UNITAID Annual Report 2009

Contents

Message from the Chair

It is precisely because economic crises are rocking industrialized countries that it becomes all the more important to ensure access to global public goods for the poorest populations.

We must of course do this by increasing official aid to development, but also by seeking and creating new sources of financing. The current crisis in capitalism is an opportunity to invent a different kind of globalization – one based on solidarity and one that promotes a more equitable distribution of wealth.

As the first laboratory of innovation to support the United Nations Millennium Development Goals, UNITAID can pave the way for other such mechanisms. It proves that small solidarity contributions from different sources can raise large sums of additional money to help attain the Millennium Development Goals – the only option we have in order to avoid social, economic and political conflicts in the twenty-first century.

The United Nations Summit on the Millennium Development Goals, in September 2010, is fast approaching. It will be a moment to reflect, take stock of progress made in global health and correct our actions to accelerate progress. In that context, it is with great pride that I have witnessed UNITAID's work in 2009 increasingly contributing to the health-related development goals.

UNITAID's efforts are clearly directed at supporting Goal 6 (to combat HIV/AIDS, malaria and other diseases) but are indirectly impacting on maternal and child health as well (Goals 5 and 4). UNITAID is one of the largest investors in integrated programmes for the prevention of mother-to-child transmission of HIV/AIDS, ensuring preventive treatment for both mothers and infants. UNITAID has delivered 19 million of the best-to-date malaria treatments to 21 countries, thus contributing to saving hundreds of thousands of lives of women and children, who are the primary casualties of malaria. And in the area of paediatric AIDS, UNITAID covers more than three quarters of children on treatment with new child-friendly medicines which are easier to take and greatly reduce the risk of resistance and treatment failure.

While tackling the three major pandemics with several global partners, UNITAID has remained true to its mandate of impacting on markets via its predictable funding model and promoting treatment access for victims of market failures – the poor in general, and women and children in particular. Thus, some of UNITAID's greatest successes have been in paediatric medicines and in bringing down the cost of previously prohibitively expensive treatments used when patients develop resistance to conventional drugs.

‘UNITAID’s work in 2009 has increasingly contributed to the health-related Millennium Development Goals…I urge new countries to join UNITAID in its quest to save lives.’

In this way, UNITAID not only fulfils its mission of providing complementary benefits to other partners’ efforts; it also makes the money stretch further because the long-term investments we are able to make give manufacturers the needed assurance to produce larger volumes of medicines and thereby reduce prices. The medicines patent pool, approved by the UNITAID Executive Board in December 2009, will further strengthen the economic benefits of the UNITAID business model by ensuring that more AIDS treatments become available at lower cost.

The added value of UNITAID does not stop at its work to stabilize medicines markets. With 70% of its funds coming from a small solidarity levy imposed on airline tickets in six countries, the UNITAID funding model does not overburden national public budgets and has proved to be crisis-proof in a time of economic uncertainty. My personal and moral commitment, as Chair of UNITAID, is to enable more countries to implement the solidarity levy on airline tickets and invest in UNITAID’s exemplary work.

Innovative financing for health, of which UNITAID is a shining example, is making a difference not only because it provides additional funds for our global work, but because it represents a new way of doing business in development. The UNITAID model is based on targeted action and rapid response, so that donors’ investments quickly translate into concrete results on the ground.

It is with that idea of efficient action and sense of urgency that I would like to close off this message. Innovative financing must be a central piece of our strategy to reach the Millennium Development Goals by 2015. I would like to express my gratitude to our current donor governments for their commitment and contribution, and urge new countries to join UNITAID in its quest to save lives.

Thank you for believing in this project since the beginning, for continuing to believe in it and for helping us extend the UNITAID spirit to all countries.

Philippe Douste-Blazy

Message from the Executive Secretary

The year 2009 was one of significant achievements for UNITAID in pursuing its mission of expanding access to treatment for the three pandemics of HIV/AIDS, malaria and tuberculosis. UNITAID's unique approach – designed to change market dynamics in underserved niches – is proving its worth across the board.

Since its creation in 2006, UNITAID has raised over US$1 billion in sustainable and predictable funds to back its market interventions. As this report shows, these interventions are working successfully to expand access, bring down prices, improve quality and speed delivery, not just for UNITAID projects but for people in poor countries everywhere. Here are just a few examples.

UNITAID action with its partner CHAI has created a market for paediatric antiretroviral (ARV) medicines where none existed before, which has brought hope and fostered survival. The outcome: the development of five new ARV medicines specially adapted for children, big price reductions and nearly 285,000 children on antiretroviral therapy, three in four of the total throughout the world.

UNITAID funding has also built the generic market for key second-line ARVs and in so doing has almost halved the price of the leading second-line regimen. The outcome: savings of US$ 300-500 million over the next three years in the cost of treating patients who need to switch from first-line to more expensive second-line drugs.

UNITAID has substantially expanded the market for the most effective malaria treatment – Artemisinin-based combination therapy (ACT) – by funding purchases in high-burden countries. The outcome: several quality assured fixed-dose combination ACTs on the market compared with one co-blister product previously.

UNITAID supplied a fifth of the long-lasting insecticide treated bednets (LLINs) delivered in 2009 as part of the international campaign against malaria. The outcome: a major contribution to the Roll Back Malaria Partnership's goal of universal access, lower prices due to volume purchases and the avoidance of capacity shortages and stock-outs in future years.

I could cite many further examples, but will content myself with just one. UNITAID, with the Global Drug Facility of the Stop TB Partnership, has created a strategic rotating stockpile for first- and second-line TB drugs. The outcome: speedier treatment of newly diagnosed cases and the avoidance of treatment disruptions that may foster the spread of drug resistant strains.

'As this report shows, UNITAID's interventions are working successfully to expand access, bring down prices, improve quality and speed delivery, not just for UNITAID projects but for people in poor countries everywhere.'

The year 2010 will see the rolling-out of the first phase of the Affordable Medicines Facility for malaria (AMFm), a multi-stakeholder initiative hosted by the Global Fund and largely funded by UNITAID. The long-awaited medicines patent pool for HIV/AIDS drugs is another breakthrough initiative that will impact the public health landscape.

In all these ways, and in others highlighted in this report, UNITAID is making a difference in the global fight against HIV/AIDS, TB and malaria, through its direct interventions and through their broader impact on access to affordable quality medicines and diagnostics across the developing world.

Building solid partnerships and ensuring the greatest added value from each one, acting on specific niches, and addressing market failures with a public health approach, are maximizing value for money as the international community struggles to reach the health-related Millennium Development Goals.

Behind these results, of course, lie the hard work and commitment of a dedicated staff, with whom it has been a pleasure and privilege to work over the past three years. And this report shows that, while much has been achieved, UNITAID does not intend to rest on its laurels.

With its innovative plan for the patent pool, its contribution to the AMFm and its ambitious targets for rolling out new diagnostic technologies for multidrug resistant TB, UNITAID is already implementing creative market-based solutions to help meet the health challenges ahead.

Dr Jorge Bermudez

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 tax on airline tickets.

Who we are and what we do

UNITAID (the International Drug Purchasing Facility) 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, such as the Clinton Health Access Initiative (CHAI) and UNICEF (United Nations Children's Fund).

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.

UNITAID's four main objectives are to:

- Ensure affordable and sustainably priced medicines, diagnostics and prevention products.
- Increase access to safe, effective products of assured quality.
- Assure availability in sufficient quantities and timely delivery to patients.
- Support development of products for specific groups such as children.

Why UNITAID is needed

An innovative mechanism for innovative action

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

Innovative and unique in three 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

3

The way it operates:

Channels funds through implementing partners towards strategic gaps in diagnosis and treatment

How the air tax works

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

Proceeds from a government-imposed solidarity levy or 'tax' on airline tickets collected from some[1] of UNITAID's 29 member countries represented about 70% of contributions to UNITAID in 2009. Other members[2] 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 tax translated into benefits

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

[1] Chile, France, Madagascar, Mauritius, Niger and the Republic of Korea.

[2] Benin, Burkina Faso, Côte d'Ivoire, Democratic Republic of Congo and Mali.

2009 highlights

Overview

- Madagascar, Cyprus and Luxembourg joined UNITAID in 2009, bringing membership to 29 countries and the Bill and Melinda Gates Foundation.[3]
- UNITAID received US$ 274 million in contributions in 2009, bringing the total since its creation in 2006 to almost US$ 1 billion.

'UNITAID, the first laboratory of innovative financing, has opened a new way and proved that its mechanisms can help us achieve the Millennium Development Goals by saving hundred of thousands of lives each year.'

Ban Ki-moon, Secretary-General of the United Nations, December 2009

- Since 2006, UNITAID has delivered drugs, diagnostics and other products to 94 countries, of which 41 are in sub-Saharan Africa, 27 in Asia, 11 in the Americas, eight in North Africa and the Middle East, and seven in Europe.
- UNITAID has funded HIV/AIDS and related drugs for nearly a million adults and children, and has delivered 19 million malaria treatments and 1.5 million tuberculosis treatments since 2006.

HIV/AIDS

By the end of 2009, UNITAID had:

- Committed US$ 565 million to four HIV/AIDS project areas in 51 countries.
- Financed treatment for HIV/AIDS for 285,000 children in 44 countries, three in four of all children on treatment globally.
- Stimulated development of five new child-friendly HIV/AIDS medicines since 2006 and brought down overall prices of paediatric antiretroviral drugs by two thirds.
- Provided more than 180,000 people with 'second-line' HIV/AIDS medicines in 29 countries.
- Spurred development of nine new second-line antiretroviral formulations since 2007 and cut treatment costs by 43%.
- Committed US$ 72 million to prevention of mother-to-child transmission (PMTCT) programmes, making UNITAID the world's biggest funder of integrated PMTCT programmes.
- Tested about 1.4 million pregnant women for HIV/AIDS and provided effective medicines to prevent transmission of HIV to their babies.

2009 highlights

Malaria

By the end of 2009, UNITAID had:

- Committed about US$ 300 million since 2006 to five malaria projects in 27 countries.
- Delivered over 19 million artemisinin-based combination therapy (ACT) malaria treatments to 21 countries.
- Committed up to US$ 130 million for the Affordable Medicines Facility for malaria (AMFm) to make ACTs more affordable and available.
- Supported quality assurance of eight additional ACT medicines over two years, all of which are fixed-dose combination tablets.
- Established a revolving credit fund for artemisinin extractors to assure adequate supplies of artemisinin in 2010–2011.
- Disbursed US$ 109 million to UNICEF to buy and distribute 20 million insecticide-treated bed nets in eight high-burden countries in 2009–2010.

Tuberculosis

By the end of 2009, UNITAID had:

- Committed US$ 88 million to four TB medicines projects in 72 countries.
- Financed purchases of nearly 785,100 first-line TB treatments in 19 countries and more than 6,200 treatment courses for patients with multidrug-resistant TB in 30 countries.
- Expanded the UNITAID-financed Strategic Rotating Stockpile to service a total of 5,800 patient treatments.

- Funded purchase by the Global Drug Facility of more than 668,100 curative and preventive TB treatments for children in 57 countries.
- Reduced prices of four key paediatric TB medicines by 10–30%.
- Supported quality assurance of seven TB drugs since 2007, including four fixed-dose combination tablets for children.
- Established rapid diagnostic capacity for MDR-TB in initial reference laboratories in four countries as part of a US$ 88 million project to support use of new diagnostic technologies in 27 countries.

Quality assurance

By the end of 2009, UNITAID had:

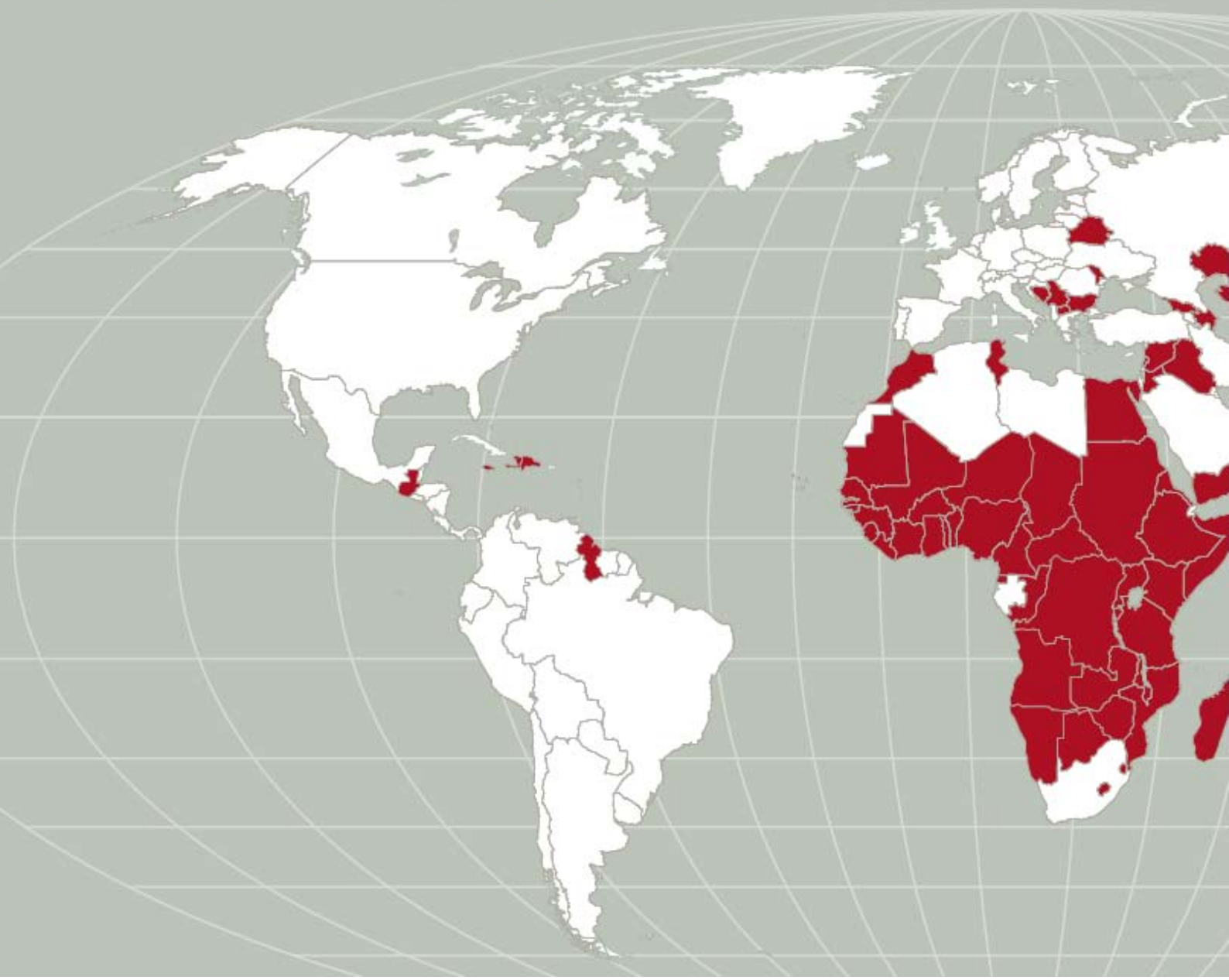
- Committed a cumulative US$ 54.5 million to support the WHO Prequalification Programme so as to increase the availability of quality medicines and diagnostics for procurement in developing countries.
- Achieved prequalification of an additional 18 UNITAID priority medicines in 2009, bringing to 29 the total number of prequalified UNITAID priority medicines since the beginning of 2007.

References

[3] Benin, Brazil, Burkina Faso, Cameroon, Central African Republic, Chile, Democratic Republic of Congo, Côte d'Ivoire, Cyprus, France, Gabon, Guinea, Jordan, Liberia, Luxembourg, Madagascar, Mali, Mauritius, Morocco, Namibia, Niger, Norway, Republic of Korea, São Tomé and Principe, Senegal, South Africa, Spain, Togo and the United Kingdom.

2009 highlights

UNITAID is helping 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.

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.

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

North Africa/ Middle East Egypt, Iraq, Jordan, Lebanon, Morocco, Syrian Arab Republic, Tunisia and Yemen.

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

HIV/AIDS

Scaling treatment up
Pushing prices down

HIV/AIDS

Scaling treatment **up**, pushing prices **down**

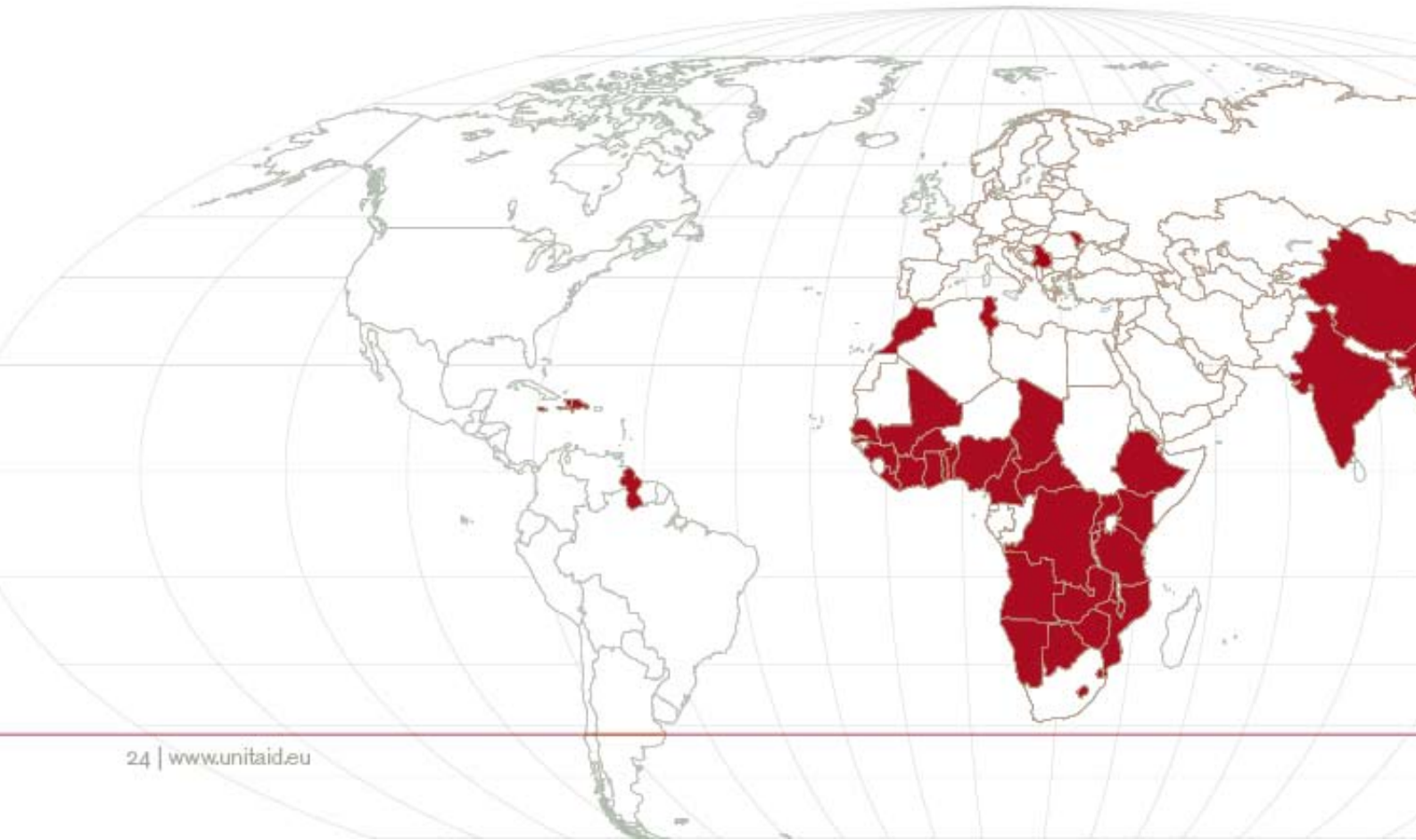
By the end of 2009, UNITAID had committed US$565 million to four HIV/AIDS project areas in 51 countries.

More have access to antiretroviral treatment, but major challenges remain

The number of people living with HIV/AIDS worldwide continues to grow, reflecting the combined effect of continued high rates of new HIV infections and the beneficial impact of antiretroviral therapy. More than 33 million people are living with HIV/AIDS today, up by a fifth since 2000.

Important progress has been achieved in preventing new HIV infections and in lowering the number of AIDS-related deaths. However, AIDS-related illnesses remain one of the leading causes of death globally and are projected to continue as a significant cause of premature mortality in the coming decades.[4]

Of the 9.5 million people estimated to be in need of antiretroviral therapy (ART), four million or just over 40% are receiving it.[5] While this represents a ten-fold increase over the last five years, more than 5.5 million people are still in urgent need of treatment. Moreover, the planned introduction of new WHO guidelines,[6] which recommend starting ART at an earlier stage of the infection, could double the number of people eligible for immediate



treatment, according to preliminary estimates. Looking further ahead, and taking into account new infections, one projection suggests that two decades from now 55 million people could require ART – a daunting challenge.[7]

Meanwhile, the virus continues to take its toll, particularly in developing countries, where 97% of those infected live. An estimated two million people died of AIDS in 2008, including 280,000 children.[8] Sub-Saharan Africa remains the most heavily affected region, accounting for more than 70% of the 2.7 million new HIV infections and deaths in 2008.

UNITAID is using its unique market model to expand supply and lower prices for quality-assured drugs, diagnostics and related products in three key areas:

- Treatment for children with HIV/AIDS
- 'Second-line' drugs for people who have developed resistance to (or serious side effects from) first-line drugs
- Prevention of HIV transmission from mother to child

References

[4] WHO, World Health Statistics 2008.

[5] UNAIDS, AIDS Epidemic Update, December 2009.

[6] WHO, 'New HIV recommendations to improve health, reduce infections and save lives', WHO press release, 30 November 2009.

[7] All-Party Parliamentary Group on Aids, The Treatment Timebomb, July 2009.

[8] UNAIDS, op cit.

HIV/AIDS (51 countries) *Angola, Antigua and Barbuda, Benin, Botswana, Burkina Faso, Burundi, Cambodia, Cameroon, Central African Republic, Chad, China, Democratic Republic of Congo, Côte d'Ivoire, Djibouti, Dominica, Dominican Republic, Ethiopia, Ghana, Grenada, Guinea, Guyana, Haiti, India, Jamaica, Kenya, Lao People's Democratic Republic, Lesotho, Liberia, Malawi, Mali, Republic of Moldova, Morocco, Mozambique, Myanmar, Namibia, Nigeria, Papua New Guinea, Rwanda, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Senegal, Serbia, Swaziland, United Republic of Tanzania, Togo, Tunisia, Uganda, Viet Nam, Zambia and Zimbabwe.*

Treating children with HIV/AIDS

2009 highlights

- Committed US$ 235 million to UNITAID's partner CHAI since the start of the project in 2006 to buy drugs and diagnostics for children in 40 countries in Africa, Asia and the Caribbean.
- Including through the Global Fund, financed treatment for HIV/AIDS for nearly 285,000 children in 44 countries by the end of 2009, three in four of all children on treatment globally.
- Stimulated development of five new child-friendly HIV/AIDS medicines since 2007 and brought down overall prices of paediatric ARVs by two thirds.

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. But 90% of the 2.1 million children living with HIV/AIDS grow up in Africa and the vast majority are beyond the reach of health services.

Identifying the needs

Nearly three quarters of a million children were estimated to need HIV/AIDS treatment in 2008, but only 38% were receiving ART.[10] 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.[11] 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 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.

Price reductions obtained for
child-friendly medicines
64% in low income countries

So 3 times as many treated for the same

have averaged
since 2006

children can be
outlay

2006

1 child treated for US$ 200

2009

3 children treated for US$ 200

Price reductions obtained for child-friendly medicines have averaged 64% in low income countries since 2006

Scaling up treatment

In 2009, UNITAID disbursed about US$ 58 million to the Clinton Health Access Initiative (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 66,000 children in 2009, and by the end of the year was delivering treatments for an estimated 255,970 children in 40 countries in Africa, Asia and the Caribbean.[12] The aim is to put an additional 70,000 children on treatment in 2010, bringing the total to over 325,000.

In 2009, UNITAID support for projects receiving grants under Round 6 allocations by the Global Fund to Fight AIDS, TB and Malaria enabled the purchase of quality-assured paediatric HIV treatments for 28,870 children in seven countries in Africa, Asia and Europe[13] (see page 76).

Increasing treatment options

By making a long-term commitment to purchase new paediatric formulations, UNITAID has succeeded in spurring manufacture of five new quality-assured child-friendly ARVs, including fixed-dose combinations containing zidovudine (AZT). These FDCs give treatment providers an alternative to the combination containing the less tolerated stavudine (d4T), which WHO recommends should be phased out because of its long-term irreversible side effects.[14]

However, treatment options for children continue to be limited compared with those for adults. Of the 22 individual AIDS medicines approved by the United States Food and Drug Administration and currently available, six are not approved for paediatric use and seven do not have any paediatric formulations.[15]

Pushing prices down

The 2009 supplier selection process, which took place in March, achieved a further 5% reduction from 2008 prices of paediatric ARVs. Thus the UNITAID/CHAI partnership was able to provide a three-in-one FDC (lamivudine/nevirapine/zidovudine) for US$ 66 per child per year, a third of the price of standard paediatric treatment in 2006. Cumulative price reductions obtained by the partnership for child-friendly medicines since 2006 have averaged 64% in low-income countries. As a result, three times as many children can be treated with the same outlay.

Providing an integrated package of care

Many children living with HIV in developing countries suffer from malnutrition, which 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).

Challenges in 2010

Two major challenges confront the paediatric HIV/AIDS project in 2010. One is the high rate at which children drop out from treatment, which CHAI is hoping to reduce through improved monitoring and follow-up. The other relates to the impact of the global economic crisis on the availability of funding from other donors after the scheduled end of the project in December 2010. By that time, and in line with UNITAID's policy of withdrawing from projects once its interventions have had the desired effect, it was hoped the market would be sustained by normal funding sources. CHAI has initiated negotiations with donors and continues to work with countries on Global Fund proposals to improve their chances of success in securing new funding. However, it is already clear that UNITAID may have to provide bridging finance into 2011 for a number of countries to maintain the market for paediatric drugs and avoid interruption of treatment.

References

[9] UNAIDS, op cit.

[10] UNAIDS, WHO, UNICEF, Children and AIDS: Fourth Stocktaking Report, 2009, p.10.

[11] Médecins Sans Frontières (MSF), Untangling the web of ARV price reductions, 12th edition, February 2010.

[12] Angola, Antigua and Barbuda, Benin, Botswana, Burkina Faso, Burundi, Cambodia, Cameroon, China, Côte d'Ivoire, Dominica, Dominican Republic, Democratic Republic of Congo, Ethiopia, Grenada, Guyana, Haiti, India, Jamaica, Kenya, Lesotho, Liberia, Malawi, Mali, Mozambique, Namibia, Nigeria, Papua New Guinea, Rwanda, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Senegal, Swaziland, United Republic of Tanzania, Togo, Uganda, Viet Nam, Zambia and Zimbabwe.

[13] Burkina Faso, Guinea, India, Lao People's Democratic Republic, Morocco, Senegal and Serbia.

[14] WHO, Rapid Advice: Antiretroviral therapy for HIV infection in adults and adolescents, November 2009.

[15] MSF, op cit.

Case study

UNITAID in Cambodia

Cambodian sisters Srey Nga, 16, and Soy, 8, have a powerful, visible bond. Wherever they go, they hold hands; the younger Soy fearful of losing her older sibling if she lets go, the older Srey holding on to her baby sister in a motherly, protective manner. All they have is each other.

Their father walked out on them after Soy was born. Then, four years ago, their mother died of an HIV-related illness. Fortunately, their uncle and his family took them in. However, after repeated bouts of illness and severe skin infections, the girls found out that they, like their mother, were HIV-positive. As a result, they were shunned and ostracized by their uncle, his family and the other villagers.

'Once I knew that I also was sick like my mother and sister, I felt hopeless and wanted to die,' said Srey Nga.

In May 2006, their uncle took them to an AIDS orphanage outside Phnom Penh, where they live to this day with 160 other AIDS orphans. Upon arrival, Srey had a change of heart. 'I saw many people who are also like me . . . so I have the will to live again.'

Srey Nga and Soy are just two of the estimated 33 million people living with HIV/AIDS today. Thanks to UNITAID funds, they are also among the 38% of children with HIV/AIDS who have access to treatment.

Their lives depend on the medicines they take every morning and night.

In partnership with the Clinton Health Access Initiative (CHAI), UNITAID has allocated US$ 2.9 million to support the treatment of more than 3,300 children in Cambodia, including Srey Nga and Soy. It also provides costly second-line therapy to nearly 2,300 adults living with HIV.

Dr Mean Chhi Vu, Director of National Centre for HIV/AIDS, Dermatology and STIs (NCHADS), in Cambodia, calls UNITAID's role, 'very important and prime time.'

UNITAID has been working with CHAI, NCHADS and the National Institute for Public Health in Cambodia to purchase and distribute a series of diagnostic kits for children under 18 months. Thanks to this joint effort, 26% of exposed infants were tested for HIV in 2008 – a major increase from just 3% in 2007.

These tests allow Dr Vu to test and treat children as young as six weeks old. 'As soon as we know children are infected by HIV, we start the treatment.'

Additionally, as the number of people resistant to antiretrovirals (ARVs) increases, UNITAID's role becomes paramount. 'UNITAID supports second-line treatment, which is very important because it is a very expensive treatment for us,' Dr Vu says.

Second-line treatment, thanks to price reductions achieved by CHAI and UNITAID, is now available at close to US$ 560 per patient per year, down from a prohibitive US$ 1,500 in 2006.

Expanding access to second-line antiretrovirals

2009 highlights

- Committed US$ 241 million to CHAI since the start of the project in 2007 to purchase quality-assured and affordable second-line antiretrovirals (ARVs).
- Including through the Global Fund, provided more than 180,000 people with second-line medicines in 29 countries in Africa, Asia and the Caribbean.
- Supplied first-line tenofovir (TDF) for nearly 50,000 patients in Uganda and Zambia.
- Stimulated development of nine new second-line ARV formulations since 2007 and cut treatment costs by 43%, with expected savings of US$ 300–500 million over the next three years.

HIV/AIDS is a life-long chronic disease, and people on antiretroviral treatment (ART) eventually need access to newer and more potent AIDS drug combinations when they become resistant to their initial set of medicines or develop serious side effects.

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.

The lack of adequate diagnostic tools, such as viral load testing, in poor countries makes it difficult to assess the need for second-line treatment. Only 2% of adults on antiretroviral therapy in 36 countries surveyed by WHO were on second-line regimens in 2008,[16] but CHAI expects this to rise to 5% by 2011.[17] Ultimately, there will be a need for third- and fourth-line drugs for people who have been on treatment a long time and developed resistance.

Second-line ARVs are much more expensive

Although prices have come down in the last few years, the newer medicines that are used in second-line treatment are far more expensive than first-generation AIDS drugs. Competition among generic manufacturers has helped slash prices of older first-line ARVs by more than 99%, from over US$ 10,000 per patient per year in 2000 to US$ 80 today.[18] By contrast, even the cheapest second-line regimen, at prices applicable to low-income countries, costs more than five times as much.

Lower prices are essential to avoid a new access crisis

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. Declining second-line ARV prices have followed the introduction of quality-assured generic alternatives, the expansion of treatment programmes which has produced 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. Otherwise national treatment programmes will be faced with massive cost increases, precipitating a second wave of the ARV access crisis seen earlier in the decade.

Moreover, WHO is recommending that treatment providers begin moving away from stavudine (d4T), a drug contained in the most commonly used first-line regimen in developing countries.[19] Stavudine is today rarely prescribed in wealthy countries because of its toxic and irreversible side effects. WHO suggests switching to tenofovir (TDF) as part of an alternative first-line regimen and also recommends tenofovir for second-line regimens. However, tenofovir has long remained unaffordable for treatment providers in developing countries.

In partnership with CHAI, UNITAID's efforts on second-line 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.

Expanding access

For 2009, UNITAID provided US$ 59 million through its partner CHAI to fund the purchase of second-line ARVs for an estimated 175,270 patients in 24 countries[20] as well as first-line tenofovir (TDF) for nearly 50,000 patients in Uganda and Zambia. UNITAID funding also enabled projects receiving Round 6 grants from the Global Fund to provide second-line ARV treatments for some 7,480 people in six countries in Africa, Asia and Europe[21] (see page 76).

Responding to high drug prices

Providing incentives to encourage new manufacturers to enter the market, thereby stimulating competition as well as expanding supply, has resulted in considerably lower prices for second-line ARVs. Already in 2007, following negotiations with leading manufacturers of generic drugs, CHAI and UNITAID were able to announce steep price reductions on seven different formulations of second-line

ARVs and tenofovir for purchase by the project. By 2008, the median price of the leading WHO-recommended second-line antiretroviral regimen had more than halved to US$ 654 from US$ 1,500 in 2006.

Further price reductions were achieved by the UNITAID/CHAI partnership across all seven second-line ARVs and tenofovir in 2009. The median price of a tenofovir-based, once-daily, first-line FDC tumbled 56% to US$ 141 per person per year in 2009 from US$ 319 in 2008. With UNITAID support, in 2009 CHAI was able to provide tenofovir in Uganda and Zambia at an even lower cost of US$ 99 per patient per year, half the price of a year earlier.

Meanwhile, the median price of the leading generic second-line drug regimen – tenofovir (TDF), lamivudine (3TC) and ritonavir-boosted lopinavir (LPV/r) – was cut by 11.5% to US$ 579 per person per year in 2009 from US$ 654 in 2008. The price of another WHO-recommended regimen – TDF, emtricitabine (FTC) and LPV/r – was slashed by nearly 30% between 2008 and 2009. These price reductions were due in part to intensified competition from new suppliers. Six additional suppliers were successful in the 2009 tender and all seven second-line products funded by UNITAID now have two or more suppliers approved by the WHO Prequalification Programme or another 'stringent regulatory authority' (SRA).

When the generic heat-stable atazanavir/ritonavir (ATV/r) becomes available in late 2010, the cost of the treatment regimen including this medicine is expected to fall to as low as US$ 500 per patient per year. An ATV/r will also reduce the pill burden to one a day compared with

Table 1 | Price reductions and new market entrants for second-line ARV regimens

Regimens	Median Price PPY US$ 2008	Median Price PPY US$ 2009	Median Price Reduction %	Number of Suppliers 2008	Number of Suppliers 2009
TDF+ 3TC (300 mg + 300mg) and LPV/r (200 mg +50 mg)	654	579 (interquartile range: 561-738)	11.5	4	5
TDF+ FTC (300 mg + 200mg) and LPV/r (200 mg +50 mg)	815 (interquartile range: 747-915)	582 (interquartile range: 582-772)	28.6	5	7

Key PPY – per patient per year; 3TC – Lamivudine; FTC – Emtricitabine; LPV/r – Lopinavir/Ritonavir; TDF – Tenofovir.

Note The median price is the price such that half the drugs were purchased at prices the same or above that level and half purchased at prices the same or below it. For the interquartile range, the lower figure is the price such that 25% of drugs were purchased for the same or less and the top figure is the price paid such that 25% of drugs were purchased for the same or more. Put another way, the prices for half the drugs purchased fell within the interquartile range. These figures are more representative of actual prices paid than an arithmetic average.

four a day for LPV/r. Technical difficulties in developing the formulation of the ATV/r FDC meant this life-saving medicine could not be delivered in 2009 as hoped, but UNITAID's Executive Board has approved funding to make ATV/r available to all beneficiary countries through 2011.

Further reductions in the cost of second-line ARV treatment are expected with the introduction of generic versions of more second-line drugs. The public disclosure of the prices paid by UNITAID and CHAI for second-line regimens is also designed to help governments negotiate lower prices with suppliers. UNITAID estimates that savings in second-line treatment costs from price reductions already achieved will be between US$ 300–500 million over the next three years.

New quality-assured medicines

UNITAID funding of the WHO Prequalification Programme (see page 74) supported quality-assurance of six second-line antiretrovirals in 2009, bringing the total since 2007 to nine.

Challenges in 2010

In line with its strategy of moving out of markets once the objectives of expanding supply and bringing down prices have been achieved, UNITAID planned to start winding down funding of second-line ARVs and tenofovir at the end of 2009. However, by then only nine countries had succeeded in switching to alternative funding for 2010, for example, through Global Fund projects. The remainder will need UNITAID bridge funding for all or part of 2010 and some countries may need UNITAID support into 2011. In May 2009, UNITAID's Executive Board approved an extension of project funding through 2011 amounting to US$ 120.4 million. UNITAID will be working with CHAI during 2010 to identify and secure funding sources for nine countries currently lacking any alternative options.

The economic environment is one reason for the uncertainty surrounding future financing as many countries have felt obliged to restrain or cut health budgets. Another reason lies with the structure of global health financing: funds to buy drugs typically come from only one or two sources and gaps between grants can lead to financing shortfalls. Several countries are still waiting for Global Fund grants to come through or lack firm commitments from in-country partners. Other factors, including rapid expansion of programmes, earlier initiation of ARV treatment and increased need for more costly second-line treatment, have also added to domestic budget pressures.

This uncertainty over funding, which the UNITAID/CHAI project was intended to overcome, risks feeding through into price negotiations with suppliers, who need reliable purchase forecasts if they are to offer lower prices.

References

[16] 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.

[17] Evidence to All-Party Parliamentary Group on Aids, The Treatment Timebomb, July 2009

[18] MSF, op cit

[19] WHO, Rapid Advice: Antiretroviral therapy for HIV infection in adults and adolescents, Nov 2009

[20] Benin, Botswana, Cambodia, Cameroon, Chad, Côte d'Ivoire, Democratic Republic of Congo, Ethiopia, Ghana, Haiti, India, Kenya, Malawi, Mali, Mozambique, Namibia, Nigeria, Rwanda, Senegal, United Republic of Tanzania, Togo, Uganda, Zambia and Zimbabwe.

[21] Djibouti, Lao People's Democratic Republic, Liberia, Republic of Moldova, Tunisia and Zanzibar (United Republic of Tanzania).

Prevention of mother-to-child transmission of HIV

2009 highlights

- Committed US$ 72 million to Prevention of Mother-to-Child Transmission programmes since the start of the project in 2008, making UNITAID the world's biggest funder of integrated PMTCT programmes.
- Tested about 1.4 million pregnant women by end-2009, through partnership with WHO and UNICEF.
- Financed treatment in 2009 for 158,865 HIV-positive pregnant women to prevent transmission to their babies, and provided ART for a further 25,300 mothers in need for their own health.
- Provided prophylaxis against opportunistic infections for nearly 51,000 HIV-positive women and more than 70,300 infants.
- Developed four new diagnostic packs and halved prices for some products.

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 17 countries.[22]

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, providing testing for anaemia and 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.

Developing more user-friendly products

Better adapted and more user-friendly products are being developed and made available under the project. These include a Mother and Baby pack that meets WHO guidelines for treatment but is also easy for mothers to use. The pack, which is now being field-tested with positive results, will be provided to all participating countries in late 2010.

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 2008, has already led to the development of four new diagnostic packs containing easy-to-use testing equipment, child-friendly drug formulations including nevirapine syrups for infant prophylaxis, and the identification of six new suppliers of ARVs.

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 19% and prices for bundles containing reagents and other testing consumables by between 7% and 48%. These reductions stem from long-term agreements negotiated through the UNICEF/UNITAID partnership with several manufacturers, as part of continued efforts in 2009 to expand the number of quality-assured manufacturers.

WHO guidelines have the potential to reduce the mother-to-child transmission risk to 5% or less

The UNITAID project is promoting implementation of the most recent WHO PMTCT guidelines, which have the potential to reduce the mother-to-child transmission risk to 5% or less. The guidelines now recommend that all HIV-positive pregnant women receive triple antiretroviral therapy throughout pregnancy and the breastfeeding period, as opposed to the previous recommendation of providing ARVs only in the third trimester of pregnancy. WHO is also recommending early ARV treatment of HIV-positive babies, with testing at the age of six weeks.

For the eight countries initially in the programme, UNITAID funding supported HIV testing for about 1.4 million pregnant women by end-2009. In addition, nearly 160,000 pregnant women diagnosed with HIV received treatment in 2009, and 51,000 HIV-positive mothers and 70,300 received co-trimoxazole prophylaxis for the prevention

'UNITAID's support for UNICEF's work is helping scale up critical programs to save the lives of children ... accelerate prevention of mother-to-child transmission (PMTCT) and scale-up linkages to paediatric HIV care and treatment. These collaborative efforts with UNITAID are truly making a difference.'

Ann Veneman, UNICEF Executive Director, Dec 2009

of opportunistic infections. During 2009, the programme was extended to nine more countries with the objective of testing nearly two million women in the first year.

Challenges for 2010

Although the take-up of testing among women in the eight countries initially supported has increased, from less than a third to nearly half between 2007 and 2009, take-up is still far from universal. And although more HIV-positive women are now on WHO's recommended treatment regimen, even in the supported countries coverage averages only about 40%. Meanwhile, accelerating early access to ART for babies has lagged well behind objectives, with less than 10% of six-week-old babies exposed to HIV being tested in the supported countries, mainly due to the need to establish testing facilities and train technicians.

References

[22] In 2009 the project was extended to nine more countries (Central African Republic, China, Haiti, Lesotho, Myanmar, Nigeria, Swaziland, Uganda and Zimbabwe) from the original eight (Burkina Faso, Cameroon, Côte d'Ivoire, India, Malawi, Rwanda, United Republic of Tanzania and Zambia).

Where next on HIV/AIDS

UNITAID is considering a number of market interventions to support the fight against the HIV/AIDS pandemic in 2010 and beyond.

These include:

- Establishing a patent pool to increase the availability and affordability of new and better adapted ARVs and other medicines (see below);
- Funding diagnostic tests for monitoring the development of resistance to antiretroviral therapy;
- Investing in sustainable local production of ready-to-use therapeutic food for use in HIV/AIDS care; and
- Expanding availability of female condoms.

The medicines patent pool initiative

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.

The pool, scheduled to start operating in mid-2010 as a separate legal entity, 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.

'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

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. UNITAID has identified 19 products from nine companies for potential inclusion, and is in the process of negotiating firm commitments.

'Pharmaceutical companies and other patent holders should sign up to the UNITAID patent pool to enable new fixed dose combinations (FDCs) and paediatric versions of HIV drugs, in return for a fair royalty on their patents.'

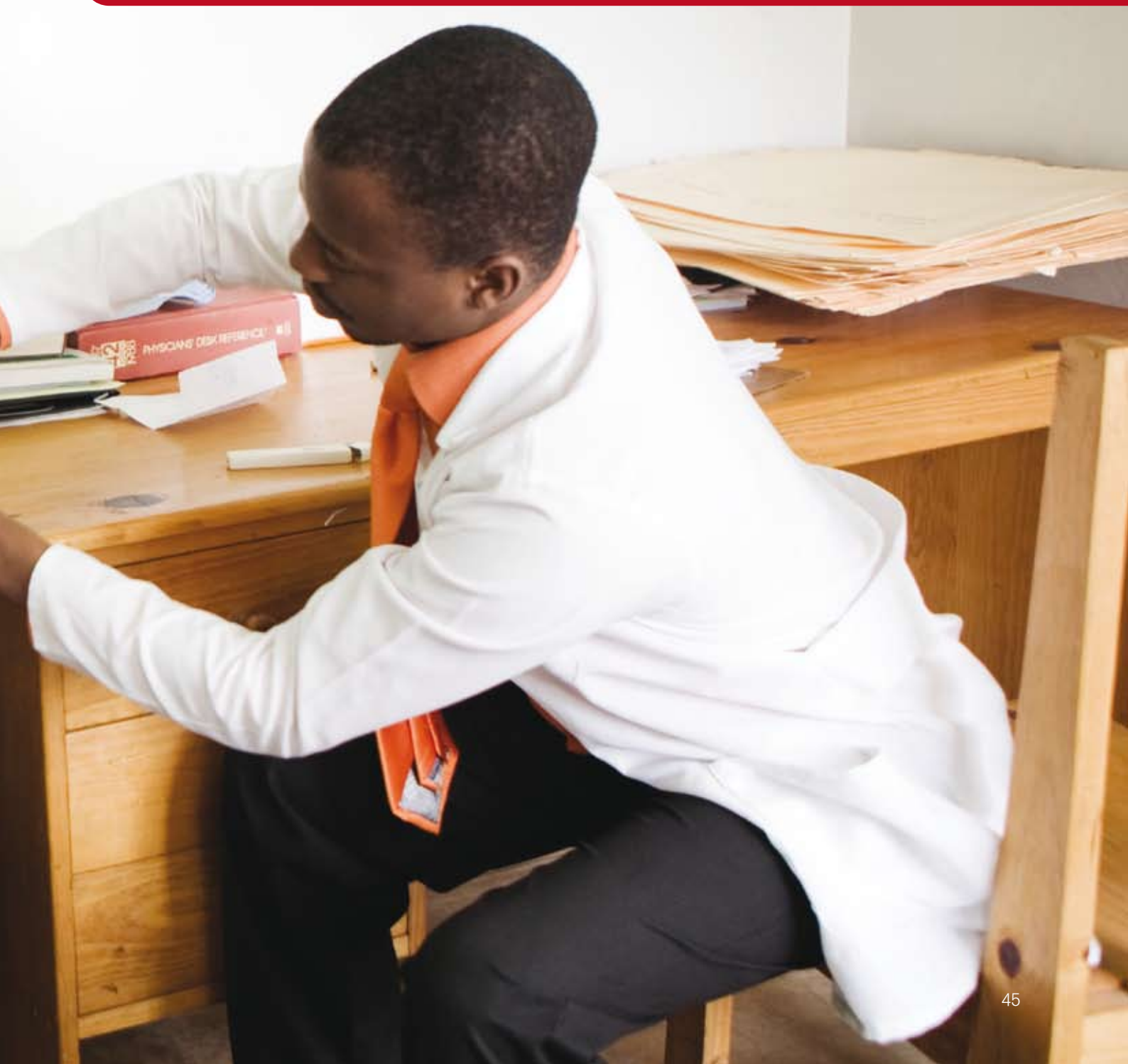
All-Party Parliamentary Group on Aids [UK]
***The Treatment Timebomb*, July 2009**

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), 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. The assessments will focus on reinforcing coordination of UNITAID partners and domestic organizations to ensure drugs and other products financed by UNITAID are widely and swiftly available to patients.

Malaria

Scaling up the best treatment, investing in prevention



Malaria

Scaling up the best treatment, investing in prevention

2009 highlights

- Committed nearly US$ 300 million since 2006 to five malaria projects in 27 countries.
- Delivered 19 million artemisinin-based combination therapy (ACT) malaria treatments to 21 countries in Africa and Asia by the end of 2009.
- Committed up to US$ 130 million for the Affordable Medicines Facility for malaria (AMFm) to make ACTs more affordable and available.
- Supported quality assurance of eight additional ACT medicines over two years, all of which are FDCs.
- Established a revolving credit fund for artemisinin extractors to assure adequate supplies of artemisinin in 2010–2011.
- Disbursed US$ 109 million to UNICEF to buy and distribute 20 million insecticide-treated bed nets in eight high-burden countries in 2009–2010.

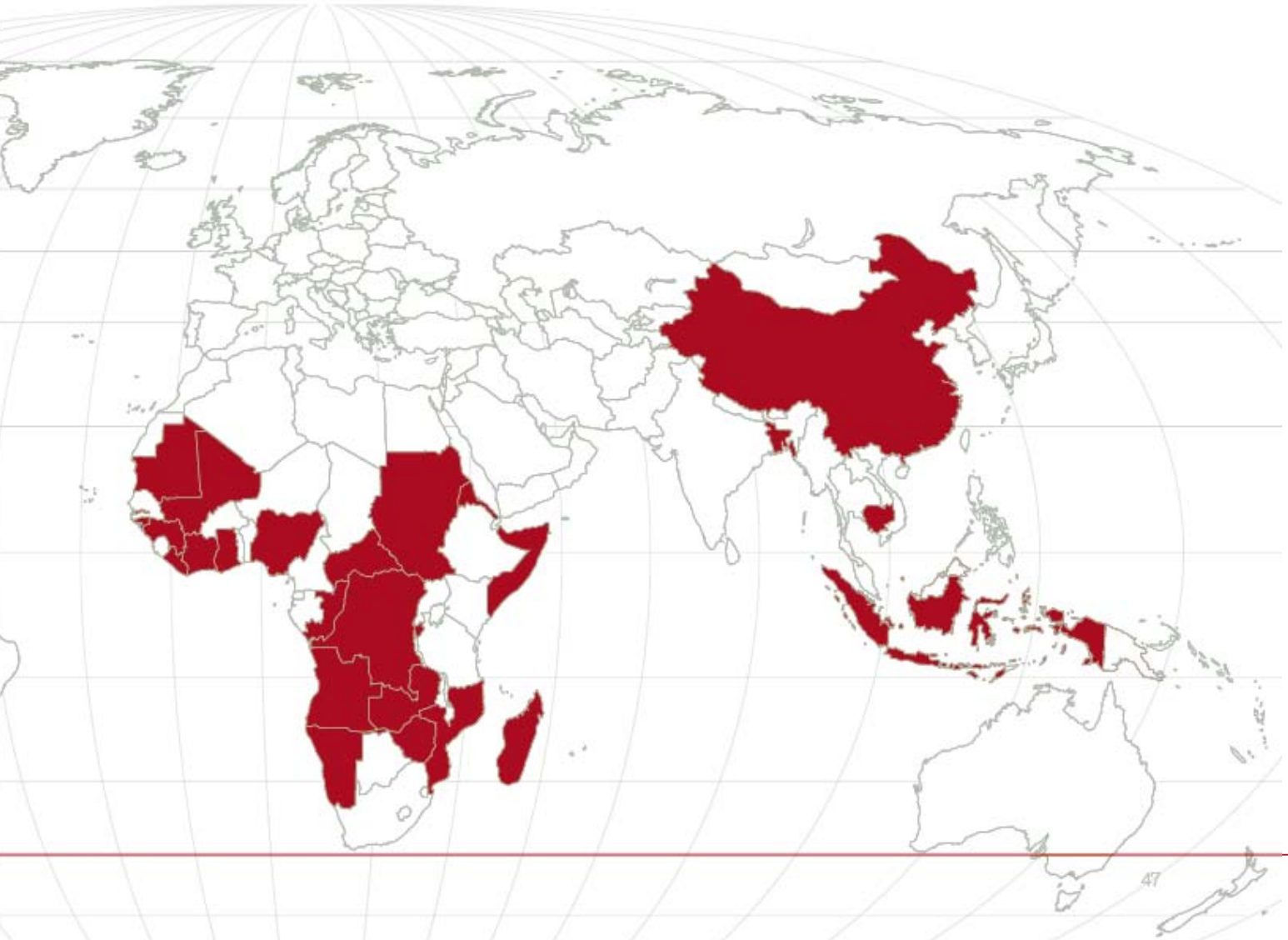
Nearly one million deaths a year despite an effective cure

Malaria is a potentially deadly disease that is transmitted through mosquito bites. Half of the world's population – or approximately 3.3 billion people in more than 100 countries and territories – are at risk of contracting malaria. In 2008 there were nearly 250 million malaria infections and almost 900,000 deaths.[23]

Africa accounted for 85% of infections and 90% of deaths, mostly among young children. 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.[24] It is also a prime cause of anaemia, low birth weight, premature birth, infant mortality and maternal deaths.

Malaria (27 countries)

Angola, Bangladesh, Burundi, Cambodia, Central African Republic, China, Congo, Democratic Republic of Congo, Côte d'Ivoire, Djibouti, Eritrea, Gambia, Ghana, Guinea, Guinea-Bissau, Indonesia, Liberia, Madagascar, Mali, Mauritania, Mozambique, Namibia, Nigeria, Somalia, Sudan, Zambia and Zimbabwe.



Malaria has a huge economic as well as human cost, affecting people's ability to work and trapping communities in poverty. It is also a major burden on health systems. In countries with a very high incidence of the disease, malaria may account for as much as 40% of public health expenditure, 30-50% of in-patient admissions and up to 60% of out-patient visits.[25]

Although malaria is curable in a matter of days, the disease can be fatal without swift diagnosis and prompt effective 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. The other priority is preventing transmission, primarily through the use of long-lasting insecticide-treated bed nets (LLINs) and the spraying with insecticides of indoor surfaces such as walls and ceilings (indoor residual spraying or IRS). The Roll Back Malaria partnership has called for universal coverage of all these interventions – rapid diagnosis, prompt treatment and prevention measures – by 2010.

Scaling up ACT provision

Because of widespread resistance in Africa and Asia to older malaria treatments, such as chloroquine and sulfadoxine-pyrimethamine, artemisinin-based combination therapy (ACT) is the only truly effective treatment currently available for endemic countries. However, governments have been reluctant to make the switch and take less effective drugs off the market because ACTs are much more expensive. 'Factory-gate' prices for ACTs average about US$ 1 or 20 times the five US cents or so charged for chloroquine or sulfadoxine-pyrimethamine.

UNITAID, together with its partners UNICEF, the Global Fund and i+ solutions, has focused its malaria efforts on market interventions to:

- Expand access to ACT treatment by increasing the supply of quality products and reducing prices;
- Assure stable supplies of quality artemisinin; and
- Accelerate coverage of long-lasting insecticide-treated nets (LLINs) by reducing delivery delays and prices.

Although 80 countries have adopted artemisinin-based combination therapy for treatment of malaria, ACTs account for only one in five anti-malarial treatments taken 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 even more of a deterrent. ACTs bought at a pharmacy may cost US$ 6 – 10 per treatment against 20 – 50 US cents for the less effective drugs.

Young children, who face the highest risk of dying from malaria, are even less likely to receive ACTs than adults. In 11 of 13 countries surveyed in 2007–2008, less than 15% of children under five with fever had received an ACT, well below the WHO target of 80%.[26]

Availability of quality assured ACTs is another concern. Low quality or inappropriate medicines – including artemisinin monotherapies in which artemisinin is the only active pharmaceutical ingredient – may not only be ineffective but can hasten the development and spread of resistant malaria strains. There are already confirmed but so far sporadic cases of artemisinin-resistant malaria. If these strains were to become generalized, the world would lose the only effective medicine it has to combat the most deadly form of malaria parasite, *Plasmodium falciparum*. Most poor countries do not have the capacity to screen and test medicines and in 2006, when UNITAID began work, only one ACT had been quality assured under the WHO's Prequalification Programme.

In 2009 UNITAID was financing two projects aimed at tackling the high cost of ACTs and increasing the availability of quality ACT medicines. These were the ACT Scale-Up Initiative, in partnership with UNICEF and the Global Fund, which runs from 2007 to 2011, and the Affordable Medicines Facility for malaria, a new international initiative hosted by the Global Fund (see below).

By the beginning of 2010, UNITAID had committed about US$ 71.3 million to provide treatment for a cumulative 54.5 million cases of malaria through mid-2011 and had already delivered about 19 million ACT treatments to 21 countries in Africa and Asia.[27] Of the total, the ACT Scale-Up initiative with UNICEF and the Global Fund accounted for US$ 49 million, the partnership with the Global Fund (Round 6) for US$ 21.5 million, while US$ 0.8 million funded a one-off emergency delivery of 1.4 million malaria treatments for Liberia and Burundi in 2007.

The large ACT purchases financed by UNITAID have contributed to production efficiencies and increased competition, which have helped to maintain the pre-existing downward trend in ACT prices. Better demand information and transparent ordering have been key factors in increasing ACT supply, by permitting manufacturers to plan production capacity and the sourcing of raw materials and active pharmaceutical ingredients (APIs). Meanwhile, competitive tendering for UNITAID-financed purchases has attracted an expanded base of suppliers.

In addition, UNICEF's 11 long-term agreements with suppliers for artemisinin-based formulations require them to maintain and rotate buffer stock to keep remaining shelf life above 80%, enabling ACTs to be delivered quickly in emergencies. The buffer stocks also shorten lead times for normal orders placed with manufacturers, because they require commensurate increases in stocks of APIs and packaging materials.

'UNITAID is at the forefront of innovative financing for major diseases, such as malaria, that affect especially the poor... In addition to helping to supply effective drugs (ACTs) through the Affordable Medicines Facility for malaria (AMFm), thanks to UNITAID millions of additional nets are reaching the countries, communities and people in need of protection.'

Professor Awa Marie Coll-Seck, Executive Director, Roll Back Malaria Partnership, December 2009

Since the ACT Scale-up project began in December 2007, eight additional ACT products have been prequalified, all of which are fixed-dose combination (FDC) tablets. One is available in dispersible form (that is, it dissolves in the mouth, so does not need to be taken with liquid). This compares with just one prequalified ACT previously, which was a co-blister product and not an FDC. However, only one FDC is designed for children and even now there are relatively few pre-qualified ACT producers.

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 antimalarial drugs, including artemisinin monotherapies, thereby delaying development of resistance as well as ensuring effective treatment.

To achieve this goal, the AMFm will negotiate lower drug prices with manufacturers, whose production costs should fall with increased and predictable demand. It will then pay 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 will launch eight Phase I projects, in Cambodia, 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 1 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.

Boosting artemisinin supply

Artemisinin, the basic chemical for ACTs, is a natural product extracted from the plant *Artemisia annua*, which is commercially grown mainly in China, Viet Nam, the United Republic of Tanzania, Kenya, Uganda and Madagascar. The global supply of ACTs depends on adequate production of good quality artemisinin, which in turn is influenced by farmers' expectations of market returns. In practice, the market has exhibited signs of the classic 'hog cycle'. Until 2005 artemisia plantings were low, reflecting low demand. When demand increased for the small production of artemisinin, prices soared as high as US$ 1,100 a kilo. This led to greater investment in artemisia planting and overproduction of artemisinin in 2006 and 2007, causing a collapse in prices to as low as US$ 140 a kilo in 2007– 2008. Artemisia plantings accordingly shrank the following year. This unstable market has posed a serious threat to the increasing global need for ACTs.

To assure global ACT supplies for 2010 – 2011, UNITAID in partnership with i+ solutions, a Dutch pharmaceutical procurement company, is implementing a project designed to help stabilize the market and boost production of quality artemisinin. The Assure Artemisinin Supply System project, to which UNITAID has committed US$ 9.3 million over two years, establishes a revolving low-interest credit fund for artemisinin extractors which have legal contractual agreements with manufacturers of WHO prequalified ACTs. The first two contractual agreements, both for China-based extractors, are expected to be signed in early 2010.

Scaling up bednet coverage

A highly effective way to prevent malaria – especially in protecting the most vulnerable groups such as young children and pregnant women – is through the use of bed nets treated with insecticides (Long-Lasting Insecticide-Treated Nets – LLINs). 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. Yet countries are far from achieving the goal set by the Roll Back Malaria partnership of universal coverage by 2010. According to the latest figures available, in 2008 less than a third of all households in malaria-endemic countries owned an insecticide-treated net and only a quarter of children under five were using one.[28]

The purchase cost represents a significant investment for individual families and health services in endemic countries. The total cost of a LLIN, including product cost, freight, distribution and supportive interventions, was estimated at about US$ 7.50 per unit in 2008.[29]

There have also been long delays in bed net deliveries. Purchase and distribution of bed nets can take as long as two years because of delays in donor funding disbursement, lengthy country procurement processes, and the lead time required by companies to manufacture and deliver the products. These delays result in lower-than-expected orders, which in turn lead to stock build-up with manufacturers. In response, manufacturers scale down production. When funding does become available, manufacturers struggle to meet demand.

To avoid this situation, in 2008, UNITAID's Executive Board approved US$ 109 million for a project with UNICEF to provide 20 million LLINs for eight malaria-endemic sub-Saharan African countries in 2009 and 2010.[30] This project was designed both to increase LLIN availability and to sustain the market in the short term. Without UNITAID intervention there was a risk that manufacturers might have scaled down production in 2008, when funding was scarce. This could have resulted in major supply shortages, given the commitment by the international community to increase purchases of bed nets from 2009.

The LLIN project, which is due for completion in May 2010, aims to increase overall bednet coverage from present levels of about 34% by about 20 percentage points. This will help supported countries to achieve the Roll Back Malaria target of universal ownership of insecticide-treated nets by the end of 2010. The distribution of LLINs to households, for which UNICEF is responsible, proceeded more slowly than hoped, in part due to domestic logistical and capacity constraints, with about 40% of the purchased bednets in the hands of individual households by end-2009. UNICEF has mobilized additional resources to speed distribution of the remaining nets in 2010.

However, the broader aim of the project has been to improve supply, reduce delivery delays and bring down bed net prices for all countries. UNITAID's intervention has allowed more predictable forecasting of orders, sending a signal to manufacturers to continue production that has resulted in steadier supply. Meanwhile, volume procurement and long-term agreements negotiated with all the principal LLIN manufacturers have brought down the ex-factory price of bednets procured through UNICEF's 2009 agreements from a weighted average of US$ 4.88 to about US$ 4.65 for large polyethylene nets. Some 80% of LLINs were delivered to destination countries within 12 weeks of the purchase order being placed.

The LLIN project also aims to stimulate an increase in the number of WHO-recommended anti-mosquito pesticides by engaging in technical discussions with potential manufacturers. At the start of the project there were four recommended LLIN products, and three more have since been granted interim recommendations.

Where next on malaria

UNITAID is considering a variety of market interventions to support the fight against malaria in 2010 and beyond.

These could include:

- Funding new ACTs to increase availability and reduce prices. A number of new ACT products are in the development pipeline;
- Supporting quality assurance services for rapid diagnostic tests for malaria. In March 2010 WHO recommended diagnostic testing in all cases of suspected malaria, which will allow for targeted use of ACTs for those who actually have the disease.

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Case study

Boosting malaria prevention and

In the village of Mpansya, three hours north of Zambia's capital Lusaka, Michael Tembo and Sabbina Nkausu Tembo live with their two daughters, Mirth, 2, and Monica, 5 months.

Michael is likely to give you a smirk or a laid-back smile, Sabinna, a strong gaze, and Mirth, a questioning look. They appear healthy and strong – you wouldn't know that until recently they lived in constant fear of contracting malaria.

'Last year I had malaria three times and my wife more than three times,' Michael says. 'But it's my daughter Mirth, who got it the most.'

Michael has reason to be concerned; malaria kills more than 2,000 children under five years of age every day. Each year, an estimated 250 million people contract malaria. Nine in ten cases occur in sub-Saharan Africa, where Michael and his family live.

Dr Karen Sichali-Sichinga, Executive Director of Churches Health Association of Zambia (CHAZ), a local partner of UNITAID and the Global Fund for AIDS, TB and Malaria, says, 'Malaria is the biggest health problem in Zambia at community level. It is endemic in our region.'

According to Dr Sichali-Sichinga, 60% of health care needs are related to malaria, making it the single most important health challenge in Zambia and placing a huge financial and human burden on the community.

To prevent the spread of malaria, UNITAID has committed US$ 109.2 million to UNICEF for the purchase and distribution of 20 million insecticide-treated bednets to eight African countries, including Zambia. The nets, placed over beds at night, prevent mosquitoes from biting unknowing sleepers. Last year, Michael and his family became the proud owners of a bednet.

'Now we can prevent it, the problem is reduced,' Michael says. 'At first, using the net was awkward. But with time… it became a reflex. You have to do it even though you have forgotten – you say "no, I have forgotten something" and then get up and cover the bed and get to sleep.'

UNITAID is also increasing access to artemisinin-based combination therapy (ACT), the best available treatment for malaria. The first shipment of UNITAID-funded ACTs arrived in Zambia in May 2009. By distributing them to rural areas, CHAZ was able to extend ACT coverage to 22 new districts and 11 health centres.

Dr Sichali-Sichinga says UNITAID supplies have made an important difference. 'Most people in the rural areas of Zambia live below a dollar a day…and they were having to buy drugs and were having to look for anti-malaria pills. What this means is that it has freed some of the monies to buy food, since they can now access malaria treatments for free.'

In partnership with the Global Fund to Fight AIDS, Tuberculosis and Malaria, UNITAID has agreed to finance more than nine million ACT malaria treatments in Zambia over the next two to three years. UNICEF will purchase and distribute the ACT treatments, helping UNITAID reach as many people as possible in need of treatment.

This commitment is crucial for people like Michael and his family, whose health today depends on the distribution of free, quality medicines.

treatment

Tuberculosis

The curable disease that continues to kill

Tuberculosis

The curable disease that continues to kill

2009 highlights

- Committed US$ 87.6 million to four TB medicines in 72 countries since 2006.
- Financed purchases of nearly 785,100 first-line tuberculosis (TB) treatments in 19 countries and more than 6,200 treatments for patients with MDR-TB in 30 countries by the end of 2009.
- Expanded the UNITAID-financed Strategic Rotating Stockpile to service a total of 5,800 patient treatments.
- Supported quality assurance for seven TB medicines since 2007, including four paediatric formulations.
- Funded purchase by the Global Drug Facility of more than 668,100 curative and preventive TB treatments for children in 57 countries by the end of 2009.
- Reduced prices of four key paediatric TB medicines by 10–30%.
- Established rapid diagnostic capacity for MDR-TB in initial reference laboratories in four countries as part of a US$ 88 million project to support use of new diagnostic technologies in 27 countries.

A rising tide of drug-resistant TB poses massive challenges

Tuberculosis (TB) is a curable contagious disease that takes a deadly toll globally, particularly in developing countries. An estimated 1.8 million people died of TB in 2008, while 9.4 million developed the disease.[31] The lack of adequate diagnostic and treatment tools makes TB a difficult disease to tackle. Because TB is generally considered a part of history in most industrialized countries, there has been little incentive for pharmaceutical companies to invest in research and development to produce better drugs and diagnostics.

The global HIV/AIDS pandemic poses additional treatment challenges. HIV-positive people, who are particularly susceptible to infection because of weak immune systems, accounted for 15% of new infections and 25% of TB deaths in 2007.[32] About 1.4 million people are estimated to be co-infected with TB and HIV, only 15% of whom are receiving appropriate treatment. Four fifths of those living with both HIV and TB are in sub-Saharan Africa.

Despite some success in reducing overall rates of TB infection, there has been a growth in drug-resistant strains of the disease, which no longer respond to the standard and most potent TB medicines. Drug resistance occurs

primarily because of improper treatment of standard (drug-sensitive) TB, but resistant strains are also being spread from person to person. There were an estimated 440,000 new infections of multidrug-resistant TB (MDR-TB) in 2008, nearly half of them in India and China.[33] The discovery of extensively drug-resistant TB (XDR-TB) over the last few years – for which there are virtually no treatment options left – has added further urgency to the need to improve diagnostic and treatment tools.

UNITAID, through its partners, has focused its TB efforts on market interventions to:

- Help curb the emergence of resistant TB strains by ensuring availability of quality-assured first-line drugs;
- Support the development of, and access to, child-friendly TB medicines;
- Expand access to quality-assured MDR-TB treatment by increasing availability and affordability; and
- Promote the scale-up of MDR-TB diagnosis using new rapid diagnostic tests.

Securing first-line TB treatment

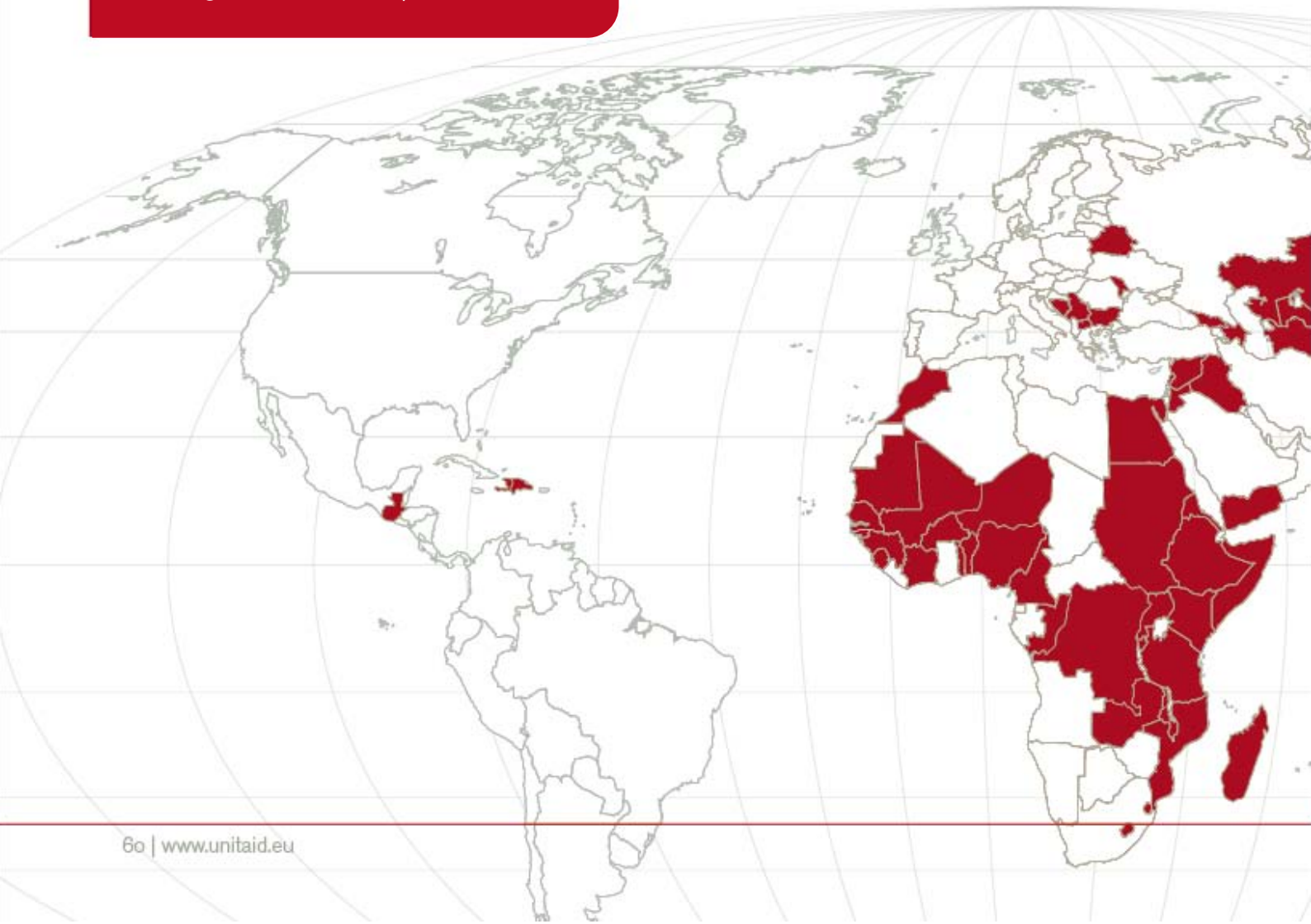
Standard first-line TB treatment requires patients to take antibiotics daily for a minimum of six months. An unfinished treatment course can lead to treatment failure and the emergence of drug resistance. The first line of defence against the development of drug-resistant TB, therefore, is broad access to first-line TB treatment with appropriate adherence and treatment follow-up.

Interruptions in supply ('stock-outs') of first-line TB drugs increase the risk of creating resistance by interrupting treatment. In response, UNITAID, through the Global Drug Facility (GDF) of the Stop TB Partnership, is ensuring steady availability of first-line drugs by financing a Strategic Rotating Stockpile (SRS). The stockpile, located in Amsterdam, enables people newly diagnosed with TB to receive treatment within three weeks of the medicines being ordered, as opposed to the customary three to six months. As countries place emergency orders, the SRS is continually restocked. In the light of the success of the SRS since its launch in 2007, UNITAID has expanded its support to cover 5,800 patients by the end of 2011, so that countries can continue to benefit from the stockpile while they improve their own drug management capacity.

UNITAID aims to:

- Provide ready access to first-line medicines, decrease drug delivery lead times and minimize the risk of stock-outs; and
- Boost supply of quality-assured TB drugs at affordable prices.

The existence of the SRS has helped reduce average lead times for first-line drug deliveries from 4–6 months to 1–3 months, and emergency orders can be filled by the stockpile in less than 30 days, half the time taken in 2008. This ensures rapid treatment and avoids stock-outs of first-line TB drugs, preventing the development and spread of drug-resistant TB. Thirty-nine countries made use of the stockpile in 2009 and no country eligible to use the stockpile experienced stock-outs. Changes in the management



and functioning of the SRS in 2009 aimed to streamline procedures with a view to further reducing delivery lead times and responding flexibly to market conditions.

In 2008 and 2009, UNITAID provided bridging finance to the Global Drug Facility to ensure an uninterrupted supply of first-line TB treatments for nearly 785,100 people in 19 countries in Africa, Asia, the Middle East and Europe.[34] All but one of the 19 countries have since successfully transferred from UNITAID support to other sources of finance for first-line TB drugs, notably the Global Fund. This is in line with UNITAID's policy of intervening to remedy specific market failures or treatment gaps and then withdrawing when the task is accomplished or taken over by others. In the case of first-line TB drugs there is no generalized shortage of supply. UNITAID's efforts are focused on improving quality, reducing delivery delays and stock-outs, and reducing or containing costs.

UNITAID was unable to reduce prices for first-line anti-TB drugs as hoped from 2008 levels of around US$ 18–19 per patient per treatment because of an increase in costs of the active pharmaceutical ingredients (APIs) and the manufacturing process. However, it maintained its goal of containing costs below US$ 20 per treatment. UNITAID's market-based strategy takes into account the fact that manufacturers will have no incentive to produce quality-assured drugs if they cannot charge more than they charge for lower quality medicines.

TB medicines (72 countries)

Afghanistan, Azerbaijan, Bangladesh, Belarus, Benin, Bosnia and Herzegovina, Bulgaria, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Congo , Democratic Republic of Congo, Côte d'Ivoire, Dominican Republic, Djibouti, Egypt, Eritrea, Ethiopia, Gambia, Georgia, Guatemala, Guinea, Guinea-Bissau, Haiti, India, Indonesia, Iraq, Jordan, Kazakhstan, Kenya, Kiribati, Democratic People's Republic of Korea, Kyrgyzstan, Lebanon, Lesotho, Former Yugoslav Republic of Macedonia, Madagascar, Malawi, Mali, Mauritania, Republic of Moldova, Mongolia, Morocco, Mozambique, Myanmar, Nepal, Niger, Nigeria, Pakistan, Papua New Guinea, Philippines, Rwanda, Senegal, Sierra Leone, Somalia, Sri Lanka, Sudan, Swaziland, Syrian Arab Republic, Tajikistan, Timor-Leste, United Republic of Tanzania, Thailand, Togo, Turkmenistan, Uganda, Uzbekistan, Viet Nam, Yemen and Zambia.

Treating children with TB

Although children account for up to a fifth of all new cases of active tuberculosis in high-burden settings,[35] 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.

In 2009, UNITAID financed purchases by the Global Drug Facility (GDF) of 373,960 curative and preventive TB treatments for children under 15, for use in 57 countries across Africa, Asia and the Middle East.[36] Since the project began in 2007, UNITAID has funded more than 668,100 child-friendly TB treatments, making UNITAID the largest single provider of quality paediatric TB medicines. The project aims to provide a cumulative 750,000 treatments for children in the 57 countries by the end of 2011, equivalent to a third of the global demand.

By helping to increase the number of manufacturers and stimulate competition, the UNITAID/GDF partnership achieved price reductions for four key paediatric TB medicines of 10–30% in 2009. There are now at least two suppliers for five of the seven quality assured paediatric formulations in blister packaging, compared with one such manufacturer in 2008. In addition, the partnership's pooled procurement strategy has reduced average delivery lead times from 15 weeks in 2008 to less than 13 weeks in 2009.

Meanwhile, UNITAID's funding support for the WHO's Prequalification Programme facilitated the prequalification of the first ever paediatric fixed-dose combination TB medicine in 2008 and the prequalification in 2009 of three more paediatric TB FDCs.

In 2009, WHO published new guidelines on paediatric TB medicines that recommend higher dosage strengths than before. This represents a major challenge for UNITAID, its partners and manufacturers. At present, there are no quality-assured fixed-dose combination paediatric drugs that meet the new guidelines. Higher-strength combinations of existing prequalified drugs are being used while dossiers with the new dosages are being developed for submission to WHO. GDF estimates that it could take two years for new approved FDCs incorporating the recommended dosage to come onto the market.

Expanding access to MDR-TB treatment

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 properly. Diagnosing MDR-TB is difficult and treating it 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. Only 7% of the estimated 440,000 cases of MDR-TB were reported to WHO in 2008 but less than half those reported were properly diagnosed and fewer still were given appropriate treatment.[37]

Addressing MDR-TB is made more problematic by the limited availability of quality medicines. Part of UNITAID's effort is thus 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.

While a six-month treatment course for first-line TB now costs about US$ 20, drugs for MDR-TB can be 50 to 200 times more expensive. The cost of treatment over 24 months for one patient with MDR-TB ranges upwards of US$ 2,000 to US$ 5,000 or more – prohibitive sums for patients in poor countries. The lack of funding to address MDR-TB has led to uncertain demand for medicines to treat and cure it. Moreover, the process for obtaining quality assurance, whether through WHO prequalification, a 'stringent regulatory authority' or an expert review panel, can be costly and lengthy. Fewer manufacturers are therefore interested in entering the market.

MDR-TB medicines, like other TB medicines, have a short shelf life of 18 months, against the 18 to 24 months needed for treatment. This short shelf life means that manufacturers only produce the medicines on demand, with a normal six-month lead time between order and in-country delivery. This delay is serious for patients, who once diagnosed with MDR-TB should have immediate treatment. But companies considering manufacture of quality drugs have little incentive to embark on research and mass production unless they can be assured of a predictable market.

By funding treatment expansion and thereby increasing demand, UNITAID acts as a catalyst for manufacturers – especially generic manufacturers – to invest in large-scale production of MDR-TB drugs and to obtain quality assurance for those products. This should in turn help improve drug quality and shorten lead times. Larger purchase volumes associated with increased demand help lower production costs through economies of scale, while increased competition among companies should also help to put downward pressure on prices.

Case study

Tackling MDR-TB in Nepal

Bimal Khatri, 35, lives in Kathmandu with his wife, two daughters, and two brothers.

He has been on tuberculosis (TB) treatment for the last year and a half – first for simple TB and then, when he didn't complete his initial treatment, he contracted multidrug-resistant TB (MDR-TB). Since then, he has worn a mask, takes a daily cocktail of 16 tablets and keeps at arm's length from his children.

'I love them,' Khatri says, 'but if I am not alive then how can I love them? Therefore I have to ask them to stay away so that they can come near me when I am okay.' In 2007, an estimated 9 million people contracted TB and 1.3 million people died from it, according to World Health Organization (WHO) estimates. Worldwide, half a million people are infected with MDR-TB, and Khatri is one of them.

Khatri takes his medicine, provided by UNITAID, at the local hospital. Over two years, an estimated US$ 790,000 of UNITAID funding has helped 600 patients with MDR-TB gain access to quality assured, life-saving treatment.

'Now I am taking medicine for the past four months and getting better,' Khatri says. 'Before I was very weak.' Every day he takes 16 to 18 pills, and six days out of seven, he receives a painful injection, making it difficult for him to walk for hours after. Treatment courses for MDR-TB are expensive and difficult – they can last two years when successful; if not, they can take up to 32 months.

Dr Bhawana Shrestha, the Clinic Manager in Kathmandu for the German Nepal Tuberculosis Project (GENTUP), says: 'Tuberculosis is one of the major public health problems in Nepal…every year we have 30,000 new TB cases in the whole population of Nepal.'

Prior to 2005, Nepal didn't have free access to treatment for MDR-TB. 'We used to say, "Okay, you are diagnosed with multidrug resistant tuberculosis, but I am very sorry, we don't have these medicines free of cost for you. So if you have money you can buy it", says Dr Shrestha. 'But otherwise, just pray to the gods.' Now, thanks to UNITAID, she prescribes medicine instead of prayers. 'We are very happy to say "we have medicine and you'll be cured"'.

Only those in higher economic brackets could afford to purchase the medicines themselves, says Dr Shrestha. 'It's not possible. It's very expensive. Maybe 1% (of the population) can afford it…' To Dr Shrestha, treating MDR-TB averts a public health crisis. 'They cannot get the medicines themselves,' she says, 'and if they could not take the medicines, they would spit MDR bacilli. And the Nepali people would get more and more MDR-TB.'

Part of the challenge in treating MDR-TB is diagnosing it in the first place. Of the estimated 440,000 with MDR-TB, less than 5% are properly diagnosed and fewer still receive appropriate treatment.

In partnership with the Foundation for Innovative New Diagnosis (FIND) and the Stop TB Partnership's Global Drug Facility (GDF), UNITAID has committed US$ 88 million to fund the use of a new diagnostic test in 27 high burden countries, including Nepal. The new test reduces the time it takes to diagnose MDR-TB from three months with older tests to two days.

The future now looks brighter, Dr Shrestha says. 'Now in Nepal we have a better supply of the drugs. Not only is it successful – Nepal is an example for the world. We have a success story.'

UNITAID action on MDR-TB aims to:

- Increase access to MDR-TB diagnosis and treatment;
- Increase the number of quality manufacturers and products;
- Decrease drug delivery lead times and prevent treatment interruptions; and
- Ensure affordability of quality-assured MDR-TB drugs.

UNITAID's market interventions for MDR-TB have four distinct components:

- Funding the purchase of quality-assured MDR-TB drugs;
- Supporting the development and submission of dossiers for quality assurance by the WHO's Prequalification Programme;
- Further expanding the UNITAID-financed Strategic Rotating Stockpile to include MDR-TB treatments; and
- Financing the large-scale rollout of rapid diagnostic tools to detect MDR-TB.

Expanding treatment

UNITAID's MDR-TB Scale-up Initiative aims to provide quality treatments to people in 18 countries across Africa, the Middle East, Asia and Europe,[38] who have been diagnosed with MDR-TB but for whom drugs are currently not available. In doing so, UNITAID is filling a treatment gap but is 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 of the initiative was to provide 5,750 patient treatments to 17 countries by the end of 2011. However, in May 2009 the Executive Board approved funding to expand the project to include India, which alone is estimated to account for a quarter of all MDR-TB infections. As a result, the target for cumulative patient treatments has been raised by 9,850 to 15,600 by the end of 2012.

By end-2009 UNITAID had financed purchase by the Global Drug Facility of the Stop TB Partnership of over 3,100 MDR-TB treatment courses in 16 of the 17 supported countries, as well as MDR-TB treatments for nearly 3'100 people in 16 countries through the Global Fund.[39]

Reducing delivery delays and 'stock-outs'

The success of the strategic rotating stockpile in preventing delays and 'stock-outs' of first-line TB drugs prompted UNITAID's Executive Board to extend the SRS to include MDR-TB drugs and expand its capacity to 5,800 patient treatments. All 74 countries and territories covered under Green Light Committee (GLC) approved country programmes, including Global Fund grantees, now have access to the SRS, and no 'stock-outs' were reported for MDR-TB countries in 2009. On average, urgent orders were met in 39 days, enabling treatment of MDR-TB to begin as soon as possible after diagnosis and thus helping to curb resistance as well as saving lives.

Since the inception of UNITAID's MDR-TB Scale-up Initiative in 2007, average delivery lead times for drugs acquired in the normal way have been reduced by four weeks to just over 14 weeks (100 days) by the end of 2009.

Improving quality and affordability

During 2009, two new MDR-TB drugs were prequalified and 13 dossiers were submitted to the WHO's Prequalification Programme.

Higher costs for the active pharmaceutical ingredients and energy for the manufacturing process have increased prices of both first- and second-line drugs, and new and better, but more expensive, formulations are being developed. UNITAID has been successful in containing project treatment costs despite these pressures, but has not been able to achieve significant price reductions for adult medicines, including for MDR-TB.

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 testing methods because they require specimens to be grown in a laboratory with sophisticated and expensive equipment. This has resulted in treatment delays and the further spread of resistance.

A new diagnostic test is now available, which cuts the time it takes to diagnose MDR-TB to just two days. This 'line probe assay', recommended by WHO, represents a revolution in MDR-TB diagnosis and will facilitate earlier treatment. It will also help in forecasting demand for MDR-TB medicines, resulting in steadier supply, shorter delivery lead times and reduced risk of 'stock-outs'.

UNITAID is investing nearly US$ 88 million over the five years 2008-2013 to support the procurement and use of this new diagnostic technology in 27 countries,[40] through its partners, the Fund for Innovative New Diagnostics (FIND), WHO's Global Laboratory Initiative and the Stop TB Partnership's Global Drug Facility (GDF). The eventual aim is to detect at least 129,000 of the nearly half a million global MDR-TB infections each year, and to permit continuous surveillance and reporting of drug resistance. More accurate and widespread diagnosis will lead to more MDR-TB patients being treated, boosting demand for MDR-TB drugs and thus providing a market stimulus to improve quality and reduce costs.

The EXPANDx-TB (Expanding Access to New Diagnostics for TB) project aims to establish quality-assured laboratories in all the supported countries, where appropriate upgrading and modernizing existing facilities including training in good laboratory practice, bio-safety and new diagnostic methods. The project also seeks to ensure that the new rapid diagnostic tools are properly integrated into TB control programmes.

Implementation began in 2009 in 12 countries. Diagnostic equipment and services are already operational in the initial reference laboratories established in Ethiopia, Côte d'Ivoire, Uzbekistan and Lesotho. In addition, the national reference laboratories inaugurated in Ethiopia and Lesotho have begun reporting MDR-TB cases to WHO and are also providing testing for HIV.

By creating new markets for diagnostic tools, UNITAID and its partners aim to boost supply, achieve economies of scale, encourage new entrants to the market, and bring prices down through economies of scale and increased competition. The project has already achieved price reductions of up to 80% for key reagents, and has identified additional suppliers for both line probe assay tests and another rapid diagnostic known as 'rapid speciation'.

Where next on tuberculosis

UNITAID is considering a variety of market interventions to support the fight against tuberculosis in 2010 and beyond.

These could include:

- Supporting access to new rapid diagnostic tools for detecting MDR-TB and XDR-TB;
- Supporting the manufacture of selected active pharmaceutical ingredients to increase the number of producers and stabilize prices;
- Fostering the development of 'fast track' prequalification for new and low-volume TB products through the WHO's Prequalification Programme;
- Supporting access to new first-line and MDR-TB medicines; and
- Supporting access to new medicines for treating XDR-TB.

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Case study

Strengthening tuberculosis laboratories in

What has been accomplished?

According to WHO, Ethiopia ranks seventh among those countries with a high burden of tuberculosis.

With an incidence of 341 per 100,000 cases in a population of over 75 million, the country has a significant interest in upgrading its laboratory infrastructure, policies and quality assurance systems in order to introduce new, more efficient and rapid diagnostics for TB. Recognising this need, the Ethiopian Health and Nutrition Research Institute (EHNRI) requested assistance from FIND and WHO to implement new TB diagnostic tools. An MOU was signed on 29 January 2008, heralding the birth of a phased approach to improve laboratory and diagnostic services.

Eight sites were identified and assessed, including two laboratories in Addis Ababa and six regional centres. From 2008 to 2009, Ethiopia witnessed an expansion of TB laboratory capacity and inclusion as one of the countries forming part of the EXPANDx-TB project.

This innovative, collaborative project funded by UNITAID enabled the establishment of two laboratories in Addis Ababa – one at the EHNRI which hosts the National Reference Laboratory for Tuberculosis and another in collaboration with Johns Hopkins University at St Peter's Hospital, which provides care to TB/HIV co-infected patients experiencing TB treatment failure or relapse.

Laboratory technicians received training on three WHO-endorsed TB diagnostic technologies:

- Liquid culture and drug susceptibility testing;
- Speciation by immune-chromatography; and
- Line probe assay.

Resources provided through the EXPANDx-TB project enabled rapid policy reform on the use of these diagnostics, including the development of an External Quality Assessment (EQA) Guideline, a Sample Referral Linkage Guideline and a National Safety Manual.

2010 will see the expansion of the LPA and liquid culture diagnostics to six regional laboratories that are performing early infant diagnosis of HIV, making Ethiopia a sterling example of an integrated TB/HIV laboratory network and demonstrating that rapid scale-up at the regional level is feasible in resource-constrained settings.

Ethiopia – what has been accomplished?

Investing in quality

The WHO Prequalification Programme

Investing in quality

2009 highlights

- Committed a cumulative US$ 54.5 million to support the WHO Prequalification Programme so as to increase the availability of quality medicines and diagnostics for procurement in developing countries.
- In 2009 an additional 18 UNITAID priority medicines were prequalified, bringing to 29 the total number of prequalified UNITAID priority medicines since the beginning of 2007.

What is the WHO Prequalification Programme?

The WHO Prequalification Programme, established in 2001, aims to increase access to medicines for HIV/AIDS, malaria and tuberculosis that meet specified quality, safety and efficacy standards. The Programme assesses both medicines and manufacturers to ensure that the United Nations and others procure quality treatments. It also works to build national quality-control capacity in countries where the regulation of medicines is weak or non-existent.

Manufacturers wishing their products to be included in the WHO list must present extensive information and open their manufacturing sites to an inspection team that checks their operations for compliance with WHO Good Manufacturing Practices.

The list of prequalified medicines produced by the Programme is used principally by United Nations agencies, including UNAIDS and UNICEF, non-governmental organizations and governments to guide their procurement decisions. However, the list 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 tuberculosis. Support for the WHO Prequalification Programme thus has a direct positive impact on UNITAID's efforts to expand access to quality treatment for the three pandemic 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 fixed-dose combinations 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.

Eighteen additional UNITAID priority medicines (ten for HIV, three for malaria and five TB drugs) were prequalified in 2009. A major achievement was the prequalification of four new products specially designed to treat HIV/AIDS in children.

In 2009, UNITAID also began funding a new project to support prequalification of priority diagnostics needed to improve detection and treatment of disease.

UNITAID support of the Prequalification Programme contributes to a free-of-charge public service for manufacturers, encouraging generic producers in poor countries to enter the market and thereby increasing country capacity for production of priority medicines. In addition, the Programme helps to create and strengthen countries' 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.

In 2010, UNITAID plans to strengthen liaison and communication with manufacturers with a view to encouraging more suppliers to go through the prequalification process. These contacts will highlight the benefits of prequalification, especially in stimulating increased purchase of their products.

Table 2 | UNITAID priority medicines prequalified, 2007 to 2009

Niche	Number 2007 – 2009	Number 2009
Second-line antiretrovirals	9	6
Paediatric antiretrovirals	5	4
First-line anti-TB products	1	0
Second-line anti-TB products	2	2
Paediatric anti-TB products	4	3
Anti-malarials	8	3
Total	29	18

Support for the Global Fund

Support for Round 6, Phase 1, of allocations by the Global Fund to Fight AIDS, Tuberculosis and Malaria is a cross-cutting project addressing all three priority diseases.

The project provides a total budget of US$ 38.7 million to strengthen the Global Fund's actions in 42 countries and increase the number of people treated.

By the end of 2009, Global Fund projects using UNITAID-financed medicines were treating 28,870 children with paediatric AIDS drugs (in seven countries) and nearly 7,480 adults with second-line ARVs (six countries). In addition, over 2 million people received artemisinin-based antimalarials (in 12 countries), and nearly 3,100 people were being treated for MDR-TB (in 12 countries).

Thank-you campaign

An awareness-raising 'Thank-you' campaign was launched at the end of September 2009.

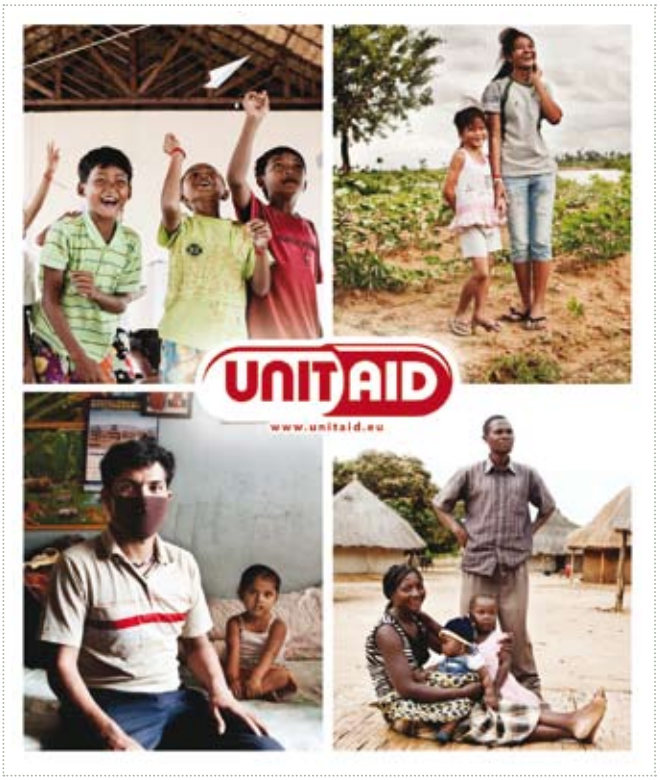
People who have benefited from UNITAID-funded projects tell their story and 'thank' contributors in the member countries for the role they have played in saving or improving their lives.

The campaign consists of a number of audiovisual products:

- A TV spot in five languages;
- A campaign website;
- Photographs/posters; and
- Editorial material.

The products tell the story of UNITAID and its achievements through case studies in three countries where UNITAID is active: Cambodia, Nepal and Zambia.

The campaign started in France and was then taken to other member countries. As of early 2010, the video spots had been shown on nearly 40 TV channels in seven countries, as well as on international networks such as CNN, Eurosport and France24, and on 250 cinema screens in the UK. Airports displaying UNITAID's posters and/or screening the video material included the Paris airports 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.



THANK YOU for helping UNITAID save lives.

Project funding commitments

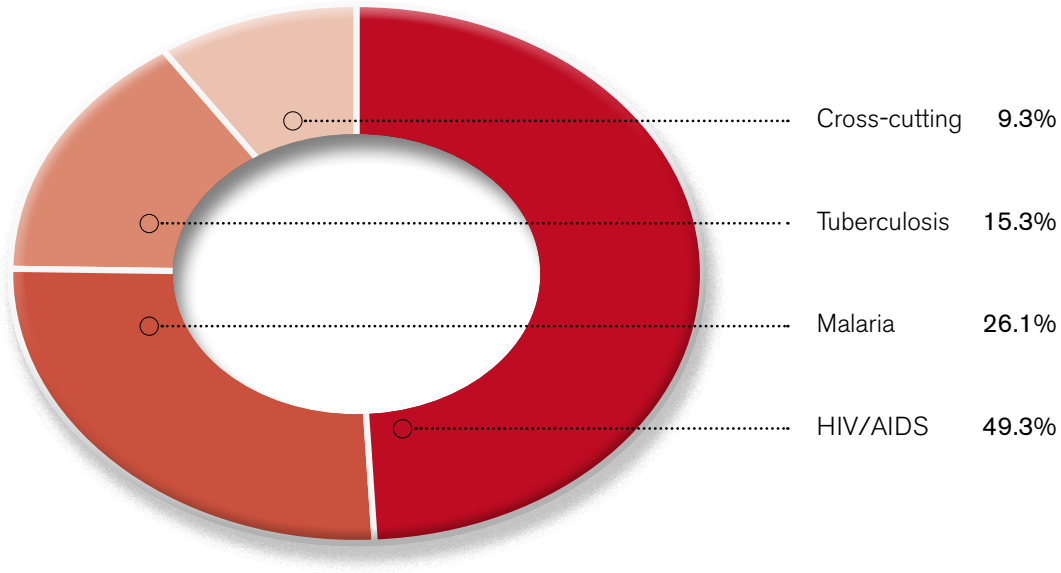
At end 2009

HIV/AIDS	US$ 000
Procurement and supply of paediatric ARVs (with CHAI)	235, 499
Procurement and supply of second-line ARVs (with CHAI)	241, 091
PMTCT (with UNICEF/WHO)	72, 029
Safeguarding availability of ARV treatment (with ESTHERAID)	15, 950
Total HIV/AIDS	**564, 569**
Malaria	
ACT scale-up initiative (with UNICEF/Global Fund)	49, 213
Liberia and Burundi (with WHO)	805
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	**298, 548**
Tuberculosis	
Increased access to first-line TB drugs (with GDF)	26, 841
UNITAID project support for paediatric TB (with GDF)	11, 604
UNITAID project support for MDR scale-up initiative (with GDF/Green Light Committee, Global Fund)	37, 661
MDR-TB acceleration of access initiative: Strategic Rotating Stockpile	11, 458
Total tuberculosis treatment	**87, 564**
MDR-TB diagnostics (with GDF/FIND/WHO)	87, 612
Total tuberculosis treatment and diagnosis	**175,176**
Cross-cutting projects	
Programme project support for quality assurance of medicines and diagnostics (with WHO)	54, 500
Global Fund Round 6[1]	52, 472
Total (16 project areas)	**1, 145, 265**

[1] Since the signing of the Memorandum of Understanding with the Global Fund, the budget has been adjusted to US$ 38.7 million to reflect the subsequent non-participation of one country in the Global Fund's HIV/AIDS treatment programmes.

Project funding commitments

At end-2009, by project category



Our partners

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

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 partners and systematically monitors projects' progress and results.

In order to refine its process for assessing partners' project proposals, UNITAID set up an Interim Expert Advisory Group in 2008 to screen and evaluate project submissions against UNITAID's strategic objective of achieving health outcomes through market impact. In 2009, UNITAID's Executive Board took steps towards establishing a permanent Proposals Review Committee made up of external experts in public health, market dynamics, health economics, supply chain management and intellectual property.

At the end of 2009, 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

UNITAID and WHO

In line with the Memorandum of Understanding signed at UNITAID's inaugural ceremony at the United Nations on 19 September 2006, 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.

Measuring our performance

UNITAID's monitoring and evaluation framework is designed to show clearly how projects contribute to UNITAID's overarching goal of making a long-term, sustainable impact on the market for priority medicines, diagnostics and related commodities.

Key components of the UNITAID strategy monitored over the course of a project are:

Access
Reaching target patient populations with treatments

Availability
Increasing availability of new drug formulations and medical products on the market and increasing the number of manufacturers of these products

Quality
Ensuring the quality of new formulations/ products and new manufacturers in the market through support to and partner interaction with the WHO Prequalification Programme

Price
Achieving price reduction (or price containment, depending on products and niche) of the product(s) over the course of the project

Delivery
Ensuring timely delivery of products from manufacturers to countries to meet programme needs for treatment

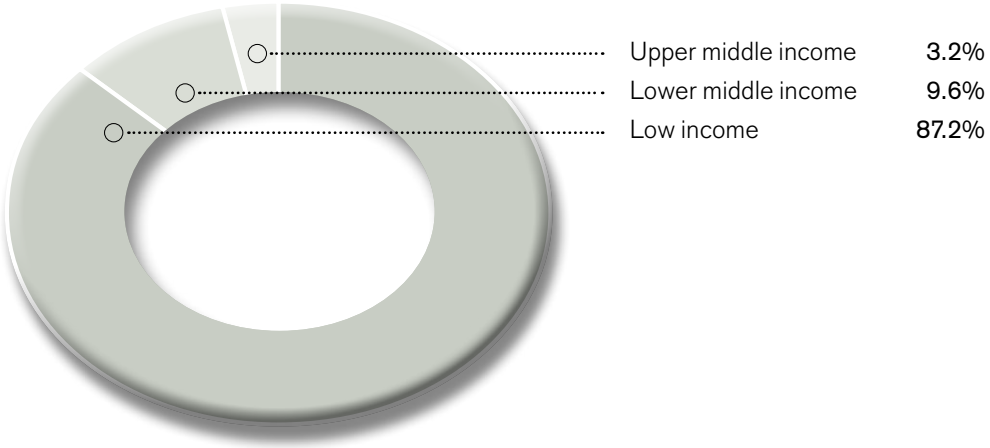
In 2009 UNITAID initiated development of a dynamic market intelligence information system to collect data on supply and demand for medicines and diagnostics for HIV/AIDS, TB and malaria. It is hoped to have this system operational by end-2010.

UNITAID monitoring also considers the broader impact of each project in relation to its impact on public health and the relevant Millennium Development Goals, especially Goal 6 on combating HIV/AIDS and other diseases, Goal 4 on reducing child mortality and Goal 5 on cutting maternal deaths.

Since UNITAID's overall objective is to serve the needs of the poorest countries and most vulnerable populations, it dedicates at least 85% of its funds to providing health commodities to low-income countries. UNITAID uses less than 10% of its funds to purchase products for lower middle-income countries and less than 5% for upper middle-income countries. This is a key consideration in monitoring and evaluating our partners' projects.

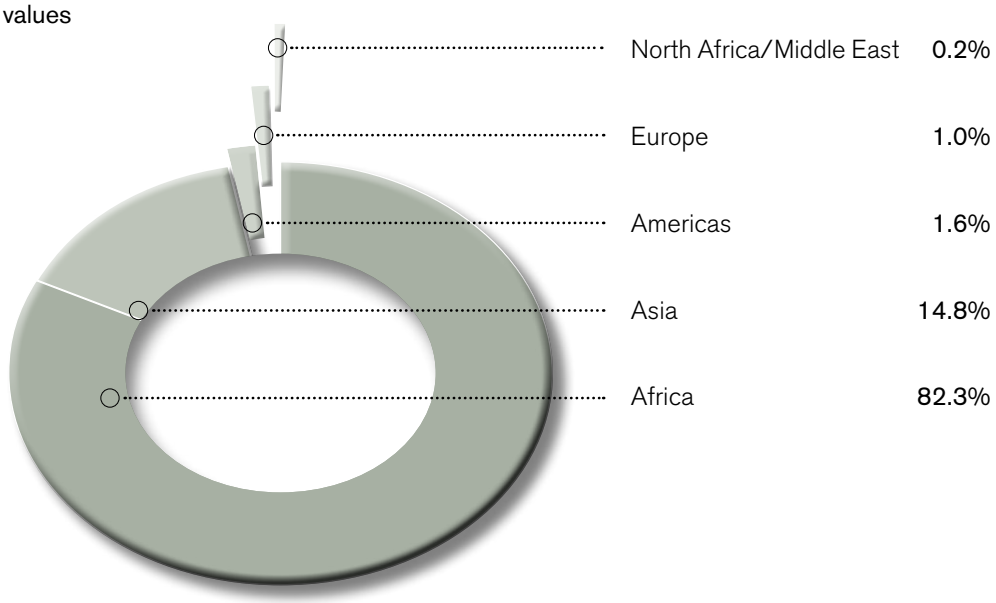
Recipient countries by World Bank income classification

Based on quantities



Recipient countries by region

Based on values



Our members

UNITAID was launched in September 2006 by the governments of Brazil, Chile, France, Norway and the United Kingdom in order to respond to the need for additional, innovative sources of funding for global health.

By the end of 2009, UNITAID's membership had grown to 29 countries and one foundation. The majority of UNITAID's member countries are in Africa. In 2009 three new countries joined UNITAID – Madagascar, Cyprus and Luxembourg.

UNITAID receives funds through airline ticket taxes or regular budget allocations. About 70% of its budget proceeds in 2009 came from the airline tax collected by the following countries: Chile, France, Madagascar, Mauritius, Niger and the Republic of Korea. Norway allocates part of its tax on carbon dioxide emissions from air travel to UNITAID.

Countries making regular budget contributions to UNITAID in 2009 were Brazil, Cyprus, Luxembourg, Spain and the United Kingdom. The Bill and Melinda Gates Foundation also provided funding support.

Some UNITAID members are in the process of introducing the airline tax but are not yet budget contributors: Benin, Burkina Faso, Côte d'Ivoire, Democratic Republic of Congo and Mali. A number of other countries have indicated their intention to join UNITAID, among them Kenya, Portugal and Montenegro.

UNITAID thus receives funding not only from the traditional donor community but also from a number of low- and middle-income countries.

Millennium Foundation

In addition to activities focused on encouraging countries to implement the air tax, UNITAID is supporting the development of a voluntary solidarity contribution scheme that will seek micro-contributions from passengers making airline reservations.

The MASSIVEGOOD initiative, implemented by the Millennium Foundation for Innovative Finance for Health, a Swiss foundation created in 2008, hopes to raise more than US$ 500 million within three years. The scheme, which will be implemented only in countries where there is no UNITAID-related air tax, was launched in the United States in March 2010 and will subsequently be extended to other countries. The US MASSIVEGOOD initiative will enable anyone buying an airline ticket online in the US to make a US$ 2 (or more) donation with a simple click.

'We are hopeful that people across the United States and other countries will rise to the call and help, with just a single click, to close the health gap between the rich and the poor.'

Philippe Douste-Blazy, Chair of UNITAID and the Millennium Foundation

'We hope MASSIVEGOOD will become a truly global phenomenon.'

Ban Ki-moon, Secretary-General of the United Nations

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 is chaired by Dr Philippe Douste-Blazy, former Foreign Minister of France and now Special Adviser on Innovative Financing for Development to the United Nations Secretary-General.

The Executive Board consists of 11 members:

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

Members of the UNITAID Executive Board At 31 March 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	Fernando Muñoz Attaché, 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
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	Joe Cerrell Director, Europe Office, Bill and Melinda Gates Foundation, London
WHO	Namita Pradhan Representative of the Director-General for Partnerships and UN Reform, World Health Organization, Geneva

Consultative Forum and Implementers' Meeting

The Consultative Forum serves as a platform for debate, advocacy, fundraising and inclusion of new partners. It provides feedback, recommendations and advice for consideration by the Executive Board.

The first meeting of the Consultative Forum was held in Geneva, Switzerland in May 2008 and the second in Dakar, Senegal in December 2008. A third meeting will be held in 2010.

The first UNITAID implementers' meeting was held on 15–16 October 2009 in Nairobi, Kenya, to discuss implementation of UNITAID-supported programmes in sub-Saharan Africa. These meetings bring together implementing partners and organizations, representatives of contributor and recipient countries, and representatives of civil society, to discuss ways of strengthening the public health impact of UNITAID's work and improving operational efficiency and effectiveness.

The Consultative Forum consists of representatives of various groups, including:

- Representatives of contributor and recipient countries, with regard to geographical balance;
- Representatives of international organizations and other partners of UNITAID;
- Representatives of civil society, including NGOs from developed and developing countries, and representatives of communities living with HIV/AIDS, tuberculosis or malaria;
- Representatives of the research-based and generic pharmaceutical industry.

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 31 December 2009 it consisted of 37 professional and support staff of 25 different nationalities. The working languages are English and French.

Secretariat expenses are modest – less than 3% of overall 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 31 March 2010

Jorge Bermudez
Executive Secretary

Philippe Duneton
Deputy Executive Secretary

Edward Vela
Senior Adviser to the Executive Secretary

Sonia Hilton
Legal Officer

Daniela Bagozzi
Communication Adviser

Ellen 't Hoen
Senior Adviser, patent pool

Brigitte Laude
Director, Administration and Finance

Raquel Child
Director, Market Dynamics and Operations

Paulo Meireles
Acting Coordinator, Operations and Portfolio Manager, HIV

Financial highlights 2009

Introduction

We are pleased to present the UNITAID financial report for 2009.

The financial statements have been audited by the External Auditor of WHO for the 2008–09 biennium. The Financial Report has been prepared in accordance with the United Nations System Accounting Standards and the Financial Regulations and Rules of the World Health Organization (WHO). In addition, UNITAID has developed supplemental internal guidance to ensure that financial risks are analysed and addressed in an effective manner and that the financial resources UNITAID is entrusted with are planned, managed and safeguarded efficiently and effectively.

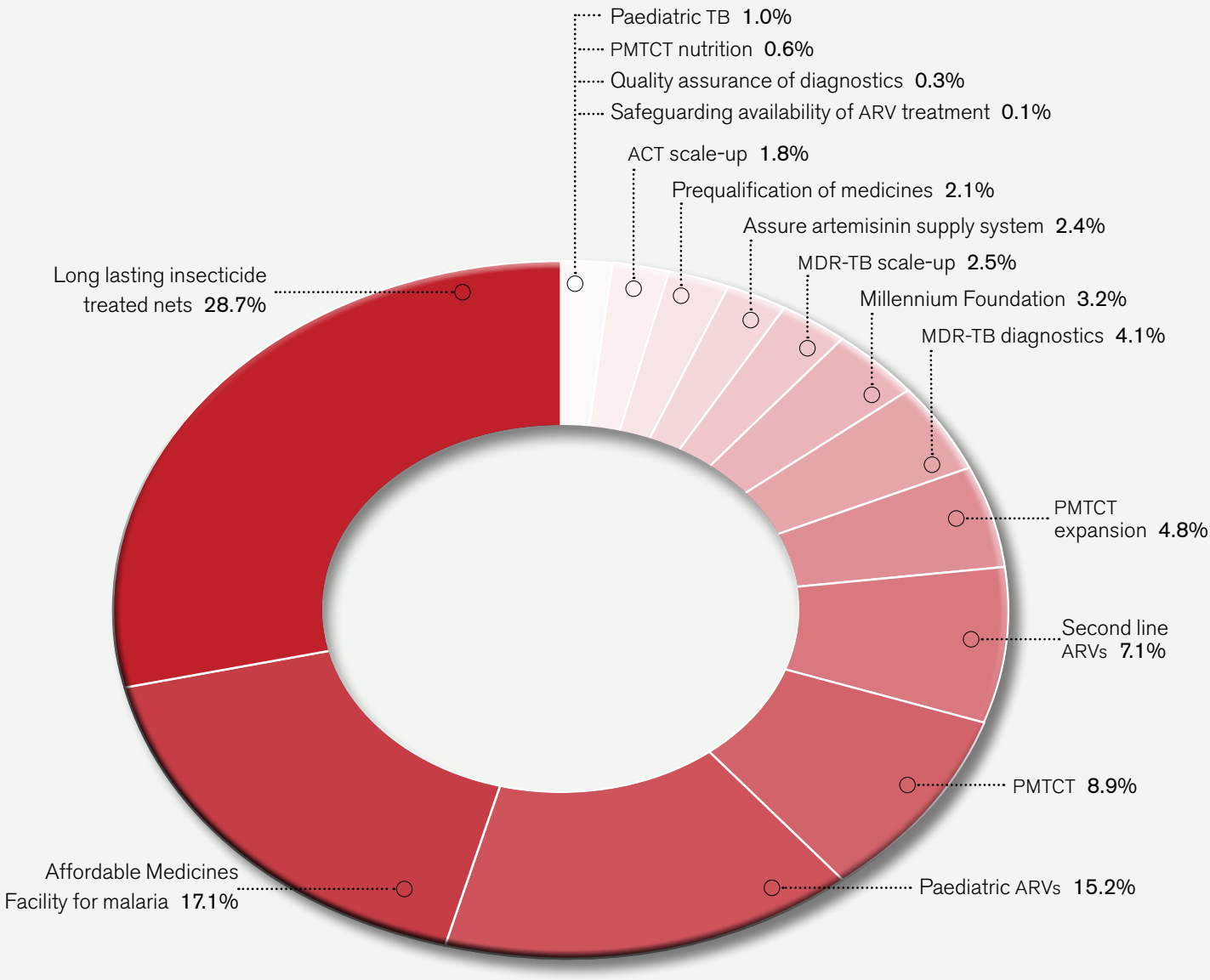
The Audited Financial Report is available on the UNITAID website (http://www.UNITAID.eu).

Financial highlights

UNITAID was established at the end of 2006. Contributions from donors totalled US$ 992 million to 31 December 2009. UNITAID has disbursed US$ 722 million to partners over the same period. While yearly income has levelled off, annual disbursements have more than doubled between 2007 and 2009. Operating costs of UNITAID represent less than 3% of overall expenditure.

Summary statement of financial perfomance	2008–2009 US$ 000	2006–2007 US$ 000
Operating revenue		
Voluntary contributions	623,146	368,889
Total operating revenue	**623,146**	**368,889**
Operating expenses		
Staff costs	8,177	1,732
Direct financial cooperation (DFC)	577,603	145,036
Consulting	2,094	331
Contractual services	3,266	687
Travel	1,907	224
General operating expenses	188	192
Total operating expenses	**593,235**	**148,202**
Surplus from operations	**29,911**	**220,687**
Financial revenue and expenses – net	15,229	1,409
Total surplus for the period	**45,140**	**222,096**

Direct financial cooperation by project, 2009



Voluntary contributions by donors

UNITAID is dependent on voluntary contributions from its donors. About 70% of UNITAID's revenue for 2006–2009 has come from a tax levied on air tickets so as to ensure a regular income to UNITAID, regardless of government budget constraints or donors' source of revenue.

UNITAID wishes to express its appreciation to all its donors and implementing partners as well as WHO for its continued support. Donors can help UNITAID build on its achievements to date and deliver even more effectively on its innovative mandate by providing multi-year, formal and timely pledges and by making timely payments of their contributions.

Revenue by donor, 2009	Value in local currency		Value in US$ (in thousands)
Bill and Melinda Gates Foundation			10,000
Brazil			9,982
Chile			1,346
Cyprus[1]			(27)
France	EUR	110,000	160,009
Luxembourg[2]			93
Madagascar	EUR	8	11
Mauritius	MUR	73,074	2,270
Niger	EUR	190	249
Norway	NOK	140,000	20,118
Republic of Korea			7,000
Spain	EUR	15,000	20,920
United Kingdom	GBP	25,000	42,115
Total revenue			274,087

Notes

[1]Chile committed and paid US$3.4 million in 2010 for 2009

[2]Contribution from Cyprus recorded and reported on in 2008 was received in December 2009 with exchange rate difference/loss of $26, 521, net contribution in US$: 602,409.64

[3]Contribution from Luxembourg recorded and reported on in 2008 was received in November 2009 with exchange rate difference/gain of $92,814, net contribution in US$: 739,644.97

Summary statement of financial position	2008–2009 US$000	2006–2007 US$000
Assets		
Cash and cash equivalents	224,750	196,187
Accounts receivable	42,782	34,174
Total current assets	**267,532**	**230,361**
Total assets	267,532	230,361
Liabilities		
Current liabilities	55	8,232
Non-current liabilities	241	33
Total liabilities	296	8,265
Net assets		
Accumulated surpluses – fund balance	267,236	222,096
Total net assets	267,236	222,096
Total liabilities and net assets	**267,236**	**230,361**

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)
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	Multidrug-Resistant TB
MSF	Médecins Sans Frontières
NGO	Non-Governmental Organization
PMTCT	Prevention of Mother-to-Child Transmission (of HIV)
RUTF	Ready-to-Use Therapeutic Food
SRA	Stringent Regulatory Authority
SRS	Strategic Rotating Stockpile
TB	Tuberculosis
TDF	Tenofovir
UK	United Kingdom
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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