



# UNICEF PROCUREMENT OF HIV/AIDS-RELATED SUPPLIES

September 2007

## 1. BACKGROUND

According to the World Health Organisation (WHO), millions of children in developing countries are either infected or affected by the HIV/AIDS pandemic. Despite significant international commitment to stemming the pandemic, many children have a parent or both parents living with HIV/AIDS. Six per cent of people living with HIV are children under the age of 15 years, with around 600,000 new infections each year. Over 15 million of children globally have lost one or both parents to the pandemic. Progress however, continues to be made at both national and international levels to improve access to much needed antiretroviral therapy (ART).

Of the estimated 2.3 million (1.7–3.5 million) children under the age of 15 years living with HIV, well over ninety per cent are thought to have become infected through mother-to-child transmission. Despite numerous statements of political commitment, a well-defined set of interventions and the existence of know-how for their implementation, the vast majority of pregnant women in need of Prevention of Mother-to-Child Transmission (PMTCT) services are not receiving them. In 2005, about 220 000 of the more than two million pregnant women estimated to be living with HIV received antiretroviral prophylaxis for PMTCT, with an estimated coverage of eleven per cent (8%–16%). Over eighty-five per cent of HIV-infected pregnant women live in sub-Saharan Africa.

Of the 2.3 million children under the age of 15 years living with HIV in 2006, almost ninety per cent of them live in sub-Saharan Africa, and about 780 000 were estimated to be in need of antiretroviral therapy. It is estimated that 115 500 (103 000–128 000) children had access to treatment by the end of 2006, representing coverage of about fifteen per cent (12%–19%). Compared to estimates for 2005 of about 75 000 children on treatment, there has been a fifty per cent increase in the number of children receiving treatment in 2006. However, coverage for children still lags behind the total estimated antiretroviral treatment coverage of twenty-eight per cent (24%–34%) in low and middle-income countries. Increasing access to treatment for children in sub-Saharan Africa is critical. In 2006, the overall percentage of people on treatment who are children was six per cent, far below the percentage of people in need of treatment who are children (14%)<sup>1</sup>.

---

<sup>1</sup> From: WHO/UNICEF/UNAIDS Progress Report April 2007. Towards Universal Access. Scaling up priority HIV Interventions in the Health Sector.  
[http://www.who.int/hiv/mediacentre/universal\\_access\\_progress\\_report\\_en.pdf](http://www.who.int/hiv/mediacentre/universal_access_progress_report_en.pdf)

**Table 2.** Estimated numbers of children aged under 15 years receiving and needing antiretroviral therapy and percentage coverage in low- and middle-income countries according to region, December 2006<sup>a</sup>

Geographical region	Estimated number of children receiving antiretroviral therapy (range) <sup>b,c</sup>	Estimated number of children needing antiretroviral therapy (range) <sup>c</sup>	Antiretroviral therapy coverage (range) <sup>d</sup>
Sub-Saharan Africa	85 000 [77 000–93 000]	680 000 [510 000–890 000]	13% [10%–17%]
Latin America and the Caribbean	15 500 [13 750–17 250]	23 000 [16 000–37 000]	67% [42%–97%]
East, South and South-East Asia	13 300 [10 600–16 000]	64 000 [32 000–120 000]	21% [11%–42%]
Europe and Central Asia	1 500 [1 400–1 600]	7 500 [3 800–14 000]	20% [11%–39%]
North Africa and the Middle East	<100 [<200]	10 000 [4 400–20 000]	<1% [0%–1%]
<b>Total</b>	<b>115 500</b> [103 000–128 000]	<b>780 000</b> [600 000–1 000 000]	<b>15%</b> [12%–19%]

Note: Some numbers do not add up due to rounding.

UNICEF has made fighting HIV/AIDS one of its top five priorities and through its efforts, contributes to the Millennium Development Goals of combating HIV/AIDS and reducing child mortality. UNICEF also actively supports efforts to reach “universal access to comprehensive prevention programmes, treatment, care and support” for HIV by 2010, as agreed at the June 2006 United Nations General Assembly High-Level Meeting on HIV/AIDS. The purpose of the initiative is to provide universal access to antiretroviral therapy (ART) to those who need it, as a human right and within the context of a comprehensive response to HIV/AIDS.

Treating parents, especially mothers, benefits children in many different ways. First, it reduces the likelihood of children being infected with HIV through mother-to-child transmission. Second, improving the length and quality of life of the mother is critical to the development of the child. Achieving the ‘Universal Access’ target and the UN Millennium Development Goals would mean fewer children dying and fewer orphans.

Children living with HIV/AIDS in developing countries have limited access to care, support and treatment due primarily to the following:

- Disease progression in children is less studied and understood, and treatment and care is still largely provided in specialist care settings.
- There are inadequate testing and healthcare facilities for children, and the fear for creating stigma in routine prevention and care settings are hampering integration into existing systems.
- ARVS suitable for use in children are often not available or accessible.
- Where liquid formulations of ARVs are available, they have the added challenge of being more costly than solid dose formulations, requiring complex administration mechanisms and cold storage.
- Marketing authorisation and registration processes in countries are often slow, delaying the entry of user-friendly formulations for children.

## **2. UNICEF'S ROLE AND CONTRIBUTION IN THE PROCUREMENT OF HIV/AIDS-RELATED SUPPLIES**

UNICEF is committed to making more treatments available and accessible to children and their parents in need through its Supply Division. The role of UNICEF Supply Division, starting in 1997, initially was limited to the procurement of supplies for pilot projects testing the feasibility of PMTCT interventions in resource poor settings. These initial efforts have evolved into an arrangement that required UNICEF Procurement Services (PS)<sup>2</sup> to supply medicines for treatment of HIV-positive mothers and their partners, as well as protecting newborn babies from HIV infection. In recent years, with additional funding mechanisms such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), UNICEF has been procuring a wide range of HIV related supplies for NGOs, governments and other UN agencies. These services are available for partners through UNICEF Procurement Services.

In 2007 UNICEF obtained approval from UNITAID, a new funding mechanism established in 2006, to roll out a project to implement PMTCT programmes in line with the revised WHO guidelines for HIV testing (August 2007) and PMTCT (August 2006), and the new guidelines specific to the diagnosis, care and treatment of children born to HIV-infected mothers (August 2006). The project is expected to start before the end of 2007 initially in eight countries.

Recognising the challenges and complexity of the ARV market, the urgency and the need for flexibility, Supply Division has set up a dedicated HIV/AIDS Unit as part of the efforts to strengthen UNICEF's response to the HIV/AIDS pandemic. This unit is responsible for the procurement of anti-retrovirals, HIV rapid, ELISA and confirmatory tests, as well as diagnostics for sexually transmitted infections. Technical assistance in selection of products, procurement and in-country logistics is coordinated from this unit.

Experiences at the country level show that UNICEF Procurement Services, used by governments and NGOs to purchase ARVs and other supplies, has had several impacts:

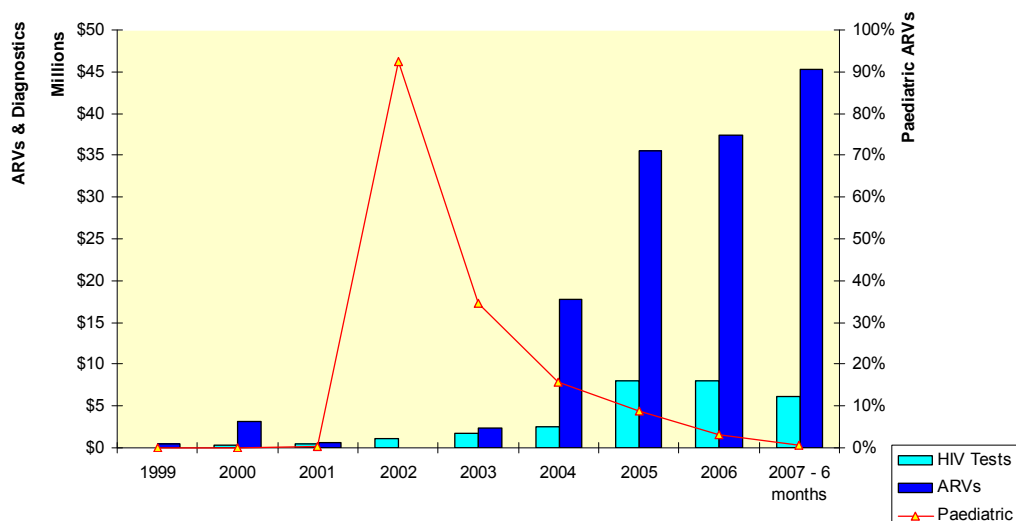
- It increases the scale and impact of government and UNICEF-supported programmes in the area of HIV/AIDS.
- More voluntary testing was observed in countries where the availability of ARVs and test kits increased.
- As a result of the strengthening of the procurement and distribution of ARVs and test kits, health services have been reinforced and the general capacity of a country to procure medicines has improved.

---

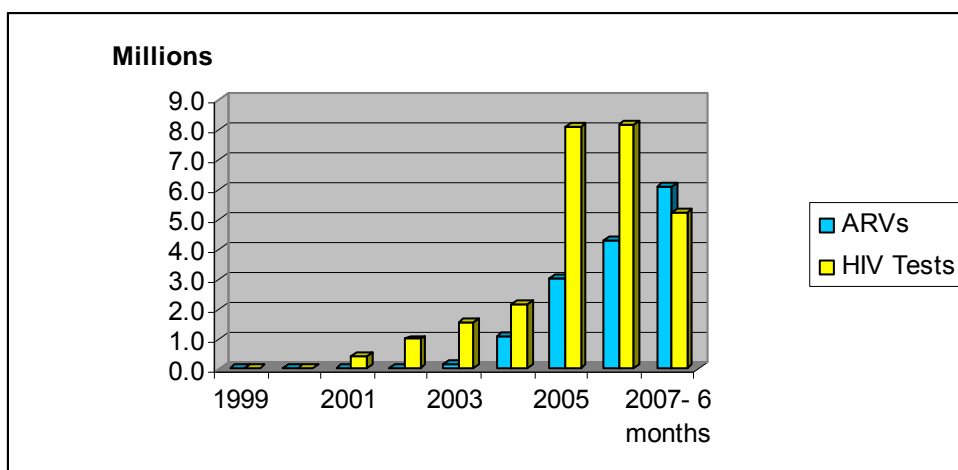
<sup>2</sup> - Through its Procurement Services, UNICEF puts its procurement expertise at the disposal of governmental and non-governmental partners in development.

### 3. PROCURING ARVS AND OTHER HIV/AIDS-RELATED SUPPLIES

In 2004, UNICEF procured over \$20 million worth of HIV/AIDS-related supplies. In 2006 this had grown to more than \$45 million. The first half of 2007 saw another increase, to over \$51 million worth of procurement. This included \$45.2 million worth of ARV supplies as well as almost \$7 million in HIV diagnostics. Unfortunately the procurement of paediatric ARVs has not grown in the same proportional manner. Year-to-date paediatric ARV procurement makes up less than one per cent of total procurement.



In 2006, Africa received ninety per cent of the ARVs and eighty-four per cent of HIV diagnostics procured by UNICEF. Almost \$10 million worth of ARVs were shipped by UNICEF to Ethiopia, \$7 million to Malawi and several million dollars worth of ARVs as well as HIV-diagnostics to partners such as Columbia University and The Elisabeth Glaser Paediatric AIDS Foundation.



\*For ARVs a unit of measure is one pack of ARVs, for HIV tests it is per one single test.

Over 94 countries have so far benefited from UNICEF's ARV procurement expertise. Most of this procurement was done through UNICEF Procurement Services (in 2006 only 4.5 per cent of ARVs were bought with UNICEF funds). An increasing number of country governments and philanthropic organisations are approaching UNICEF for ARV procurement and supply management, as programmes continue to grow with respect to the number of people put on treatment.

The continuous and uninterrupted supply of ARVs is essential to the treatment of patients. In 2005, UNICEF set up a warehouse stock of ARVs for emergency supplies that continues to be available for partners and country programmes. This buffer stock can be used if a country faces the threat of ARV shortage. It can also help in providing very small volumes of ARVs to local NGOs.

The safety, efficacy and quality of ARVs purchased by UNICEF are assessed via the WHO Pre-qualification Programme. UNICEF prioritises purchases of those ARVs that have been pre-qualified by WHO. Halfway through 2007, over 41 originator and 90 generic ARVs have been fully reviewed and pre-qualified. Where no WHO-prequalified ARV products exist, UNICEF has a policy of supplying either USFDA or EMEA certified ARVs or performing independent quality evaluations in addition to verifying national registration in the recipient country.

As part of the United Nations, UNICEF is concerned with the intellectual property aspects of buying ARVs. Supply Division reviews the patent and regulatory status of individual products, a difficult but vital task to find the best supply solutions for each country. In all cases, UNICEF will adhere to international and national law. See also: [http://www.who.int/medicines/areas/policy/wto\\_trips/en/index.html](http://www.who.int/medicines/areas/policy/wto_trips/en/index.html)

Prices of ARV medicines have fallen since their introduction in 2000 in the developing countries and have become more affordable through competitive procurement. UNICEF also fosters collaboration with partners on accelerating access to commodities through pricing initiatives. For instance, UNICEF is a partner in the UNAIDS Access Initiative and the Clinton Foundation pricing initiative.

At the same time, UNICEF is interested in other market developments. UNICEF Supply Division has over 42 purchase arrangements with pharmaceutical and diagnostic companies as well as distributors for procurement of HIV/AIDS-related supplies and procures over 40 different antiretroviral formulations from generic as well as originator pharmaceutical manufacturers. The organization is encouraging the development of a wider range of paediatric formulations, especially as fixed-dose combinations. Greater choice in formulations at reduced prices would allow UNICEF to strengthen its engagement and that of partners in treating infants and young children.

#### **4. OFFERING PROCUREMENT-RELATED SERVICES TO PARTNERS**

Procuring ARVs is a complex undertaking that requires accurate forecasting, leading to reliable and continuous supply of quality medicines up to the end user. In addition to buying and shipping ARVs and test kits, UNICEF provides other services through its procurement services framework, such as:

- **Forecasting and distribution planning:** Challenges arise due to the absence of consumption data and experience in nationwide ART programmes. By working with the government and other partners, UNICEF can provide technical support for needs assessment, guidance in translation of needs into clear

procurement plans, with accurate forecasts, distribution planning, as well as programme and policy considerations.

- **Ensuring continuous supply:** Supply Division maintains an emergency stock of ARVs that are immediately available in emergency situations to avoid interruptions in supply.
- **Partnerships:** UNICEF is a partner of a large range of organisations in the field of HIV/AIDS such as UNITAID, The Global Fund, MSF, The World Bank, SCMS, UNAIDS, Clinton Foundation, WHO, UNDP, the AIDS Medicines and Diagnostics Service (AMDS) and many others. These partnerships have been established to expand access to safe, efficacious, quality and cost-effective treatment for HIV/AIDS.
- **Capacity building:** Procurement Services strives for consistency with the Paris Declaration of Aid Effectiveness and aims at knowledge transfer to partners on planning, product expertise, procurement, logistics or other supply chain-related advice considered relevant to PS partners.

## 5. THE PROCUREMENT PROCESS

The process of using Procurement Services is outlined in detail on the UNICEF website, together with a Request for Cost Estimate form.

In brief, the process is as follows:

1. You submit a complete **Request for Cost Estimate Form** to UNICEF Procurement Services or your local UNICEF Country Office for screening.
2. A **Cost Estimate** for the supplies and services you require is prepared and sent to you with a letter of offer.
3. A signed **Memorandum of Understanding (MOU)** must be received prior to any procurement activity. If you do not have a valid agreement, we inform you accordingly.
4. Upon receipt of your advance payment and a signed MOU, procurement activities commence.
5. UNICEF Supply Division places the orders against existing Long Term Arrangements (LTAs) with suppliers where possible.
6. Status reports are available online to your local UNICEF Country Offices and can be sent to you if needed.
7. The supplier(s) and freight invoices are paid by UNICEF Supply Division. A **Statement of Accounts** is sent to you along with a customer survey form for you to complete and return.
8. If any funds remain unused, they are either re-programmed or returned as per your decision.

### **Preliminary documentation**

The Memorandum of Understanding (MOU): This outlines UNICEF Procurement Services processes and sets out the terms and conditions for individual transactions. The validity period of a standard agreement is ongoing, with a 90 days termination clause for both parties. Standard versions of MOUs in English, French and Spanish are available on the UNICEF website, [www.unicef.org/supply/index\\_purchasing.html](http://www.unicef.org/supply/index_purchasing.html).

Procurement plans: In order to ensure the uninterrupted supply of treatments and HIV/AIDS products when they are needed, UNICEF Supply Division should be informed and sent a copy of forecasts at the earliest. Ideally, this should include a

detailed description of the health needs, a list of all the products required and for how long, and a budget description for all the resources required.

### **Requesting a Cost Estimate**

A Request for Cost Estimate Form can be downloaded from the UNICEF website, [www.unicef.org/supply/index\\_purchasing.html](http://www.unicef.org/supply/index_purchasing.html). The following details, provided by the PS partner are essential:

- **Product description:** Using the international non-proprietary name (INN), or generic name, and including the dosage form and strength per product.
- **Quantities:** The total number of tablets/capsules or ml of liquid required (or if known the number of packs and the pack size).
- **Patent status:** As several of the medicines for use in HIV/AIDS care and support, including ARVs, are currently protected by patents in many countries, any information on patents for the products required should be shared with UNICEF Supply Division. UNICEF Supply Division can provide advice on which patents may be applicable to specific countries. As a first step, summarising what is known about the patent situation of each product required, and possible actions taken by governments to make use of the flexibilities in the TRIPS agreement, could facilitate processes. More information on this topic is available from Supply Division.
- **WHO/National treatment guidelines:** UNICEF procurement of ARVs is guided by recommendations from WHO. An indication of whether the country's National Treatment Guidelines for HIV Care and Support and guidelines for Prevention of Mother to Child Transmission as recommended by WHO will facilitate procurement. Further information is available from:  
<http://www.who.int/hiv/pub/guidelines/adult/en/index.html>  
<http://www.who.int/hiv/pub/guidelines/pmtct/en/index.html>  
<http://www.who.int/hiv/pub/guidelines/art/en/index.html> (children)

## **6. HANDLING FEES**

UNICEF charges a handling fee to cover the cost of providing Procurement Services, which is 4% for supplying ARVs and HIV diagnostics to Least Developed Countries (LDCs) and 4.5% for Medium Developed Countries.

The handling fee is established at the minimum amount UNICEF reasonably concludes is required to meet the costs of providing PS. This includes staff, travel, communication, equipment, administrative and other overhead costs associated with offering and executing PS (including responses to requests for Cost Estimates, implementation of agreements, and processing, monitoring and reporting on PS agreements).

A buffer is used to protect UNICEF from fluctuations in the commodity market and foreign exchange as some goods are procured in currencies other than the US Dollar. It is also used to cover other unforeseen events that might occur. When a Procurement Services transaction is closed, the unused portion of the buffer is returned to the partner or re-programmed for future transactions, as decided by the partner.

The current standard buffer level for non-warehouse goods is 10% (5% for ARVs) on the cost of the goods. The buffer does not apply to goods stored in and issued from the warehouse.

For more information on potential procurement through UNICEF Supply Division, please contact UNICEF Procurement Services, via email: [psid@unicef.org](mailto:psid@unicef.org)

## 7. GUIDANCE AND CHECKLIST

A clear understanding of the following issues will contribute to a successful procurement project:

Description of needs: Defining the specifications (for products), terms of reference (for consultants) and the scope of work (for services) is often complex. UNICEF Supply Division can assist upon request.

Forecasting: For planning purposes, manufacturers require long-term forecasts for products and quantities, preferably for six to 24 months, which take account of the following: safety stocks, the shorter shelf-life of ARVs and test kits, cold-storage and cold transportation considerations, warehousing capacity and in-country logistics.

Order quantity and ordering interval: It is important to establish the quantity required per product per period (preferably three months), and ideally plan two orders in advance.

Delivery lead-time: It is vital to establish when the products are required to arrive in-country, and integrate this in the procurement plan. Lead times can be up to six months for some products.

Quality assurance of products: UNICEF recommends and promotes the use of WHO pre-qualified products and commodities. Further information, updated regularly, is available on the following websites, and from UNICEF Supply Division.

WHO Prequalification Scheme: <http://mednet3.who.int/prequal/>

On HIV test kits: [http://www.who.int/diagnostics\\_laboratory/evaluations/hiv/en/](http://www.who.int/diagnostics_laboratory/evaluations/hiv/en/)

On ARVs: [http://mednet3.who.int/prequal/lists/hiv\\_suppliers.pdf](http://mednet3.who.int/prequal/lists/hiv_suppliers.pdf)

On CD4/Viral load: [http://www.who.int/diagnostics\\_laboratory/evaluations/cd4/en/](http://www.who.int/diagnostics_laboratory/evaluations/cd4/en/)

Packaging of ARVs and rapid test kits: The specific packaging materials (e.g. PVC/aluminium blister packs, or high density polyethylene bottles) are included in the product description of ARVs on the WHO prequalification list, and should be taken into account when planning as the type of packaging used affects the stability and shelf life of the products.

Other associated products: Items such as basic laboratory equipment and associated consumables, hepatitis test kits and test kits for sexually-transmitted infections, medicines for opportunistic infections, etc. are also available through UNICEF Procurement Services. See the list in the on-line UNICEF Supply Catalogue at <http://www.supply.unicef.dk/Catalogue/>

Budget: Please inform UNICEF of the budget source for the procurement.

Pre-shipment inspection: Please inform UNICEF if pre-shipment inspections are required for ARVs and other products imported into the country of use.

Consignee: Full consignee details, including a contact person must be provided. UNICEF only serves as the consignee for supplies in exceptional cases, such as risk of loss or mishandling.

Product pricing and status of country: Product prices vary depending on a variety of factors including the country's HIV prevalence, geographical location or funding source. In addition take care to ensure that differentiation is made between WHO pre-qualified and non-prequalified products when price comparisons are made.

Registration/ Marketing authorization: Please inform UNICEF which ARVs and medicines for opportunistic infections are registered in-country, i.e. have a Marketing Authorization, or other such document.

## 8. MORE INFORMATION

For more information on ARVs, test kits and diagnostic equipment procurement and other HIV/AIDS-related procurement, please contact UNICEF Procurement Services, via email: [psid@unicef.org](mailto:psid@unicef.org)

You can also visit the Procurement Services pages on the UNICEF website at [www.unicef.org/supply/index\\_procurement\\_services.html](http://www.unicef.org/supply/index_procurement_services.html) as well as the Supply Division HIV/AIDS pages via: [http://www.unicef.org/supply/index\\_fighting\\_hiv.html](http://www.unicef.org/supply/index_fighting_hiv.html)

### A record number of HIV-positive people receiving antiretroviral therapy in Malawi

COPENHAGEN, March 2007: A record 85,000 HIV-positive people are receiving antiretroviral therapy (ART) in Malawi, through a joint effort by the Government of Malawi, UNICEF, donors and other partners.

“In Malawi the procurement, storage and distribution of medicines is a major challenge. This is why we call on UNICEF Procurement Services, as UNICEF is experienced in procurement and distribution and has quality systems in place”, explained Washington Kaimvi, the Director of Finance and Administration from the Malawi National AIDS Commission, during a visit of a delegation from Malawi to UNICEF Supply Division in Copenhagen.

The role of UNICEF Procurement Services in supporting the Government of Malawi in its fight against AIDS has been threefold:

- procuring quality antiretroviral medicines (ARVs) and test kits at the best price (for a value of \$9.2 million in 2006);
- ensuring the in-country distribution; and
- throughout the process transferring knowledge and experience to its government counterparts.

“We went from having 3,000 people on ART in 2003 to 85,000 people at the end of 2006. This rapid scaling-up is due to UNICEF, who has been able to procure regular and emergency antiretroviral medicines. We believe we got the best prices, and delivery was always timely”, Kaimvi said.

Dr. Kelita Kamoto, who is the Head of the HIV Unit in the Malawi Minister of Health's office, underlined that “another major challenge in Malawi is the capacity – capacity of people, infrastructure and systems”. Staff from the Central Medical Store came to Supply Division in 2006 to learn about the principles of procurement, storage and distribution of medicines. UNICEF also organised a study tour of four countries in Southern Africa for Malawi staff so that they can learn about their systems and improve their own systems in Malawi.

The National AIDS Commission also plans to learn more about procurement and in-country logistics from UNICEF, as Procurement Services has been coordinating the in-country distribution to 140 sites in collaboration with a private company. This is a major contribution to the success of the ART programme in Malawi as it ensures that supplies are available at all sites in a timely manner.

### Partnerships are essential

In Malawi, UNICEF works with many partners to improve the supply chain. The Government uses pool funding, which means that donors such as DfID, NORAD, CIDA, USAIDS, the World Bank etc, as well as the Government itself contribute to the same project. The challenge now is to mobilise local resources so that Malawi does not rely on external funding. Sustainability is especially important for the HIV/AIDS programme as plans must be made for the long-term – HIV-positive people will continue to require ARVs over the years

“Since the Government of Malawi uses a lot of public funds (whether it comes from external donors or Malawi itself), we must be transparent and accountable. We must ensure that there are systems in place so that Malawi can report on the use of funds”, says Kaimvi. UNICEF and the Government of Malawi work together to harmonize their reports.

#### Future plans

Malawi does not plan to stop there. An additional 40,000 HIV-positive people will receive anti-retroviral therapy by the end of 2007, bringing the total to over 120,000. The number of sites UNICEF Procurement Services delivers medicines to will increase from 140 to 184 by October 2007. There is also a deliberate effort to increase the number of HIV-positive children on treatment.

“Ideally, Malawi should procure medicines for its people on its own. We should have our own efficient systems. We need to develop them with help from UNICEF, so that UNICEF can focus its resources and assistance on other problems. Our partnership with UNICEF will evolve. Our objective is to increase the capacity and efficiency of the Central Medical Store, so that all HIV-positive people in Malawi can receive ART” concluded Kaimvi.

While fighting HIV/AIDS is a key priority in Malawi, the country also continues addressing other health problems such as malaria, which remains the main killer in Malawi. In 2006, the Government of Malawi procured some \$5.6 million worth of mosquito nets, insecticides, antimalarials and malaria test kits through UNICEF.