UNITAID Annual Report 2011

UNITAID

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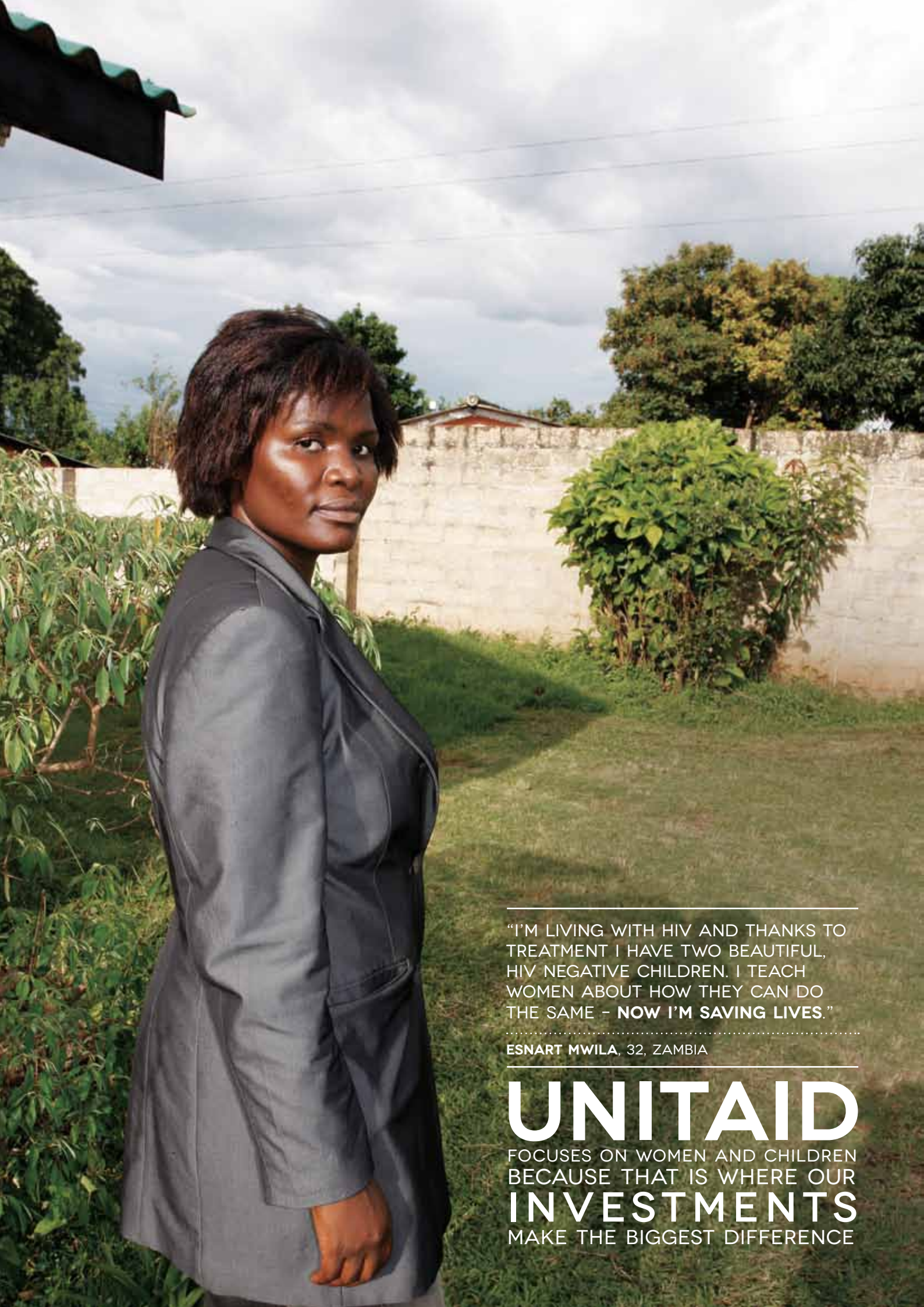
UNITAID Annual Report 2011

FIVE YEARS OF INNOVATION **FOR BETTER HEALTH**

Disclaimer: The data in this report were presented at the UNITAID 15th Executive Board Meeting in December 2011 and are based on implementer reports up to June 2011, unless otherwise indicated. "A Key Performance Indicator Report" with a full set of data for UNITAID's work in 2011 will be released later in 2012.


"I'M LIVING WITH HIV AND THANKS TO TREATMENT I HAVE TWO BEAUTIFUL, HIV NEGATIVE CHILDREN. I TEACH WOMEN ABOUT HOW THEY CAN DO THE SAME – **NOW I'M SAVING LIVES**."
ESNART MWILA, 32, ZAMBIA
UNITAID
FOCUSES ON WOMEN AND CHILDREN
BECAUSE THAT IS WHERE OUR
INVESTMENTS
MAKE THE BIGGEST DIFFERENCE

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ABOUT **UNITAID**

UNITAID uses innovative approaches to increase access to treatments and diagnostics for HIV/AIDS, malaria and tuberculosis in low-income countries. It is the first global health initiative to work through market interventions to make life-saving products better and more affordable.

The bulk of UNITAID's resources come from a small levy on airline tickets in several countries, while the rest is provided primarily by multi-year contributions from governments. This long-term and predictable stream of funding allows UNITAID to provide incentives for manufacturers to supply quality public health products at a reduced price and bring new formulations to market.

UNITAID complements the work of other global health agencies by targeting underserved markets such as paediatric HIV treatments or cutting-edge diagnostic tools. Funds are then strategically channelled to correct shortcomings in these markets through UNITAID's implementers on the ground. Implementers ensure that those in need have access to improved and affordable products. They then report to UNITAID on the public health impact of their actions and use of funds.

FIVE YEARS OF **INNOVATION**

UNITAID was established in 2006 by the governments of Brazil, Chile, France, Norway and the United Kingdom. Today it is backed by a formidable "North-South" membership, including Cyprus, Korea, Luxembourg, Spain and the Bill & Melinda Gates Foundation alongside Cameroon, Congo, Guinea, Madagascar, Mali, Mauritius and Niger. Civil society groups also govern UNITAID, giving a voice to non-governmental organizations and communities living with HIV, malaria and tuberculosis.

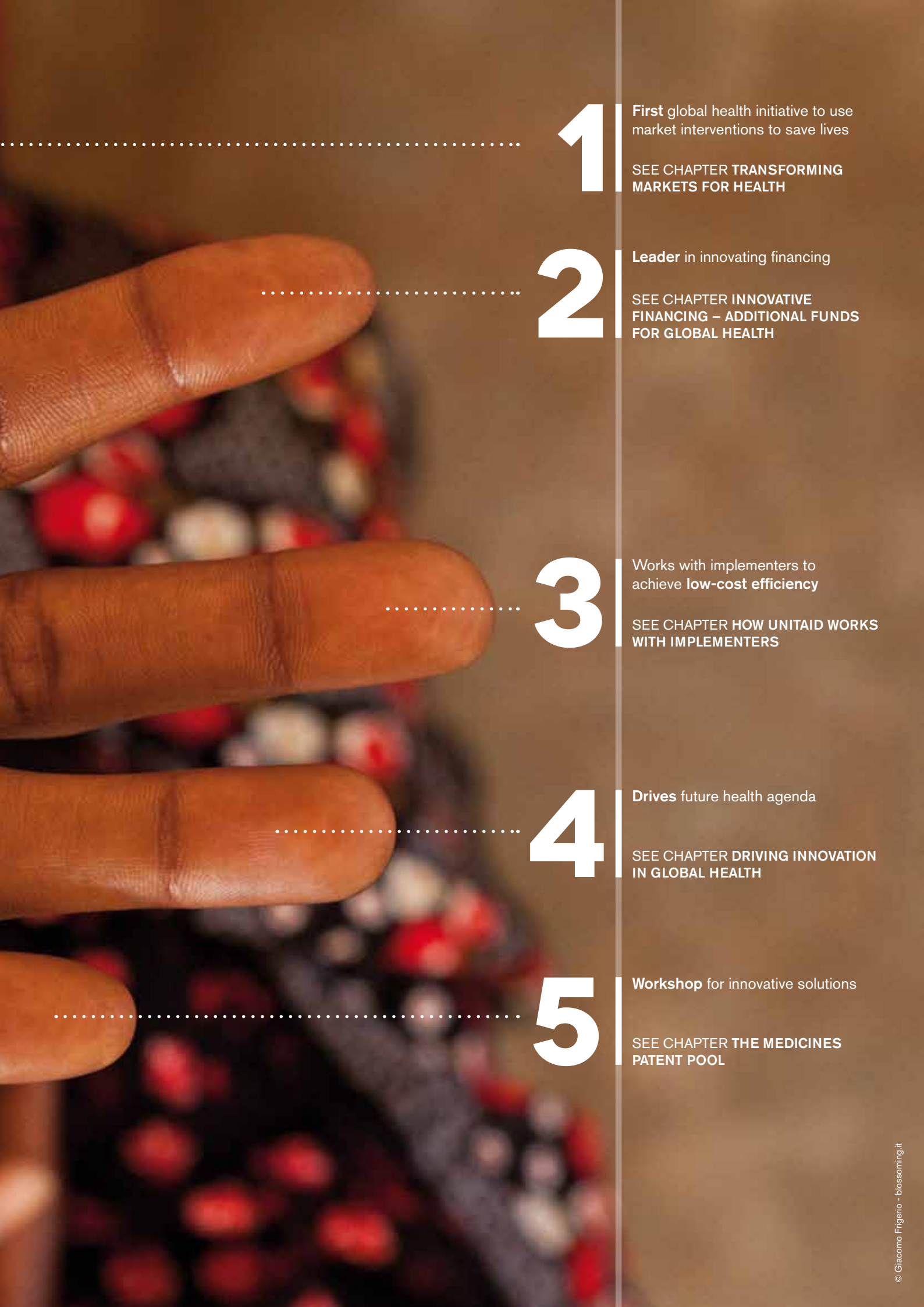
Based in Geneva and hosted by the World Health Organization, UNITAID has been entrusted by these members to use *innovative financing*– the world's first "solidarity contribution" – for *innovative impact*.

FIVE years later, UNITAID has directly contributed to the remarkable decrease in deaths from HIV/AIDS, malaria and tuberculosis.

FIVE years later, UNITAID has demonstrated that innovation can make markets work for the neediest.

For instance, this approach works for children: UNITAID investments provided incentives for manufacturers to enter the previously neglected market of adapted paediatric HIV drugs. Today, UNITAID funds **seven** out of **ten** children receiving HIV medicines.

FIVE years later, **UNITAID has raised US$ 2.1 billion and funds projects in 94 countries.**



1

First global health initiative to use market interventions to save lives

SEE CHAPTER **TRANSFORMING MARKETS FOR HEALTH**

2

Leader in innovating financing

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Works with implementers to achieve **low-cost efficiency**

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LETTER FROM THE CHAIR

On a recent visit to Liberia, a hospital official told me that blood samples of babies born to mothers living with HIV are sent to South Africa because there are no local testing facilities. "God knows when we get the results back," he said.

While innovation puts an array of products in our hands in rich countries, the global poor suffer from a lack of access to life-saving technology. This gap cannot last– it costs lives and saps productivity in low-income countries. It contributes to a geopolitical instability that has serious consequences for world peace.

UNITAID was created five years ago to correct these injustices. Through our involvement, innovative financing for development has blossomed and has given hope to those who want to see the Millennium Development Goals achieved by 2015. By creating a sustainable stream of revenue from one of the symbols of today's globalised world – air travel – we've invested in neglected markets to bring products to low-income populations for HIV, malaria and tuberculosis, specifically adapted to their needs.

UNITAID is the first laboratory for innovative financing for development and a living, working example of global solidarity. Thanks to our leadership, we are now on the path towards the first global solidarity tax. In order to implement this we need to move into other activities that benefit from globalisation today. Beyond air travel, this includes internet, mobile telecommunications and of course, financial transactions.

How would this work? A minute and painless financial transaction tax on stocks, bonds and derivatives would not adversely affect global financial markets. On the contrary, it would enable financial leaders to deliver a strong message to the world by supporting global solidarity and allocating a proportion to those most affected by the financial crisis in low-income countries.

PHILIPPE DOUSTE-BLAZY

Chairman, UNITAID Executive Board
and UN Under Secretary-General in
charge of Innovative Financing
for Development

Just imagine the resources it could bring to address global challenges. With just a 0.1% tax on stocks, 0.01% for bonds and 0.01% for derivatives, such a tax could collect 100 billion euros in the European Union alone.

When we created UNITAID we decided to focus on global health issues and concentrate on the achievement of the Millennium Development Goal 6 – to combat HIV/AIDS, malaria and tuberculosis. As a doctor, I felt particularly attached to these causes. We have proven that innovative financing works and now is the time to learn from UNITAID's example. The global community must guarantee access to other basic human rights: clean drinking water, food, primary education and basic sanitation services. I am strongly convinced that given our successes, we can now make these public goods truly universal.

LETTER FROM THE EXECUTIVE DIRECTOR

UNITAID has celebrated its fifth birthday. Five is the age of maturity for new organizations. It is the age of the first independent evaluation of our performance, which has just started. It is the year of taking stock of achievements and preparing new strategies for the future. In the first five years of its existence, UNITAID has become a key player in the Global Health architecture and a driver of the global agenda on access to medicines for the poor.

This is thanks to an original model combining innovative financing and a unique approach to global markets for health commodities, reaching dramatic results in access to high-quality and low-priced medicines in developing countries.

The achievements described in this report are the result of the dedication and passion of the staff of UNITAID (and I wish to pay tribute to my predecessor Jorge Bermudez), the guidance and wisdom of the UNITAID Board, the work of the implementers on the ground, supported by UNITAID grants, and the participation of civil society organizations worldwide.

In 2011, UNITAID finalised a landscape analysis of medicines and diagnostics markets, for HIV, tuberculosis and malaria; this analysis now guides the priorities setting for UNITAID and many other organizations. We have started to support actions to transform the market of diagnostic tests without which quality care for the three diseases is impossible. We have opened the possibility of supporting market entry for new technologies adapted to the needs of poor countries. And in 2011, we received the first contribution from corporate social responsibility funding - from the Chinese airline HNA.

DENIS BROUN

Executive Director, UNITAID

UNITAID's role is more critical than ever for global health as funding from traditional sources faces serious threats. The support we receive from new member countries and innovative financing, the emphasis we place on South-South cooperation for appropriate technology and access, the capacity we have developed to transform markets to make them work for the poor are all cornerstones of the continuing success of UNITAID in 2012.

INNOVATIVE FINANCING

ADDITIONAL FUNDS FOR GLOBAL HEALTH

UNITAID raised 60% of its funds in 2011 through a small levy on air tickets – a leading example of innovative financing in today's challenging environment. Nine countries have implemented the air ticket levy: Cameroon, Chile, Congo, France, Madagascar, Mali, Mauritius, Niger and the Republic of Korea. Norway allocates part of its tax on CO2 emissions.

Much has changed since the first countries adopted the air ticket levy in 2006. The financial crisis has seen the flat-lining of global health budgets while the international community is in danger of not meeting goals set out in 2000 to fight global poverty. Yet UNITAID's funding has remained stable – clear evidence that financing for poverty eradication through innovative means can weather an economic storm.

HOW DOES IT WORK?

The air ticket levy can range from US$ 1 for economy-class tickets to US$ 40 for business- and first-class travel. Passengers in transit are exempt and countries themselves can decide what rate and ticket class they would like to include.

The air ticket levy is implemented through the adoption of a law or decree. The levy is simply added to an existing airport tax, with all or some of the funds going to UNITAID. It respects countries' tax sovereignty - no international regulations prohibit the introduction of such a measure.

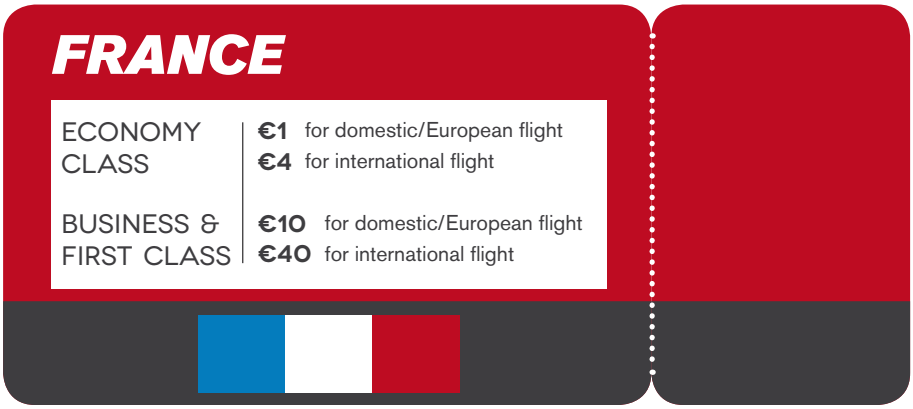
UNITAID IN ACTION

ONE DOLLAR MEANS:

- an HIV test kit for a pregnant mother;
- life-saving malaria treatment for two children;
- one day of HIV treatment for an adult patient;
- one week of TB treatment;
- one week of HIV treatment for a child.

TWO SIDES OF THE SAME TICKET

SPOTLIGHT ON FRANCE AND CAMEROON



When France applied the air ticket levy in July 2006, there were worries that France's travel and tourism sector could be adversely affected. 2011 was an opportunity to reflect on the experiences of one of the first UNITAID member countries to adopt the air ticket levy. The public health impact has been undeniable, but five years and an economic crisis later, how has France fared?

The French National Assembly released a report on the air ticket levy in July 2011. Calling it a "French success," the report found that the levy "had no negative effect on traffic or on air sector jobs while revenue did not suffer much from the financial crisis." Despite the ailing global economy and events such as the *Eyjafjallajökull* eruption in Iceland, revenue is stable at around €160 million per year.

On April 5, 2011, the air industry had its say when UNITAID held a joint conference with airline and airport representatives at the French Civil Aviation Authority (DGAC). The DGAC is in charge of air traffic control in France and is also responsible for collecting the proceeds of the levy. The Director General of the DGAC Patrick Gandil was clear in his support:

"I would like to pay tribute to UNITAID's work and thank the French air transport sector and passengers for their contribution to this public health initiative. As the largest contributor, France is proud."

France applies the levy to every departing flight, yet this has not deterred visitors. According to 2006-2010 figures from the United Nations World Tourism Organization, France was the world's top tourist destination a year after the air ticket levy was implemented in 2007. In 2010 it was still the most popular.

Therein lies another beauty of the levy: foreign tourists and French residents alike take part, bringing more resources to bear. For a country like France, this means reaping the benefits of a bustling tourist economy for global poverty eradication – responsible tourism on an enormous scale.


UNITAID says "merci" to travellers at Charles de Gaulle airport

At the end of 2010, France pledged a yearly sum of €110,000,000 from the levy to UNITAID for the period 2011-2013 – an important commitment to sustainability.

France's experience has since spurred other countries to adopt the air ticket levy. One encouraging development has been the adoption by African states, the "other side of the ticket."

"THE TAX ON AIRLINE TICKETS HAS NOT PENALISED AIR TRANSPORTATION IN RELATION TO OTHER MODES OF TRANSPORT, AS THE RATES REMAIN REASONABLE."

AIR FRANCE MAGAZINE
JANUARY 2010

CAMEROON

€1 (655 CFA FRANCS)
for domestic flight

€4 (3000 CFA FRANCS)
for international or economy class flight

Some of the world's fastest growing economies are in Africa. Unfortunately, HIV/AIDS, malaria and tuberculosis continue to wreak havoc on workers' livelihoods and their families. According to the Roll Back Malaria Partnership, malaria causes a GDP "growth penalty" of up to 1.3% per year in some African countries.

Increased economic growth brings more air traffic and a group of African countries are now helping to address these systemic health issues in their own backyards by implementing UNITAID's air ticket levy. Cameroon is one fine example of this commitment: Central Africa's largest economy has also an HIV prevalence of 5.3%.

UNITAID has committed US$ 17 million to Cameroon since 2006 but as a UNITAID member, the country has started to give back through the air ticket levy.

In August 2011, a UNITAID delegation visited Cameroon to review UNITAID-funded projects and hold UNITAID's first "in-country" Consultative Forum in the capital city Yaoundé. At the forum, the government announced its first donation to UNITAID from proceeds of the air levy. The delegation also heard from a wide-range of medical and civil society actors about UNITAID's impact (see photo). Funds have been used to create a market for paediatric HIV care, provide thousands of HIV-positive mothers with treatments to stop transmission of the virus to their newborns and deliver tuberculosis treatments for children and adults.


UNITAID delegation at the Cité Verte hospital (Yaoundé)

While air traffic in countries like Cameroon is lower than other contributing countries, the levy is a strong sign of commitment to global health causes. According to UNAIDS, two-thirds of all AIDS expenditures in Africa come from external sources. UNITAID offers a chance to contribute through a "painless" source of revenue and

enables a chain of "internal solidarity" from those who can purchase a plane ticket to those who cannot afford essential medicines.

A diverse coalition of countries from Africa has entrusted UNITAID to negotiate the best possible prices and market conditions to improve the health of their populations. UNITAID members like Madagascar, with its bustling tourist economy, or Mali, with its growing diaspora, have already joined. At a meeting on innovative financing in Bamako on June 2011, Mali announced its second contribution of US$ 305,000 from air levy proceeds. At the same meeting, the Republic of Guinea announced the establishment of a levy on all flights taking off from national soil. Currently Benin, Burkina Faso, Liberia and Kenya are also studying implementation of the air ticket levy.

Fogué Foguito
HIV ACTIVIST
CAMEROON

"By providing a modest contribution Cameroon – like other recipient countries – can show that there is more joy in giving than in receiving."

INNOVATIVE FINANCING FOR THE FUTURE – THE FINANCIAL TRANSACTION TAX

UNITAID is proof that globalisation can give back through "painless" levies on transactions. In the wake of a crippling financial crisis, many have looked to a Financial Transaction Tax (FTT) as the next step in innovative financing.

The Chairman of UNITAID's Board Philippe Douste-Blazy took the lead in the global FTT debate in 2011, advocating for such a measure while pushing for some of the proceeds to be allocated to poverty eradication. The year was marked by growing support for a FTT – from the French parliament in June to a group of G20 countries including France, Germany, Brazil, Argentina and South Africa. As momentum grew in the run up to the G20 Summit in Cannes, UNITAID commissioned 99 Partners, a financial consultancy firm, to assess the feasibility of such a tax in Europe.

This report was presented in September at UNESCO, in a remarkable conference bringing together NGO campaigners with members of the financial community, including the head of France's security regulator. The guide recommends implementing a FTT similar to the UK Stamp Duty and applying it to bonds and derivatives transactions. At low rates, the report estimates such a tax can generate around US$ 30 billion annually in the European Union. After analyzing other successful experiences with FTTs, the report found that the introduction of such a tax on a national basis should have no significant negative impact on national financial markets.[1]

[1] The report can be downloaded on http://www.unitaid.eu/

BRAZIL'S LONG-STANDING SUPPORT OF UNITAID

ANTONIO PATRIOTA

Minister of External Relations
of the Federative Republic of Brazil

ALEXANDRE PADILHA

Minister of Health
of the Federative Republic of Brazil

As a founding member of UNITAID, Brazil joins all its partners in celebrating this fifth anniversary, which represents an important step forward in bringing together governments, private entities, non-governmental organizations and other actors in support of global health causes.

Our Government is committed to enhancing prevention measures as well as providing access to diagnosis and treatment, including medicines, as exemplified by the Programme Farmacia Popular consisting of a network for sale and distribution of a set of essential medicines at affordable prices. Brazil is also committed to promote access to medications all over the world as a means of reinforcing health systems, especially in the developing world where reducing the costs of treatment is essential to saving lives. Better and affordable drugs are a permanent objective to be pursued if we truly want to build universal health coverage, tackle inequities and fight poverty. No democracy is complete without ensuring health to all people.

We are proud to be at the forefront of initiatives like UNITAID, whose impressive achievements are translated into millions of people currently having access to treatment of HIV, TB and malaria.

Health is a human right and a core element of development. It is a responsibility of all and UNITAID's five years of achievements show that governments and societies can act together.

Antonio Patriota
Minister of External Relations
of the Federative Republic of Brazil

Alexandre Padilha
Minister of Health
of the Federative Republic of Brazil

VALUE FOR MONEY
SPOTLIGHT ON BRAZIL AND UNITED KINGDOM

A key part of UNITAID's business model rests on long-term commitments from its members. Along with the air ticket levy, these "multi-year" commitments enable UNITAID to guarantee high volume purchases, reduce prices and invest in the development of adapted medicines.

As governments today are rethinking their global health commitments, UNITAID's multilateral funding structure allows donors from both North and South to pool their resources, offering better value for money while meeting official development aid requirements.[2]

A founding country of UNITAID in 2006, Brazil's success story in fighting its national HIV/AIDS epidemic is matched by its remarkable journey in becoming a donor state. Through negotiating price reductions with international pharmaceutical companies on key anti-retroviral medicines, Brazil ensured free access to treatment for its citizens living with HIV. This successful HIV/AIDS response – which emerged from civil society initiatives – is widely regarded around the world.

Brazil took an additional step towards universal access on May 2011, when President Dilma Rousseff ratified a law stipulating that Brazil would donate US$ 2 per international flight to UNITAID. This commitment should reach US$ 12 million a year.

[2] UNITAID contributions, including proceeds from the air ticket levy, are reportable as ODA according to the OECD Development Assistance Committee

UNITED KINGDOM

Another founding member of UNITAID, the United Kingdom is a leader in innovative finance and a committed supporter of multilateral organizations. At the beginning of 2011, the United Kingdom carried out a review of its main beneficiaries, assessing against a set of criteria including cost control, delivery of outcomes, focus on poor countries and accountability.

UNITAID overall performance was assessed as "Good Value for Money." Among its strengths:

- Significant price reductions of key medicines
- Good focus on fragile states
- Highly focused on cost-effectiveness
- Decision-making structures include the views of the partners and beneficiaries

Following this review, the United Kingdom announced a **multi-year pledge** of £53 million a year for the period 2011-2013, totalling £159 million.

"TOGETHER WE ARE SUPPORTING GROUND BREAKING INITIATIVES DESIGNED TO HELP COUNTRIES GET BETTER ACCESS TO THE RIGHT DRUGS AT THE RIGHT PRICES AND AT THE RIGHT TIME. AND IT IS WORKING. NOT ONLY IS UNITAID MAKING A DIFFERENCE TO PEOPLE'S LIVES, OTHER ORGANISATIONS ARE FOLLOWING OUR LEAD AND WORKING CLOSELY WITH US, RECOGNISING THE IMPORTANCE OF USING AND SHAPING MARKETS."

STEPHEN O'BRIEN
UK MINISTER AT THE DEPARTMENT FOR INTERNATIONAL DEVELOPMENT IN THE UK

STEPHEN O'BRIEN

UK Minister at the Department for International Development in the UK

THANK YOU TO OUR CONTRIBUTING MEMBERS

AFRICA

Members	2011 contributions (US$ 000)	2006-2011 contributions (US$ 000)
Cameroon	1,018	1,018
Congo	1,090	1,090
Guinea		49
Madagascar	12	27
Mali	526	928
Mauritius	1,937	7,032
Niger		281

AMERICAS

Members	2011 contributions (US$ 000)	2006-2011 contributions (US$ 000)
Bill & Melinda Gates Foundation	10,000	50,000
Brazil		37,202
Chile	2,282	20,400

NORTH-SOUTH SOLIDARITY

ASIA

Members	2011 contributions (US$ 000)	2006-2011 contributions (US$ 000)
Republic of Korea	7,000	28,000

EUROPE

Members	2011 contributions (US$ 000)	2006-2011 contributions (US$ 000)
Cyprus	488	1,578
France	144,251	996,899
Luxembourg	611	1,961
Norway	18,761	109,550
Spain	(2,813)	81,603
United Kingdom of Great Britain and Northern Ireland	85,072	262,088

TRANSFORMING MARKETS FOR HEALTH

UNITAID works through market interventions to improve access to treatment for HIV/AIDS, tuberculosis, and malaria in low-income countries.

In a global health ecosystem where numerous actors work to fight these diseases, UNITAID plays a crucial role by identifying market shortcomings. High prices, unadapted products or poor delivery times are all possible shortcomings that result in the loss of life for the most vulnerable, especially children.

UNITAID then uses its predictable funding commitments to incentivise manufacturers to invest, innovate and supply quality treatments and diagnostics at affordable prices and in acceptable formulations. These interventions impact not only those countries receiving UNITAID support, but also other countries and global health actors that benefit from price reductions, improved product quality and innovation.

After five years of a market-based approach, many of UNITAID's targeted markets are healthier today. More adapted products exist for children and the entry of new suppliers – generic producers – has driven prices down through increased competition and economies of scale. But markets are dynamic in nature. UNITAID will continue to track the evolution of market shortcomings and provide innovative solutions to address them.

UNITAID'S MARKET IMPACT FRAMEWORK

UNITAID funds market interventions through time-limited projects, which are implemented by partners. Only projects that demonstrate a clear market-based approach and innovative solutions receive funding. All projects are underpinned by five distinct steps, a "Market Impact Framework:"

CASE FOR INTERVENTION | **PATHWAY FROM MARKET TO PUBLIC HEALTH IMPACT**

1 PUBLIC HEALTH PROBLEM

The starting point for any UNITAID intervention is a public health problem caused by insufficient access to treatments or diagnostics

2 MARKET SHORTCOMING

UNITAID describes shortcomings that lead to low access and indentifies the reasons why they exist

3 INNOVATIVE MARKET INTERVENTION

Through partners, UNITAID develops innovative market interventions

4 SUSTAINABLE MARKET IMPACT

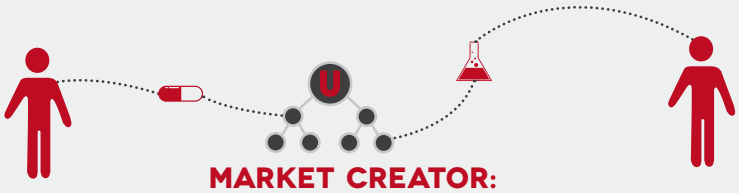
Interventions aim to yield both short-term market impact (lower prices, better quality, improved formulations) and long-term sustainable impact, where manufacturers invest, innovate and compete

5 PUBLIC HEALTH & VALUE FOR MONEY

The end result is an increased number of healthier people with access to quality products. Interventions provide value for money because market impact extends to all countries, even those not receiving UNITAID support

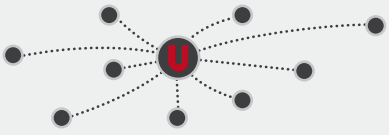
HOW UNITAID WORKS IN MARKETS

UNITAID market interventions take three distinct forms:



MARKET CREATOR:

PROVIDE INCENTIVES FOR MANUFACTURERS TO PRODUCE DRUGS WITH SUBSTANTIAL PUBLIC HEALTH BENEFITS TO THOSE IN NEED BUT UNATTRACTIVE AS THESE ARE PRODUCTS WITH LOW DEMAND THAT YIELD LITTLE PROFIT



MARKET CATALYST:

IDENTIFY AND FACILITATE ADOPTION AND UPTAKE OF NEW AND/OR SUPERIOR PUBLIC HEALTH PRODUCTS

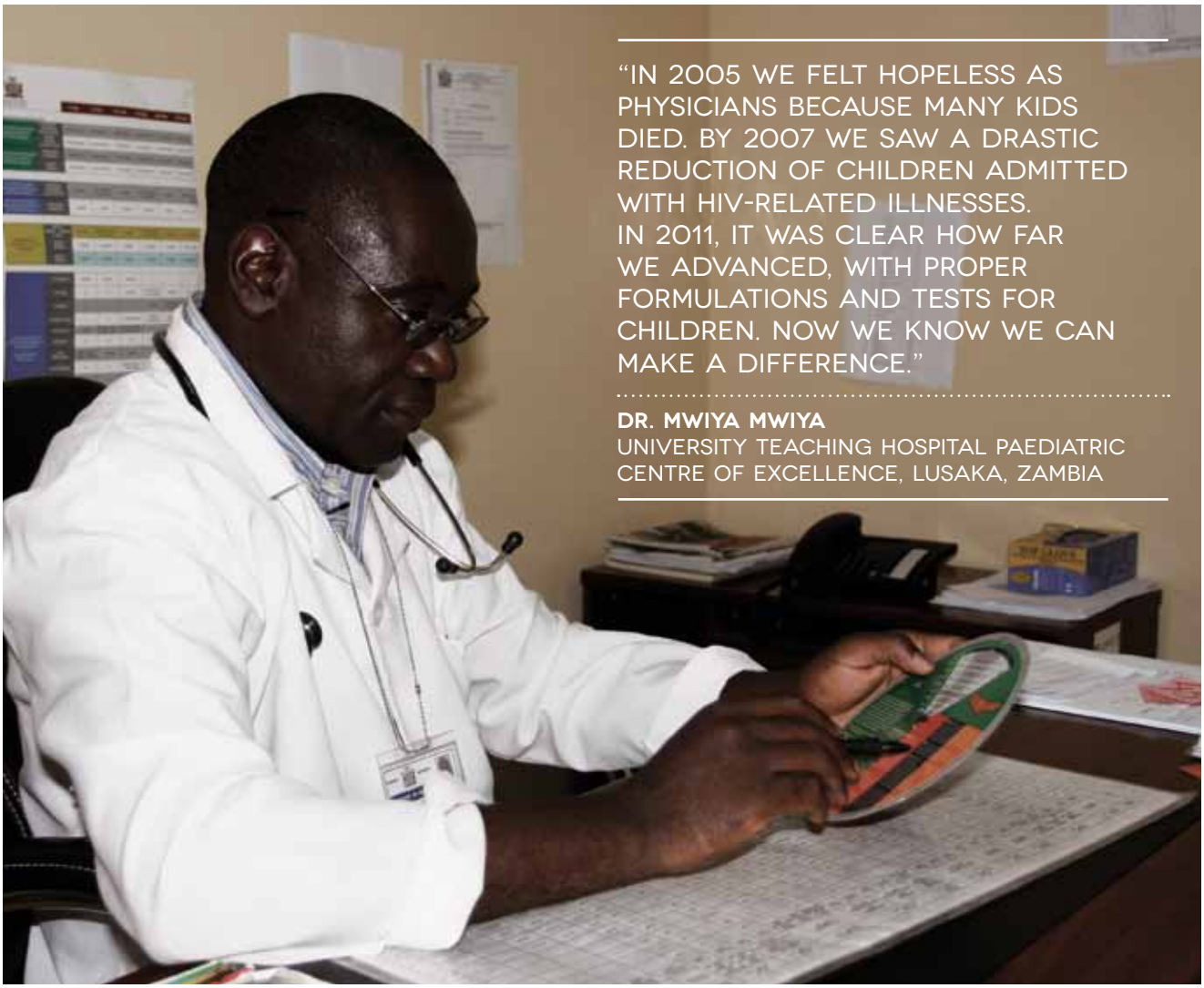
MARKET FIXER:

ADDRESS SEVERE MARKET INEFFICIENCIES THAT CONTRIBUTE TO LOW ACCESS TO QUALITY-ASSURED PUBLIC HEALTH PRODUCTS

How do these approaches work in practice? The next section features five of UNITAID's main projects in 2011 and how they create, catalyze or fix markets for public health impact.

CREATING MARKETS

PAEDIATRIC HIV
BETTER MEDICINES FOR CHILDREN



"IN 2005 WE FELT HOPELESS AS PHYSICIANS BECAUSE MANY KIDS DIED. BY 2007 WE SAW A DRASTIC REDUCTION OF CHILDREN ADMITTED WITH HIV-RELATED ILLNESSES. IN 2011, IT WAS CLEAR HOW FAR WE ADVANCED, WITH PROPER FORMULATIONS AND TESTS FOR CHILDREN. NOW WE KNOW WE CAN MAKE A DIFFERENCE."

DR. MWIYA MWIYA
UNIVERSITY TEACHING HOSPITAL PAEDIATRIC CENTRE OF EXCELLENCE, LUSAKA, ZAMBIA

INTRO

An HIV-positive orphan in Kenya faced with a gruelling daily regimen of syrups. A grandmother in Zambia faced with a journey from clinic to home carrying a conspicuous plastic bag of medicines for her HIV-positive grandchild.

These were just some of the faces of market shortcomings before 2006, when the absence of suitable and affordable HIV treatments for children in low-income countries meant many HIV-positive infants did not live to see their first birthdays. Shortly after its creation in 2006, UNITAID partnered with the Clinton Health Access Initiative (CHAI) and made this challenge one of its first priorities.

UNITAID's investment has since created a healthy market for child-friendly HIV medicines, including game-changing "fixed-dose combinations." Through UNITAID investments, these single pill formulations of multiple drugs have replaced expensive syrups that were a burden to both health providers and children. Five years on, UNITAID provides lifesaving antiretroviral treatments to over 350,000 children and is the world's largest funder of paediatric HIV drugs. UNITAID and CHAI's partnership for children is considered a leading success story in access to paediatric medicines.[3]

Today, the same orphan living with HIV in Kenya takes a simple pill twice a day. As for the grandmother in Zambia – she now slips a few inconspicuous pill packs in her handbag, avoiding the stigma still associated with the disease.

MARKET SHORTCOMING

In 2005, increasing donor funding for the HIV/AIDS response encouraged generic competition and reduced prices for adult HIV antiretroviral treatments (ARVs), which suppress the HIV virus.

Yet paediatric ARVs were a neglected market. In wealthier countries, children today are rarely born with HIV thanks to testing and treatment for HIV-positive mothers. The lack of paediatric HIV in wealthy countries meant there was little incentive for companies to invest in child-friendly antiretrovirals, despite the 2.3 million children living with HIV in sub-Saharan Africa. Low demand meant lack of competition and high prices for antiretroviral treatment.

Of the few paediatric antiretrovirals available in sub-Saharan Africa, most were syrups, with up to 18 foul-tasting doses a day. Medicines were expensive and hard to store. Meanwhile, an underdeveloped market for early infant diagnosis of HIV meant specialized tests for HIV were prohibitively expensive – in 2006 less than 10% of infants born to HIV-positive mothers were tested for the virus.

MARKET INTERVENTION

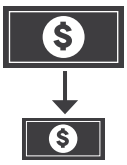
As the project started in 2006, UNITAID invested heavily in paediatric HIV medicines and diagnostic tests in Africa, Asia and the Caribbean. CHAI and UNITAID used "pooled procurement" across 40 countries to give suppliers an incentive to manufacture. They also worked to aggregate demand forecasting for ARVs.

Drug suppliers have volume minimums to manufacture known as "batch sizes." Grouping many volume orders together across multiple countries – called pooled procurement – allows orders to meet these batch sizes. UNITAID's long-term funding commitments gave suppliers the confidence to manufacture and the incentive to invest in new child-adapted formulations.

To make up for the barriers to early infant diagnosis, UNITAID and CHAI convinced suppliers to lower prices through coordinated procurement. They also encouraged the development of new "bundled" products which package equipment, laboratory consumables and sample collection materials into one product. These approaches enabled governments to efficiently roll out advanced HIV infant testing laboratory services in their country (for more information on early infant diagnosis, see chapter *Driving Innovation in Global Health*).

Finally, many children living with HIV suffer from malnutrition, which reduces their ability to absorb medicines they take. To address this, another part of UNITAID's integrated package of HIV care involved the large-scale purchase of Ready-to-Use Therapeutic Food, a fortified nut paste high in proteins and vitamins.

[3] "The Global Partnership for Development: Time to Deliver," MDG Gap Task Force Report 2011



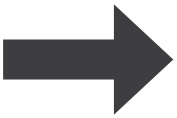
MARKET IMPACT

Today signs of a healthy market abound: lower antiretroviral prices, more generics, adapted formulations, more competition and an increase in awareness among caregivers about new products. Thanks to high volume drug purchases, price reductions have been significant – over 80% across all paedia tric formulations since 2006. The great majority of these products are provided by multiple generic manufacturers, leading to market competition and reduced prices.

There are currently nine new child-adapted fixed-dose combinations available. A leading paediatric fixed dose combination, AZT + 3TC + NVP (zidovudine/lamivudine/nevirapine) costs US$ 130 per patient today – instead of US$ 252 as in 2006.

Fixed-dose combinations decrease the number of products required to treat a patient by combining them in one pill. Through June 2011, 19 countries in the project procured fixed-dose combinations. Approximately 97% of the children benefitting from the project are on fixed-dose combinations, compared with only 48% in 2008. This means easier adherence to treatments and easier storage for clinics. CHAI has worked extensively with country governments to train health workers on the use of fixed-dose combinations and uptake has been impressive *(see infographic on next page)*.

UNITAID's commitment to testing has paid off as well, with considerable price reductions on early infant tests. Almost 8 million early infant diagnosis tests have been distributed. CHAI has provided training and mentorship to countries to expand testing capacity for early infant diagnosis and ensure that laboratory best practices will be sustained in the long-term.



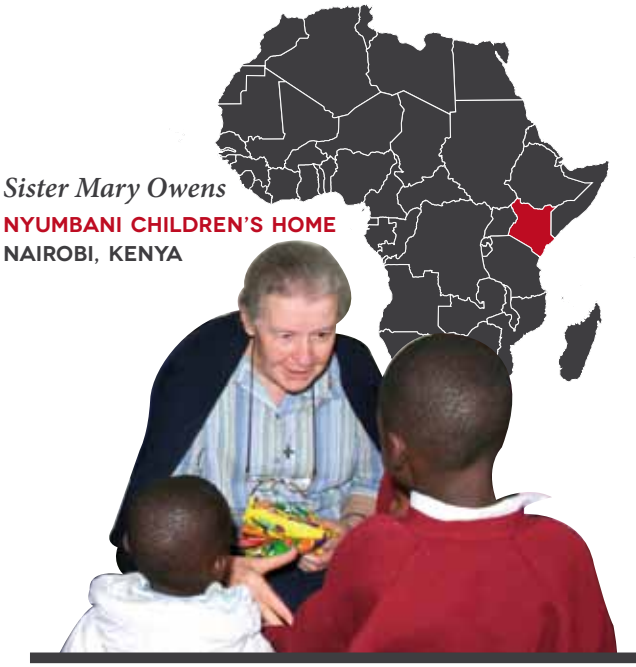
THE FUTURE

At the UNITAID Executive Board meeting in December 2011, the Board committed US$ 62 million to continue supporting the HIV Paediatric project into 2012.

UNITAID's commitment means more children can be treated with less money and better products. Fewer children are being born HIV-positive in low-income countries, thanks to successful efforts to halt mother to child transmission of HIV. This declining drop in demand means that maintaining a healthy paediatric market will be difficult. UNITAID and CHAI are working to secure other funding sources for this project through the Paediatric ARV Procurement Working Group (created in 2011) and a dedicated transition team supported by UNITAID.

FIXED-DOSE COMBINATIONS

CHILD-FRIENDLY MEDICINES



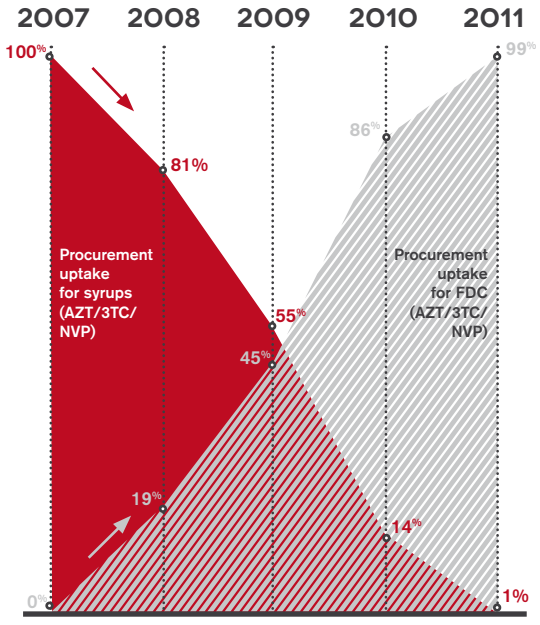
Sister Mary Owens
NYUMBANI CHILDREN'S HOME
NAIROBI, KENYA

Sister Mary Owens runs Nyumbani Children's Home, an orphanage for children living with HIV in Nairobi. Today Nyumbani provides life-saving treatment to over 2,000 children. Thanks to UNITAID funding, children receive child-friendly fixed-dose combinations (FDCs).

What does this mean for Sister Mary Owen's work?

*"I recently had a conversation with one of our teenagers who had difficulties taking her HIV medicines in school. I asked her 'How is it now?' She responded: 'Oh, that's no problem, now. You see I only take one tablet in the morning and one at night.' **This is the gift of the fixed-dose combination.**"*

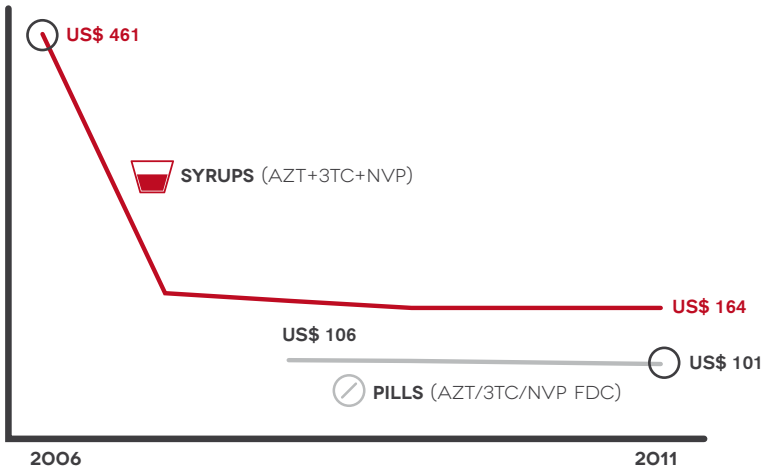
PROCUREMENT UPTAKE FOR FDCS



HOW PROCUREMENT UPTAKE CHANGED

16 SYRUPS A DAY → **3** PILLS A DAY → **1** FDC PILL A DAY

PRICE REDUCTION FOR SYRUPS AND FDC (AZT/3TC/NVP)



AZT + 3TC + NVP
SYRUP
PACK PER MONTH
9

AZT / 3TC / NVP FDC
PILLS
PACK PER MONTH
3

KEY BENEFITS OF FDCS

- Easier to administer to infants
- Better taste
- Less bulky to store
- Less stigma
- Reduces risk of measurement errors

TREATING CHILDREN LIVING WITH HIV
A DOCTOR'S PERSPECTIVE

As any parent knows, it can be difficult to give medicine to infants and young children. Even for the most mundane illnesses, parents worry about having the most easy-to-take meds for their kids. But for HIV-positive children and their caretakers in Zambia, it wasn't just difficult to dose – until recently it often meant the difference between life and death.

"There were few options for HIV-positive children before 2006," says Dr. Mutinta Nalubamba, a paediatric specialist who worked at the Zambian Ministry of Health. "It wasn't a pretty picture – we were cutting adult pills in half. It was quite distressing for us clinicians."

Only a few years ago it was costly and complicated to treat HIV-positive children in Zambia. The few paediatric formulations available were expensive and foul-tasting syrups that required refrigeration – in a country where many homes still lack a refrigerator.

Dr. Mwiya Mwiya, today the Clinical Director at the University Teaching Hospital Paediatric Centre of Excellence in Lusaka, remembers that his staff would use clay pots or sand pits so patients could store the drugs at home. "We felt hopeless as physicians because there was nothing one could do at the time," he says. "We saw a lot of children dying when they shouldn't have been dying."

In 2006 UNITAID and CHAI began operations in Zambia to create a market for paediatric HIV care. By working with the Ministry of Health, CHAI's in-country team helped to train paediatricians, health workers and clinicians throughout the country on the special care needed to treat HIV-positive children. National guidelines on treatment were drawn up with CHAI's assistance.

Crispin Moyo is the National Coordinator for antiretroviral treatment at the Ministry of Health. "When UNITAID and CHAI came on board, we managed to expand our formulas to include paediatric formulations, basically similar to what adults had," he says. "We didn't know what the demand was for these products in Zambia. With the help of these partners we were able to bring in a lot of stock to deal with any eventuality."

Child-friendly fixed-dose combinations (FDCs) were introduced in the country in 2008, replacing burdensome syrups. But uptake was slow and the market remained fragmented with 20 different paediatric drugs available. Only two of these were fixed-dose combinations. In 2010 CHAI worked with the Ministry of Health to gain buy-in for these formulations, advocating for new guidelines and developing training materials.

One innovation used by CHAI was the "dosing wheel" (see photo of Dr. Mwiya Mwiya). This easy-to-use device helped clinicians figure out how much medicine to give based on a child's weight.

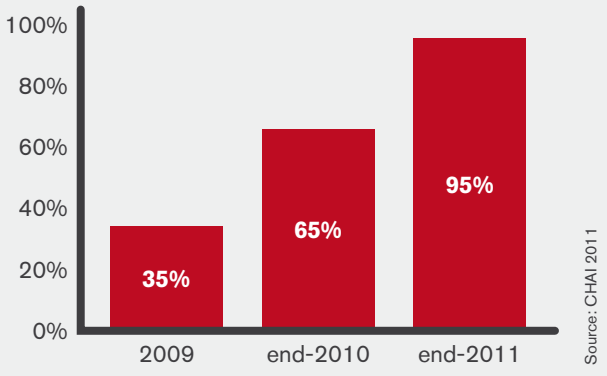
"For paediatric care we needed to make the parents comfortable and create interest for fixed-dose combinations," says Dr. Moyo. "Many people in HIV clinics had no experience with children so we had to sensitize clinicians. It was thought that HIV medication had horrible toxic side effects for children – working with a few children we were able to demonstrate that this wasn't the case."

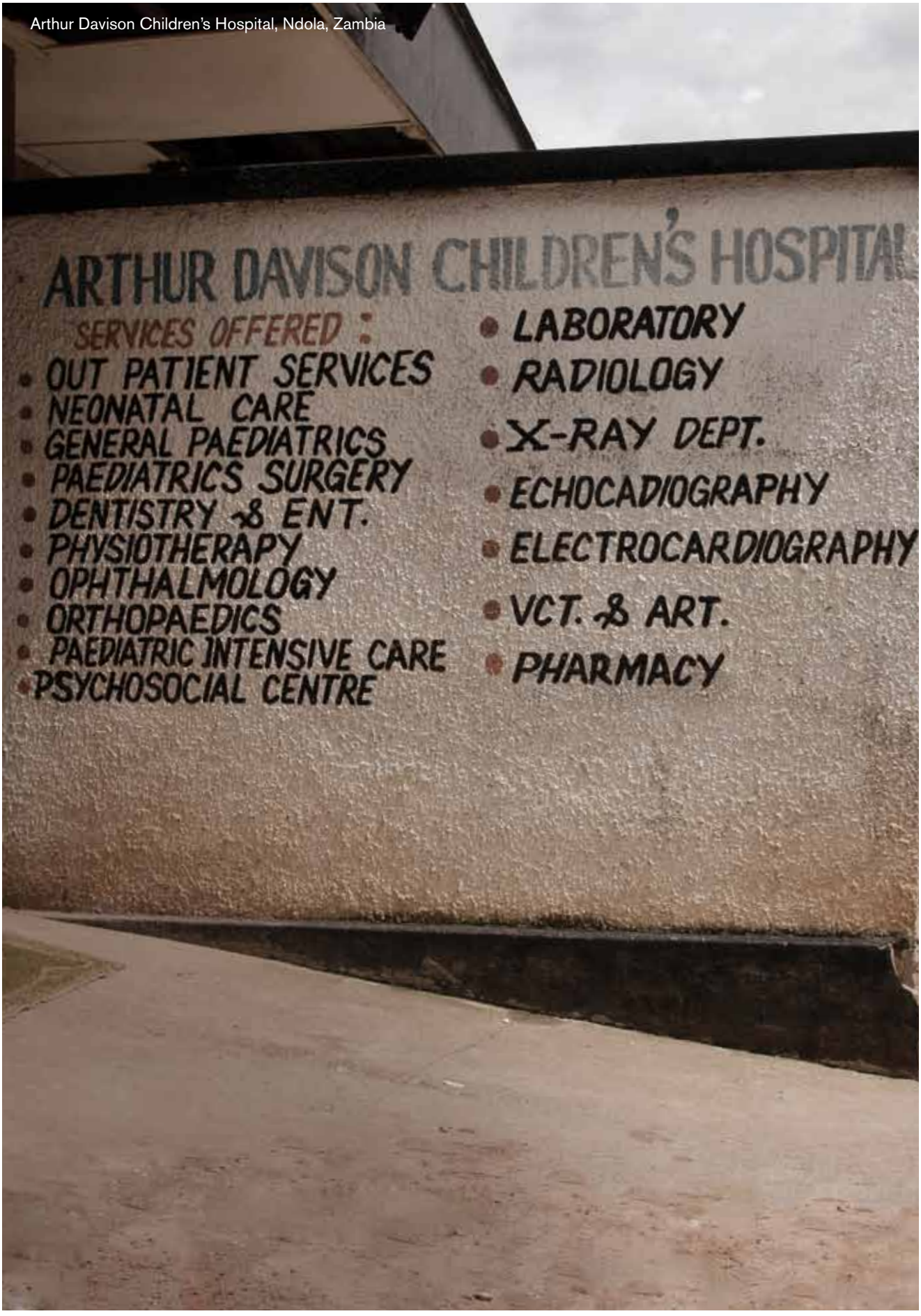
By 2011, eight drugs were used in Zambia and five were fixed-dose combinations. Uptake has been exceptional. At the end of 2006 only 7,000 kids in Zambia were on treatment. Today over 27,000 are on treatment thanks to UNITAID funding.

Dr. Mwiya Mwiya told the story of one of these children: "I had one child born with HIV. She was about five and she almost died. We started treatment, but around 2007 it was clear that her family couldn't store the drugs. We put her on fixed-dose combinations when they were made available - we soon saw the opportunistic infections she was suffering from disappear.

Today she is healthy. Initially the parents were so discouraged that they didn't want another child. After their child was saved, they came to me and said they wanted another baby. We discussed prevention of mother to child transmission, they followed my advice and fortunately the mother delivered an HIV-negative baby boy."

% PAEDIATRIC PATIENTS ON FDCS IN ZAMBIA



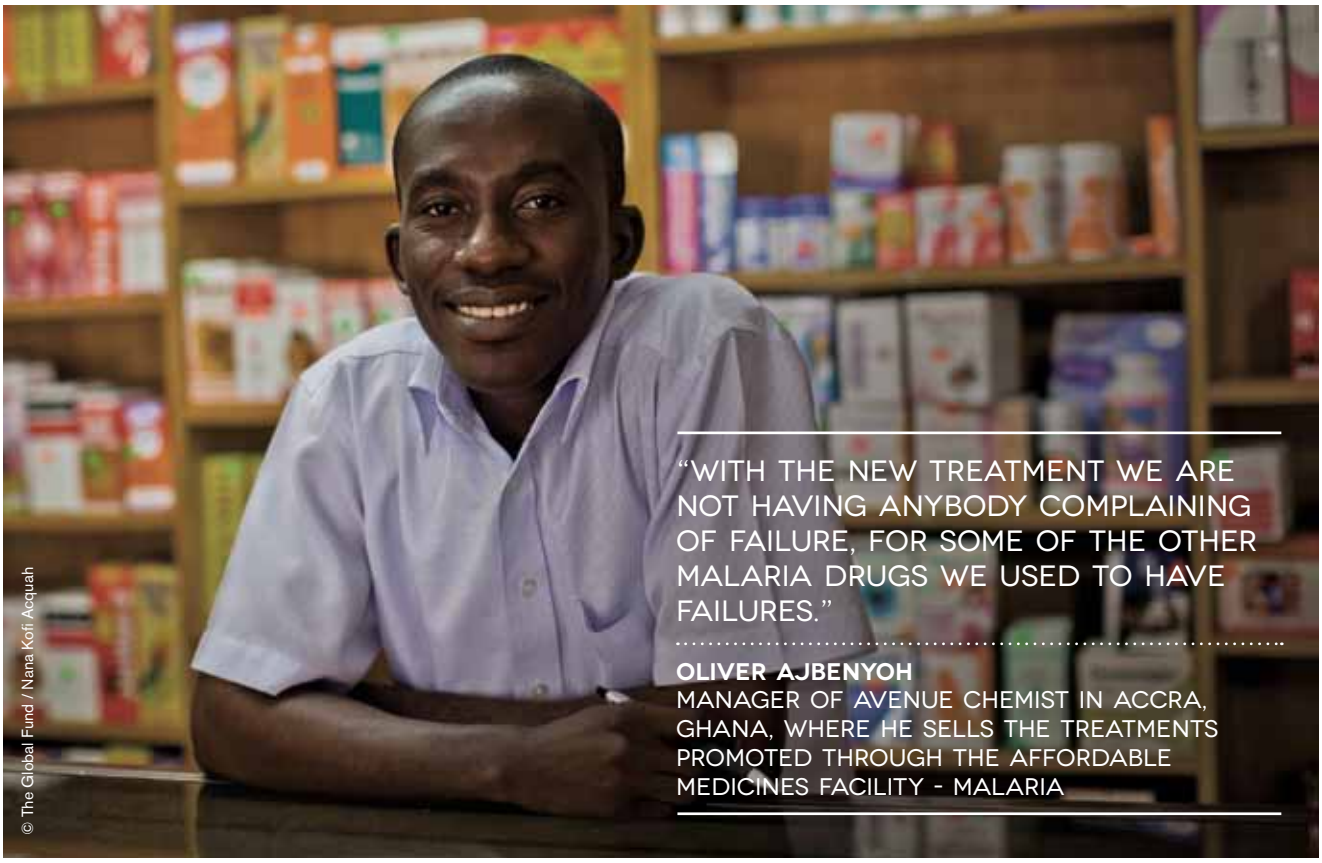


Arthur Davison Children's Hospital, Ndola, Zambia

CREATING MARKETS

AFFORDABLE MEDICINES FACILITY - MALARIA

A CONSUMER MARKET FOR THE BEST ANTI-MALARIAL DRUG



© The Global Fund / Nana Kofi Acquah

"WITH THE NEW TREATMENT WE ARE NOT HAVING ANYBODY COMPLAINING OF FAILURE, FOR SOME OF THE OTHER MALARIA DRUGS WE USED TO HAVE FAILURES."

OLIVER AJBENYOH
MANAGER OF AVENUE CHEMIST IN ACCRA, GHANA, WHERE HE SELLS THE TREATMENTS PROMOTED THROUGH THE AFFORDABLE MEDICINES FACILITY - MALARIA

INTRO

The Affordable Medicines Facility – malaria (AMFm) aims to put *artemisinin-based combination therapies* (ACTs) – the most effective malaria treatments available today – on the shelves and into the hands of consumers who need them the most. As the majority of people in malaria-endemic countries buy medicines themselves when malarial fever strikes, the AMFm was set up to make ACTs affordable while pushing out the ineffective medicines sold today in shops and pharmacies.

"It's a win-win for wholesalers, retailers and consumers," says Charles Allotey, director of a local health NGO in Ghana. "For retailers and wholesalers, it is good business as the market has been created. For consumers, the price has been set by the AMFm. They now know how to access the best price for ACTs and it is easy for them to question what they buy."

The AMFm pilot project was launched in July 2010 in seven countries and the first price and availability surveys were released in 2011: In a year, prices for ACTs were brought down by up to 20 times in four of the pilot countries - Ghana, Kenya, Madagascar and Nigeria. Quality ACTs can now be bought in many private stores and pharmacies in some of these countries for as little as US$ 0.33.

UNITAID is the largest funder of the AMFm, providing US$ 130 million for co-payments to manufacturers, along with the United Kingdom (US$ 66 million) and the Bill and Melinda Gates Foundation (US$ 20 million). The Global Fund to Fight AIDS, Tuberculosis and Malaria is the host and manager of the AMFm. The pilot is being implemented in seven countries until end-2012: Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania and Uganda.

MARKET SHORTCOMING

In malaria-endemic countries, over 60% of patients access anti-malarial treatments through "private sector" channels – clinics, pharmacies and market stalls. With over 216 million cases in 2010, malaria is rampant enough that many prefer to "self-treat" and purchase medicines themselves After all, malaria is curable by over-the-counter medicines – but left untreated it can kill in a matter of days.

WHO recommends ACTs as the first-line treatment for malaria, especially for the most deadly form of malaria, caused by the parasite *P. Falciparum*. ACTs use a combination of drugs that includes artemisinin, which is extracted from a 2,000 year old Chinese herbal remedy called *Artemisia annua*. Until the AMFm, ACTs were provided almost entirely by the public sector: hospitals and government-run clinics. Yet long waits and stock-outs deter many in affected countries from accessing ACTs through these channels.

In malaria-endemic countries, the overwhelming majority of consumer purchases at "private sector" outlets are older anti-malarials such as chloroquine, which can be bought for under US$ .50 in stores. Once widely used to treat malaria, today chloroquine is being rendered ineffective due to growing resistance. Oral artemisinin "monotherapies" are also cheaper in the private sector in endemic countries. Since artemisinin needs to be taken in combination with other medicines to keep the malaria parasite from becoming resistant, monotherapies pose a considerable risk.

MARKET INTERVENTION

The AMFm aims to create a market where consumers can buy ACTs across the public, private and not-for-profit sectors at a price lower than monotherapies and competitive with drugs such as chloroquine. In essence, the AMFm seeks to shift the business model for ACTs from "low-volume, high-margin" to "high-volume, low-margin." How does it work?

The AMFm first negotiates a discounted price for ACTs with manufacturers, ensuring that the price is the same for importers from the public sector (e.g. Ministry of Health) and private sector (e.g. a national wholesaler). By 2011, evidence was clear that price negotiations were beginning to work, with price reductions of 80% for all buyers. This was the first achievement of the AMFm.

The AMFm then pays a proportion of this reduced price directly to manufacturers, in the form of a subsidy, or "co-payment." Importers of ACTs then only pay the remainder of the sales price. These reduced prices are passed on to private wholesalers and then to retailers such as pharmacies and stores. At each of these levels there is a profit for the seller but the final retail price is affordable. In essence, discounts are passed down the line from importer to retailer. UNITAID's financing for the AMFm goes to the co-payment fund, paid directly to manufacturers.

An essential part of the pilot involves large-scale public education and awareness. All AMFm medicines feature a recognizable logo and have clear labelling indicating the recommended retail price. Pilot countries have launched marketing campaigns to let consumers know about the availability of affordable ACTs. In Kenya, highly successful radio campaigns have reached millions of potential consumers. In Ghana, posters and television ads have relayed simple and powerful messages. In Madagascar, a musical video *ACTm Je t'aime* spread the message through Malagasy rhythms.

FACES OF THE AMFm
GHANA

What do consumers in Ghana know about the new anti-malaria drug "with the green leaf?" An informal survey carried out by local NGO Health Access Network in Accra on behalf of UNITAID offers a Ghanaian perspective on the ACTs provided through the AMFm.

"Malaria is so endemic in Ghana, malaria medicines are a real lucrative business," says Charles Allotey, director of Health Access Network. "The difference now is that price has been set, retailers can't go above the ceiling." A few of the respondents have their say:

ELIOT
"I don't like to go to hospitals with long queues, especially when I have malaria. Now I just walk into the pharmacy and get my drug with the green leaf. The price is fantastic and the initiative should be promoted in all areas of Ghana."

AMA DUFIE OSEI BONSO, PHARMACIST
"We stock ACTs, the ones with the green leaf. People prefer it because it's subsidised and affordable. Parents like the paediatric medicines, because the taste is sweetened. When the customer comes by, they usually buy for their family so we stock it in large quantities."

CHRISTIANA AMOAMAH APAU
"I use ACTs, the one with the green leaf. I've used it for my kid and for my husband. I know the recommended price and it's affordable."

SAMUEL OFORI TETTEH
"Emphasis on the ACTs with the green leaf was made on national television – this prompted my inquiry. It must be advertised more. I've lived in the northern parts of Ghana and have been to rural communities without access to health care. This programme could bless more people in rural areas – I think the government should take this to the outskirts of our country."

Co-paid ACTs were delivered to Ghana in the summer of 2010. Since then, communications campaigns have been launched and pharmacists and chemical centres have been trained by the government.

In Ghana informal price checks carried out in April 2011 show that subsidised ACTs are selling in shops in parts of the capital, Accra, at prices ranging from 60 US cents to US$ 1.20, down from US$ 9 per adult treatment before the AMFm. In early June 2011, the Ghana National Malaria Control Program presented findings from a survey of 808 facilities: 56 percent of respondents had AMFm co-paid ACTs in stock.

AMFm Marketing Poster - Ghana

MARKET IMPACT

An independent evaluation of the AMFm pilot project is currently under way that will help decide on the future of the AMFm. Results vary between countries and evaluating consumer uptake is difficult, but early evidence shows some promising results. By June 2011 the AMFm had delivered 46 million ACTs to "first-line" buyers in participating countries. Consumers are paying between US$ 0.33 and US$ 1.32 per ACT treatment – down from US$ 8 to US$ 10 a year earlier. Between 2010 and 2011, the market size for ACTs has doubled in size.

A price survey by Health Action International (HAI) conducted in June 2011 showed evidence of increased availability and reduced prices of AMFm ACTs compared to originator-brand ACTs in Ghana, Kenya, Nigeria and Tanzania. According to HAI, AMFm medicines were found in the private sectors (clinics, pharmacies) of all four countries, but not in every outlet visited. The survey also found considerable price variations within countries, particularly in Nigeria, Ghana and Tanzania.

As malaria is the leading killer of children in endemic countries, the AMFm must ensure that paediatric ACTs are made available for parents purchasing for their children. The HAI survey found that the absolute availability of paediatric formulations is less than that of adult pack sizes. The AMFm aims to remedy this by giving priority to paediatric pack sizes in 2012. In August 2011, the AMFm introduced a system of levers to shape demand for paediatric formulations. According to the Global Fund, between August 2011 and February 2012, paediatric pack sizes and formulations represented 66% of all ACT treatments approved.

In December 2011 UNITAID committed an additional US$ 50 million to the AMFm to allow for the completion of the independent evaluation.

SECURING RAW MATERIALS

The launch of the AMFm has caused a considerable increase in global demand in artemisinin, the active ingredient in artemisinin-based combination therapies. Between 2009 and 2012, demand for approved ACTs increased by around 170% as a result of the AMFm and increased donor funding for ACTs.

To secure the supply of artemisinin, UNITAID's **"Assured Artemisinin Supply Service"** project has become one of the key components in the effort to increase the global supply of artemisinin.

Launched in 2009, this project aims to encourage farmers to produce artemisinin and incentivize extractors to sell the product to manufacturers of ACTs. Since the processing, growing, harvesting and extracting artemisinin takes about 18 months, farmers need incentives to grow the plant in place of staple food products. Through agreements between artemisinin extractors, prequalified ACT manufacturers and i+solutions (a supply-chain management NGO), UNITAID provides loans to artemisinin extractors so artemisinin supply can meet demand. Pre-financing from UNITAID allows extractors to purchase additional stocks of *Artemisia annua* and increase production of refined artemisinin.

By end-2011, 36 metric tonnes of artemisinin has been secured through contracts between growers and extractors, which is nearly 15% of global demand. Nearly 5 metric tonnes have been delivered to ACT manufacturers. UNITAID is also hoping to see a major breakthrough in the production and marketing of semi-synthetic artemisinin which is expected to enter the market in 2013.

ACT FORECASTING

To deal with growing uncertainty about future trends in the market for ACTs, UNITAID finances and helps coordinate quarterly forecasts to inform policy makers and market participants. These "ACT forecasting services" are carried out by the Boston Consulting Group (BCG) and its partners – the Clinton Health Access Initiative (CHAI) and Fundacion Zaragoza Logistics Center (MIT-Zaragoza). All studies are overseen by a Steering Committee composed of representatives from organizations such as UNITAID, RBM, WHO, and the Global Fund.

THE BULK OF ARTEMISININ PRODUCTION WAS HISTORICALLY IN CHINA AND VIETNAM, WHERE THE PLANT HAS BEEN USED AS A HERBAL FEVER REMEDY FOR THOUSANDS OF YEARS. BIONEXX (PICTURED) IS THE SOLE ARTEMISININ PRODUCER IN MADAGASCAR, WITH SEED IMPORTED FROM VIETNAM. PRODUCTION HERE IS SUPPORTED BY UNITAID THROUGH THE A2S2 PROJECT. OVER 5,000 SMALL FARMERS ARE INVOLVED IN PRODUCTION.

CATALYSING MARKETS

ADULT SECOND-LINE HIV

REDUCING PRICES FOR CONTINUITY OF TREATMENT

Dr. William Musoke, Mildmay Health Centre, Kampala

INTRO

Five years ago, Dr. William Musoke could do very little when his patients failed their HIV treatment at the Mildmay health centre in Kampala, Uganda. While "first-line" treatment was offered for free, the "second-line" drugs needed when patients became resistant or developed side effects were too expensive. "The only choice was for the patient to pay themselves," Dr. Musoke recalls.

Since 2007, Dr. Musoke's clinic (pictured above) has been able to offer free second-line treatment, thanks to UNITAID's support. Through funding the Clinton Health Access Initiative's (CHAI) work to increase access to these drugs, UNITAID has achieved equal successes throughout low-income countries. UNITAID and CHAI have encouraged more producers to enter the market and achieved price reductions of up to 60% for key second-line antiretrovirals. Access has been provided for over 100,000 patients per year needing to transfer to second-line medicines.

"For those of us involved in HIV care for over ten years, we've seen how many of our patients need immediate second-line treatment," says Dr. Musoke. "Since UNITAID and CHAI's intervention, the drugs have become available and nobody has missed treatments. It gives us the confidence to emphasize to our patients that they need to switch to second-line treatment as a last option to live."

MARKET SHORTCOMING

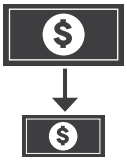
Every year an estimated 2-3% of people on life-sustaining antiretroviral (ARV) treatment need to make a switch to more potent drug combinations called "second-line" drugs. An underdeveloped market for these drugs contributed to low access before 2006.

As described in the previous chapter, competition between generic manufacturers helped slash prices of "first-line" ARVs in developing countries, with approximately three million on treatment by 2006, up from around 200,000 in 2001. But at the same time, the number of people treated with second-line ARVs was far lower with only 40,000 people receiving in 2006. This meant that few people who became resistant to their first-line medicines were transitioned onto life-saving second-line medicines. The end result was often death.

Why the low access? In 2006, second-line prices were too expensive for patients in poor countries and appropriate formulations adapted for low-resource settings were not available. There was only one dominant supplier. Second-line ARVs tend to be more expensive to produce than first-line medicines as many contain higher doses of active pharmaceutical ingredients. Moreover, low demand from country programs and excessive transaction costs prevented manufacturers from achieving economies of scale. Complicated treatment guidelines and numerous possible regimens further fractured an already small market into several smaller pieces.

MARKET INTERVENTION

With UNITAID investments, CHAI used a series of interventions to increase the number of suppliers and bring second-line prices down. This included pooled procurement to consolidate demand (see chapter Paediatric HIV for description) and price negotiations. Technical assistance was given to producers on methods to improve production efficiency and develop adapted formulations. UNITAID funding offered a reliable and timely payment stream to suppliers. At the same time, CHAI offered technical assistance to countries to transition people to second-line treatment when needed.



MARKET IMPACT

Five years later, UNITAID's interventions have spurred dramatic price reductions. By 2011, 12 new quality-assured generic manufacturers of second-line HIV medicines have entered the market, fostering healthy generic competition. Today, the leading second-line regimen (TDF+3TC & LPV/r) costs about US$ 527 per patient per year as opposed to US$ 1500 per year in 2006 *(see infographic on page 39 about price reductions achieved for the antiretroviral drugs in this regimen)*.

As of 2011, the number of people treated with second-line HIV medicines has increased more than six-fold. The expected savings, through UNITAID's market impact, will be between US$ 300 and US$ 500 million in the next three years.

Another key development has been the introduction of better adapted formulations and a lower pill burden. Prior to 2006, all second-line antiretrovirals in low-income countries required refrigeration. In 2010, atazanavir and heat stable ritonavir singles were launched in 11 countries. These heat-stable formulations allow for simpler delivery and storage of drugs, helping patients adhere to their drugs and giving caregivers confidence to switch patients from first- to second-line treatment. By 2010 there were two manufacturers producing six heat-stable fixed-dose combinations for second-line treatment.

In November 2011, WHO Prequalification and the Food and Drug Administration approved the first heat-stable atazanavir/ritonavir fixed-dose combination. This should reduce the cost of the leading second-line regimen to less than US$ 400 per patient per year.

The second-line project has been highly successful in terms of overall public health impact and a sustainable, positive impact on the market. As more patients need to make the life-saving switch to second-line, the healthier market created by UNITAID and CHAI now provides positive benefits to purchasers outside of UNITAID-funded countries. Lower prices and improved quality further increase access and coverage beyond UNITAID's focus countries: CHAI's Procurement Consortium allows over 70 member countries to access lower prices and better quality products. This means more people treated with less money.

"NEW PRICE REDUCTIONS, WHICH HAVE BEEN AGREED TO BY A WIDE RANGE OF SUPPLIERS, WILL PROVIDE MILLIONS OF PEOPLE WITH INCREASED ACCESS TO BETTER, CHEAPER AND MORE CONVENIENT FIRST AND SECOND-LINE DRUG REGIMENS. WE HAVE HELPED ALMOST FOUR MILLION PEOPLE GAIN ACCESS TO LIFE-SAVING MEDICINE, AND I'M PROUD THAT WE CAN NOW REACH MILLIONS MORE."

PRESIDENT BILL CLINTON

SECOND-LINE TREATMENT IN UGANDA
A DOCTOR'S PERSPECTIVE

In 2006, the situation for second-line HIV treatment was desperate in Uganda. Not only did exorbitant prices deter clinicians from switching patients to second-line drugs when needed, but the poor formulations then available in the country required refrigerated storage. Even the endemic stigma faced by HIV patients could be deadly.

"Before 2006 we were using soft-gel capsules with a huge pill burden and need for refrigeration," says Rogers Sekabira, Pharmaceutical Coordinator at Baylor Uganda in Kampala. "It was a major challenge for patients, especially those who had to take their medicines to work. This meant making their HIV status public."

For second-line patients at clinics in Uganda, pill burden could reach 10 capsules a day. Drug stock-outs were common. One HIV treatment centre in Kampala, Mildmay Uganda, was forced to charge patients for second-line treatments. When the clinic began offering free first-line treatment in 2004, some of the new patients had already been on and off treatment since 1998, causing drug resistance. Options were limited for these people.

Things changed in Uganda when UNITAID/CHAI began the second-line project in 2007. By the end of the year, Mildmay was able to offer its clients free second-line treatment. According to the Mildmay Clinical Manager Dr. William Musoke, his staff soon saw the full effects of the project. "The clinicians were no longer worried about continuity of care," he says. "When the new second-line drugs came in later down the line, they were heat-stable at room temperature so we could prescribe a 3-4 months course for a patient. Now patients can come in two or three times a year to get their drugs."

In 2010, UNITAID/CHAI launched atazanavir and heat-stable ritonavir ARVs in Uganda. "Now we can just tell a client to take two pills a day – one atazanavir and one ritonavir with no refrigeration," says Mr. Sekabira at Baylor Uganda. "Counselling has been made simpler and clinicians can feel comfortable in making the switch from first- to second-line."

CHAI works directly with the Ugandan Ministry of Health, so its programmes have national reach. "Back to 2006, many of clinicians did not have enough information about second-line drugs," said Mr. Sekabira. "With CHAI, many of our clinicians have been trained and have sufficient information about the drugs."

Mildmay Uganda has close to 300 second-line patients today. Dr. Musoke offers one their stories:

"A patient was referred to us from another clinic - when we looked at his history, we saw that he had started and stopped many different treatments, causing failure. We put him on standard second-line in 2008. We emphasized continuity at the time - we told him that this time you won't have problems getting your medicines thanks to their availability.

Two years later, he was symptom-free. He's still taking the medicines and is doing very well. His initial problem was not adhering to treatment. Now he knows there is a steady supply of drugs. He's alive, he can tend to his family, our job was made easier – everyone is happy."

"FOR THOSE OF US INVOLVED IN HIV CARE FOR OVER TEN YEARS, WE'VE SEEN HOW MANY OF OUR PATIENTS HAVE FAILED AND NEED IMMEDIATE TREATMENT. SINCE CHAI AND UNTAID'S INTERVENTION, THE DRUGS HAVE BEEN AVAILABLE AND NOBODY HAS MISSED TREATMENTS. IT GIVES US THE CONFIDENCE TO EMPHASIZE TO OUR PATIENTS THAT THEY NEED TO TAKE SWITCH TO SECOND-LINE TREATMENT AS A LAST OPTION TO LIVE."

DR. WILLIAM MUSOKE
MILDMAY HEALTH CENTRE IN KAMPALA

SECOND-LINE HIV MEDICINES

LOWER PRICES, MORE COMPETITION, BETTER PRODUCTS

Rogers Sekariba
PHARMACEUTICAL COORDINATOR AT BAYLOR UGANDA

"Now we can tell a client to take two pills a day – one atazanavir and one ritonavir with no refrigeration. Counselling has been made simpler and clinicians can feel comfortable in making the switch from first- to second-line."

CATALYSING MARKETS

FIXING MARKETS

MULTI-DRUG RESISTANT TUBERCULOSIS

INNOVATIVE SOLUTIONS FOR AN ANCIENT DISEASE

INTRO

Ko Min Min was a successful shop owner in Mandalay, Myanmar, but when he was diagnosed with multi-drug resistant tuberculosis (MDR-TB), he had to sell his business. MDR-TB incapacitated him. Luckily, a local health worker came to his house twice a day to deliver drugs, provided by UNITAID funding (pictured above). The side effects of treatment were severe. But after two years of intensive treatment, he was declared cured in July 2011.Today he's looking forward to getting back to business – and marrying. "Tell my story to the world, to show how your life can change," he says. "One day you own a store then the next day you are broken. But now thanks to free medicines, my life will change again."

Ko Min Min's form of multi-drug resistant tuberculosis is difficult and expensive to treat. It requires patients to submit to an arduous daily regimen of pills and injections. But in reality, most of the estimated 500,000 annual cases of MDR-TB are not even diagnosed or not treated. Manufacturers are therefore reluctant to invest in better products.

UNITAID uses a portfolio of projects to tackle MDR-TB. In addition to supplying the drugs that saved Ko Min Min's life through the **MDR-TB Scale Up Initiative**, UNITAID runs two other MDR-TB projects: A **Strategic Rotating Stockpile** of medicines to stabilise the supply of MDR-TB drugs and the **EXPANDx TB** initiative to accurately detect and monitor MDR-TB.

MARKET SHORTCOMING

When people do not take their full treatment course, the tuberculosis bacilli becomes resistant. Patients with this form of TB require an intensive treatment course that usually lasts from 18 to 24 months.

Production for many of these medicines is on a "made-to-order" basis. This results in small production batch sizes, contributing to increased cost and long lead times. The small market size limits competition. Hence, a second-line treatment regimen can cost more than US$ 2,400 while a first-line treatment regimen costs less than US$ 40. The second-line market is low-volume, high-price – a volatile combination.

STRATEGIC ROTATING STOCKPILE

Because of the challenges involved in supplying MDR-TB treatments, countries face the risk of stock-outs. The Strategic Rotating Stockpile (SRS) is UNITAID's response, consisting of medicines sufficient for 5,800 MDR-TB treatments. Implemented by the STOP TB Partnership through its Global Drug Facility, it is the first global effort of its kind. The SRS permits emergency orders to be serviced with expediency and reduces lead times. It also facilitates the consolidation of market demand by permitting manufacturers to produce medicines more efficiently.

By 2011, the SRS has reduced lead times for urgent orders from to around 30 days, from 101 days in 2007. Up to June 2011, 47 countries received orders from the Strategic Rotating Stockpile, according to Global Drug Facility. SRS usage is at 68% per month (urgent and off cycle orders). No stock-outs were reported in countries covered by the SRS up to June 2011 – in the case of Nepal, the SRS was used to successfully prevent a stock-out situation.

In addition to the SRS, UNITAID has used the MDR-TB Scale-Up Initiative to deliver MDR-TB treatments to countries – over 7,000 treatments have been delivered as of 2011 to 14 high-burden countries. As part of UNITAID's investment in MDR-TB treatment, the number of suppliers has gone up – from five in 2007 to 13 in 2011.

EXPANDx TB

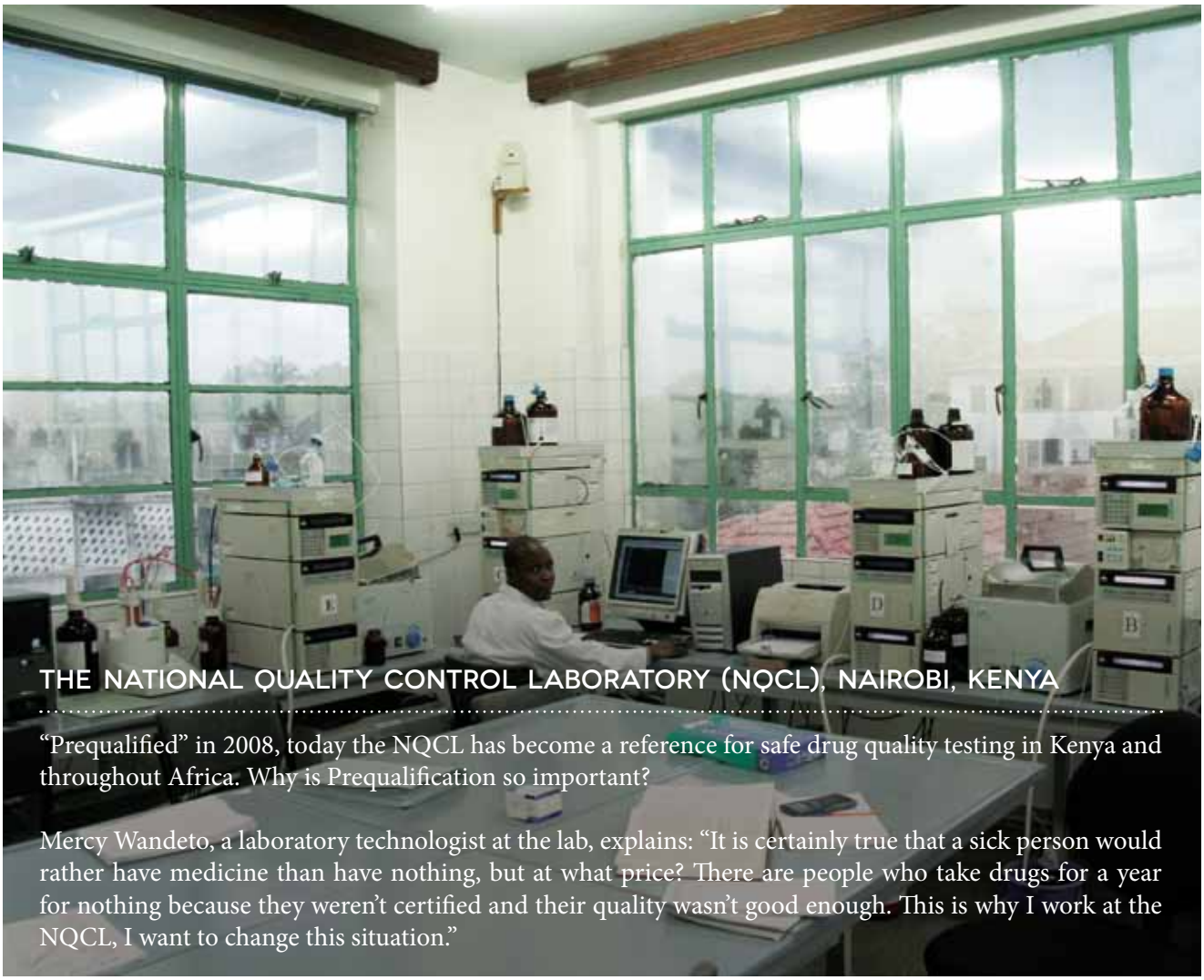
It is estimated that less than 5% of tuberculosis patients receive appropriate testing. Using traditional testing methods, identifying MDR-TB typically takes up to four months. Through its investment in EXPANDx TB, UNITAID seeks to reduce this gap by bringing state-of-the-art technologies and laboratory services to countries most afflicted by tuberculosis. EXPANDx TB is implemented by the Foundation for Innovative New Diagnostics, the Global Laboratory Initiative, and the STOP TB Partnership with its Global Drug Facility.

Through EXPANDx TB, eight low-income, high-burden TB countries now have fully functioning laboratories, equipped with a new diagnostic test called the "line probe assay." These advanced tests can detect MDR-TB in two days so patients can start immediate and effective treatment. Over 4,000 MDR-TB cases have been detected using these facilities. EXPANDx has also achieved price reductions of up to 80% for sophisticated diagnostic equipment and supplies through competitive tenders. New laboratory infrastructure and successful technology transfer has been established in 18 countries.

FIXING MARKETS

WHO PREQUALIFICATION PROGRAMME

QUALITY MEDICINES FOR EVERYONE



THE NATIONAL QUALITY CONTROL LABORATORY (NQCL), NAIROBI, KENYA

"Prequalified" in 2008, today the NQCL has become a reference for safe drug quality testing in Kenya and throughout Africa. Why is Prequalification so important?

Mercy Wandeto, a laboratory technologist at the lab, explains: "It is certainly true that a sick person would rather have medicine than have nothing, but at what price? There are people who take drugs for a year for nothing because they weren't certified and their quality wasn't good enough. This is why I work at the NQCL, I want to change this situation."

INTRO

To provide quality health products for low-income countries, UNITAID is the principal funder of the World Health Organization Prequalification programme for HIV, TB and malaria medicines. This programme evaluates medicines and manufacturing plants based on a stringent set of criteria, guaranteeing safety and efficacy.

A key part of UNITAID's project portfolio since 2006, Prequalification ensures that new drugs and user-friendly formulations brought to market are of the highest quality. As UNITAID only funds products that have been prequalified by this programme or by a national stringent regulatory authority, increasing the number of quality-assured manufacturers also helps to achieve price reductions for medicines.

MARKET SHORTCOMING

The catalytic increase in funding for HIV/AIDS, malaria and tuberculosis over the last decade presented a new market challenge for the international community. Many of the medicines that appeared were specifically adapted for developing countries, such as paediatric formulations for HIV and TB or powerful artemisinin-based malaria combinations. Quality regulation for these new products was limited, due to low demand in richer countries with extensive pharmaceutical quality assurance. Generic manufacturers supplied the lion's share of new products being purchased by United Nations agencies, leading to a considerable regulatory gap.

MARKET INTERVENTION

The Prequalification programme was set up in 2001 to provide unified standards of quality and safety of products. With UNITAID's creation in 2006, the need for a comprehensive and stringent mechanism to assess quality became critical. UNITAID funding of Prequalification began in December 2006 to meet this demand.

UNITAID's support now enables its implementers to negotiate with a wide range of quality-assured manufacturers – both originator and generic – for favourable long-term procurement agreements. UNITAID thus offers generic manufacturers a "free-of-charge" public service to enter the market, spurring more price competition. The programme also provides a list of prequalified products, a vital tool for any agency or organization involved in bulk purchasing of medicines.

Manufacturers that wish to have their products on the Prequalification list must present extensive product information and open their manufacturing sites to an inspection team. Thirty-eight inspections were carried out during January to June 2011. The majority of inspections were carried out in India; other inspections were carried out in Benin, Brazil, China, Kenya, Morocco, Russia, South Africa and Zimbabwe.

MARKET IMPACT

To date, 41 priority medicines have been prequalified and have entered the market. This includes 24 medicines for HIV (19 second line and five paediatric) and 10 medicines for tuberculosis (three first-line, three second-line and four adult).

For malaria medicines, UNITAID's support of Prequalification has been crucial for improving access to artemisinin-based combination therapies (ACTs) over the last five years. In 2006 there was only one quality-assured manufacturer of these powerful anti-malarial drugs. Moreover, they were in a difficult-to-use form, called a co-blister package. Today there are seven prequalified generic manufacturers of ACTs, producing 11 relevant ACT formulations – eight of these products are fixed-dose combinations. One of these products is a child-adapted dispersible ACT: artemether+lumefantrine, essential for a disease which killed almost 700,000 children in 2010. A major achievement in 2011 was the prequalification of artesunate injections, which are recommended to treat severe malaria.

Another key activity is the prequalification of quality control laboratories around the world. By prequalifying laboratories like the National Quality Control Laboratory in Kenya (see photo), this programme ensures that quality-control is being correctly carried out in those countries that need it the most.

HOW UNITAID WORKS WITH IMPLEMENTERS

UNITAID uses a partnership approach to its market interventions, to reduce transactions costs and ensure optimal use of resources.

All market intervention projects are managed by implementers, all organizations active in the fight against HIV/AIDS, malaria and tuberculosis. UNITAID's funded implementers provide their own human, technical and financial resources. UNITAID's secretariat in Geneva supervises all time-limited projects, coordinating their activities and ensuring programme and financial monitoring and reporting. While the secretariat is hosted by the World Health Organization, it enjoys a large degree of autonomy to take a flexible and proactive approach to its market interventions. This direct, strategic approach is unique in the public health funding area and contributes to UNITAID's cost-effective and efficient way of doing business.

PROJECT FUNDING

UNITAID's Executive Board selects projects that are aimed at UNITAID's chosen markets for medicines, diagnostics and related health commodities. All funding requests are reviewed by an advisory group of external experts. The Executive Board then takes all decisions related to approval of funding for specific projects.

UNITAID's unique market approach is applied consistently across all UNITAID activities. This includes **strategic prioritisation** - decision making about which markets to prioritise and **project selection** - decision making about which proposals to fund as well as impact assessment.

Inputs supporting strategic and effective Board decision-making towards maximal market and public health impact include:

Landscape analyses provide background information and market intelligence on current and future trends in disease, technology and market characteristics for medicines, diagnostics, and prevention used in HIV/AIDS, tuberculosis, and malaria. *(See chapter Driving Innovation in Global Health)*

Primary criteria to guide strategic prioritisation and project selection including: (i) potential market impact; (ii) potential public health impact; (iii) value for money; and (iv) innovation; as well as consideration for principles embedded in the UNITAID Constitution, including: (i) leveraging; (ii) equity; and (iii) relative value-add.

Guiding portfolio principles to monitor the spread of funding within UNITAID's portfolio of projects, including balance of funds across: the three diseases, types of products, number and size of investments; and investments per organization.

Financial analyses of actual and expected funding against committed expenditure to determine resources available for new projects.

SUSTAINABILITY

While UNITAID's mission is long-term, its objectives for particular markets are time-limited. A cornerstone of UNITAID's market impact model is eventual evolution out of a market once a shortcoming has been addressed.

Implementers assume the responsibility for ensuring that:

- Countries have successfully integrated the targeted products into their national health financing, procurement and supply systems. Sufficient domestic or external funding must be assured to continue purchasing the product
- Implementers and/or other funding organizations must be able to sustain the impact of their market intervention

Given the uncertain environment for global health funding, UNITAID has worked closely with its implementers to ensure that predictable finance is in place following the end of existing and future projects.

In 2011, the Secretariat proactively engaged with a working group to better understand and take actions with respect to sustainability issues in existing projects (most notably Paediatric HIV and adult second-line HIV projects).

UNITAID currently supports ten implementers:

IMPLEMENTER SPOTLIGHT: **ESTHERAID**

One of the key challenges that UNITAID faces is making sure that products that it supports reach people in need. In January 2011, an original partnership was launched to trace and ensure delivery of health products from central medical stories to loc¬al clinics down to the patients themselves.

Called "ESTHERAID," this partnership brings UNITAID together with French NGO Esther *(Together for a Therapeutic Hospital Solidarity Network)* for the first programme of its type in West Africa. ESTHERAID provides technical support to improve supply chain management of health products in Burkina Faso, Benin, Cameroun, Central African Republic and Mali over a period of three years.

UNITAID funds either paediatric antiretrovirals or second-line HIV treatments in all these countries and ESTHERAID works with ministries of health to ensure their correct use at treatment centres for people living with HIV. It also works to optimize the quality of diagnosis, treatment and monitoring of patients. Each country response is adapted and ESTHERAID intends to double the amount of paediatric and second-line patients in each country:

Benin: There is insufficient access to antiretrovirals due to stock-outs and poor usage of diagnostic tools. ESTHERAID is strengthening the pharmaceutical supply system and focusing on procurement centres and pharmacies.

The Louis Pasteur Clinic is part of the ESTHERAID project. Mothers who come to give birth here are offered free HIV screening. In 2011 every baby born at the clinic to an HIV-positive mother was born HIV-free.

Burkina Faso: HIV treatment is available but inconsistent quality of medical services is still a barrier. ESTHERAID is working with the University Hospital in Bobo Dioulasso to decentralise treatment to the regions.

Cameroon: Health care services are still spread thin. ESTHERAID is boosting the national supply system and strengthening regional referral centres.

Mali: The difficult in supplying outlying treatment centres cripples access to essential medicines and few children have access to treatment. ESTHERAID is strengthening regional hospitals and making sure laboratory services reach the periphery.

Professor Koumakpai
PAEDIATRICIAN AT THE CNHU HUBERT MAGA
COTONOU, BENIN

More than 200 children are on HIV treatment at Professor Koumakpai's clinic. Through ESTHERAID, she has helped train others in her country on paediatric HIV care.

Central African Republic: In late 2010, only one facility delivered paediatric care in the country. ESTHERAID focuses on supporting the decentralisation of paediatric healthcare to 10 regional facilities.

ESTHERAID's in-country presence allows both partners to act quickly to address access problems. In 2011, Esther discovered that HIV treatments bought by UNITAID had been blocked at the airport for almost two months in Benin. Authorities didn't want to release treatments so Esther and UNITAID jointly negotiated with authorities to release the products and provide quality testing.

This flexible approach allows both partners to take the lead in coordinating with all global funders and national authorities to avoid stock outs. Importantly, this partnership brings UNITAID-purchased HIV products to those who need them most: women, children and patients waiting for desperately-needed second-line treatment.

CLINTON HEALTH ACCESS INITIATIVE

The Clinton Health Access Initiative (CHAI) is committed to strengthening integrated health systems in the developing world and expanding access to care and treatment for HIV/AIDS, malaria and tuberculosis. CHAI's solution-oriented approach focuses on improving market dynamics for medicines and diagnostics; lowering prices for treatment; accelerating access to life-saving technologies; and helping governments build capacity for quality care and treatment programs.

In 2002, President Bill Clinton established CHAI to turn the tide of the HIV/AIDS pandemic in the developing world. Today, CHAI agreements enable access to affordable drugs and diagnostics to more than 70 countries, and staff work on-the-ground in more than 20 countries to help scale up care and treatment.

FOUNDATION FOR INNOVATIVE NEW DIAGNOSTICS

The Foundation for Innovative New Diagnostics is dedicated to developing affordable, easy-to-use and cutting edge diagnostic tests that save lives in the poorest areas of the world. From the initial idea and discovery stage to putting new tests into practice, the organization works with multiple and diverse groups, from academia, industry, donors, partners in the field, Ministries of Health and the World Health Organization.

GLOBAL DRUG FACILITY

The Global Drug Facility (GDF) is a Stop TB Partnership initiative to increase access to high quality tuberculosis (TB) drugs for DOTS implementation, a TB control strategy.

GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA

The Global Fund to Fight AIDS, Tuberculosis and Malaria was created to dramatically increase resources to fight three of the world's most devastating diseases, and to direct those resources to areas of greatest need. Since its inception in 2002, the Global Fund has been a major engine driving this remarkable progress.

I+SOLUTIONS

i+solutions is an independent, international, not-for-profit organization specializing in pharmaceutical supply chain management for low and middle income countries.

ROLL BACK MALARIA PARTNERSHIP

The RBM Partnership is the global framework to implement coordinated action against malaria. The Partnership is comprised of more than 500 partners, including malaria endemic countries, their bilateral and multilateral development partners, the private sector, nongovernmental and community-based organizations, foundations, and research and academic institutions.

STOP TB PARTNERSHIP

The Stop TB Partnership is leading the way to a world without tuberculosis, a disease that is curable but still kills three people every minute.

UNICEF

UNICEF works on the ground in 156 countries and territories to help children survive and thrive, from early childhood through adolescence. UNICEF supports child health and nutrition, good water and sanitation, quality basic education for all boys and girls, and the protection of children from violence, exploitation, and AIDS.

WORLD HEALTH ORGANIZATION

WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

DRIVING INNOVATION IN GLOBAL HEALTH

UNITAID has created a unique place for itself amongst global health initiatives through its focus on innovation and market interventions. In 2011, UNITAID began forging out new opportunities to develop this approach in a field that could drive the global health agenda for the decade to come: innovative "point-of-care" diagnostic technology.

Making simpler, cost-effective diagnostic tools available in resource-limited settings is critical to the successful scale-up of treatment access for HIV/AIDS, malaria and tuberculosis. While the last few years have seen unprecedented advances in diagnostic technology, a new approach is needed to make sure these technologies reach those in need – from sprawling urban centres to isolated villages. This era of diagnostics presents a new set of investment opportunities for UNITAID to help revolutionize patient care.

As part of a year-long effort to understand opportunities in diagnostics, the UNITAID Secretariat commissioned landscape analyses in the area of HIV/AIDS, malaria and tuberculosis in 2011. Landscape reports are undertaken or commissioned by the UNITAID Secretariat to provide the relevant analyses that underpin much of strategic project prioritisation work and decision-making. These publications also have an immense public value to all concerned with access to health commodities.

UNITAID's first diagnostic landscape for HIV/AIDS was published in June 2011. This landmark report enables buyers of health commodities for developing countries to choose from a range of innovative products that will make their HIV/AIDS response more effective.

DECADE OF DIAGNOSTICS

Diagnostics are the gateway to HIV/AIDS care and treatment but there are still considerable barriers to access in resource-limited settings. Today, many diagnostics facilities are centralized and require trained staff and specialised infrastructure. Patients are often "lost" due to great distances between testing centres and home. Diagnostics needs to be moved to the "periphery" and closer to the point-of-care so patients can get their results quickly.

UNITAID's Diagnostic Landscape[4] maps the development and imminent coming to market of a wide range of simple, cost-effective technologies adapted for use at "point-of-care" in poor health systems and rural areas by non-specialised healthcare workers. The report describes the testing continuum required for the HIV patient, the current diagnostic market landscape and existing barriers to access.

Although the market is robust and efficient, access to HIV diagnostics is poor in resource-limited settings, according to the report. Testing needs to be simplified and decentralized. Increasing the level of access to robust, high-quality diagnostics in resource-limited settings is crucial to facilitate the successful treatment of HIV/AIDS. It will maximize the preventative impact of treatment and ensure an appropriate response to drug resistance, a problem likely to grow in coming years.

Diagnostics for HIV/AIDS can be divided into three categories (see insert for explanation): i) tests to facilitate initial diagnosis ii) tests to stage the patient and (iii) tests to monitor the patient after beginning treatment.

[4] Available on http://www.unitaid.eu/

For the initial diagnosis, there are a large number of tests available, of which rapid HIV antibody tests are the most common for patients older than 18 months. These tests are easy-to-use, convenient and self contained. In the form of a lateral flow strip or cassette, these tests can be completed in less than 10 minutes. It is assumed the market for initial diagnosis for patients over 18 months is robust – these tests can cost as little as 50 cents.

The landscape report covers three types of HIV technologies where progress can be made:

Early Infant Diagnosis (EID): The most widely used test for EID is a DNA PCR molecular test, requiring complex equipment and skilled personnel. With investments from UNITAID, the price of EIDs has come down and CHAI has trained personal in its use (see paediatric HIV chapter). But increased availability of EID at the point-of-care could drive access to the hardest-to-reach areas in developing countries. There are at least two point-of-care assays to be launched soon.

CD4 Testing: There are a number of good laboratory-based platforms but there is still a need for good and cost-effective point-of-care CD4 testing options. Current options require transporting samples over potentially huge distances in patchy conditions. Cost-effective point-of-care is needed and several options are already on the market.

Viral Load Testing: There are a good number of sophisticated laboratory-based platforms but there is limited access in resource-limited settings. Viral load testing that could be conducted at the point-of-care would reduce the need for training and lower the cost of testing. There are currently no point-of-care viral load assays on the market but there are a number in development. There is very little viral load testing done in the public health sector in resource-constrained countries.

An updated version of this landscape will be issued in 2012 and additional landscapes for malaria and tuberculosis diagnostics will also be published in early 2012.

MOVING FORWARD

UNITAID strategic focus in these areas is aligned with the international community's priorities for HIV/AIDS, malaria and tuberculosis. In June 2010, UNAIDS and the World Health Organization launched "Treatment 2.0," a radically simplified HIV care and treatment platform, calling for increased access to point-of-care diagnostics and monitoring tools.

At its Board meeting on March 2012, UNITAID will approve proposals for innovative diagnostics. Following this, UNITAID will issue an open call for innovative ideas.

HIV DIAGNOSTICS AT A GLANCE

Within a few weeks of HIV infection, a patient's body will produce antibodies to defend against the virus. In poor settings, low-cost HIV rapid tests are the most common tool used to measure the presence of these antibodies. Although they are accurate and easy to use, **HIV rapid tests** are not an effective diagnostic tool for children under 18 months – more complex testing is required, called **Early Infant Diagnosis**. As infants retain maternal antibodies that could result in a misleading diagnosis, the only way to test infants is with DNA testing that requires skilled personnel.

HIV directly attacks CD4 T lymphocyte cells. Measuring their count through **CD4 testing** is the most important laboratory measure - the lower the patient's CD4 count, the more HIV has progressed. A patient's CD4 count is one of the important determinants for when a patient should start treatment.

The HIV virus also causes an increase in the number of viral particles circulating in the patient's bloodstream. Once antiretroviral treatment starts, the best measure of the effectiveness of the drugs is a patient's **viral load**, or number of viral particles, over time. Viral load tests are vital for signaling when a patient needs to switch from first-line to second-line antiretrovirals.

THE MEDICINES PATENT POOL

INTRODUCTION

In 2010, UNITAID created the Medicines Patent Pool as an unprecedented response to the rising global need for affordable HIV treatment.

Patents can act as a barrier to producing medicines at affordable prices. Where there are patent barriers, licences are needed to allow generic manufacturers to produce quality, low-cost versions of medicines. Licences are therefore crucial if affordable, appropriate HIV treatments are to continue to be available for people who most need them.

The Pool acts as a "one-stop shop" for licences needed by generic manufacturers and product development partnerships to make the medicines needed by people living with HIV. Civil society groups affiliated with UNITAID sought the creation of a patent pool - the first of its kind for HIV medicines - in order to ensure such licences would be available.

2011

In 2011, the first full year of its existence, the Pool achieved several key milestones. In July, it signed a licence agreement with Gilead Sciences for five HIV products: emtricitabine (FTC), tenofovir (TDF), cobicistat (COBI), elvitegravir (EVG) and a fixed-dose combination of FTC, TDF, COBI and EVG known as "the Quad." The agreement covered 100-112 countries, representing between 82.7 – 87.6% of people living with HIV in low- and middle- income countries, a wider geographical scope than any previous voluntary licensing agreement with a pharmaceutical company. The Pool's first agreement, signed in September 2010 with the US National Institutes of Health, covered all low and middle-income countries. Both licensing agreements set standards in terms of transparency: the full texts of both have been published on the Pool's website for anyone to be able to read and comment on.

> "WE WELCOME THE PATENT POOL INITIATIVE LAUNCHED BY UNITAID IN ORDER TO FACILITATE THE PRODUCTION OF AFFORDABLE GENERIC MEDICINES WELL-ADAPTED FOR USE IN RESOURCE-POOR SETTINGS, AND WE ENCOURAGE THE VOLUNTARY PARTICIPATION OF PATENT OWNERS, PRIVATE AND PUBLIC, IN THE PROJECT."
>
> **G8 DECLARATION**
> G8 SUMMIT OF DEAUVILLE,
> MAY 26-27 2011

In April of 2011, the Pool launched its Patent Status Database for HIV Medicines, which it has kept regularly updated, adding new countries and medicines. Created in collaboration with national patent offices through the World Intellectual Property Organization, the database now covers 69 countries and 24 antiretrovirals. The database is the most complete single source of open access information about critical HIV related patents in developing countries.

In December 2011 UNITAID's Executive Board decided to continue support for the Medicines Patent Pool for the next four years, in recognition of the Pool's work to increase access to affordable drugs.

At the end of 2011, the Pool was in ongoing negotiations with 6 additional patent holders: Boehringer-Ingelheim, Bristol-Myers Squibb, F. Hoffman La-Roche, Sequoia Pharmaceuticals, the US National Institutes of Health, and ViiV Healthcare [a joint venture of GlaxoSmithKline and Pfizer].

POOL
HOW IT WORKS

1

A regularly updated list of target HIV medicines is compiled with experts, based on medical needs and potential patent barriers

2

Pool invites holders of relevant HIV medicine patents to enter negotiations. First letters went out on World AIDS Day 2010

3

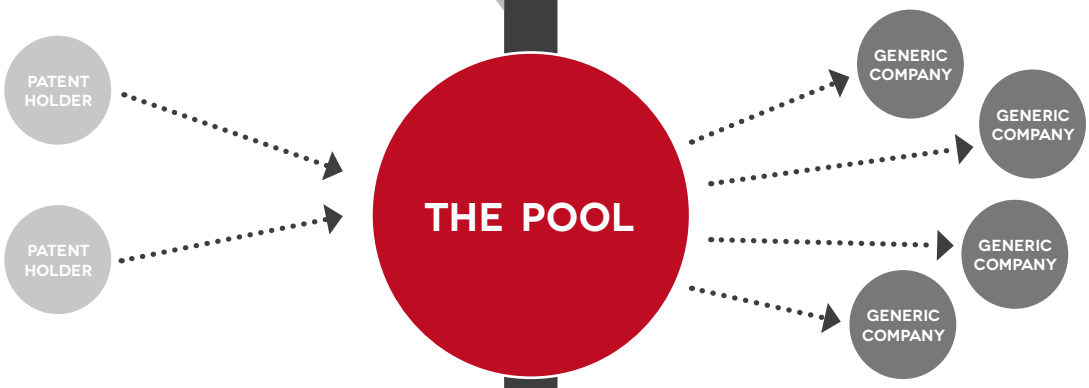
Negotiations with willing companies. The Pool seeks licences that push the status quo on voluntary licensing: covering more countries, containing public-health oriented terms and conditions. The aim is to reach all people living with HIV in developing countries

4

Once the Pool's governing bodies have decided that a licence represents an improvement, it signs an agreement with the patent holder. The licence and terms and conditions are published on the Pool's website - an unprecedented level of transparency in a field where licences have always been negotiated in secret

5

Once a signed licence is "in" the Pool, qualified generic companies or product development organizations can obtain licences in order to produce HIV medicines at lower cost and develop adapted formulations. Patent holding companies receive a fair royalty on sales



6

The Pool works with sublicensees on product development and regulatory approval until HIV medicines are brought to market to impact **public health.**

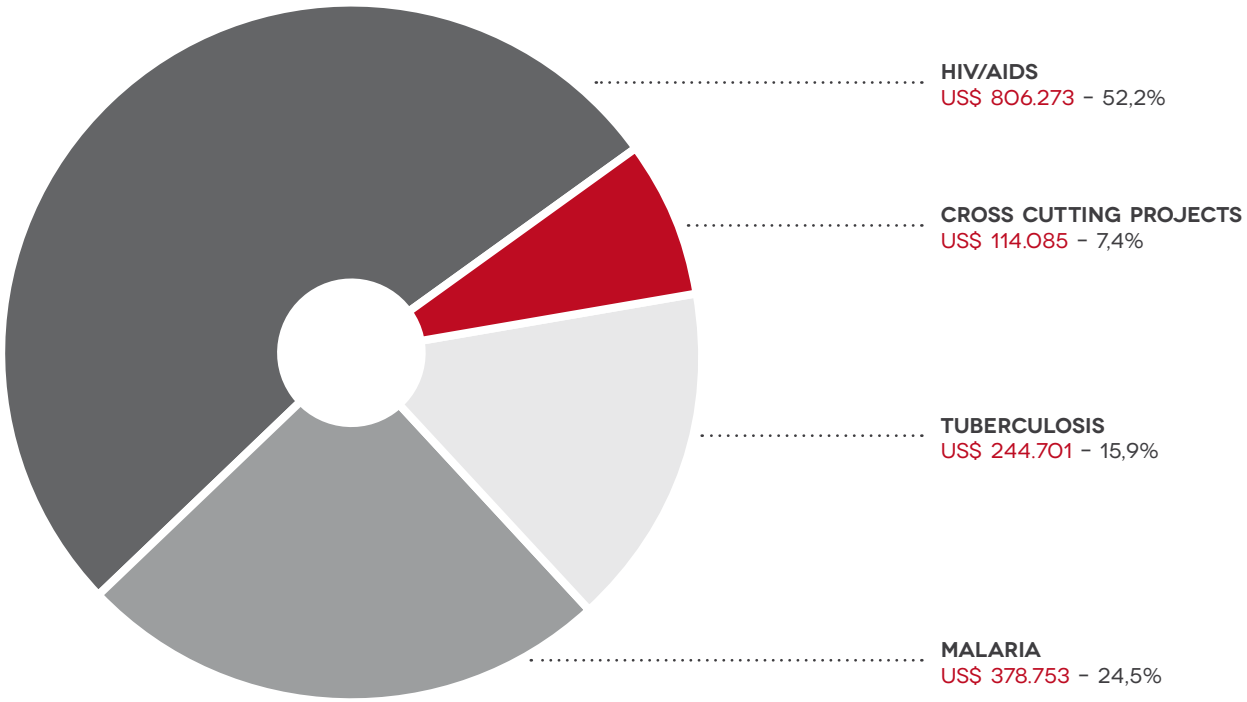
UNITAID'S PROJECT PORTFOLIO

UNITAID's portfolio of projects includes a balance of projects for each disease (HIV/AIDS, malaria and tuberculosis). The top 10 countries benefiting from UNITAID funding in 2011 were: Nigeria, Zambia, Uganda, Kenya, India, Democratic Republic of Congo, Mozambique, Zimbabwe, Sudan and Ethiopia.

TOTAL AMOUNT COMMITTED FOR ALL PROJECTS (2006-2011)

US$ **1,543,812,000**

PROJECT FUNDING COMMITMENTS AT THE END OF 2011 BY PROJECT CATEGORY, IN US$000



HIV/AIDS PROJECT PORTFOLIO AND MARKET OVERVIEW

TOTAL AMOUNT COMMITTED (2006-2011): **US$ 806,273,000**

The 30th anniversary of the discovery of AIDS in 2011 was an occasion to review the great strides made in providing treatment so HIV-positive people can live full, healthy lives. Of the approximately 34 million people who live with HIV, about 95% are in low- and middle-income countries. At the end of 2010, almost 7 million people in these countries were receiving antiretroviral therapy.

Yet considerable work remains. Following a new set of WHO guidelines in 2010 that recommended starting treatment at an earlier stage of the disease, it is now estimated that 18.3 million people living with HIV in these low- and middle-income countries will be in need of treatment by the year 2015. Groundbreaking findings were also released in 2011 showing that early usage of antiretrovirals can cut HIV transmission to a sexual partner by 96 percent.

Unfortunately, 2011 also saw some major setbacks to funding for a continued scale-up of HIV treatment, threatening to reverse some of the gains made in the last decade. The unprecedented growth in global funding for HIV/AIDS has led to the establishment of a competitive generic antiretroviral market – the total value of this market in 2010 is estimated at US$ 835 million. For diagnostics, expanded access to CD4 and viral load testing will help to optimize the impact of HIV treatment, with viral load playing a critical role in identifying patients who need second-line treatment.

UNITAID's project portfolio for HIV/AIDS has played a fundamental role in creating and catalyzing this global market, especially for adult second-line and paediatric antiretrovirals. In sub-Saharan Africa, where women suffer the burden of the HIV/AIDS epidemic, UNITAID is also strengthening services in the prevention of maternal to child transmission of HIV (PMTCT).

1. PAEDIATRIC HIV/AIDS PROJECT

Description: Create market for paediatric antiretrovirals, early infant diagnostics and other components.

Amount Committed (2006-2011): US$ 380,058,000[5]

Selected 2011 Highlights

- The project currently supports 25 countries. 15 countries have already transitioned to other funding sources
- Overall price reductions of 80% since start of project – 2011 price reductions of up to 8%
- Approximately 97% of children benefitting from project are on fixed-dosed combinations (FDCs)
- Over 86,000 PCR tests for babies born to HIV-positive mothers in the first quarter of 2011

2. SECOND-LINE HIV/AIDS PROJECT

Description: Catalyze the market for second-line antiretrovirals through supplier selection techniques that increase the number of quality-assured second-line products and reduce their prices.

Amount Committed (2006-2011): US$ 305,799,000

Selected 2011 Highlights

- Cumulative price reductions of up to 60% for key second-line antiretrovirals
- Since the launch of Atazanavir and heat stable Ritonavir singles in 2010, 11 countries have accessed these formulations
- A 2011 supplier selection process saw the addition of six newly eligible formulations
- 15 of the 25 countries in this project have transitioned to alternative funding sources

[5] All amounts Executive Board approved amounts

3. PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV (PMTCT)

Description: UNITAID is the world's largest funder of integrated PMTCT programmes and a major player in the drive to reach the 2015 target of no children born with HIV. UNITAID has supported three PMTCT projects since 2007 to test, treat and support HIV-positive women and their infants.

UNITAID's support to UNICEF for integrated PMTCT has encouraged national governments and other global health agencies to actively fund integrated PMTCT programmes of their own.

Amount Committed (2006-2011): US$ 104,466,000

Selected 2011 Highlights

- Over 7 million HIV tests and over 800,000 antiretroviral treatments were provided to HIV-positive women to prevent mother-to-child transmission of the disease
- Over 8 million infants tested for HIV using early infant diagnostic tests (PCR-based)
- Considerable progress made by Rwanda, Malawi and Zambia in achieving targets for PMTCT products, including HIV tests for pregnant women, antiretroviral treatment for HIV-positive women for prophylaxis, CD4 test provision and HIV tests for infants born to positive mothers

4. ESTHERAID

Description: Improve supply chain management from national medical stories to treatment centres in five West African countries. Support the efforts of medical centres and treatment sites by making sure that UNITAID-supplied tests and treatments are received and used.

Amount Committed (2006-2011): US$ 15,950,000

Selected 2011 Highlights

- ESTHER and the Coordinated Procurement Planning initiative[6] are sharing information on supply chains and stock outs for the five participating countries to better align product support for these countries

[6] Comprised of PEPFAR, World Bank, the Global Fund, UNITAID and the World Health Organization

MALARIA PROJECT PORTFOLIO AND MARKET OVERVIEW

TOTAL AMOUNT COMMITTED (2006-2011): **US$ 378,753,000**

Malaria is the leading killer of children and pregnant women in high burden countries. Roughly one child dies every 45 seconds from malaria, the vast majority in sub-Saharan Africa. Malaria has been a serious health problem for centuries, as the killer parasite that causes the disease has an uncanny ability to adapt and become resistant to medicines.

A concerted effort over the last decade to scale-up the malaria response through preventative mosquito nets and treatment has made a difference. External expenditure on malaria control has increased from $35 million in 2000 to $1.5 billion in 2009. According to the Roll Back Malaria Partnership, global malaria deaths have dropped by an estimated fifth over the last decade. 43 countries have cut malaria deaths by 38%, with 11 of them in Africa.

An important part of this global drive to reduce malaria deaths to near zero has been the scale-up of access to artemisinin-based combination therapies (ACTs). An estimated 287 million ACT treatments were purchased in 2011, up from 11.2 million in 2005. The market for WHO-prequalified ACTs is primarily donor-funded and until recently was dominated by one manufacturer. Today there are seven WHO-prequalified manufacturers producing 11 ACT formulations. Still, ACTS are still underused in private sector channels in sub-Saharan Africa, where the disease burden is the greatest and counterfeit and substandard products still are common.

1. AFFORDABLE MEDICINES FOR MALARIA (AMFm)

Description: Create a consumer market for ACTs by reducing the price paid by end-users through a subsidy mechanism to the private sector. The pilot phase of the AMFm is currently implemented through nine programmes in eight countries.

Amount Committed (2006-2011): US$ 180,000,000

Selected 2011 Highlights

- Co-payment for 110,335,560 ACT treatments worth US$ 112,535,892 has been approved as of June 2011
- 46,247,222 ACTs delivered to first-line buyers in the private sector as of June 2011
- Consumers now paying between US$ 0.33 and US$ 1.32 per ACT- down from US$ 8 to US$ 10 per ACT
- Market doubled for 2010-2011 with a number of generic manufacturers making quality ACTs

2. ACT SCALE-UP

Description: Raise artemisinin-based combination therapies (ACT) treatment targets and provide market stability for these quality treatments.

Amount Committed (2006-2011): US$ 78,888,000

Selected 2011 Highlights

- 36 million ACTs delivered to eight malaria-endemic countries since 2007
- Procurement lead times significantly reduced and no stock-outs of ACTs reported from countries

3. ASSURED ARTEMISININ SUPPLY SERVICE (A2S2)

i+solutions Triodos

Description: Support the production of Artemisia in order to help stabilize the price of Artemisinin, the key ingredient in artemisinin-based combination therapies (ACTs). The project provides loans to artemisinin extractors through agreements between the artemisinin extractor, i+Solutions and a prequalified ACT manufacturer.

Amount Committed (2006-2011): US$ 9,280,000

Selected 2011 Highlights

- Two loan agreements to supply additional 18 metric tonnes (MT) of artemisinin completed with Vedic-ABE and Bionexx-Innovexx
- Technical support to facilitate sales agreement for 18.5 MT additional artemisinin provided to Mediaplantex and Hung Thinh (Vietnam), AfroAlpine (Uganda) and Xieli (China)
- Delivery of 3.93 MT to ACT manufacturers
- A total of $1.37 million in loans has been paid back

4. LONG LASTING INSECTICIDE TREATED NETS
(PROJECT COMPLETED DECEMBER 2010)

unicef

Description: This project created healthy market conditions – increased access, better quality and shorter production lead times – for long-lasting insecticide treated bed nets (LLINs). Over 20 million quality bed nets were provided to eight malaria-endemic countries.

With funding delayed by donors, UNITAID intervened to stop critical supply shortages and incentivize manufacturers to increase capacity in a timely distribution of nets before the rainy season. UNITAID's support contributed to almost 20% of the total nets delivered in 2009.

Amount Committed (2006-2011): US$ 109,250,000

5. ACT SCALE-UP FOR BURUNDI AND LIBERIA
(PROJECT COMPLETED DECEMBER 2007)

unicef

Description: Supported the rapid delivery of about 720,000 ACT treatments to Burundi and 680,000 to Liberia over the months between March and December 2007. This "emergency" project was designed to prevent a shortage of ACTs at the end of a Global Fund grant for the two countries. UNITAID's support was instrumental in ensuring that the two countries were covered for these vital medicines while they waited for fresh funding for their malaria programmes.

Amount Committed (2006-2011): US$ 1,335,000

TUBERCULOSIS PROJECT PORTFOLIO AND MARKET OVERVIEW

TOTAL AMOUNT COMMITTED (2006-2011): **US$ 244,701,000**

Tuberculosis (TB) is an ancient killer that still ravages the developing world – it is one of the major causes of death for people with HIV/AIDS. Every year over nine million people become ill with TB and nearly two million die from this curable disease.

Out-dated and ineffective treatment and diagnostics make TB difficult to tackle - the last TB drug with a completely new active ingredient was discovered almost half a century ago. Although tuberculosis used to be a leading cause of death in Europe and North America, today there is little incentive for pharmaceutical companies to invest in research and development to produce better products.

Treatment suffers from this dearth of innovation. Today's treatment course for TB is long at six months. Interruptions in treatment causes drug-resistant strains (MDR-TB), which are prohibitively expensive to treat, taking up to 18-24 months with second-line treatment. Proper diagnostics is crucial to identify drug-resistant strains so patients can start appropriate treatment – poor access to better diagnostic technology means the second-line market remains small. Finally, paediatric TB is on the rise with almost 50,000 case detections annually – specially-adapted and affordable medicines are needed to combat this killer of children in poor countries.

UNITAID's portfolio of TB projects aim to address these deficiencies in the market for TB treatment and diagnostics, both for drug-resistant TB treatment and diagnostics as well as for paediatric TB care.

1. FIRST LINE ANTI-TB DRUGS INITIATIVE

Description: Purchase first-line tuberculosis drugs to minimize the risk of stock-outs through the Stop TB Partnership Global Drug Facility. As interruption in TB treatment leads to drug-resistance, this project stops TB from spreading in communities.

Amount Committed (2006-2011): US$ 27,646,000

Selected 2011 Highlights

- 785,080 first line treatments delivered to 19 countries to provide uninterrupted treatments as of June 2011

2. MDR-TB SCALE-UP INITIATIVE

Description: Improve the price, number and quality of second-line TB medicines in order to increase the number of patients on treatment. Stabilise the market by increasing the number of manufacturers.

Amount Committed (2006-2011): US$ 55,667,000

Selected 2011 Highlights

- 7,000 MDR-TB treatments (24 -month course) provided to 14 high burden countries

3. MDR-TB STRATEGIC ROTATING STOCKPILE

Description: Fix the market for MDR-TB by facilitating faster lead times to quickly get patients on treatments in emergency situations. Prevent the rapid spread of drug-resistant TB.

Amount Committed (2006-2011): US$ 11,802,000

Amount Committed (2006-2011): US$ 22,232,000[7]

Selected 2011 Highlights
- Stockpile established of 5,800 patient treatments
- Lead times for urgent orders are below the target of two months
- Stockpile usage is above the target of 60% per year

4. PAEDIATRIC TB PROJECT

Description: Create a market for child-friendly TB medicines for children under-5 years of age through increasing the number of manufacturers and stimulating competition. As a result of this market approach, UNITAID is the second-largest provider of paediatric TB medicines.

Amount Committed (2006-2011): US$ 37,691,000

Selected 2011 Highlights
- As of 2011, over 900,000 curative and preventative treatments provided for children in 57 countries
- Funding provided to facilitate development of child-adapted medicines that meet new WHO guidelines for paediatric TB treatment
- Long-term agreements with manufacturers saw price reductions of up to 30% for key formulations until WHO changed its paediatric TB guidelines in 2010, recommending higher doses of medicine. New formulations not expected to be on the market for another two years

5. EXPANDx TB (MDR-TB DIAGNOSTICS)

Global Laboratory Initiative (GLI)

Description: Introduce new and rapid technologies as well as laboratory service to accelerate access to MDR-TB diagnosis. The goal is to identify an estimated 119,000 MDR-TB patients in 27 countries and enable appropriate treatment.

Amount Committed (2006-2011): US$ 89,663,000

Selected 2011 Highlights
- Eight low-income, high-burden TB countries now have fully functioning laboratories using state-of-the-art *Line Probe Assay* tests to detect drug-resistance and start appropriate treatment. Over 4,000 MDR TB cases have been detected using these facilities
- Testing for MDR-TB is now quicker and more efficient to stop the spread of MDR-TB

[7] Proposal withdrawn

CROSS-CUTTING

TOTAL AMOUNT COMMITTED (2006-2011): **US$ 114,085,000**

1. UNITAID PROJECT SUPPORT FOR QUALITY ASSURANCE OF MEDICINES

Description: Increase the number of prequalified UNITAID medicines for HIV/AIDS, malaria and tuberculosis.

Amount Committed (2006-2011): US$ 53,110,000

Selected 2011 Highlights
- Inspection of 38 manufacturing sites completed
- 6 finished pharmaceutical products prequalified
- 3 active pharmaceutical ingredients for ACTs to treat malaria prequalified
- 3 new quality control laboratories prequalified

2. UNITAID PROJECT SUPPORT FOR QUALITY ASSURANCE OF DIAGNOSTICS

Description: Increase the number of quality-assured tools to diagnose and monitor treatment for HIV/AIDS and malaria.

Amount Committed (2006-2011): US$ 8,475,000

Selected 2011 Highlights
- Manufacturing sites for 11 new diagnostic products being inspected
- Re-inspection of four product applications is underway
- 1 new rapid diagnostic test for malaria prequalified

3. UNITAID SUPPORT FOR GLOBAL FUND ROUND 6, PHASE 1

Description: Scale up access to treatment and reduce prices of medicines for the treatment of HIV/AIDS, MDR-TB and malaria through Global Fund grants in Round 6, Phase 1.

Amount Committed (2006-2011): US$ 52,500,000

Selected 2011 Highlights
At the end of 2010, the project had supplied the following products in 42 countries:
- 31,197 paediatric HIV treatments
- 2,650,652 artemisinin-based combination therapies
- 3,223 treatments for MDR TB

MILLENNIUM FOUNDATION

The Millennium Foundation mobilizes private sector support for UNITAID and works directly with global industries to create tailored Corporate Social Responsibility programmes. Established in 2008 on a grant provided by UNITAID, the Millennium Foundation is an independent foundation.

In 2010, the Millennium Foundation launched its Voluntary Solidarity Contribution project in Spain with major travel and tourism partners to raise money for HIV/AIDS, malaria and tuberculosis through customer micro-donations. This project was discontinued in October 2011 after a fundraising campaign with the Spanish Red Cross.

On December 13, 2011, air-transport conglomerate HNA Group became the first Chinese partner of the Millennium Foundation, committing US$ 800,000 to UNITAID.

GOVERNANCE

EXECUTIVE BOARD

The Executive Board is the decision-making body of UNITAID and makes all decisions relating to strategy and policy, other than those delegated to the secretariat.

The Executive Board determines UNITAID's objectives, scope and work plan, and approves all partnership arrangements with other organizations and institutions. It also monitors UNITAID's progress and approves UNITAID budgets and financial commitments. The Board generally takes its decisions by consensus.

The Executive Board consists of 12 members:

- One representative nominated by each of the six countries (Brazil, Chile, France, Norway, Spain and the United Kingdom);
- One representative of African countries designated by the African Union;
- One representative of Asian countries;
- Two representatives of relevant civil society networks (non-governmental organizations and communities living with HIV/AIDS, malaria or TB);
- One representative of the constituency of foundations; and
- One representative of the World Health Organization.

PROPOSAL REVIEW COMMITTEE

An independent, impartial team of experts tasked with providing scientific, public health, market impact and economics advice to the UNITAID Executive Board on proposals and related projects submitted for funding.

ADVISORY GROUP ON FUNDING PRIORITIES

An independent expert panel that assists in identifying potential priority niches of high-market and public health impact to be funded by UNITAID consistent with the UNITAID Strategy endorsed by the Board.

MEMBERS OF THE UNITAID EXECUTIVE BOARD

AS AT DECEMBER 2011

CHAIR OF THE BOARD	**Philippe Douste-Blazy** Chairman, UNITAID Executive Board and UN Under Secretary-General in charge of Innovative Financing for Development
BRAZIL	**Maria Nazareth Farani Azevêdo** Ambassador and Permanent Representative of Brazil to the United Nations and other International organizations in Geneva
CHILE	**Pedro Oyarce** Ambassador and Permanent Representative of Chile to the United Nations and other international organizations in Geneva
FRANCE	**Mireille Guigaz** Ambassador for the fight against HIV/AIDS, TB and Malaria, Permanent Mission of France to the United Nations and other international organizations in Geneva
NORWAY	**Sidsel Bleken** Senior Adviser, Ministry of Foreign Affairs, Section for Climate Change, Global Health and Sustainable Development
UNITED KINGDOM	**Carlton Evans** Policy and Programme Manager, Global Funds Department, Department for International Development, London
SPAIN	**José Luis Solano Gadea** Ambassador at Large for Public-Private Partnership in Global Health, Spanish Agency for International Development Cooperation, Madrid
AFRICAN COUNTRIES	**Shree Baboo Chekitan Servansing** Ambassador and Permanent Representative of Mauritius to the United Nations and other international organizations in Geneva
ASIAN COUNTRIES	**Enna Park** Director-General, Development Cooperation, Ministry of Foreign Affairs and Trade, Seoul
NON-GOVERNMENTAL ORGANIZATIONS	**Kim Nichols** Co-Executive Director, African Services Committee, New York
COMMUNITIES LIVING WITH THE DISEASES	**Esther Tallah** Cameroon Coalition against Malaria, Yaoundé
CONSTITUENCY OF FOUNDATIONS	**Girindre Beeharry** Director of Strategy, Global Health Bill and Melinda Gates Foundation, Seattle
WHO	**Hiroki Nakatani** Assistant Director-General HIV/AIDS, Tuberculosis, Malaria and Neglected Tropical Diseases, World Health Organization, Geneva
AMFm COMMITTEE	**Kirsten Myhr** Vice-Chair, representative of the UNITAID Board on the AMFm Committee

FINANCIAL HIGHLIGHTS 2011

UNITAID is pleased to present its financial statements for the year ended 31 December 2011.

The Financial Statements of the Report have been prepared in accordance with the United Nations System Accounting Standards (UNSAS) and the Financial Rules and Regulations of the World Health Organization (WHO). They have been audited by the Auditors of WHO. The summary statements of Financial Performance and Financial Position are presented below. The full Financial Report for the year ended 31 December 2011 is available on UNITAID website (http://www.unitaid.eu).

From 2012 onwards, WHO will be applying the International Public Sector Accounting Standards (IPSAS) to its accounts and to the financial statements. UNITAID, as an entity hosted by WHO, will be adopting IPSAS with the same effective date.

The funds entrusted by the donors to UNITAID have been managed in accordance with the applicable WHO Financial Rules and Regulations. The Executive Board of UNITAID has also adopted the Financial Management Policy Framework in 2011. The policies and guidelines of the framework, incorporating UNITAID specific financial guidance, were applied in the areas where WHO financial rules were either silent or not sufficiently tailored to the operating model of UNITAID.

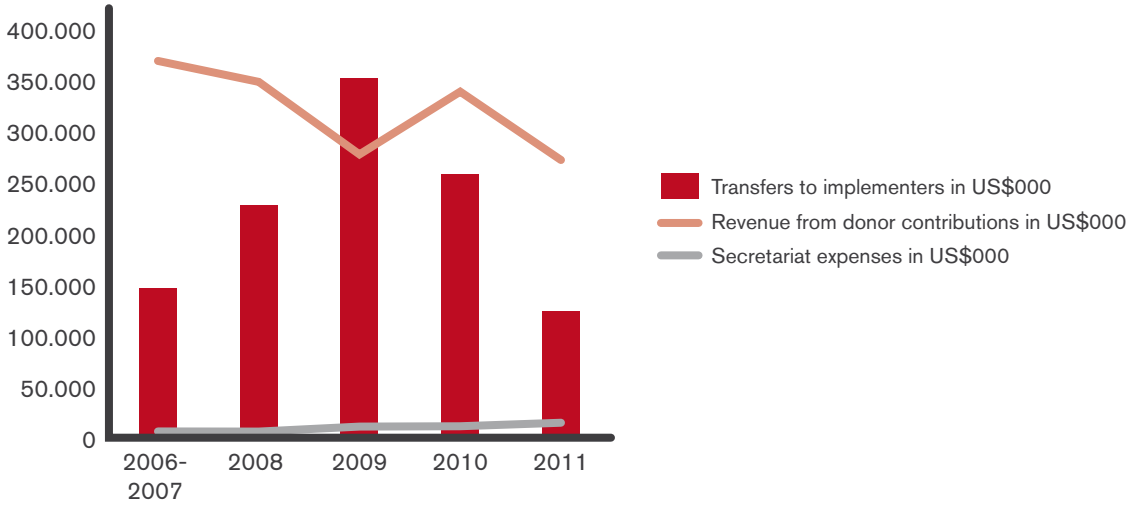
FINANCIAL HIGHLIGHTS

UNITAID was established at the end of 2006. As of the end of 2011, contributions from 17 donors totaled US$1,600m. Since its establishment, UNITAID disbursed to its implementers US$1,103m in total, of which US$380m was disbursed in the biennium 2010-2011. In 2011, the transfers to implementers represented **88.7%** of the overall expenses of UNITAID.

SUMMARY STATEMENT OF FINANCIAL PERFORMANCE

	2011 in US$000	2010 in US$000	2009 in US$000
Operating revenue			
Voluntary contributions for the period	270,235	337,437	274,087
Financial revenue and expense - net	5,353	4,946	10,230
Total operating revenue	275,588	342,383	284,317
Operating expenses			
Staff and other personnel costs	8,155	6,893	4,758
Transfer to implementers	123,518	257,300	350,907
Consulting and contractual Services	6,075	3,736	4,340
Travel	1,287	929	1,083
General operating expenses	174	149	100
Total operating expenses	139,208	269,007	361,188
Surplus for the period	136,380	73,376	(76,871)

UNITAID REVENUE FROM DONOR CONTRIBUTIONS 2006/2007 TO 2011 VERSUS TRANSFERS TO IMPLEMENTERS AND SECRETARIAT EXPENSES, IN US$000



SUMMARY STATEMENT OF FINANCIAL POSITION

	2011 in US$000	2010 in US$000	2009 in US$000
Current assets	566,530	341,636	267,532
Non-current assets	88,148		
Current liabilities	88,319	137	55
Non-current liabilities	89,366	886	241
Net assets	476,992	340,613	267,236
Total liabilities and net assets	654,677	341,636	267,532

LIST OF ACRONYMS AND ABBREVIATIONS

ACT	Artemisinin-based Combination Therapy
AIDS	Acquired Immune Deficiency Syndrome
AMFm	Affordable Medicines Facility - Malaria
API	Active Pharmaceutical Ingredient
ART	Antiretroviral Therapy
ARV	Antiretroviral drug
ATV	Atazanavir
AZT	Azidothymidine (Zidovudine)
CHAI	Clinton Health Access Initiative
D4T	Stavudine
DFID	Department for International Development (UK)
DLT	Diagnostics and Laboratory Technology
ESTHER	Ensemble pour une Solidarité Thérapeutique Hostpitalière En Réseau
FDC	Fixed-Dose Combination
FIND	Foundation for Innovative New Diagnostics
GDF	Global Drug Facility (Stop TB Partnership)
GLC	Green Light Committee
Global Fund	Global Fund to Fight AIDS, TB and Malaria
GMP	Good Manufacturing Practice (WHO)
HIV	Human Immunodeficiency Virus

LLIN	Long-Lasting Insecticide-treated Net
MDR-TB	Multi-Drug Resistant TB
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
NGO	Non-Governmental Organization
ODA	Overseas Development Aid
PMTCT	Prevention of Mother-to-Child Transmission (of HIV)
RDT	Rapid Diagnostic Tests
RUTF	Ready-to-Use Therapeutic Food
SRA	Stringent Regulatory Authority
SRS	Strategic Rotating Stockpile
TB	Tuberculosis
TDF	Tenofovir
UN	United Nations
UNAIDS	United Nations Joint Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant TB

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UNITAID SECRETARIAT

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Unitaid is hosted and administered by the World Health Organization