



RESULTS BEYOND INVESTMENT

ANNUAL REPORT 2012



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Letter from the Chair



Philippe Douste-Blazy

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

When French President François Hollande gave his first speech at the United Nations General Assembly in September 2012, he outlined the way forward in the fight against global poverty. President Hollande urged the world to follow UNITAID's example and 'globalize solidarity'. He announced that part of the money raised by the French financial transaction tax would be allocated to international development, and he challenged other countries to join France in this endeavour.

It was one of the most powerful calls for innovative financing for development that we've heard for a long time.

Six years ago, UNITAID was born at the 61st Session of the United Nations General Assembly. I was there, as the French Minister of Foreign Affairs, alongside French President Jacques Chirac, Brazilian President Luiz Inácio Lula da Silva and high-level representatives from Chile, Norway and the United Kingdom. We launched UNITAID to inject desperately needed funds into the fight against HIV/AIDS, malaria and tuberculosis (TB). At the time, victory against these diseases seemed far off.

Times have changed. Thanks to our work and that of our partners, the tide is turning. HIV infection rates have fallen in a number of African countries due to increased availability of HIV medicines; new drugs and diagnostics are finally in the pipeline for the ancient killer, TB; international funding for malaria control has risen from less than US\$ 100 million in 2000 to an estimated US\$ 1.84 billion in 2012.

Yet despite these successes, we risk failure if new sources of financing are not created. The Organization for Economic Cooperation and Development reported that foreign aid from the richest countries shrank by 4% in 2012.

The on-going economic crisis is forcing millions more people into gruelling poverty, as foreign aid dries up and economic growth slows down. While the West is paying for the financial crisis with deficits and persistent unemployment, the world's poorest are paying with lost lives. More than two billion people live on less than \$2 a day and lack access to the most basic global public goods: nutrition, sanitation, education and health. Such global inequality can only lead to increased conflict and unrest, despite the impressive growth rates seen in many developing countries.

We need to take UNITAID's success in innovative financing to the next level and harness the power of numbers. On January 23 2013, European Union Finance Ministers gave the green light for 11 European countries to proceed with a financial transaction tax. President Hollande has said that at least 10% of the proceeds from France's financial transaction tax should go towards international development.

I would take this a step further: 50% must go to poverty eradication. In only six years, UNITAID has proven that solidarity is the best investment for the proceeds of globalization.

Letter from the Executive Director



Denis Broun

UNITAID Executive Director

In 2012, we saw just how far reaching UNITAID's influence has become only six years after it was created.

Our investments continue to make a difference in people's lives in low-income countries. Notably in 2012, millions of subsidised malaria treatments were distributed through the private sector in Africa with UNITAID financing. Over 400,000 children are now on HIV treatment thanks to UNITAID interventions. Our strategic rotating stockpile of medicines for multi-drug resistant tuberculosis has helped to prevent the spread of this disease by avoiding stock-outs and treatment interruptions.

In addition, our results are felt beyond the countries we invest in, thanks to the catalytic nature of our interventions. For HIV medicines, the price reductions we obtained are accessed by the Global Fund and PEPFAR, enabling them to provide treatments for three times as many patients with the same money. A significant price reduction for a new rapid TB test is allowing dozens of countries, often using their own funds, to diagnose individuals at an early stage of their disease and to treat a greater number of patients.

The WHO Prequalification programme, principally funded by UNITAID, has allowed 67 medicines from low-cost generic producers to enter the market.

The success of this approach is increasingly recognized. In 2012, UNITAID's market-shaping strategy was lauded during an independent evaluation of our first five years. The evaluation cited UNITAID as a model for international development and noted that a host of other organizations and governments are now reaping the benefits for their own work.

Finally, our new Strategy for 2013-2016 defines what products we will bring to market for low-income countries to help reach 15 million people with HIV medicines, reduce TB deaths by 50 percent and reduce malaria deaths to near zero.

UNITAID will continue to play its unique role in global health. It will remain forward-looking and flexible, poised to continue delivering the best returns for the international community. We are only one part of the larger global effort to fight these diseases, but I am proud that we are making such a critical contribution.

About UNITAID

UNITAID shapes markets for quality-assured products to treat, diagnose and prevent HIV/AIDS, malaria and TB in developing countries. Financed largely by a levy on air tickets, UNITAID invests in high-impact market interventions to make health products more affordable, more available and more adapted for the world's poorest people.

+ The majority of members support UNITAID through innovative financing

INNOVATIVE MEMBERSHIP

Launched in 2006 by the governments of Brazil, Chile, France, Norway and the United Kingdom, UNITAID is backed today by 17 contributing members from around the globe. The majority of these members support UNITAID through a variety of innovative financing mechanisms such as air ticket levies or carbon emission taxes. The rest provide long-term traditional commitments.

+ UNITAID interventions have a 'multiplier' effect so more people can be treated or diagnosed for less money

INNOVATIVE MARKET INTERVENTIONS

Hosted by the World Health Organization (WHO), UNITAID occupies a unique role among global health organizations with its differentiated investment approach. It focuses on addressing market shortcomings for health products at the global level. UNITAID identifies these shortcomings, then incubates, selects, launches and manages time-limited market interventions carried out by top global health implementers. These market interventions save lives in the countries directly targeted and also have a 'multiplier effect': when markets are transformed at the global level, other governments or donors are able to purchase better products at a lower cost than previously.

Forward-looking and willing to support promising and novel approaches, UNITAID ensures that its innovative source of income is well invested.

WHY MARKET SHAPING?

Market conditions often deny people in developing countries access to vital medicines – this is especially true for HIV/AIDS, malaria and TB, which kill about four million people every year. Manufacturers usually have no incentive to produce products tailored to these vulnerable populations – such as child-friendly treatments or diagnostic tests that can be used in rural communities.

Despite the overwhelming need for appropriate health products, developing countries are faced with unaffordable prices, insufficient availability and low quality, poorly adapted products. UNITAID addresses this situation by building competitive markets in which manufacturers and distributors have appropriate incentives to sustainably invest, innovate, and supply quality health products at affordable prices and in acceptable formulations to developing countries.


+ UNITAID is the only global health organization that focuses on transforming markets for health products at the global level in order to improve public health


UNITAID RESULTS¹


UNITAID has made a unique contribution to the response to HIV/AIDS, TB and malaria since its creation in 2006.

BETTER PRODUCTS, HEALTHIER LIVES

UNITAID market interventions have led to a dramatic increase in access to life-saving products for developing countries.

+  **400,000** children on quality-assured HIV treatment

+  **327,000,000** of the best malaria treatments distributed

+  **1,500,000** infants tested for HIV


+  **15,000** treatment courses distributed for multi-drug resistant TB

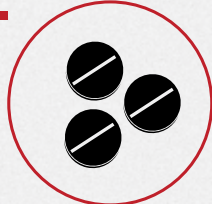
+  **8,000,000** HIV tests for pregnant women

MARKETS IMPROVED FOR THE POOR


UNITAID shapes markets for essential health products, to ensure that improvements are accessible to all, even countries not supported by UNITAID.

+  **80%** price reduction on HIV medicines for kids

+  **80%** price reduction for the best treatments for malaria

+  **60%** price reduction on second-line HIV medicines

+  **40%** price reduction on new rapid test for TB

+  **67** medicines prequalified by the WHO for safe use in developing countries

¹ All results as of 30 June 2012 except for malaria treatments distributed (AMFm)

Chapter One

2012:
UNITAID'S
APPROACH
VALIDATED



As the economic crisis continued to affect development budgets in 2012, UNITAID's approach provided a compelling model and a sound alternative to traditional development funding.

UNITAID's Independent Evaluation — a Business Model to Follow

UNITAID's first independent evaluation, an in-depth assessment of the organization's initial five years, was conducted in 2012. In their final report, evaluators concluded that UNITAID is a 'pioneering innovative financing mechanism' that 'has validated its business model of identifying, selecting and funding market-shaping interventions carried out by implementing partners'.

The evaluation was executed by an independent firm, which had full access to UNITAID documentation and carried out an in-depth analysis of all UNITAID's investments. During the process, over 100 stakeholders including UNITAID Executive Board Members, staff, and implementers were interviewed.

The evaluators concluded that UNITAID's unique approaches could help 'tackle global development challenges beyond HIV/AIDS, malaria and TB'. Among their findings they noted:

On UNITAID market interventions:

The evaluation broadly validated UNITAID's overarching approach of funding time-limited interventions aimed at shaping market outcomes in critical niche markets.

On UNITAID's market-shaping influence:

There are strong indications that many [of UNITAID's] projects achieve better outcomes than those of traditional investments in public health service delivery because of a multiplier effect. This effect is due to other programmes taking advantage of the improved market outcomes of UNITAID-funded projects, such as improved availability or lower prices of products... These market-shaping approaches could provide important lessons to other agencies and countries seeking to increase programme effectiveness.

On UNITAID's multilateralism:

It is highly likely that the successful market and health outcomes could only have been achieved by a multilateral agency - indeed, it is hard to imagine that any bilateral agency or private entity could have achieved what UNITAID has achieved in this time frame.

As part of its review, the evaluation team also visited Kenya and Cameroon to see how market interventions are implemented and to interview government officials and community-level representatives.

“UNITAID has been doing the right things to contribute to significant positive outcomes in the fight against the three diseases.”

Independent Evaluation of UNITAID (December 2012)

INDEPENDENT EVALUATION COUNTRY VISITS

KENYA²



With almost **US\$ 100 million invested in health products for Kenya** by UNITAID, the evaluation team found that UNITAID had achieved a significant impact on public health in Kenya. Among its findings:

- The role played by UNITAID in negotiating cheaper prices for commodities and drugs cannot be overemphasized.
- Evaluators reviewed the pilot project of the UNITAID-funded Affordable Medicines Facility – malaria, which has created a local market for high quality malaria treatments. “During the field interviews of senior medical staff, access to artemisinin-based combination therapies was reported at all levels”, said the evaluators. “There was a significant reduction in the price of the medicines and reduced stock-outs at the government health facilities.”
- An HIV project coordinator in Homa Bay told evaluators ‘the days of crushing tablets and making solutions are long gone’, thanks to UNITAID’s paediatric HIV market interventions.



52,800
kids on
child-adapted
HIV treatment



45,570
adults on
second-line
HIV treatment



Over 40 million
artemisinin-based
combination therapies
distributed

² Figures as of 30 June 2012

CAMEROON³



The independent evaluation noted UNITAID’s clear impact on the decline in HIV/AIDS prevalence and mortality. Cameroon is a UNITAID-contributing member through the air ticket levy. The team found members of the government **very supportive of the country’s decision to contribute to UNITAID** and transparency in its use of funds. Among its findings:

- Thanks to UNITAID’s market interventions, child HIV regimens have gone from 16 doses of syrup per day to just one pill taken morning and evening.
- Government representatives appreciated UNITAID’s model of working with in-country implementers. According to them, **it avoids duplicating existing efforts** and provides ‘savings that allow allocation of funds to other activities’.
- Evaluators found that UNITAID’s interventions have brought paediatric and second-line antiretroviral prices down by nine fold, allowing the government and other organizations to buy treatments at much lower prices than prior to the interventions.



4,489
kids on
child-adapted
HIV treatment



8,542
adults on
second-line
HIV treatment



285,000
HIV tests for
pregnant women
distributed

³ Figures as of 30 June 2012

Innovative Financing — UNITAID is an Example to Follow



François Hollande
President of France

+ “I want to applaud the success of UNITAID, which was financed by a levy on plane tickets. This is the path upon which we have embarked. Now we must take the next step.”

Since its inception, UNITAID has raised 65% of its funds through a small levy on air tickets in nine countries: Cameroon, Chile, Congo, France, Madagascar, Mali, Mauritius, Niger and the Republic of Korea. In addition, Norway allocates part of its tax on CO2 emissions. When the first countries adopted it in 2006, this levy was commonly acknowledged as one of the only innovative financing initiatives to collect small contributions for international development. Even though the average contribution is only US\$ 2, more than US\$ 1 billion has been collected in six years.

During the opening of the 67th United Nations General Assembly, French President François Hollande said that UNITAID’s success was an inspiration to set aside a portion of new funds for global health causes.

A Painless Contribution

An important factor in the success of innovative financing is the ‘painless’ nature of minute transaction levies, both politically and economically, borne arguably by those individuals who can most afford to pay.

In July 2012, the United Nations World and Economic Survey explored UNITAID’s political approach. ‘It seems that parliaments in the participating countries have been willing to adopt the air ticket levy because it would be earmarked for a specific public benefit that is popularly supported’, the report noted. ‘The fact that participating governments are adopting this tax in concert seems to further enhance its political appeal.’

Meanwhile, no evidence has emerged of any negative effect on air traffic. In fact, airlines have recently confirmed their support for the levy. To mark World AIDS Day 2012, Air France attached a video message to ticket confirmation emails, thanking travellers for helping to save lives.

Several other innovative financing options have great potential for the health sector. The concept of innovative financing covers a large range of mechanisms. Amongst others, the International Financial Facility for Immunization (IFFIm), Advanced Market Commitments (AMC) and Debt-to-Health have already proved their worth in raising funds for pandemic diseases.

A promising new mechanism entered the field in 2012, when France became the first country to enact a post-2008 economic crisis financial transaction tax (FTT). It became effective as of August 2012, levying a 0.2% transaction tax on share purchases. In his speech at the United Nations General Assembly in September 2012, President Hollande announced that 10% of the revenues from France’s new FTT would go to development, including the fight against pandemic diseases and climate change.

In the same way as the air ticket levy, the FTT has a very limited impact on the financial sector. According to the International Monetary Fund, Brazil, China, Hong Kong, India, Italy, Singapore, South Africa, South Korea, Switzerland, Taiwan,

the United Kingdom, and the United States have all imposed unilateral taxes on financial transactions, at various times, with various rates. Although the revenues from these mechanisms are not allocated to development, their implementation in so many countries proves the feasibility and wide acceptance of the FTT. In 2011, UNITAID released a ground-breaking study that analysed these taxes and concluded that the introduction of a European FTT would have no significant negative impact on national financial markets.

Early in 2013, European Finance Ministers agreed to implement a financial transaction tax under the ‘enhanced co-operation’ rule. Austria, Belgium, Estonia, Germany, Greece, France, Italy, Portugal, Slovakia, Slovenia and Spain will determine the modalities of this levy, which will be introduced by 2014. The question of whether revenues raised from the European FTT will be allocated to development has not yet been fully debated.



FACTS ABOUT UNITAID’S AIR TICKET LEVY:

- **Does not distort competition:** Applied uniformly to all domestic and international flights
- **Low-cost for passengers:** Ranges from US\$ 1 for economy tickets to US\$ 40 for business and first class travel
- **Not paid by airlines:** Zero effect on revenue and profitability, air traffic, travel industry jobs and the tourism industry in general
- **Not applied** to inbound and transit passengers
- **Implemented by existing national authorities:** No new administrative machinery or mechanism needs to be created – no additional cost.

MOZAMBIQUE 2012

Lives Saved — UNITAID's Paediatric HIV Programme

+ “We can learn a great deal from UNITAID which has led the way in creating a new revenue stream that has saved hundreds of thousands of lives”

President Bill Clinton

International Aids conference,
July 2012

Very few children are born with HIV in wealthy countries nowadays, so there is little incentive for the pharmaceutical industry to develop child-friendly medicines. In 2006, UNITAID identified this gap and invested heavily in paediatric HIV medicine and HIV testing of infants in developing countries, through a programme implemented by the Clinton Health Access Initiative (CHAI). Suppliers were given an incentive to manufacture new child-adapted formulations via UNITAID grants. Several generic suppliers entered the market – negotiations with these manufacturers and increased competition led to price reductions of up to 80%.

Over 400,000 kids are now taking adapted HIV medicines.



Pictured, children living with HIV in Mozambique – all on UNITAID-financed treatment.

SWAZILAND 2012

After UNITAID — Swaziland’s Successful Transition to Domestic Funding

Swaziland has the world’s highest HIV/AIDS prevalence rate and a generation of kids orphaned by the disease. In recognition of this problem, its government is committed to ensuring the best treatment for children living with HIV and has made this a priority for domestic funding. **The country is now moving on from UNITAID support of its paediatric HIV programme, and will be entirely self-sufficient by the end of 2013.**

“Assistance is not forever and when it ends, we must not be caught by surprise”, says Dr Velephi Okello, National Antiretroviral Treatment Coordinator of the Swaziland National AIDS Programme.

UNITAID market interventions are time-limited. They are designed to make needed health products available and affordable on a sustainable basis. Before a project ends, UNITAID works with its partners to ensure that funding for the improved product access will be continued. In the majority of the 40 countries supported by its paediatric HIV programme, UNITAID and its implementer CHAI have transitioned funding to domestic sources or external donors, including the Global Fund to Fight AIDS, Tuberculosis and Malaria or the President’s Emergency Plan For AIDS Relief (PEPFAR).

In Swaziland, the Ministry of Health will fund all paediatric HIV drugs.

Swaziland has already made remarkable progress in paediatric HIV treatment. In 2006 only 1,500 children were on treatment. **By 2012, UNITAID funding helped over 7,000 children to take child-adapted medicines: about 70% of those in need.** The Ministry of Health, with assistance from CHAI, successfully replaced the bulky, foul-tasting syrups that were used to treat kids with easier-to-take pills.

One challenge is to ensure that manufacturers continue to provide for this relatively small market. Swaziland has one of the most successful programmes in Africa to prevent new infections through childbirth, but children are still being infected – often during breastfeeding, according to Dr Okello. The declining number of children born with HIV means a shrinking market for manufacturers.

“CHAI has helped us to forecast properly for paediatric HIV medicines so we can budget appropriately”, says Dr Okello. “Every quarter, our forecasting team looks at the numbers of children in need of treatment and determines which drug regimens should be ordered.”

According to Tibuyile Sigudla, Antiretroviral Pharmacist at the Central Medical Stores, this process provides more reliable demand information for manufacturers. “We are still relying on the building blocks set up by CHAI and UNITAID and we align our paediatric drug orders with the same time periods used during the UNITAID project”, she says.

UNITAID has assisted Swaziland through this transition period, which began in 2011; just as it helps other countries that are moving on to new funding sources. Emergency funding will be available until end-2013, in case there are unforeseen circumstances that reduce the availability of medicines during the transition period.

“2011 was difficult because of a fiscal crisis, but, in 2012, the government released funds for paediatric HIV treatments and we have been able to procure drugs”, says Dr Okello. “We haven’t had shortfalls for children.”



Photo shows HIV health worker walking to meet patients.

“Assistance is not forever and when it ends, we must not be caught by surprise.”

Dr Velephi Okello

National ART Coordinator of the Swaziland National AIDS Programme.

SOUTH AFRICA AND BRAZIL 2012

Market Impact in Action

+ “We have been able to get more people tested within the budget that we have and we’ve saved money on tests and treatments”

Lindiwe Mvusi,
Director of TB Control,
Department of Health, South Africa

UNITAID market interventions have a ‘multiplier effect’, allowing other global health funders and governments to take advantage of lower prices or better products that are the result of UNITAID-funded projects. In other words, even countries that do not directly receive UNITAID support can benefit from UNITAID’s market impact.

In August 2012, UNITAID, PEPFAR, USAID, and the Bill & Melinda Gates Foundation announced the achievement of a 40% global price reduction for a new rapid diagnostic test for TB in 145 high-burden and developing countries. A perfect example of market impact: this deal was an important component of UNITAID’s scale up of the GeneXpert® TB test (see page 56 for more information).

Brazil and South Africa achieved cost-savings of US\$ 2.23 million in only three months through this price reduction, despite not being directly supported by UNITAID.

South Africa has become the world’s biggest implementer of GeneXpert® TB diagnostics, while Brazil will be rolling the technology out in 2013.

The multiplier effect from UNITAID’s market impact has been felt in both countries. “We’ve been able to procure more cartridges thanks to this price reduction”, said Lindiwe Mvusi, Director of TB Control at the Department of Health in South Africa. “We have been able to get more people tested within the budget that we have and we’ve saved money on tests and treatments.”



**US\$ 2.23 million:
cost-savings achieved in only
three months for a rapid TB test
in two countries not directly
supported by UNITAID –
Brazil and South Africa.**

Chapter Two

**UNITAID'S
MEMBERS**



UNITAID's members include 28 member states and one foundation: Benin, Brazil, Burkina Faso, Cameroon, Central African Republic, Chile, Republic of Congo, Cote d'Ivoire, Cyprus, France, Gabon, Guinea, Liberia, Luxembourg, Madagascar, Mali, Mauritius, Morocco, Namibia, Niger, Norway, Republic of South Korea, Sao Tome and Principe, Senegal, South Africa, Spain, Togo, United Kingdom and the Bill and Melinda Gates Foundation.

France's Support of UNITAID



Laurent Fabius
French Minister of Foreign Affairs

France is a UNITAID founding country and its leading donor, thanks to the revenue from the international solidarity levy on airline tickets. France is pleased to have contributed to the success of this initiative, which rallies developed countries, emerging countries, low-resource countries and civil society around the same objectives.

Together, and thanks to the innovative programmes developed by UNITAID, it has been possible to significantly cut the price of medicines for the three major pandemics, and to accelerate the market availability of better-adapted drugs, in particular for children.

The successes scored by UNITAID demonstrate the feasibility and added value of innovative financing for development. The solidarity levy on airline tickets in France has not had a negative impact on air traffic or on tourism. All revenue generated by this levy has been used to finance health programmes in developing countries.

Access to quality drugs by people in developing countries is a priority for French development policy. Our commitment to UNITAID is complementary to our support for the Global Fund to Fight AIDS, Tuberculosis and Malaria. I invite all countries to establish innovative financing mechanisms for development and to join us in the useful UNITAID adventure.

UNITAID Contributing Members

UNITAID's contributing members provide sustainable long-term funding in order for it to shape markets for global health. Nine countries currently contribute through the air ticket levy, which has proven to be a predictable and 'crisis-proof' source of income. Meanwhile, other countries such as the United Kingdom make traditional multi-year contributions. Together, these funds allow UNITAID to plan its strategic market interventions effectively.

UNITAID is notable for the remarkable make-up of its multilateral membership and the diversity of support, which includes both wealthy and developing countries. Some countries, such as the Republic of Korea and Chile, have implemented the air ticket levy, while an emerging country donor, Brazil, has chosen a matching fund mechanism.

Furthermore in 2012, UNITAID welcomed its first contribution from the private sector, specifically, US\$ 770,000 from the HNA Group. The Chairman of the HNA group, Mr Chen Feng, also continued to advocate for UNITAID.

One particularly progressive factor that differentiates UNITAID from other health organizations is the inclusion of African members. The reason for this success is that the money raised by innovative financing mechanisms is provided only by the individuals who can arguably afford to pay.

The Air Ticket Levy in Africa

Several African countries are using their vibrant economic growth to support UNITAID and to generate additional domestic resources for the response to HIV/AIDS, malaria and TB. Cameroon, the Republic of Congo, Madagascar, Mali, Mauritius and Niger have all implemented UNITAID's air ticket levy, applying their own rates to either domestic or international flights. Hence, even countries that benefit from UNITAID support are also contributing members. They have recognized the value of being part of a global initiative and use its leverage to access better prices for medicines for their own populations.

UNITAID and Market Shaping: A Long Term Commitment

The United Kingdom was one of the first countries to recognise the potential of market-shaping approaches to make a real difference for global health. Through the Department for International Development (DFID), it has prioritised initiatives that aim to transform global health product markets and provide good value for money for its investments.

Since its creation, UNITAID has been at the core of the United Kingdom's support for market-shaping. In 2007 the UK made a 20 year commitment to UNITAID of up to 60 million Euro per year.

UNITAID intervenes in markets to create a new status quo, paving the way for large-scale cost-savings and improved products, ready for uptake by both disease-endemic countries and the global health organisations which support them. The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria is one such organisation. In 2012 for example it has been able to benefit from the three-fold price reduction and improved products for HIV antiretroviral treatments for adults and children which UNITAID has achieved. This has enabled it to save millions of dollars and provide better health outcomes to millions of people. So in addition to the direct impacts of its grants – in terms of health impacts and healthier markets – DFID's investment in UNITAID also adds value to our complementary investments, in new product development through our research budget; in AIDS, TB and Malaria results through the Global Fund; and in country-level support to

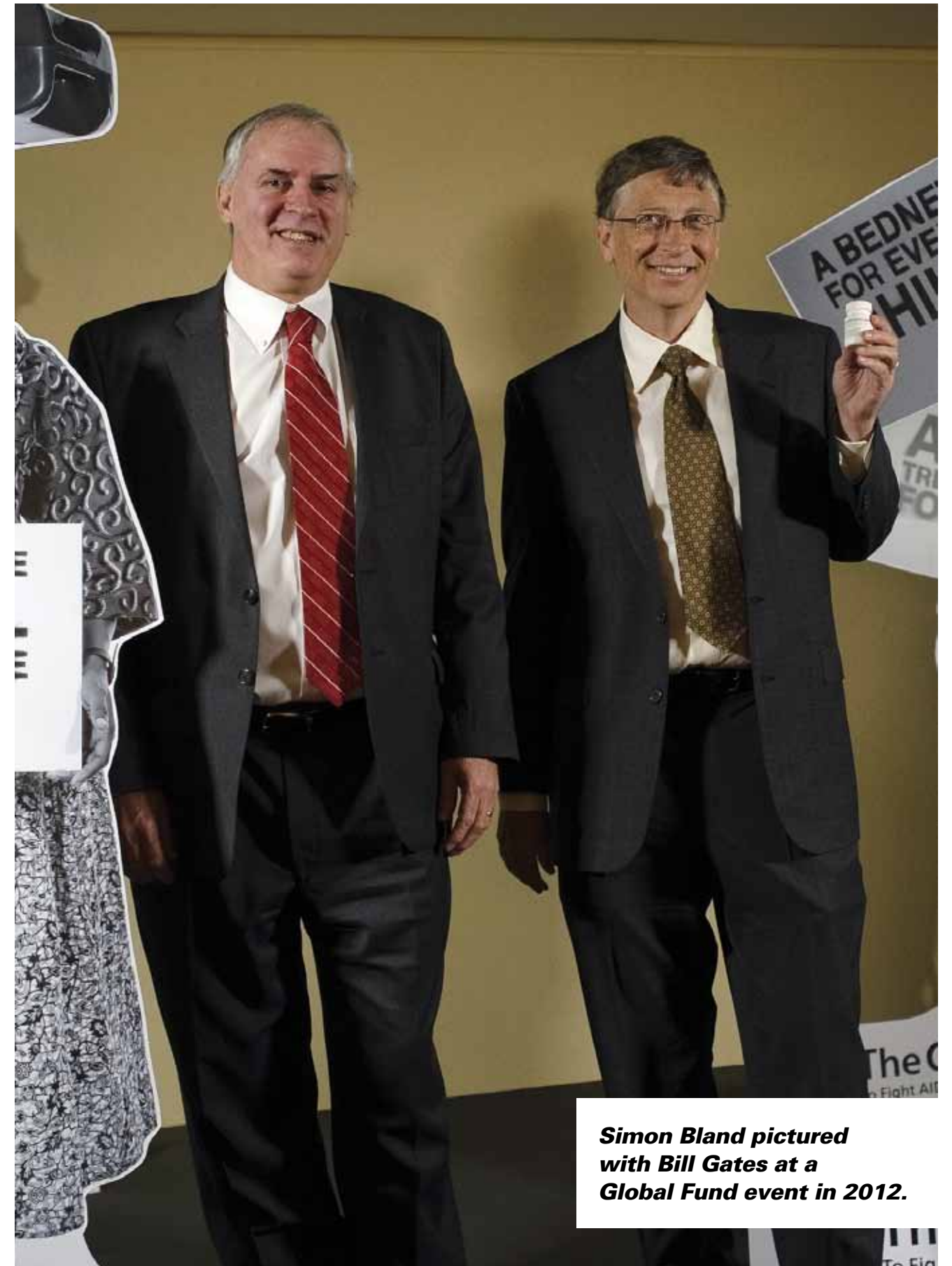
health systems and services through our bilateral programmes.

After six years UNITAID has had some notable successes across the three diseases. Market shaping has proven to be a viable proposition with benefits reaching far beyond projects' geographical boundaries. Going forward, the challenges are well recognised. In a world of scarce resources there is continual need for UNITAID to prioritise the very best opportunities for intervention and demonstrate that it provides the very best value for money. As an organisation which relies so heavily on partnerships, it must ensure it has a suitably broad range of capable implementers to make the investment goals a reality. And as a market catalyst it must ensure that its interventions are ever more strategically focused on achieving impact. UNITAID's new Strategy 2013-2016 sets out a good platform for this and credible implementation will be vital in making it happen.

In a short space of time UNITAID has forged a pioneering role for itself in global health and will continue to be valued for its ability to innovate. As trusted partners, UNITAID and the Global Fund will - together - continue to play a key role in the fight against the three diseases.

Simon Bland

Head of the Global Funds Department, DFID
Chair of the Global Fund to Fight HIV/AIDS,
Tuberculosis and Malaria Board



Simon Bland pictured with Bill Gates at a Global Fund event in 2012.



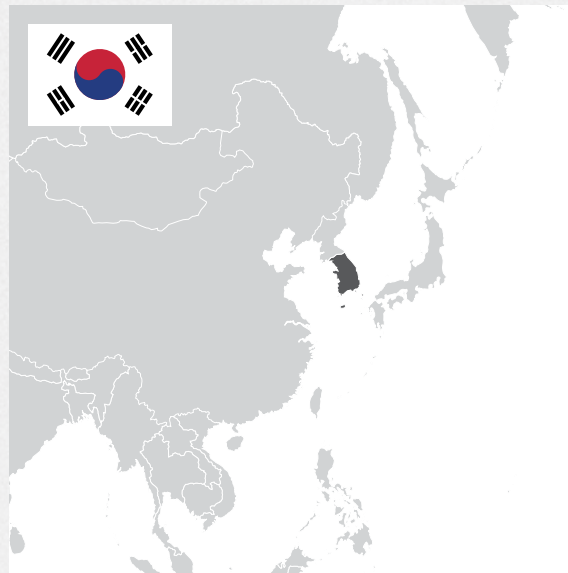
Spotlight on **KOREA**

In 2007, the Republic of Korea became the first Asian country to implement an air ticket levy. Called the 'Global Poverty Eradication Contribution', the levy of 1000 won is applied to every flight leaving Korean soil. Around 15 billion won has been collected each year, with about half going to UNITAID.

In the run-up to the five-year anniversary of the ticket levy in 2012, the Korea International Cooperation Agency conducted an evaluation of the mechanism. Among its findings: a survey of 1000 Korean citizens under 18 years of age found that 82% of respondents thought that air ticket levy was 'necessary'.⁴

In August 2012, the Korean National Assembly voted to extend the air ticket levy for another five years.

Only twenty years ago, the Republic of Korea was an aid recipient. Today, it is a major donor and a member of the OECD Development Co-operation Directorate. With UNITAID and the air ticket levy, it is also at the forefront of innovative initiatives to raise more money for development.



+ US\$ 1
per ticket

+ "It is time for the Korean people to be proud of their pioneering role on the global stage, and to take note of Korea's contribution to UNITAID's fight against diseases in Africa."

Myoung-hwan Cho

Professor
Department of Biological Sciences
Konkuk University

⁴ Korea International Cooperation Agency, *Evaluation Report of the Korea Air Ticket Solidarity Contribution*, 2012



Spotlight on **CHILE**

Chile was the first country to adopt the airline ticket levy for UNITAID. Today, it applies a flat rate of US\$ 1 per ticket on international flights.

Along with France and Brazil, Chile was an early supporter of innovative financing for development – it was one of the three sponsors of the January 2004 'Geneva Declaration', calling on the international community to create new sources of funds for global poverty eradication. In early 2006, the Chilean government announced its intention to establish an air ticket levy and it began collecting funds by March 2006. UNITAID was officially launched by Brazil, France, Chile, Norway and the United Kingdom on 19 September 2006 at the 61st Session of the General Assembly of the United Nations.

Since then, Chile has supported UNITAID with a fixed amount from the proceeds of the air ticket levy.

"There has been absolutely no effect on air traffic or the economy," said noted Chilean economist Ricardo Ffrench-Davis Muñoz of the University of Chile, who has worked with successive Chilean governments to implement innovative financing initiatives. "Chile's experience with the air ticket levy has been a positive lesson for other small countries looking to take part in larger global poverty eradication initiatives."

In September 2012, Chile reiterated its long-standing commitment to UNITAID during a visit to the country by UNITAID Executive Director Denis Broun.



+ US\$ 1
per ticket

+ "UNITAID's multilateral model reaffirms Chile's commitment to South-South cooperation, and at the same time, ensures real benefits and opportunities to increase access to medical products for HIV/AIDS, tuberculosis and malaria. UNITAID provides its members with a concrete way to implement the principle of equity in health."

Dr Luis Castillo

Undersecretary of Assistance Networks

UNITAID CONTRIBUTING MEMBERS

Member contributions to UNITAID since 2006.



AFRICA

Members	2006-2012 contributions (US\$ 000)	2012 contributions (US\$ 000)
Cameroon	1,430	412
Congo	1,090	
Guinea	49	
Madagascar	30	3
Mali	928	
Mauritius	8,741	1,709
Niger	281	



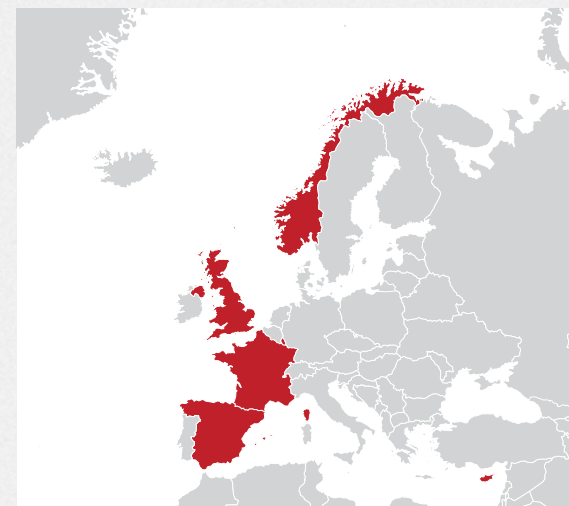
AMERICAS

Members	2006-2012 contributions (US\$ 000)	2012 contributions (US\$ 000)
Brazil	37,202	
Chile	24,043	3,643



ASIA

Members	2006-2012 contributions (US\$ 000)	2012 contributions (US\$ 000)
Republic of Korea	35,000	7,000



EUROPE

Members	2006-2012 contributions (US\$ 000)	2012 contributions (US\$ 000)
Cyprus	2,066	488
France	1,140,307	143,408
Luxembourg	1,961	
Norway	131,096	21,546
Spain	81,603	
United Kingdom of Great Britain and Northern Ireland	349,259	87,171



FOUNDATIONS

Members	2006-2012 contributions (US\$ 000)	2012 contributions (US\$ 000)
Bill and Melinda Gates Foundation	60,000	10,000
Millennium Foundation	1,072	1,072

Chapter Three

**NEW
INVESTMENTS
IN 2012**



UNITAID incubates and develops innovative market interventions that improve the lives of people in developing countries by addressing market shortcomings for HIV/AIDS, malaria and TB health products. The following chapter describes this process and introduces some new grants that were initiated in 2012.

A Disciplined Grant-Making Process to Shape Markets

In June 2011, the UNITAID Executive Board gave the green light to launch an enhanced proposal development and review process – essentially rethinking how the organization makes its investments. **In 2012, funding decisions were made using this process:** UNITAID's Executive Board approved US\$ 237,253,061 of investments, which included 15 new market interventions – the largest amount approved by UNITAID in a single year.

Thanks to this approach, UNITAID successfully entered the field of point-of-care diagnostics, and has become a leader in shaping markets for these game-changing technologies. In addition, new investments were approved that will allow hundreds of thousands of children to access better and more affordable medicines for the three diseases. These new investments – described in this chapter – involve new implementers and new project types, including interventions that focus on enabling market entry of new medicines and tests.

UNITAID's enhanced process for funding market interventions is based on expert analysis. It is open-minded, informed by evidence, and forward thinking: monitoring for new opportunities to develop market-shaping interventions is an on-going activity. The process allows for better targeting of investments and maximizes value for money.



WHAT CONSTITUTES A MARKET SHORTCOMING?

- **Availability:** The optimal medicine or technology to effectively prevent, diagnose or treat a particular disease or condition is not currently available.
- **Affordability:** The medicine or technology is offered at a price that imposes an unreasonable financial burden on governments, donors, individuals, or other payers.
- **Quality:** The medicine or technology is of sub-standard quality or there is a lack of reliable information about the quality of the product. This includes not only the quality of the final, finished product, but also the quality of starting and intermediary materials used to manufacture the final product.
- **Acceptability/adaptability:** The medicine or technology is not available or accessible in a format, formulation, or dose that is appropriate for use in a given population or setting.
- **Delivery:** Supply chain management systems are unable to equitably provide the right product or technology to the right person, in the right presentation, at the right dose, and at the right time with the least potential for error and at the lowest cost.

+ **“Working with UNITAID, we developed a market intervention to ensure the supply of child-friendly treatments. This will allow the TB Alliance, for the first time, to expand our work and focus on telescoping the time it takes for new paediatric TB drugs to reach children in need.”**

Mel Spigelman
CEO, TB Alliance

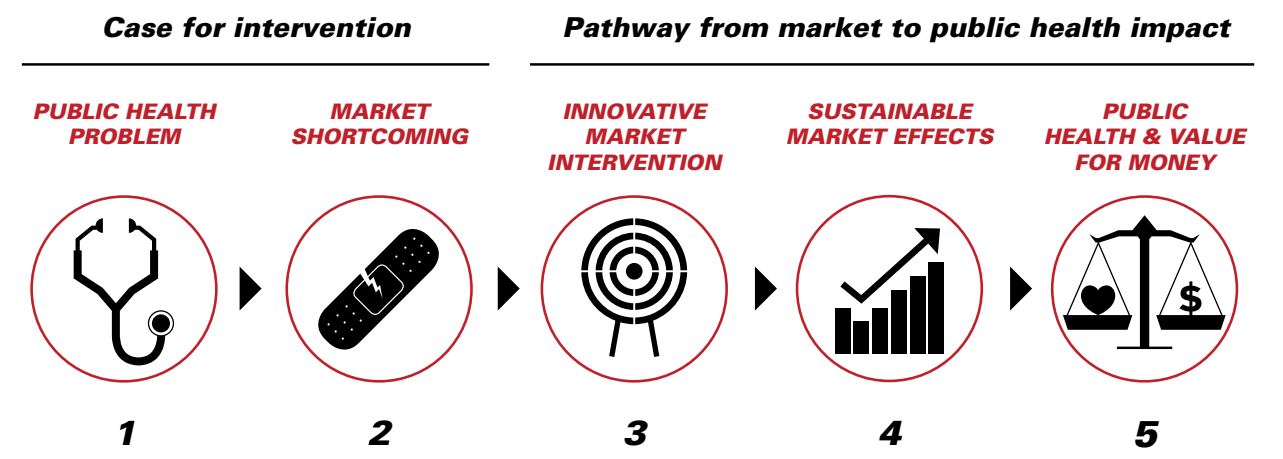
+ **“There was a productive back-and-forth between UNITAID and DNDi, including scrutiny and tough questions that helped us sharpen our proposal - particularly around affordability and price.”**

Rachel Cohen
Regional Executive Director, DNDi



MARKET IMPACT FRAMEWORK

The **UNITAID Market Impact Framework** is a technical framework that defines UNITAID's market-shaping approach. The logic in this framework is applied consistently across all key UNITAID activities: strategic investment prioritization; proposal development, technical evaluation, and selection; portfolio and project management; monitoring and evaluation; and impact assessment.



HOW UNITAID MAKES GRANTS

2 GENERATE IDEAS

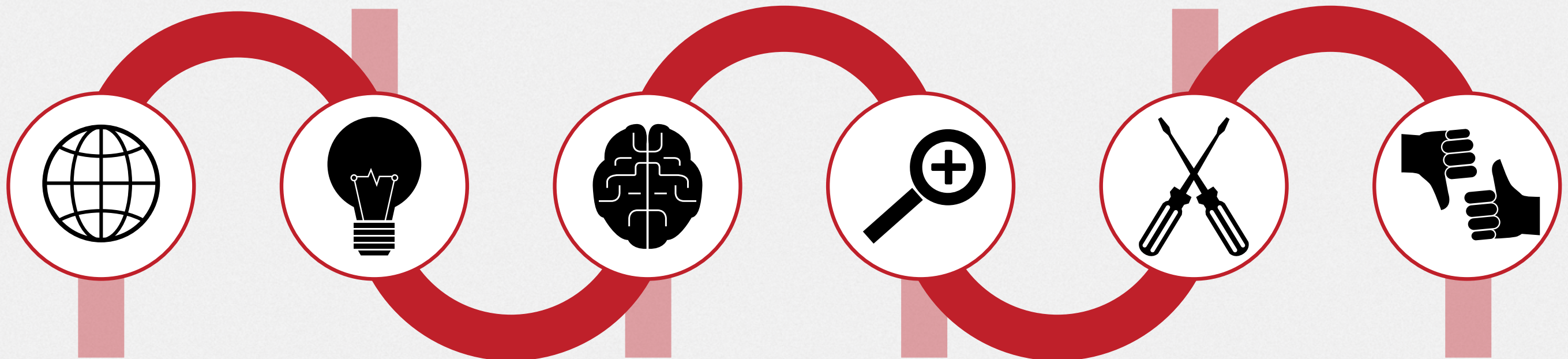
Through landscape reports, UNITAID gains a clear understanding of market shortcomings and new opportunities for investment

The incubation process for ideas begins.

5 DEVELOP/DESIGN

UNITAID chooses the most promising letters of intent, from organizations that it is confident can do the work

Successful proponents are invited to submit full proposals and receive guidance from UNITAID. Proposals are shaped to ensure they are catalytic; sustainable after UNITAID's initial investment; and will lead to healthier populations.



1 EXPLORE

UNITAID produces landscape reports that map the product markets for HIV/AIDS, malaria and TB. These reports provide up-to-date intelligence on:

Disease: The public health problem and access issues to be addressed.

Technology: Overview of products on the market and how the pipeline of new products could address any disadvantages.

Market: Overview of market from a supply and demand perspective.

3 EXPERT INPUT

Informed by its market intelligence, UNITAID seeks expert advice on potential opportunities for market-based interventions that can improve access to health products

UNITAID brings people together in market forums to further develop and refine opportunities.

4 SEEK PROPOSALS

UNITAID invites applicants to submit a letter of intent outlining their ideas. Potential proposals that are consistent with UNITAID's Strategic Objectives are identified

UNITAID actively seeks ideas that are aligned with its Strategic Objectives, but also opens funding routes for innovative ideas that are within its mandate.

6 DECIDE

Submitted proposals undergo a robust technical evaluation by independent experts to help inform final decisions on funding commitments by UNITAID's Executive Board

The UNITAID Executive Board decides which proposals to fund, based upon guiding principles of UNITAID's Constitution.

A Market Dynamics Approach to Public Health

+ “As a start-up making a point-of-care malaria diagnostic product, UNITAID’s landscape reports meant we didn’t lose time figuring out the competition: the reports were extremely valuable”

Wouter Bruins,
Amplino

UNITAID plays a leading role in improving public health by using market approaches. In order to navigate complex market spaces, UNITAID has developed a set of tools to target its investments and to aid other global health stakeholders involved in shaping markets for HIV, TB, and malaria commodities.

Landscape Reports

The UNITAID Secretariat regularly publishes market ‘landscape reports’ to provide market intelligence on products that are used for the diagnosis, prevention and treatment of the three diseases. These reports compile research and analyses conducted by UNITAID staff and by external experts to provide the information needed to identify and design high-impact market interventions.

UNITAID’s landscape reports are developed with substantial input from key players, including donors, international organizations, and leading experts in the field.

The first landscape reports were produced in 2011. Using this information and expert review of proposals, UNITAID selected and funded a

number of innovative diagnostic interventions in 2012, investing approximately US\$ 200 million in this field. Technical versions of UNITAID’s landscape reports are made publically available and have become a public good for others working in global health. They are updated every six months.

All landscape reports are available at:
<http://www.unitaid.org/how/market-approach>

Market Forums

UNITAID landscape reports are discussed in Market Forums that involve a broad range of stakeholders. In 2012, UNITAID conducted its first Market Forum to discuss UNITAID’s malaria landscape reports and attract new partners with

capacity to implement interventions on UNITAID’s behalf. These forums are novel, in that they bring together market experts from different product types within a disease (medicines, preventives, diagnostics) to discuss market approaches to a disease in a wide ranging manner.

The Market Share

In 2012, UNITAID launched the ‘Market Share,’ an e-newsletter covering the latest news on treatment, diagnostic, and preventive commodities for HIV, TB, and malaria excerpted from journals, newspapers, blogs and other global health publications.

The market share is available at:
<http://www.unitaid.org/themarketshare>



UNITAID STRATEGIC OBJECTIVES 2013-2016

UNITAID’s 2013-2016 Strategy includes a set of Strategic Objectives. These objectives describe how UNITAID intends to contribute to the long-term goals of the global health community for HIV/AIDS, TB, and malaria by increasing access to the key treatment, diagnostic, and preventive products to prevent new infections and provide effective treatment.

1. Increase access to simple, **point-of-care diagnostics** for HIV/AIDS, TB, and malaria.
2. Increase access to affordable, adapted **paediatric medicines** to treat HIV/AIDS, TB, and malaria.
3. Increase access to emerging medicines and/or regimens, as well as new formulations, dosage forms, or strengths of existing medicines that will **improve the treatment of HIV/AIDS and co-infections such as viral hepatitis**.
4. Increase access to artemisinin-based combination therapies (ACTs) and emerging medicines, including paediatric formulations, which in combination with appropriate diagnostic testing will improve the **treatment of malaria**.
5. Secure supply of **second-line TB medicines**, and increase access to emerging medicines and regimens that will improve treatment of both drug-sensitive and multi drug-resistant TB.
6. Increase access to **preventives for HIV/AIDS, TB and malaria**.

New Technologies to Improve the Quality of HIV Care

Mozambique stretches 2,300 km along the Indian Ocean from South Africa to Tanzania. Over half the population lives in rural communities, and the country has one of the lowest ratios of health care workers to people globally. HIV prevalence is over 11%, one of the highest rates in the world.

Nevertheless, Mozambique is seeing a quiet revolution in its rollout of UNITAID-funded 'point-of-care' HIV diagnostic technology. This presents a tantalizing vision of the future for African countries at the centre of the HIV epidemic. These technologies bring essential HIV testing and monitoring closer to where patients live, reducing the need for centralized laboratories and highly skilled technicians.

In only a few years, pilot projects, using these portable technologies, have halved the number of HIV-positive patients that do not return to the clinic after an initial diagnosis in some areas of Mozambique.⁵ In large district hospitals, regional clinics or even on kayaks in the remote north of the country, Mozambican health workers have used these new technologies to provide patients with results quickly and then offer them immediate treatment.

In 2011, UNITAID began to landscape the market for diagnostic products, and later launched a

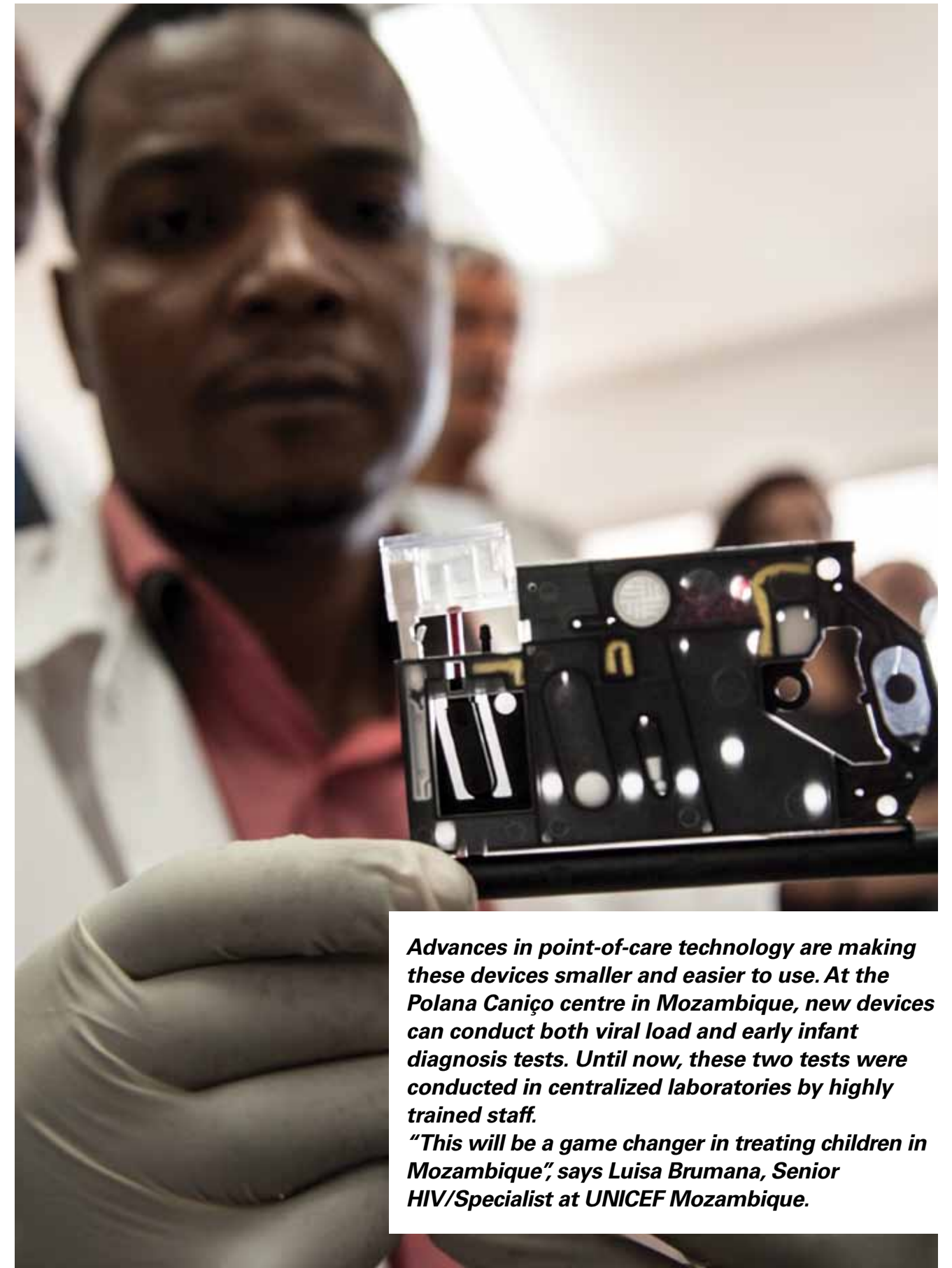
call for new proposals. Following this process, UNITAID announced, in 2012, investments of more than US\$ 140 million to support the introduction and scale up of innovative new HIV diagnostics through a number of market interventions. This amounts to the largest ever investment in diagnostic products.

UNITAID investments will target point-of-care products for the three most critical diagnostic tests for people living with HIV, which are necessary to make immediate clinical management decisions:

CD4 Testing: A measure of the patient's immune system, known as the CD4 count, is used to determine when HIV infected patients need to start antiretroviral therapy.

Viral Load Testing: The results of these tests signal when patients need to make the life-saving switch from first-line to second-line antiretrovirals.

Early Infant Diagnosis: Infants retain maternal antibodies against HIV for a period after birth: hence, a test that detects anti-HIV antibodies could result in a misleading result and misdiagnosis. The best way to test for HIV infection in infants is to use DNA testing; current techniques can only be carried out by skilled personnel and require sophisticated laboratory equipment.



Advances in point-of-care technology are making these devices smaller and easier to use. At the Polana Caniço centre in Mozambique, new devices can conduct both viral load and early infant diagnosis tests. Until now, these two tests were conducted in centralized laboratories by highly trained staff.

"This will be a game changer in treating children in Mozambique", says Luisa Brumana, Senior HIV/Specialist at UNICEF Mozambique.

⁵ Jani IV et al. *Effect of point-of-care CD4 cell count tests on retention of patients and rates of antiretroviral therapy initiation in primary health clinics: an observational cohort study.* The Lancet, advance online publication, 26 September 2011, doi:10.1016/S0140-6736(11)61052-0

Challenge and market shortcomings:

UNITAID's 2011 and 2012 HIV diagnostics landscape reports revealed numerous market shortcomings that contribute to poor access to testing for CD4, viral load and early infant diagnosis. Traditional diagnostics provide good results, but they require significant infrastructure and skilled technicians. They are very expensive and are not available in many of the settings where they are most needed.

UNITAID's landscape reports also demonstrated the great promise represented by several innovative point-of-care diagnostic products in the development pipeline. These products are expected to come to market in the next few years. They offer enormous potential in terms of lower prices and ease of use in remote settings that lack highly skilled staff and sophisticated infrastructure.

Mozambique offers an example of the benefit of point-of-care diagnostics. One challenge was the considerable loss to follow up of HIV positive patients in this country. In the Polana Caniço health facility in Mozambique's capital city Maputo, blood samples were collected once a week and sent to laboratories for CD4 analysis. For patients living in the outskirts of the city or in rural areas, the difficulty and cost of travel meant that many never returned to get their result. For patients that did return, it could take weeks or months to receive the results. Loss to follow up can exceed 50% in similar settings throughout Africa: patients may not return to the health care system until they are seriously ill.

In 2010, UNITAID and the Clinton Health Access Initiative (CHAI) started to pilot new point-of-care diagnostic CD4 devices in Mozambique. The devices can operate for eight hours without electricity and produce rapid results, with a printout available on the spot. According to Dr Ilesh Jani, Director of Mozambique's National Institute of Health, the introduction of these devices has seen a considerable decrease in patient loss to follow up. Waiting times for results at Polana Caniço have dropped from one month to 20 minutes, thanks to the new devices. Patients can, in

theory, be started on antiretroviral treatment on the same day as they receive their diagnosis.

Apart from Mozambique and Zimbabwe, point-of-care technologies have yet to be deployed on a large scale. Significant barriers still exist to introduce newer products into communities that are in the greatest need of them. Research and development for point-of-care products is complex and expensive. Until recently, few incentives existed for large, established diagnostic manufacturers to develop affordable, easy-to-use, point-of-care equipment designed specifically for low-resource settings. A few suppliers dominate the market, with limited competition for these essential tests. Currently, no viral load or early infant diagnosis tests are available on the market as a point-of-care test.



Market Interventions:

In 2012, the UNITAID Executive Board approved four complementary investments to create a healthy market for point-of-care HIV diagnostic products.



IMPROVE ACCESS TO, AND DECREASE THE PRICE OF, POINT-OF-CARE HIV DIAGNOSTICS

Amount Committed: US\$ 20 Million
Implementers: Clinton Health Access Initiative (CHAI)/UNICEF

The project will lower barriers and accelerate access to point-of-care HIV diagnostics in seven high-burden countries: Ethiopia, Kenya, Malawi, Mozambique, Tanzania, Uganda and Zimbabwe. Beyond the direct public health impact of improving testing services in these countries, the project will also impact markets for these projects more broadly. UNITAID's purchasing power will be leveraged to drive demand and lower costs to ensure that testing sites outside the target countries also have access to high quality, affordable point-of-care HIV diagnostics.

The target for the project is to increase the number of testing sites in the seven target countries from about 650 in 2010 to more than 2,200 by 2014, according to CHAI and UNICEF.



OPP-ERA PROJECT

Amount Committed: US\$ 2.4 Million
Implementer: France Expertise Internationale (FEI)

This grant aims to stimulate the market entry of new manufacturers and suppliers of viral load and early infant diagnosis technologies, thus reducing the price of these tests. OPP is an innovative system to detect HIV viral load, which enables equipment and reagents from different manufacturers and suppliers to be used together. This diagnostic system is flexible, rapid, and easy to use, with appropriate-sized equipment for peripheral settings. The OPP system can be used not only for HIV viral load testing and early infant diagnosis, but also to detect other infectious agents.

UNITAID will finance OPP-ERA for an initial pilot stage in 4 countries: Burundi, Cameroon, Côte d'Ivoire, and Guinea.



OPERATIONAL RESEARCH IN HEALTH SYSTEMS

Amount Committed: US\$ 28.7 million
Implementer: Médecins Sans Frontières (MSF)

This project will implement point-of-care CD4 and routine viral load testing for HIV treatment monitoring in eight MSF-supported HIV/AIDS programs in Africa: Lesotho, Malawi, Mozambique, South Africa, Uganda and Zimbabwe. This project will help countries, developers, and funders better understand how novel HIV diagnostics fit within a healthcare system, and drive needed policy change to allow products to be used in country.

MSF aims to demonstrate the feasibility, cost-effectiveness and positive effect on patient outcomes of radically decentralising viral load monitoring and CD4 testing from top level reference laboratories down to district level facilities.

According to MSF, more than 207,000 patients will receive at least one viral load test during the three years of the project.

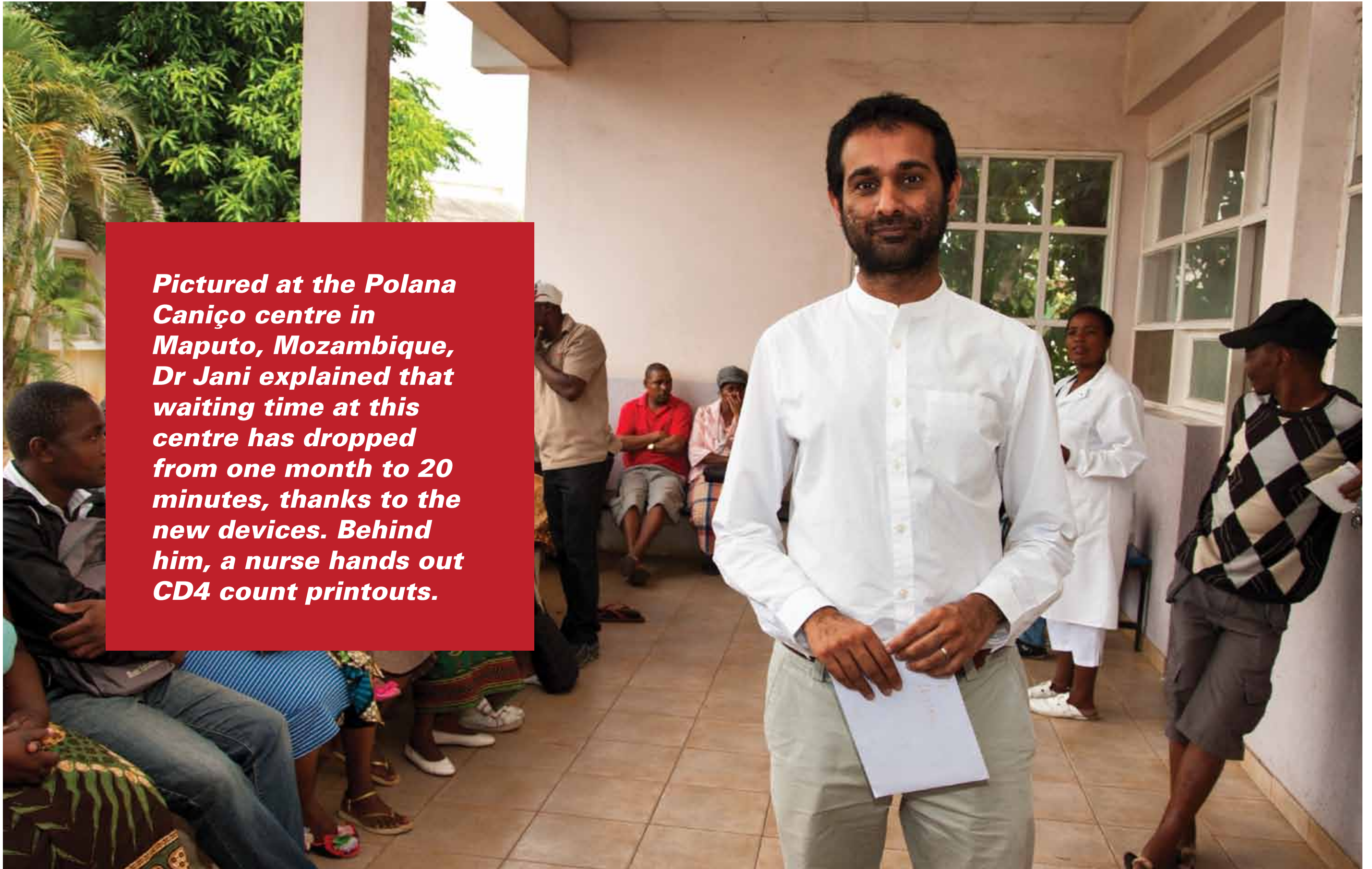


MARKET ENTRY OF POINT-OF-CARE HIV DIAGNOSTICS

A key component of these interventions will be the support for market entry initiatives. UNITAID will help new manufacturers with diagnostic products in late-stage development to overcome the hurdles to putting their products on the market. Accelerated market entry of these products will give developers the incentive to enter the market, be competitive and continue to innovate.

UNITAID will provide funding to four point-of-care diagnostics developers – for three CD4 and one viral load/early infant diagnosis tests – to support completion of final field validation trials, product registration, and other late-stage commercialization steps. This will accelerate the launch and availability of these products, and induce market competition.

Pictured at the Polana Caniço centre in Maputo, Mozambique, Dr Jani explained that waiting time at this centre has dropped from one month to 20 minutes, thanks to the new devices. Behind him, a nurse hands out CD4 count printouts.



Addressing the Neglected Disease of Childhood Tuberculosis

+ “We have to split adult formulations and getting the right dose for children is challenging. We urgently need appropriate formulations.”

Dr Anneke Hessling,
Desmond Tutu TB Centre

South Africa's Dr Anneke Hessling, from the Desmond Tutu TB Centre, and Dr Adrie Bekker, a neonatologist at the Tygerberg Children's Hospital, are at the frontline of the struggle to provide adequate TB treatment for kids. They care for Ayanda, a baby boy born prematurely.

Ayanda was diagnosed with TB shortly after birth and spent five months in hospital on daily treatment.

Since he could not swallow pills, Ayanda needed intravenous TB drugs in the beginning. But even if he could take pills, there is still no optimal treatment. Today, there are no correctly formulated TB drugs designed for children and for the youngest children like Ayanda, there is often uncertainty even about what the dose should be.

“We have to split adult formulations and getting the right dose for children is challenging”, says Dr Hessling. “For babies, not only is it difficult to get the drugs into them, but we don't actually know if the recommended dose is safe. We urgently need appropriate formulations.”

In December 2012, the UNITAID Executive Board committed up to US\$ 16.7 million to the TB Alliance to support the development and production of appropriate paediatric TB medicine formulations.

Challenge and market shortcomings:

Since 2007, UNITAID had been addressing paediatric TB through a market intervention with the Global Drug Facility of the Stop TB partnership. UNITAID investments enabled price reductions of up to 30% for key child TB formulations. However, in 2010, the WHO changed its guidelines for treating children with TB, recommending higher dosages.

So today, there are no appropriate medicines for the 500,000 new cases of paediatric TB annually. Infants and young children are at increased risk of suffering from severe forms of TB that can leave them blind, deaf, paralysed or mentally disabled. TB spreads in close quarters, affecting whole families.

Many children are never diagnosed and the WHO was only able to provide the first official estimate of paediatric TB deaths in 2012: 64,000 in 2011.⁶ Public health experts agree that the actual number of child deaths is likely to be significantly higher. Nevertheless, the small number of cases means there is no market incentive for manufacturers to make adapted formulations.

The goal of UNITAID's new paediatric TB grant is to produce medicines that adhere to the new guidelines.

Market Intervention:

TB Alliance and UNITAID aim to develop a correctly dosed and quality-assured child-friendly first-line TB treatment that adheres to the 2010 WHO recommendations. It is expected that this product will be available within three years. This work will also help speed the development of other paediatric regimens, which are currently in the pipeline.

TB Alliance will work with drug companies to formulate the right dosages for children and create incentives for drug companies to become involved in drug development for paediatric formulations. It will also drive policy and regulatory change to facilitate scale up of treatment.

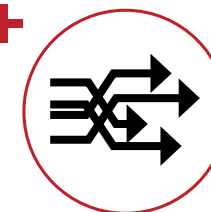
GOALS

+



Fixed-dose combinations specifically developed for children will become available in the right doses and in child-friendly formulations

+



Clarify regulatory pathways and remove market entry barriers to enable scale up of access to therapy

⁶ WHO. *Global tuberculosis report 2012*. Geneva, World Health Organization, 2012.



A nurse cuts adult TB pills at a paediatric ward in Maputo, Mozambique, in order to treat children.

Rapid Malaria Testing to Better Target Care

+ “We must be much more accurate in case management, both to ensure that we treat the true cause of fevers, and to ensure the rational use of malaria medicines”

Denis Broun,
Executive Director, UNITAID

In the hands of community health workers, personnel in large district hospitals or local pharmacists, rapid diagnostic tests (RDTs) could become a key part of the global response to malaria in endemic countries. Portable and easy-to-use, RDTs detect antigens produced by the malaria parasite, providing results in less than 25 minutes in resource-limited settings.

Recent studies show that the majority of patients with fever are treated for malaria without a confirmatory diagnosis. Valuable resources are wasted on malaria treatments for those who do not have malaria, and the real cause of fever often goes untreated.

In malaria-endemic African countries, many people seek their malaria treatments in the private sector: at pharmacists, market stalls and other outlets. Diagnostic testing in the private sector is minimal. The results of one recent study found that, in some high-burden African countries, less than 10% of children under five years of age for whom care for fever was sought in the private sector received a diagnostic test for malaria.⁷ Another study in two endemic regions of Tanzania found that 80% of patients that purchased malaria treatment had fever due to a non-malarial condition.⁸

⁷ Littrell, M., et al. Monitoring fever treatment behavior and equitable access to effective medicines in the context of initiatives to improve ACT access: baseline results and implications for programming in six African countries. *Malaria Journal*, 2011, 10:327.

⁸ Briggs M et al. Prevalence of malaria parasitemia and medication utilization patterns among clients seeking care for malaria or fever in drug shops in Tanzania, March – May 2012. *ASTMH 2012. Poster session 24: LB-110.*



Nankya Agnes has a full kit of medicines and other interventions to treat malaria in this rural area.

Community health worker Nankya Agnes in Kambungu, Uganda

In 2012, the UNITAID Executive Board approved two new projects to introduce malaria RDTs into private sector outlets in various contexts, and to improve the quality of RDTs on the market.



CREATING A PRIVATE SECTOR MARKET FOR QUALITY-ASSURED RDTs IN MALARIA-ENDEMIC COUNTRIES

Amount Committed: US\$ 34.3 million

Implementers: Population Service International (PSI), Foundation for Innovative New Diagnostics (FIND), Malaria Consortium and WHO

This project will create a private sector market for RDTs in five sub-Saharan African countries by promoting diagnosis among providers and consumers; regulating prices in the distribution chain and managing provider incentives; ensuring RDT quality; making RDTs accessible to private providers through a reliable supply chain; and creating a conducive policy and regulatory environment. The project will also document country lessons and experiences.



SUSTAINABLE GLOBAL AND NATIONAL QUALITY CONTROL FOR MALARIA RAPID DIAGNOSTICS TESTS

Amount Committed: US\$ 9.4 million

Implementers: The Foundation for Innovative New Diagnostics (FIND), WHO, Centers for Disease Control and Prevention, Hospital for Tropical Diseases

This project will support the WHO/FIND Product and Lot Testing programs, which produce and publish data on RDT performance, and monitor the quality of batches of RDTs before use. The long-term sustainability of these programs will also be promoted through the development of quality control testing based on recombinant antigen panels, which will avoid the need to send RDTs to distant laboratories for quality checks. The project will also support a move to user-fees to cover the costs of central evaluations, and transitioning lot testing to country programmes.



In a remote region in Northern Mozambique, Samuel travels from village to village on his bicycle, using RDTs to test children and treating them appropriately.

Community health worker Samuel Jacinto in Muripatana, Mozambique

Portable and easy-to-use, RDTs detect antigens produced by the malaria parasite, providing results in less than 25 minutes in resource-limited settings.

New Rapid Diagnostic Technologies for TB

Improved diagnostic technology is finally being brought to bear against one of the world's leading causes of death by an infectious disease: TB.

Until recently, the only technique available to most laboratories in developing countries dated from the 1880s and involves detecting the TB bacillus under a microscope. Testing for the deadly multi-drug resistant form of TB (MDR-TB) requires another cumbersome method: growing the bacteria in laboratory cultures, a process that takes months. Quick diagnosis and immediate treatment is vital to prevent the spread of TB, which is easily transmitted when people with active disease cough or sneeze in close proximity to other people.

In June 2012, the UNITAID Executive Board approved US\$ 30 million to scale up access to the Xpert MTB/RIF, a new rapid test that can provide an accurate result for TB and MDR-TB in only two hours. Based on the GeneXpert® system, Xpert MTB/RIF is a molecular diagnostic system that was recommended by the WHO in 2010.

Meanwhile, promising technologies are in the pipeline that can bring rapid diagnostic TB testing

to more remote settings. According to UNITAID's 2012 Tuberculosis Landscape Report, at least four new products, recently available or expected in early 2013, may be appropriate for use closer to the point-of-care in resource-limited settings.

GeneXpert® Scale up and Price Reduction:

Under the leadership of Stop TB Partnership's Global Drug Facility (GDF) and the WHO, UNITAID will provide approximately 1.4 million Xpert MTB/RIF test cartridges and over 200 machines to 21 low- and middle-income countries. These automated machines require minimal training and results are quickly available on a computer screen.

The high cost of cartridges has prevented many countries from introducing Xpert MTB/RIF on a large scale. In August 2012, UNITAID, PEPFAR, USAID, and the Bill & Melinda Gates Foundation obtained a 40% price reduction for the cartridges. This price reduction will allow an accelerated rollout of the test, and will apply to more than 145 national TB programmes and public sector purchasers in low- and middle-income countries.

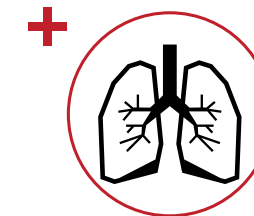


MDR-TB and TB/HIV Co-Infection

There were an estimated 630,000 prevalent cases of MDR-TB worldwide in 2011. MDR-TB can be spread from person-to-person. It can develop when patients are unable to complete their treatment course; are prescribed the wrong treatment or dose(s); or if the supply of drugs is not available. Xpert MTB/RIF detects resistance to rifampicin, one of the most commonly used first-line drugs for the treatment of TB.

Xpert MTB/RIF also detects TB in patients co-infected with HIV. TB is difficult to detect with traditional technologies in people living with HIV, but it is the leading cause of death among people living with HIV in Africa.

This grant follows UNITAID's continuing EXPANDx TB project, which has equipped 27 low-income and high-burden TB countries with fully functioning laboratories to detect MDR-TB in two days using new TB diagnostic tools such as liquid culture and the line probe assay, which analyses DNA in sputum samples.



The results of a recent modelling exercise using data from Southern Africa found that use of Xpert MTB/RIF would prevent 132,000 TB cases and 182,000 TB deaths over 10 years, thus reducing the proportion of the population with active TB by 28%.⁹

⁹ Menzies NA, Cohen T, Lin H-H, Murray M, Salomon JA (2012) Population Health Impact and Cost-Effectiveness of Tuberculosis Diagnosis with Xpert MTB/RIF: A Dynamic Simulation and Economic Evaluation. *PLoS Med* 9(11): e1001347. doi:10.1371/journal.pmed.1001347

Better HIV Treatment for Infants and Young Children

New data released for World AIDS Day 2012 heralded a decline in the number of children infected with HIV at birth, a testament to successful programmes to halt mother-to-child transmission of the disease.¹⁰

Nevertheless, there were 300,000 new infections in children in sub-Saharan Africa in 2011; the majority of children were infected in the womb or during birth. About 3.3 million children are living with HIV today and paediatric antiretroviral coverage is still lower than treatment coverage for adults.¹¹

UNITAID has made great strides in improving this situation: by creating a market for affordable fixed-dose combinations, which combine multiple medicines in one pill. Before this market intervention, most HIV treatments available for children in low-income countries were syrups which had to be taken in several foul tasting doses a day.

To continue its commitment to HIV care for children, UNITAID made a call for proposals for paediatric HIV in 2012. As a result of this process, the UNITAID Executive Board awarded up to US\$ 17.3 million to the Drugs for Neglected Diseases initiative (DNDi) in December 2012 to make new paediatric HIV treatments available for infants.

Challenge and Market Shortcoming:

Protease inhibitor-based regimens are considered the most appropriate regimen for infants and young children by the WHO, but they are poorly adapted to children's needs. In 2008, WHO recommended initiating treatment of HIV-infected infants and young children with a potent regimen containing the protease inhibitors, ritonavir-boosted lopinavir (LPV/r). Currently, paediatric LPV/r is only available as a liquid formulation with a high alcohol content that tastes terrible and requires refrigeration.

Paediatric HIV treatment is complicated, and dosing strategies change as the child grows from infancy to adolescence. Without appropriate treatment, about 35% of HIV-positive children will die before their first birthday. Better treatments are needed for younger children.

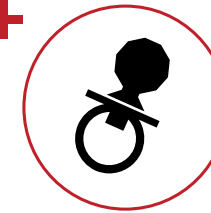
Market Intervention:

DNDi and UNITAID aim to replace this liquid formulation with a more tolerable version that is palatable and does not require refrigeration. Possible formulations include sprinkles, minitabs or granules that could be mixed with food or given with breast milk.

This market intervention has three main goals:

- To develop and register two 4-in-1 fixed-dose combinations of WHO-recommended LPV/r-based antiretroviral regimens in formulations that are appropriate for infants.
- To develop and register a complementary granule formulation of ritonavir that can be added to the 4-in-1 LPV/r-based fixed-dose combination during simultaneous treatment of HIV and TB.
- To introduce improved LPV/r-based products into the market in order to provide better treatments to infants immediately, to create a demand for the product, and to promote in-country adoption.

GOALS



307,000 to 440,000 children under three years of age will benefit from the new formulation from 2015 onwards, according to DNDi.



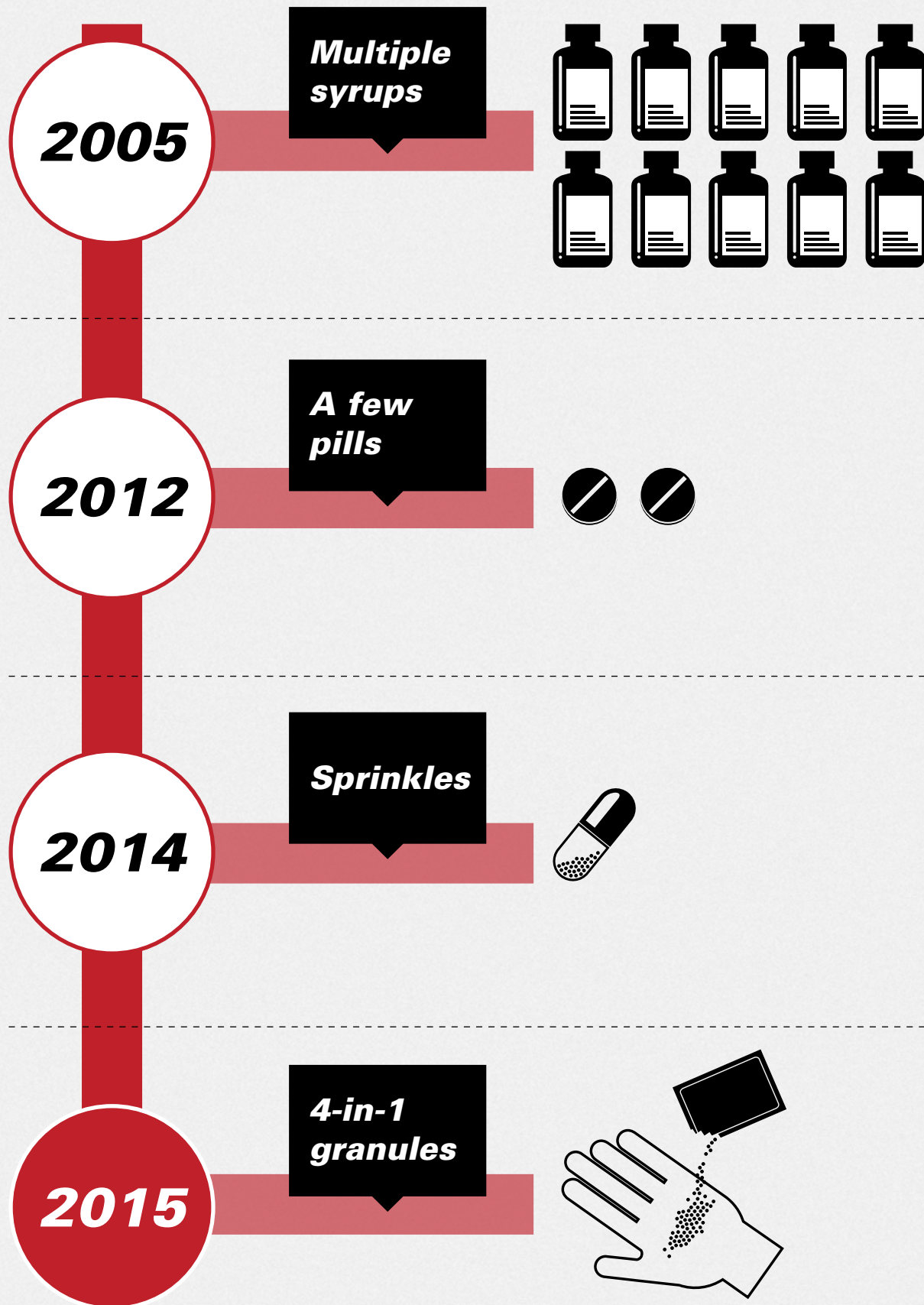
Affordable and cost-effective treatment.



A young child struggles to take HIV medications in South Africa. More adapted formulations for the smallest kids are needed.

¹⁰ Between 2009 and 2011 antiretroviral prophylaxis prevented 409,000 children from acquiring HIV infection in low- and middle-income countries. Source: UNAIDS. Global Report on the AIDS epidemic. Geneva, UNAIDS, 2012.

¹¹ Only 28% of children that require life-saving treatment are actually receiving it, compared to over 50% of adults in low-and middle-income countries. Source: UNAIDS. Global Report on the AIDS epidemic. Geneva, UNAIDS, 2012.



UNITAID has created better medicines for children – new investments will focus on infants and young children.

Accelerating Global Adoption of the Best Severe Malaria Treatment

Three year old Saudat was at death's doorstep last year when she was brought into Murtala Mohammed Specialist Hospital in Kano State, Nigeria. She had severe malaria, which is nearly always deadly if untreated.

Like Saudat, countless children are brought into the hospital every year with severe malaria, often unconscious, convulsing and with high fever. Saudat was given injectable artesunate, a new treatment recently introduced into Kano State that can save lives more quickly than existing treatments. Within 48 hours, Saudat had regained consciousness and was on the road to recovery (pictured, right).

In December 2012, the UNITAID Executive Board approved an **investment of up to US\$34 million to accelerate the global adoption of injectable artesunate** and prepare healthcare workers to quickly integrate this drug into their standard of care. This grant will be implemented by the Medicines for Malaria Venture (MMV), the Clinton Health Access Initiative (CHAI) and the Malaria Consortium.

Challenge and market shortcomings:

Out of 219 million estimated annual malaria cases, approximately eight million are severe.¹²

Typically, children diagnosed in hospitals with severe malaria are given intravenous (IV) quinine. It is a cumbersome process: the IV drip needs to be changed every eight hours and treatment can last seven days. With a shortage of health workers in endemic countries, the need for such intense monitoring puts a high burden on the health care system and increases the risk for patients.

Clinical trials results published in 2010 showed that injectable artesunate is 22.5% more efficacious than quinine in reducing mortality in children.¹³ Artesunate can be administered rapidly through IV injection over 3-5 minutes or as an injection. Only two doses are administered on the first day of treatment, and the drug is given once daily thereafter.

Despite being recommended by the WHO since 2011, several market shortcomings have limited the use of injectable artesunate. Inadequate advocacy, education and training have led to poor acceptance by patients and healthcare providers. Injectable artesunate costs three times more than injectable quinine, due to the low volume manufactured and the lack of competition. Currently, there is only one WHO prequalified supplier of injectable artesunate.

¹² Of the estimated 660,000 annual global deaths from malaria, 86% occur in children under five years of age. Source: World Health Organization. *World Malaria Report 2012*. Geneva, World Health Organization, 2012.

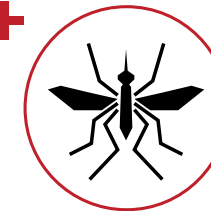
¹³ The Lancet, Volume 376, Issue 9753, Pages 1647 - 1657, 13 November 2010

Market Intervention:

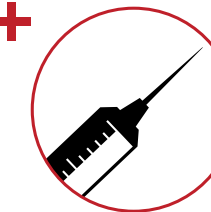
MMV and UNITAID will create a market for injectable artesunate and introduce it as an alternative to quinine for the treatment of severe malaria. MMV will also encourage the market entry of a second supplier of injectable artesunate through negotiation in order to increase competition.

To ensure that children are given a chance to reach hospital for treatment of severe malaria, this grant will also support the market entry of rectal artesunate. A community health worker or a mother can administer these suppositories; in effect, 'buying time' while the child is transported to hospital. Currently, no rectal artesunate product has been WHO-prequalified or approved by a stringent regulatory authority, despite being recommended by the WHO for the pre-referral treatment of severe malaria. This project will provide technical support to manufacturers of artesunate suppositories so that they can attain regulatory approval of the product.

GOALS



110,000 to 140,000 additional lives will be saved over the grant's life-cycle, according to MMV.



Reduce the price of injectable artesunate by 30%.



"In Kano State, quality injectable artesunate costs about US\$ 2 while non quality-assured brands cost US\$ 1.30 – this is a huge margin when you look at the large volumes needed."

Dr Nasir Bashir,
CHAI, Nigeria

Chapter Four

SPOTLIGHT ON CURRENT GRANTS



How UNITAID implements grants and a spotlight on selected on-going UNITAID market interventions.

HOW UNITAID IMPLEMENTS GRANTS

UNITAID has adopted a collaborative approach to managing its grants, working closely with implementers. This disciplined grant management process ensures that UNITAID funds are securely invested, have maximum impact and project results are clearly reported to stakeholders and the wider public.

IMPLEMENTATION

Even before the UNITAID Executive Board approves a grant proposal, UNITAID builds a strong relationship with the implementer. UNITAID ensures that all its investments complement each other, and that it provides support to implementers at every stage of the project.

PROJECT MANAGEMENT

Project Management at UNITAID is underpinned by a robust quality management system to ensure consistent, high performance and continuous improvement. This includes the implementation of a set of tools to prevent, detect and address fraud.

REPORTING/EVALUATION

UNITAID monitors grant implementation through annual and semi-annual reports and commissions mid-term and end-of-project independent evaluations for all of its funded projects. UNITAID reports on the success of its progress using various tools (see right).

TRANSPARENCY AND ACCOUNTABILITY

UNITAID is transparent and efficient in its governance, agreements and operations. All UNITAID Executive Board decisions and grant-related agreements and documents are publically available on UNITAID's website.

SUSTAINABILITY

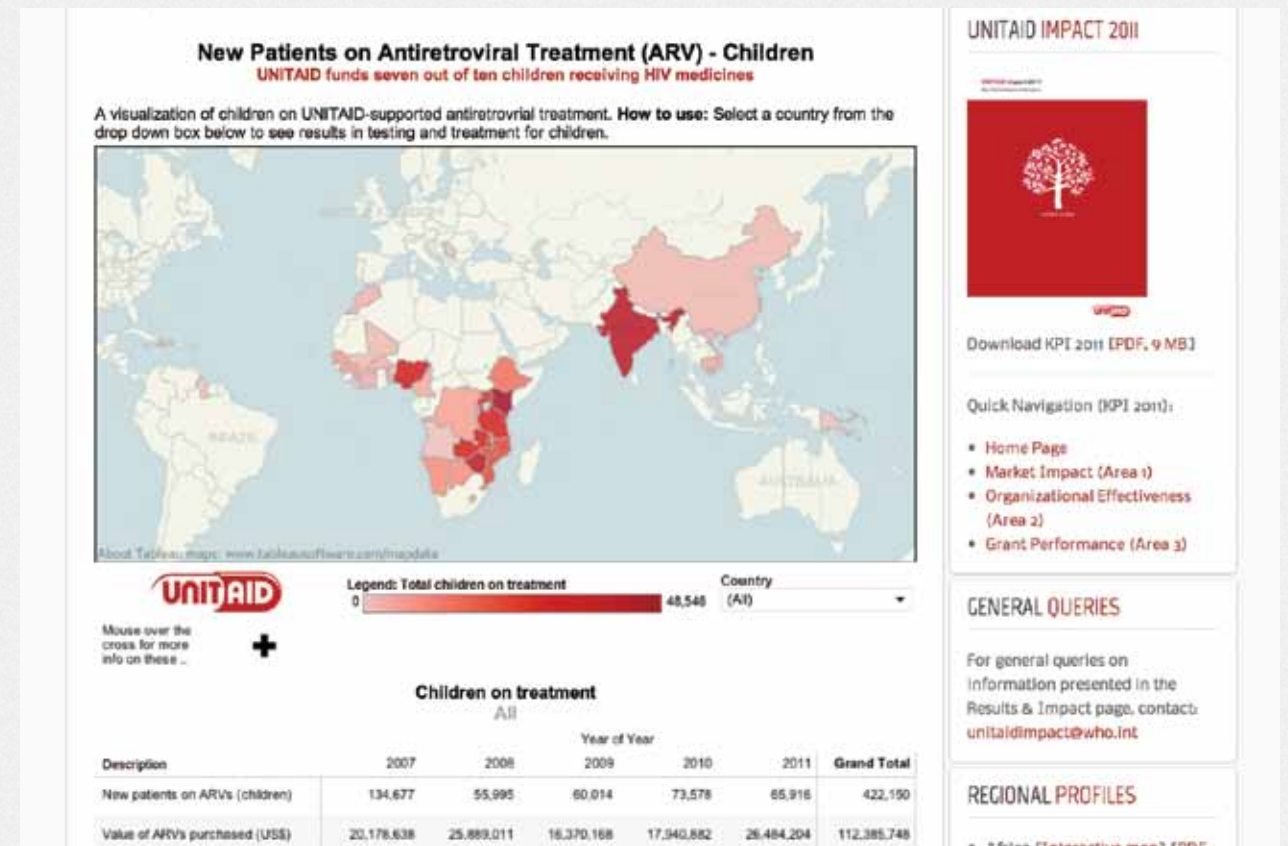
UNITAID market interventions are catalytic, lasting from three to five years. UNITAID is clear with its implementers about the time-limited nature of funding, and ensures that implementers are transparent with project countries so that the benefits of the project are sustained for the longer term.



Measuring Success

UNITAID measures its success based on the impact on the market for medicines, diagnostics and related products of public health importance for HIV/AIDS, TB and malaria. UNITAID monitors and reports via a set of Key Performance Indicators (KPIs) developed specifically for this purpose. A KPI Report is released on June 30th of every year, summarizing data from the reporting year on UNITAID's performance and impact.

In 2012, UNITAID rolled out a set of multimedia tools to measure the success of UNITAID grants, including interactive data visualizations and country investment profiles. Through these tools, UNITAID is able to track the progress of its grants over time and demonstrate its achievements in an easily accessible way.



These tools are all available on <http://www.unitaid.org/impact>

A 'Game-Changer' for Quality Malaria Treatments in the Private Sector

+ Over 290,000,000 effective treatments distributed

+ AMFm Consumer price reductions¹⁴:
Nigeria: 66%
Kenya: 77%
Ghana: 67%
Tanzania: 82%
Niger: 51%

UNITAID is the largest funder of the Affordable Medicines Facility – malaria (AMFm), which has increased access to the most effective treatment against malaria in seven African countries.

The AMFm negotiates price reductions and provides a subsidy to manufacturers of quality-assured artemisinin-based combination therapies (ACTs). Previously, the price of ACTs in endemic countries was prohibitively high for consumers, who usually purchased cheaper, yet far less effective, anti-malarial medicines from local shops.

Since the launch of its pilot project in July 2010, the AMFm has dramatically increased the use of ACTs, especially in private sector outlets. An independent evaluation of the AMFm released in October 2012 found that, in five pilot countries, ACT retail prices for patients were significantly reduced, and ACTs were more available. Even in the most remote rural areas of Kenya and Ghana, the evaluation found that AMFm-branded ACTs were readily available.

UNITAID's investment has enabled almost **290,000,000 quality-assured treatments** to be distributed so far. Before the AMFm was launched, there was only one manufacturer and no paediatric formulations of ACT were available. Thanks to UNITAID's investments, there are **now seven generic manufacturers making high quality and affordable ACTs**, including paediatric formulations.



Lucas Ojiro, a reseller of AMFm treatments in the outskirts of Kisumu town, Kenya

The AMFm is hosted by the Global Fund to Fight AIDS, Tuberculosis and Malaria. In November 2012, the Global Fund Board decided to integrate the AMFm into core Global Fund grant management and financial processes, following an orderly transition period in 2013.

During this transition period, the lessons learned from the AMFm – such as the need for manufacturer negotiations and details of the subsidy mechanism – will be integrated into core Global Fund processes. The Global Fund will act as the host for the AMFm until 31 December 2013. Afterwards, eligible countries will be able to allocate funding from their core Global Fund grants and determine how the money should be spent.

UNITAID will support the transition of the AMFm during 2013 to ensure that the ACT supply to endemic countries is safeguarded, and there is a smooth transition to the new mechanism, with no or minimal market disruption. The UNITAID Executive Board has approved up to US\$ 31 million for the transition of the AMFm.



Viola Chelangat, a pharmacy attendant at Main Street pharmacy in Kisumu with AMFm anti-malarial drugs

¹⁴ ICF International and the London School of Hygiene and Tropical Medicine, Independent Evaluation of the AMFm, <http://www.theglobalfund.org/en/amfm/independentevaluation/> Accessed 1 February 2013.

ESTHERAID



One of UNITAID's key challenges is to make sure that the products it supports reach people in need. In 2008, UNITAID launched an original partnership to trace and ensure delivery of health products from central medical stores to local clinics to the patients themselves.

Called 'ESTHERAID', this partnership brings together UNITAID with the French operator

ESTHER (Together for a Therapeutic Hospital Solidarity Network) for the first programme of its type in West Africa. ESTHERAID provides technical support to improve the supply chain management of UNITAID-supported health products in Benin, Burkina Faso, Cameroon, Central African Republic and Mali.

A few highlights from 2012:

BURKINA FASO

HIV treatment is available but the inconsistent quality of medical services is still a barrier to good patient care. The supply chain is fragmented and the provision of hospital services to people living with HIV in remote regions is inconsistent. ESTHERAID is working with the University Hospital in Bobo Dioulasso to decentralise treatment to the regions and to improve the quality of patient care delivery.

ESTHERAID has enhanced viral load testing at Bobo Dioulasso hospital and created a collection system for blood samples. The best measure of the effectiveness of HIV treatment is a patient's viral load, which determines when patients need to switch to second-line treatment.

CENTRAL AFRICAN REPUBLIC (CAR)

In late 2010, only one facility delivered paediatric care in the country. ESTHERAID is decentralising paediatric HIV services to 10 regional facilities, through the Paediatric Centre in Bangui.

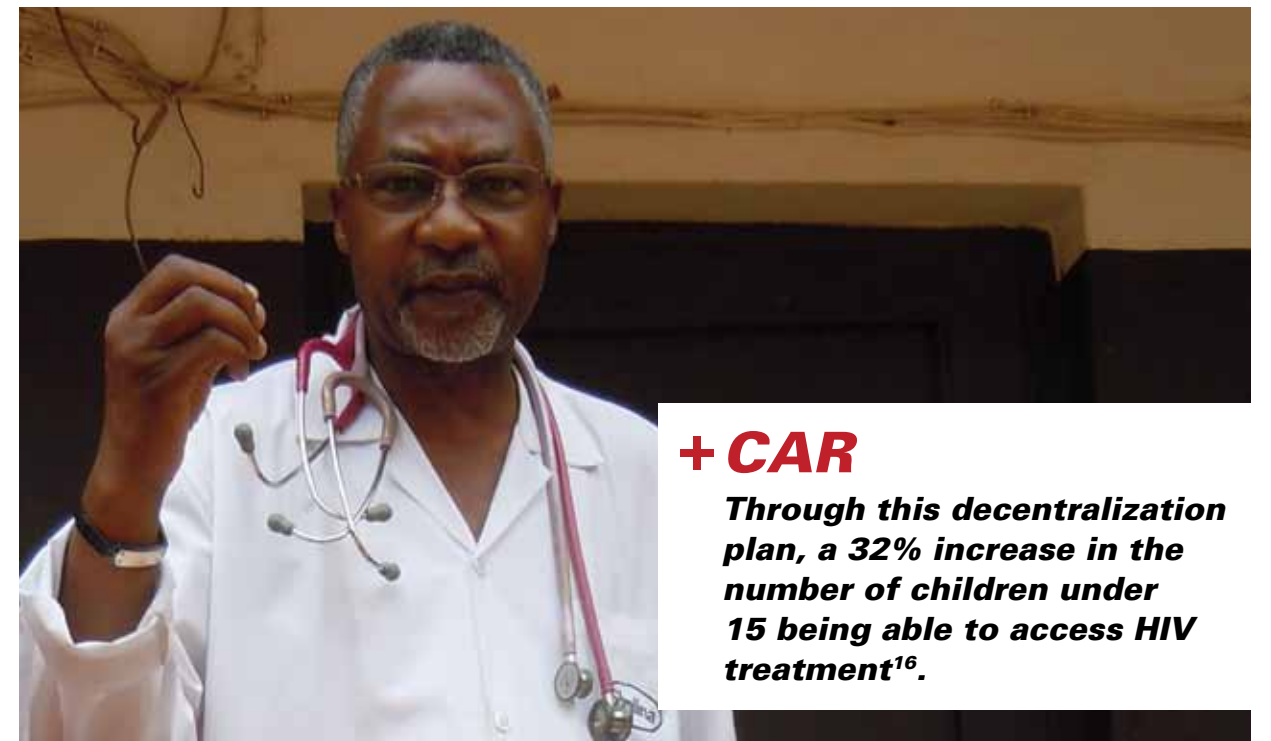


+ BURKINA FASO

Through improved viral load testing, a 75% increase in the number of patients identified as needing second-line HIV treatment¹⁵.

Dr Adrien Sawadogo of Bobo Dioulasso hospital, a regional reference for treatment and care for people living with HIV

¹⁵ ESTHER Annual Report 2012



+ CAR

Through this decentralization plan, a 32% increase in the number of children under 15 being able to access HIV treatment¹⁶.

Jean Chrysostome Gody leads the decentralization plan in Bangui

¹⁶ ESTHER Annual Report 2012

The World's Only Strategic Rotating Stockpile for MDR-TB Drugs

While new diagnostics such as GeneXpert® are emerging to improve testing for MDR-TB, treatment of the infection remains extremely difficult. MDR-TB patients must submit to an arduous daily regimen of pills and injections that lasts up to two years. The WHO estimates that in 2011, less than half of patients with MDR-TB successfully completed treatment.¹⁷ Supply interruptions – which are common for MDR-TB medicines – contribute to this low adherence.

In 2007, UNITAID created the Strategic Rotating Stockpile to avoid stock outs for MDR-TB medicines and reduce delivery times. Implemented by the Global Drug Facility (GDF) of the Stop-TB Partnership, the Strategic Rotating Stockpile consists of medicines sufficient for 5,800 MDR-TB treatments that can be accessed by countries at short notice. This stockpile is continuously replenished and the costs to UNITAID are very limited as it is funded by working capital.

In five years, the Strategic Rotating Stockpile has proven to be an essential tool for responding to emergency orders from high-burden countries. By June 2012, it had reduced delivery lead-times of 4-6 months to 46 days. Based on the most

recent GDF report statistics, from January to June 2012, as many as 50 country programmes had ordered MDR-TB medicines through this mechanism.

The Strategic Rotating Stockpile also encourages quality-assured generic manufacturers to stay in the market by providing a source of reliable orders for their products.



MDR-TB stock-outs are not only a developing country issue: A survey released in 2012 by the Centers For Disease Control and Prevention (CDC) found that **more than 80% of health departments** in the United States had difficulties obtaining MDR-TB drugs.

Reasons cited include: nationwide shortages, shipping delays and lack of resources.

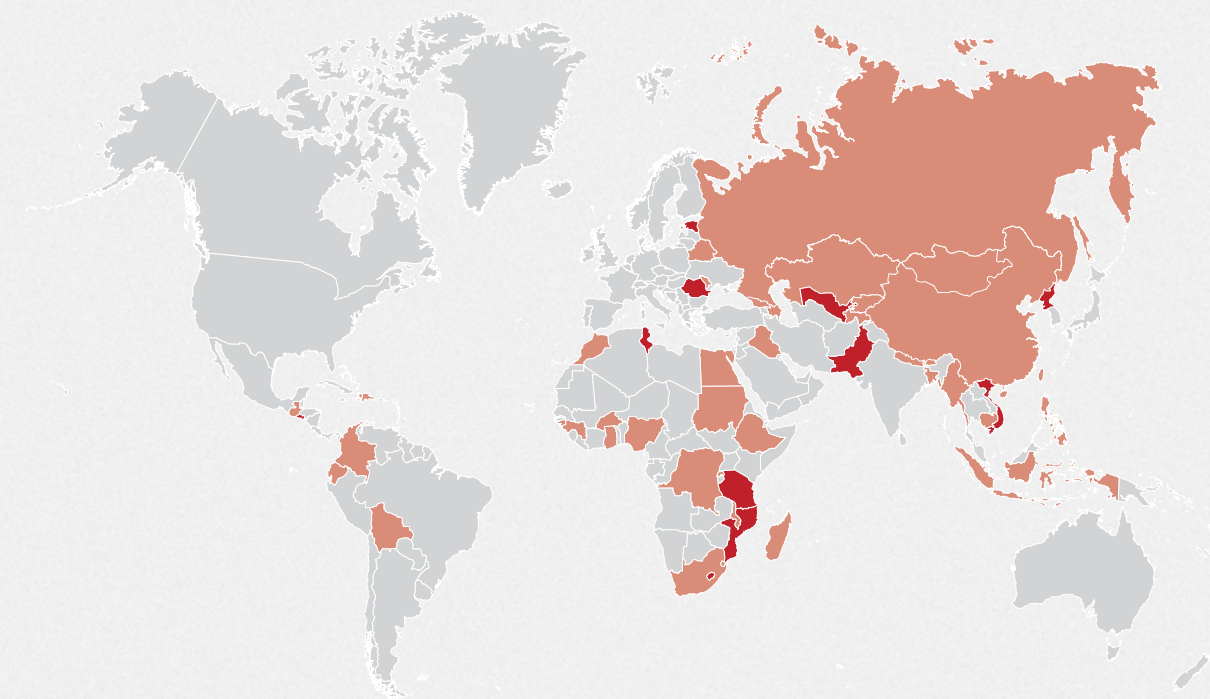
¹⁷ WHO. *Global tuberculosis report 2012*. Geneva, World Health Organization, 2012.

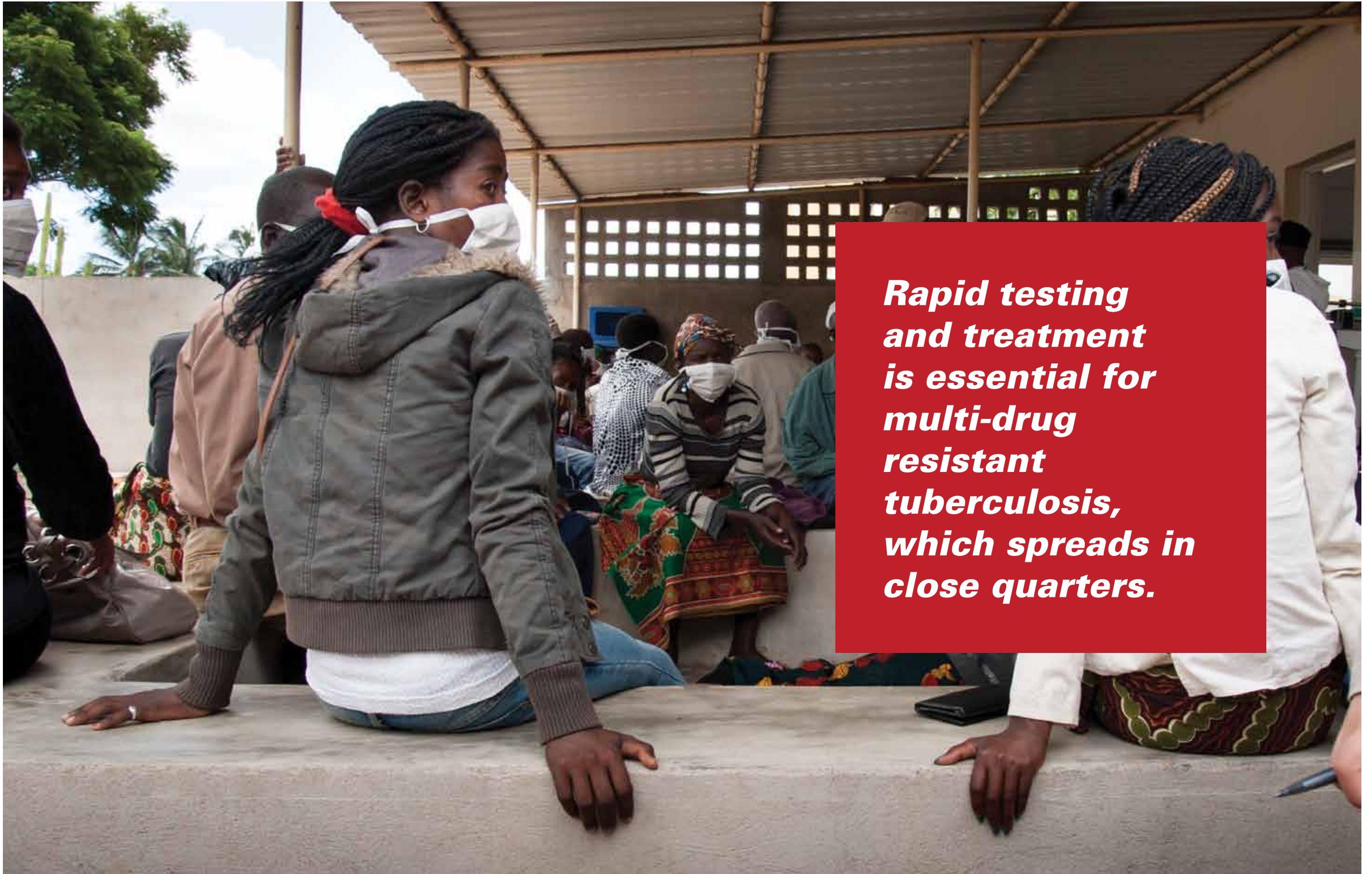
COUNTRIES THAT ACCESSED THE STRATEGIC ROTATING STOCKPILE

as of 30 June 2012

Highlighted countries had emergency orders.

Rapid testing and treatment is essential for multi-drug resistant tuberculosis, which spreads in close quarters





Rapid testing and treatment is essential for multi-drug resistant tuberculosis, which spreads in close quarters.

Helping Low-Cost Producers Enter the Market

+ 15
UNITAID priority diagnostic products have been prequalified

To ensure that it purchases products of the highest quality, UNITAID is the main funder of the WHO Prequalification (PQ) programme. This programme evaluates medicines, diagnostics and manufacturing plants on the basis of a stringent set of criteria, thus guaranteeing the safety and efficacy of products, and, as a result, protects patients' health. It is the only global quality assurance programme for medicines.

The WHO Prequalification programme ensures that the billions of US dollars worth of medicines purchased by international agencies meet international quality standards – providing an essential service for millions of patients every year. This programme has been a key part of UNITAID's project portfolio since 2006, benefitting almost all of UNITAID's market interventions.

The Prequalification programme facilitates the market entry of new manufacturers while preserving quality. To gain prequalification, manufacturers must supply comprehensive information about their product, and WHO inspection teams visit their manufacturing sites. Producers from Europe, India and China have been prequalified for sale internationally.

As of 30 June 2012, generic manufacturers

+ 67
UNITAID medicines prequalified

supply over **80%** of all HIV antiretroviral drugs, **73%** of malaria treatments and **100%** of all TB medicines purchased with UNITAID funds. Many of these products are fixed-dose combination pills (FDCs), combining multiple drugs into one. The Prequalification programme ensures that these UNITAID 'priority products' meet the highest standards of quality, in the absence of strong regulatory authorities in many developing countries.

For example, in 2006, there was only one manufacturer of an improved formulation of artemisinin-based combination therapy (ACT), the best treatment for malaria. Today, there are seven generic manufacturers making ACTs, with eight of their products being prequalified FDCs.

Bringing prices down

UNITAID only funds products that have been prequalified by this programme or by a national stringent regulatory authority. Once a product has been prequalified, it can be purchased by UNITAID or other funders, and its manufacturer is approved for business.

Increasing the number of quality-assured manufacturers therefore fosters competition and helps drive prices down.

A Sustainable Market for Second-Line Adult Antiretroviral Treatment¹⁸

HIV is a life-long condition. People on antiretroviral treatment eventually will need newer and more potent drug combinations when they develop side effects or become infected with a drug resistant virus. Every year, an estimated 2-3% of people on first line, life-sustaining treatment need to switch to second-line antiretrovirals.

With its implementer the Clinton Health Access Initiative (CHAI), UNITAID created a generic market for second-line antiretrovirals by increasing the number of suppliers and spurring dramatic price reductions. **Second-line antiretroviral treatment costs are now less than \$500 per patient per year, down from \$1,500 just 3 years ago, mainly due to UNITAID's interventions.**

Prior to 2006, all second-line antiretrovirals in low-income countries required refrigeration. In 2010, UNITAID and CHAI launched generic heat-stable formulations that do not require refrigeration, helping patients adhere to their drugs and giving caregivers the confidence to switch patients from first- to second-line treatment.

This market intervention ended on 31 December 2012 having provided treatments to over 100,000 patients in 25 countries. UNITAID

funding has been successfully transitioned to other donors in these countries and, importantly, the price reductions generated by this project have been passed on to national governments and other global health funders.



NUMBER OF NEW GENERIC SUPPLIERS IN 2012

	2012	2007
Eligible suppliers for TDF/3TC 300/300 mg	4	1
Eligible suppliers for TDF/FTC 300/200 mg	5	2
Eligible suppliers for LPV/r 200/50mg	4	4
Eligible suppliers for ATV 300 mg	2	0
Eligible supplier for ATV/r 300/100 mg	1	0

¹⁸ CHAI Annual Report 2012

THE MEDICINES PATENT POOL

The Medicines Patent Pool (MPP) was formed in July 2010 with the support of UNITAID. Its mission is to increase access to affordable, appropriate HIV medicines in developing countries through voluntary licensing of patents for key HIV medicines.

In 2012, the Medicines Patent Pool focused on building and expanding the expertise that underpins this mission. Some highlights from 2012:

- The MPP's Patent Status Database for selected HIV medicines is the world's largest open-access repository of patent information on HIV medicines. Reliable patent data can be hard to come by, but the MPP works closely with the World Intellectual Property Organization and national and regional patent offices to confirm the data and keep it up-to-date.

In 2012, the Patent Pool added data for 11 additional countries to the database – Albania, Azerbaijan, Bolivia, Bosnia and Herzegovina, Costa Rica, the Dominican Republic, Georgia, Lithuania, Moldova, Montenegro and Turkey – bringing the total number of countries covered to 78.

In 2012, the MPP added data for a new fixed-dose combination (TDF/FTC/RIL)¹⁹ – bringing the total number of patents covered to 71 for 25 HIV medicines.

You can access the database here:

<http://www.medicinespatentpool.org/patent-data/patent-status-of-arvs/>

- The Medicines Patent Pool also forged stronger connections with key stakeholders in 2012 by giving sub-licences to three key generics manufacturers; intensifying negotiations with patent holders; launching a formal consultation process with people living with HIV and civil society; and expanding its web presence through the publication of a newly redesigned website in April 2012 and wider social media activity.
- Hetero Pharmaceuticals, Emcure Pharmaceuticals and active pharmaceutical ingredient manufacturer Laurus Labs took licences from the MPP in 2012 for the production of medicines licensed to the MPP in 2011 by Gilead Sciences, bringing the total number of sub-licensees to five.



ON THE MPP'S PATENT STATUS DATABASE:

“An essential impartial reference source.”

Global Fund to Fight AIDS, Tuberculosis and Malaria

“An invaluable step towards furthering access to treatment.”

UNICEF

¹⁹ Tenofovir/emtricitabine/rilpivirine



Chapter Five

2012:
UNITAID
UP CLOSE

UNITAID's market-based approach, selected 2012 events, Secretariat, Governance, grant portfolio and financial highlights 2012.

Selected 2012 Events



In December, UNITAID was centre stage at the 'Virgin Radio Fans' TV show in Paris, the only event in the world where artists thank their fans. Mika, M, BB Brune and other French pop stars took a second to say merci to the millions of French air travellers that have helped saved lives.

Pictured: French superstar Mathieu Chedid ('M') with UNITAID Chair Philippe Douste-Blazy.



UNITAID was an active participant at the International AIDS Conference in Washington D.C., 22-27 July 2012. Through a variety of satellite sessions and events, UNITAID announced investments in point-of-care HIV diagnostics, disseminated its market intelligence and listened to a wide-range of experts about possible areas for future UNITAID investments.



To mark World AIDS Day 2012, UNITAID collaborated with the International Labour Organization (ILO) in Geneva to honour people living with HIV who have not only taken control of their lives but are now helping others to do the same. Dr Margaret Chan, Director-General of the WHO and ILO Director-General Guy Ryder were among those present for an exhibition of portraits by UNITAID Technical Officer Gelise McCullough, inspired by those working to save lives with UNITAID's investments.



“The French government has since spearheaded the creation of a wonderful multi-government program called UNITAID, which funds the purchase of HIV/AIDS medications and other global health needs for poor countries through a small tax on the purchase of airline tickets.”

Excerpt from “Love Is the Cure” by Elton John, copyright © 2012. Reproduced by permission of Hodder and Stoughton Limited

The UNITAID Secretariat

+ The Secretariat of UNITAID carries out day-to-day operations; drives the strategic direction of the organization; gathers market intelligence; and develops cutting-edge methodologies and approaches to shape markets for health products

UNITAID and the World Health Organization (WHO)

WHO serves as UNITAID's trustee and also hosts its Secretariat. UNITAID derives significant benefits from its proximity to WHO programmes in HIV/AIDS, malaria and TB, and also draws on the global network of WHO regional and country offices. The operations of the Secretariat (including recruitment, procurement, financial matters and management of the Trust Fund) are administered in accordance with the Constitution of UNITAID and WHO rules.

UNITAID Secretariat

The Secretariat of UNITAID carries out day-to-day operations; drives the strategic direction of the organization; gathers market intelligence; and develops cutting-edge methodologies and approaches to shape markets for health products. The Secretariat manages relationships with implementers, and coordinates their activities, in order to ensure both programme and financial monitoring and reporting.

The Secretariat prepares project reports and budgets for approval by the Board, and reports on the results of the actions undertaken and the use of UNITAID resources. Just over 60 people are employed by the Secretariat, with 29 nationalities represented.

In-Country Consultations

UNITAID does not have offices in the countries where its investments are rolled out but relies on its implementers for in-country information. In addition, UNITAID works closely with the full gamut of global health stakeholders in countries, from civil society and patient groups to Ministries of Health.

To liaise directly with these stakeholders, UNITAID conducts 'in-country consultations' every year in countries where UNITAID support is received. Through these consultations, UNITAID engages stakeholders, listens to country needs, coordinates efforts, and takes stock of UNITAID's impact. UNITAID also addresses implementation, local supply chain management, local manufacturing and challenges regarding sustainability.

Importantly, feedback received by in-country stakeholders feeds directly into UNITAID market intelligence by informing the Secretariat of market shortcomings and challenges that could be met by future UNITAID market interventions.



IN-COUNTRY CONSULTATION ZAMBIA: 28 FEBRUARY 2012

The Minister of Health Dr Joseph Kasonde opened UNITAID's in-country consultation. In his address to the 100 participants that took part, he praised his country's civil society in organizing the event. From 2007 to 2012, UNITAID has invested over US\$ 65 million in Zambia²⁰. Minister Kasonde said that the Zambian Government was committed to the partnership with UNITAID and ensuring that the support received is put to good use. The Minister stated he will personally follow-up on the outcomes and recommendations of the consultative meeting.

Digital Communications

UNITAID significantly ramped up its digital outreach in 2012, communicating directly with a wider online audience than ever before. A revamped website was launched in April 2012, along with enhanced social media feeds. For the first time, interactive data visualizations of all UNITAID grants were posted online, allowing users to view each investment by country and by project.

By December 2012, UNITAID had doubled its presence on Twitter and Facebook, and nearly tripled daily website visits.

Have a look at www.unitaid.org

IN-COUNTRY CONSULTATION UGANDA: 22-26 OCTOBER 2012

UNITAID's in-country Consultation in Uganda brought together over 100 participants from government, civil society, implementers and pharmaceutical companies, along with UNITAID Board Members, to discuss how to work together more efficiently. It was also an opportunity for the UNITAID Community Support Team to meet: over 20 participants from eight countries met to discuss ways in which civil society can assist UNITAID to engage at country level.

²⁰ As of 30 June 2012

UNITAID EXECUTIVE BOARD

The Executive Board is the decision-making body of UNITAID that 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 five founding countries (Brazil, Chile, France, Norway and the United Kingdom);
- One representative of African countries designated by the African Union;
- One representative of the Asian countries;
- One representative of Spain;
- 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 expertise to the UNITAID Executive Board on proposals and related projects submitted for funding.

Advisory Group on Funding Priorities

A committee of seven international experts in HIV/AIDS, TB and malaria that assists in identifying potential priority areas of market and public health impact, which could be funded by UNITAID.



UNITAID EXECUTIVE BOARD MEETINGS 2012:

- Special Session of the UNITAID Executive Board on Diagnostics 26-27 March 2012
- 16th UNITAID Executive Board 12-13 June 2012
- 17th UNITAID Executive Board 3-5 December 2012

UNITAID EXECUTIVE BOARD MEMBERS:

CHAIR

Dr Philippe Douste-Blazy
Under-Secretary-General of the United Nations
Special Adviser on Innovative Financing for Development

CHILE (VICE-CHAIR)

H.E. Mr Pedro Oyarce
Ambassador and Permanent Representative of Chile to the United Nations and other international organizations in Geneva

BRAZIL

H.E. Ms Maria Nazareth Farani Azevêdo
Ambassador and Permanent Representative of Brazil
Permanent Mission of Brazil to the United Nations and other international organizations in Geneva

FRANCE

Ms Mireille Guigaz
French 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

Ms Kari Marjatta Hoel
Adviser, Section for Climate Change, Global Health and Sustainable Development
Norwegian Ministry of Foreign Affairs

SPAIN

Mr José Luis Solano Gadea
Ambassador at Large for Public-Private Partnership in Global Health
Spanish Agency for International Development Cooperation

UNITED KINGDOM

Mr Carlton Evans
Policy and Programme Manager
Global Funds Department
Department for International Development (DFID)

WHO

Dr Hiroki Nakatani
Assistant Director-General
HIV/AIDS, Tuberculosis, Malaria and Neglected Tropical Diseases

AFRICAN COUNTRIES

H.E. Mr Abdul Samad Minty
Ambassador, Permanent Representative
Permanent Mission of South Africa to the United Nations and other international organizations in Geneva

S.E. Mr Omar Hilale (Alternate)
Ambassador Permanent Mission of the Kingdom of Morocco to the United Nations and other international organizations in Geneva

ASIAN COUNTRIES - Republic of Korea

Ms Yeoung-ju OH
Deputy Director-General
Ministry of Foreign Affairs and Trade (MOFAT)

COMMUNITIES LIVING WITH THE DISEASES

Mr Nelson Juma Otwoma
National Coordinator, NEPHAK (National Empowerment Network of People Living with HIV/AIDS in Kenya)

FOUNDATIONS

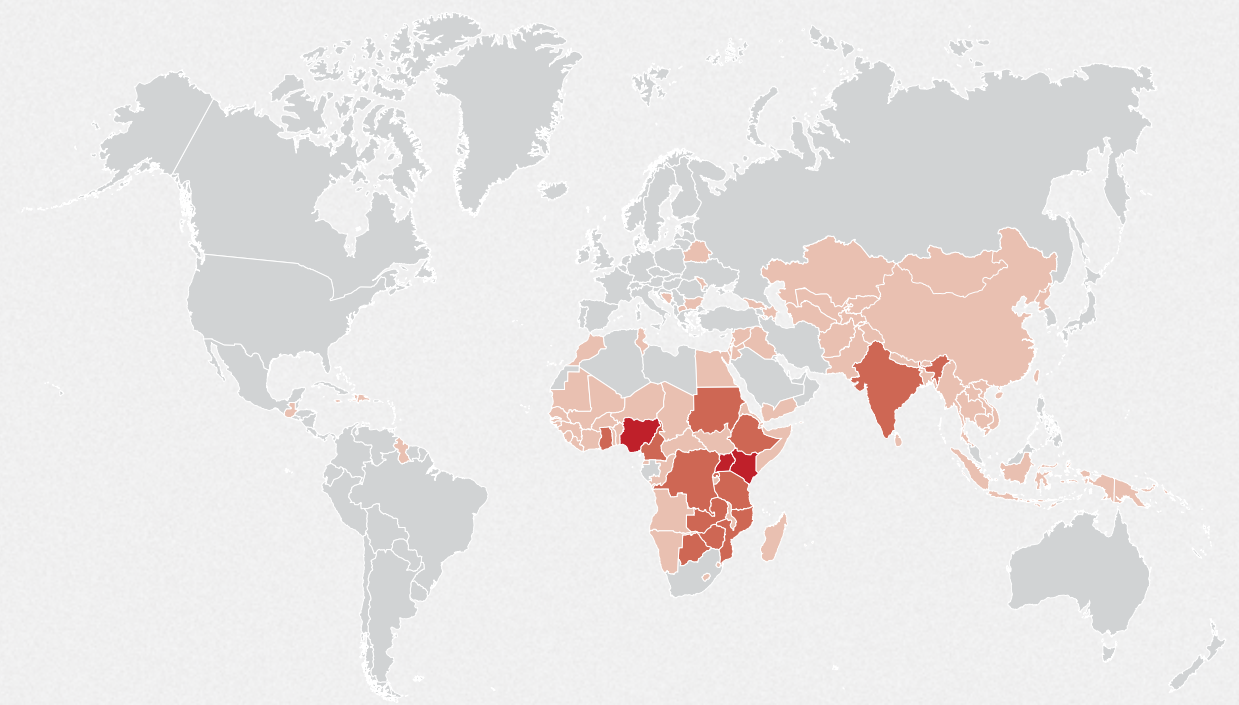
Ms Blair Hanewall
Deputy Director, Innovation Introduction
Integrated Delivery
The Bill & Melinda Gates Foundation

NGOs

Ms Kim Nichols
Co-Executive Director
African Services Committee

UNITAID'S GRANT PORTFOLIO

UNITAID has investments in 94 countries – below is a heat map of UNITAID investments in health products by country.²¹



Country income focus:

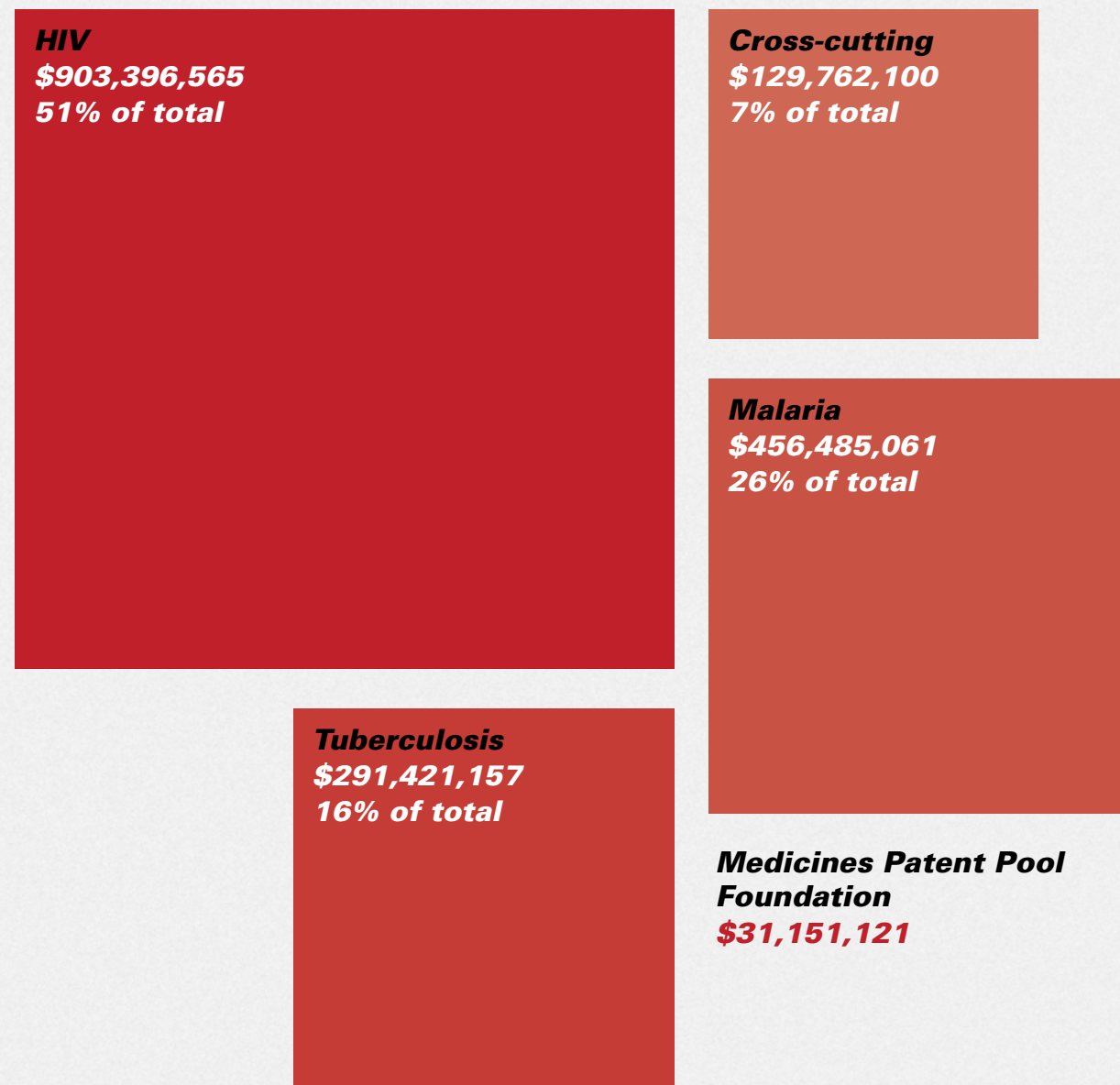
UNITAID dedicates funds that are used to purchase health products to:

- at least 85 percent to low-income countries,
- no more than 10 percent to lower-middle income countries, and
- no more than 5 percent to upper middle income countries.

²¹ All data as of 30 June 2012. Visit <http://www.unitaid.eu/what/countries> for detailed data.



Project funding commitments at the end of 2012 by intervention area:



+ Total Amount of UNITAID Executive Board commitments 2006–2012: US\$ 1,781,064,883 (except to Medicines Patent Pool)

HIV/AIDS Investment Portfolio

1. PAEDIATRIC HIV/AIDS PROJECT

Implementer: Clinton Health Access Initiative
Amount Committed: US\$ 388,057,634
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2006-2013

2. SECOND-LINE HIV/AIDS PROJECT

Implementer: Clinton Health Access Initiative
Amount Committed: US\$ 305,799,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2006-2012

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

Implementer: UNICEF
Amount Committed: US\$ 104,466,308
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2006-2011

4. ESTHERAID - EASING AND SAFEGUARDING THE AVAILABILITY OF ANTIRETROVIRAL TREATMENTS

Implementer: Esther
Amount Committed: US\$ 15,950,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2006-2013

5. ACCELERATING ACCESS TO INNOVATIVE POINT-OF-CARE HIV DIAGNOSTICS

Implementer: Clinton Health Access Initiative/UNICEF
Amount Committed: US\$ 20,000,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2012-2013

6. IMPLEMENTATION OF CD4 AND VIRAL LOAD TESTING IN DECENTRALIZED, REMOTE AND RESOURCE-LIMITED SETTINGS IN MSF HIV PROGRAMMES

Implementer: Médecins Sans Frontières
Amount Committed: US\$ 28,696,023
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2012-2016

7. OPEN POLYVALENT PLATFORMS FOR SUSTAINABLE AND QUALITY ACCESS TO VIRAL LOAD IN RESOURCE-LIMITED SETTINGS

Implementer: France Expertise Internationale
Amount Committed: US\$ 2,400,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2012-2013

8. MARKET ENTRY OF AN IMPROVED SOLID PROTEASE INHIBITOR-BASED FIRST ANTIRETROVIRAL COMBINATION THERAPY FOR INFANTS AND YOUNG CHILDREN WITH HIV/AIDS

Implementer: DNDi
Amount Committed: US\$ 17,336,000

9. MANUFACTURE AND VALIDATION OF RAPID POINT OF CARE CD4 TESTING IN INDIA

Implementer: The Burnett Institute
Amount Committed: US\$ 1,627,000

10. OPERATIONAL STUDIES TO VALIDATE AND ACCELERATE UPTAKE OF POINT-OF-CARE CD4 COUNTERS

Implementer: Daktari Diagnostics
Amount Committed: US\$ 2,687,000

11. UPTAKE OF A NOVEL, DISPOSABLE POINT-OF-CARE CD4 TEST IN DEVELOPING COUNTRIES

Implementer: Zyomix
Amount Committed: US\$ 7,534,000

12. PROVIDING ACCESS TO EARLY INFANT DIAGNOSIS AND VIRAL LOAD MONITORING BY SAMBA

Implementer: Diagnostics for the real world
Amount Committed: US\$ 8,843,600

Tuberculosis Investment Portfolio

1. PAEDIATRIC TB PROJECT

Implementer: Global Drug Facility of the Stop TB Partnership
Amount Committed: US\$ 14,225,781
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2006-2012

2. PAEDIATRIC TB PROJECT EXTENSION

Implementer: Global Drug Facility of the Stop TB Partnership
Amount Committed: US\$ 23,465,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2012-2016

3. MULTI-DRUG RESISTANT TB SCALE UP INITIATIVE

Implementer: Global Drug Facility of the Stop TB Partnership/ Green Light Committee
Amount Committed: US\$ 53,371,575
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2007-2012

4. MULTI-DRUG RESISTANT TB ACCELERATION AND ACCESS INITIATIVE - STRATEGIC ROTATING STOCKPILE

Implementer: Global Drug Facility of the Stop TB Partnership
Amount Committed: US\$ 14,097,545
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2008-2012

5. MULTI-DRUG RESISTANT TB ACCELERATION & ACCESS INITIATIVE - STRATEGIC REVOLVING FUND

Implementer: Global Drug Facility of the Stop TB Partnership
Amount Committed: US\$ 22,232,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2008-2011

6. MULTI-DRUG RESISTANT TB DIAGNOSTICS (EXPANDX)

Implementer: Global Drug Facility of the Stop TB Partnership/ Foundation for Innovative New Diagnostics / Green Light Committee
Amount Committed: US\$ 89,663,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2009-2013

7. FIRST-LINE ANTI-TUBERCULOSIS DRUG INITIATIVE

Implementer: Global Drug Facility of the Stop TB Partnership
Amount Committed: US\$ 27,646,256
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2007-2011

8. SCALING UP ACCESS TO CONTEMPORARY TB DIAGNOSTICS (GENEXPERT®)

Implementer: Cepheid
Amount Committed: US\$ 4,100,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2013 onward

9. MDR-TB SCALE UP INITIATIVE SCALING UP ACCESS TO CONTEMPORARY TB DIAGNOSTICS (GENEXPERT®)

Implementer: Stop TB Partnership
Amount Committed: US\$ 25,900,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2013-2015

10. PAEDIATRIC TB CENTRE OF EXCELLENCE

Implementer: TB Alliance
Amount Committed: US\$ 16,720,000

Malaria Investment Portfolio

1. ARTEMISININ-BASED COMBINATION THERAPY (ACT) SCALE UP INITIATIVE BURUNDI AND LIBERIA

Implementer: UNICEF/WHO
Amount Committed: US\$ 1,334,755
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2007

2. ACT SCALE UP INITIATIVE

Implementer: Global Fund to Fight AIDS, Tuberculosis and Malaria/UNICEF
Amount Committed: US\$ 78,887,568
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2007-2011

3. AFFORDABLE MEDICINES FOR MALARIA (AMFM)

Implementer: Global Fund to Fight AIDS, Tuberculosis and Malaria
Amount Committed: US\$ 180,000,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2009-2011

4. LONG LASTING INSECTICIDE TREATED NETS

Implementer: UNICEF
Amount Committed: US\$ 109,250,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2009-2010

5. ASSURED ARTEMISININ SUPPLY SYSTEM (A2S2)

Implementer: i+Solutions
Amount Committed: US\$ 9,280,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2009-2013

6. SUSTAINABLE GLOBAL AND NATIONAL QUALITY CONTROL FOR MALARIA RAPID DIAGNOSTICS TESTS

Implementer: FIND
Amount Committed: US\$ 9,441,777
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: Five years

7. CREATING A PRIVATE SECTOR MARKET FOR QUALITY ASSURED RDTs IN MALARIA-ENDEMIC COUNTRIES

Implementer: Population Services International
Amount Committed: US\$ 34,290,561
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: Three years

8. IMPROVING SEVERE MALARIA OUTCOMES

Implementer: Medicines for Malaria Venture
Amount Committed: US\$ 34,000,000

Cross-Cutting Investment Portfolio

1. PREQUALIFICATION OF MEDICINES

Implementer: WHO
Amount Committed: US\$ 66,110,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2006-2012

2. QUALITY ASSURANCE OF DIAGNOSTICS

Implementer: WHO
Amount Committed: US\$ 10,475,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2009-2013

3. UNITAID SUPPORT TO THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA ROUND 6

Implementer: Global Fund to Fight AIDS, Tuberculosis and Malaria
Amount Committed: US\$ 52,500,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: 2006-2012

4. PREVENTING PATENT BARRIERS

Implementer: Lawyers Collective
Amount Committed: US\$ 677,000
Cumulatively approved by UNITAID Executive Board as of the end of 2012 for: Three years

Summary Statements of Financial Performance and Financial Positions

SUMMARY STATEMENTS OF FINANCIAL PERFORMANCE AND FINANCIAL POSITIONS

The UNITAID Financial Statements have been prepared in accordance with the International Public Sector Accounting Standards (IPSAS). As a first-time adopter of IPSAS in 2012, UNITAID has restated the opening balances of 2012 to meet the IPSAS requirements.

Summary statements of financial performance and financial positions are presented below. The full Financial Report for the year ended 31 December 2012 is available on the UNITAID website (www.unitaid.org). The 2012 Financial Statements of UNITAID were certified by the External Auditors of WHO.

While subject to the WHO Financial Rules and Regulations, UNITAID had developed financial policies and guidelines to direct and support its grant-making activities. As the portfolio of UNITAID grants grows and becomes more

diverse, UNITAID has continued to strengthen and adapt its Financial Management Policy Framework and practices to ensure that donor resources entrusted to UNITAID are managed, used and safeguarded as effectively as possible by UNITAID and its implementing partners.

FINANCIAL HIGHLIGHTS

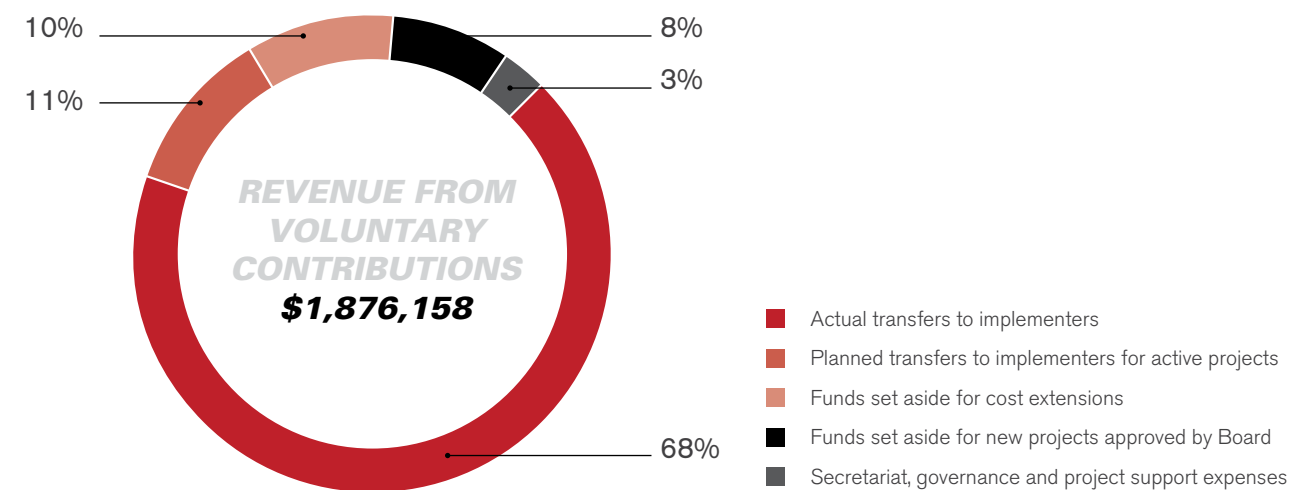
Since its establishment in late 2006, UNITAID has received US\$ 1.8 billion of contributions from donors, committed US\$ 1.8 billion and disbursed US\$ 1.3 billion to implementers. In 2012, disbursements to implementing partners totalled US\$ 165 million, representing 90% of the overall expenses of UNITAID in 2012. Governance and Secretariat costs represented the remaining 10% of 2012 expenses.

While 'value for money' is a key consideration for the UNITAID Board to fund a project proposal, UNITAID applies this same principle to its own operations and strives to minimize its operating costs.

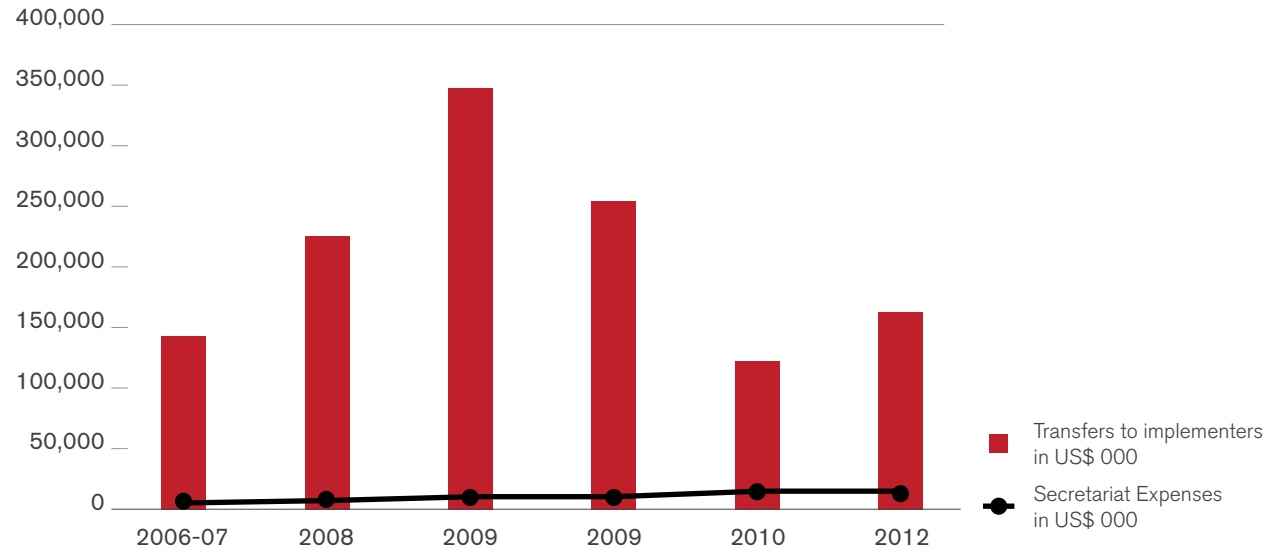
SUMMARY STATEMENT OF FINANCIAL PERFORMANCE

	2012 in US\$000	2011 in US\$000
<i>Operating revenue</i>		
Voluntary contributions	276,452	270,235
Financial revenue and expenses - net	1,977	5,353
Total Revenue	278,429	275,588
<i>Operating expenses</i>		
Grants to implementers	164,739	123,518
Staff and other personnel costs	10,605	8,122
Consulting & Contractual Services	6,783	6,142
Travel	1,411	1,256
General operating expenses	164	170
Total operating expenses	183,702	139,208
Surplus for the period	94,727	136,380

DISTRIBUTION OF UNITAID VOLUNTARY CONTRIBUTIONS SINCE INCEPTION THROUGH 2012 IN US\$000

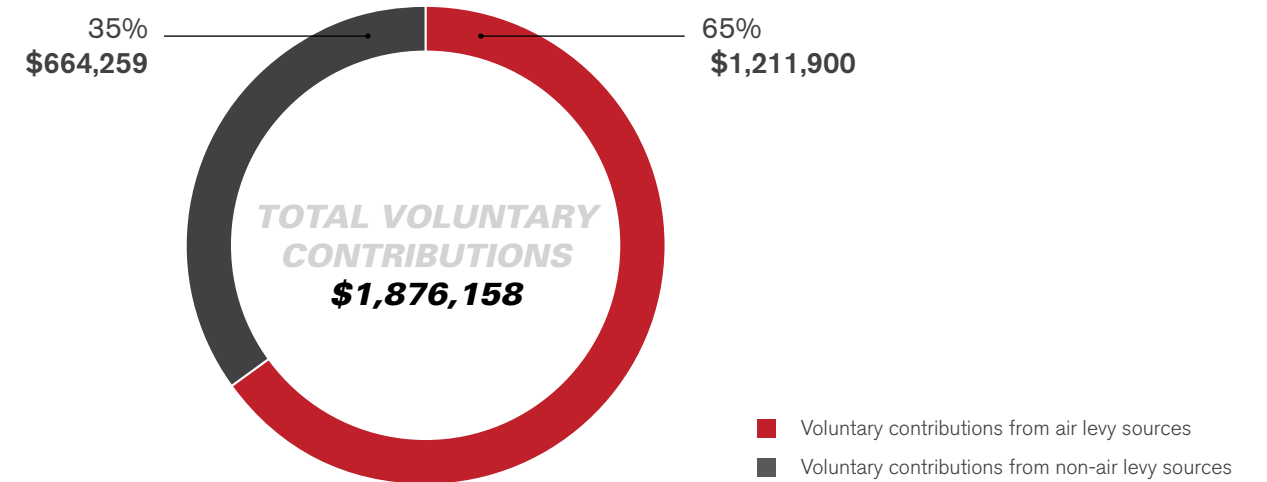


TRANSFERS TO IMPLEMENTERS VERSUS SECRETARIAT EXPENSES 2006-2012



2012 Voluntary Contributions of UNITAID from the air ticket levy accounted for 56% of the total value of voluntary contributions. Cumulatively, since UNITAID's inception through 2012, voluntary contributions from the air ticket levy have accounted for 65% of total contributions received.

DISTRIBUTION OF VOLUNTARY CONTRIBUTIONS OF UNITAID SINCE INCEPTION THROUGH 2012 BY AIR LEVY AND NON-AIR LEVY SOURCES
IN US\$000



SUMMARY STATEMENT OF FINANCIAL POSITION

	2012 in US\$000	2011 (Restated) in US\$000
Current assets	667,157	566,616
Non-current assets	488	88,148
Current liabilities	95,268	89,658
Non-current liabilities	2,103	89,559
Net assets	570,274	475,547
Total liabilities and net assets	667,645	654,764

Notes

Notes



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