly distributing products from only two generic suppliers (Cipla and Ranbaxy). The low quantities imported and the mark-ups taken by these two suppliers are another barrier against price competition.

For second-line treatment, it is recommended to use a combination that includes a boosted protease inhibitor: {(zidovudine [AZT]+ lamivudine [3TC]) or abacavir [ABC]} + (didanosine [ddl] or tenofovir [TDF]) + (indinavir/ritonavir [IDV/r] or lopinavir/ritonavir [LPV/r] or nelfinavir [NLF]). If second-line treatment fails, it is common to resort to a genotype test in order to identify potential active drugs from the portfolio of the available ARVs to construct a salvage, or third-line therapy.

Tenofovir (TDF) and emtricitabine (FTC) are still not available in Morocco, but according to the Ministry of Health, they will be provided in the next command of the National AIDS Program. These two drugs are not currently registered and the NAP will probably use a temporary import authorization to obtain them. Lopinavir/ritonavir (LPV/r) capsules are available but not registered. According to the MoH, the heat-stable formula will replace lopinavir/ritonavir gel capsules very soon. Efavirenz (EFV) is registered and available. Atripla (EFV + FTC + TDF) and the pediatric fixed-dose combination of stavudine/ lamivudine/ nevirapine (d4T/3TC/ NVP) are not registered and not yet available in the country.

### **Drug registration process**

According to many observers, drug registration of ARVs is a real problem in Morocco. Drug companies do not necessarily register their ARVs in the country, probably because of the limited market for such products, since the prevalence of HIV remains low. When ARVs are registered, it is usually at the request of the MoH or NGOs.

Some companies like Abbott and Gilead, who lack representation in the country, have not registered their ARVs. In these cases, the NAP use a “temporary import authorization” provided by the drug registration authorities. This authorization must be renewed for each order. The companies justify non-registration by citing the slow and complicated procedures of the registration process, which they negotiate when other drugs with greater markets are involved. According to the Ministry of Health, procedures are not more complicated in Morocco than in other countries, yet the companies do not register when there is little financial incentive, which is the case for ARVs.

Recently, a committee has been put in place by the MoH to develop a strategy for reducing the price of ARVs. The registration problem has been identified as one of the major obstacles that should be addressed. The goal would be to encourage more generic competition by registering the maximum number of generics versions. A fast-track procedure will be put in place to encourage Moroccan suppliers to play a key role in competition between companies.

### **Drug stock-outs**

During the past few years, many efforts have been made to avoid the ARV stock-outs that were very common in the first years of the program, but have become rare in the last few years. Nevertheless, at the end of 2006 and beginning of 2007 problems with the ARV procurement system resulted in stock-out for two drugs: nelfinavir (Viracept) and lopinavir/ritonavir (Kaletra).

The shortage occurred because some drugs planned for 2006 availability could not be purchased (FDC of stavudine/lamivudine/nevirapine [d4T/3TC/NVP] and stavudine/lamivudine [d4T/3TC], tenofovir [TDF], and tenofovir/emtricitabine [TDF/FTC]). This resulted in increased consumption of nelfinavir and lopinavir/ritonavir that was not anticipated. For drugs such as Abbott's lopinavir/ritonavir combination, which requires refrigeration since the heat-stable formula is still not available, the MoH would stagger the orders. Another reason for the stock-out was the expectation of renewing the Moroccan proposal to the Global Fund. In prior years, orders were realized by July; this year, because the country was waiting for the Global Fund decision, the 2007 order was not submitted on time. Finally, stock-outs may also be attributed to delays in delivery by the companies: Abbott for Kaletra (LPV/r) and Roche for Viracept (NLF).

Fortunately, there were no treatment interruptions. The treatment educators of the Moroccan NGO ALCS played a key role organizing sharing of drugs, involving people who had sufficient provisions of ARVs. The MoH and the Global Fund management team ordered exceptional quantities of drugs and pharmaceutical companies were urged to deliver rapidly. ALCS allocated also some of the funds raised in a TV telethon (Sidaction Maroc 2005) to buy the needed Kaletra (LPV/r).

### **Recommendations**

In order to avoid stock-outs in the future it is recommended that:

- Planned purchasing should be honoured.
- MoH and funders like the Global Fund should take into consideration the transition period between two rounds to ensure the sustainability of the treatment program.
- MoH should take into consideration the time required for delivery and pharmaceutical companies should avoid delays in delivery.
- For the specific case of lopinavir/ritonavir, the delayed introduction of the heat-stable formula with less refrigeration should be addressed.

## Nigeria



*By Olayide Akanni, Journalists Against AIDS (JAAIDS) Nigeria, and Bede Eziefule, Centre for the Right to Health (CRH)*

Nigeria's HIV treatment program commenced with 25 sites in 2001. As of June 2007, 210 sites were providing ART across the country.

Nigeria's program is supported by three principal actors: the government, PEPFAR, and the Global Fund. All three have supported the establishment of ART and PMTCT sites across the country. Other actors include MSF.

Given the rapid scale-up of treatment embarked upon by the three key actors, first-line treatment is now available across the country. However, sites are still not equitably distributed within the 36 states of the Federation and many PLWHA still have to travel long distances in order to access treatment. In addition, monitoring tests are not free in all centers.

In 2001, the Nigerian Government initiated provision of affordable ARVs to the many Nigerians living with HIV/AIDS. From 2002 to 2005, the federal government provided them with a 75 percent subsidy, which meant that patients were required to pay the remaining 25 percent. Since 2006, however, all ARVs have been provided free of charge through the public sector and at PEPFAR-supported sites, after former Nigerian President Olusegun Obasanjo announced (in December 2005) a free treatment policy for HIV-positive individuals.

ARVs provided at tertiary institutions run by the federal government are centrally procured by the National AIDS and STD Control Program (NASCAP), a program under the Department of Primary Health Care and Disease Control of the Federal Ministry of Health (FMOH). Three other parastatals are involved in procuring drugs under the government program: the federal Ministry of Finance, which facilitates the procurement of ARVs; pharmaceutical companies; and Federal Central Medical Stores (FCMS), a government agency that receives and stores the drugs. Drugs are then distributed from the FCMS to the treatment centers across the country. In 2001, drugs were being procured from Cipla (at an average cost of \$350 per patient per year); and Ranbaxy (\$320 per patient per year).<sup>1</sup> By 2004, the government was also procuring ARVs from Ranbaxy at a cost of \$300 per patient per year.

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<sup>1</sup> Journalists Against AIDS Nigeria. "Saving the Nigerian ARV Programme: Options for sustainability." January 8, 2004. [www.nigeria-aids.org/eforum/msgRead.cfm?ID=2207](http://www.nigeria-aids.org/eforum/msgRead.cfm?ID=2207)

## NIGERIA

As of November 2007, the unit cost of ART per patient per year could not be ascertained. Several attempts were made by the researchers to obtain this information from the staff of the Federal Ministry of Health, but they refused to disclose the information stating that “official approval to release such information was required.”

### Government budgetary allocations for ARVs

Year	Amount
2001	N100,000,000 (\$825,000)
2002	N450,000,000 (\$3.71 million)
2003	N850,000,000 (\$7 million)
2004	N1,500,000,000 (\$12.36 million)
2005	N845,730,000 (\$6.97 million)
2006	N2,480,926,173 (\$20.44 million)

Source: NASCAP 2007

PEPFAR program implementers, meanwhile, partner with other organizations to facilitate the procurement of ART. For instance, Family Health International’s Global HIV/AIDS Initiative Nigeria (FHI/GHAIN), which runs one of the largest PEPFAR-implemented ART programs in Nigeria, partners with Axios International, a corporation specializing in health care systems for chronic disease management and drug delivery. Axios manages the procurement and distribution of GHAIN’s ARVs as well as drugs for treating HIV-related OIs. With USAID support, Axios obtained approval from Nigeria’s National Agency for Food and Drug Administration and Control (NAFDAC) to import ARVs into the country. NAFDAC representatives meet each shipment of medicines as it arrives and take samples to test for quality assurance.<sup>2</sup>

Under the Global Fund-supported grant, the Principal Recipient (NASCAP) procures ARVs, test kits, laboratory reagents, and other consumables through Crown Agents. MSF procures abacavir (ABC) from GlaxoSmithkline (GSK), Nigeria; all of its other ARVs are imported.<sup>3</sup>

### Suppliers of ARVs

Major sources of ARVs in Nigeria include international pharmaceutical companies and Indian generic drug manufacturers Ranbaxy and Cipla. In addition, several domestic pharmaceutical companies are producing ARVs locally (both adult and pediatric formulations). In a bid to increase market share, the local manufacturers are calling on the Nigerian government to increase tariffs on imported ARVs and to discourage aid agencies and foreign governments from donating free drugs.<sup>4</sup>

<sup>2</sup> FHI/GHAIN newsletter. “Axios International’s Groundwork Allows GHAIN to Provide Antiretroviral Therapy.” June 2005.

<sup>3</sup> Interview with MSF Campaigner/Communications Officer.

<sup>4</sup> PLUS News. “NIGERIA: Local ARV manufacturers want state support.” October 12, 2007. [www.plusnews.org/Report.aspx?ReportId=74766](http://www.plusnews.org/Report.aspx?ReportId=74766)

## Drug registration

When a shipment of drugs arrives either at the FCMS or other points (as in the case of the PEPFAR program), batch samples are collected and tested for quality by NAFDAC officials. If the ARVs pass inspection, individual boxes are issued a stamp of approval. The testing process can take up to four weeks to complete.<sup>5</sup>

## First-line regimens

Before 2006, the ART adult guidelines recommended stavudine/ zidovudine (d4T, 40mg or 30mg)/(AZT) plus lamivudine/ nevirapine (3TC/NVP) or efavirenz (EFV) as first-line regimens. The new guidelines recommend zidovudine (AZT) or tenofovir (TDF) plus lamivudine (3TC) or emtricitabine (FTC) plus efavirenz (EFV) or nevirapine (NVP) as preferred first-line, with the option to use stavudine (d4T, 30mg) or abacavir (ABC) plus lamivudine (3TC) or emtricitabine (FTC) plus efavirenz (EFV) or nevirapine (NVP).

Similarly, the drug regimen in children has also been changed. The recommended first-line regimen is zidovudine (AZT) plus lamivudine (3TC) plus nevirapine (NVP) or efavirenz (EFV), with options of stavudine (d4T) plus lamivudine (3TC) plus nevirapine (NVP) or efavirenz (EFV); or abacavir (ABC) plus lamivudine (3TC) plus nevirapine (NVP) or efavirenz (EFV).

Fixed-dose combination syrups and tablets have also been introduced for pediatric use. There is a plan to replace stavudine (d4T) fixed-dose combinations with zidovudine (ZDV)-containing combinations, when available. Current ART regimen options were informed by WHO recommendations.

Before 2004, PMTCT used single-dose nevirapine (NVP) monotherapy. However, since 2006 revised PMTCT guidelines introduced combination therapy as recommended by WHO.

## Second-line treatment

Second-line treatment is available to those who require it, but in general it is not as readily available as first-line drugs in all the centers. Second-line treatment is provided free of charge at federal government and PEPFAR-supported sites.

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<sup>5</sup> Partners for Health Reformplus/Abt Associates Inc., DELIVER/John Snow, Inc., and POLICY Project/Futures Group. Nigeria: Rapid Assessment of HIV/AIDS Care in the Public and Private Sectors. August 2004.

**Diagnostic tests**

Diagnostic tests are also provided at no cost to clients at federal government and PEPFAR-supported sites. However, there are variations with respect to the provision of such tests. According to one HIV-positive individual accessing treatment at the Federal Medical Centre Owerri, Imo State, in southeastern Nigeria, diagnostic tests in his treatment facility were not free. He said that CD4 count tests cost about \$8 each and that patients must pay for viral load tests conducted outside the facility (since it does not offer such tests). Both government and PEPFAR sites are supposed to offer CD4 monitoring tests at no cost to the patient, but some of these centers have yet to offer the tests for free.

**Additional free support**

The free treatment policy announced by the federal government in December 2005 also includes free services other than ART provision, such as PMTCT services for pregnant women. Moreover, some facilities visited by the researchers in Lagos and Abuja provide free support services such as Caesarian-section surgery for HIV-positive mothers giving birth and free infant formula for newborn infants.





## **Philippines**

*By Nenet L. Ortega, Noel Quinto, and Eddy Razon*

### **Background and current situation**

The HIV epidemic in the Philippines has been characterized by the Department of Health and UNAIDS as “low and slow” but “hidden and growing.” Since 1984, when the first individual was diagnosed, a cumulative total of 2,916 HIV cases have been officially registered (although WHO estimates that perhaps 10,000 Filipinos may be HIV-positive but unaware of their serostatus). According to the official numbers, 2,146 (74 percent) are asymptomatic and 770 (26 percent) have been diagnosed with AIDS, of whom 304 have died. (The official numbers do not include those diagnosed outside of the country.)

The Philippines government has launched numerous prevention initiatives yet has given comparatively limited attention to treatment, care, and support. Until early 2000, HIV treatments were available only through clinical research conducted by commercial interests, although participants were often not adequately informed about the purpose, risks, or potential benefits of these studies.

In 2003, the Philippines government vowed to provide all HIV-positive Filipinos with access to comprehensive treatment, care, and support. Staff from government-funded regional and local medical facilities trained personnel in HIV/AIDS case management; these individuals are now members of what is called the HIV/AIDS Core Team (HACT).

Despite this commitment, initial government treatment plans were not realized due to drug procurement problems. Ultimately, initiation of the government’s HIV treatment program depended on receiving money from the Global Fund, which was not disbursed until 2004. However, even once funding was available to support 150 people on ART, the government was slow to deliver. Drugs only became available in the first quarter of 2006 and free ARVs were finally provided in March and April 2006 to qualified HIV-positive persons.

## PHILIPPINES

The government's initial inability to procure sufficient ARVs was due to the following:

- the essential ARVs were not registered with the Philippines National Drug Formulary;
- bulk procurement quantities could not be estimated because HIV clinics could not produce data on the actual number of persons in need of ARVs or those currently receiving them;
- drug distribution mechanisms were not yet organized;
- diagnostic tests were unavailable, including those for CD4 counts, viral load, and liver function; and
- standard treatment guidelines had not yet been established.

The delay was so critical that WHO intervened in the third quarter of 2005 to facilitate procurement of the needed ARVs. Even then, significant problems arose. Inaccurate estimates resulted in overstocks of Duovir (lamivudine/zidovudine) and nevirapine at the same time that a stock-out of efavirenz occurred.

### **ART in the Philippines today**

As of October 2007, nearly all of the almost 500 people diagnosed with AIDS in the Philippines are not receiving ART. Many have chosen not to begin treatment because they fear potential side effects, a situation that indicates a lack of appropriate treatment literacy and education among HIV-positive individuals. Although there are now 11 treatment centers distributed around the country, the number of adequately trained and competent health providers capable of providing HIV/AIDS management remains limited.

Currently, all ART purchases are supported by the Global Fund, and drugs are available free of charge through the government treatment program. Of those on ART, the majority are taking efavirenz, which is classified as a first-line medicine and an alternate to nevirapine if patients on the latter develop side effects. A few are taking a second-line drug, Kaletra (lopinavir/ritonavir).

### **Ongoing challenges to effective HIV treatment delivery**

#### Human resources

- Rapid turnover of trained health providers at treatment centers has negatively affected the quality of service delivery.
- Many providers at the treatment centers have insufficient knowledge about ART.

## PHILIPPINES

- Not all treatment centers have community-based partners that can conduct treatment follow-up, counseling, and home visits for those on ART.

### Standards and guidelines

- Treatment centers have no single protocol or set of standards regarding treatment counseling or treatment literacy and education for clients or family members. This negatively impacts adherence and understanding of how to address side effects.
- There is no well-established mechanism to refer clients to other potentially useful health and social services.
- The Global Fund supports only one diagnostic test for free, the CD4 count. All other tests, for viral load, liver function, etc., require payment.
- Screening for TB is by X-Ray only. Such tests are offered infrequently if at all, even if patients exhibit symptoms.

### Sustainability of access to medicines

- The Global Fund currently funds all purchases of ARVs. The government has yet to announce how (or even if) it will take on this responsibility after Global Fund support ends in 2010.
- Except for cotrimoxazole, medicines to treat OIs are rarely available through the public sector. These shortfalls exist because local governments in regions with treatment centers are not shouldering their responsibilities. Clients with OIs are therefore forced to purchase drugs with their own funds, if they have them.

## Recommendations

### **Civil society**

- Scale up treatment advocacy at different levels among different entities, including other NGOs, in order to generate support for the treatment agenda.
- Communities and organizations of PLWHA should seek to further “humanize” the epidemic by discussing HIV/AIDS openly and candidly. Individuals living with TB should be included in these efforts because their treatment issues are similar to those facing PLWHA, even when patients are not co-infected.
- Support the community-led development of a strategic advocacy agenda for the Philippines.
- Increase advocacy and education efforts toward universal access.

## PHILIPPINES

- Increase training and capacity building for treatment advocates, educators, and counselors for PLWHA.
- Increase advocacy on the lack of well-trained health personnel involved in HIV/AIDS treatment.

### **Government agencies**

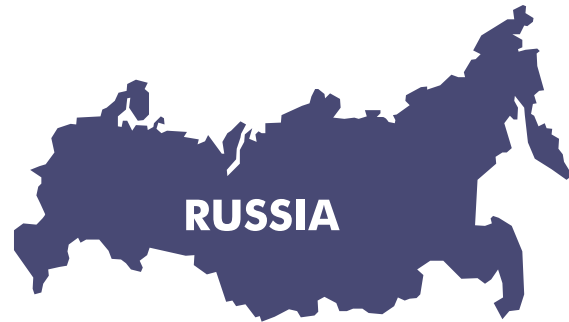
- Commit to meeting the government's promise of making treatment available to all people living with HIV/AIDS who need it. Treatment should be considered to include medicines for TB and OIs, as well as ARVs.
- Train and build capacity among health care providers in the conduct of treatment literacy, education, and advocacy.
- Consider "task shifting" as a way to offset the shortage in health personnel involved in HIV/AIDS treatment.

### **Donors and funders**

- Provide support for treatment literacy and education campaigns among all local stakeholders, including PLWHA and health care personnel.
- Provide support to build the technical capacity of health care personnel in HIV treatment management.
- Provide technical capacity-building to governments on drug procurement, sustainability, and stocks.

## Russia

*By Shona Schonning, Smiljka de Lussigny,  
and Sergey Kovalevsky*



### **Pharmaceutical management**

In Russia, approximately 30,000 PLWHA are receiving antiretroviral drugs according to the Ministry of Health (MoH). This is around 40% of the 70,000 people that the MoH estimates are in need of treatment and is more than 10 times higher than the number receiving ARV only 4 years ago. While considerable progress has been made in Russia's effort to scale up access to ARVs, a variety of problems related to registration, procurement, supply chain management, and drug quality, in addition to multiple problems related to developing adequate services for PLWHA, have slowed progress and, in some cases, endangered lives.

### **Registration and procurement**

Before drugs are purchased in Russia, they must be included in the national registry. But numerous cases of long-term hold-ups in the registration process have been reported. For some drugs, the process takes only a couple of months, while for others it takes years. Clear reasons for the delays are not given and corruption is suspected.

Drug purchases are arranged through a centralized tender. This is a great improvement over the past when drugs were purchased in separate tenders by Russia's 86 regions, leaving great room for corruption and price manipulation. New problems have arisen, however. Although a computerized system for tracking drug requirements at the country's AIDS Centers has been developed, through which AIDS Centers enter the quantities of drugs they require, the Federal standard on the quantities of drugs that should be ordered is often not followed. According to one authority interviewed, the training of AIDS Center personnel on quantities of drugs to be ordered has been inadequate. This has resulted in overstocking some drugs and stock-out of others.

The tender process in Russia has also been problematic. In 2006, a central tender failed to lead to contracts for the purchase of drugs and resulted in stock-outs throughout the country. In 2006, corruption is suspected as the cause of a situation that nearly led to the purchase of the very expensive drug, darunavir, in quantities inappropriate given the treatment experience of Russian PLWHA. This purchase was averted though, as civil society activists rallied to stop the tender. The unreasonable quantities were included in a governmental standard that contradicted existing

treatment practice. The Minister annulled the standard, referring to its flaws as a “statistical mistake.”

The procurement process in Russia remains complicated and not clearly understood by civil society activists, which limits their ability to fully exercise their potential “watchdog” role. Some progress has been made in this area though. For example, after the scandal around the flawed standard, civil society representatives were invited to participate in meetings to redraft the list of drugs to be included in the treatment standard.

## **Stock-outs**

Since the scale-up of treatment access began in Russia, stock-outs and subsequent treatment interruptions have been commonly reported. There have been a variety of causes of the stock-outs. As mentioned above, a failed tender in 2006 led to stock-outs (fortunately this situation has not repeated), as have inaccurate quantifications of amounts of drugs needed. On several occasions, drugs have been held up in customs, which has led to a stock-out. Russia has refused to accept some offers for technical assistance to enhance its supply chain management system and it has refused to purchase drugs with the assistance of structures like the International Procurement Agency and UNICEF, which have proven ability to obtain low prices and consistent supply even for large populations like Russia’s.

Stock-outs have led to interruptions in treatment for patients and some patients have had to change treatment regimens even though not medically necessary. Others have continued on treatment with only bi- or monotherapy and were taken off of therapy altogether. The results of these situations are the risk of viral resistance and worsened health outcomes.

## **Viracept recall**

Russia was among the countries affected by the 2007 recall of Viracept (nelfinavir). Patients throughout the country received differing messages about the recall and the way the situation was handled by the AIDS Centers reveals the need for greater coordination within the health care system. The Russian NGO, Community of PLHIV, actually distributed information about the recall three weeks before a national order on the recall was issued. Once the order was made, some patients were told to stop taking Viracept immediately and were given a different combination. Others were taken off of Viracept without having it replaced by an equivalent drug; others were told to continue taking it.

## **Quality and selection of drugs**

Obtaining a high quality product does not appear to be the first priority in making pharmaceutical purchases in Russia. The first-line regimen recommended for

treatment-naive patients in Europe is available in only one combination in Russia. Few generic ARV drugs are purchased in Russia and some of those that have been purchased are of questionable quality. The generic drug Stag (stavudine) is commonly used as a first-line drug in Russia even though it failed to pass the WHO prequalification test and is no longer recommended for first-line use. Ritonavir to be used in the national program is produced by the Russian company, Makis-Pharma, and is made in Russia using substances produced by the Indian company Hetero, which have also not been prequalified by WHO.<sup>1</sup> In addition to risks involved with using non-prequalified drugs, as information about questionable quality and anecdotal stories about side-effects spread within the HIV-positive community, distrust for generic drugs grows, making activists less likely to push strongly for the use of generics in Russia to reduce pharmaceutical prices.

Another dangerous problem with the selection of drugs in Russia is that the national narcotics policy does not allow for use of narcotics for addiction treatment. Therefore methadone and buprenorphine, which are included in the WHO Model List of Essential Medicines, cannot be used for opioid substitution therapy. This has had a disastrous effect on HIV prevention and treatment uptake and adherence among IDUs, who are those most affected by the epidemic.

### **Pricing**

Most of the drugs Russia purchases are brand name drugs. Comprehensive and comparative analysis of the prices of ARVs in Russia has yet to be done. Russia's growing economy led the World Bank to categorize Russia as an upper middle income country in 2006, and pharmaceutical companies began to use this as an argument to sell drugs to Russia at elevated prices. Prices in Russia are estimated to be ten times higher than in neighboring Ukraine, which has a comparable prevalence rate. High pharmaceutical prices are taking resources away from programs that could combat the many barriers blocking access to treatment in Russia. Throughout the country treatment uptake has been low, and even once treatment is initiated, Russia has an unusually high rate of drop-out from treatment programs (more than 10%). Considerable work and resources are still needed to develop integrated treatment facilities, provide comprehensive social and treatment literacy services, and provide adequate addiction treatment and other services to support successful ARV treatment.

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<sup>1</sup> From an analytical letter to the MoH by the NGO, the Community of PLHIV, on the recall of Viracept, alternative substitution, and the inclusion of atazanavir and darunavir in the list of drugs to be purchased. July 20,2007.

## Uganda

*by Richard Hasunira, Prima Kazoora, Aaron Muhinda, Rosette Mutambi, and Beatrice Were*



The limited provision of support and care services to PLWHA remains the weakest link in the national response to the HIV/AIDS epidemic in Uganda. For the most part, the provision of such services has been left to the non-governmental sector. The major NGOs providing such services, including TASO, Uganda Cares, and AIM, have helped people access ART, but their capacity is limited.

The latest figures from the MoH indicate that the number of people accessing ART reached 100,000 in the 2006–2007 fiscal year.<sup>1</sup> That is far less than half of the estimated 234,500 who need treatment now. As of October 2007, there were a total of 212 ART centers across the country.

At the accredited centers, ARVs are provided free of charge, but private facilities charge for consultation and treatment of OIs. PLWHA also must arrange and pay for their own transport, which can be complicated if not impossible when they live far from treatment centers. (Transport costs are particularly significant during drug stock-outs, when patients are simply told to “keep checking” or are referred to other, usually more distant centers. Referral for a routine CD4 count test can create a burden: Most up-country districts do not have CD4 count machines; as a result, many patients must travel hundreds of kilometers to obtain such tests.)

The ongoing difficulties associated with accessing ART are the primary reasons behind the high drop-out rate from treatment.

### **Drug registration process**

All pharmaceutical products intended for human use are supposed to be registered by the National Drug Authority (NDA) before they are sold or used in Uganda. The registration procedures are set out in the guidelines on the Registration of Pharmaceuticals for Human Use in Uganda (revised July 2006).

The drug registration process is working relatively well in Uganda. The country has an elaborate drug registration procedure set out in the guidelines on Registration of Pharmaceuticals for Human Use in Uganda. The only problem is that the process is fairly cumbersome and registration can take as long as six months at a minimum—and that length of time is potentially applicable only when the applicant does not



make any mistakes or leave gaps in the drug's dossier at the time of submission or is not presenting a drug from an unfamiliar manufacturer. Unfortunately, many applicants have been asked for clarifications and additional information, which consume valuable time and lead to further delays in processing their applications. There have been such delays in the registration processes of several new ARVs, developments that have led to interruptions in treatment for PLWHA in need.

The delays are often caused by incomplete information provided by applicants as well as the lengthy laboratory analyses required. NDA has been known to deny a drug registration altogether if the samples provided for analysis do not meet the required quality standards. But even for successfully registered drugs, registration has to be renewed upon payment of registration renewal fees payable annually as well as "retainance" fees payable every three years. Drugs that default on such fees are deregistered.

Uganda's first-line ART regimen, as defined by the National ART Policy, consists of zidovudine (AZT) or stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP) or efavirenz (EFV). The standard second-line regimen is zidovudine (AZT) + didanosine (ddI) + lopinavir/ritonavir (LPV/r). There is no standard third-line treatment. It should be noted that as of October 2007, the first- and second-line options were under review because of the changing nature of HIV and the emergence of new ARVs.

### **ARV stock-outs**

Drug stock-outs are a growing problem in the delivery of ART in Uganda. The entire country has in the recent past experienced shortages of certain drugs. Up-country ART centers in particular have become accustomed to intermittent drug supplies. People on ART have gone without drugs in the districts of Katakwi, Pallisa, Luwero, Soroti, Hoima, and Mityana. In Moroto, people who were on efavirenz were given cotrimoxazole instead for up to four months, even though the latter has never been prescribed to treat HIV. In Nebbi, meanwhile, drug shortages meant that some infants went without drugs for several days. At some centers, patients were switched back from second-line to first-line treatment even though first-line therapy previously had failed.

Field visits were conducted October 15–19, 2007 as part of the annual National Health Assembly and Joint Review Mission. Researchers found that stock-outs had occurred in most districts at one time or another. Between April and September 2007, for example, only two out of a sample of seven centers in eastern Uganda did not experience drug stock-outs. The rest did not have the drugs they needed for between 15 to 60 days, according to the MoH's report on the supervision of ARV supply chain management for the third quarter of 2007.

## UGANDA

### Extracts from the MoH's report on the supervision of ARV supply chain management (third quarter of 2007)

District	Name of facility	Number of patients on cotrimoxazole prophylaxis	Number of patients on first-line ART	Maximum capacity that can be handled at center	Days out of stock in last six months
Sironko	Budadiri HC IV	148	66	0-99	60 days
	Mayembe HC IV	1,650	32	100-199	30 days
Butaleja	Busolwe Hospital	516	103	100-199	0
Kapchorwa	Kapchorwa Hospital	298	51	100-199	15 days
Nakapiripirit	Tokora HC IV	91	15	0-99	45 days
Kumi	Atutur HC IV	1,434	408	300-399	0
Abim	Abim Hospital	131	43	0-99	30 days

Source: Uganda MoH

The underlying cause of drug stock-outs has a lot to do with demand outstripping supply. As noted previously, the number of people currently on ART was less than half of those estimated to be in need. The situation has been made worse by an inefficient procurement and distribution system, which on occasions has resulted in the expiry of ARVs in the national stores as well as at district levels. This has occurred even as ART centers reported stock-outs, and resulted in acknowledgement of the need to monitor third party-supplied ARVs.

The stock-out problem has reached such critical levels that the National Forum of People Living with HIV/AIDS Networks in Uganda (NAFOPHANU) and the Consortium of Advocates for Access to Treatment (CAAT) led a public demonstration and presented a petition to the MoH in August 2007, pleading for consistent and improved supply of ARVs to all the accredited 212 ART centers across the country.

<sup>1</sup> Annual Health Sector Performance Report 2006/2007, October 2007

## Zambia

*By Felix Mwanza and Paul Kasonkomona*



Zambia has a standard first-line regimen composed of nevirapine (NVP) + lamivudine (3TC) + stavudine (d4T, 30mg). Efavirenz (EFV), zidovudine (AZT), and now Truvada (tenofovir/emtricitabine [TDF/FTC]) are also used. Second-line regimens are mainly composed of Kaletra/Aluvia (lopinavir/ritonavir [LPV/r]); abacavir (ABC); Truvada (TDF/FTC); tenofovir (TDF); didanosine (ddI). There is no standard salvage therapy and most health care providers are not trained to administer it.

Zambia is somehow in a unique position especially when it comes to the purchasing of ARVs. The government does not purchase ARV drugs using locally mobilized resources. ARVs are purchased through John Snow, Inc. (JSI), which procures ARVs in bulk on behalf of the MoH, Catholic Relief Services, the Center for Infectious Disease Research in Zambia (CIDRZ), a PEPFAR program, and MSF; in short all dispensers of ARVs procure them through this process.

The most commonly purchased ARVs and/or groupings are nevirapine (NVP), Combivir (lamivudine/zidovudine [3TC/AZT]), efavirenz (EFV), Kaletra (lopinavir/ritonavir [LPV/r]), abacavir (ABC), and didanosine (ddI).

The drug registration process is mostly handled by the NGOs that dispense the drugs, which causes concern that if these NGOs pull out, then problems can arise. The foreign NGOs that are in the forefront have their way of doing things and government okays this process and is very reluctant to take ownership. Therefore, if an NGO suggests that such a drug requires to be registered there is really no objection from government.

Newer drug products that have been registered include: tenofovir (TDF); efavirenz (EFV); emtricitabine (FTC); lopinavir/ritonavir (LPV/r, as Aluvia tablets or Kaletra capsules); ritonavir (r, separately); Atripla (EFV+FTC+TDF); and new Indian generic pediatric FDCs of stavudine/ lamivudine/ nevirapine (d4T/3TC/NVP). Zambia is already procuring and using all of these drugs. The challenge is accessing them, especially in rural areas and in other districts due to other factors such as lack of qualified medical personnel to dispense the drugs. Atripla is used to replace combinations containing stavudine 40mg (Triomune 40).

## ZAMBIA

In gathering this information we conducted focus group discussions with three groups in three provinces, namely Luapula, North Western, and Copperbelt provinces respectively. Thirty activists and/or informants were interviewed; then we spoke with health care workers and other caregivers. The following are a summary of the responses:

- Most people do not know that there are newer drugs, and were hearing about these drugs for the first time.
- People receive whatever the health facility will provide to them and do not know that there are alternative drugs that are better.
- In three focus group discussions no one had knowledge concerning the drug registration process.
- People at some health facilities, who have either not tolerated one combination or another and have requested that they be switched to other combinations, have been told to stick to their current combinations as the others are not available.
- It is difficult to demand better drugs if you don't know that they exist. People think that ARVs are like drugs for other illnesses, where there is just one drug available for everyone.

It is disappointing to learn that government has been reluctant to get involved in the procurement process, since the NGOs are doing the actual procuring. Therefore, they are reluctant to push for changes in trade agreements such as TRIPS, as they say that it does not affect them because they are not the ones that are purchasing the drugs, but the NGOs, using donor and multilateral money. All the government does in the end is to say that everything that comes in from international NGOs is considered to be governmental, as they are the ones that sign and negotiate for these agreements. They don't feel that it is necessary for the government to advocate against some of these agreements because Zambian money is not used to purchase the drugs.



## Zimbabwe

*By Matilda Moyo, Carol Mubaira, and Martha Tholanah*

The majority of the 91,000<sup>1</sup> people on ARV treatment in Zimbabwe by October 2007 were receiving drugs free of charge through the government program. Although an additional 10,000 people were thought to be self-sponsoring their treatment in July 2007, it is believed this number has reduced significantly to perhaps 6,000 in October, because of factors such as inflationary price increases and the unavailability of drugs at pharmacies due to a government imposed price freeze, which was instituted in July.

The most commonly used ARVs and combinations in Zimbabwe are stavudine + lamivudine + nevirapine (d4T+3TC+NVP, marketed as Stalanev 30 and 40); lamivudine + zidovudine (3TC+AZT, marketed as Combivir); and lamivudine + stavudine (3TC+d4T, marketed as Coviro 30 and 40). Among the newer drugs that are available but not widely distributed are efavirenz, lopinavir/ritonavir, and emtricitabine.

Varichem, a largely government-owned local pharmaceutical company, manufactures Stalanev, most of which is used for the government ARV program; pharmacies receive the excess. The most popular imported drugs are from the Indian pharmaceutical companies Cipla and Ranbaxy.

While some other drugs such as indinavir are also available, they are too expensive for most people.

### **Factors affecting drug prices**

Zimbabwe, currently in its eighth year of economic recession, is battling massive hyperinflation. According to the Central Statistical Office (CSO), the year-on-year inflation rate for the month of July 2007 was at 7,634.8 percent. In an attempt to rein in galloping inflation, the government in July 2007 froze the price of most goods retroactive to their price a few weeks earlier. Businesses, including pharmacies, were forced to reduce their prices, in some instances by up to 50 percent.

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<sup>1</sup> Ministry of Health and Child Welfare (MoH&CW).

However, since manufacturing prices were not affected by the price freeze directive, the subsequent effect was an acute shortage of goods as businesses stopped restocking because they could not afford to resell goods at a loss. Most goods however, became available on the parallel<sup>2</sup> market through unauthorized dealers and at extremely high prices. The prohibitive cost, and, in some cases, unavailability, of ARVs at private pharmacies fuelled the illegal market for the life-prolonging drugs.

While some people in need of ART turned to the parallel market for their drug supplies, others were forced to resort to the government program where, although drugs are free, there is a long waiting list, or people drop treatment altogether.

## **The drug registration process**

The Medicines Control Authority of Zimbabwe (MCAZ) is the drug regulatory authority in the country. All drugs that have been authorized for sale by private and public distributors are required to undergo rigorous tests by the authority before registration takes place. The tests include verifying the drugs' registration status in their country of origin, analyzing for active ingredients, investigating potential side effects, and assessing if the drugs meet WHO standards. According to an official at MCAZ, the registration process takes a minimum of six months and costs about US\$2,250, an amount that is difficult to raise for local companies given foreign currency shortages.

Some pharmacists believe the registration process works effectively and properly. However, others consider it to be time-consuming and expensive. Reducing the high fees charged by MCAZ and speeding up the registration process would encourage pharmaceuticals to register more drugs, enabling pharmacies to stock a wider variety of drugs.

## **Drug stock-outs**

Stock-outs at both private pharmacies and government hospitals occur regularly for various reasons. For example, at government hospitals stock-outs largely occur due to fuel shortages. As a result, medicines cannot be moved from the central or provincial drug store to the various district hospitals. At private pharmacies, stock-outs occur because of excess demand for certain products such as Stalanev FDCs. Furthermore, manufacturers may withhold shipping their products prior to price increases and stock-outs may occur while awaiting government approval for new prices.

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<sup>2</sup> Illegal/ unofficial market.

## ZIMBABWE

In addition, foreign currency, which is required for importing drugs for pharmacies and raw materials for local drug manufacturers, is in short supply and this contributes towards drug stock-outs. For example, Varichem requires \$1 million monthly to procure raw materials for ARV production.<sup>3</sup>

The pharmaceutical industry is advocating for the government to eliminate duties on raw materials used to manufacture drugs.<sup>4</sup> Currently, manufacturers are charged between 50–60 percent duty on imported raw materials, which increases the production costs of drugs and pushes the retail price beyond the reach of many people. Scrapping the duty would reduce the costs and subsequently make drugs more affordable.

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<sup>3</sup> IRIN PlusNews. "ZIMBABWE: Scepticism over govt plan to treble ARV beneficiaries." January 11, 2007. <http://www.irinnews.org/Report.aspx?ReportId=64385>

<sup>4</sup> Zimbabwe Television (ZTV) News. October 2, 2007.

## SHORT SUMMARY



## Pakistan

By Prof. M. Ismail,  
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### ART access in Pakistan

There are two standard ART regimens that are provided by the National AIDS Control Program (NACP) in Pakistan. The first-line regimen, which follows WHO guidelines, consists of zidovudine (AZT) or stavudine + lamivudine + nevirapine (d4T+3TC+NVP) or efavirenz (EFV). Costs range from \$300–\$500 per person per year. The second-line regimen is didanosine (ddI) + tenofovir (TDF) + lopinavir/ritonavir (LPV/r); costs for this regimen are much higher, averaging \$3,500–\$4,500 per person per year. The Global Fund is supporting the government in purchasing ARVs.

The most recent data as of October 2007 indicate that a total of 1,200 people in Pakistan are registered at the 16 treatment and care centers across Pakistan. Of those, 480 people are on ART through the NACP and provincial AIDS control programs. Stock-outs do occur, but for the most part medicines have been consistently available.

The government provides ART free of charge. However, many patients have difficulty affording related costs such as travel (to treatment and care centers) and getting adequate nutrition. Also, the availability of second-line drugs and pediatric formulations remains limited. Diagnostics tests, such as CD-4 and viral load tests, are available free only in three big cities: Islamabad, Lahore and Karachi. It is difficult for many people to gain access to these centers on their own. Some NGOs are providing logistic support to expand access to these facilities.

### Challenges to ART access

#### Human resources capacity

The number of trained doctors and other medical staff is insufficient. In particular, many health care workers have limited knowledge and information about HIV treatment. More doctors, nurses, and other qualified medical staff are needed to provide appropriate care, particularly in rural areas.

## PAKISTAN

### Access for marginalized groups and rural populations

High-risk groups, in particular injecting drug users and MSM, face extensive legal, economic, and social stigma and discrimination in Pakistan. In general, they lack sufficient awareness of HIV risk factors and far too rarely seek out HIV testing services. Their access to treatment is also limited by the fact that members of marginalized groups tend to live in rural and less developed parts of the country. Obtaining HIV treatment and care in such regions is difficult and complicated across the spectrum because of a lack of easily accessible treatment centers.

Part of the problem is that most health care workers prefer living in urban areas for professional and economic reasons. It has proven extremely difficult to identify qualified personnel who are able and willing to work in rural areas, even when treatment centers have been established.