UNITAID Annual Report 2010

UNITAID

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UNITAID Annual Report 2010

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Message from the Chair

In this era of complex and often conflicting interests we need innovative ideas to redress major imbalances and ensure a decent living for every single human being. Human rights are violated every day in developing countries due to the extreme poverty that affects more than one billion people. These are the chilling facts: a child born in the developing world is twenty five times more likely to die in the first five years of life than one born in the north. This life-gap is both unfair and unacceptable.

We all know that Official Development Aid has been stagnating at approximately US$ 120 billion a year and that there is a gap between what we have at our disposal and what we need. The scissor effect between public resources and the need to ensure that every human being can access global public goods, including health and climate protection, is a major challenge. But it also constitutes an historical opportunity – one we must seize without hesitation.

We must revisit our approach to global solidarity and harness the wealth of the world by finding new funding instruments. Innovative sources of finance and private sector participation are increasingly emerging as very much part of the solution.

UNITAID was created for that reason. Five years ago five heads of State – from Brazil, Chile, France, Norway and the United Kingdom - and the United Nations Secretary General, made the political decision to create an innovative mechanism to boost financing for health and development. That mechanism became UNITAID - the first ever agency to collect a global tax from airline travel and reinvest the funds into the fight against AIDS, TB and malaria in developing countries.

That painless tax for the traveller - one or two dollars, generally - is nonetheless a great sign of global solidarity. Today, those small solidarity contributions have helped UNITAID collect almost US$ 2 billion. This is the very first time that governments have decided to impose a global tax to make globalization work better for the poor. Since 2006, more countries have joined UNITAID, and we now have 14[1] countries which have passed a parliamentary law to introduce a solidarity contribution, and nine already contributing to UNITAID. Norway collects funds through a contribution on CO_2 emissions.

UNITAID also represents the first ever solidarity contribution implemented at a national level but managed by a supranational entity. In that way, it sets a trend that could be followed to tackle other global challenges by a global citizenry: such as hunger, climate change, economic development, etc.

So UNITAID is a laboratory of innovation in several ways: the way it collects funds; by promoting South-South cooperation; by including in its governance structure the UN, governments, private foundations (the Gates Foundation) and civil society; and by spending

[1] Benin, Burkina Faso, Cameroon, Chile, Congo Brazzaville, France, Guinea, Ivory Coast, Madagascar, Mali, Mauritius, Niger, Norway, South Korea.

those funds in novel ways: through market-based interventions, which create new markets in developing countries and bring the price of treatments down, thus enabling the treatment of more people for less money.

And that experiment - started less than five years ago - has repeatedly shown that it can work. With a focus on neglected patient groups - the poorest in developing countries, children, and people who no longer respond to conventional treatment and need superior, more expensive medicines - UNITAID is able to redress market imbalances and encourage dynamic price competition. For example, UNITAID currently funds three out of four children worldwide receiving treatment for HIV/AIDS and its secure financing has helped achieve reductions of almost 50% in the cost of key child-formulated HIV drugs.

Other UNITAID target areas include prevention of HIV/AIDS transmission from mother to child and second-line antiretrovirals for HIV/AIDS, expanding access to quality-assured multi-drug resistant TB treatments, and delivering artemisinin-based combination therapy for malaria, plus long-lasting insecticide-treated mosquito nets. Simultaneously the groundbreaking Medicines Patent Pool – created by UNITAID - aims to open the door to cheaper generic HIV drugs.

UNITAID represents a unique business model and an effective public-private partnership. Through its innovative spending approach, we are pushing towards the achievement of universal access to public goods. UNITAID finances projects that are implemented by multilateral agencies already active on the ground such as the Clinton Health Access Initiative, the Bill and Melinda Gates Foundation, UNICEF, the Global Fund and the World Health Organization. This efficient way of working ensures that the money is spent on treatments - not on bureaucracy - and avoids duplication.

The challenge today is to maintain the momentum of innovation in health financing and spending and to invent a new architecture that will encourage not only the globalization of economic growth, but also the globalization of solidarity. New sources of funding and new ways of making the money work are essential today if we are to meet the international community's targets - the Millennium Development Goals - and end senseless suffering.

Innovative financing is about opening the door to new, private players to join the fight against poverty and ill health; it is about leveraging the benefits of market economies.

What has been accomplished with solidarity airline levies and mass tourism could be mirrored tomorrow in other economic sectors, such as communications, the internet, financial transactions, the tobacco industry, etc. These are activities that profit most from economic globalization but paradoxically contribute the least to the financing of universal public goods.

The benefits of innovation in funding go far beyond public health. Local and international conflicts in the 21st century feed on hopelessness, humiliation and anger. We can remove much of that hopelessness by boosting the race to meet the Millennium Development Goals with innovative ideas that work.

In conclusion, innovative financing is designed to generate additional resources, and not to replace traditional funding. The concept is to build on globalized economic sectors and public-private partnerships, without hampering growth or creating distortions. Innovative financing is based on shared interests and the awareness that all stakeholders can contribute to the same goal – universal access to public goods and making the world a healthier, safer place to live.

Philippe Douste-Blazy, Chairman, UNITAID Executive Board,
UN Special Adviser on Innovative Financing for Development

Message from the Executive Secretary

2010 was another important year for UNITAID and for the multi-partner initiatives that we help to enable and develop. Our core activities continue unchanged: promoting the availability of affordable and adapted medicines for people in developing countries, and shaping markets to make them attractive to pharmaceutical companies. However, notable developments in 2010 included the launch of new multi-partner initiatives; the establishment of the Medicines Patent Pool as a separate legal entity; a new board-approved UNITAID strategy for 2010-2012; and the appointment of key staff to oversee our market impact activities, finance and administration.

Our new UNITAID strategy for the period 2010-2012 sets out our priorities for the coming years and leaves open the possibility to invest in future projects where there are clear market results and public health benefits. Any future investments will be determined following in-depth assessments and evidence obtained through market intelligence on priority product niches and strategic partnerships in one of the three pandemic diseases.

It was also in 2010 that UNITAID achieved an enhancement of the proposals submission and review process in order to provide more effective guidance to partners and the UNITAID Proposals Review Committee, which evaluates funding requests against UNITAID's strategic objective of achieving health outcomes through market impact. An Advisory Group on Funding Priorities was created to assist the Executive Board in identifying potential priority niches of high market and public health impact to be funded by UNITAID.

A significant step was taken in June 2010, when the Executive Board approved the key performance indicators and decided to expand them to include three high-level global indicators related to coverage of treatment and diagnosis for the three diseases and the overall mission and goals of UNITAID for the period 2010-2012. These high level indicators were conceived to allow performance monitoring of the implementation of the new UNITAID strategy in reaching market impact objectives; organizational effectiveness; and contribution to health outcomes in countries.

In early 2011, the United Kingdom's Multilateral Aid Review assessed UNITAID overall performance as "Good Value for Money", and highlighted its contribution to Millennium Development Goals 4, 5 and 6, which relate to fighting the three diseases, reducing child deaths and improving maternal health.

One development in 2010 that has given us cause for concern is that the competition from generic manufacturers - which has made access to treatment possible for millions of people living with HIV/AIDS - may be under threat. Under the terms of a free trade agreement currently being negotiated between India and the European Union, costly patents could soon be extended.

UNITAID relies heavily on generic manufacturers to supply quality-assured, patient-friendly, low-cost HIV/AIDS medicines in over 50 countries. If manufacturers cannot meet these demands, a lot of the progress we have made in the last seven years could be jeopardized.

Nearly 5.2 million people have access to ARV treatment today thanks to the production of low-cost quality generic medicines. Indian manufacturers currently account for more than 80% of these medicines — supplying the majority of developing countries – and 65% of the total value (US$ 463 million) of ARV purchases.

Many of the free trade agreements that have been concluded or are currently being negotiated between industrialized and developing countries contain measures that restrict access to medicines. These agreements may delay or limit competition from generic drugs, including: patent term extensions beyond the 20 years required by TRIPS; data exclusivity (potentially delaying registration); and border enforcement measures that could block international trade in generic medicines when they are suspected of infringing patents in transit countries.[2]

Our core activity in promoting the availability of affordable and adapted medicines for people in developing countries is threatened by these developments. We need to redouble our efforts and ensure that the poorest and most vulnerable people are not neglected and that effective programmes are adequately funded. The 33 million people living with HIV and AIDS today have a right to health. We call on all stakeholders to guarantee universal access to HIV prevention, treatment, care and support and to safeguard the progress that has been achieved.

Jorge Bermudez, UNITAID Executive Secretary until June 2011

At the close of his four-year tenure Dr Bermudez, who returns to the Ministry of Health in Brazil in August 2011, paid tribute to his colleagues at UNITAID and congratulated them on the many breakthroughs achieved since 2006.

[2] Brenda Waning, Ellen Diedrichsen, Suerie Moon (2010). A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries. *Journal of the International AIDS Society* 2010.

Mission

UNITAID'S mission is to help increase access to treatment for HIV/AIDS, malaria and tuberculosis for people in developing countries by **using market leverage to lower prices and increase availability** of appropriate high-quality drugs and diagnostics.

UNITAID raises funds from **long-term sustainable and predictable sources**, principally through a levy on airline tickets.

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Who we are and what we do

UNITAID funds are mostly derived from innovative sources of finance that are SECURE, ADDITIONAL, SUSTAINABLE and PREDICTABLE.

UNITAID funds are used in INNOVATIVE ways to provide MARKET INCENTIVES for manufacturers to increase supplies of quality drugs and diagnostics at affordable prices and develop needed new products.

UNITAID was established in 2006 to support existing efforts to achieve the 2015 United Nations Millennium Development Goals, especially Goal 6 on combating HIV/AIDS and other diseases.

UNITAID's mission is to help increase access to treatment for HIV/AIDS, malaria and tuberculosis for people in developing countries by using market leverage to lower prices and increase availability of appropriate high-quality drugs and diagnostics.

UNITAID raises funds from sustainable and predictable sources, principally through a tax on airline tickets. These funds are then disbursed to international partners working in global health and health commodities procurement.

UNITAID enters into long-term commitments with its partners to finance the purchase of drugs, diagnostics and other products. They then negotiate with suppliers on the basis of agreed goals and targets. These strategic purchases are designed to alter market dynamics by providing incentives to manufacturers to correct market failures, such as medicines that do not exist in the right formulations, are not produced in sufficient quantities or are too expensive.

UNITAID action pushes prices down through economies of scale and competition from new entrants attracted by an expanded market. Moreover, by funding purchase only of quality-assured drugs that are approved by the World Health Organization's Prequalification Programme or another 'stringent regulatory authority', UNITAID helps boost availability and lower prices of high-quality medicines.

UNITAID also uses its purchasing power to encourage the development of new drugs better adapted to patients' needs, such as paediatric formulations and fixed-dose combination (FDC) treatments. By combining several ingredients, FDCs enable patients to take only one pill a day instead of several, improving treatment quality and adherence, reducing the risk of resistance and simplifying supply chains.

Why UNITAID is needed

HIV/AIDS, malaria and tuberculosis (TB) kill more than 4 million people every year, taking a heavy toll on families and communities in low- and middle-income countries. Tackling these treatable diseases has been a priority of the international community over the last decade. However, a critical barrier to reversing the high mortality burden has been the unavailability of tests and treatments, either because they are too expensive or because the needed tools do not exist.

It is not only poverty that puts essential drugs and diagnostics out of reach of poor people. Patents tend to keep prices of newer products high. And often the medicines and diagnostic tools adapted for treating diseases prevalent in poor countries do not exist at all, because healthcare companies have no market incentive to produce or develop them. Where appropriate products do exist, because they respond to a market need in the industrialized world, their price is set according to purchasing power in wealthy countries.

Among the most dispiriting outcomes have been the dearth of medicines adapted for children, the lack of new diagnostics and medicines to identify and treat resistant strains of TB, and the high cost of 'second-line' antiretroviral drugs for HIV/AIDS, which are prohibitively priced for patients in poor countries.

UNITAID's unique approach aims to remedy these market deficiencies with targeted time-limited interventions designed to create viable markets for new medicines or attract the entry of more suppliers. By guaranteeing sustainable, predictable funding for the purchase of drugs and diagnostics, it provides the necessary incentives for industry to produce the goods that are so desperately needed.

The large long-term orders placed by UNITAID's partners produce economies of scale that help bring prices down for all, so helping countries and patients outside its direct field of action. The entry of more producers into a market also puts downward pressure on prices by increasing competition. Lower prices mean more drugs and treatments can be provided for the same outlay. Thus the 64% price reductions obtained for key paediatric AIDS medicines since November 2006 have enabled three times as many HIV-positive children to be treated for the same amount of money.

UNITAID identifies niche markets where intervention is likely to have a tangible public health impact. It will withdraw from a particular market once the market failure has been addressed and governments or other funders are in a position to take advantage of lower prices or greater availability to integrate the products into their normal financing and procurement systems.

UNITAID's contribution to the fight against HIV/AIDS, TB and malaria must thus be measured, not simply in terms of numbers of patients treated under UNITAID-funded projects, but in the global public health impact of its market interventions that stand to benefit many millions of people throughout the developing world.

In sum:

- UNITAID raises additional funds for global health through an innovative air tax and in other ways that ensure long-term predictable finance for selected projects.
- UNITAID targets underserved niches, such as paediatric medicines, where its unique funding model can have a tangible and sustainable impact on the market.
- UNITAID market interventions are specifically designed to increase supply, improve quality, stimulate the development of needed new products, and reduce prices through economies of scale and intensified competition.
- UNITAID action thereby helps improve availability and accessibility of quality drugs, diagnostics and other health products for all developing countries.

"UNITAID is a prime example of the rapid, flexible and innovative action needed to develop a sustainable long-term response to AIDS and reach universal access to HIV prevention, treatment, care and support."

Michel Sidibé, UNAIDS Executive Director

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An innovative mechanism for innovative action

UNITAID is innovative and unique in two ways:

1. **The way it collects funds:**
   First example of a government-imposed solidarity tax for global health - the 'air tax' on airline tickets

2. **The way it makes those funds work:**
   First example of a global health agency to pursue public health outcomes through market impact

How the air levy works

One extra dollar makes little difference to a passenger - to a child with malaria, it can mean the difference between life and death.

Eight of UNITAID's 28 member countries were donating proceeds from a government-imposed solidarity levy or 'tax' on airline tickets at the end of 2010, representing 63% of contributions to UNITAID. Another four members are in the process of implementing the levy.

The tax is applied to all flights departing from countries that impose it, and is paid by passengers when purchasing their tickets, normally as an addition to existing airport taxes. Airlines are responsible for declaring and collecting the levy. Passengers in transit are exempt, thus avoiding any further administrative burden for airports in participating countries. The solidarity levy fully respects countries' tax sovereignty.

For passengers, the cost of the air tax is very low compared to the total cost of a ticket. It can range from US$ 1 for economy-class tickets to US$ 10 and US$ 40 for business- and first-class travel. Different rates can be set according to a country's level of development and there is an extra option to vary the charge according to the distance travelled. Some countries in Africa have chosen to impose the levy only on international flights or on business- and first-class tickets.

The air levy translated into benefits

ONE DOLLAR =

- An HIV test kit for a pregnant mother
- One week of HIV treatment for a child
- One day of treatment for a patient on second-line ARVs
- Life-saving malaria treatment for two children
- One week of first-line TB treatment

Participating countries: Cameroon, Chile, France, Madagascar, Mali, Mauritius, Niger and the Republic of Korea.
Countries proposing to participate: Benin, Burkina Faso, Côte d'Ivoire, Democratic Republic of Congo.

CHILE	Fixed rate on international flights		
	US$ 2		Two children cured of malaria
FRANCE	Domestic/European flight	International flight	
Economy class	€1	€4	
Business and First class	€10	€40	One HIV-positive child treated
NIGER	Domestic/West African flight	International flight	
Economy class	US$ 1.20	US$ 4.70	
Business and First class	US$ 6	US$ 24	One adult cured of TB

"Thanks to a pioneering group of countries (...) a mechanism called UNITAID, based on a levy on airline tickets, has made it possible to mobilize substantial amounts of resources (...) The results achieved show that (...) a minute fraction of funds to be drawn from the multitudes of global financial transactions (...) provide essential care to those who need it most. It is of our duty, in light of reduced ODA funding, to build on the undeniable success of (...) UNITAID, and to encourage the International community towards greater solidarity mobilization in order to address both the large and numerous challenges we face in meeting the Millennium Development Goals."

His Excellency Mr Amadou Toumani TOURE, President of the Republic of Mali

A market approach to global public health

UNITAID increases access to quality-assured treatments for HIV/AIDS, malaria and tuberculosis in low-income countries by using innovative, global market-based approaches to make treatment products more affordable and more widely available.

UNITAID's market-based approach hinges on three specific actions depending on the circumstances in a given market:

1. **Catalysing markets:** identifying and facilitating adoption and uptake of new and superior medicines or diagnostics

In partnership with the Clinton Health Access Initiative (CHAI), UNITAID has facilitated the entry of a new HIV/AIDS medicine, tenofovir, into numerous developing country markets. By creating demand and reducing the price of tenofovir by more than 70%, more than one million people today have access to this new generation medicine.

2. **Creating markets:** by providing incentives for manufacturers to produce otherwise unattractive products with low market demand but substantial public health benefits

UNITAID and CHAI have opened up markets for second-line and paediatric HIV/AIDS medicines, to enable greater access for otherwise neglected patient groups in developing countries (children and people who grow resistant to first-line treatment). Through UNITAID's purchasing power, the price of paediatric medicines has decreased by 64% and five new child-friendly medicines have been brought to market; while over 100,000 patients are receiving second-line treatment per year.

3. **Addressing severe market inefficiencies** (e.g. grossly inaccurate demand forecast, excessive transaction costs, etc. that contribute to low access)

In collaboration with the Global Drug Facility and the Stop TB Partnership, UNITAID has helped to stabilize the TB market by creating a strategic rotating stockpile of TB medicines and thereby significantly reduced delivery lead times and avoided stock outs in participating countries.

UNITAID funds global partners' public health interventions with tangible market impact. UNITAID uses market interventions as tools to increase access to products, thereby improving the health of people living in developing countries.

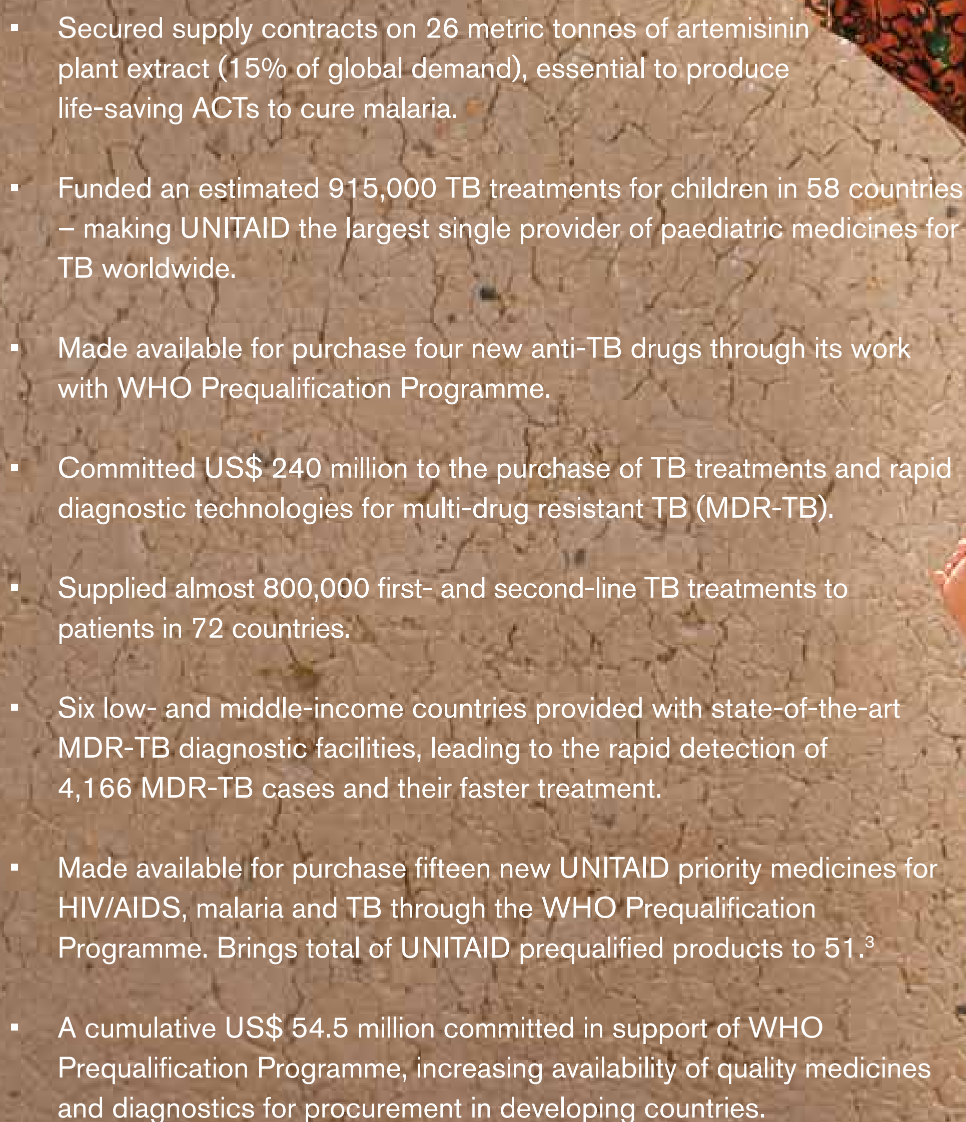
"One terrific example of a creative financing mechanism is UNITAID's groundbreaking effort to raise funds for development. They established a small tax on airline tickets, and the combined contributions would help scale up access to life-saving HIV/AIDS, tuberculosis, and malaria treatments, lower the prices of drugs and tests, and accelerate the pace at which they reach those in need... It was a brilliant idea and is a proven model that has unearthed new channels of givers and founded new platforms for them to give."

Former US President Bill Clinton

2010 Highlights

By the end of 2010, UNITAID had:

- Pledged US$ 800 million to HIV/AIDS medicines and diagnostics in 51 countries.
- Committed US$ 104.5 million to the prevention of mother-to-child HIV/AIDS transmission (PMTCT) in 16 countries. Since 2008, eight million pregnant women were tested for HIV/AIDS and 800,000 HIV-positive pregnant women were provided with quality ARVs to prevent transmission of HIV to their infants in nine high-burden countries.
- Disbursed US$ 380 million to provide quality, child-formulated ARVs for more than 360,000 children worldwide - and exceeded targets for reaching new children in need of treatment through UNITAID's support for CHAI.
- Cut costs of quality second-line ARV treatments by 53% since 2008, bringing immediate price benefits to 113,000 adults living with HIV.
- Established the Medicines Patent Pool for AIDS medicines; set to cut the cost of life-saving HIV drugs by US$ 260 million over next five years and improve access to treatments in developing countries.
- Provided 36 million high-quality malaria treatments to 32 high-burden malaria countries.
- Provided 20 million long-lasting insecticide-treated bed nets to accelerate scale-up of malaria prevention in partnership with UNICEF.
- Made available for purchase a new priority rapid diagnostic test for malaria through WHO's Prequalification Programme.



- Secured supply contracts on 26 metric tonnes of artemisinin plant extract (15% of global demand), essential to produce life-saving ACTs to cure malaria.
- Funded an estimated 915,000 TB treatments for children in 58 countries – making UNITAID the largest single provider of paediatric medicines for TB worldwide.
- Made available for purchase four new anti-TB drugs through its work with WHO Prequalification Programme.
- Committed US$ 240 million to the purchase of TB treatments and rapid diagnostic technologies for multi-drug resistant TB (MDR-TB).
- Supplied almost 800,000 first- and second-line TB treatments to patients in 72 countries.
- Six low- and middle-income countries provided with state-of-the-art MDR-TB diagnostic facilities, leading to the rapid detection of 4,166 MDR-TB cases and their faster treatment.
- Made available for purchase fifteen new UNITAID priority medicines for HIV/AIDS, malaria and TB through the WHO Prequalification Programme. Brings total of UNITAID prequalified products to 51.[3]
- A cumulative US$ 54.5 million committed in support of WHO Prequalification Programme, increasing availability of quality medicines and diagnostics for procurement in developing countries.

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[3] For dossiers accepted from 2007 to end of 2010.

UNITAID is having an impact on people living with the three diseases in 94 countries

SUB SAHARAN AFRICA

Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Congo, Democratic Republic of Congo, Côte d'Ivoire, Djibouti, Eritrea, Ethiopia, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Sierra Leone, Somalia, Sudan, Swaziland, United Republic of Tanzania, Togo, Uganda, Zambia and Zimbabwe.

AMERICAS

Antigua and Barbuda, Dominica, Dominican Republic, Grenada, Guatemala, Guyana, Haiti, Jamaica, Saint Lucia, St Kitts and Nevis, and St Vincent and the Grenadines.

ASIA

Afghanistan, Azerbaijan, Bangladesh, Bhutan, Cambodia, China, India, Indonesia, Lao People's Democratic Republic, Kazakhstan, Kiribati, Democratic People's Republic of Korea, Kyrgyzstan, Mongolia, Myanmar, Nepal, Pakistan, Papua New Guinea, Philippines, Sri Lanka, Tajikistan, Thailand, Timor-Leste, Turkmenistan, Ukraine, Uzbekistan and Viet Nam.

EUROPE

Belarus, Bosnia and Herzegovina, Bulgaria, Georgia, Former Yugoslav Republic of Macedonia, Republic of Moldova and Serbia.

NORTH AFRICA/MIDDLE EAST

Egypt, Iraq, Jordan, Lebanon, Morocco, Syrian Arab Republic, Tunisia and Yemen.

“Complementing traditional Overseas Development Aid from Governments, innovative financing mechanisms, built on stable, additional, predictable and long-term funding, play a decisive role in progress towards the Millennium Development Goals... UNITAID, hosted by WHO, facilitates the purchase of medicines at reduced prices for HIV/AIDS, malaria and tuberculosis in low-income countries. More than 90 countries have benefited from (...) substantial price reductions on medicines. This fully illustrates the efficacy and dependability of this type of financing.”

Ambassador Jean-Baptiste Mattei, Permanent Representative for France to the United Nations and International Organizations in Geneva

UNITAID action on the three diseases

HIV/AIDS

Scaling Treatment UP
Pushing Prices DOWN

- **By the end of 2010 UNITAID had committed a total of US$ 305.8 million (since 2007) to the Clinton Health Initiative (CHAI) for the purchase of quality-assured and affordable second-line ARVs.**
- **Twenty-six countries have benefited from the UNITAID-supported second-line adult HIV/AIDS treatment project.[4]**
- **By the end of 2010 successful transition of countries such as Benin, Ethiopia, Mali and Namibia to alternative funding sources.[5]**
- **In 2010, over 113,000 people were receiving second-line treatment in 20 African, Caribbean and Asian project countries.[6]**
- **An estimated 39,850 people received the new generation first-line treatment tenofovir in Uganda and Zambia.**
- **Better treatment and testing for people living with HIV in five high-burden West African countries through ESTHERAID, a joint initiative of UNITAID and ESTHER.**

[4] Benin, Botswana, Burkina Faso, Burundi, Cambodia, Cameroon, Chad, Côte d'Ivoire, Democratic Republic of Congo, Ethiopia, Ghana, Haiti, India, Kenya, Malawi, Mali, Mozambique, Namibia, Nigeria, Rwanda, Senegal, Tanzania, Togo, Uganda, Zambia, and Zimbabwe.
[5] New funding sources include Ministries of Health, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the President's Emergency Plan for AIDS Relief (PEPFAR).
[6] Benin, Botswana, Burundi, Cambodia, Cameroon, Chad, Democratic Republic of Congo, Ethiopia, Haiti, India, Kenya, Mali, Mozambique, Namibia, Nigeria, Senegal, Togo, Uganda, Zambia, and Zimbabwe.

51 countries

AMERICAS

Antigua and Barbuda, Dominica, Dominican Republic, Grenada, Guyana, Haiti, Jamaica, St Lucia, St Kitts and Nevis, St Vincent and the Grenadines.

ASIA

Cambodia, China, India, Lao People's Democratic Republic, Papua New Guinea, Myanmar, Viet Nam.

EUROPE

Republic of Moldova, Serbia.

NORTH AFRICA/MIDDLE EAST

Morocco, Tunisia.

SUB SAHARAN AFRICA

Angola, Benin, Botswana, Burkino Faso, Burundi, Cameroon, Central African Republic, Chad, Democratic Republic of Congo, Côte d'Ivoire, Djibouti, Ethiopia, Ghana, Guinea, Kenya, Lesotho, Liberia, Malawi, Mali, Mozambique, Namibia, Nigeria, Rwanda, Senegal, Swaziland, United Republic of Tanzania, Togo, Uganda, Zambia and Zimbabwe.

Infection rates have fallen, but 10 million people still need access to antiretroviral treatment

For the first time since the earliest cases of HIV/AIDS came to light, more than a quarter of a century ago, the AIDS epidemic is beginning to change course as the number of people newly infected with HIV is declining and AIDS-related deaths decreasing.[7]

Between 2001 and 2009, the rate of new HIV infections stabilized or decreased by more than 25% in at least 56 countries around the world, including 34 countries in sub-Saharan Africa, which continues to be the region most affected by the epidemic with 69% of all new HIV infections.[8] In 2009, 5.25 million people had access to HIV treatment in low- and middle-income countries, accounting for 36% of those in need.

However, while progress has been made in preventing new HIV infections and in lowering the numbers of AIDS-related deaths, 10 million people living with HIV and AIDS are still waiting for treatment. The challenge ahead continues to be access to treatment, including affordable, quality-assured medicines adapted to patients in low-resource settings. Moreover, with WHO treatment guidelines now recommending earlier treatment initiation and newer, more robust medicines, both the number of patients needing to start treatment quickly and the related costs will skyrocket.

UNITAID action in this area therefore has been and will continue to be critical. By working to increase the availability of patient-adapted medicines and by creating new markets and slashing prices, UNITAID has been impacting on the HIV/AIDS treatment landscape by making funds stretch further and by ensuring market entry for a number of new products.

Treating children with HIV/AIDS

2010 Highlights

- More than 362,000 children in 35 countries are benefiting from child-friendly HIV/AIDS medicines with UNITAID support;
- Committed US$ 380 million to the Clinton Health Access Initiative (CHAI) since 2006 for paediatric medicines and diagnostics;
- Committed over US$ 68 million towards the purchase of antiretrovirals (ARVs) and related commodities for the UNITAID Paediatric Project;
- Contributed to the treatment of an additional 70,000 children;
- Prices of leading paediatric ARV regimens have fallen by 49% as a result of UNITAID intervention since project launched; and
- Approximately 85% of paediatric patients now on child-friendly FDCs, up from 69% in 2009 and 48% in 2008.

[7] UNAIDS (2010) Report on the global AIDS epidemic.
[8] UNAIDS (2010) Op cit.

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Every minute of every day, a child under the age of 15 becomes newly infected with HIV, and every two minutes a child dies of AIDS.[9] In developed countries, paediatric HIV/AIDS is for the most part under control. Prevention of mother-to-child transmission has been largely successful, and infants and children have access to diagnostics and antiretroviral therapy.

At the end of 2009, there were 2.5 million children under the age of 15 living with HIV around the world, and an estimated 370,000 children contracted HIV during the perinatal and breastfeeding period. Global treatment coverage for HIV-positive children was 28% in 2009, a notable progress, but the rate is lower than the antiretroviral therapy (ART) coverage for adults (36%).

Furthermore, the success in tackling paediatric HIV/AIDS in wealthy countries means there has been little market incentive for companies to invest in child-appropriate antiretroviral medicines (ARVs). The first quality-assured, three-in-one fixed-dose combination (FDC) pill for children did not become available until 2006, five years after its adult equivalent.[10] Until then, the only option for children was to take up to 16 often foul-tasting syrups a day, or even small amounts of crushed adult tablets, which is complicated for caregivers to administer and carries an obvious risk of over- or under-dosing. Combining several medicines into one pill makes it easier for children to adhere to their treatment, improving its effectiveness and slowing the development of resistance.

In 2006, UNITAID decided to make the supply of commodities for paediatric HIV/AIDS treatment one of its first priorities, as a contribution to the global drive for universal access to ARVs. By creating a guaranteed market where none existed before, UNITAID has aimed to expand supply, increase the number of quality manufacturers and products (especially for new fixed-dose combinations), reduce prices and cut drug delivery lead times.

Commodities financed with UNITAID resources under this project include ARVs, medicines for treatment of opportunistic infections, diagnostics (including some laboratory equipment) and ready-to-use therapeutic food (RUTF) for the treatment of severe malnutrition.

UNITAID’s efforts on paediatric HIV/AIDS, in partnership with the Clinton Health Access Initiative (CHAI), seek to:

- Expand access to fixed-dose combination (FDC) drugs and support development of new quality FDCs and other child-friendly medicines;
- Reduce prices of paediatric HIV/AIDS drugs and other quality products;
- Increase supply and reduce prices of diagnostic and monitoring tests for children; and
- Provide an integrated package of care for children with HIV/AIDS, including therapeutic food to remedy malnourishment.

[9] UNAIDS, Op cit.
[10] Médecins Sans Frontières (MSF), *Untangling the web of ARV price reductions*, 12th edition, February 2010.

Scaling up paediatric treatment

In 2010, UNITAID disbursed approximately US$ 68 million to CHAI to purchase quality-assured and affordable paediatric ARVs, diagnostics, and other products needed for re-nourishment and to stave off opportunistic infections. The partnership reached an additional 71,000 children in 2010, exceeding the 2010 target of 66,500 and totalling more than 362,000 children on treatment by the end of 2010.

Early Infant Diagnosis programmes financed by UNITAID and implemented by CHAI in 2010 experienced a 30% increase in testing volumes globally compared to 2009. CHAI Africa and India EID programmes conducted 373,000 tests, which represent 38% of all HIV-exposed infants and 80% of women accessing prevention of mother-to-child transmission (PMTCT) programmes.

UNITAID has championed the use of FDCs for children since it became involved in paediatric HIV medicines in 2006. In 2010, all of the 35 beneficiary countries were procuring FDCs, representing a sum of US$ 15.7 million on FDC purchases, a 32% increase in 2010 alone. From a patient treatment perspective, approximately 85% of the patients benefiting are now on FDCs, up from 69% in 2009 and 48% in 2008.

Availability of quality paediatric HIV medicines

In 2010, three paediatric HIV medicines were in the prequalification pipeline. Access to cheap generic versions of such medicines will only be possible when an identical product is submitted by different manufacturers. The shortage of prequalified paediatric medicines is a source of concern as the most recent set of WHO guidelines recommend that children start treatment as early as possible after diagnosis and suggest that where necessary they receive a complex set of drugs including protease inhibitors to reduce the likelihood of drug resistance. However, this will require more resources and higher levels of funding.[11]

The supplier selection process concluded in March 2010 and CHAI achieved price reductions ranging from 2-10% compared to 2009 prices on many ARV formulations, amounting to an overall price reduction of 49% on leading paediatric ARV regimens since the start of the Project versus prevailing prices in low-income countries.

Providing an integrated package of care

Many children living with HIV in developing countries suffer from malnutrition, which, apart from putting them in different health risks, reduces their ability to absorb treatment. Through UNITAID, children are also provided with Ready-to-Use Therapeutic Food (a fortified nut paste high in protein and vitamins) to remedy malnourishment and increase the effectiveness of treatment, as well as antibiotics and other medicines needed to stave off opportunistic infections (see section on PMTCT p. 32).

[11] UNICEF, UNAIDS, WHO, UNFPA and UNESCO (2010), ibid.

CASE STUDY

UNITAID-funded diagnostics saving the lives of children in Mozambique

When *Paulo's parents died from AIDS-related complications shortly after his premature birth in June 2010, his grandmother took him to a health centre in Sofala province, Mozambique. The baby was small and under-nourished, so staff treated him for malnutrition and used specialist equipment to test for HIV. Happily, Paulo's DNA PCR result at six months was negative and with appropriate care he soon regained weight and strength.

Paulo was fortunate that his grandmother was able to take him to a health centre equipped with a range of HIV diagnostic and monitoring tools, and a supply of ARV medicines. These tools and medicines were funded through a US$ 4.8 million UNITAID grant to support CHAI programmes in Mozambique. This key UNITAID intervention has helped to improve testing, referral and treatment services in health centres in a number of sub-Saharan countries, including Mozambique's Beira city health clinic where Paulo was treated.

However, many families do not have access to HIV testing. The lack of adequate diagnostic tools, including DNA PCR testing, in poor countries such as Mozambique has made it difficult to assess the need for treatment with HIV medicines.

At the end of December 2010, 17,395 children were receiving treatment in Mozambique thanks to the life-saving partnership of CHAI and UNITAID.

*The real name of the child has been changed for confidentiality reasons.

Expanding access to second-line antiretrovirals

Although the vast majority of patients are still on their first line of treatment, the need for newer 'second-line' medicines is increasing rapidly, with an estimated 2-3% of first-line patients requiring a switch to second-line drugs each year. In poor countries the lack of adequate diagnostic tools, such as viral load testing, makes it difficult to assess the need for second-line treatment. In 2008, WHO estimated that only 2% of adults on antiretroviral therapy in 36 countries were on second-line regimens,[12] but CHAI expects this to rise to 5% by 2011.[13] Ultimately, there will be a need for third- and fourth-line drugs for people who have been on treatment a long time and have developed resistance.

The average price paid for second-line regimens is substantially higher than the price paid for first-generation AIDS drugs; their cost remained up to 30 times higher than the least expensive first-line regimens.[14] Prices are influenced by a variety of factors – but whatever the reason, cost remains one of the barriers to increasing access to treatment and care services. Second-line ARVs tend to be more expensive to produce than first-line medicines and some contain higher doses of active pharmaceutical ingredients. But their high cost mainly reflects patent protection that restricts competition and small production volumes.

Second-line ARV prices have declined following the introduction of quality-assured generic alternatives, the expansion of treatment programmes (producing economies of scale), and new pricing policies by pharmaceutical companies which have increased competition between quality-assured products. However, as the number of people who need access to second-line regimens continues to grow, further price reductions will be essential. The alternative is to see national treatment programmes faced with massive cost increases, precipitating a second wave of the ARV access crisis seen earlier in the decade.

In partnership with CHAI, UNITAID's efforts on second-line adult ARVs aim to:

- Expand access to second-line ARVs by building a generic market;
- Further reduce prices of priority second-line drug regimens; and
- Fund purchases of tenofovir (TDF) to create a viable market and bring prices down.

UNITAID-CHAI second-line project

In 2010, UNITAID provided US$ 61 million through its partner CHAI to fund the purchase of second-line ARVs for an estimated 71,342 patients in 20 countries as well as first-line tenofovir (TDF) for nearly 39,850 patients in Uganda and Zambia. The second-line project currently represents an estimated 77% of second-line ARV demand in generic-accessible low- and middle-income countries (excluding Argentina, Brazil, China, Mexico and South Africa).

The project's market impact on price and competition has been encouraging: in 2010, eight newly eligible second-line formulations were added to the project. Seven out of nine products now have two or more SRA approved suppliers, and in June 2010, single formulations of atazanavir (ATV) and ritonavir (RTV) were added, further facilitating the price reduction of second-line regimens.[15]

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[12] Françoise Renaud and Boniface Dongmo Nguimfack, *Use and prices of antiretroviral therapy in resource-limited countries: A dynamic market*, Presentation to consensus meeting of WHO ART guidelines for adults and adolescents, WHO/HIV Department, Geneva, 14-16 October 2009.
[13] Evidence to All-Party Parliamentary Group on Aids, *The Treatment Timebomb*, July 2009.
[14] WHO (2010). Transaction prices for antiretroviral medicines and HIV diagnostics from 2008 to October 2010.
[15] For many countries, these estimates are based upon patient data or estimates provided by the country's Ministry of Health and/or treatment partners. In cases where patient figures were not provided or were not in line with actual volumes ordered, patient estimates were calculated based on the number of patients that could reasonably be treated from the volumes ordered.

CHAI continues to prepare for the introduction of a generic, heat-stable FDC of ATV/r into the project. Although the FDC formulation of ATV/r is not on the market at this time, in 2010 UNITAID granted approval for introduction of ATV and heat-stable RTV single formulations for procurement through the Project. In 2011, a co-pack of ATV, heat-stable RTV, and TDF+3TC is expected to be introduced and, although timelines are currently uncertain, the ATV/r FDC formulation will eventually follow. CHAI also continues to support forecasting exercises at both the global and country levels to prepare for future procurements of these drugs.

Transition and sustainability

UNITAID's mandate is to invest in time-limited interventions to address market shortcomings. UNITAID has proved its ability to remedy shortcomings and through its HIV projects has contributed to:

1. Developing a paediatric ARV market that previously did not exist, and

2. Reducing the price of second-line ARV regimens by as much as 70% on certain products.

UNITAID, in consultation with a range of stakeholders, is developing a comprehensive transition and sustainability framework that will be presented to the UNITAID Board in December 2011. PEPFAR has noted the importance of ensuring continued UNITAID support for second-line ARVs and paediatric treatment until UNITAID's treatment commitments can be transitioned to another partner.

Transitioning for second-line ARVs is on track, with funding from UNITAID until the end of 2011. With regards to paediatric ARVs, UNITAID funding is secure until December 2012.

PEPFAR and the Global Fund are working together with UNITAID to determine what portion of UNITAID's treatment obligations can be picked up by the Global Fund in 2011-2012 and thereafter to avert interruptions in care.

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Prevention of Mother-to-Child Transmission of HIV

2010 Highlights

- UNITAID disbursed US$ 71 million in 2010 in support of PMTCT activities. The total amount committed is US$ 104.5 million.
- UNITAID, UNICEF and WHO sign agreement to extend PMTCT 1 project until end-2011.
- Through UNITAID's support, UNICEF has negotiated better prices for the diagnostic tools needed to detect HIV in pregnant women and to infants born to HIV-positive pregnant women.
- Since start of project 850,626 HIV-positive pregnant women have received ARVs to prevent mother-to-child transmission; 64,877 HIV-positive pregnant women have received ART; 197,090 HIV-positive mothers have received co-trimoxazole and ready-to-use therapeutic food (RUTF) to prevent opportunistic infections; 201,991 HIV-exposed children received co-trimoxazole and RUTF to prevent opportunistic infections.

Innovative approaches to PMTCT

The overwhelming majority of children with HIV/AIDS are infected through the preventable transmission of the virus from the mother during pregnancy, in childbirth or through breastfeeding. UNITAID, together with its partners UNICEF and WHO, aims to reduce the number of children born with HIV through an innovative, family-oriented approach being implemented in 16 countries.[16]

The interventions include increasing access to HIV/AIDS testing and treatment for expectant and nursing mothers and infants as well as providing HIV-positive mothers with appropriate continuing ARV treatment. The project also includes a nutritional component, testing for anaemia and the provision of energy-dense, ready-to-use therapeutic food (RUTF), to address malnutrition and under-nourishment among pregnant women and HIV-exposed infants, essential for antiretroviral therapy to be effective.

Supplying more effective HIV medicines to children

In 2010, WHO revised guidelines on PMTCT, HIV and infant feeding, called for the provision of highly efficacious antiretroviral regimens for PMTCT, including ART for pregnant women in need of treatment for their own health, and, for the first time, prophylaxis to mother or baby during breastfeeding, where breastfeeding is judged to be the safest option.[17] These guidelines offer an opportunity for even more dramatic achievements in averting new HIV infections in infants and improving maternal and child health and survival.

[16] In 2010 the project was expanded to nine more countries (Central African Republic, China, Haiti, Lesotho, Myanmar, Nigeria, Swaziland, Uganda and Zimbabwe) from the original seven (Cameroon, Côte d'Ivoire, India, Malawi, Rwanda, United Republic of Tanzania and Zambia).
[17] World Health Organization (2010). *Guidelines on HIV and Infant Feeding: Principles and recommendations for infant feeding in the context of HIV and a summary of the evidence.*

However, despite remarkable gains, HIV/AIDS is still one of the major causes of maternal mortality in generalized epidemic settings and one of the leading causes of death among women of reproductive age globally.[18] It is for this reason that global initiatives to improve maternal and child health outcomes highlight PMTCT as a priority, particularly in countries with a high HIV burden.[19]

In low- and middle-income countries in 2009, 53% of pregnant women living with HIV received ARVs in PMTCT programmes, compared to 45% in 2008 and 15% in 2005.[20] In sub-Saharan Africa, this proportion increased from 45% in 2008 to 54% in 2009.[21] About one third of infants born to HIV-positive mothers received ARVs for PMTCT; coverage has increased only slightly, to 35% in low- and middle-income countries from 32% in 2008.[22] For many countries, 80% coverage was the universal access target for both HIV testing and the provision of highly efficacious ARVs for PMTCT.

The goal of virtual elimination of mother-to-child transmission[23] by 2015 is possible if three targets are reached by the end of 2011. These targets are: 80% coverage of effective ARVs for PMTCT in 10 of the 22 countries with the greatest number of HIV-positive pregnant women; provision of ART to at least 50% of HIV-positive pregnant women eligible for treatment; and reduction by 50% of the current unmet need for family planning among all women.[24]

UNITAID in support of PMTCT

UNITAID has to date disbursed US$ 71 million in three projects aimed at PMTCT in high-burden countries.

The PMTCT II expanded the original project into an additional nine countries. Meanwhile, an extension of the PMTCT I project within the timeline was aimed at ensuring that countries identified alternative sources of funding for PMTCT commodities and that no treatment interruptions occurred during the transition.

Countries being funded by the PMTCT I project include: Cameroon, Côte d'Ivoire, India, Malawi, Rwanda, United Republic of Tanzania and Zambia.

"Thanks to UNITAID and our other partners, we are helping to virtually eliminate mother-to-child transmission of HIV in the communities hardest hit by the HIV/AIDS crisis. Together, we are offering new hope to the most vulnerable families – and helping to achieve a generation free of HIV/AIDS."

Anthony Lake, UNICEF Executive Director

[18] Murray, Christopher J. L., et al., 'Maternal mortality for 181 countries, 1980–2008: A systematic analysis of progress towards Millennium Development Goal 5', *The Lancet*, vol. 375, no. 9726, 8 May 2010, p.1609; World Health Organization, Women and Health Report: Today's evidence, tomorrow's agenda, WHO, Geneva, 2009. Quoted in: UNICEF, UNAIDS, WHO, UNFPA and UNESCO (2010): Fifth stocktaking report, UNICEF, New York, 2010.
[19] For example, the Secretary-General's Global Strategy for Women's and Children's Health, launched in September 2010, and the 'H4+' commitment by WHO, UNICEF, UNFPA, the World Bank and UNAIDS.
[20] WHO, UNICEF, UNAIDS (2010). *Towards Universal Access: scaling up priority HIV interventions in the health sector: Progress Report 2009*, pp 89.
[21] WHO, UNICEF, UNAIDS (2010). Op cit, pp 89.
[22] *Towards Universal Access.* Quoted in: UNICEF, UNAIDS, WHO and UNFPA (2010). *Children and AIDS: Fifth stocktaking report*, New York, 2010.
[23] Virtual elimination occurs when less than 5 per cent of children born to HIV-positive mothers are infected.
[24] WHO, UNICEF, UNAIDS (2010), Op cit.

UNITAID's efforts on PMTCT, in partnership with WHO and UNICEF, aim to:

- Expand access to provider-initiated HIV testing and counselling in antenatal, maternity and postpartum services;
- Reduce the proportion of infants born with HIV by providing better ARV regimens to women and their new-borns;
- Ensure HIV-infected infants are identified and treated at an early stage;
- Provide prophylaxis to prevent opportunistic infections among HIV-positive women and their babies;
- Increase access to ART for HIV-positive mothers; and
- Achieve a continuous supply of suitable high-quality medicines, diagnostics and other commodities while pushing prices down.

UNITAID's collaboration with UNICEF and WHO, which began in December 2007, has already led to the development of four new diagnostic bundles, listing the specific items needed to perform diagnostic tests in a laboratory. In this way the bundles facilitate planning and quantification of laboratory items to be used for diagnostic tests. New child-friendly drug formulations, including nevirapine syrups for infant prophylaxis, and the identification of six new suppliers of ARVs have also been achieved within the time frame of the collaboration.

Volume purchases enabled by UNITAID funding have achieved significant cost savings for seven ARVs used in UNICEF PMTCT country programmes, while prices for rapid diagnostic tests have come down by 18% and prices for bundles containing reagents and other testing consumables by as much as 39%. These reductions stem from long-term agreements negotiated through the UNICEF/UNITAID partnership with several manufacturers, as part of continued efforts in 2009/2010 to expand the number of quality-assured manufacturers.

Where next on HIV/AIDS

Strengthening UNITAID's impact on the ground

In 2009, UNITAID's Executive Board approved funding of US$ 16 million for a French government-sponsored initiative, ESTHER (Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau). The ESTHERAID project was divided into two phases: phase 1) to conduct a series of country assessments of what additional support might be needed to strengthen the public health impact of UNITAID's HIV/AIDS projects, and phase 2) the implementation of projects that address the needs identified in phase 1. Initial assessments identified three areas of intervention, namely:

- Improving procurement and supply management of products for treatment centres.
- Optimizing the rational use of drugs by improving the quality of practice in patient diagnosis, treatment and monitoring.
- Strengthening monitoring systems of care in order to improve ARV demand forecasting.

In 2010, an agreement was reached on the second phase of the ESTHERAID project which would begin in early 2011. The ESTHERAID project is expected to compliment existing UNITAID projects by strengthening firstly the supply chain management of commodities bought with UNITAID funds in five African countries (Benin, Burkina Faso, Cameroon, Mali and Central African Republic), secondly to improve the rational use of HIV-related commodities in those countries and finally to improve demand forecasting for HIV products so as to ensure more effective procurement going forwards.

Malaria

Scaling up the best treatment, investing in prevention

2010 highlights:

- Committed US$ 328.7 million since 2006 to six malaria projects in 32 countries.
- 20 million long-lasting insecticide treated nets (LLINs) were delivered to eight high malaria burden countries in 2009. In 2010, all of these nets were distributed to households by UNICEF.
- Delivered over 36 million artemisinin-based combination treatments (ACTs) to 21 countries in Africa and Asia.
- Since 2009, transferred US$ 130 million to the ACTs co-payment fund - Affordable Medicines Facility for malaria (AMFm).
- Established a revolving credit fund for artemisinin extractors to ensure the production of an additional 40 metric tonnes of artemisinin in 2010-2011.

32 countries

ASIA

Bangladesh, Cambodia, China, Indonesia.

SUB SAHARAN AFRICA

Angola, Burundi, Central African Republic, Republic of the Congo, Côte d'Ivoire, Djibouti, Democratic Republic of Congo, Eritrea, Ethiopia, Gambia, Ghana, Guinea-Bissau, Guinea, Kenya, Liberia, Madagascar, Mali, Mauritania, Mozambique, Namibia, Niger, Nigeria, Somalia, Sudan, United Republic of Tanzania, Uganda, Zambia and Zimbabwe.

Nearly one million deaths a year - despite an effective cure

Malaria kills more than 2,000 children under five every day - roughly one child every 45 seconds - and accounts for a fifth of all under-five deaths in sub-Saharan Africa.[25] Estimates indicated the declining trend in malaria, but mortality and morbidity levels are still very high. In 2009, 781,000 people died from malaria, down from nearly one million in 2000, and 225 million people contracted malaria in 2009, a fall from 244 million in 2005.[26] Africa accounted for 85% of infections and 90% of deaths, mostly among young children. Malaria is also a prime cause of anaemia, low birth weight, premature birth, infant mortality and maternal deaths.

Although malaria is curable in a matter of days, the disease can be fatal without early diagnosis and prompt treatment. Immediate intervention is particularly important for the most vulnerable groups – young children, pregnant women and people with weak immune systems, such as those living with HIV/AIDS. Beyond diagnosis and treatment of cases, preventing transmission through the use of long-lasting insecticide-treated nets (LLINs) and the application of indoor spraying of houses with effective insecticides are key interventions.

UNITAID, in collaboration with implementing partners - WHO, UNICEF, the Global Fund and i+solutions - has focused its malaria efforts on public health and market interventions to:

- Expand access to ACT treatment by increasing the volume of supply of quality products and reducing prices;
- Finance additional supply of quality artemisinin; and
- Accelerate coverage of LLINs by reducing delivery delays and prices.

Scaling up ACT provision

Although 77 of the 86 countries with endemic *falciparum* malaria have adopted artemisinin-based combination therapy (ACT) as the first line of treatment against malaria, estimates indicate that ACTs account for only one in five anti-malarial treatments undertaken and are provided almost entirely through the public sector. For the 60% of patients who buy anti-malarial medicines over the counter, the high price of ACTs is a deterrent. ACTs bought at a pharmacy may cost US$ 6-10 per treatment against US$ 20-50 cents for less effective drugs.

UNITAID supports the funding of ACTs through two projects: the ACT Scale-up project and the Global Fund's Round 6 Phase 1. For the ACT Scale-up project, UNITAID has committed to delivering 27 million ACT treatments under the Global Fund's Round 6 Phase 1. The cumulative delivery of UNITAID-funded ACT treatments as of the end of 2010 is estimated at US$ 45.7 million, inclusive of the 1.4 million ACT treatments for Liberia and Burundi under a separate (and already closed) project.

[25] Roll Back Malaria Partnership, *World Malaria Day 2010: Africa Update*, April 2010.
[26] WHO, *World Malaria Report 2010.*

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By the third quarter of 2010, UNITAID support for the ACT Scale-up project led to an increase in treatment targets of Global Fund grants in eight countries,[27] and raised overall ACT treatment targets to 82 million patients – almost 50% more than the situation before UNITAID provided additional funding. Even greater increases in treatment targets can be expected as the remaining UNITAID allocations are disbursed.

"I thank UNITAID for providing ground-breaking solutions to some of the most intractable problems in malaria control. UNITAID's innovative approaches are helping to lower ACT prices, secure predictable supplies of artemisinin, improve ACT market stability, and ensure a predictable and sustainable source of funding to tackle malaria."

Prof. Awa Marie Coll-Seck, Executive Director of the Roll Back Malaria Partnership

The Affordable Medicines Facility for malaria (AMFm)

The Affordable Medicines Facility for malaria (AMFm), hosted by the Global Fund, is a new initiative launched in April 2009 to provide affordable, effective and quality-assured ACTs for patients seeking treatment in both the public and private sectors. The AMFm aims to lower the price of an ACT treatment to that of chloroquine or sulfadoxine-pyrimethamine, which could more than triple ACT usage from current levels. Its ultimate goal is to push out of the market substandard and ineffective anti-malarial drugs, including artemisinin mono-therapies, thereby delaying development of resistance as well as ensuring effective treatment.

To achieve this goal, the AMFm negotiates lower drug prices with manufacturers, whose production costs should fall with increased and predictable demand. It then pays a large proportion of this lower price (a 'co-payment') directly to manufacturers on behalf of eligible buyers. These buyers will be expected to pass on the price benefit to patients. In addition, participating countries must implement specific measures to ensure widespread and equitable distribution and the correct use of ACTs.

In early 2010, the AMFm launched seven Phase I projects, in Ghana, Kenya, Madagascar, Niger, Nigeria, Uganda and the United Republic of Tanzania, to assess the effectiveness of the mechanism before expanding it to other malaria-endemic countries. Phase I is planned to last two years and cost US$ 340 million. UNITAID is providing a crucial funding commitment of up to US$ 130 million for the ACT co-payment fund, the other donors being the UK's Department for International Development and the Bill and Melinda Gates Foundation.

UNITAID, through its capacity as Vice-Chair of the AMFm ad hoc committee, will ensure timely completion of price negotiations with ACT manufacturers. Together with its partners, the Roll Back Malaria Partnership and the Global Fund, UNITAID will also take the lead in forecasting global demand and supply for ACTs which is an important element in assuring stable supplies of the medicine and the raw material.

The AMFm Phase I aims to deliver 225 million treatments by 2012.[28] AMFm co-paid ACTs are already being supplied to Phase I countries, with the first batch of 500,000 treatments delivered to Kenya in August 2010. As of December 2010, 69 eligible orders for 29.9 million treatments worth US$ 27.8 million in co-payments have been approved.

[27] Cambodia, Ghana, Madagascar, Sudan, Indonesia, Zambia, Ethiopia and Mozambique.
[28] Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Uganda and the United Republic of Tanzania.

The AMFm brings the new approach of subsidizing 90% of the purchase cost of ACTs and extends this subsidy to the private sector market. UNITAID support to AMFm doubled the size of the ACT market in 2010.

The achievements of the AMFm in relation to its objectives will be assessed by an independent evaluation, which will decide the future of the AMFm based on its findings and recommendations of the AMFm ad hoc committee. The success of the AMFm will largely depend on the capacity of countries to ensure the rational use of ACTs supported by confirmed diagnosis, need-based quantification, appropriate distribution and the prevention of illegal use and diversion.

"The Affordable Medicines Facility for malaria is a breakthrough in global health. It will help to treat the millions of people who suffer from malaria illness, prevent deaths and prolong the effectiveness of new anti-malarial medicines. It is a striking example of partnerships that really work."

Robert B. Zoellick, President of the World Bank Group

Securing a sustainable supply of artemisinin

The progressive increase in access to effective anti-malarial treatment observed over the last few years, coupled with the launch of the AMFm, is expected to increase global demand for ACTs. Ensuring the production of the required amount of ACT treatments is contingent on securing adequate supplies of artemisinin, which is extracted from the medicinal plant *Artemisia annua*. Erratic supply and pricing of artemisinin and the complexity of the market creates challenges for establishing predictable ACT supply and forecasting demand.

In an effort to secure additional sources of artemisinin needed to ensure adequate supply of ACTs, UNITAID decided to support the "Assured Artemisinin Supply Service (A2S2)" project, endorsed by RBM partners. The A2S2 project was launched in July 2009 with the principal objective of securing 40 metric tonnes (MT) of additional artemisinin in two years. In addition to providing critical technical support to the artemisinin extractors and actors in the supply chain, contracts for 16 MT of artemisinin in China and Madagascar with a total loan value of US$ 3.2 million were concluded in 2010. The artemisinin production assured through this project comes on top of the annual production of 73-100 MT, and the combined quantity is expected to meet the global ACT demand until 2012.

The impact of the project on the overall supply and demand for artemisinin is likely to be influenced by the global demand for ACTs. In situations where the demand for ACTs is high, the price of artemisinin will probably rise if supply fails to meet demand. However, if ACT demand falls, Artemisia growers and extractors could halt production of the much-needed ingredients. This scenario is also likely to create supply shortages and a potential price hike. The endeavour for semi-synthetic artemisinin and the prospects of achieving this breakthrough by 2013 is likely to influence the overall picture of the market for artemisinin and ACTs.

In 2010, WHO published treatment guidelines recommending a parasitological confirmation of diagnosis in all patients suspected of having malaria before starting treatment. UNITAID supports this move towards universal diagnostic testing of malaria as a critical step forward in the fight against malaria as it will allow for the targeted use of ACTs for those who actually have malaria and will help reduce irrational use of the medicine and the emergence and spread of drug resistance. UNITAID Strategy 2010-2012 incorporates support for existing quality assurance services for rapid diagnostic tests (RDTs) and for motivating the development of improved RDTs.

CASE STUDY

Bionexx and the Artemisinin Supply Initiative

Bionexx is an enterprise based in Madagascar, and one of only a handful of African companies introducing large-scale cultivation of Artemisia, a plant that yields the natural extract used in Artemisinin Combination Therapy (ACT) for effective malaria treatment. Thanks to a UNITAID investment of US$ 9.3 million to support the Assured Artemisinin Supply System (A2S2) initiative,[29] Bionexx began carrying out field trials with high-yielding seeds. It analysed extraction and purification technologies and launched the commercial phase of its operations in 2008.

In 2010, according to Bionexx, over 5,000 small farmers in Madagascar were now involved, with all the attendant development and labour-related benefits for agricultural communities in a low-income African country.

UNITAID helped launch the Assured Artemisinin Supply System (A2S2) initiative 2010-2012 to help meet ACT demand for the life-saving plant-extract by pre-financing artemisinin production and sales to ACT manufacturers.

In 2010 Bionexx signed a contract with A2S2 Project and Cipla, a large Indian generic drug company that produces ACTs, to deliver six metric tonnes of pure artemisinin. Under the agreement with A2S2, Bionexx received a cash payment of US$ 1.2 million to bridge the pre-harvest and shipment season. The loan is intended to cover a maximum of 60% of the export contract. Once Cipla received the artemisinin, it makes a payment to Triodos Bank managing the A2S2 project fund and the payment difference (40%, minus interest) is then advanced to Bionexx. Without the support provided by the A2S2 project, Bionexx would have faced difficulties in meeting the orders it has received from Cipla.

Last year an estimated 90% of the world's crop was grown in China and Viet Nam. Expanding cultivation of the plant to other regions of the world – through companies such as Bionexx – will help to ensure additional supply of artemisinin, and bring production closer to areas with large numbers of malaria patients.

[29] A2S2 is executed by a consortium of four organizations: i+Solutions operates as the lead agency, FSC Development Services Ltd, Artepal and Triodos Sustainable Trade Fund which manages the Artemisinin Pre-Finance Facility.

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Scaling up Access to Long-Lasting Insecticide Treated Nets (LLINs)

One of the tools used to prevent malaria is the use of bed nets treated with effective insecticides. These repel or kill mosquitoes coming into contact with the insecticide on the netting material. Where full coverage is achieved, LLINs are estimated to reduce clinical episodes of malaria by 50% on average.[30]

Accelerating scale-up of LLINs for malaria prevention is one of the projects supported by UNITAID. Launched in February 2009 with an approved funding of US$ 109 million, 20 million LLINs were procured and distributed in 2010 to beneficiary households in eight malaria endemic countries in sub-Saharan Africa.[31] The countries were prioritized based on their low LLIN coverage, which was way below the 2010 Roll Back Malaria target of 80%. The procurement of WHO Pesticide Evaluation Scheme (WHOPES) - recommended items through this project is believed to have motivated the submission of new products for assessment.

Project implementation has been remarkable, particularly with respect to procurement, delivery lead-time and in-country distribution. Through this project, a lead-time from order of LLINs to delivery of less than 12 weeks was achieved for 80% of the purchase orders, and almost all LLINs (98%) were distributed to beneficiary households in 2010. The only remaining batch of LLINs in the Central African Republic will be distributed in early 2011.

The project has also achieved price reductions. The median price reduction of LLINs procured was US$ 4.36 for small nets, US$ 4.62 for large nets and US$ 6.21 for conical nets.

The estimated increase in household coverage for LLINs is approximately 18% and the price reductions achieved through this project are considerable. However, as the service life of LLINs is limited to three to five years, depending on the conditions of use, the need for replacement, as well as distribution of LLINs to new and unreached households, requires long-term commitment and investment. Therefore, the need to support new technologies and to create the market environment for competitive and affordable prices will remain one of the priority areas for UNITAID.

[30] WHO (2010). Op cit.

[31] Angola, Republic of Congo, Central African Republic, Democratic Republic of Congo, Guinea-Bissau, Nigeria, Sudan and Zimbabwe.

Where next on malaria

UNITAID is considering a variety of market interventions to support the fight against malaria in 2011 and beyond:

- Funding new ACT projects to increase availability and reduce prices.
- Supporting prequalification of user friendly ACTs and innovative products.
- Supporting quality assurance of rapid diagnostic tests for malaria.
- Exploring options to increase access to malaria diagnostic tests and to ensure treatment based on parasitological confirmation.
- Increasing and assuring raw material, artemisinin, for producing ACTs.

"The support provided by UNITAID to the Global Fund has made a great difference in the lives of countless numbers of people suffering with malaria and multi-drug resistant tuberculosis."

Michel Kazatchkine, Executive Director, the Global Fund to Fight AIDS, Tuberculosis, and Malaria

TB
The curable disease that continues to kill

2010 highlights:

- UNITAID has committed US$ 37.3 million for first-line paediatric TB medicines since the inception of the project in 2007.
- Price reductions in paediatric anti-TB medicines of up to 40% were achieved through UNITAID's support to GDF. However, changes in WHO guidelines for treatment of TB in children have spurred UNITAID to work with GDF and WHO to make the new, higher dose medicines available for purchase as quickly as possible.
- Cumulatively committed US$ 87.6 million for MDR-TB diagnostic equipment and achieved 80% price reductions in diagnostics technologies supported by UNITAID.
- Ensured uninterrupted flow of first- and second-line anti-TB drugs through the Strategic Rotating Stockpile.
- Supplied a total of 915,359 patient treatments for children, including 380,744 curative treatments and 534,615 preventive treatments in 56 countries.
- UNITAID will expand access within an extended timeframe (2009-2013) to diagnostics for 119,000 MDR-TB patients (20% of the estimated total global burden).

72 countries

AMERICAS

Dominican Republic, Guatemala, Haiti, Peru.

ASIA

Afghanistan, Azerbaijan, Bangladesh, Bhutan, Cambodia, Democratic People's Republic of Korea, Kazakhstan, Kiribati, Kyrgyzstan, India, Indonesia, Mongolia, Myanmar, Nepal, Pakistan, Papua New Guinea, Sri Lanka, Tajikistan, Thailand, Timor-Leste, Turkmenistan, Uzbekistan, Viet Nam.

EUROPE

Belarus, Bosnia and Herzegovina, Bulgaria, Georgia, Former Yugoslav Republic of Macedonia, Republic of Moldova.

NORTH AFRICA/MIDDLE EAST

Egypt, Iraq, Jordan, Lebanon, Morocco, Syrian Arab Republic, Yemen.

SUB SAHARAN AFRICA

Benin, Burkina Faso, Burundi, Cameroon, Cape Verde, Côte d'Ivoire, Democratic Republic of Congo, Djibouti, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Kenya, Lesotho, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Nigeria, Rwanda, Senegal, Sierra Leone, Somalia, Sudan, Swaziland, United Republic of Tanzania, Togo, Uganda, Zambia.

TB: A major killer of children in poor countries

The TB burden among children worldwide is currently estimated to range from 9.6% to up to 20% of all TB cases and WHO estimates that of the nine million annual TB cases globally about one million occur in children.

In HIV-infected children the risk of co-infection with TB is very high and often results in deafness, blindness, paralysis and mental retardation. Malnutrition also often accompanies TB, and one of the first indications that a child has TB is when he or she is unable to gain weight, with an accompanied loss of energy and a cough lasting for more than three weeks.[32]

Although children account for up to a fifth of all new cases of active tuberculosis in high-burden settings,[33] paediatric TB diagnosis and treatment has been largely neglected and there is a dearth of appropriate and adapted paediatric TB drug formulations. UNITAID's paediatric TB project aims to foster the creation of a market for quality paediatric drugs for children under 15, including special formulations for children under four years old.

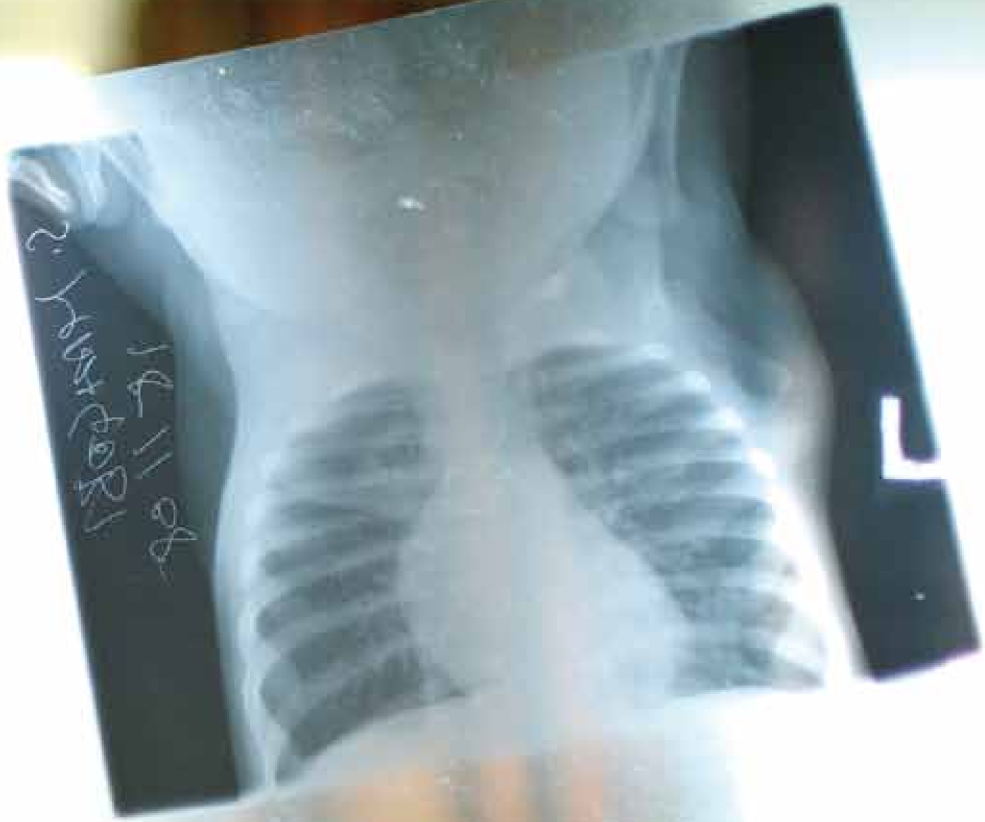
UNITAID: Leading player in paediatric TB medicines

At the close of 2010 UNITAID had delivered about 25% more treatments for children than had been planned, bringing the cumulative total of children having access to child-friendly formulations to 952,226 patients. This success was due to increased numbers of manufacturers and stimulated competition. Through its market approach UNITAID is now one of the largest providers of quality paediatric TB medicines, second only to the Global Fund.

The UNITAID/GDF partnership also continued to achieve price reductions of 40% for two key paediatric FDCs in 2010. Fourteen of the 18 UNITAID priority TB medicines were prequalified or approved over the period between 2007 and 2010. Average delivery lead times were reduced by 11 days (to 76 days) in 2010 and no treatment disruptions were reported.

UNITAID's focus on paediatric drug volumes will be crucial in ensuring the continued supply of transitional FDCs, development of new optimal FDCs and their ultimate rapid introduction and uptake.

[32] More information is available at: http://www.searo.who.int/en/Section10/Section2097/Section2106_10681.htm
[33] Science Daily, *Lack of Tuberculosis Trials in Children Unacceptable*, August 2008.



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The first line of defence

Standard first-line TB treatment requires patients to take antibiotics daily for a minimum of six months. An unfinished treatment course can lead to treatment failure and the emergence of drug resistance. The first line of defence against the development of drug-resistant TB, therefore, is broad access to first-line TB treatment with appropriate adherence and treatment follow-up. Remaining at the heart of the Stop TB Strategy is DOTS, with WHO reporting achievements in implementing countries. The five components of DOTS are:

1. Political commitment with increased and sustained financing.

2. Case detection through quality-assured bacteriology.

3. Standardized treatment with supervision and patient support.

4. An effective drug supply and management systems.

5. Monitoring and evaluation system and impact measurement.

UNITAID support for first-line TB medicines for adults rests on a two-pronged strategy: providing bridge funding for 19 countries identified by the GDF for a period of two years and financing the supply of first-line TB medicines to be accessed during emergencies.

In 2010 UNITAID participation in the supply of first-line TB medicines lead to a 23% price reduction of these essential drugs, and followed successful UNITAID efforts to contain the cost of first-line TB medicines to less than US$ 20 per treatment.

A rising tide of drug-resistant TB poses massive challenges

Tuberculosis is a major global health problem. Each year, there are around nine million new cases of TB, and close to two million people die from the disease.[34] Yet TB is, in most instances, a curable disease. Using combinations of first-line drugs introduced into treatment between the 1950s and 1980s, around 90% of people with drug-susceptible TB can be cured in six months.

All countries are affected, but most cases (85%) occur in Africa (30%) and Asia (55%), with India and China alone accounting for 35% of all cases. There are 22 high-burden countries that account for about 80% of the world's TB cases, and which have been given particular attention in TB control since around the year 2000.[35]

Globally, the absolute number of cases is increasing slowly, although the number of cases per capita (usually expressed as the number of cases per 100,000 population), is falling by around 1% per year. TB ranks as the eighth leading cause of death in low- and middle-income countries (seventh for men and ninth for women); among adults aged 15–59 it ranks as the third most common cause of death, after HIV/AIDS and ischaemic heart disease.[36]

[34] *Global tuberculosis control: a short update to the 2009 report.* Geneva, World Health Organization (WHO/HTM/TB/2009.426). Quoted in: STOP TB Partnership: The Global Plan to Stop TB 2011-2015 (2010).
[35] The 22 countries are: Afghanistan, Bangladesh, Brazil, Cambodia, China, the Democratic Republic of the Congo, Ethiopia, India, Indonesia, Kenya, Mozambique, Myanmar, Nigeria, Pakistan, the Philippines, the Russian Federation, South Africa, Thailand, Uganda, the United Republic of Tanzania, Viet Nam and Zimbabwe.
[36] Lopez AD et al. *Global burden of disease and risk factors.* New York, Oxford University Press and the World Bank, 2006. Quoted in: STOP TB Partnership: The Global Plan to Stop TB 2011-2015 (2010).

TB is now the leading cause of death for people living with HIV. In 2009, 1.7 million HIV-positive people were screened for TB and close to 80,000 of those without active TB were enrolled on isaniazid prevention treatment (IPT). The numbers screened are equivalent to about one third of the people living with HIV who are on antiretroviral therapy (ART), about 10% of the people living with HIV who are estimated to be in need of ART and about 5% of the estimated total number of HIV-positive people worldwide.[37]

Rolling out rapid MDR-TB diagnostics

Lack of diagnostic capacity is a crucial barrier to an effective response to MDR-TB. Detecting MDR-TB, and determining the drugs to which a patient is resistant, have typically taken up to four months using traditional laboratory testing methods with sophisticated and expensive equipment. This has resulted in treatment delays and the further spread of resistance.[38]

UNITAID is investing nearly US$ 88 million over a five-year period (2009-2013) to support the procurement and use of new diagnostic technologies in 27 countries.[39] By creating new markets for diagnostic tools, UNITAID and its partners aim to boost supply, encourage new entrants to the market, and bring prices down through economies of scale and increased competition. More importantly, delay for getting laboratory results has decreased from four months to TWO days.

The overall goal of UNITAID's five-year support to the EXPANDx-TB project is to narrow the large diagnostic gap in MDR-TB control by expanding and accelerating access to new and rapid diagnostic technologies within appropriate laboratory services at country level, accompanied by the necessary know-how for technology transfer, and ensuring these new technologies are properly integrated within TB control programmes, thereby addressing one of the key obstacles to the scale-up of MDR-TB care.

"...Laboratory capacity is the Achilles heel in our fight against TB and MDR-TB. The ability to diagnose patients in these 27 recipient countries is a crucial step towards meeting targets for TB treatment."

Dr Mario Raviglione, Director, WHO/STB

It is anticipated that UNITAID's investment will translate into an estimated 119,000 MDR-TB patients being diagnosed by 2013 and treated through the MDR-TB Acceleration of Access Initiative and the Global Fund's round system. In 2010, 2,356 MDR-TB cases were detected through the project, bringing the cumulative number of patients detected to 4,166 in six countries entering the routine reporting phase of the project.

[37] WHO (2010). Global Tuberculosis Control 2010.
[38] Cited in: http://www.finddiagnostics.org/media/news/101126.html
[39] Azerbaijan, Bangladesh, Belarus, Cameroon, Côte d'Ivoire, Democratic Republic of Congo, Djibouti, Ethiopia, Georgia, Haiti, India, Indonesia, Kazakhstan, Kenya, Kyrgyzstan, Lesotho, Republic of Moldova, Myanmar, Peru, Senegal, Swaziland, Tajikistan, United Republic of Tanzania, Uganda, Uzbekistan, Viet Nam and Zambia.

In 22 of the 27 high-burden countries, assessments of laboratory needs and preparedness have been carried out, as well as infrastructure upgrades and training of staff. Technology transfer has begun, paving the way for accelerated patient diagnosis and eventual routine surveillance of drug resistance at country level. Six countries started diagnosing patients in 2010. The project has also already achieved reductions of up to 80% in the price of sophisticated diagnostic equipment and supplies through competitive tenders.

"We are grateful to UNITAID for their continued support of this project, which represents a shining example of TB partners working together to achieve solid goals that will translate into reduced TB transmission and lives saved."

Dr Marcos Espinal, former Executive Secretary, Stop TB Partnership

Expanding access to MDR-TB treatment

Drug-resistant TB is the man-made result of interrupted, erratic, or inadequate TB therapy. **(TB ALLIANCE)**

Multidrug-resistant TB (MDR-TB) is a form of TB that is difficult and expensive to treat and fails to respond to standard first-line drugs. If this was not enough, treating MDR-TB is a lengthy, expensive and extremely challenging process, requiring patients to submit to an arduous regimen of pills and painful daily injections with significant side effects for up to two years. Furthermore, treating MDR-TB is made more problematic by the limited availability of affordable novel medicines with shorter treatment regimens.

WHO estimates that nearly 4% of people with TB have multidrug-resistant tuberculosis (MDR-TB), which sets in when people with standard tuberculosis do not get appropriate treatment or fail to take their treatment correctly. According to WHO, only a tiny proportion of MDR-TB cases are properly treated, and the general response to MDR-TB has been weak.

Part of UNITAID's effort is therefore aimed at encouraging more manufacturers to produce quality medicines and to discourage use of non-quality-assured medicines, which risk provoking treatment failure and further drug resistance.[40] Aiming at very high standards is a necessity but leaving the large majority of MDR-TB patients (>90%) to inadequate practices will have no impact on the M/XDR-TB situation and will not protect second-line medicines.

In 2010, the largest WHO MDR-TB survey reported the highest rates ever of MDR-TB, with peaks of up to 28% of new TB cases in some areas of the former Soviet Union. There were an estimated 440,000 cases of MDR-TB in 2008. The 27 countries (15 in Europe) that account for 86% of all such cases have been termed the 27 high MDR-TB burden countries.[41] The four countries that had the largest number of estimated cases of MDR-TB in absolute terms in 2008 were China (100,000), India (99,000), the Russian Federation (38,000) and South Africa (13,000). By July 2010, 58 countries and territories had reported at least one case of extensively drug-resistant TB (XDR-TB).[42] Most recent estimates show that 19.9% of all MDR-TB patients are in low-income countries, 62.6% in lower middle-income countries, 16.5% are in upper-middle countries and 0.9% in high-income countries.

[40] WHO, *Multidrug and Extensively Drug-Resistant TB (M/XDR-TB): 2010 Global Report on Surveillance and Response*, March 2010.
[41] WHO (2010). Global Tuberculosis Control.
[42] WHO (2010). Global Tuberculosis Control.

UNITAID's MDR-TB Scale-up Initiative aims to provide quality treatments to people in 18 countries. In doing this UNITAID is filling a treatment gap and also expanding the market by encouraging existing manufacturers to step up production of quality drugs and new suppliers to enter the market. The original goal was to treat 5,756 patients, but this was raised to 15,600 patient treatments in 2010. This increase is due to UNITAID's support to India for 9,580 patient treatments. By the end of 2010 UNITAID had financed over 3,973 MDR-TB treatment courses and 6,525 patient treatments ordered by GDF for delivery in Q1 2011. In 2010 an additional five new MDR-TB products (injectables and oral tablets) were prequalified.

Strategic Rotating Stockpile

UNITAID has to date provided US$ 21.5 million to the Strategic Rotating Stockpile (SRS) to avoid treatment disruption and to respond flexibly to challenges and bottlenecks in the supply of first- and second-line TB drugs, effectively contributing to halting the spread of drug-resistant TB. The stockpile allows urgent orders to be serviced without causing interruptions to standard orders, and accelerates access to life-saving treatments at an affordable price.

The SRS was created in 2007 to meet emergency requests from countries facing potential stock-outs and running the risk of treatment disruptions. This market-based approach to addressing the current bottlenecks in the global TB public health sector makes it possible for countries not only to have access to affordable quality assured medicines, but allows them to build national drug management capacity. Through UNITAID-guaranteed volume-based financing, the SRS reduced the median lead time for urgent orders in 2010 to 19 days. Last year a total of 54 countries benefited from the SRS in comparison to 39 countries in 2009. The SRS also facilitates greater purchasing power for the Global Drug Facility to negotiate prices based on predictable funding.

The SRS complements the UNITAID MDR-TB Scale up Initiative, stimulates the market for MDR-TB drugs and provides access to all Greenlight Committee-approved projects and programmes in countries across Africa, the Middle East, Asia and Europe,[43] where patients have been diagnosed with MDR-TB, but for whom drugs are currently not available. The utilization rate (volume of stockpile used), has increased to an average of 72% annually.

[43] Azerbaijan, Burkina Faso, Cambodia, Dominican Republic, Democratic Republic of Congo, Guinea, Haiti, India, Kenya, Kyrgyzstan, Lesotho, Malawi, Republic of Moldova, Mozambique, Myanmar, Nepal, Timor-Leste and Uzbekistan.

Transition/sustainability

In 2010, a UNITAID-initiated meeting achieved closer contacts and coordination between the various stakeholders within the MDR-TB niche, namely the Global Fund, the Global Drug Facility (GDF), the Green Light Committee (GLC) and partners.

In order to have a smooth transitioning for the paediatric TB project, the GDF held a series of workshops and training sessions for national TB programmes on planning and implementation of adapting national guidelines following the publication of new WHO recommendations on rapid advice treatment in December 2010.

By June 2010, the role of UNITAID serving as a bridge financing mechanism for first-line drugs was achieved in the 19 supported countries. This was mainly due to the fact that the GDF had already entered into discussions with funding mechanisms to ensure that ongoing work could be continued. Twelve countries had transitioned from UNITAID support to the Global Fund, three had transitioned with their own government budgets and one country had transitioned from UNITAID support with World Bank monies. A further three countries received emergency grant support from the GDF.

Where next on tuberculosis

UNITAID will consider a variety of market interventions to support the fight against tuberculosis in 2011 and beyond. These could include:

- A fixed-dose combination product of appropriate strength for children;
- Support access to new first-line paediatric medicines and new medicines for treating XDR-TB;
- Invest in better diagnostic tools and point-of-care tests, and support access to new rapid diagnostic tools for detecting MDR-TB and XDR-TB;
- Support the development of novel drugs and manufacturers of selected Active Pharmaceutical Ingredients to increase the number of producers and stabilize prices;
- Foster the development of ‘fast track’ prequalification for new and low-volume TB products through the WHO Prequalification Programme;
- Integrate commodities addressing TB/HIV co-infection.

CASE STUDY

Scaling Up the fight against MDR-TB in India

Two million people are diagnosed with TB in India every year – one fifth of all cases reported globally. India has the largest TB burden of any country in the world and it remains one of the country's leading causes of mortality, killing nearly 1,000 men, women and children each day. Perhaps even more significantly, India also has more MDR-TB cases than any other country in the world.

In 2010, UNITAID – in partnership with the Global Drug Facility (Stop TB Partnership), the Global Fund and the Greenlight Committee - supported a scale-up of life-saving MDR-TB treatment in India, representing a new phase of the MDR-TB Scale Up Initiative, which seeks to increase the number of patients receiving second-line drugs and have a positive impact on market dynamics for these drugs, through improvement in price, quality and delivery.

UNITAID also signed an agreement with the Ministry of Health in India to strengthen 40 MDR-TB diagnostics laboratories throughout the country. Following intensive technical support and preparation of the round 9 Global Fund proposal, India's national Tuberculosis Programme received a grant of US$ 13 million from the Global Fund, with the Foundation for Innovative New Diagnostics (FIND) as a sub-recipient to support EXPAND-TB activities.

To accelerate the introduction and scaling up of newer technologies in the identified laboratories, a proposal was submitted to India's Ministry of Health to establish a training facility. This was subsequently approved at the national TB Institute, Bangalore which is also one of the country's leading National Reference laboratories. The UNITAID Executive Secretary and the TB Portfolio Manager with FIND's CEO have visited EXPAND-TB supported sites to review the UNITAID-funded projects.

In 2010 FIND India also assessed a total of 26 Culture and Drug Susceptibility Testing (DST) sites. It is expected that at least nine Culture and DST sites will be using the new Line Probe Assay diagnostic technology for patient care activities by early 2011. At the end of 2010, 1,792 LPA results were available for the programme, 740 patients were identified as MDR-TB cases, and 480 patients at seven sites were started on treatment with second-line medicines.

Working jointly with the Global Drug Facility (Stop TB Partnership) and the Global Fund, UNITAID has committed US$ 87.6 million to fund the use of new diagnostic tests in 27 high-burden countries, including India. The new test reduces the time taken to diagnose MDR-TB from three months – the time taken with older tests – to just two days.

Investing in Quality

UNITAID supports WHO Prequalification Programme

2010 highlights:

- US$ 53 million committed by UNITAID to the WHO Prequalification Programme, increasing availability of quality medicines and diagnostics for procurement in developing countries.
- Prequalified 38 new health products - including 15 UNITAID priority medicines for HIV/AIDS, malaria and TB.
- Prequalified six quality control laboratories (QCLs).
- Conducted capacity-building training sessions for participants from national regulatory bodies, quality control laboratories and manufacturers.
- Provided significant capacity-building for TB medicines manufacturers in China.
- Completed survey of quality of anti-malarial drugs in six African countries.

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What is the WHO Prequalification Programme?

The WHO Prequalification Programme, established in 2001, aims to ensure unified standards of quality, safety and efficacy of medicines that can be procured through the United Nations system, national governments and other agencies. Medicines for HIV/AIDS, malaria and tuberculosis that are of high public health and market importance are some of the products prioritized for prequalification.

In addition, the Programme helps to create and strengthen national quality control and regulatory systems for medicines, hastening regulatory approvals in recipient countries. Through the Programme, UNITAID is also supporting the development and updating of global norms and quality standards.

UNITAID's support of the Prequalification Programme contributes to a free-of-charge public service for manufacturers, encouraging generic producers in developing countries to enter the market, thereby increasing country capacity for production of priority medicines.
The list of prequalified medicines produced by the programme has become a vital tool for any organization involved in the bulk purchase of medicines, whether at national or international level.

Why UNITAID support?

UNITAID funds only quality-assured medicines to treat HIV/AIDS, malaria and TB. Support for the WHO Prequalification Programme thus has a direct positive impact on UNITAID's efforts to expand access and higher market share to quality treatment for the three diseases. It increases the number of new, high-quality manufacturers (including generic producers) of existing drugs, boosting supply and spurring price competition. It also facilitates the timely introduction of new quality-assured drugs, including FDCs and paediatric formulations, by speeding the processing of applications from pharmaceutical companies.

In addition, UNITAID funding for the Prequalification Programme covers field sampling and analysis of drugs purchased with UNITAID support. Testing and sampling involves the participation of some local laboratories in order to help develop local capacity.

Activities in 2010

UNITAID has to date disbursed US$ 17 million of the US$ 53 million committed. The number of dossiers for UNITAID priority products received since the start of the UNITAID support has more than doubled, and 45 products (38%) have been prequalified and evaluation of the remaining 73 dossiers (62%) is ongoing. In 2010, 36 of the 51 products received from ten countries were accepted for assessment by WHO/PQP.

UNITAID support to WHO/PQP has also enabled the re-assessment of 579 product variations in 2010 compared with 381 in 2009 and 252 in 2008. The variations assessed were mainly related to additional new sources of active pharmaceutical ingredients (APIs), specification and test procedure changes for APIs and finished pharmaceutical product specifics (FPPs), changes in packaging material and size and changes in API and FPP manufacturing sites and processes.

Six quality control laboratories were prequalified in 2010,[44] bringing the total number of prequalified quality control laboratories to nine. In the area of regulatory capacity-building, eight training sessions with an average of 53 participants were held in 2010, and technical support was provided to four Chinese and Indian manufacturers.

Prequalification of medicines for UNITAID disease niches

In 2010, a total of 36 products were prequalified of which 15 are UNITAID priority medicines for HIV/AIDS, tuberculosis and malaria. The prequalified products include new, generic and innovator products. The three new products include artesunate injectable, isoniazid tablets for TB and efavirenz for HIV/AIDS. Supporting and ensuring speedy prequalification processes for UNITAID priority medicines, prequalification of APIs and in-country sampling and testing of quality of medicines supplied by UNITAID will be strengthened in the project implantation years ahead.

The table below summarizes the overall progress of the product dossier assessment and prequalification status.

Table 1: UNITAID priority medicines prequalified, 2007 to 2010

PRODUCT	Dossier Accepted for Assessment	Products Prequalified
Second-line antiretrovirals	37	36
Paediatric antiretrovirals	7	4
First-line anti-TB products	17	3
Second-line anti-TB products	19	1
Paediatric anti-TB products	10	4
Anti-malarials	28	7
Total	118	55

[44] Ukraine (two labs), Peru (one lab), Uruguay (one lab), Plurinational State of Bolivia (one lab) and Canada (one lab).

Prequalification of quality assurance of diagnostics for HIV/AIDS and malaria

The *Quality Assurance of Diagnostics* launched in March 2009 has completed most of the activities and processes required to initiate product dossier evaluation and prequalification. To date a total of 18 product dossiers are under review and applicants of 21 other diagnostic products identified as UNITAID priority have been invited to submit their applications with a complete product dossier.

Some of the major achievements of the project included: completion of the WHO/DLT Prequalification of Diagnostics Business plan for 2009-2013, setting-up of formal prioritization criteria for the evaluation of diagnostics and evaluation protocol for rapid diagnostic tests, CD4 and viral methods of diagnosis. With the recruitment of additional staff expected to be completed by the beginning of 2011, the pace of implementation of the project is expected to speed up the prequalification of more diagnostic products for HIV and malaria.

"UNITAID support of WHO's Prequalification Programme is crucial in ensuring that HIV/AIDS, malaria and TB patients in resource-limited countries receive quality-assured medicines at the most affordable price."

Margaret Chan, WHO Director-General

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The Medicines Patent Pool

"This is an historic day. UNITAID has now put in place a mechanism that will make medical advances work for the poor, while compensating companies for sharing their technology."

Philippe Douste-Blazy, Chairman of UNITAID's Executive Board, December 2009

"This license underlines the U.S. Government's commitment to the Medicines Patent Pool and its goal to increase the availability of HIV medicines in developing countries. We are now discussing licensing to the Medicines Patent Pool other patents that could have a positive impact on the treatment of HIV/AIDS."

NIH Director, Francis S. Collins, on the occasion of NIH's first license to the pool

In December 2009, after more than a year of preparation, UNITAID's Executive Board took a landmark decision to establish a patent pool for HIV/AIDS medicines. By September 2010, the pool had reached its first licensing agreement - with the world's largest funder of bio-medical research, the US National Institutes of Health. In November 2010 the MPP became a separate legal entity, supported by UNITAID under a five year Memorandum of Understanding.

The pool aims to make newer medicines available in patient-adapted form, at lower prices, for low- and middle-income countries. UNITAID has committed to provide start-up funds of up to US$ 4 million over the next year. Expected savings from lower prices are estimated at a minimum of US$ 260 million over a five-year period, releasing resources to give more people access to life-saving drugs.

Widespread patenting represents a significant barrier to access to essential drugs, partly by keeping prices high and partly by hindering development of combined medicines that involve drugs patented by different companies. Full implementation of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) means newer ARVs will increasingly be under patent protection in low- and middle-income countries. The patent pool, the first established for HIV/AIDS medicines, will offer licenses for patents held by pharmaceutical companies, universities and government institutions. Generic producers and other manufacturers will pay royalties for licences to use these patented technologies, enabling them to make lower cost versions of newer drugs and a wider array of fixed-dose combination medicines, including special formulations for children. At the same time, this system rewards the research-based pharmaceutical companies for providing access to their intellectual property.

The pool is aiming to promote reductions in the prices of existing ARVs and stimulate production of newer first- and second-line ARVs by increasing the number of generic producers of these medicines and spurring competition in the market. UNITAID also plans to ensure that manufacturers using the pool meet agreed quality standards. However, the success of the initiative will depend on patent holders' willingness to put their patents into the pool. The pool is currently in negotiation with five companies for potential inclusion.

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Millennium Foundation

The Millennium Foundation is an independent, private and non-profit foundation established in November 2008 on a grant provided by UNITAID. Its mission is to implement the Voluntary Solidarity Contribution (VSC) project, which was designed as an innovative way to raise additional and sustainable funds for UNITAID.

The VSC project was publicly launched in late 2009 and early 2010 under the brand name “MASSIVEGOOD”. The idea is to allow individuals booking airline tickets online to make small voluntary US$ 2 or €2 micro-donations. Corporate donors also have access to the MASSIVEGOOD donation programme. MASSIVEGOOD has been launched in the United States and in Spain.

Following findings from an independent review commissioned by UNITAID, the project’s strategy was revised in mid-2010. A pilot project in partnership with the Spanish Red Cross started in December 2010 and is ongoing. Currently, the Millennium Foundation is actively re-orienting the initial business model of the VSC Project towards new partnerships through 2011.

Thank-you campaign

UNITAID's 'Thank-you' campaign continued to be successful in 2010, following the high visibility it received in the previous year. The campaign aimed to raise awareness of UNITAID achievements through case studies in three countries where UNITAID is active: Cambodia, Nepal and Zambia.

At the end of 2010, the campaign had been aired on over 40 TV channels, newspapers and magazines, 250 cinema screens in the UK, also on billboards and on video screens in major international airports, such as Paris Charles de Gaulle and Orly and 11 regional airports in the UK and Spain. The estimated total value of the *pro bono* publicity was over US$ 6 million.

The 'Thank-you' campaign consists of a number of audiovisual products: a TV spot in five languages; a campaign website; photographs/posters; and editorial material.

THANK YOU for helping UNITAID save lives

© Giulio Di Sturco

Governance

Executive Board

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

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

The Executive Board consists of 12 members:

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

Members of the UNITAID Executive Board

At December 2010

Chair of the Board	***Philippe Douste-Blazy*** UN Under-Secretary-General and Special Adviser on Innovative Financing for Development
Brazil	***Carlos Alberto Den Hartog*** Ambassador, Coordinator-General of Innovative Financial Mechanisms for Eradication of Hunger and Poverty, Ministry of Foreign Affairs, Brasilia
Chile	***Pedro Oyarce*** Ambassador, Permanent Mission of Chile to the United Nations and other international organizations in Geneva
France	***Patrice Debré*** HIV/AIDS Ambassador, Ministry of Foreign Affairs, Paris
Norway	***Sissel Hodne Steen*** Minister Counsellor, Permanent Mission of Norway to the United Nations and other international organizations in Geneva
United Kingdom	***Gavin McGillivray*** Head, International Financial Institutions Department, Department for International Development, London
Spain	***Fidel López Álvarez*** Spanish Ambassador for HIV/AIDS Spanish Agency for international development cooperation, Madrid
African countries	***Shree Baboo Chekitan Servansing*** Ambassador and Permanent Representative of Mauritius to the United Nations and other international organizations in Geneva
Asian countries	***Kyung-hoon Sul*** Director, Development Cooperation Bureau, Ministry of Foreign Affairs and Trade, Seoul
Non-governmental organizations	***Mohga Kamal Yanni*** Senior Health Officer, Oxfam, Oxford, UK
Communities living with the diseases	***Esther Tallah*** Cameroon Coalition against Malaria, Yaoundé
Constituency of Foundations	***Girindre Beeharry*** Director of Strategy, Global Health Bill and Melinda Gates Foundation, Seattle
WHO	***Hiro Nakatani*** Representative of the Director-General for Partnerships and UN Reform, World Health Organization, Geneva
AMFm Ad hoc Committee	***Kirsten Myhrs*** Vice-Chair on behalf of UNITAID

Secretariat

The secretariat of UNITAID is responsible for carrying out and managing day-to-day operations and for coordinating implementation of the work plan. The secretariat manages relationships with partners and coordinates their activities, in order to ensure programme and financial monitoring and reporting.

The secretariat implements the policy set by the Executive Board and provides support to the Consultative Forum. It prepares project reports and budgets for approval by the Board, and reports on the results of the actions undertaken and the use of resources.

The secretariat is headed by Dr Jorge Bermudez (Brazil), Executive Secretary. At the close of 2010 it consisted of 37 professional and support staff representing 20 different nationalities. The working languages are English and French.

Secretariat expenses are modest – less than 3.4% of overall 2010 expenditure. UNITAID is thus fulfilling the mandate to operate in a manner that minimizes overhead costs.

The secretariat of UNITAID is hosted by the World Health Organization (WHO) in Geneva, Switzerland. The operations of the secretariat (including recruitment, procurement, financial matters and management of the UNITAID Trust Fund) are administered in accordance with the Constitution of UNITAID and WHO rules. There are authorized adaptations or exceptions to WHO administrative procedures and practices in order to meet UNITAID's specific needs.

Senior management group

At end 2010

Jorge Bermudez
Executive Secretary

Philippe Duneton
Deputy Executive Secretary

Raquel Child
Director, Market Dynamics and Operations

Brigitte Laude
Director, Administration and Finance

Brenda Waning
Coordinator, Market Dynamics

Edward Vela
Senior Adviser to the Executive Secretary

Sonia Hilton
Legal Officer

Daniela Bagozzi
Communication Adviser

Paulo Meireles
Acting Coordinator, Operations and Portfolio Manager, HIV

Our Partners

UNITAID channels its funds through partners active in the fight against HIV/AIDS, malaria and tuberculosis.

At the end of 2010, UNITAID was providing funding support to ten partners:

- ESTHER (Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau)
- Foundation for Innovative New Diagnostics (FIND)
- Global Drug Facility (Stop TB Partnership)
- Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria
- i+solutions
- Roll Back Malaria Partnership
- Stop TB Partnership
- UNICEF
- Clinton Health Access Initiative (CHAI)
- World Health Organization

World Health Organization

unicef

Stop TB Partnership

ROLL BACK MALARIA

Project funding

In assessing requests for funds, UNITAID's Executive Board selects projects that are aimed at UNITAID's chosen niches for medicines, diagnostics and related commodities and can be expected to have a positive and significant impact on the market. All UNITAID funding requests are reviewed by an advisory group of external experts.

Once a project has been approved and the funds committed, the implementing partner enters into negotiations with quality-assured manufacturers to achieve two main goals: ensuring that the needed products are available in a timely manner, and reducing their price through bulk purchasing and pooled procurement. Having secured these objectives, the partners purchase the products and supply them to countries through national partners which may include governments, NGOs and procurement agents. UNITAID is in regular contact with its partners and systematically monitors the progress and results of projects.

Assessing project proposals

In 2009, the UNITAID Board decided to formalize the expert technical review of proposals hitherto assured by the Interim Expert Advisory Group by establishing the independent Proposals Review Committee (PRC). The PRC is thus mandated with evaluating funding requests against UNITAID's strategic objective of achieving health outcomes through market impact, and making recommendations for Board consideration in selecting projects for UNITAID funding. The PRC is composed of external experts in fields such as public health, market dynamics, health economics, supply chain management and intellectual property.

Identifying priority diseases niches

In 2010, the proposals submission and review process was enhanced in order to provide more effective guidance to parties submitting project proposals to the PRC. In 2010, UNITAID established an independent advisory group (the Advisory Group on Funding Priorities - AGFP) to assist the Executive Board in identifying potential priority niches of high-market and public health impact to be funded by UNITAID. The AGFP advises and reports to the Policy and Strategy Committee.

UNITAID and WHO

WHO serves as UNITAID's trustee and also hosts its secretariat. WHO was a natural choice, given its role as the coordinating authority on international health. WHO offers UNITAID a strategic platform from which to operate and provides important legal, financial, administrative and technical support. UNITAID's secretariat enjoys a large degree of autonomy within WHO and is free to take a flexible approach towards fulfilling its mission objectives.

UNITAID derives significant benefits from its proximity to WHO programmes in HIV/AIDS, malaria, tuberculosis and health systems, as well as from the global network of WHO regional and country offices. These benefits include WHO advice on norms and standards as well as technical and policy support to its member states.

UNITAID collaborates closely with WHO technical units, and relies on WHO guidelines for managing the control of diseases. UNITAID is also a major supporter of the WHO Prequalification Programme.

Resource mobilization

By the end of 2010, UNITAID membership had grown to 29 countries and one foundation. UNITAID's support base is varied and comprises a number of low- and middle-income countries that provide funding through airline ticket levies or regular budget allocations. In 2010, a number of countries indicated their intention to join UNITAID, among them Kenya, Portugal and Montenegro. Mali began to make contributions to UNITAID in 2010.

Predictable funding central to UNITAID objectives

Multi-year commitments from donors are at the core of the UNITAID business model, which needs funding predictability to shape markets in developing countries for better access to medicines and testing equipment for AIDS, malaria and TB. For UNITAID to make credible funding commitments to its Implementing Partners a sustainable and predictable funding stream from donors is imperative.

In 2010, discussions were held with various governments to enhance the sustainability and predictability of UNITAID contributions, and to expand the number of low-, middle- and high-income countries to adopt the air tax and/or provide funds to UNITAID. This would serve to diversify its donor base and thereby reduce risk and volatility in funding levels.

Air levy

UNITAID receives its funds through airline ticket levies, or taxes, and regular budget allocations. In 2010, 63% of UNITAID revenue came from the airline tax collected by the following countries: Chile, France, Madagascar, Mali, Mauritius, Niger and the Republic of Korea. Norway allocates part of its tax on carbon dioxide emissions from air travel to UNITAID. Other countries are in the process of introducing the airline tax but are not yet budget contributors. These are: Benin, Burkina Faso, Côte d'Ivoire and the Democratic Republic of Congo.

For passengers, the cost of the tax is very low compared to the total cost of a ticket. It can range from US$ 1 for economy tickets to US$ 40 for business and first class travel. It is applied to all flights departing from countries that impose it and is paid by passengers when purchasing their tickets, normally as an addition to existing airport taxes. Airlines are responsible for declaring and collecting the levy.

The air levy is complemented by multi-year contributions from a number of other members.[45]

A number of other countries have indicated their intention to join UNITAID, among them Kenya, Portugal and Montenegro.

New multi-year funding commitments

Countries making regular budget contributions to UNITAID in 2010 were Brazil*, Cyprus, Luxembourg, Norway, Spain and the United Kingdom. The Bill and Melinda Gates Foundation also provided funding support. In 2010, France, which is UNITAID's main donor country, pledged a yearly sum of about EUR 110 million for the period from 2011-2013, in a bid to strengthen UNITAID's continued capacity to impact on medicine markets for better patient access. The United Kingdom has also pledged a yearly sum of GB£ 53 million for the same period. The Republic of Korea has committed US$ 7 million to UNITAID for 2011 and Brazil has signalled its intention of providing US$ 11 million for 2011.

Total commitments to UNITAID stand at US$ 252 million for 2011.

***Brazil:** *The 2010 pledge from Brazil equivalent to US$ 13.2 million is expected to be officially confirmed in 2011 and will be recorded as confirmed.*

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[45] Brazil, Cyprus, Luxembourg, Spain, the United Kingdom and the Bill & Melinda Gates Foundation.

Voluntary contributions by donors

2010 Revenue

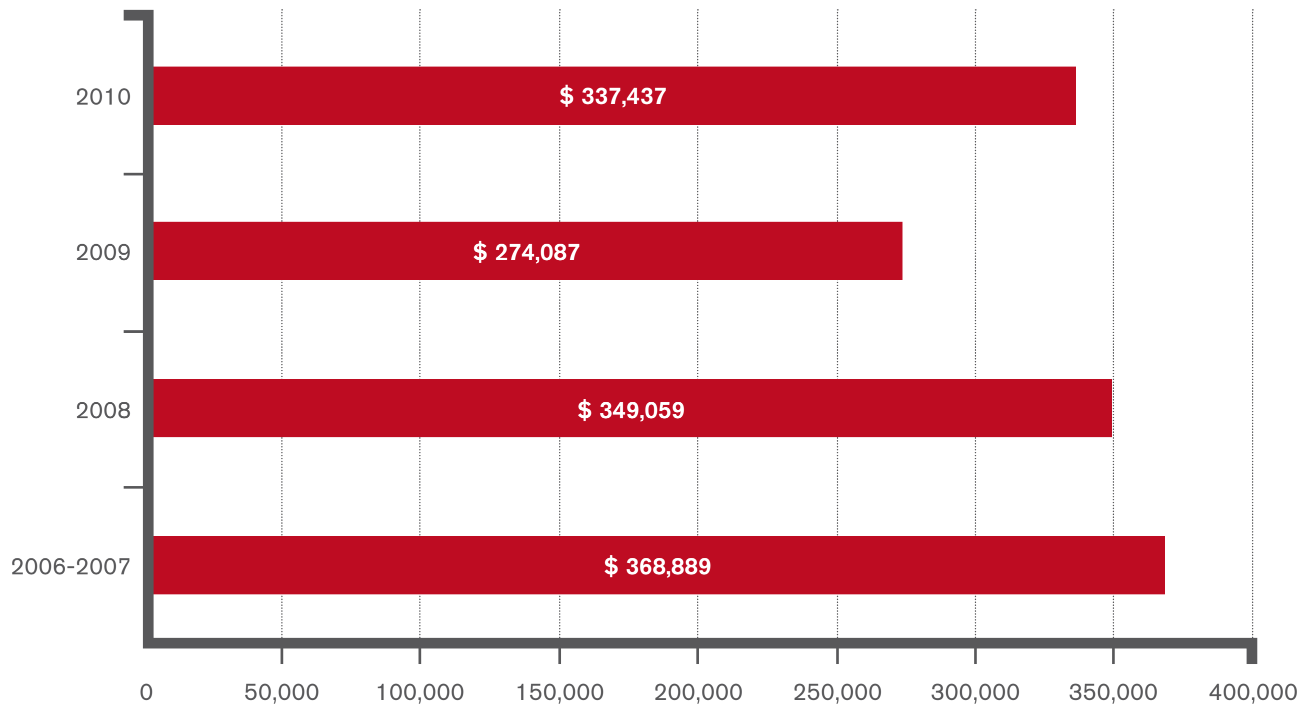
	Non-US$ pledge/payment currency (in thousands)		**Value in US$** (in thousands)
Bill and Melinda Gates Foundation			10,000
Chile			7,439
Cyprus	EUR	400	488
France	EUR	147,567	197,654
Luxembourg	EUR	500	611
Madagascar	EUR	3	4
Mauritius	MUR	35,000	1,104
Mali	EUR	316	402
Norway	NOK	140,000	22,831
Republic of Korea			7,000
Spain	EUR	15,000	21,097
United Kingdom	GBP	45,000	68,807
Total revenue			**337,437**

2006-2010 Revenue by donor, 2006-2010

	Value in US$ (in thousands)
Bill and Melinda Gates Foundation	40,000
Brazil	37,202
Chile	18,118
Cyprus	1,090
France	852,648
Guinea	49
Luxembourg	1,351
Madagascar	15
Mali	402
Mauritius	5,095
Norway	90,789
Republic of Korea	21,000
Spain	84,415
United Kingdom	177,016
Total revenue	**1,329,190**

UNITAID cumulative revenue since inception

Thousands US$



Financial Highlights 2010

We are pleased to present the UNITAID financial report for 2010.

The Financial Statements of the Report have been prepared in accordance with the United Nations System Accounting Standards (UNSAS) and the Financial Rules and Regulations of the World Health Organization (WHO). They have been audited on interim basis by the Auditors of the WHO. The summary Statement of Financial Performance is presented below. The full Financial Report for 2010 is available on the UNITAID website (http://www.unitaid.eu).

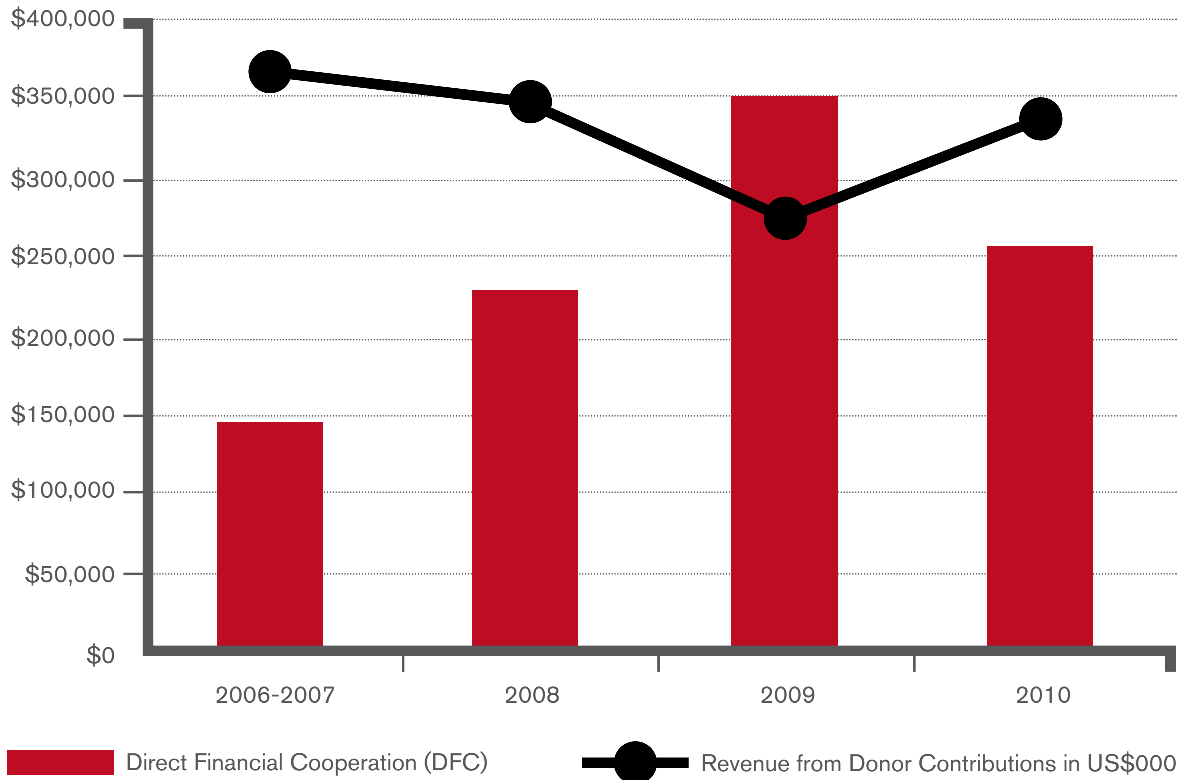
Financial Highlights

UNITAID was established at the end of 2006. Contributions from donors total US$ 1.329 million as of December 2010. Over the same period, UNITAID disbursed US$ 955 million to partners, of which US$ 608 million was disbursed in years 2009 and 2010. In 2010, the UNITAID Secretariat operating expenses represented 3.6% of overall operating expenses and 3.7% of the disbursements to the Implementing Partners.

Summary Statement of Financial Performance and Financial Position

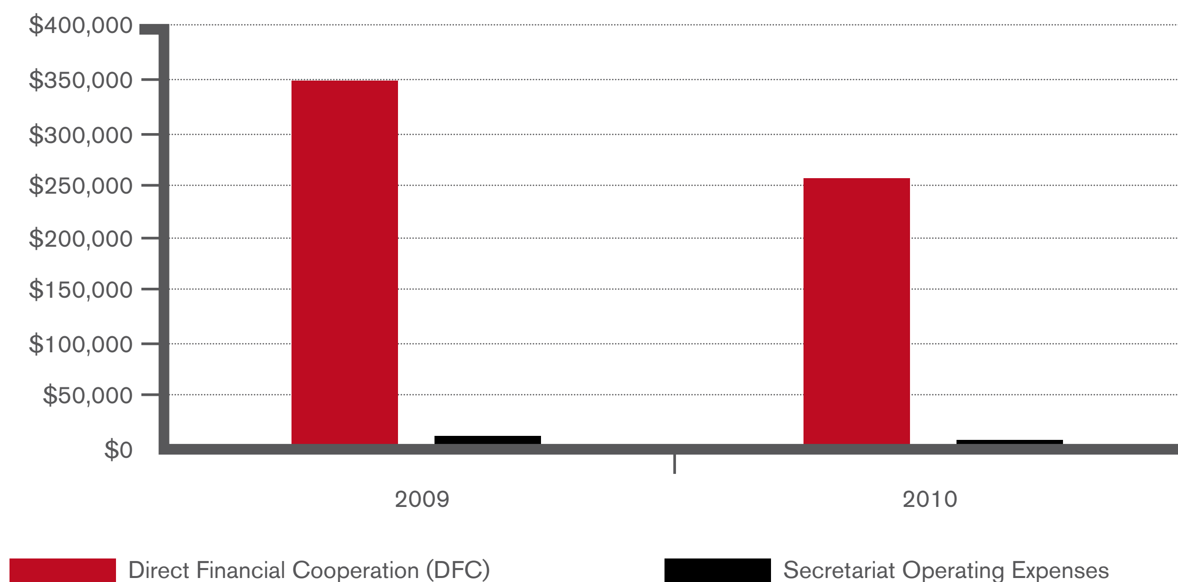
Summary Statement of Financial Performance	2010 in US$000	2009 in US$000	2008 in US$000
Operating Revenue			
Voluntary Contributions	337,437	274,087	349,059
Financial revenue and expense - net	4,946	10,230	4,999
Total Operating Revenue	**342,383**	**284,317**	**354,058**
Operating Expenses			
Staff and other personnel costs	6,893	4,758	3,419
Direct Financial Cooperation	257,300	350,907	226,696
Consulting and contractual Services	3,736	4,340	1,021
Travel	929	1,083	824
General operating expenses	148	100	134
Total Operating Expenses	**269,006**	**361,188**	**232,047**
Surplus for the Period	**73,377**	**(76,871)**	**122,011**

UNITAID Revenue from Donor Contributions 2006/2007 to 2010 versus Direct Financial Cooperation (DFC), in US$000



UNITAID Secretariat Operating Costs 2009 and 2010 versus Total Operating Expenses, in US$000

UNITAID Secretariat Operating Costs 2009 and 2010 versus Direct Financial Cooperation (DFC), in US$000



Summary Statement of Financial Position	2010 in US$000	2009 in US$000	2008 in US$000
Current Assets	341,636	267,532	366,485
Current liabilities	137	55	22,187
Non-current liabilities	886	241	191
Accumulated surpluses/(deficits)	340,613	267,236	344,107
Total liabilities and net assets	341,636	267,532	366,485

Project funding commitments at end 2010[46]

HIV/AIDS	US$ thousand
Procurement and supply of paediatric ARVs (with CHAI)[47]	380,058
Procurement and supply of second-line ARVs (with CHAI)[48]	305,799
PMTCT (with UNICEF)	104,466
Safeguarding availability of ARV treatment (with ESTHER)	15,950
Total HIV/AIDS	**806,273**
MALARIA	
ACT scale-up initiative (with UNICEF/Global Fund)[49]	78,888
ACT Liberia and Burundi (with UNICEF/WHO)	1,335
Affordable Medicines Facility for malaria (with Global Fund)	130,000
Assure artemisinin supply system (with i+solutions)	9,280
Accelerating scale-up of LLINs (with UNICEF)	109,250
Total malaria	**328,753**
TUBERCULOSIS	
Increased access to first-line TB drugs (with GDF)	26,841
UNITAID project support for paediatric TB (with GDF)	37,276
UNITAID project support for MDR scale-up initiative (with GDF/Green Light Committee, Global Fund)	54,046
MDR-TB acceleration of access initiative: Strategic Rotating Stockpile	11,458

[46] The Board-approved amounts for projects are taking into consideration also firm commitments for 2011.
[47] MoUs to be finalized in early 2011.
[48] MoUs to be finalized in early 2011.
[49] Changes to MoU not expected (Board approved ceiling is not expected to be reached).

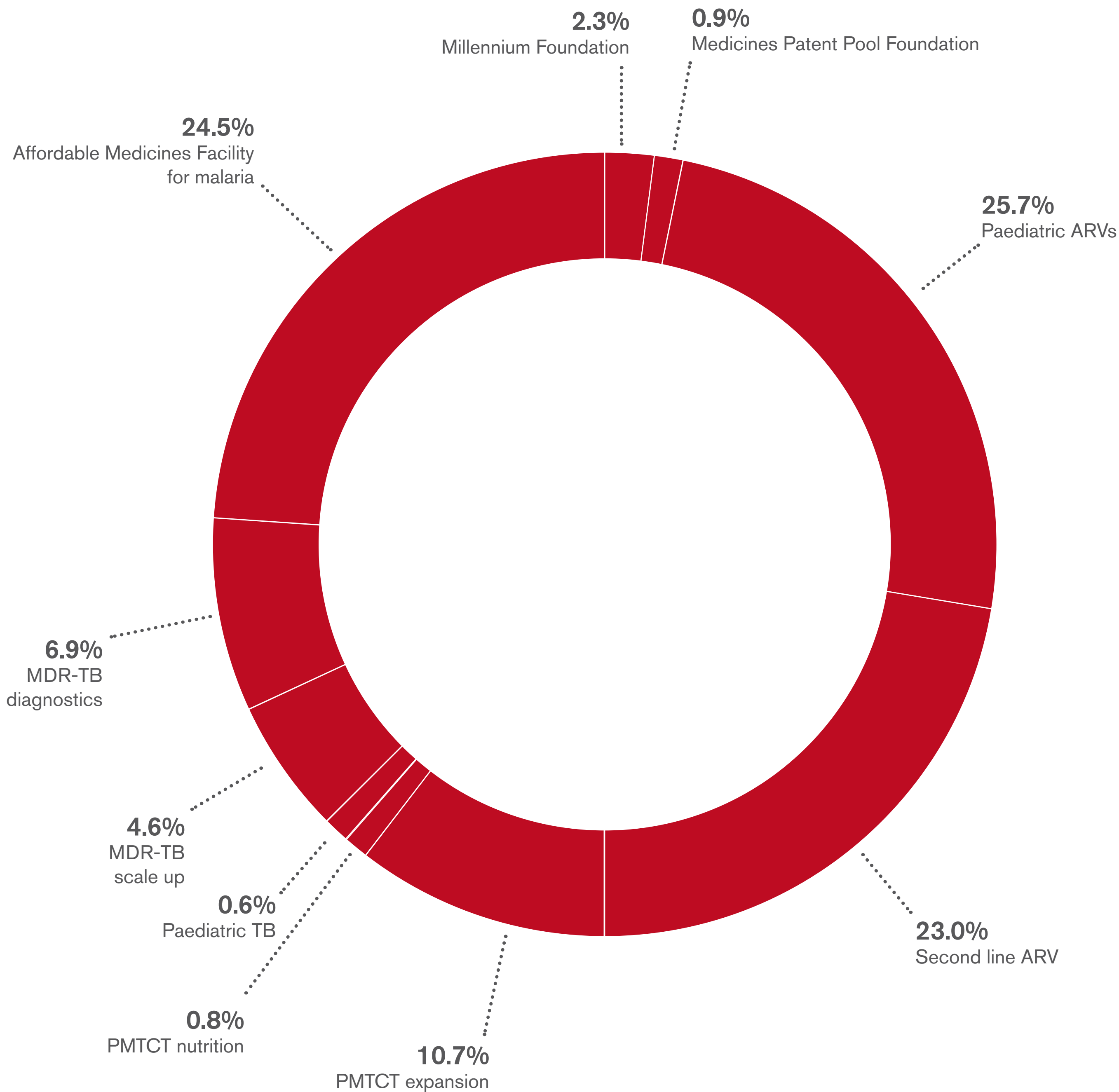
MDR-TB Strategic Revolving Fund[50]	22,232
Total tuberculosis treatment	**151,853**
MDR-TB diagnostics (with GDF/FIND/WHO)	87,612
Total tuberculosis treatment and diagnosis	**239,465**
CROSS-CUTTING PROJECTS	
Programme project support for quality assurance of medicines and diagnostics (with WHO)	54,500
Global Fund Round 6 (with Global Fund)	52,500
Total Cross-Cutting Projects	107,000
Total (16 project areas)	**1,481,491,110**

Project funding commitments
At end-2010, by project category

Cross-cutting	7.2%
Tuberculosis	16.2%
Malaria	22.2%
HIV/AIDS	54.4%

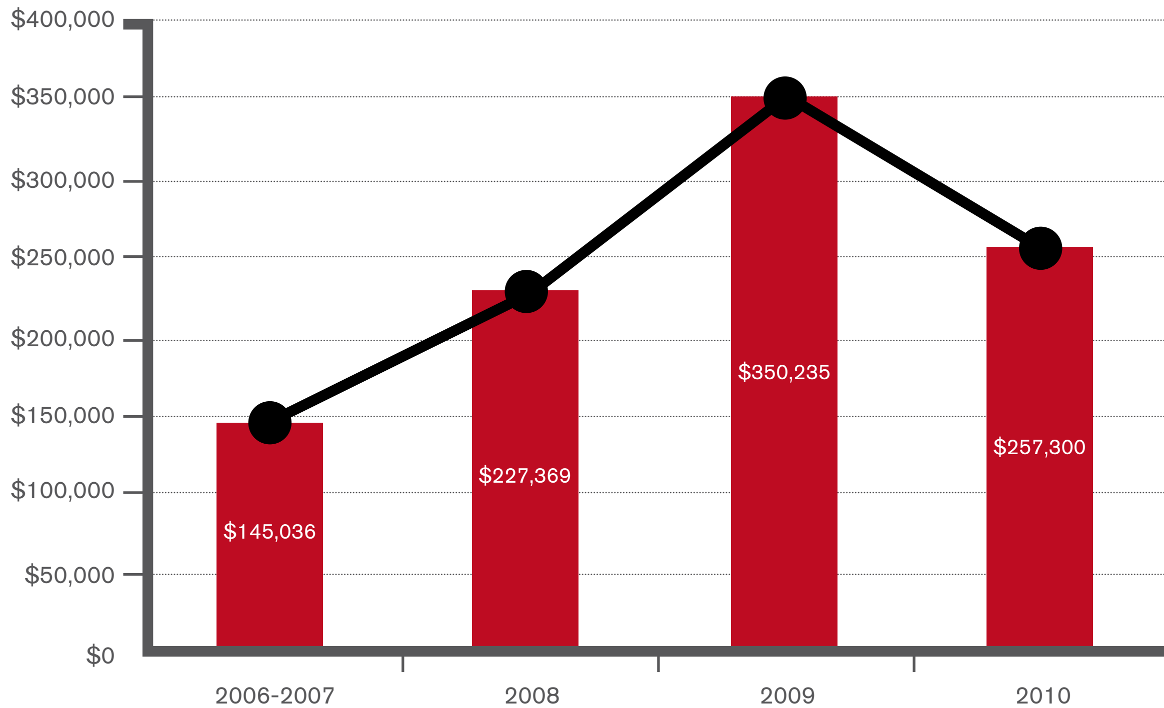
[50] Proposal withdrawn.

Direct financial cooperation by project, 2010



Direct financial cooperation

Transfers to Partners 2006 - 2010: US$ 980m



List of acronyms and abbreviations

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

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

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