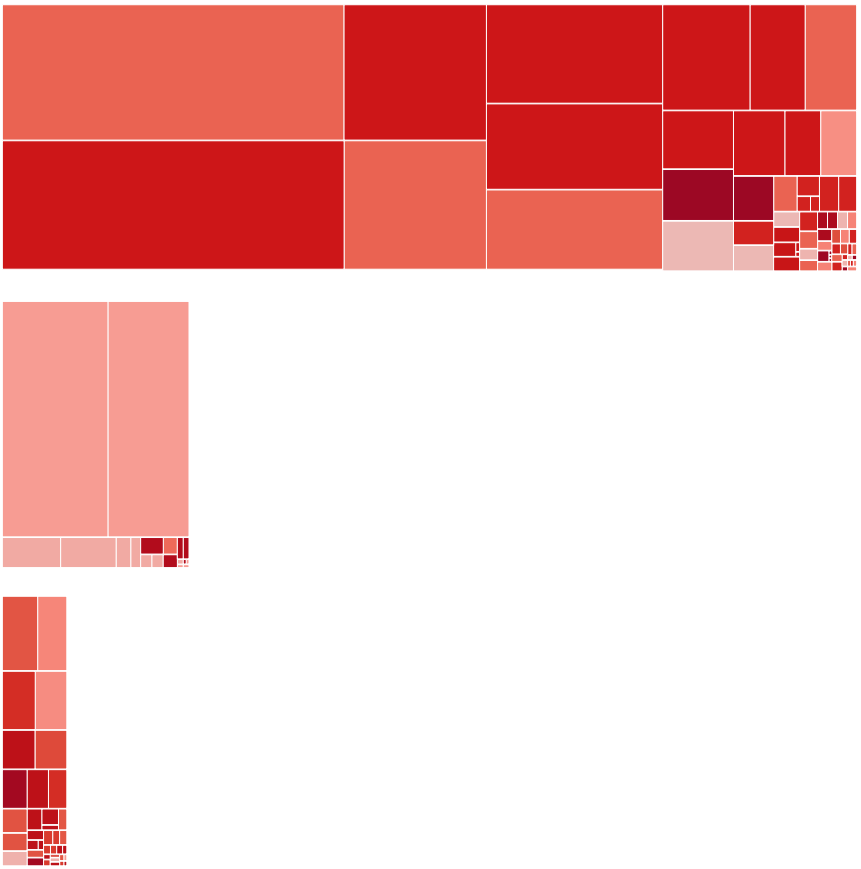
ANNUAL REPORT 2013

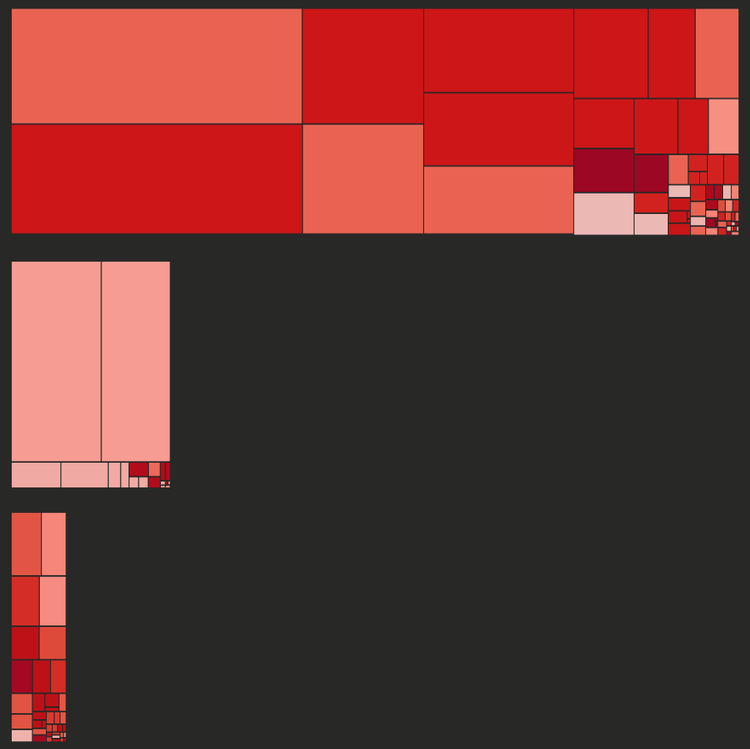
TRANSFORMING MARKETS SAVING LIVES



UNITAID

ANNUAL REPORT 2013

TRANSFORMING MARKETS SAVING LIVES



Cover shows donor-funded purchases of medicines for HIV (top), malaria (middle) and tuberculosis (below) by product formulation and pack size in 2012. The market for tuberculosis is small but heavily fragmented - one of the many reasons why UNITAID focuses on transforming markets to save lives! See page 67 for more.

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The reality that HIV/AIDS, malaria and tuberculosis (TB) are still major public health issues was painfully clear during my recent visit to a dusty open-air TB centre in Mozambique. Hundreds of people crowded together under a corrugated tin roof to get TB medicines, while others waited for their results. Many were living with HIV. Yet in a small sweltering room, printers relayed test results sent by text message from nearby clinics, where UNITAID is introducing high-tech diagnostic machines.

The contrast between technology and poverty is revealing: amazing progress is being made in developing countries to transform health care. However, we have a long way to go, especially as the 15-year campaign to achieve the Millennium Development Goals (MDGs) draws to a close in 2015.

The international community can claim some victories, such as halving the death rate for children in two decades. Nevertheless, there were still 6.6 million child deaths in 2012, with the majority from treatable infectious diseases. Likewise, millions have been lifted from poverty in countries such as China and Brazil, but billions in the poorest countries still live without basic needs: sanitation, clean water and nutrition.

This is why UNITAID's role as a laboratory for innovation is as important as ever. Our time-tested approach – working with the private sector to reduce prices and develop appropriate formulations of medicines – must be applied to other public health challenges. Hepatitis C, one of the major causes of death for HIV-positive people, could be one such area. Looking further ahead, cancer drugs could benefit from this same private-public approach. Such cooperation must drive the post-2015 era.

Importantly, UNITAID has proved that innovative financing is the way forward to address global inequality. UNITAID's success has catalysed the Financial Transaction Tax in Europe and influenced the French President to dedicate a portion of the money raised by this tax to development. I am currently working with several African leaders to implement taxes on natural resource extraction, to ensure there is long-term domestic financing for poverty eradication programmes.

2013 has shown that conflict, from Syria to the Sahel, can erase decades of development progress in only a few months. While conflict creates poverty, the inverse is true: global inequality is the main driver of conflict and instability. If we are to finally put a stop to the seemingly endless spiral of conflict, we need to address inequality with sustainable solutions. Innovative financing can provide the resources to make these solutions a reality.

DR PHILIPPE DOUSTE-BLAZY

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

UNITAID's first years were dedicated to large-scale interventions to shape the markets for healthcare products for HIV/AIDS, malaria and TB. These changes improved the lives of hundreds of thousands of people in low-income countries by enabling them to access high quality healthcare products at reasonable prices. We have since moved further upstream in the pharmaceutical value chain, and now occupy a unique space where innovation is essential.

Our new Strategy, adopted by our Executive Board at the beginning of 2013, is at the heart of this transformation. Through a robust analysis of product markets for the three diseases, we have explicitly stated how we intend to invest in six 'Strategic Objectives', which are described in this report.

A new generation of projects is now being developed and implemented. UNITAID has diversified its base of grantees, almost doubling their number since 2012. Likewise, it has expanded the type of interventions it supports – ranging from large procurement-related activities to tailored interventions with very specific market effects as their goal, including those focused on innovation, market entry, market introduction, and intellectual property issues.

By investing in quality products designed to make treatment simpler for patients, UNITAID interventions also impact health systems and enable them to operate more effectively. Simplified treatment regimens and improved formulations minimise the number of pills that patients need to take. Better diagnostic technologies can reduce the time that patients spend waiting at health facilities for their test results. These innovations also have indirect benefits that increase the value for money of UNITAID's investments, including cost savings, and improvements that allow facilities to operate more effectively and serve greater numbers of individuals in need of treatment and care.

To ensure our investments are truly catalytic, we are working more closely than ever with partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund). The rollout of the Global Fund's New Funding Model in 2014 offers new opportunities for collaboration. Meanwhile, we are collaborating with civil society to promote access to new diagnostic technologies, and increase the speed at which they are introduced in communities.

Almost twenty years ago, people thought it impossible to reach even a few thousand people in Africa with life-saving HIV treatment. The global health community proved them wrong. Today, more than 10 million people are on HIV treatment in low- and middle-income countries. But we need to triple that number to control the HIV epidemic. To make this happen, we need even better medicines and technologies, in the right formulations and at the right prices. This is why UNITAID's business model is more relevant than ever.

DR PHILIPPE DUNETON

Executive Director a.i.

UNITAID uses innovative financing to transform markets for products to test, treat and prevent HIV/AIDS, malaria and tuberculosis (TB) in developing countries. Using resources from a levy on air tickets and long-term government contributions, UNITAID invests in high impact market interventions to make health products more affordable, more available and better adapted for low-income populations.

GLOBAL LEADERSHIP AND UNIQUE ROLE

UNITAID was launched in 2006 at the United Nations General Assembly by the governments of Brazil, Chile, France, Norway and the United Kingdom to help reach the health related Millennium Development Goals. UNITAID is hosted by the World Health Organization (WHO) and is currently supported by 17 contributing members from around the world.

A NEW STRATEGY TO TRANSFORM MARKETS

UNITAID's Strategy 2013-2016 guides the organization's response to HIV/AIDS, malaria and TB. In total, these global epidemics kill almost 4 million people every year. Forward looking and flexible, UNITAID collects intelligence on product markets for these diseases in order to inform its investments, which are implemented by the world's top development organizations.

UNITAID's Strategy is aligned with the goals of the global health community:

- Provide 15 million people with HIV medicines by 2015;
- Reduce TB prevalence and death due to TB by 50%;
- Reduce malaria deaths to near zero.

VALUE FOR MONEY

UNITAID's approach is complementary to the work of other public health actors, as it concentrates on shaping product markets at the global level. The improved market conditions that UNITAID secures through its catalytic market interventions – such as improved quality, lower prices or new formulations – are available to anyone purchasing products in the market. This includes other global health partners, such as the Global Fund and the United States President's Emergency Plan for AIDS Relief (PEPFAR), but also national treatment programmes from low-income countries and civil society organisations.

UNITAID makes public money go further:

For countries and global health actors, UNITAID's price reductions allow more products to be bought with the same money.

UNITAID accelerates access to better technologies:

For health workers, better products help reduce the burden that HIV/AIDS, malaria and TB impose on health systems.

UNITAID saves lives:

Quicker results, easier-to-take medicines, less toxic treatment all lead to healthier lives!

UNITED to innovate: spotlight on UNITAID members

France

2013 began with an important milestone for both UNITAID and France.

In January, the French Civil Aviation Authority announced that its 'air ticket levy' had collected more than €1 billion since its implementation in July 2006. A small fee of approximately €1 for domestic and €4 for international economy flights is used by France to finance UNITAID. It is widely heralded as one of the most successful initiatives for innovative financing for development, or raising money for low-income countries from activities that benefit the most from globalization – with zero negative impact.

At the United Nations General Assembly in September 2013, President François Hollande announced a 12.7% rise in the levy, thus increasing the levy paid on an economy domestic flight by 13 euro cents and on international flights by 51 euro cents.[1] In addition to France, eight other UNITAID member states use an air ticket levy to raise funds for UNITAID: Cameroon, Chile, Congo, Madagascar, Mali, Mauritius, Niger and the Republic of Korea.

€1 Billion

RAISED BY THE FRENCH AIR TICKET LEVY FROM 2006-2013

[1] Code général des impôts, CGI. - Article 302 bis K.

LEADING THE INNOVATIVE FINANCING AGENDA

The success of the air ticket levy has catalysed other innovative financing initiatives. President Bill Clinton called UNITAID 'France's gift to the world' at a special event to honour UNITAID in May 2013, in part because it paved the way for new ways to leverage small contributions to achieve a large impact.

UNITAID's Chair Dr Philippe Douste-Blazy is the UN Under-Secretary General for Innovative Financing and has helped lead the global conversation about sustainable ways to raise money to combat global inequality. In cooperation with the Leading Group for Innovative Financing, Dr Douste-Blazy advocates for additional financing measures to cover gaps in poverty elimination – particularly to reduce child mortality.

One initiative directly influenced by UNITAID's work has been the Financial Transaction Tax, currently being introduced by 11 European countries. France implemented the tax in March 2012: a 0.2% tax on share purchases. In 2013, France became the first country to allocate a proportion of the money raised by this tax towards the fight against global poverty. At the United Nations General Assembly in 2013, President Hollande said that UNITAID's success had paved the way for this. 10% of the financial transaction tax's receipts were allocated to development in 2013.

“UNITAID FOUND THE WAY TO MARRY THE MASSES OF THE PEOPLE WHO BENEFIT WITH THE MASSES OF THE PEOPLE WHO GIVE.”

President Bill Clinton - PARIS 2013

Norway

Another founding member of UNITAID, Norway, contributes to UNITAID through its development assistance budget. Norway is UNITAID's third largest donor.

In 2013, the Norwegian Ministry of Foreign Affairs carried out a review of Norway's support of multilateral organisations. The review found that UNITAID 'reinforces the efforts of the Global Fund'. According to the review, UNITAID provides 'more health for the money' because of its innovative financing and large-scale purchasing to reduce prices. The review also noted UNITAID's 'poverty perspective,' and its constitutional mandate to spending 85% of its disbursements on low-income countries.

UNITAID's commitment to women's and children's health is also important for Norway's development priorities. In January 2013, UNITAID shared its approach with a high level panel on *Accelerating Progress in Saving the Lives of Women and Children* that was held in Oslo, Norway.[2] UNITAID discussed how its experiences with market shaping could be used to increase access to essential medical products that would reduce death rates in women and children.[3]

"UNITAID WORKS IN AN INNOVATIVE WAY THAT PROVIDES 'MORE HEALTH FOR THE MONEY.'"

Norway Ministry of Foreign Affairs Review of UNITAID, 2013

[2] A report of the meeting is available here: http://www.norad.no/en/thematic-areas/global-health/maternal-child-and-womens-health/accelerating-process-2013-report

[3] Accelerating progress in saving the lives of Women and Children,' The Global Campaign for the Health Millennium Development Goals – Report 2013.

Why market shaping?

UNITAID shapes markets so that manufacturers and distributors have the appropriate incentives to invest, innovate, and supply quality health products at affordable prices and in acceptable formulations to developing countries.

MARKET SHORTCOMINGS

To shape markets, UNITAID identifies five types of shortcomings in markets that need to be overcome:

1. The medicine or technology to effectively prevent, diagnose or treat a particular disease or condition is not currently **available**.
2. The medicine or technology is offered at a **price** that imposes an unreasonable financial burden on governments, global health partners, individuals, or other payers.
3. The medicine or technology is of sub-standard **quality** or there is a lack of reliable information on the quality of the product.
4. The medicine or technology is not accessible in a format, formulation, or dose that is **appropriate for use** in a given population or setting.
5. **Supply chain** management systems are unable to equitably provide the right product or technology to the people who need it.

50%

PRICE REDUCTION OBTAINED BY UNITAID FOR DRUGS USED IN PROGRAMMES FINANCED BY THE GLOBAL FUND

FRENCH MINISTRY OF FOREIGN AFFAIRS, AUGUST 2013

THE REALITIES OF MARKET SHORTCOMINGS

The challenges facing the Meconta District Hospital in Mozambique help to illustrate why diagnostics were a focus for UNITAID investments in 2013. One lab technician (pictured) serves 200,000 people in this remote northern region. There is extremely limited diagnostic capacity for malaria and TB – two major diseases in the province. One microscope is used for both diseases. The high salt content in the water can falsify results. Intermittent power cuts make microscopy difficult.

Despite these challenges, dedicated local health workers make do with the available technology to handle hundreds of cases a day. Child mortality has decreased in the region, thanks to their efforts. UNITAID removes barriers to new health products that would improve lives but also lessen the burden on health systems – rapid diagnostics, adapted treatments and other innovative products. Imagine what the committed health workers in Meconta could do with these tools!

"If you look from a stream perspective, UNITAID is upstream and the Global Fund is downstream. UNITAID pushes the innovation and the market shaping for commodities and the market forces that will put them in the range of affordability, so that institutions like the Global Fund can support countries to access those commodities."

Mark Dybul, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria

The Global Fund
To Fight AIDS, Tuberculosis and Malaria

OUR VISION TO TRANSFORM MARKETS AND SAVE LIVES

UNITAID's Strategy 2013-2016 features six Strategic Objectives to guide the organization; these are described in the following pages. A clear and transparent process has been created to achieve these objectives:

EXPLORE

UNITAID collects **market intelligence** to inform Strategic Objectives. In 2013, UNITAID produced over ten 'Landscape Reports,' which provide comprehensive and up-to-date intelligence on product markets and technologies. These reports also give a clear understanding of market shortcomings and identify opportunities to improve them. To summarize these findings, UNITAID launched a '**Market Dynamics Dashboard**' in 2013; it is an online tool that is updated monthly.

GENERATE IDEAS

Two **market fora** were held in 2013, one for malaria and one for TB. These are unique platforms used by UNITAID to gather leading health experts together, and to establish a consensus on market challenges and refine areas for exploring market interventions.

SEEK PROPOSALS

Periodically, UNITAID launches a call for **ideas**, known as 'letters of intent' (LOIs). These short concept notes describe an idea and successful candidates are invited to develop full proposals. In May 2013, UNITAID launched a call for ideas linked to its Strategic Objectives.

DEVELOP/DESIGN

Applicants who send the most promising LOIs are invited to develop full proposals, which are developed in conjunction with the UNITAID Secretariat's expertise.

DECIDE

The **Proposal Review Committee**, an independent team of global health experts, rigorously evaluates proposals against defined criteria in order to evaluate the likely impact of each intervention. Only the best projects are recommended for funding. In 2013, UNITAID's Executive Board approved over $140 million in grants.

IMPLEMENT

UNITAID manages grants and monitors their success through close surveillance and independent evaluations. UNITAID publishes Key Performance Indicator reports each year to show the performance of its grants.

STRATEGIC OBJECTIVE 1

Increase access to simple point-of-care diagnostics for HIV/AIDS, tuberculosis and malaria

HIV/AIDS

UNITAID is leading the effort to bring portable and easy-to-use HIV diagnostic tools out of the development pipeline and into communities where they are needed most.

30%

HAVE ACCESS TO VIRAL LOAD TESTING IN DEVELOPING COUNTRIES

UNITAID MARKET DYNAMICS DASHBOARD MARCH 2014

Diagnostic technology can help make HIV a manageable condition for populations in low-income areas. A wealth of emerging products – known as 'point-of-care' diagnostics – can be used to rapidly measure an individual's response to HIV treatment without having to refer patients to central hospitals. Point-of-care diagnostics bring essential HIV monitoring closer to where people live, reducing the need for centralized laboratories and skilled technicians and enabling tests to be carried out while patients wait. These tools can help determine if individuals are adhering to HIV treatment or if changes in the regimen are required – an essential part of managing any chronic condition.

In its current strategic period, UNITAID has made removing market barriers to these tools a priority, with over $140 million invested so far in a range of market interventions. UNITAID's unique role allows it to work with both the largest global health organizations, as well as with small companies, to bring innovative products to market.

UNITAID aims to create a sustainable and competitive market for diagnostic products, so that global health partners can maximize their investments and countries can integrate these tools into their health systems. By shaping markets, UNITAID can ensure that people living with HIV in low-income countries can benefit from the enormous technological advances that are being made in HIV care.

CHALLENGES AND MARKET SHORTCOMINGS

CD4 testing is used to monitor the number of a particular type of immune cell (CD4 cells). Access to CD4 testing is approximately 60% of the predicted need in developing countries. CD4 testing is used to determine when an HIV-infected person needs to start treatment. Until recently, CD4 testing was only available in central hospitals, meaning patients had to travel long distances to be tested and then wait for weeks before they receive their test results. This delayed initiation of HIV treatment. Approximately half of CD4 laboratory-based test results are never received by patients, according to recent estimates. A considerable proportion of patients do not return for the results. Currently, laboratory-based CD4 test machines cost up to $90,000, while new point-of-care devices on the market can cost up to $25,000.

Access to viral load testing, which indicates treatment effectiveness, is approximately 30% of the estimated need. The viral load test measures the number of HIV copies in a millilitre of blood and is the most important tool to determine if HIV treatment is working. Effective HIV treatment reduces the level of the virus in the blood to 'undetectable.' People with an 'undetectable' viral load also have a low risk of transmitting HIV and are healthier overall.

In its 2013 Guidelines, WHO recommended implementing viral load testing for HIV treatment monitoring as the preferred approach. While viral load testing is part of standard HIV care for patients in high income countries, access to viral load monitoring in remote settings is very limited. No viral load point-of-care devices are currently on the market. Viral load machines range from $100,000 to $225,000. Individual tests can cost up to $70 each. The machines require extensive and complex laboratory infrastructure, and trained staff are needed to operate them.

Access to infant diagnostic testing for children born to HIV-infected mothers is approximately 35% of the estimated need. As explained in the next section (paediatric HIV), these diagnostics are vital to enable infants to start life-saving treatment as soon as possible.

60%

HAVE ACCESS TO CD4 TESTING IN DEVELOPING COUNTRIES

UNITAID MARKET DYNAMICS DASHBOARD MARCH 2014

TRANSFORMING MARKETS IN 2013

Clinton Health Access Initiative/UNICEF

The Clinton Health Access Initiative (CHAI) and UNICEF are implementing a UNITAID grant to reduce market barriers and accelerate access to point-of-care HIV diagnostics in seven high-burden countries: Ethiopia, Kenya, Malawi, Mozambique, Tanzania, Uganda and Zimbabwe.

Few point-of-care products are available to be deployed in the field. In 2013, CHAI and UNICEF began planning activities with the Ministries of Health in these countries for the adoption of these tools when they become available. The first point-of-care CD4 machines were delivered in 2013, and healthcare workers were trained to use them. These counters run on battery power and can be deployed in remote clinics to provide test results within an hour. Modules are connected to a central database for data collection and analysis. In December 2013, the UNITAID Executive Board approved the next four-year phase of this project.

Médecins Sans Frontières

With UNITAID funding, Médecins Sans Frontières (MSF) is implementing point-of-care CD4 and viral load testing in eight MSF-supported HIV/AIDS programmes: in the Democratic Republic of Congo, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Uganda and Zimbabwe. The project aims to establish the feasibility of routine viral load testing in resource-limited settings. The project will assess which existing and pipeline devices are suitable for specific contexts; how they can have the greatest impact on treatment outcomes; and to what extent viral load testing can be decentralised.

A global network to improve access and quality of HIV monitoring technologies

UNITAID is supporting the London School of Hygiene and Tropical Medicine for the harmonization of regulatory processes for HIV monitoring devices across Africa. The project will develop standardized evaluation protocols; a network of evaluation sites; and a toolkit to facilitate the evaluation and adoption of technologies.

OPP-ERA: BRINGING VIRAL LOAD TESTING TO WEST AFRICA

In West Africa, UNITAID is funding *France Expertise Internationale* (FEI) to stimulate market entry of new HIV monitoring tools. While access to viral load testing in Southern and Eastern Africa is low, availability is even lower in West Africa, at approximately 7% of estimated need. This project will scale up viral load testing in four countries where vital HIV monitoring is more or less unavailable: Burundi, Cameroon, Côte d'Ivoire, and Guinea.

FEI is piloting an innovative system to detect 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 more peripheral settings.

The OPP-ERA project was launched in September 2013 in Abidjan, Ivory Coast. It is being implemented by a French consortium spearheaded by FEI, in conjunction with its partners ESTHER, the Agency for Research on AIDS and Viral Hepatitis, SOLTHIS and Sidaction.

7%

HAVE ACCESS TO VIRAL LOAD TESTING IN WEST AFRICA

"OPP-ERA WILL OPEN THE MARKET TO NEW TECHNIQUES AND NEW MOLECULAR BIOLOGY TESTS, WHICH ARE BETTER ADAPTED AND LESS EXPENSIVE THAN CURRENTLY AVAILABLE TECHNIQUES."

Professor Christine Rouzioux,
Necker Hospital and University of Paris Descartes.

FROM THE PIPELINE INTO HIV-AFFECTED COMMUNITIES

UNITAID's 'market entry' programme is an innovative response to a major challenge in the roll-out of affordable point-of-care HIV diagnostics technology. Developers often encounter difficulties in financing late-stage commercialization and product development. UNITAID grants accelerate the market entry of promising point-of-care tools to stimulate competition between developers.

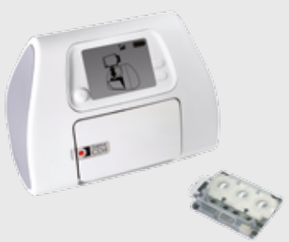
UNITAID's Strategy 2013-2016 allows it to make strategic market entry grants directly to developers. Synergies with other UNITAID investments will result in products becoming widely available at affordable prices.

While venture capital funding for small companies is driven by private equity, UNITAID's Market Entry investments aim to drive down prices and improve the lives of people living with HIV. In 2013, four grants were made, focusing on late-stage product development and optimization, in-country field evaluation, commercialization and regulatory approval.

Burnett Institute
CD4 point-of-care test

Zyomyx
CD4 point-of-care test

Daktari Diagnostics
CD4 point-of-care test



Diagnostics for Real World
Viral load/early infant diagnosis point-of-care test

Saving Lives: From Rural Clinic to District Hospital in Malawi

Among the rolling hills and tea plantations of Southern Malawi, people are living with some of the highest rates of HIV infection in the world. Yet this region is also a success story in the global response to the disease. HIV medicines are readily available for free; the number of new HIV infections has fallen; and deaths have been halved over the last decade.

Now, with UNITAID funding, MSF is rolling out routine viral load testing in remote areas of Southern Malawi and piloting innovative ways to get results quickly to patients and caretakers. Successes in 2013 offer a tantalizing peek into a future where technology and good practices offer quality chronic HIV care in rural communities throughout Africa.

As part of UNITAID's grant, MSF is piloting 'dried blood spot' sample techniques in Thyolo district, a large, remote area with an HIV prevalence rate of approximately 14-16%. In the photo on the previous page, a health worker prepares a dried blood spot sample at the Bvumbwe Health Centre.

Blood samples are collected from decentralized sites, such as Bvumbwe Health Centre, and then delivered by motorbike to the central Thyolo District Hospital, pictured, where they are analysed in the laboratory. Viral load results are sent back to health workers via SMS. "We are influencing policies nationally and internationally and other districts are coming to see our good work," said the Thyolo District Medical Officer, Dr Michael Murowa.

At the Namitambo Health Centre, in the remote Chiradzulu District, MSF is rolling out SAMBA, the first available near point-of-care viral load device, as part of the UNITAID grant. Chiradzulu has an HIV prevalence rate of approximately 17%.

SAMBA can be rolled out in more peripheral health care facilities and is the first of a rich pipeline of near point-of-care technology to be deployed at this level. Laboratory clerk, Violet Jombo, is pictured above, reviewing viral load counts measured with SAMBA at the Namitambo Health Centre. One strong advantage of point-of-care devices is that they require limited staff training. Violet had little medical experience before she started working at the UNITAID project.

One woman, Mercy Banda, walked 7 km to the clinic to get her viral load test. Clinicians suspected her treatment was failing, and tested Mercy's blood, using SAMBA, as she waited outside. If Mercy's viral load was found to be over 1,000 copies per ml, clinicians would start three months of adherence counselling, working together with Mercy to help her take medications as prescribed.

TUBERCULOSIS

2013 was a ground breaking year for the introduction of advanced diagnostics for drug-resistant tuberculosis. More affordable and even better tools are needed.

Multi-drug resistant tuberculosis (MDR-TB), a TB strain that is resistant to the two most powerful first-line treatments for TB, is an undeniable global threat. In order to stop its spread, individuals need to be diagnosed and put on treatment quickly before they infect others. However, access to testing is very limited: fewer than one in four of the estimated 450,000 cases of MDR-TB were detected in 2012.

For several years, UNITAID has been accelerating the introduction of innovative diagnostic technologies for TB. In 2013, UNITAID started the largest global roll out of GeneXpert®. This state-of-the-art molecular diagnostic machine reduces the time to diagnose drug-resistant strains of TB from weeks to a few hours. Meanwhile, UNITAID's five-year old EXPAND-TB project has made huge progress in strengthening laboratory-based diagnostics for MDR-TB. Until these technologies were introduced, the only technique available to test for MDR-TB involved growing the bacteria in laboratory cultures.

UNITAID's Strategy 2013-2016 hopes to build on these catalytic investments and facilitate the introduction of new point-of-care diagnostics from several competing suppliers, at lower prices than those currently charged.

19%

HAVE ACCESS TO DIAGNOSTICS FOR MULTI-DRUG RESISTANT TB

UNITAID MARKET DYNAMICS DASHBOARD MARCH 2014

40%

PRICE REDUCTION ACHIEVED ON NEW RAPID TB TEST, WITH OVER $18.9 MILLION SAVED IN THE FIRST YEAR

PROGRESS AND CHALLENGES IN 2013

GeneXpert® generated excitement in 2013. In September, the TBXpert project was launched in Yangon, Myanmar. Co-ordinated by WHO and the Stop TB Partnership, over 220 GeneXpert® machines and 1.4 million test cartridges are being delivered to 21 countries in Africa, Eastern Europe and Asia through this project. GeneXpert® detects resistance to rifampicin, one of the most commonly used first-line TB treatments, and is also sensitive enough to detect TB in patients who are co-infected with HIV.

In conjunction with PEPFAR, USAID, and the Bill & Melinda Gates Foundation, UNITAID obtained a 40% price reduction for GeneXpert® cartridges in 145 low- and middle-income countries. High-burden TB countries not in the TBXpert project, such as South Africa and Brazil, are now also able to take advantage of better prices. Over $18.9 million in global cost-savings have been achieved in the first year after this 'buy-down'.

But with only one supplier of highly sensitive rapid TB diagnostics, the current market is a monopoly. This limits opportunities to negotiate prices: each GeneXpert® costs approximately $17,000 and, despite price reductions, the cost per cartridge is still high.

Another challenge is that GeneXpert® is not a 'true' point-of-care device. The machine needs laboratory infrastructure and relies on a constant source of electricity. Approximately 60% of patients with suspected TB cases seek care in decentralized health clinics, where power outages are common and basic infrastructure is lacking.[4]

UNITAID's 2013 TB Diagnostics Technology and Market Landscape pointed out a number of new and emerging products in the pipeline that could be deployed closer to the point-of-care. UNITAID will continue to monitor the market to identify opportunities for investment.

[4] WHO/TDR/FIND (2006) Diagnostics for tuberculosis Global demand and market potential Diagnostics for tuberculosis Global demand and market potential, Geneva.

Saving Lives: Expand-TB

In TB hospitals across the globe, the 'EXPAND-TB' logo has become the hallmark of a modern, efficient approach to diagnosis for drug-resistant TB. On the outskirts of cramped urban centres from the Indian subcontinent to sub-Saharan Africa, technicians in these carefully controlled laboratories use molecular approaches to detect drug-resistant TB bacteria, extracting bacterial DNA from sputum samples.

72,000

CASES DETECTED BETWEEN 2009 AND 2013 THROUGH THE EXPAND-TB PROJECT IN 27 COUNTRIES

The EXPAND-TB Project was launched in 2009 in 27 high-burden TB countries with funding from UNITAID. Today, 92 laboratories have been fitted with state-of-the-art technology to diagnose MDR-TB – many of these labs did not have the capacity to diagnose MDR-TB before. Staff have been trained in the precise process needed to test potentially dangerous samples in a safe environment.

Between 2009 and 2013, almost 72,000 MDR-TB cases were detected through this project. In 2012, this accounted for one third of the total people with MDR-TB detected globally. In India, a total of 16,000 people with MDR-TB were detected in 2012 with support from EXPAND-TB. This accounts for 90% of the MDR-TB cases reported in this country.[5]

EXPAND-TB is a collaboration between WHO and the Global Laboratory Initiative (GLI), the Stop TB Partnership's Global Drug Facility (GDF), and the Foundation for Innovative New Diagnostics (FIND).

[5] World Health Organization. Reaching People with MDR-TB. Geneva, World Health Organization, 2014.

MALARIA

In many malaria-endemic countries, the majority of fevers are not caused by this mosquito-borne parasite. To target treatment better, UNITAID is making rapid testing available where many people seek care: the private sector.

There were an estimated 207 million cases and 627,000 deaths from malaria in 2012. Despite this heavy burden of infection, non-malarial illnesses such as pneumonia and diarrhoea are often the real cause of fever, especially in children. Testing is essential to ensure that fevers are treated correctly and valuable resources are not wasted by prescribing antimalarials when they are not needed. Without testing, non-malaria cases may be treated with an antimalarial, leading to a potentially life-threatening situation because the real cause of the fever goes untreated.

Progress is being made in improving access to diagnostic tests. WHO estimates that between 2010 and 2012, the proportion of suspected malaria cases that received a test in the public sector (government-run hospitals and clinics) increased from 44% to 64%. Most of this change was due to the increased use of rapid diagnostic tests (RDTs). RDTs are portable, easy-to-use, and detect the antigens produced by the malaria parasite in less than 25 minutes.

40%

SEEK MALARIA CARE IN THE PRIVATE SECTOR

Since 2010, WHO has recommended testing before treating all fever cases, but significant barriers exist to making this a reality. There is still limited access to quality RDTs in the public sector. Access in the private sector – pharmacies and drug shops – is virtually non-existent. This creates a problem, as an estimated 40% of people with malaria seek care in the private sector.[6]

UNITAID's Strategy 2013-2016 details a number of innovations that could increase testing for all forms of malaria, including emerging technologies that test urine instead of blood or use hand-held readers to offer highly sensitive results. UNITAID is now focused on increasing access to RDTs in the private sector and creating quality control systems for RDTs.

TRANSFORMING MARKETS IN 2013

The low uptake of RDTs in the private sector is largely due to lack of demand by retailers and patients. Education and guidance are needed for retailers, while countries should put the necessary policies in place to allow the sale and use of RDTs in the private sector. As highlighted in UNITAID's 2013 Malaria Diagnostics Market Landscape, results from both studies and pilot projects have shown that pharmacies are capable of testing customers and delivering the right treatment.

Creating a Private Sector Market for RDTs

How do we make a business case to private pharmacies in malaria-endemic countries to stock RDTs and use them with their customers? Can we help them manage fevers that are not caused by malaria?

A project funded by UNITAID to create a private sector market for RDTs in five African countries could pave the way for future approaches. Launched in 2013, this project is implemented by Population Service International (PSI) in partnership with the Malaria Consortium, FIND and WHO.

[6] World Health Organization. World Malaria Report 2010. Geneva, World Health Organization, 2010.

PSI is implementing the project in Kenya, Madagascar and Tanzania. It is working directly with private outlets, marketing RDTs to retailers and encouraging providers to stock the products. The Malaria Consortium is working in Nigeria and Uganda with RDT manufacturers to provide RDTs and services to private sector outlets. The lessons learned from both of these projects will be used to inform approaches that can scale up the use of RDTs throughout the private sector.

Sustainable Quality Control for RDTs

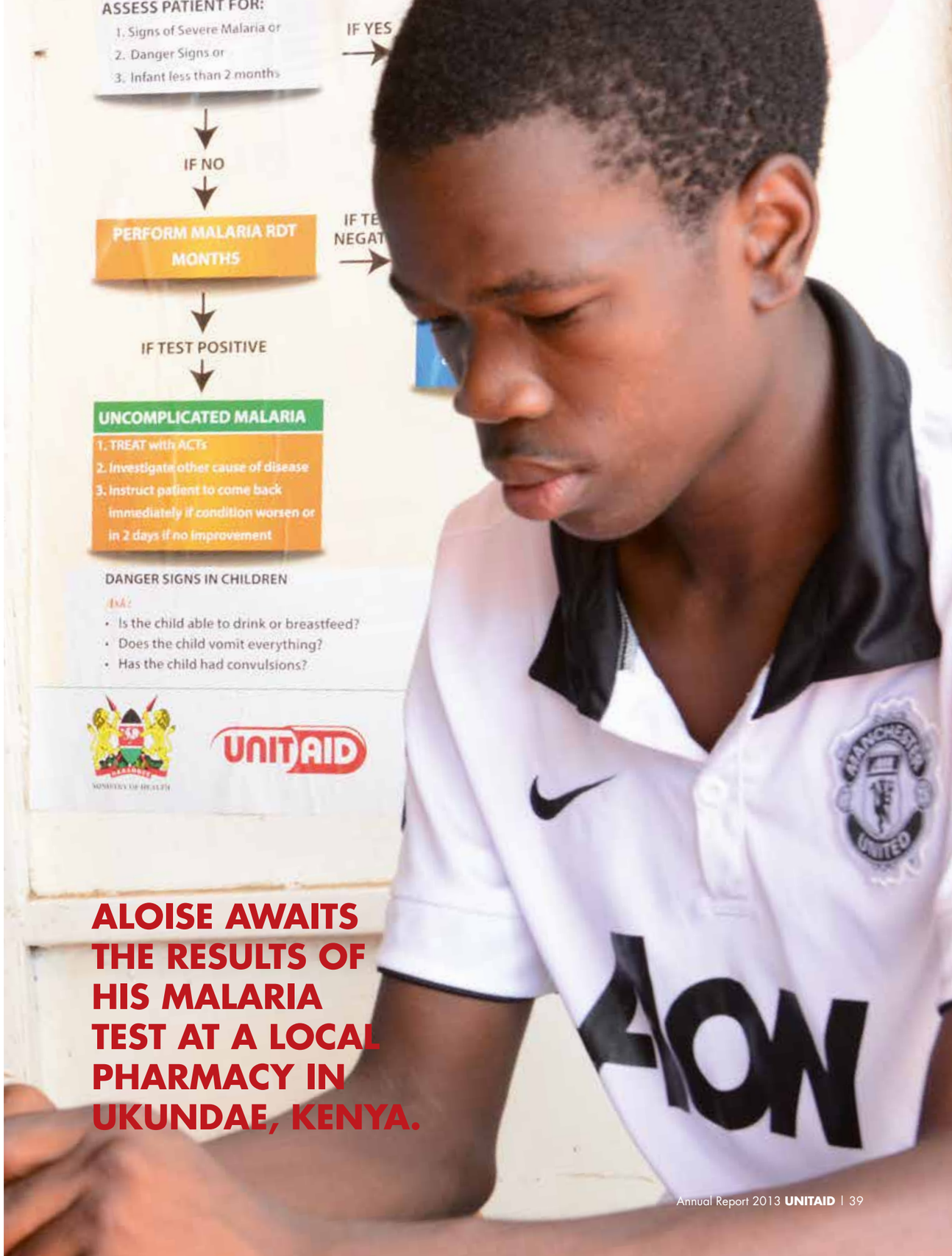
The RDT market is supplied by multiple manufacturers who sell varying types and qualities of products. To improve quality standards, UNITAID is funding WHO/FIND's RDT Product and Lot Testing Programme, a key service that forms the basis for WHO recommendations on selection and procurement of RDTs. This programme tests the types and quality of RDTs, both prior to purchase and after delivery of RDTs at the country level.

UNITAID's grant is enabling the programme to transition to the use of 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 RDT product performance testing and transition the lot-testing capacity to country programmes.

Saving Lives: Rapid testing for Malaria in the Private sector

Aloise, an 18-year-old living in Ukundae, Kenya, has a fever. He visits his local pharmacy, Otieno Chemist, for malaria treatment – he has had the disease before and knows how damaging it can be if left untreated.

Boniface, the pharmacist, works at one of the 50 registered private sector outlets in the Kwale district which have been trained in 2013 by PSI Kenya with UNITAID funding to recommend and administer discounted RDTs.



ALOISE AWAITS THE RESULTS OF HIS MALARIA TEST AT A LOCAL PHARMACY IN UKUNDAE, KENYA.

Boniface explains to Aloise that only a small proportion of fevers in the area is due to malaria and discusses the benefits of testing. Aloise agrees to buy an RDT and Boniface obtains a small blood sample for testing by a simple pinprick to the finger.

“Before, customers would ask for malaria treatment and I had no way of knowing what they really had,” explained Boniface. “I feel now that I can give a much better level of care to my customers and give them better reason to trust my advice.”

Part of the PSI grant involves explaining the benefits of malaria testing to the local community, especially mothers of young children. “We have to boost the RDT use from two sides,” explains Terry Muchoki of PSI Kenya. “Training the pharmacists to advise their customers is very important, but we also need to build awareness amongst the potential customers so that they are receptive to being tested.”

PSI has developed a range of social-marketing publications and activities, including a touring road show to spread the rapid testing message in towns and villages. “We have found that education by listening is the most effective way to get the message across,” explains Tom Ngaragari from PSI Kenya.

Back in the pharmacy in Ukundae, Aloise waits for twenty minutes for his results: negative. Boniface makes a recommendation for further testing at a nearby health facility.

STRATEGIC OBJECTIVE 2

Increase access to paediatric medicines to treat HIV/AIDS, malaria and tuberculosis

HIV/AIDS

While UNITAID has revolutionized diagnosis and treatment for children living with HIV, work is still needed. UNITAID must continue to innovate for these children, until the day that no baby is born with HIV.

20%

HIV TREATMENT COVERAGE FOR CHILDREN, COMPARED TO 34% FOR ADULTS

UNITAID MARKET DYNAMICS DASHBOARD MARCH 2014

One of UNITAID's most important achievements has been its creation of a paediatric HIV market, through a market intervention implemented by the Clinton Health Access Initiative (CHAI). Through this project, UNITAID put 470,000 children on treatment – the majority of the approximately 650,000 children on treatment around the world. In 2005, the number was only 10,000.

Yet today's number is still a fraction of the total number in need. With 3.3 million children living with HIV, there is only an estimated 20% antiretroviral treatment coverage for children, as opposed to 34% for adults with the current eligibility criteria for treatment. These criteria changed in July 2013 when WHO released new Guidelines for HIV Treatment, recommending treatment for all children under five years of age.

Despite global efforts, children are being left behind. Imagine: a child born with HIV only has a 50% chance of seeing their second birthday. A child with access to HIV treatment has the chance to live a healthy life.

Paediatric HIV is one of UNITAID's Strategic Objectives. UNITAID's business model – innovative diagnostics, reducing prices and facilitating the entry of better medicines – is needed to keep paediatric HIV from becoming a neglected disease.

Why should UNITAID continue to invest in paediatric HIV?

The success of prevention of mother to child programmes in wealthy countries has resulted in very few cases of paediatric HIV. There is little incentive for companies to develop child-friendly antiretrovirals (HIV medicines) for children living with HIV in developing countries. Starting in 2006, UNITAID invested heavily in paediatric antiretrovirals through CHAI, using pooled procurement to incentivize suppliers to manufacture new child-friendly formulations. Several generic suppliers entered the market – negotiations with these manufacturers and increased competition led to price reductions of up to 80% since 2006.

50%

PRICE REDUCTION IN 2013 FOR INFANT HIV TESTING PRODUCTS. LESS COMPLICATED TECHNOLOGY IS NEEDED

REASON 1

Need for Better Diagnostics

The lack of appropriate diagnostics is a major reason for the low treatment coverage for children. Infants retain maternal antibodies against HIV for over a year after birth. Hence, a rapid HIV test that detects anti-HIV antibodies could result in a misleading positive diagnosis.

Instead, highly sensitive molecular testing for babies known as 'early infant diagnosis' (EID) is essential. EID machines analyse RNA or DNA in a blood sample to detect HIV. Traditional, lab-based EID products are poorly adapted for low-resource settings because they are complicated to use and maintain; and require a reliable power supply, sophisticated infrastructure and skilled technicians to operate them.

Since 2006, UNITAID funding has enabled CHAI to engage directly with suppliers and governments to roll-out EID services and negotiate lower prices. In 2013, CHAI negotiated a 50% price reduction with Abbott Molecular Diagnostics for EID testing commodities, according to CHAI.

EID machines are located in central hospitals, often at considerable distances from remote communities. According to some estimates, half of the positive EID results are not received by the babies' caregivers: HIV infected babies who are not known to be infected fail to receive the life saving treatment that they need. The point-of-care technology described in the previous chapter is desperately needed for EID. UNITAID HIV diagnostics landscape reports have shown that the pipeline for innovative technologies that are easy-to-use and portable is rich: the challenge will be to ensure they are affordable for use in low-income countries.

THIS LABORATORY-BASED EARLY INFANT DIAGNOSTIC MACHINE AT QUEEN ELIZABETH CENTRAL HOSPITAL IN BLANTYRE, MALAWI CONDUCTS EID TESTING FOR ALL OF SOUTHERN MALAWI. DRIVERS LEAVE THE HOSPITAL ONCE A WEEK TO PICK-UP SAMPLES FROM RURAL AREAS.

REASON 2

An Uncertain Market

Efforts to eliminate the transmission of HIV from mother to child have been successful, with a 35% decline in the number of children newly infected from 2009 to 2012. HIV-infected mothers are treated during and after pregnancy to stop HIV transmission to their babies. For manufacturers of paediatric drugs, this translates into a shrinking and less attractive market, despite 260,000 children being born with HIV in 2012. WHO estimates that by 2020, 1.8 million children will still need antiretroviral treatment.

The market for child-friendly HIV medicines is only a fraction of the size of the adult antiretroviral market. As the paediatric market consists of small orders from several countries, suppliers are unable to respond quickly to these low-volume individual orders. Forecasting the estimated demand is difficult. This fragmented demand, and the special characteristics of the treatment needs for children, leads to higher prices than for adult treatments. Paediatric antiretrovirals are still twice as expensive as adult medicines.

To stabilize the market, the UNITAID Executive Board approved a grant to CHAI in December 2013 to create the 'Innovation in Paediatric Market Access' Initiative (IPMA). CHAI, in collaboration with the Paediatric ARV Procurement Working Group, will help countries order paediatric medicines; strengthen their forecasting capability for paediatric medicines; and coordinate procurement of these drugs.

Patent barriers can also lead to high prices and lack of availability of child-adapted formulations in countries that need these drugs. In February 2013, the UNITAID-funded Medicines Patent Pool entered into a collaboration with ViiV Healthcare to improve access to a key paediatric HIV medicine, Abacavir. This collaboration will allow low-cost versions of promising new medicines to be manufactured and sold in low-income countries. More work is still needed to ensure that access to other key products is increased.

60

PAEDIATRIC HIV TREATMENT FORMULATIONS

2014 UNITAID HIV MEDICINES LANDSCAPE

1.8 million

ESTIMATED NUMBER OF CHILDREN THAT WILL STILL NEED HIV TREATMENT IN 2020

WHO

REASON 3

Need for Better Formulations

Paediatric HIV treatment is complicated and requires very different dosage strengths, dependent upon a child's weight.

UNITAID has made great progress in facilitating adapted formulations for older children. Suppliers were given the incentive to make child-friendly fixed-dose combinations (FDCs) that include multiple antiretrovirals in a single pill. FDCs replaced the bulky and foul-tasting syrups that were the only option for children before UNITAID's intervention. Nevertheless, the market is still extremely fragmented, with more than 60 formulations available for paediatric HIV treatment, including multiple formulations of the same drug for different weight and age bands.

In its 2013 HIV guidelines, WHO recommended that all children under the age of three years be given a powerful class of antiretrovirals called protease inhibitors. However, currently available protease inhibitors only exist in a liquid form with a high alcohol content that tastes terrible and requires refrigeration.

With the support of UNITAID, the Drugs for Neglected Diseases initiative (DNDi) is working with the Indian generic company Cipla to develop a safe and child-friendly FDC treatment that includes the WHO-recommended protease inhibitors. This new 4-in-1 paediatric formulation, specifically adapted for infants and young children who cannot swallow tablets, will be easy to give with soft food or breast milk. Unlike current liquid formulations, the capsules will not require refrigeration and will be easy to dose.

MALARIA

Malaria is one of the major causes of child death in developing countries. UNITAID is shaping markets for better products in hospitals and communities to address the most deadly form of the disease.

Every year, thousands of children are brought into hospitals across Africa with severe malaria. Left untreated, severe malaria leads to almost certain death within 48 hours. In 2012, malaria killed an estimated 482,000 children under five years of age, according to WHO. New tools exist to combat severe malaria, but there are significant market barriers to their introduction.

CHALLENGES AND MARKET SHORTCOMINGS

In most cases, children diagnosed in hospitals with severe malaria are given intravenous quinine, a cumbersome and dangerous treatment that can last up to seven days and requires close vigilance to administer. Quinine has been used to treat malaria for centuries, but it has serious side effects.

In its 2011 malaria treatment guidelines WHO recommended injectable artesunate, a new, more effective and safer product for severe malaria. Although this product can be administered rapidly and with minimal training, uptake has been low. It is made by a single WHO-approved supplier and is up to three times more expensive than quinine, which is often purchased from local manufacturers and distributors. According to the UNITAID 2013 Medicines Market Landscape Report, less than 15% of the total estimated quantity of injectable artesunate needed to treat severe malaria was procured in 2012.

15%

OF THE NEEDED QUANTITY OF THE BEST TREATMENT FOR SEVERE MALARIA WAS PURCHASED IN 2012

UNITAID 2013 MALARIA MEDICINES LANDSCAPE MARCH 2014

Many children living in remote communities who fall ill with severe malaria are hours away from hospital care. For these 'pre-referral' cases, WHO recommends the use of rectal artesunate. A community health worker or a mother can administer these suppositories, buying time while the child is transported to hospital for curative treatment. Access to this product is limited though: no WHO-approved rectal artesunate product is currently on the market.

TRANSFORMING MARKETS IN 2013

UNITAID is accelerating the adoption of these effective medicines. A market intervention implemented by the Medicines for Malaria Venture (MMV) will increase use in six countries: Cameroon, Ethiopia, Kenya, Malawi, Nigeria and Uganda. Uptake and use of injectable artesunate will be supported, and additional suppliers will be encouraged to enter the market. Assistance is also being given to rectal artesunate manufacturers to gain WHO approval.

By creating a sustainable market for injectable artesunate, this intervention aims to increase demand for, and uptake of, injectable artesunate in the six countries, and to reduce the price of injectable artesunate by at least 30%. Price reductions will also be available to countries outside the project.

TUBERCULOSIS

TB is one of the top ten causes of childhood death, yet there are no child-friendly medicines. To end this neglect, UNITAID is funding the introduction of paediatric-adapted treatments.

An airborne disease, TB spreads in cramped quarters, often within families living in poverty. WHO estimated that 74,000 children died of TB in 2012. The actual death toll is likely to have been much higher. The exact number of children living with this disease is unknown because of a lack of proper diagnosis: the sputum samples needed to test for TB are very hard to collect from children.

According to UNITAID's 2013 TB Medicines Landscape Report, up to 1 million children may need treatment for TB every year. Only a small proportion of children with TB are actually treated and the market for TB medicines for children is fragmented and fragile.

CHALLENGES AND MARKET SHORTCOMINGS

A pressing challenge is the lack of child-friendly TB medicines. With no appropriate alternatives available, treatment providers cut and crush adult pills in order to treat children. This leads to improper dosing, treatment failure, spread of this highly contagious disease, and conditions ripe for the development of drug-resistant strains. Many children receive medicines of unknown quality.

35%

OF CHILDHOOD TB CASES TREATED

UNITAID MARKET DYNAMICS DASHBOARD MARCH 2014

In 2010, WHO changed its guidelines for treating children with TB, recommending higher dosages. Since then, no fixed-dosed combination with the correct dosing has been made available. For new TB drugs, trials have been delayed for their use in children. Why the neglect? A limited return on investment means the business case to enter this market is not attractive.

TRANSFORMING MARKETS IN 2013

In response to this need, UNITAID is funding the TB Alliance to develop appropriate child-friendly TB treatments; these are expected to be available in 2016. This work will help speed the development of other paediatric regimens that are now in the pipeline. The project will also map the paediatric TB market and accurately quantify the size of the burden of disease among children to help engage the interest of developers in this market. In 2013, the project reached a milestone, when TB Alliance entered into a collaboration with the first potential manufacturer: Svizera Europe, one of the leading global supply and distribution companies for TB medicines.

STRATEGIC OBJECTIVE 3

Increase Access to Treatment for HIV/AIDS and Co-infections

96%

OF HIV DRUGS FINANCED BY NON-DOMESTIC SOURCES ARE GENERICS

New treatment regimens for HIV/AIDS and co-infections are emerging that are less toxic than older medicines. UNITAID can help reduce barriers to their introduction, but the clock is ticking.

The pipeline for 'new generation' medicines is rich, with novel medicines showing great promise in efficacy and safety. This is especially true for hepatitis C (HCV), one of the leading causes of death for HIV-infected people. The end of 2013 saw the approval of the first HCV treatment that does not require complementary injections, providing hope of a better way to cure this viral disease. For now though, high prices will keep these products out of reach for low-income populations.

It took almost a decade for the 'first generation' of HIV antiretrovirals to reach developing countries at a great scale. Due to the removal of patent barriers, generic competition slashed prices from $10,000 a year at the end of the 1990s to less than $140 a year today. In 2012, 96% of antiretrovirals financed by major HIV funding agencies were generics.

Will a 'new era' with more extensive intellectual property barriers and high prices deter access to emerging antiretrovirals for low-income populations? Will optimal regimens be formulated as 'fixed-dose combinations', which are easier to take?

In 2013, these questions became even more relevant as WHO issued new HIV treatment guidelines. Developing countries rely on WHO guidance on HIV management to determine their own policies. The new WHO guidelines recommend treating adults at an earlier stage of HIV infection, before the immune system is compromised. They also recommend putting people on safer formulations that can be twice as expensive as older, and sometimes toxic, regimens.

High prices are also a major issue for second-line HIV medicines, which are used when resistance appears to the initial treatment regimen. UNITAID has already directly intervened in this market to stimulate generic competition, achieving price reductions of 50% on the most commonly used regimen. Nevertheless second-line medicines are still more than twice as expensive as first-line regimens; new second-line regimens and formulations are needed. Investments by UNITAID in improved viral load testing in Africa will identify more people who are in need of second-line treatment. Price reductions are critical to ensure linkage to treatment after drug resistance has been diagnosed.

As part of its Strategy 2013-2016, UNITAID aims to ensure that low-income countries benefit from the same, modern approach to HIV management as patients in high-income settings. Addressing intellectual property issues will be key to promoting equity.

50%

PRICE REDUCTION OBTAINED BY UNITAID FOR KEY HIV SECOND-LINE REGIMEN

THE MEDICINES PATENT POOL

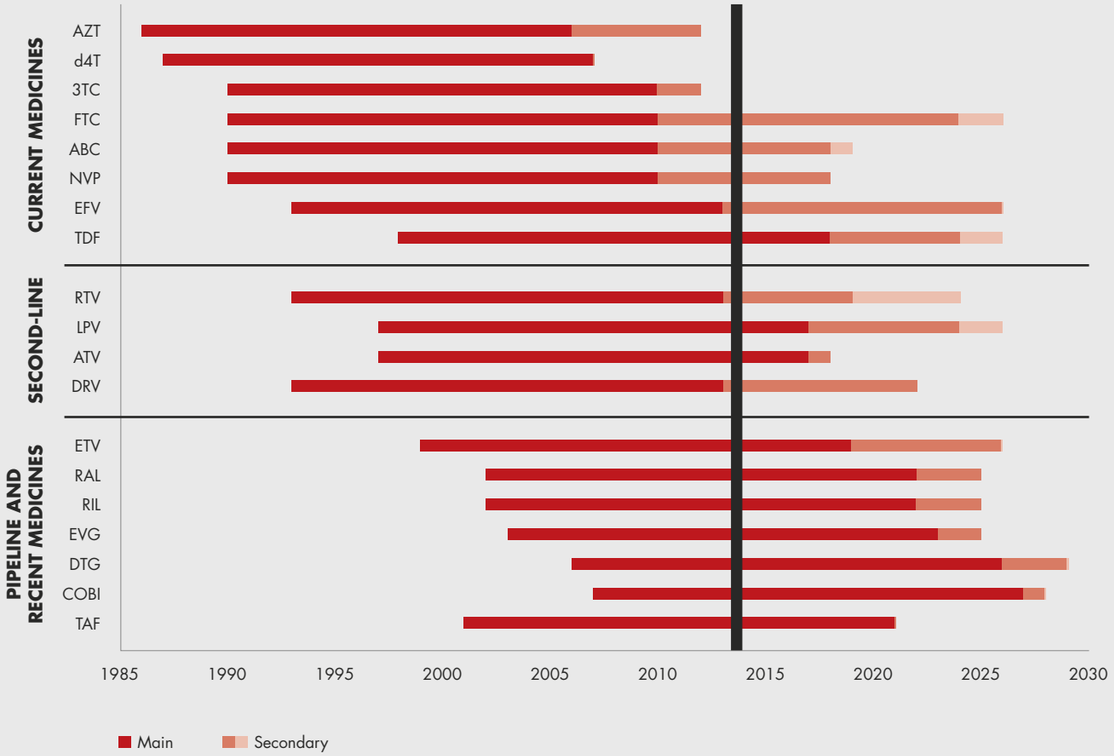
UNITAID created the Medicines Patent Pool (MPP) in 2010 to enhance access to appropriate, affordable HIV medicines. It does this by negotiating licenses with key pharmaceutical companies and other patent holders for the production of low-cost, generic versions of priority antiretrovirals.

In 2013, the MPP made significant strides to bring patent holders to the negotiating table. The MPP signed licensing agreements with ViiV Healthcare, (a joint venture between GlaxoSmithKline, Pfizer, and Shionogi), as well as with Roche and Bristol Myers Squibb (BMS). It also began negotiations with AbbVie on paediatric treatments, and with ViiV and Gilead on dolutegravir and tenofovir alafenamide fumarate, respectively (see Looking Forward section).

The MPP agreement with ViiV focused on a key paediatric HIV medicine that is part of WHO priority regimens for children under 10 years of age. The agreement with Roche secured a 90% price cut for valganciclovir, a treatment for a blindness-causing HIV related infection, in 138 countries. In its first agreement for a WHO-preferred second-line therapy, the MPP's deal with BMS for atazanavir covers more than 110 countries where almost 90% of people with HIV live. The WHO estimates that there will be more than one million people on second-line treatment by 2016 and many more will need access to these therapies.

Six generic manufacturers - Aurobindo Pharma Limited, Shasun Pharma Solutions, Laurus Labs, Hetero Labs, Emcure Pharmaceuticals Limited and Shilpa Medicare - have now licensed medicines to the MPP. The MPP is actively assisting them with development, manufacturing and registration plans to ensure quality generic medicines are provided to those most in need in low-and middle-income countries.

PATENT STATUS OF HIV MEDICINES



Spotlight on two promising 'new generation' treatments:

TENOFOVIR ALAFENAMIDE (TAF):

Tenofovir-based regimens are preferred by WHO but side effects can occur in certain patients who take tenofovir. TAF is a new pro-drug of tenofovir with fewer side effects. A patent on TAF has been granted or is pending in several low- and middle-income countries, including sub-Saharan African countries, and will only expire in 2021.

DOLUTEGRAVIR (DTG):

DTG is extremely potent; can be taken once daily; and has a high barrier to resistance. DTG was approved by the FDA in August 2013. The main patent will only expire in 2026. It has been granted in a significant number of countries and is pending in others.

BARRIERS TO EMERGING MEDICINES

HIV Medicines: Patent Barriers

Intellectual property barriers are recognised as one of main challenges to access for the next generation of HIV medicines. New products are likely to be granted 20-year patents, even in low- and middle-income countries that previously did not grant patents for pharmaceutical products. Patents keep the prices of HIV medicines high and hinder the development of adapted formulations. The timeline on the opposite page shows that older medicines – some with damaging side effects – are largely off patent, while newer medicines will be on patent for decades.

UNITAID's 2013-2016 Strategy continues the organization's commitment to a 'pro-public health' approach to intellectual property. Current UNITAID investments reflect this commitment. As described in the previous inset, the UNITAID-founded Medicines Patent Pool is at the cutting edge of approaches to increase access to generic medicines. A new project with the Lawyer's Collective in India will help prevent the granting of low-quality patents, which can delay generic production.

Hepatitis C Medicines: High Prices

An estimated 150-180 million people worldwide are infected with HCV and up to 500,000 die every year. Approximately 16% of the HIV-infected population is co-infected with HCV. Until recently, the only cure involved a combination of injections and oral tablets; the treatment lasted nearly a year. In addition to having limited efficacy, this regimen caused serious side effects that deterred patients from finishing the full course of treatment.

New HCV medicines are available or poised to enter the market: they work more quickly and effectively than current regimens. Approximately 10 of these drugs have reached an advanced stage in clinical trials. In December 2013, the US Food and Drug Administration (FDA) approved the first pill that may not require weekly interferon injections. At the end of 2013, this medicine cost $84,000 for a 12-week course.

In 2013, UNITAID published its first effort to gather market intelligence on products for the diagnosis and treatment of HCV. This scoping report stressed the need for high-quality, affordable and well-adapted products for treatment of HCV.

STRATEGIC OBJECTIVE 4

Increase Access to Treatment of Malaria (ACTs)

UNITAID has played a decisive role in increasing access to artemisinin-combination therapies (ACTs), the best treatment for malaria. Further efforts will be needed to stabilize this volatile market.

10%

HAVE ACCESS TO ACTs IN THE PRIVATE SECTOR

UNITAID MARKET DYNAMICS DASHBOARD MARCH 2014

In 2013, WHO announced that over a million deaths were averted thanks to the scale-up of global malaria control between 2001 and 2010. An important part of this effort has been the increased use of ACTs. Although ACTs are highly effective and use a combination of drugs to strengthen treatment and reduce the likelihood of drug resistance, their high price has been a barrier to widespread access.

ACT deliveries increased from 11 million treatments in 2005 to 331 million in 2011. UNITAID's investments have been key to this expansion, with over 333 million ACT treatments distributed through various UNITAID-funded market interventions since 2006[7]. Despite these efforts, it is estimated that access to ACTs in the public sector is approximately 20% of the need, whereas it is about 10% of the need in the private sector.[8]

CHALLENGES AND PROGRESS IN 2013

The main ingredient in ACTs is artemisinin, an ancient Chinese herbal remedy derived from the sweet wormwood plant. It takes approximately 12-18 months to grow the plants and extract artemisinin from them. Due

[7] As of 30 June 2013

[8] Based on median proportion of ACTs among antimalarials given to febrile children across 12 African countries in the public and private sectors.

to this lengthy cycle, the market cannot respond to sudden changes in demand, which results in large swings in both the supply and price. Retail prices for ACTs are high. Less effective medicines and poorer quality treatments are cheaper and more widely available, especially in the private sector.

To address these high prices and other barriers to access, UNITAID was the main investor in the AMFm (Affordable Medicines Facility - malaria) pilot project, which negotiated price reductions and provided subsidies to country-based wholesale distributors of quality ACTs. Hosted by the Global Fund, the AMFm allowed consumers to access subsidized ACTs in both the private and public sectors. It achieved consumer price reductions of up to 80% in seven African countries. As of end-2013, AMFm was integrated into the Global Fund's New Funding Model to provide countries the option to allocate funding to support the provision of subsidized ACTs to the private sector.

UNITAID's 2013 Market Forum pointed out the risk posed by a significant drop in ACT demand when the AMFm was integrated into the Global Fund. In order to mitigate this risk, UNITAID continues to support the production of quarterly global ACT demand and procurement forecasts that provide projections of the likely quantity of WHO-approved ACTs that will be needed, and the resulting demand for artemisinin.

As described in previous sections, children under the age of five years account for almost 80% of all malaria deaths. To treat malaria before it progresses to severe malaria, ACTs must be given to children. There is need for a more competitive market for child-friendly ACTs, especially for 'dispersible' tablets that can be dissolved in water. As emphasized in UNITAID's Market Dynamics Dashboard, retail-level availability of dispersibles is approximately 11-14%.[10]

Finally, malaria parasite resistance to artemisinin is emerging as a potential global threat. Widespread resistance to older malaria medicines has rendered them largely ineffective in many areas. So far, resistance to artemisinin has been detected in South-East Asia. New and diverse products are needed to avert future resistance.

333 million

ACT TREATMENTS DELIVERED THROUGH UNITAID INVESTMENTS SINCE 2006

[10] Health Action International. Retail prices of ACTs co-paid by the AMFm and other antimalarial medicines: Ghana, Kenya, Madagascar, Nigeria, Tanzania and Uganda. Report of price tracking surveys. September-October 2012.

STRATEGIC OBJECTIVE 5

Increase access to second-line tuberculosis medicines

Multidrug-resistant TB is extremely hard to cure. UNITAID has increased access to treatments and helped to secure their supply. New medicines have promise – but will low-income populations have access?

17%

HAVE ACCESS TO MDR-TB TREATMENT IN 2012 - LONG WAITING LISTS ARE COMMON

UNITAID MARKET DYNAMICS DASHBOARD MARCH 2014

Multidrug-resistant tuberculosis (MDR-TB) has been one of UNITAID's priorities since its creation, with significant investments to scale-up medicines. Meanwhile, UNITAID's investment in improved MDR-TB testing has led to an increase in the number of cases diagnosed in recent years. These interventions have helped to stabilize the market for quality MDR-TB medicines, contributing to price reductions of up to 32% for certain drugs offered by the Global Drug Facility of the Stop TB Partnership.

Progress has been made, but a huge gap remains. Access to MDR-TB treatment in 2012 was only 17% of need, with an estimated 170,000 deaths from the disease.[11] There are considerable market shortcomings that contribute to this low access, but new TB drugs and new regimens are finally becoming available, as described below.

CHALLENGES AND MARKET SHORTCOMINGS

Drug-resistant strains of TB can emerge in patients if their TB treatment is interrupted or if their drugs are of poor quality. They can also be infected with a drug-resistant strain from an infected person.

MDR-TB has much lower cure rates than TB – only approximately half of those who complete treatment are cured. MDR-TB treatment costs approximately $1,800 to $6,700 for a quality course in the public sector – compared to just over $20 for a first-line treatment course. Regimens

[11] Based on number of patients with MDR-TB enrolled on second-line treatment (77,321) / estimated total new MDR cases (450,000) in 2012 (WHO/Global TB report 2013).

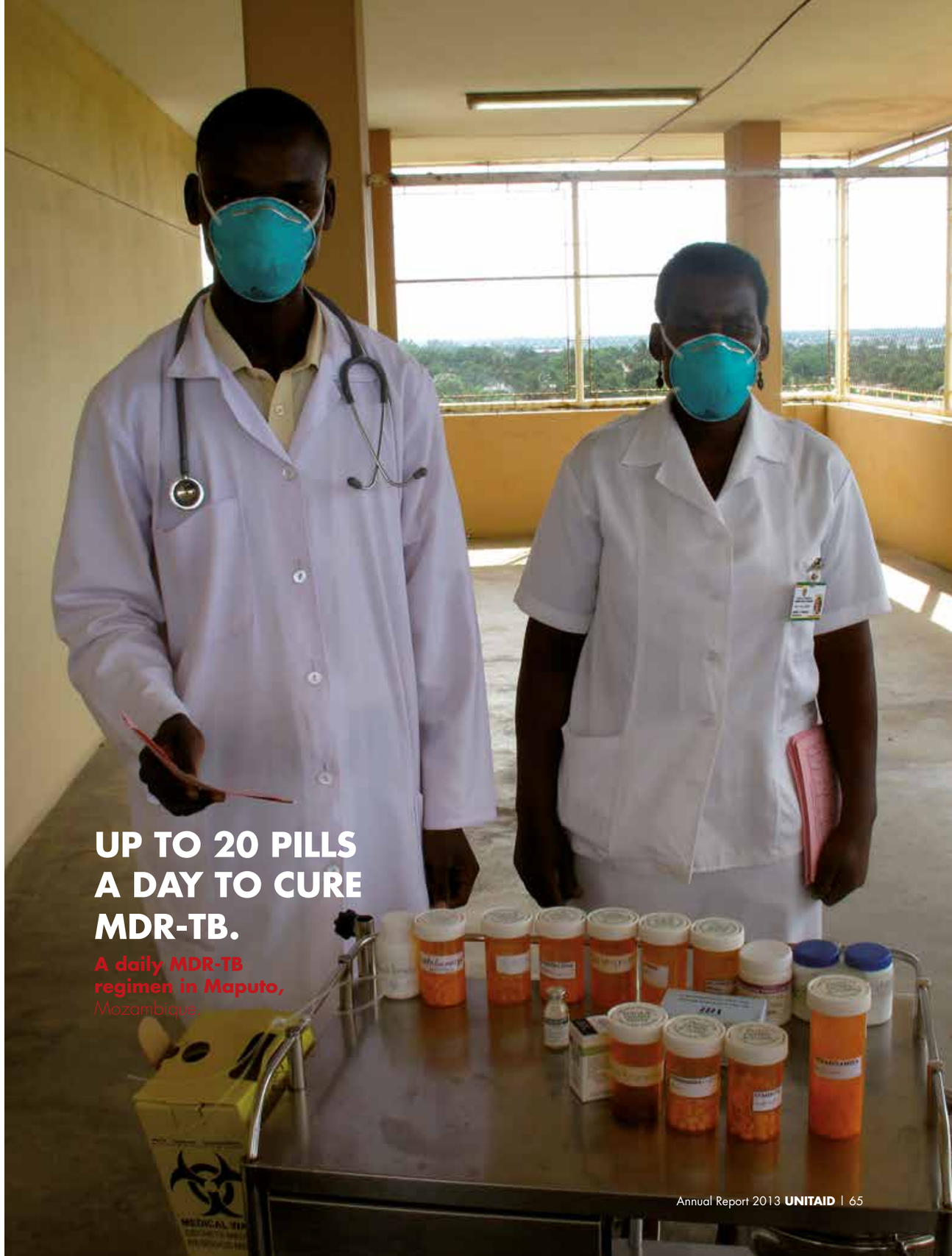
consist of an arduous regime of daily medicines over a two-year period, including eight months of injections. Medicines are toxic and have many serious side effects.

As highlighted in UNITAID's 2013 TB Medicines Landscape Report, the MDR-TB medicines market is small and heavily fragmented. Volumes for MDR-TB drugs are low – the total number of patients enrolled in MDR-TB treatment programmes is approximately 1% of the number who take first-line TB treatment. The market is unattractive from a commercial perspective, with few incentives to innovate. Furthermore, there are many public and private sector buyers in the MDR-TB market, primarily in middle-income countries where the MDR-TB burden is very high (Brazil, China and India). Global health partners therefore have less leverage to implement market shaping interventions.

TRANSFORMING THE MARKET IN 2013

The MDR-TB medicines market faces challenges in forecasting, with supply shortages and stock-outs. To address this, UNITAID finances a continuously replenished 'rotating stockpile' of MDR-TB drugs, allowing countries to access emergency orders of medicines and thus avoid treatment interruptions. In 2013, 67 country programmes ordered drugs from the stockpile.

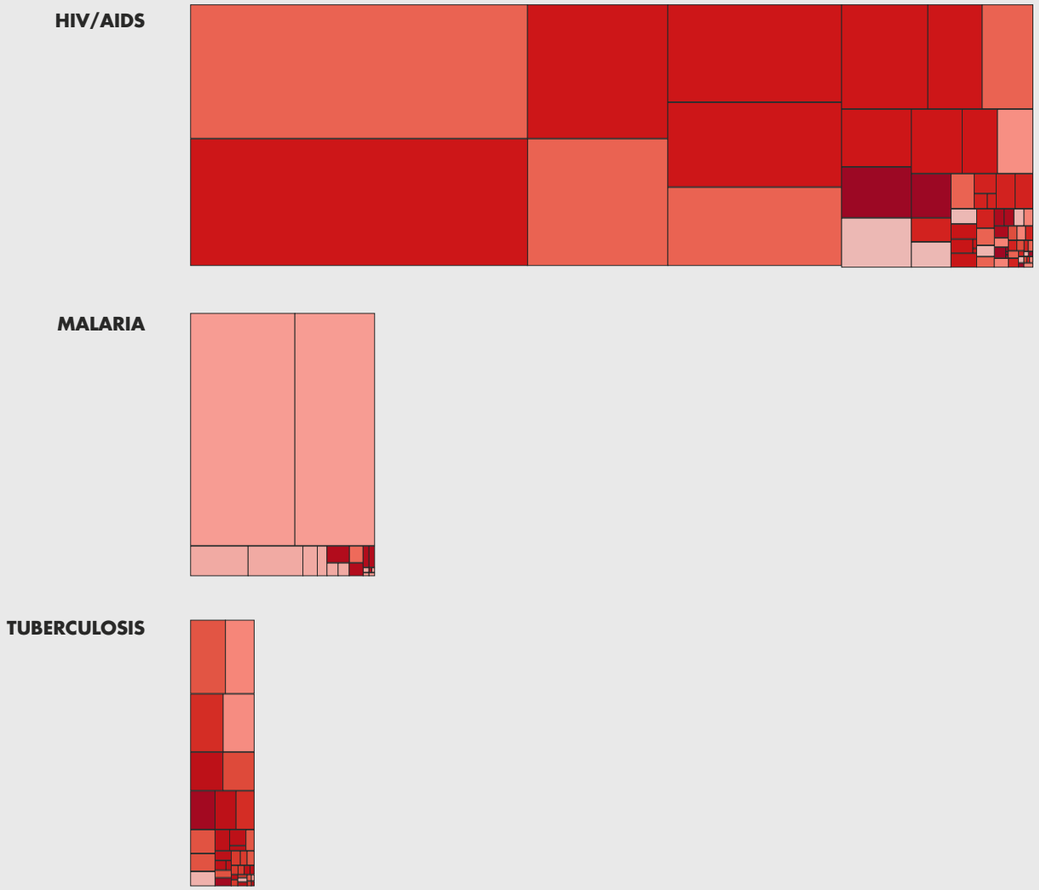
In December 2013, the UNITAID Executive Board committed a further $14.9 million to the stockpile, which is hosted by the Global Drug Facility, expanding the stockpile to 12,000 MDR-TB regimens and extending the project until 2015. Co-ordination with the Global Fund is being undertaken in order to link the stockpile to the Global Fund's Rapid Supply Mechanism for MDR-TB drugs when UNITAID's funding ends.



UP TO 20 PILLS A DAY TO CURE MDR-TB.

A daily MDR-TB regimen in Maputo, Mozambique

DONOR-FUNDED PURCHASES OF MEDICINES BY PRODUCT FORMULATION AND PACK SIZE, 2012.



CAN WE SIMPLIFY A FRAGMENTED MARKET?

Better MDR-TB treatment is on the horizon. In December 2012, the US Food and Drug Administration (FDA) approved bedaquiline, the first new TB medicine in over 40 years. In November 2013, the European Medicines Agency (EMA) granted temporary approval for delamanid, also developed specifically for MDR-TB. Shorter regimens are also being explored, including one that lasts only nine months.

While these developments generate some hope, more trials are needed to judge the safety and effectiveness of the new drugs, and questions about their price and availability are also unanswered. Until this evidence is available, standard MDR-TB therapy will still involve a large number of possible drug combinations. High-burden MDR-TB countries are currently estimated to use upwards of 40 or 50 unique MDR-TB regimens, according to UNITAID's 2013 TB Medicines Landscape Report.

As a comparison, donor-funded markets for HIV and malaria drugs are much larger, and yet are significantly less fragmented – as dramatically illustrated by the graphic on this page. What causes market fragmentation? Many purchasers from the public and private sectors; multiple regimens and multiple manufacturers for each drug; and no fixed-dose combinations are all important factors.

An analysis of donor-funded purchases of drugs by product formulation and pack size for HIV, malaria and TB reveals the large number of TB regimens that are bought by funders (graphic).

Future market interventions that simplify and consolidate the fragmented TB market could revolutionize care for the hundreds of thousands of patients around the world who are affected by MDR-TB. This theme was explored in the 2013 TB Market Forum hosted by UNITAID and USAID.

Saving Lives: Cured Patients Speak Out in Myanmar

There are no better experts on the difficulties of completing two years of gruelling MDR-TB treatment than the patients themselves. UNITAID played a catalytic role in financing the first pilot MDR-TB treatment programme in Myanmar and below, two patients who benefited tell their stories.

KO MIN MIN:
A NEW LIFE AFTER MDR-TB

Ko Min Min
during his treatment two years ago

Ko Min Min was a successful shop owner in Mandalay, but when he was diagnosed with MDR-TB, he had to sell his business. He had already lost his younger brother and sister to drug-resistant TB.

Ko Min Min was admitted to the Patheingyi TB Hospital on the outskirts of Mandalay city for treatment. After his discharge, a trained health worker visited him every day at home to help him take an arduous cocktail of pills. It was not easy. During the two years of intense treatment Ko Min Min suffered from dizziness and joint pains. Yet he persevered, and was declared finally cured in July 2011.

MDR-TB survivors play an important role in telling patients that there is a light at the end of the tunnel. U San Lin has embraced this role. At a widely publicized launch event held by UNITAID in September 2013, U San Lin proudly stood in front of the assembled national media to tell his story. He now works with Myanmar's treatment programme to visit, and convince, other patients to keep their eyes on the prize and finish their MDR-TB treatment. "I would like to share my knowledge and help other patients finish their treatment," he said.

U SAN LIN:
HELPING OTHER MDR-TB PATIENTS

STRATEGIC OBJECTIVE 6

Increase access to preventatives for HIV/AIDS, tuberculosis and malaria

$20

THE ESTIMATED PRICE OF AN EASY-TO-PRODUCE MALE CIRCUMCISION DEVICE

New tools are emerging that could help curb transmission of the three diseases. They must be priced right for low-income populations.

HIV/AIDS

According to UNAIDS, the annual number of new HIV infections decreased by 50% or more in 26 countries between 2001 and 2012. Recent research has revealed an increase in risky sexual behaviour in a number of sub-Saharan countries.

In August 2013, UNITAID released the first-ever landscape report on HIV prevention tools, detailing an unprecedented range of products to prevent HIV transmission. The report found that new tools hold promise, but high prices, low manufacturing capacity and weak demand are still barriers to the use of these products in developing countries.

Trials in three sub-Saharan countries showed that circumcising adult men reduces their risk of acquiring HIV infection by 60%. UNAIDS has set a goal of 20 million male circumcisions in Africa by 2015 and although many medical circumcisions have been carried out, this goal will not be reached if access is not accelerated. New **non-surgical circumcision devices** could transform this. One product was approved by WHO in 2013, but at approximately $20 per device, it is prohibitively expensive.

There is also a promising pipeline for **'female-initiated' devices**, such as female condoms and vaginal microbicide gels. Female condoms are 20 times more expensive than male condoms, but new innovations could improve their acceptability, while expansion of production capacity could improve their affordability.

Antiretroviral-based microbicide gels also have promise, with one clinical trial in 2010 South Africa showing a 39% reduction in HIV infection in women who used the microbicide consistently. Currently, no microbicide gel is approved for use, and UNITAID's report showed that only two products have a likely chance of being rolled out over the next several years.

Tuberculosis

Vaccinations and preventative therapy are two of the main strategies used to prevent TB. Preventative therapy is only currently used in children. The only available vaccine has limited effectiveness, and new vaccines are not expected to be commercially available until 2020 or later. UNITAID's role in TB prevention focuses on reducing transmission by increasing access to appropriate TB diagnostics and medicines. UNITAID will continue to monitor developments in this market.

Malaria

A highly effective way to protect families from malaria-infected mosquitoes is through the use of long-lasting insecticide-treated nets (LLINs). As highlighted in UNITAID's 2013 Malaria Vector Control Landscape Report, approximately one-third of the population of sub-Saharan Africa sleeps under an LLIN. Some challenges face the LLIN market, not least declining funds for malaria control. Other challenges include: mosquitoes are acquiring resistance to the insecticide used to treat the nets; and some LLINs do not meet the minimum durability standards to last the recommended three years.

UNITAID has intervened in this market, notably from 2009-2010 to stop supply shortages and incentivize manufacturers to increase production capacity. UNITAID's support – 20 million nets – contributed to almost 20% of the total nets delivered in 2009.

SEASONAL MALARIA CHEMOPREVENTION

UNITAID's 2013 Malaria Market Forum pointed to one promising area where a market shaping intervention could make a difference: seasonal malaria chemoprevention (SMC), or the use of antimalarials to prevent malaria during the rainy season. By giving children prophylactics at monthly intervals during this high-risk period, drug levels are maintained in the blood to prevent malaria.

In 2012, WHO recommended SMC in areas of highly seasonal malaria transmission across the Sahel sub-region of Africa. From approximately July to November, malaria cases peak in this region. Following this recommendation, a number of countries across the Sahel implemented SMC programmes, including Burkina Faso, Chad, Mali, Niger, Nigeria (pictured, above), Senegal and Togo. Evidence in these countries so far has shown that SMC during the transmission season (3-4 months) in children less than 5 years of age prevents approximately 75% of all malaria episodes.

According to the Malaria Forum's participants, efforts to introduce SMC were recently disrupted in the Sahel region of Africa due to supply issues. Timely supply is key to ensure that children receive their treatments each month during the rainy season. As there is currently only one supplier of the co-blistered SMC regimen with limited production capacity, market-based interventions are needed to ensure that a reliable supply of quality-assured medicines are available as SMC is scaled-up in Africa.

Strategic Objectives at a glance

STRATEGIC OBJECTIVE 1

Increase access to simple point-of-care diagnostics for HIV/AIDS, tuberculosis and malaria

HIV: Accelerate access to point-of-care HIV diagnostics with one of the largest investments to bring products out of the development pipeline and into communities.

TB: Help to stop the spread of multidrug-resistant TB by scaling up the use of new diagnostic technologies, with the aim of eventually facilitating access to new point-of-care devices.

Malaria: Ensure that the causes of fevers are treated appropriately, by making rapid testing for malaria available where patients often seek care: the private sector.

STRATEGIC OBJECTIVE 2

Increase access to paediatric medicines to treat HIV/AIDS, tuberculosis and malaria

HIV: UNITAID has revolutionized the diagnosis of, and treatment for, children living with HIV. It remains committed to innovating for these children and will increase access to specialized diagnostics; reduce prices of HIV healthcare products; and introduce child-friendly drug formulations.

TB: Help to end the neglect of paediatric TB by developing child-friendly medicines.

Malaria: Shape markets for better products that can be used in hospitals and in communities to treat the most deadly form of malaria.

STRATEGIC OBJECTIVE 3

Increase access to treatment for HIV/AIDS and co-infections

New treatment regimens for HIV/AIDS and co-infections are emerging that are less toxic than older medicines. UNITAID can help reduce barriers to their introduction, but time is short.

STRATEGIC OBJECTIVE 4

Increase access to treatment of malaria

UNITAID has played a decisive role in scaling-up access to ACTs. Further efforts will be needed to stabilize the volatile market.

STRATEGIC OBJECTIVE 5

Increase access to second-line TB medicines

Multidrug-resistant TB is hard to cure. UNITAID has increased access to treatments and helped to secure their supply. Promising new medicines are being approved – UNITAID could help ensure low-income populations have access.

STRATEGIC OBJECTIVE 6

Increase access to preventatives for HIV/AIDS, tuberculosis and malaria

UNITAID is monitoring new tools that are emerging to help curb transmission of HIV, TB and malaria. Promising market interventions could increase access to seasonal malaria chemoprevention during the rainy season.

IMPROVING QUALITY OF MEDICINES AND DIAGNOSTICS FOR MILLIONS

UNITAID is the main funder of the WHO Prequalification Programme – the only global quality assurance programme for medicines and diagnostics.

The WHO Prequalification Programme has improved the quality of medicines and diagnostics for HIV/AIDS, malaria and TB that are used by millions of people in low-income countries. It contributes greatly to UNITAID's market shaping approach, as it ensures that UNITAID 'priority products' are safe, efficacious and protect patients' health. During the 2013-2016 Strategic period, UNITAID will continue to fund and work closely with the Prequalification Programme.

The Prequalification Programme evaluates medicines, active pharmaceutical ingredients, diagnostics and medical devices on the basis of a stringent set of criteria. When WHO includes a product on its list of prequalified products, it provides national governments and global health partners with confidence about the product's quality when they are deciding which product to purchase. The Programme has prequalified over 200 products for treatment of HIV/AIDS: 85-90% of HIV antiretrovirals financed by the Global Fund, UNICEF and UNITAID were WHO prequalified generics.[12]

Prequalification is key for market shaping, as it enables low-cost generic products and new formulations adapted to meet the needs of patients living in low-income settings to enter the market. To gain prequalification status, manufacturers must supply comprehensive information about their product, and WHO inspection teams visit their manufacturing sites.

[12] Ellen F M 't Hoen et al. A quiet revolution in global public health: The World Health Organization's Prequalification of Medicines Programme, Journal of Public Health Policy, January 2014

FUNDING

Prequalification was established by WHO in 2001, and UNITAID began its support in 2006. In December 2013, the UNITAID Executive Board approved a $50 million extension to the Programme for three years. Currently, UNITAID and the Bill & Melinda Gates Foundation provide the vast majority of the support for the Programme. Moving forward, additional funders will need to support this vital global public health service.

"EVERY DOLLAR INVESTED IN THE [PREQUALIFICATION] PROGRAMME SAVES $170 IN PUBLIC MEDICINE PROCUREMENT."

Ellen 't Hoen,
Medicine Law and Policy Expert

SPOTLIGHT ON SELECTED PREQUALIFIED PRODUCTS IN 2013

2013 saw the first-time approval of some novel products by the Prequalification Programme.

Voluntary Male Circumcision Device: In May 2013, for the first time, WHO prequalified a non-surgical male circumcision device. Although this means that the device is now eligible for large-scale purchase by funding agencies, UNITAID calls for more competition in the market to reduce the price of this key product. Several other non-surgical devices are also currently going through the prequalification process.

Semi-Synthetic Artemisinin: In May 2013, WHO prequalified the first semi-synthetic version of artemisinin, the main chemical compound used in ACT production (see Strategic Objective 4 in previous section). The naturally growing raw ingredient is subject to seasonal disruptions, but the manufacture of the semi-synthetic compound will provide artemisinin on a predictable basis. This will help to stabilize prices and secure the supply of artemisinin and ACTs.

UNITAID up close

EXECUTIVE BOARD

The Executive Board is the decision-making body of UNITAID.

All funding decisions are made by the Executive Board, which also provides an essential leadership role for UNITAID. The Executive Board takes a forward-looking view that emphasizes strategy, value creation and resource allocation. It approves all partnership arrangements with other organizations and institutions. The Executive Board ensures that UNITAID achieves its objectives, promotes transparency and makes decisions in a timely and efficient way.

UNITAID's founding countries – Brazil, Chile, France, Norway and the United Kingdom – each nominate one representative to the Board. The African Union (represented by South Africa and Morocco), Asian countries (represented by the Republic of Korea) and Spain also each have one seat. The foundations constituency has one seat, represented by the Bill and Melinda Gates Foundation, as does the World Health Organization (this is a non-voting seat).

Civil society groups representing non-governmental organizations (NGOs) and communities living with the three diseases have two representatives on the Board. These civil society groups have a significant voice, contributing their experience and knowledge to help ensure that funds are spent on the interventions that will have the most impact.

Chair of the Executive Board

Dr Philippe Douste-Blazy is the Chair of the UNITAID Executive Board and was re-elected by the Executive Board in June 2013. He is also UN Under Secretary-General in charge of Innovative Financing for Development.

The Vice-chair position is held by Chile, represented by Dr Guy Fones.

Finance and Accountability Committee

The Finance and Accountability Committee was established by the Board of UNITAID to assist the Board in fulfilling its responsibilities with regard to UNITAID's financial planning, management, performance and accountability, as well as risk management and internal controls.

The Chair position is held by the UK.

Policy and Strategy Committee

The Policy and Strategy Committee was established by the Board of UNITAID to assist the Board in fulfilling its responsibilities with respect to development and oversight of UNITAID's programme, strategy and policy. The Committee advises the Board on UNITAID's overall strategic planning and development of core policies, and on implementation of resolutions brought to the Board that concern policy and strategy.

The Chair position is held by France.

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.

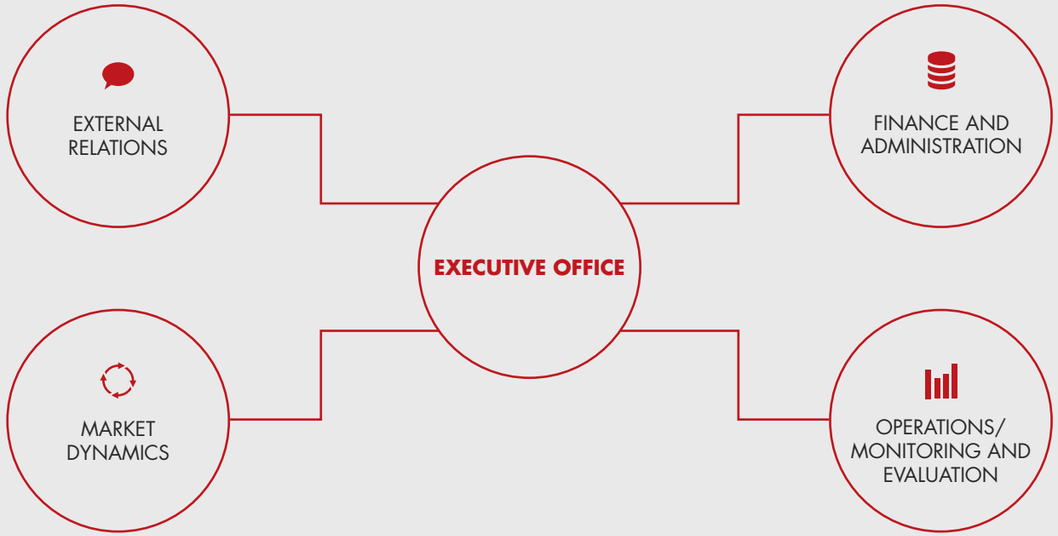
The Committee is chaired by Dr Andy Gray and the vice-chair is Ms Stephanie Simmons.

SECRETARIAT

The UNITAID Secretariat

The Secretariat of UNITAID carries out the day-to-day operations of the organization; gathers market intelligence to inform grant making; and manages the organization's grant portfolio. It is an innovation incubator – working with global partners to develop cutting-edge approaches to shape markets for health products. The Secretariat manages projects and budgets, after approval by the Board, and reports on project results and the impact of UNITAID investments.

60 people are employed by the Secretariat.



LISTENING TO PEOPLE LIVING WITH THE DISEASES

UNITAID meets with Mozambican civil society organization Rensida

Transparency, accountability and partnerships

UNITAID takes a proactive approach to the way it incubates and manages its grants. This process is leading to improved performance in terms of transparency, efficiency and accountability.

TRANSPARENT GRANT MAKING

2013 saw the implementation of UNITAID's strengthened grant making structure. This has increased the quality of the proposals received and ensured that they are aligned with UNITAID's Strategic Objectives.

In 2013, UNITAID began establishing a market intelligence system to provide comprehensive and timely information on product markets; expand the Secretariat's capacity to analyse information; and better inform the grant making process. UNITAID publishes these insights externally and provides a vital public service for all public health actors by sharing its market intelligence.

ROBUST GRANT MANAGEMENT

UNITAID is working more closely with its grantees than ever before. The introduction in 2013 of strengthened grant development and management processes, based on the principles of UNITAID's Quality Management System (see inset) has set a clear path from Board approval of grants to project implementation and management.

Importantly, UNITAID has strengthened its fraud and loss reporting system and established a clear and coordinated approach to prevent, detect, investigate and correct fraud and loss in an appropriate and timely manner. UNITAID grantees are required to report all suspected cases of fraud.

Grantees submit reports twice a year and independent evaluations are made available on the UNITAID web site.

IMPROVED QUALITY AND RISK MANAGEMENT

2013 saw two major initiatives for UNITAID's internal performance.

A **Quality Management System** was introduced, based on the International Organization for Standardization standard (ISO 9001:2008). This system applies a results-based infrastructure to organizational management, resource development and management, grant development and management and measurement, analysis and improvement.

UNITAID also finalized a **Risk Management Policy** to set an appropriate balance between risk-taking innovation and risk management.

ACCOUNTABLE REPORTING

Since its creation, UNITAID has used Key Performance Indicators (KPIs) to measure the overall performance of its grants and enable donors to assess the impact of UNITAID's interventions. With its Strategy 2013-2016, UNITAID has revised its KPIs to better meet its needs and measure the organization's performance in relation to its Strategic Objectives.

UNITAID developed a portfolio management tool, UNIPRO, that allows better management of data that comes from grantees. UNIPRO includes an on-line reporting tool which will be used by grantees in 2014 to directly input grant reports. Data from UNIPRO is seamlessly integrated into interactive dashboards available on UNITAID's website at http://www.unitaid.org/en/impact.

UNITAID uses several other tools to monitor its performance: audits, internal management indicators, routine monitoring, evaluation of grant performance and external organizational evaluations, which all play a role in strengthening and improving UNITAID's performance.

STRATEGIC PARTNERSHIPS

UNITAID's impact depends on strong partnerships with other organizations in global public health. Partnerships transform market intelligence, new research and ideas for solutions into innovative projects. UNITAID works with partners to ensure that its interventions provide sustainable access to products.

In 2013, strategic partnership activities were held with the Global Fund, WHO, UNAIDS, the Stop-TB Partnership, the Roll Back Malaria Partnership, PEPFAR, USAID, the Bill and Melinda Gates Foundation, OECD and the Global Health Investment Fund and Children's Investment Fund Foundation.

UNITAID's market shaping role is crucial for the Global Fund, the world's main funder for the three diseases. Through close cooperation with the Global Fund, UNITAID maximizes the impact of its initiatives and secures their sustainability.

Civil Society plays a major part in the structure and business model of UNITAID. Communities affected by the diseases as well as civil society networks are represented and actively engaged in the governance structures. Moreover, UNITAID promotes in-country engagement with civil society to gather information on market effects as they translate at country level and to ensure that interventions are benefitting people's needs.

COUNTRY ENGAGEMENT

UNITAID has become more engaged with countries that benefit from its grants. UNITAID conducts 'in-country consultations' every year to listen to country needs, in order to fine-tune its investments, coordinate efforts and take stock of UNITAID's impact.

Mozambique March 2013

UNITAID Chair Philippe Douste-Blazy led a delegation to launch new diagnostic projects and hold meetings with the Mozambican Government to encourage the adoption of innovative financing measures. A stakeholders meeting brought together over 80 representatives from government, grantees, civil society and other key partners.

Myanmar September 2013

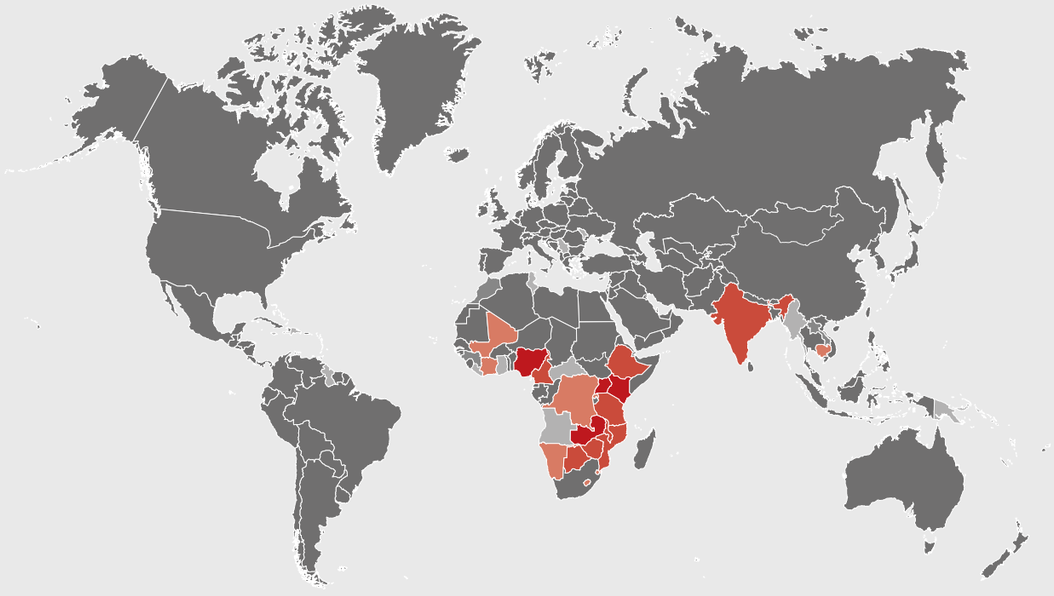
A high-level delegation from UNITAID was in Myanmar for the launch of the UNITAID-funded TBXpert project in Yangon. A consultation was organized with local and international NGOs, as well as members of civil society.

“As the need to expand access to lifesaving medicines intensifies, the role UNITAID will play in finding innovative solutions will be ever more critical. UNITAID’s ability to break new frontiers in innovative financing could transform the landscape of public health.”

Michel Sidibe, Executive Director, UNAIDS

UNAIDS

INVESTMENTS IN PRODUCTS: HIV/AIDS[13]



100M - 50M

Uganda	76.047.090
Zambia	59.518.868
Nigeria	49.925.804
Kenya	49.765.820

50M - 10M

Mozambique	31.265.384
Zimbabwe	27.008.748
Malawi	26.792.678
India	22.607.523
Botswana	18.292.689
Cameroon	16.942.219
Tanzania, United Republic of	16.636.615
Ethiopia	12.667.716

10M - 5M

Rwanda	8.635.865
Congo, the Democratic Republic	7.904.080
Swaziland	5.288.654
Lesotho	5.274.486
Côte d'Ivoire	4.593.023
Cambodia	4.508.749
Mali	4.420.187
Namibia	4.106.768

5M - 1M

Burundi	3.979.879
Togo	3.702.675
China	3.595.214
Burkina Faso	3.327.747
Haiti	3.040.722
Senegal	2.373.975
Viet Nam	1.610.200
Benin	1.350.043
Chad	1.140.465

1M - 100.000

Republic Of Moldova	732.283
Dominican Republic	717.729
Angola	689.991
Liberia	603.961
Papua New Guinea	459.982
Myanmar	303.752
Central African Republic	286.084
Tunisia	252.270
Guyana	188.291
Jamaica	154.245
Oecs	140.899
Ghana	134.964
Serbia	104.000

100.000 - 0

Djibouti	74.088
Guinea	66.000
Morocco	37.200
Lao People's Democratic Republic	12.183

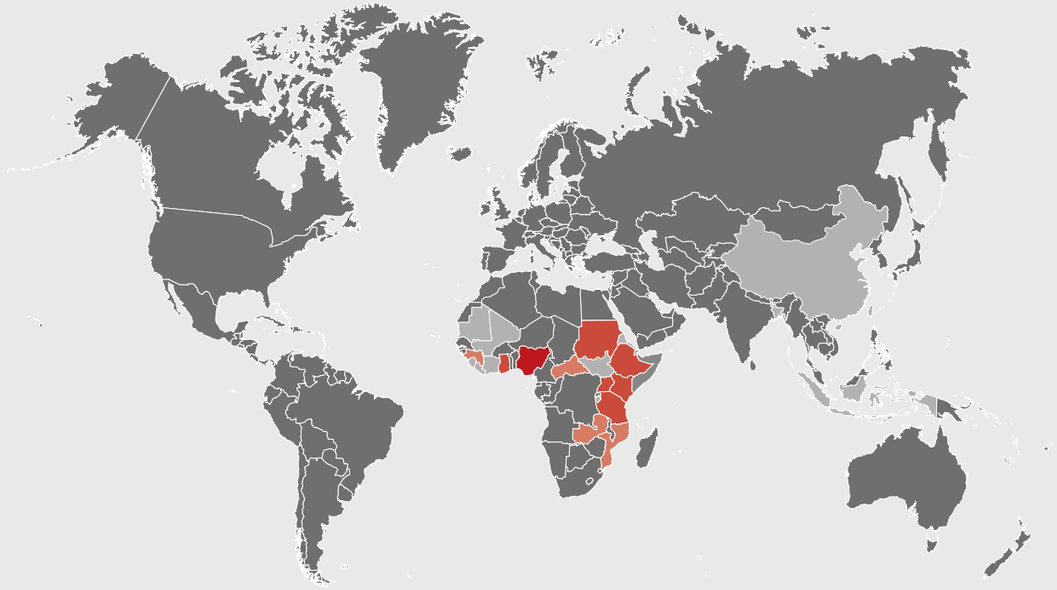
[13] All data for heat maps as of 30 June 2013. Maps only detail investments in commodities

HIV GRANT PORTFOLIO

	BOARD-APPROVED AMOUNT ($)	MAIN GRANTEE(S)
HIV/AIDS		
ACTIVE[14]		
Accelerating access to innovative POC HIV diagnostics	55,000,000	CHAI, UNICEF
Estheraid - Easing and safeguarding the availability of ARV treatments	15,950,000	ESTHER
Implementation of CD4 and VL testing in decentralized, resource-limited settings	28,696,023	MSF
Manufacture and validation of rapid POC CD4 testing in India	1,627,000	The Burnett Institute
Market entry of an improved solid protease inhibitor-based first-line antiretroviral combination therapy for infants and children with HIV/AIDS	17,336,000	DNDi
Open polyvalent platforms for sustainable and quality access to VL in resource limited settings (OPP-ERA)	2,400,000	FEI
Operational studies to validate and accelerate uptake of POC CD4 counters	2,687,000	Daktari
Paediatric ARV Program	418,474,634	CHAI
Uptake of a novel, disposable CD4 POC test in developing countries	7,534,000	Zyomyx
COMPLETED		
PMTCT Expansion	50,009,221	UNICEF
PMTCT Initiative and Extension	49,692,859	UNICEF
PMTCT Nutrition	4,764,228	UNICEF
Second Line ARV Program	305,799,000	CHAI

[14] Active grants relate to projects that had programmatic activities in 2013

INVESTMENTS IN PRODUCTS: MALARIA



100M - 50M

Nigeria	128.853.820

50M - 10M

Ghana	43.733.039
Kenya	42.268.396
Uganda	41.956.429
Tanzania, United Republic of	31.217.201
Congo, The Democratic Republic	23.450.583
Sudan	19.145.219
Ethiopia	11.667.473

10M - 5M

Mozambique	9.164.821
Guinea	8.841.088
Zambia	6.305.044
Central African Republic	5.444.520

5M - 1M

Angola	3.697.500
Gambia	3.428.900
Niger	3.275.774
Madagascar	3.158.582
Cambodia	2.282.729
Congo	2.192.700
Zimbabwe	2.064.000
Namibia	1.087.500

1M - 100.000

Guinea-Bissau	862.531
South Sudan	799.064
Mali	748.016
Eritrea	577.978
Burundi	428.609
Liberia	376.731
Côte D'ivoire	325.463
Bangladesh	315.875
Mauritania	230.076
China	179.100
Indonesia	134.255

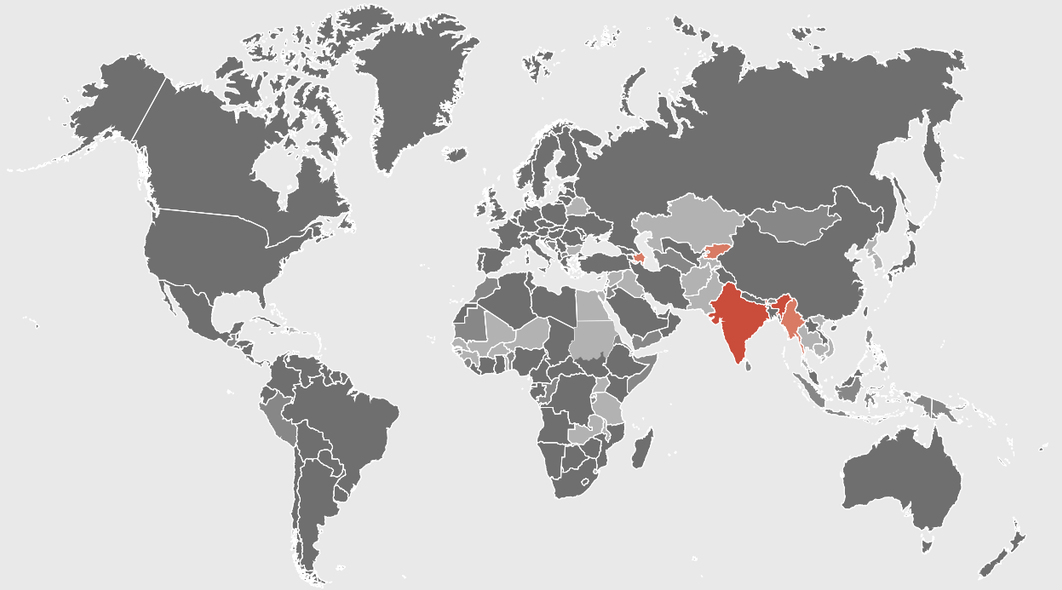
100.000 - 0

Somalia	31.062
Djibouti	7.456

MALARIA GRANT PORTFOLIO

	BOARD-APPROVED AMOUNT ($)	MAIN GRANTEE(S)
MALARIA		
ACTIVE		
Creating a Private Sector Market for Quality Assured RDTs in Malaria-Endemic Countries	34,290,561	PSI
Improving severe malaria outcome	34,000,000	MMV
Sustainable Global and National Quality Control for Malaria Rapid Diagnostics Tests	9,441,777	FIND
Affordable Medicines for Malaria (AMFm)	210,970,824	GFATM
Assured Artemisinin Supply System (A2S2)	9,280,400	i+solutions
COMPLETED		
ACT Scale-up Initiative	78,887,568	UNICEF, GFATM
ACT Scale-up: Liberia and Burundi	1,334,755	UNICEF, WHO
Long Lasting Insecticide Treated Nets	109,250,000	UNICEF

INVESTMENTS IN PRODUCTS: TUBERCULOSIS



100M - 50M

50M - 10M

India	29.407.713

10M - 5M

Azerbaijan	5.891.758
Myanmar	5.283.863
Kyrgyzstan	5.104.107

5M - 1M

Kenya	3.568.031
Lesotho	3.520.235
Bangladesh	3.197.844
Uzbekistan	2.959.495
Nigeria	2.370.048
Georgia	2.325.528
Republic Of Moldova	2.075.571
Cameroon	1.715.791
Nepal	1.373.727
Ethiopia	1.310.614
Mozambique	1.203.271
Congo, the Democratic Republic	1.091.343
Côte d'Ivoire	1.065.815
Madagascar	1.055.817
Haiti	1.038.310

1M - 100.000

Tajikistan	744.467
Cambodia	707.228
Belarus	695.260
Pakistan	667.743
Uganda	643.662
Dominican Republic	614.493
Rwanda	598.408
Tanzania, United Republic of	585.943
Egypt	551.962
Viet Nam	545.748
Kazakhstan	507.295
Guinea	489.117
Djibouti	378.764
Swaziland	360.764
Afghanistan	337.813
Burkina Faso	311.232
Malawi	272.124
Zambia	253.536
Niger	244.316
Mali	242.989
Sudan	241.457
Bulgaria	229.446
Iraq	185.561
Senegal	155.631
Syrian Arab Republic	136.862
Korea, Democratic People's Republic Of	130.736
Thailand	104.369
Togo	102.921

100.000 - 0

Bhutan	99.000
Indonesia	89.349
Morocco	88.454
Peru	83.015
Gambia	74.922
Somalia	73.950
Sri Lanka	68.887
Bosnia and Herzegovina	63.232
Papua New Guinea	55.338
Sierra Leone	53.847
Guatemala	50.136
Timor-Leste	44.753
Benin	33.761
Yemen	25.724
Mongolia	24.000
Turkmenistan	14.398
Burundi	13.446
Eritrea	10.786
Congo	7.544
Jordan	6.257
Guinea-Bissau	5.420
Macedonia, the Former Yugoslav Republic of	4.594
Mauritania	4.233
Kiribati	2.811
Philippines	2.220
Lebanon	2.088
Cape Verde	1.825

TUBERCULOSIS GRANT PORTFOLIO

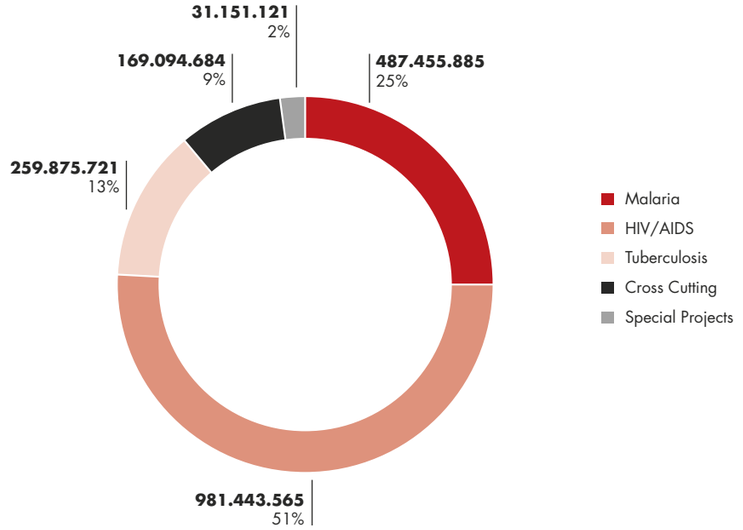
	BOARD-APPROVED AMOUNT ($)	MAIN GRANTEE(S)
TUBERCULOSIS		
ACTIVE		
MDR-TB Acceleration and Access Initiative - Strategic Rotating Stockpile	28,988,220	STOP TB/GDF
Multi Drug Resistant TB Diagnostics (EXPAND)	89,663,000	STOP TB/GDF, FIND, WHO-GLI
Paediatric TB Centre of Excellence	16,720,000	TB Alliance
Paediatric TB Project	13,486,671	STOP TB/GDF
Multi Drug Resistant Tuberculosis (MDR-TB) Scale-Up	53,371,575	STOP TB/GDF
Scaling up access to contemporary TB diagnostics (GeneXpert)	25,900,000	WHO
COMPLETED		
First Line TB Program	27,646,256	STOP TB/GDF
Scaling up access to contemporary TB diagnostics (Buy-down)	4,100,000	Cepheid

CROSSCUTTING

	BOARD-APPROVED AMOUNT ($)	MAIN GRANTEE(S)
ACTIVE		
Prequalification of Medicines	104,246,728	WHO
Prequalification of Diagnostics	22,641,680	WHO
Preventing Patent Barriers	677,100	Lawyers Collective
COMPLETED		
Support to the Global Fund Round 6	41,529,176	GFATM
SPECIAL PROJECTS		
Medicines Patent Pool Foundation	31,151,121	MPP Foundation

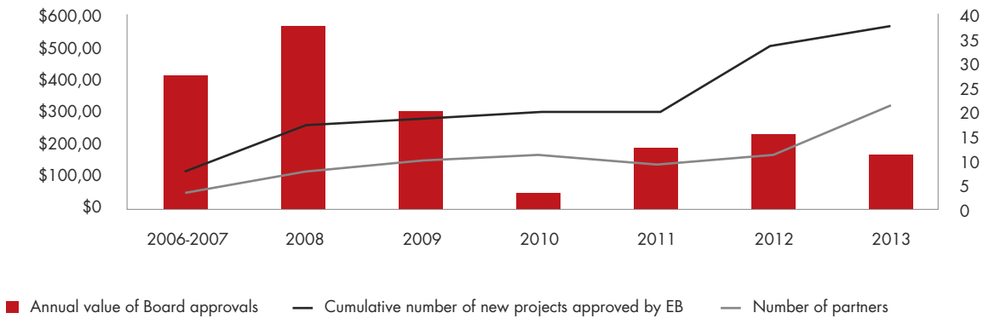
* Active grants relate to projects that had programmatic activities in 2013

Project funding commitments at the end of 2013 by intervention area



EVOLUTION OF UNITAID'S INVESTMENTS

With the growth of UNITAID's portfolio of grants, the nature and size of the grants has also evolved. There is a general shift from big commodity purchase interventions to supporting the market entry of new medicines and diagnostics, with smaller grants implemented by a more diverse base of grantees.



2013
Key Financials

UNITAID Financial Statements are prepared in accordance with the International Public Sector Accounting Standards (IPSAS). Summary statements of financial performance and financial positions are presented below. The full Financial Report for the year ended 31 December 2013 is available on the UNITAID website (www.unitaid.org). The 2013 Financial Statements of UNITAID were certified by the External Auditors of WHO.

While subject to the WHO Financial Rules and Regulations, UNITAID has developed financial policies and guidelines to guide its grant-making activities. As the portfolio of UNITAID grants grows and becomes more diverse, UNITAID continuously strengthens and adapts 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 grantees.

FINANCIAL HIGHLIGHTS

Since its establishment in 2006, UNITAID has received $2.2 billion of contributions from donors, committed $1.9 billion and disbursed $1.4 billion to grantees. In 2013, disbursements to grantees totalled $126 million, representing 86% of the overall expenses of UNITAID. Governance and Strategy design and implementation support and other Secretariat costs represented the remaining 14% of 2013 expenses.

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

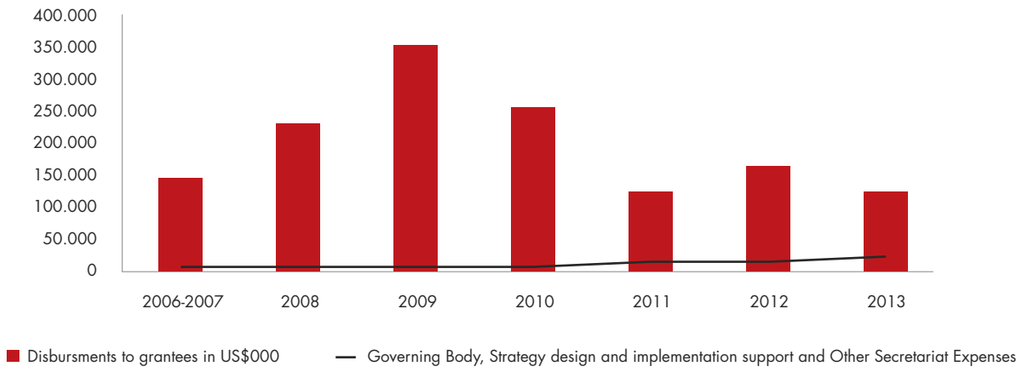
Summary statement of financial performance

	2013 in US$000	**2012** in US$000
Operating revenue		
Voluntary contributions	279 668	276 452
Financial revenue and expenses - net	3 688	1 977
Total Revenue	**283 356**	**278 429**
Operating expenses		
Disbursements to grantees	125 873	164 739
Staff and other personnel costs	12 325	10 605
Consulting & Contractual Services	7 190	6 783
Travel	1 185	1 411
General operating expenses	203	164
Total operating expenses	**146 776**	**183 702**
Surplus for the period	**136 581**	**94 727**

Summary statement of financial position

	2013 in US$000	**2012** in US$000
Current assets	716 318	667 157
Non-current assets	12 000	488
Total assets	**728 318**	**667 645**
Current liabilities	6 900	95 268
Non-current liabilities	14 564	2 103
Net assets	706 854	570 274
Total liabilities and net assets	**728 318**	**667 645**

Transfers to grantees versus other expenses 2006-2013

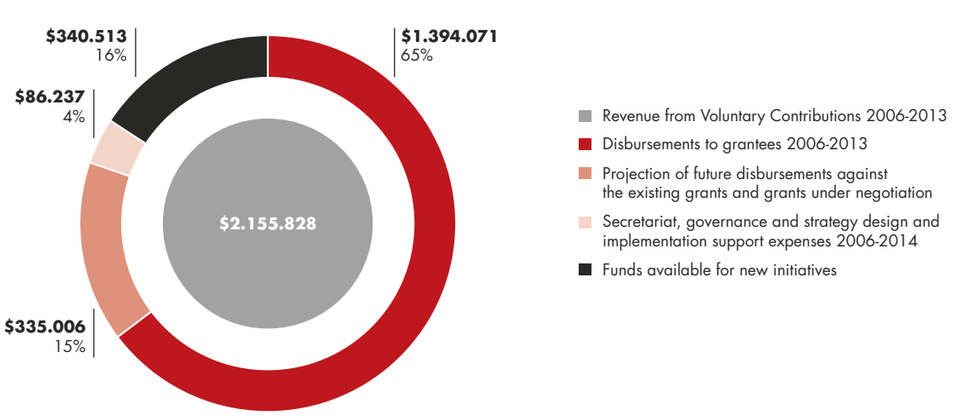


VOLUNTARY CONTRIBUTIONS

UNITAID's 2013 voluntary contributions from the air ticket levy were 57% of the total value of voluntary contributions. Cumulatively since inception through 2013, voluntary contributions from the air ticket levy were 64% of total contributions received.

Donors	2006-2013	2013
Bill & Melinda Gates Foundation	70 000 000	10 000 000
Brazil	37 201 761	
Cameroon	1 429 767	
Chile	28 043 000	4 000 000
Congo	1 090 000	
Cyprus	2 555 210	488 400
France	1 289 764 026	149 456 522
Guinea	49 000	
Luxembourg	1 960 647	
Madagascar	30 239	
Mali	928 000	
Mauritius	10 425 716	1 684 973
Millenium Foundation	2 572 201	1 500 000
Niger	281 355	
Norway	152 462 758	21 367 521
Republic of Korea	39 000 000	4 000 000
Spain	81 602 737	
United Kingdom	436 430 286	87 171 053
Total	**2 155 826 702**	**279 668 469**

Dispersal of UNITAID voluntary contributions since inception through 2013



Selected Events - 2013

THOUGHT LEADERSHIP – MARKET SHAPING

2013 Artemisinin Conference
Nairobi, Kenya - January 2013
The focus of the 2013 Artemisinin Conference was market dynamics and supply chain needs for ACTs.

Consultation on Access to HIV Medicines in Middle-Income Countries (MICs)
Brasília, Brazil - June 2013
The Consultation was organized to better understand the markets for HIV medicines in middle-income countries and the specific access challenges that patients face, and to explore the role MICs can play in pharmaceutical innovation primarily around the development of needed HIV formulations.

7th IAS Conference on HIV Pathogenesis, Treatment and Prevention
Kuala Lumpur, Malaysia - June 2013
One satellite event focused on testing and treatment for children living with HIV. The second session provided a strategic framework on implementation of 2013 WHO guidelines for CD4 and viral load monitoring.

6th Multilateral Initiative for Malaria Pan-African Malaria Conference
Durban, South Africa - October 2013
UNITAID discussed market-based approaches to malaria control, with presentations from experts on key market challenges and opportunities for intervention.

44th Union World Conference on Lung Health
Paris, France - October/November 2013
One session was held on catalysing the paediatric TB drug market. Another session focused on 'Life after Xpert' and discussed the pipeline of TB diagnostics. UNITAID also partnered with the National Press Foundation to train 15 journalists from high-burden TB countries on lung health issues. More information can be accessed at: http://j2jlunghealth.org/

11th International Congress on AIDS in Asia and the Pacific
Bangkok, Thailand - November 2013
The International Congress on AIDS in Asia and the Pacific is the largest forum on HIV/AIDS held in the region.

62nd Annual Meeting of the American Society of Tropical Medicine and Hygiene
Washington DC, USA - November 2013
UNITAID discussed the challenges in ensuring access to effective and safe treatment for severe malaria.

17th ICASA Conference 2013
Cape Town, South Africa - December 2013
UNITAID was present at the biggest AIDS conference in Africa with a special events booth to reach out to civil society and communities living with HIV.

THOUGHT LEADERSHIP – INNOVATIVE FINANCING

African Leaders Malaria Alliance
January 2013
UNITAID Chair Philippe Douste-Blazy urged African leaders to use innovative financing to fill the $3.6 billion gap in global malaria control.

5th Tokyo International Conference on African Development (TICAD V)
June 2013
UNITAID was active at this international symposium on development and discussed how innovative solidarity levies could secure additional funds to reach the MDGs.

MARKET FORA

TB: July 2013, Washington DC, USA.
Co-hosted with USAID, this Forum illuminated the path forward for new interventions in TB.

Malaria: September 2013, Paris, France.
Co-hosted with the Bill and Melinda Gates Foundation, this Forum discussed the increasingly diverse and complex malaria product markets and examined a range of market shaping responses.

REACHING OUT: 'YOUR FLIGHT CAN SAVE A LIFE'

Paris Dinner in Honour of UNITAID.
President Bill Clinton was the guest of honour at a special dinner hosted by UNITAID Chair Philippe Douste-Blazy at Luc Besson's Cité du Cinéma in Paris in May 2013. The President was in France to pay tribute to UNITAID at an event that gathered over 400 notables, including the French First Lady Valérie Trierweiler, French Minister of Finance Pierre Moscovici, French Minister of Justice Christiane Taubira, Deputy Minister for Development Pascal Canfin, French Government Spokesperson Najat Vallaud-Belkacem and politician François Bayrou.

'For a life, for a dream'
Seven French heartthrobs teamed up to release a single in support of UNITAID, called 'For a life, for a dream.' The singers - Brice Conrad, Louis Delort, Emmanuel Moire, Mickael Miro, Florent Mothe, Florent Torres and Mathieu Mendes – also recorded a music video.

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