

UNITAID 07

ANNUAL REPORT

UNITAID



TOGETHER TO HEAL

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Special acknowledgements

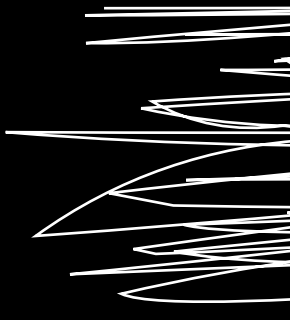
The Secretariat wants to pay tribute to friends that were instrumental in the beginnings of UNITAID. Special thanks to Sandrine Boucher (former Policy and Strategic Coordinator, Secretariat), Jean Dussourd (France), Carlos Paranhos (Brazil), Ernesto Rubarth (Brazil), Claudio Rojas (Chile), Turid Kongsvig (Norway), Carole Presern (United Kingdom), Yong-Soo-Lee (Republic of Korea), Dan Kress (Gates Foundation), Christine Kafando (Association Espoir pour Demain), the team from the French Ministry of Foreign Affairs Economics Department (Jacques Lapouge, Véronique Aulagnon and Sebastien Hua), NUOI (Guilhaume Delvalée), DCGID (Aurélien le Chevallier and Joan Valadou), and Members of the team of Mc Kinsey Company (in particular, Céline Vuillequiez) that was supported by the Bill and Melinda Gates Foundation. We, especially, appreciate the pro-bono contributions of Kate Romain, Esq. and Paul, Weiss, Rifkind, Wharton & Garrison LLP. Nothing could have been achieved without their input and their commitment.

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UNITAID, THE “GLOBAL HEALTH START-UP”

It is a great privilege for me to present UNITAID's first Annual Report. Since the adoption by the UN General Assembly of the Millennium Declaration in 2000, initiatives aimed at improving public health have been at the forefront of the achievement of the Millennium Development Goals. UNITAID is one of them.

But UNITAID is not just another organization in an all-too-encumbered public health landscape. From the inception, our idea was to be different. We wanted to become the missing link between governments, civil society and communities affected by HIV/AIDS, malaria and tuberculosis by focusing on one single issue - the mass improvement of access to more affordable and better quality drugs and diagnostics, thanks to truly innovative, predictable, sustainable and additional funding.

This Annual Report presents many facts and figures, and it gives good news - UNITAID's first promises have been kept.

UNITAID and its partners have concluded, sometimes at a very fast pace, the terms of their cooperation. There have been massive reductions in prices, lead times have been shortened, and the quality of targeted drugs and diagnostics has improved.

In 14 months of activities, there have been remarkable achievements that resulted from truly concerted efforts of a dedicated and competent Secretariat. As Chairman of UNITAID's Executive Board, I feel it was a good start; however, so much remains to be done. I am confident that UNITAID, the «global health start-up», will do always more and better in the times to come. I have recently been appointed by the Secretary General of the United Nations as his Special Adviser for Innovative Financing for Development. This is an extraordinary challenge for me, as the achievement of the Millennium Development Goals desperately needs additional and new sources of funding. It is also an exceptional tribute paid to the work achieved through UNITAID, which I see as one of the most promising blueprints for innovative financing.

Philippe Douste-Blazy
Chairman of UNITAID's Executive Board



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SCALE UP ACCESS TO MEDICINES

UNITAID was launched on 19 September 2006 by five countries, and since that time our membership has grown to include 27 nations. I am delighted to introduce our first Annual Report and Accounts.

Each year nearly 11 million children die worldwide from the three big killers: HIV/AIDS, malaria and tuberculosis. More than half of these deaths are avoidable if we can just scale up access to the care, medicines and vaccines that already exist. UNITAID has been created to take action to help save those lives. We are dedicated to providing better ways of identifying HIV/AIDS, malaria and tuberculosis in poor and vulnerable populations, and providing access to the drugs and treatments that can help give those people back their health.

UNITAID is part of the global response to meet the challenge of the three big pandemics. Everyone affected by HIV/AIDS, malaria and tuberculosis, no matter where they live on the planet, should have access to the drugs and treatments that can mean the difference between life and death. The commitment to help those in need is already strong. Of the eight Millennium Development Goals adopted by the United Nations in 2000 and to be achieved by 2015, three are specifically health related: to reduce child mortality; to improve maternal health; and to combat HIV and AIDS, malaria and other diseases. Nearly 190 countries have since signed up to support those goals, and the World Health Assembly each year has reiterated its support for member states in achieving them. It is our job to help carry out that task. We need to be relentless in turning the commitment to tackle the threat to poor and vulnerable populations from HIV/AIDS, malaria and tuberculosis into practical action to deliver improved health to those in need.

The challenge of combating the world's three major pandemics – HIV/AIDS, malaria and tuberculosis – is enormous. With the mandate UNITAID has been given by the United Nations, and with the commitment from our governing bodies, I am confident that we can rise to meet that challenge. We may follow, we may lead, but we are not alone.

Dr Jorge Bermudez
Executive Secretary of UNITAID

QUALITY OF DRUGS

Twenty-one new quality drugs have been added to pre-existing WHO pre-qualified products, including three for malaria and five for tuberculosis, thanks to our funding to the WHO Prequalification program in 2007. Planning and implementation of a comprehensive sampling and testing programme in the field has been developed jointly with WHO, which, besides testing quality of products, also strengthens regulatory capacity in countries.

HIV/AIDS

In partnership with the Clinton HIV/AIDS Initiative (CHAI), improving access to and availability of paediatric anti-retrovirals (ARVs) in 38 countries has been implemented. The expectation is to expand HIV/AIDS treatment and care to additional 100,000 children, and the same scaling-up level is anticipated until 2010. Not only is UNITAID one of the major funders for paediatric ARVs, but it has also facilitated the introduction of a new fixed-dose combination for children to substitute 16 doses of syrup to just three pills daily. By ensuring the completion of more treatments, resistance to first-line treatments is decreased.

UNITAID is influencing market dynamics, increasing access to treatment, reducing prices, ensuring quality products and reducing the delivery time of medicines to countries in need. Reduction of prices for first-line paediatric treatments, from US\$ 200 to US\$ 60 per patient per year, is a dramatic contribution to scaling-up access and ensuring a sustainable and a larger market.

By establishing a partnership with the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO), UNITAID is accelerating the global scale-up of national PMTCT (Prevention of Mother-to-Child Transmission) of HIV programmes. This enhances the care of pregnant women and their infants by provisioning high-quality diagnostics, treatments and family-inclusive services on a comprehensive approach to care.

MALARIA

Approximately 40% of the world's population is at risk of malaria, mostly in low and middle-income countries. UNITAID, in partnership with UNICEF and WHO, has addressed scaling-up of Artemisinin-based combination therapies (ACT) to Burundi and Liberia, and it has avoided the risk of disruption of treatments. Additionally, and in collaboration with UNICEF and The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), Rounds 1 to 5, delivery of ACT to eight countries has been committed and 13 countries are being supported within the scope of the Global Fund Round 6.

TUBERCULOSIS

UNITAID joins with its partners to ensure that the control of tuberculosis (TB) is being addressed by:

- Making first-line treatments available and accessible in countries;
- Facilitating access for children to appropriate TB paediatric formulations; and
- Making treatments for multi-drug resistant TB available and affordable.

A «stock-out» of first-line treatments for TB has been avoided in 2007, through a partnership between UNITAID and the Stop TB Partnership Global Drug Facility (GDF), by establishing a strategic stockpiling of the products that reduced overall treatment costs. Provision of appropriate-strength paediatric drugs has been ensured, and a total of 180,000 paediatric anti-tuberculosis treatments for children in 35 countries were provided in 2007. Significant price reductions have been achieved.

Treatment against multi-drug resistant tuberculosis is supported by UNITAID and its partners WHO, the Stop TB Partnership (Stop TB) and the Global Fund. The treatment of 4,716 patients is being made possible in 17 countries by funding through the Global Drug Facility. The lack of necessary diagnostics facilities is a major topic for consideration with our partners, as it hampers scaling up access to treatment for MDR-TB.

“MEDICINES ARE
IN THE NORTH
PATIENTS ARE
IN THE SOUTH”

We live in an unequal world. The less developed countries represent 84% of the world's population and suffer more than 93% of the disease, and yet they benefit from less than 11% of global health expenditure.

UNITAID exists to help tackle that imbalance. Our mission is simple: to provide lower-cost life saving medicines for HIV/AIDS, malaria and tuberculosis for people living in countries. The organization was created to address the issues related to the imbalance between population and drug market, high prices and unsuitable treatment regimens.

UNITAID has come a long way in the short time since it was launched in September 2006. Its added value is already clear, in terms of market impact, price reductions, more adaptable drugs and faster delivery to countries. This unique innovative financing facility has established solid partnerships with those fighting the diseases firsthand, and it has provided the means and support to help them do it.

“UNITAID has already achieved 45% price cuts in drugs used against AIDS, malaria and tuberculosis, for the poorest countries of Africa. Time has come for us to give it a new push”.

President Lula da Silva of Brazil, United Nations, 62nd General Assembly, 25th September 2007

THE WAY FORWARD

The way forward and defining future projects are surely the most challenging issues for UNITAID. A new process has been opened with the development of *Pilot Guidelines for the Submission of Project Proposal* and *Pilot Guidelines for the Submission of Concept Notes*.

These guidelines will make a difference in the sense of broadening potential partnerships. Systematic review and assessment of ongoing achievements related to our main objectives are challenging tasks; these will strengthen the amount and the range of tools necessary to enhance access to quality products globally.

New challenges abound; these include additional innovative mechanisms for funding apart from the solidarity contribution on air tickets, which must also ensure sustainability and predictability on the long-term. In addition, UNITAID added value in the implementation of the future Affordable Medicines Facility for malaria (AMFm), which will represent a comprehensive approach to scale-up access to ACT, will be a priority insight in the near future.

A solid strategic approach is emphasized during the quick phase-in and phase-out of niches, in order to achieve long-term and continuous global health impact. UNITAID works through strong partnerships with other global public health players to ensure the best use of resources.

The complementarities between UNITAID and the Global Fund are being addressed with the process of the road map for strategic collaboration; this focuses on opportunities in each of the three disease areas, as well as cross-cutting information sharing, and it highlights the challenge of cementing UNITAID's place as a strategic player in the global health financing landscape.

New niches for action will be decided upon in order to ensure the most impact in the most needed and strategic areas. UNITAID is making a difference today. The goal for 2008 and forward is to continue to grow to make a bigger difference tomorrow.



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GET TOGETHER TO HEAL

MISSION

UNITAID's mission is to contribute to the scale up of access to treatment for HIV/AIDS, malaria and tuberculosis for the people in countries by leveraging price reductions of quality drugs and diagnostics, which currently are unaffordable for many countries, and to accelerate the pace at which they are made available.

This is achieved by making the treatments for these diseases more affordable and speeding up their supply through increased efficiency in the treatment markets.

UNITAID fills a unique and critical gap in the global health financing landscape. It concentrates its efforts on markets where the reduction in the cost of drugs and improvement in supply of high-quality products will have the most impact.

ISSUES

UNITAID was specifically created to respond to the following issues:

- A drug market that is typically structured around demand in the Northern hemisphere and, therefore, does not provide the quantity of drugs required by countries at a price that patients can afford;
- High prices for drugs and other health-related products; and
- Drug combinations and dose frequencies that are not suitable for the needs or comfort of some patients (e.g. children) and that contribute to lower rates of treatment completion.

OBJECTIVES

With these issues in mind, UNITAID has the following objectives in order to speed up access to medicines against HIV/AIDS, malaria and tuberculosis:

- Generate long-term price reductions on medicines and diagnostics, as well as stabilize the market;
- Improve drug quality;
- Shorten the lead time of drug delivery; and
- Drive the development of patient-friendly drugs appropriate for use in countries.

PRINCIPLES

Impact market dynamics through long-term predictable funding

UNITAID funding is based mostly on an air ticket levy. This is an innovative financing source that ensures stable and continuous contributions. It also allows UNITAID to ensure manufacturers and countries, with ongoing commitment on large-scale programmes, to access treatment. UNITAID will base its price reduction strategy on market competition. With sustainable, predictable and additional funding to generate a steady demand for drugs and diagnostics, UNITAID's goal is to trigger price reductions on quality drugs and diagnostics and increase their availability and supply. UNITAID endeavors to deliver better quality drugs at the lowest possible prices.



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Ensure its resources are additional to current initiatives

UNITAID's funding contributions should not replace, divert or substitute existing contributions. UNITAID should aim at supporting national and international efforts and complementing the role of existing international institutions. Additionality is assessed both in terms of funding from other partners and treatments provided to patients.

Serve the needs of the lowest income countries and most vulnerable populations (eligibility criteria)

As stated in its Constitution, UNITAID's objective is to serve the needs of the lowest income countries and most vulnerable populations. To reach this goal it was decided that at least 85% of UNITAID funds should be dedicated to purchase drugs and other products for countries, based on the classification made by international institutions such as the World Bank. No more than 10% of UNITAID funds should be spent on countries, and no more than 5% of UNITAID funds in countries; priority is given to those with a high disease prevalence and to vulnerable groups.

Ensure transparency to stakeholders and to the public

UNITAID is an organization mainly financed through public funding, and, as such, it is focused on transparency and information-sharing. There is particular emphasis on the use of its funds, prices paid for drugs and products, and the impact of its actions. Thus, proposals from our partners for UNITAID funding must include commitments to transparency and information-sharing. UNITAID will be accountable and transparent to stakeholders and to the public, and it will establish policy documents and publish information on its website with the intention of making information available in the most transparent way.

**“SERVE THE NEEDS
OF THE MOST
VULNERABLE
POPULATIONS”.**

Be accountable and develop clear accountability of all of the partners implementing its actions

UNITAID is accountable for the use of its funds. This also applies to its partners. Those seeking funds from UNITAID must establish clear monitoring indicators to assess the success of project implementation, and the progress against these indicators must be reported to UNITAID to establish accountability for results. Continuous reports will trigger further disbursement of funds.

Be an instrument of true global solidarity

UNITAID goes beyond the traditional frontier between the North and the South. As countries make contributions, irrespective of their level of development, the effect is clear- there is a common determination to reduce suffering and to make globalization more equitable.

HISTORY

In September 2000 the United Nations General Assembly adopted the U.N. Millennium Declaration and launched the eight Millennium Development Goals (MDGs). The Goals reflected a consensus of all countries and all leading development institutions on what needs to be done by 2015. Three of the goals were health related and included action on maternal health, the reduction of child mortality as well as the fight against HIV/AIDS and malaria.

In September 2004 a group of 44 pioneering countries agreed on the need for additional stable resources to deliver the three health goals, and committed to working on innovative funding mechanisms. At the request of Brazil, Chile, France and Spain, the work on the implementation of innovative development financing mechanisms accelerated. The need to get drugs to the world's poorest people was identified as a primary target.

UNITAID TIMELINE

September 2006 - France, Brazil, Chile, Norway and the United Kingdom decide to create an international drug purchase facility called UNITAID to be financed with sustainable, predictable resources.

November 2006 - Hosted by the World Health Organization in Geneva, UNITAID Secretariat becomes operational. The first medications funded by UNITAID are children's HIV/AIDS anti-retroviral drugs (Paediatric ARVs) and they are delivered within weeks to China, Malawi and Papua New Guinea, in cooperation with the Clinton HIV/AIDS Initiative. Price reductions and an increase in the availability of children's anti-retroviral drugs are announced.

February 2007 - Eighteen African countries commit to join UNITAID including Benin, Burkina Faso, Cameroon, Central African Republic, Congo, Côte d'Ivoire, Gabon, Liberia, Madagascar, Mali, Mauritius, Morocco, Namibia, Niger, Sao Tome and Principe, Senegal, South Africa and Togo.

May 2007 - Spain joins UNITAID. The First Consultative Forum is held. Price reductions for second line ARVs of between 25 to 50% in 66 countries are announced.

July 2007 - Guinea joins UNITAID.

November 2007 - The Bill and Melinda Gates Foundation joins UNITAID.

December 2007 - The Republic of Korea joins UNITAID and becomes the first Asian country to support the initiative.



GOVERNANCE

Executive Board

The Executive Board is the decision-making body for UNITAID. It makes all decisions relating to UNITAID (except for those delegated to the Secretariat), including the approval of all partnership arrangements with other organizations and institutions. The Board generally takes its decisions by consensus.

The 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 (the Republic of Korea);
- Two representatives of relevant civil society networks (NGOs and Communities Living with the Diseases);
- One representative of the constituency of foundations (the Bill and Melinda Gates Foundation); and
- One representative of the World Health Organization.

Secretariat

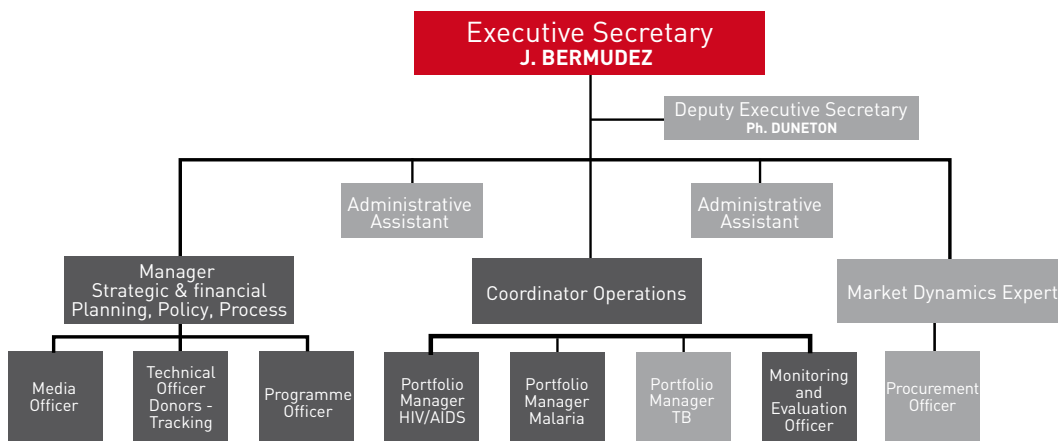
The Secretariat of UNITAID implements the policy set by the Executive Board. It prepares proposed work plans and budgets for approval by the Board, and reports on the results of the actions undertaken and the use of resources. The Secretariat also provides support to the Consultative Forum.

The Secretariat is also responsible for carrying out and managing the day-to-day operations and coordinating implementation of the work plan. It manages relationships with partners, and coordinates their activities, to make sure that the programme is operating efficiently, and that adequate financial monitoring and reporting arrangements are in place and operating effectively. UNITAID Secretariat is hosted by the World Health Organization in Geneva, Switzerland. Its operations, including recruitment, procurement, finance and management of the UNITAID Trust Fund, are administered in accordance with the WHO rules and regulations. The relationship with WHO is governed by a hosting agreement, which allows adaptations or exceptions to WHO administrative procedures and practices to meet needs of UNITAID.

The running costs of the Secretariat are modest. Expenditure incurred since UNITAID was a set-up amount of US\$ 6.4 million, or 1.75% of the budget. This sum corresponds with the requirement that UNITAID operates in a way that keeps its administrative expenditure to a minimum.

The Secretariat, headed by Dr. Jorge Bermudez, Executive Secretary, is currently composed of 15 people from 10 different nationalities. The working languages are English and French.

UNITAID Secretariat Structure





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Consultative Forum

The Consultative Forum was established as a platform for debate, advocacy, fund raising and the inclusion of new partners. Its first meeting in Geneva on May 8, 2007 brought together 120 key figures involved with UNITAID. They included members, partners, countries where UNITAID's support increased access to drugs and commodities, Non Governmental Organizations (NGOs) and communities, international organizations, and the pharmaceutical industry.

The Consultative Forum encouraged UNITAID to develop the coordination of its interventions with other institutions (such as the Global Fund, WHO, UNAIDS and GAVI Alliance) in order to share a global vision and to strengthen the recipient countries' national health systems. It welcomed the support given by the UNITAID Constitution for the use by countries of compulsory licensing under the TRIPS (Trade-related aspects of Intellectual Property Rights) framework where intellectual property barriers hamper competition and price reduction.

The Consultative Forum also supported the funding provided to the WHO Drug Prequalification Programme, and it recommended that UNITAID extends its actions to:

- Fund quality diagnostics in countries in order to lower their prices and make them more widely available; and
- Consider the ready-to-use therapeutic food as an associated component of projects.

TRANSPARENCY

Operating in a transparent and accountable manner is a permanent concern for UNITAID. UNITAID makes the fullest disclosure of records possible, according to a specific transparency policy adopted by its Executive Board in May 2007.

(http://www.unitaid.eu/images/governance/transparency_policy.pdf).

In particular, UNITAID's website (www.unitaid.eu) discloses the Minutes of each Executive Board meeting, the text of all decisions adopted, approved proposals presented by partners, UNITAID's budget and many other documents helpful to understand how UNITAID operates and what are its activities and outcomes.

EXECUTIVE BOARD – KEY DECISIONS 2006/07

In 2006-2007, the Board approved the first programmes of actions totaling US\$ 222.4 million. The Chairman's summary, resolutions endorsed and documents, approved by the Board, along with the full minutes of the Board meetings are available at www.unitaid.eu



UNITAID PERFORMANCE

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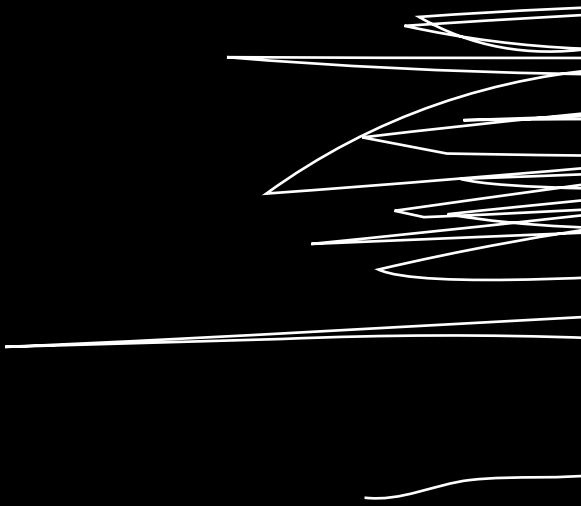
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MAKING A DIFFERENCE

UNITAID is playing a unique and leading role in the actions against HIV/AIDS, malaria and tuberculosis. By focusing its efforts on providing adequate medicines for children, acting to reduce the cost of vital drugs, and increasing availability of «second-line» treatments - vital back up drugs used when first-line treatments fail- UNITAID has helped to both scale up access to medicines and treatments and draw attention to important but neglected health issues.

We are also pioneering new and innovative mechanisms for scaling up diagnosis and treatment for HIV/AIDS, malaria and tuberculosis. By guaranteeing sustainable, predictable and long-term funding we can ensure the supply of drugs and treatments, build strong partnerships with current initiatives, and make a positive impact on how the markets for those drugs and treatments work.

UNITAID ADDS VALUE

UNITAID uses its funding to make a difference in five specific ways:

- Creating a sustainable and predictable market for drugs;
- Reducing prices so that more drugs can be purchased within tight budgets;
- Improving the quality of drugs through the WHO drug pre-qualification programme which encourages manufacturers to invest in both new products and in niche areas;
- Manufacturing drugs that are better adapted to patient needs – for example, fixed-dose combinations; and
- Delivering drugs faster to places where they are most needed.

MARKET IMPACT

By guaranteeing sustainable, predictable revenues for the purchase of drugs, UNITAID plays an important role in influencing manufacturers.

For each target market, UNITAID analyses the dynamics of the market in order to identify and target key problem areas. Based on this understanding, UNITAID uses its purchasing power to drive long-term changes in the global market that will increase access to drugs for those in countries. This market-specific orientation is unique to UNITAID, and we anticipate that the resulting price reduction will benefit other funding organizations and, in turn, dramatically scale up access to treatment.

PRICE REDUCTION

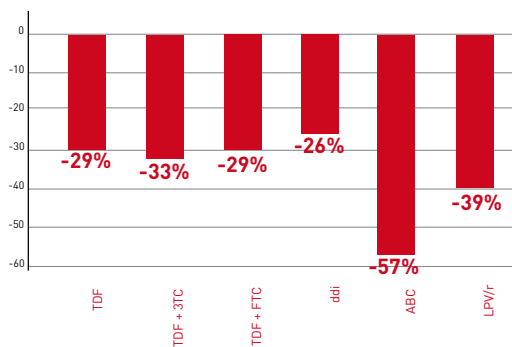
Although prices of HIV medicines have generally been reducing over the last five years, UNITAID has driven them down even further. UNITAID in partnership with the Clinton Foundation HIV/AIDS Initiative started a US\$ 35.9 million dollar project to improve access to and availability of paediatric ARVs in 38 countries.

The first phase of this project ended in December 2007. The main objectives included: the expansion of HIV/AIDS treatment and care to 100,000 new children; the stimulation of market competition and the development of paediatric formulations and fixed-dose combinations that were not previously available; and the contribution to price reductions of anti-retroviral drugs and monitoring and diagnostic tests. Among its accomplishments, this project enabled the reduction of paediatric anti-retroviral drugs by an average of 40%, facilitated the introduction of triple paediatric fix dose combinations (FDCs) and other paediatric formulations, and has supplied diagnostics and treatment for 102,000 young people (including 62,000 new treatments) in 38 countries as of November 2007. The UNITAID Board has approved the project extension for 2008, and it has stressed the interest to continue to provide funds until 2010. The extension for 2008 has a budget of US\$ 58.5 million.

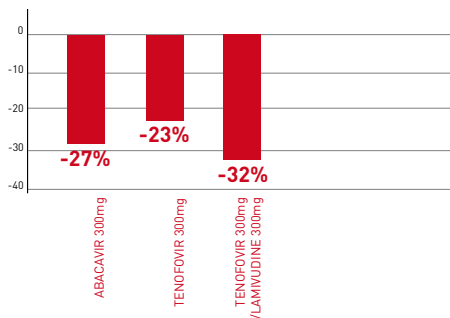
Efforts to secure significant price cuts for six adult second-line ARV formulations have been made possible through UNITAID's strategic collaboration with CHAI. US\$ 35.9 million was committed by UNITAID for this purpose in 2007 to cover commodities in 27 countries, 23 of which are in Sub-Saharan Africa. Relative to on the income-level of the country in question, price reductions achieved so far have ranged between 23% and 49%. Although the price of second-line regimens remain significantly higher than first-line regimens, the extension of the Second-Line Project until 2009 will enable UNITAID to negotiate with suppliers and reduce the price of a priority regimen to approximately US\$ 400 per person per year. UNITAID estimates that with a 20% reduction, donors and low-income countries could save over US\$ 600 million on ARVs by the end of the decade.

UNITAID ADDED VALUE ON PRICE

REDUCED PRICES :
more drugs available for the same budget



30 November 2006
on antiretroviral
for HIV positive children
(with the Clinton foundation)



8 May 2007
on second-line
antiretroviral
(with the Clinton foundation)



©WLF/Gary Hampton



©WHO/TDR/Grump



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©Thomas Moran

PROMOTING BETTER QUALITY DRUGS

Ensuring new, good quality products to treat HIV, malaria and TB is essential to maintaining successful efforts to reduce the global burden of disease from these causes. UNITAID is helping to support the process of getting new formulations and products on the market quickly. For example, with one year's support from UNITAID and co-funding by the Bill & Melinda Gates Foundation, WHO's Prequalification Programme completed the assessments and inspections to pre-qualify an additional 21 products including five anti-tuberculosis and three anti-malarial medicines. The prequalification of anti-tuberculosis and anti-malarial products represented a significant achievement in 2007, since they were the first products to be pre-qualified since 2005 and 2006. UNITAID support enabled:

- Streamlining of the process between receiving a complete dossier and the first assessment or inspection of manufacturing sites;
- Development of tools to increase transparency and allow public monitoring of the prequalification process;
- The doubling of the number of training workshops for capacity building of manufacturers and regulatory authorities in resource-limited countries;
- The organization of 10 technical assistance missions for manufacturers to support improvements in the quality of their products; and
- Development of guidelines and standards to facilitate global quality assurance activities, including pharmacopoeial monographs and chemical reference substances.

In addition, planning and implementation of a comprehensive sampling and testing programme have been developed. Four countries - Kenya, Tanzania, Uganda and Zambia - have indicated their willingness to pilot this initiative, which will be carried out with the respective national regulatory authorities and with protocols that take into consideration the precise requirements of each country. At an early stage, this activity will cover anti-retrovirals and co-trimoxazole; by the end of June, a second phase will expand the number of countries and products to be tested. UNITAID support has further enabled the WHO Prequalification Programme to restart the prequalification of laboratories in low and middle income countries. Training for laboratory staff and technical assistance were organized to help laboratories proceed further in the prequalification procedure. In total 102 staff members from 51 countries from four regions were trained and three national quality control laboratories in Africa were assisted.

ADAPTING DRUGS TO PATIENT NEEDS

One size does not fit all when it comes to drug formulations to treat HIV, malaria and TB. Children especially are in need of formulations that are adapted to their size and use. Currently, adult formulations are provided to children in reduced form. For example, although 10% of TB cases are in children, paediatric TB has been largely neglected, with little focus on the specific treatment needs of children.

Based on WHO guidelines, UNITAID is using its sustainable funding to attract new suppliers to the market and to foster the creation of new paediatric formulations and fixed-dose combinations (FDCs) of medicines. It aims to achieve significant price reductions for these products of up to 25% by 2010.

In January 2007, UNITAID provided financial support to the Global Drug Facility (GDF) of the Stop TB Partnership for the provision of appropriate-strength paediatric drugs for children under age 15 and to ensure the development of new child appropriate formulations for infants under age five.

DELIVERING DRUGS FASTER TO MEET COUNTRY NEEDS

In high disease burden countries, demand for the medicines required can exceed supply. UNITAID is working to ensure that countries have the supplies that they need at the right time and in the right place.

For example, UNITAID programme support, in collaboration with UNICEF and WHO, has been critical in speeding up the delivery of emergency supplies of Artemisinin-based Combination Therapies (ACT drugs) in Liberia and Burundi. The emergency supplies were delivered to Liberia and Burundi for timely distribution.

The rapid deliveries were enabled by UNITAID's quick decision-making process and strategic partner-selection, and they benefited from prior negotiations with manufacturers and suppliers.

UNITAID's support in 2007 ensured that 678,275 ACT treatments were delivered in Liberia and a further 722,953 treatments to Burundi in that year.

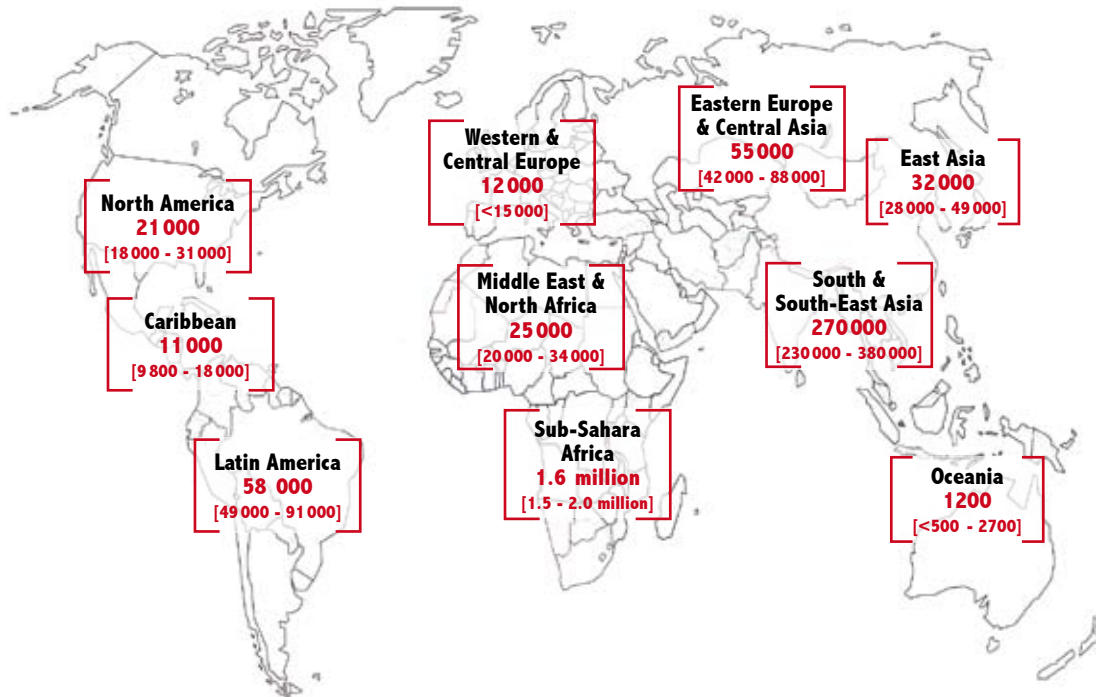
PRINCIPLE ACTIVITIES

FIGHTING THE THREE PANDEMIC



FIGHTING HIV/AIDS

ESTIMATED ADULT AND
CHILD DEATHS FROM AIDS,
2007



Source of Data: UNAIDS; 2007 AIDS Epidemic Update

TOTAL: 2.1 [1.9 - 2.4] MILLION

HIV/AIDS is one of the most serious epidemics in countries and remains a serious challenge to public health. Although some progress has been made, the impact of the epidemic remains high. UNAIDS and WHO estimate that, in 2007, 33.2 million people were living with HIV worldwide. Over two million people died of AIDS in 2007. Sub-Saharan Africa remains the most seriously affected region.

Children are particularly affected by HIV. In 2007, 2.5 million children were infected and 330,000 children died. Transmission of the virus from infected mothers to their children occurs because these women do not have access to preventive anti-retroviral treatment during and after pregnancy. In fact, only 11% of pregnant women living with HIV in 2005 received ARV prophylaxis. Nearly 90% of HIV positive children live in sub-Saharan countries, a region that remains a priority for UNITAID support.



In December 2006, only two million people were receiving anti-retroviral treatment in low and middle-income countries, representing 28% of the estimated 7.1 million people in need. Although the highest burden is in sub-Saharan Africa, only 1.3 million people on anti-retroviral treatment (28%) are in this region.

Countries are unable to scale up anti-retroviral treatment to meet their growing need because of several factors among which are human resources shortages and other health systems related gaps; the high cost of ARVs (including the even greater expense of 2nd line ARVs); diagnostic tests for early diagnosis of people living with HIV in particular identifying pregnant women at risk of transmitting the disease to their children; and the poor or low access to paediatric ARVs. The following sections provide an overview of the actions that UNITAID is taking to address these specific problems in high burden countries.

ANTI-RETROVIRAL (ARV) DRUGS FOR CHILDREN

As an example of the improvement UNITAID is making to a child's quality of life and disease outcome, the new fixed-dose combinations (FDC) requires a patient to take only three pills a day instead of the alternative 16 doses of syrup. The result is that more treatments are completed and resistance to first line drug treatments is reduced.

UNITAID ADDED VALUE ON QUALITY

Pediatric FDC make easier HIV/AIDS treatment, for patients but also for healthcare professionals.

UNITAID use of funds allows to have manufactured drugs **better adapted** to patient needs (fixed-dose combinations)





©UNAPIS/L Taylor



©WHO/Pierre Viot

Paediatric ARVs: an example of market analysis

A strategic role of UNITAID is to understand and assess the market of medicines and diagnostics of the different areas which UNITAID supports, and considerable work has been done on analysis of pharmaceutical markets. More recent assessment of some of the HIV/AIDS areas has shown that UNITAID is well positioned to influence the market in 4 different ways to benefit patients treated by UNITAID-funded products. These are by:

- Increasing access to anti-retroviral treatment, including fixed-dose combination (FDC) medicines and encouraging more suppliers to enter the market;
- Reducing ARV prices available to people in low income countries;
- Making internationally certified quality ARVs available; and
- Reducing the delivery time of ARVs to countries.

UNITAID is actively addressing these objectives. For example, with the Paediatric ARV area, UNITAID may contribute to the increase of the number of children treated. A baseline of 170,000 treatments was established for early 2008, aiming at achieving 270,000 children in treatment by the end of the year, and 100,000 additional children a year may be supported in 2009 and 2010, amounting to 470,000 children in treatment by the end of 2010.

The price of first-line ARV regimens has been reduced significantly, from US\$ 200 to US\$ 60 per patient per year, since the beginning of the Paediatric HIV/AIDS project, and is not expected to be reduced significantly in the next few years. However, the low prices will be made increasingly available by increased uptake of these products.

A larger and sustainable market stimulates industry to formulate new quality products. In 2008 UNITAID will extend the Paediatric ARV Project to make funds available, to source 14 new paediatric treatment formulations, and in particular AZT-based FDCs, which are more suitable for children. As new formulations are submitted by manufacturers to WHO or other regulatory agencies, UNITAID makes them available to patients through the Paediatric ARV project, and in compliance with national treatment guidelines.

Reducing delivery times of products to patients and avoiding stock out situations are the key concerns for the Paediatric HIV/AIDS project. ARV delivery lead times, for example, have been reduced from 13 to 10 weeks, and UNITAID and CHAI are assessing options to reduce it even further in 2008.

50 RECIPIENT COUNTRIES FROM UNITAID FUNDS AGAINST HIV / AIDS

AFRO

- Angola
- Benin
- Botswana
- Burkina Faso
- Burundi
- Cameroon
- Chad
- Cote d'Ivoire
- DRC
- Ethiopia
- Ghana
- Guinea
- Kenya
- Lesotho
- Liberia
- Malawi
- Mali
- Mozambique
- Namibia
- Nigeria
- Rwanda
- Senegal
- Swaziland
- Tanzania
- Togo
- Uganda
- Zambia
- Zimbabwe

SEARO

- India
- Thailand

WPRO

- Cambodia
- China
- Lao
- Papua New Guinea
- Vietnam

AMRO

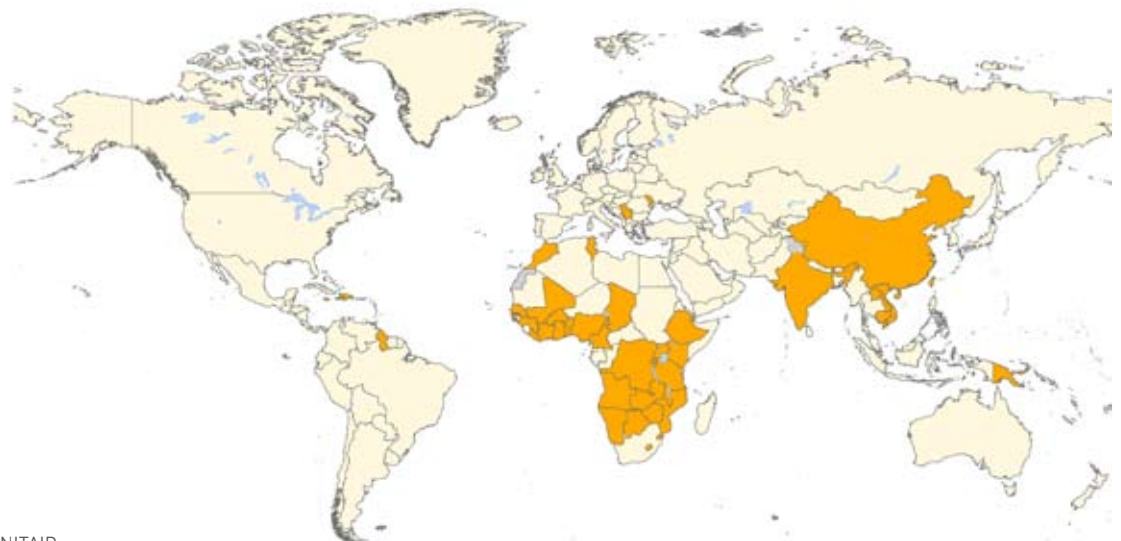
- Dominican Rep.
- Guyana
- Haiti
- Jamaica
- OECS (Dominica, St Lucia, Antigua & Barbuda, Grenada, St Christopher & Nevis, St Vincent & Grenadines)

EURO

- Moldova
- Serbia

EMRO

- Djibouti
- Morocco
- Tunisia



UNITAID funding against HIV/AIDS, 2007
 ■ Recipient countries
 ■ No data

SECOND-LINE HIV/AIDS ANTI-RETROVIRAL DRUGS

In May 2007, UNITAID, in partnership with the Clinton Foundation HIV/AIDS Initiative, disbursed US\$ 35.9 million designed to benefit 26 countries to provide adult second line ARVs. The objective is to influence the market to reduce the price of key second-line drugs. While promoting price reduction, the project is stimulating market competition and providing incentives to new manufacturers of anti-retroviral drugs. UNITAID is currently supplying second-line anti-retroviral drugs for 56,000 new patients in 22 countries. The UNITAID Board has approved a budget of US\$ 64.3 million for 2008, and the project is expected to continue its price negotiation and supply activities through 2009.

Anti-retrovirals funded by UNITAID are those that are prequalified by WHO or another equally stringent international regulatory agency. As some products come from a single or limited number of sources, UNITAID encourages non-prequalified manufacturers to submit a complete dossier for the prequalification of their products. This ensures that quality, new ARVs are available on the international market.

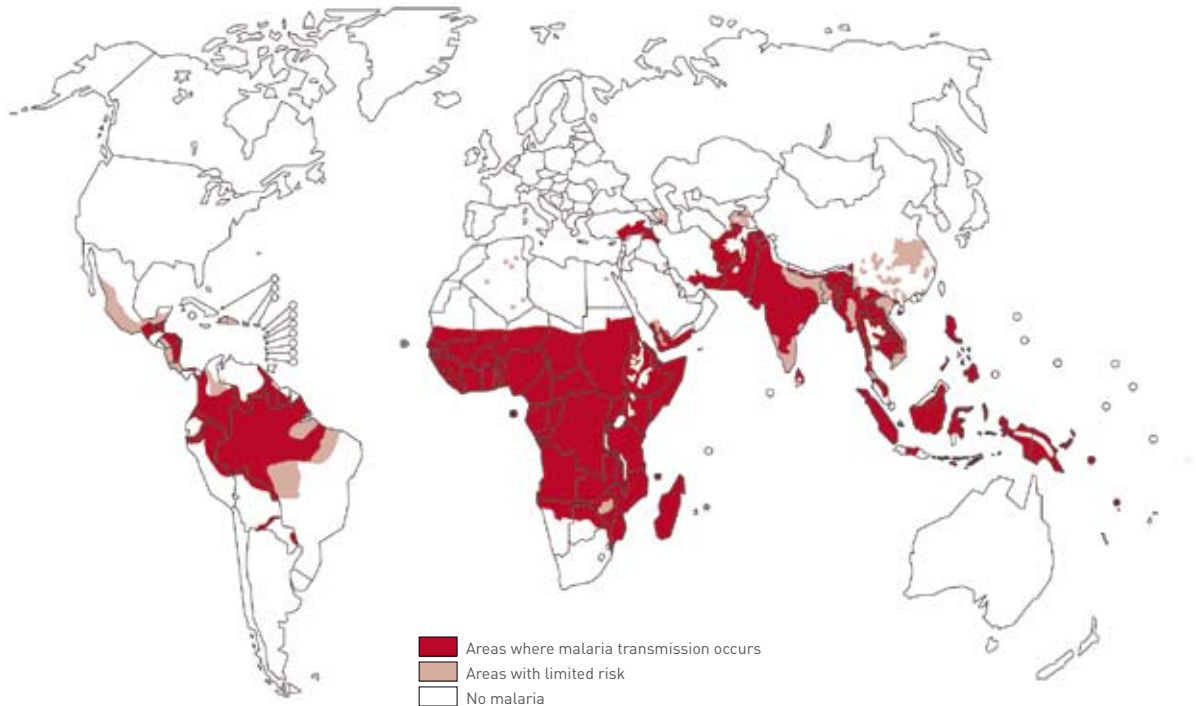
ACCELERATION OF PREVEN- TION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT) AND SCALING UP OF LINKAGES TO PAEDIATRIC HIV CARE AND TREATMENT FOR 2007-2009

This initiative is being undertaken by UNITAID in partnership with UNICEF and WHO to support the acceleration of the global scale-up of national PMTCT programmes. It is designed to enhance the care of infected pregnant women and their infants and fill the existing gap in the provision of quality drugs and diagnostics and family-inclusive services. In the framework of further implementation of WHO's recent PMTCT guidelines for treating pregnant women and preventing HIV infection in children in low resource settings, UNITAID is providing US\$ 20.8 million for the procurement and delivery of high quality HIV drugs, diagnostics and related PMTCT commodities, including more effective anti-retroviral (ARVs) drug combination treatments for treating pregnant women and preventing HIV in infants at a lower cost, for a period of 24 months. Infants identified as being infected with HIV, will be referred for treatment through UNITAID/ CHAI paediatric HIV/AIDS treatment programmes. Recipients are in seven low-income countries (Burkina Faso, Cote d'Ivoire, India, Malawi, Rwanda, Tanzania and Zambia), and in one low-middle-income country (Cameroon). The women and infants reached are being closely monitored against the specific targets set. In addition, increased access to primary prevention and family planning services will be secured in the eight countries via the improved integration of PMTCT services into antenatal care and stronger linkages with sexual and reproductive health services.

| Interventions | Targets | | | | | | |
|---------------|---|---|--|--|--|--|---|
| | HIV+ Pregnant Women receive more efficacious ARVs for PMTCT | No. of HIV + Pregnant Women receiving CD4 tests | No. of HIV + Pregnant Women in need of AntiRetroviral treatment* | No. of HIV + mothers in needs of Cotrimoxazole | HIV-exposed infants access to PCR-testing at 6 wks** | HIV-exposed infants receive Cotrimoxazole 6 months if PCR tested | HIV-exposed infants receive Cotrimoxazole 24 months if not PCR tested** |
| Total Year 1 | 51.303 | 45.085 | 5.972 | 28.231 | 33.715 | 24.850 | 19.652 |
| Total Year 2 | 117.181 | 109.731 | 17.090 | 71.235 | 73.997 | 46.713 | 51.511 |

FIGHTING MALARIA

MALARIA 2006



Source of Data: National Travel and Health 2007

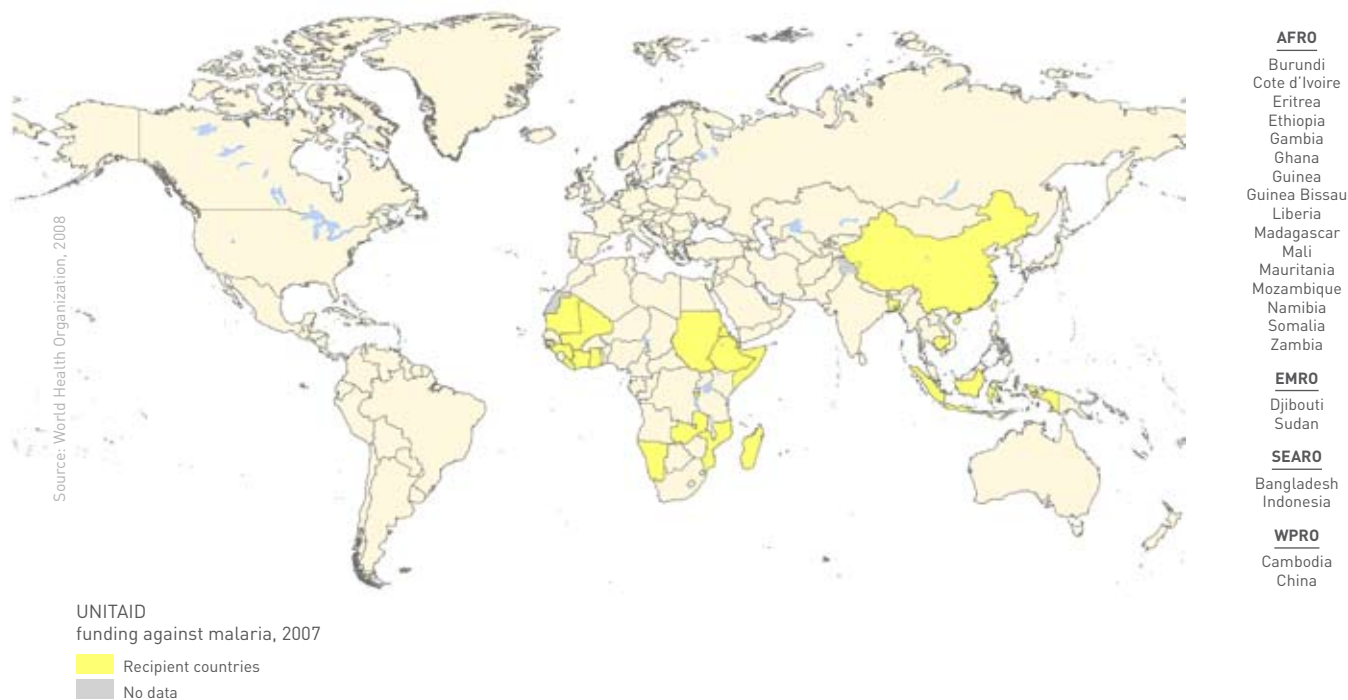
Malaria is a disease that can be transmitted to all ages. It is caused by parasites of the species *Plasmodium* that are spread from person to person through the bites of infected mosquitoes.

The common first symptoms – fever, headache, chills and vomiting – appear 7 to 25 days after infection. If not treated promptly with effective medicines, falciparum malaria can cause severe illness that often leads to death.

Approximately 40% of the world's population, mostly those living in the countries, are at risk. Each year, more than 500 million people become ill with malaria (approximately 1% progress to severe disease). Most cases and deaths are in sub-Saharan Africa, however, Asia, the Americas, the Middle East, parts of Europe and parts of the Pacific Region are also affected. Early diagnosis and prompt treatment with anti-malarial drugs are the basic elements of malaria control.

Unfortunately, the rapid spread of antimalarial drug resistance over the past few decades has required more intensive monitoring of drug resistance to ensure proper management of clinical cases. Where malaria has become resistant to chloroquine and sulfadoxine-pyrimethamine, treatments widely available and used in countries, treatment with artemisinin-based combination therapies (ACTs) is recommended. ACTs are more expensive and less accessible to people in endemic malaria areas.

22 RECIPIENT COUNTRIES FROM UNITAID FUNDS AGAINST MALARIA



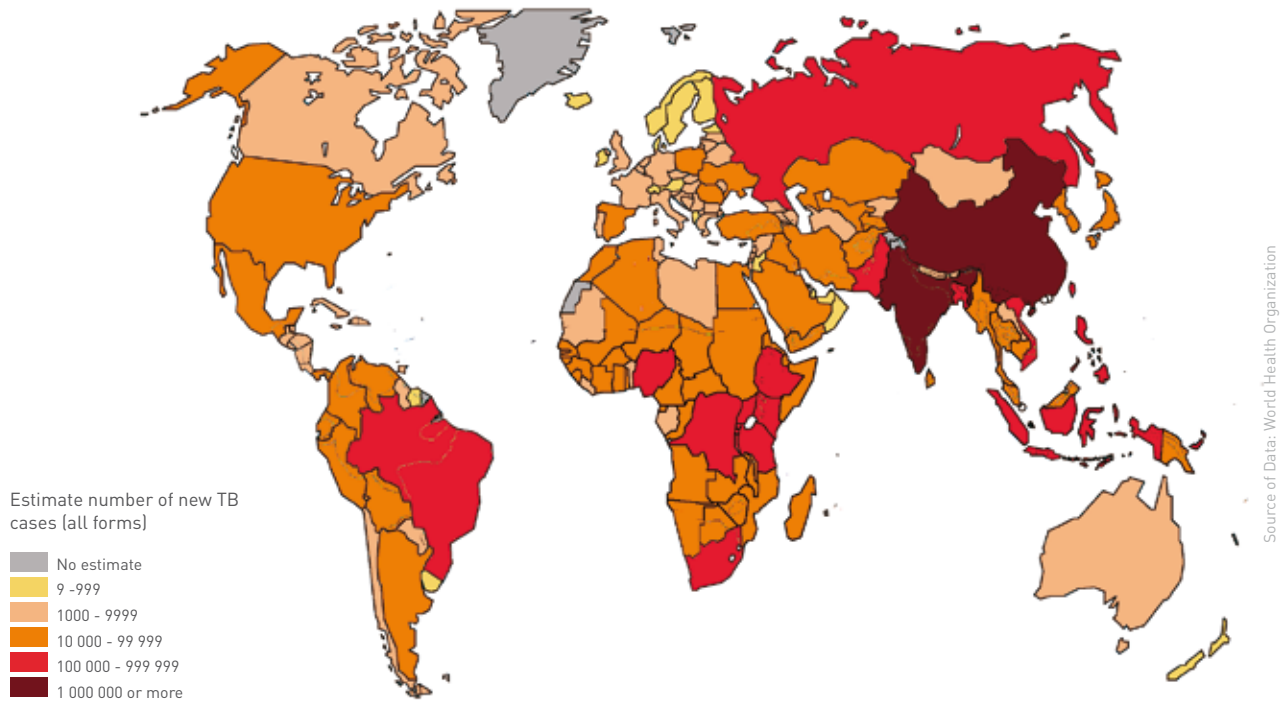
SCALING UP ARTEMISININ-BASED COMBINATION THERAPIES (ACT)

UNITAID is contributing to efforts to scale-up malaria control in endemic countries by helping to make artemisinin-based combination therapies (ACTs) more accessible and more affordable. UNITAID, in partnership with UNICEF and WHO, delivered more than 1.4 million ACT treatments in Burundi and Liberia, which faced risks of disruption in treatments in 2007. The close collaboration between UNITAID and its partners made it possible for the medicines to reach Liberia and Burundi for timely distribution to save lives.

In late December 2007, UNITAID finalized a Memorandum of Understanding (MOU) with UNICEF and the Global Fund to complement the delivery of ACTs in eight countries through the Global Fund's funding allocations (Rounds 1 to 5). The budget ceiling for this scale-up project is US\$ 78.9 million, and it will support the identified grants for the remainder of their lives. The beneficiary countries are: Cambodia, Ethiopia, Ghana, Indonesia, Madagascar, Mozambique, Sudan, and Zambia. UNITAID has also committed to provide US\$ 21.5 million for 13 countries including Bangladesh, Cambodia, China, Cote d'Ivoire, Djibouti, Eritrea, the Gambia, Guinea, Guinea Bissau, Mali, Mauritania, Namibia, and Somalia, through the Global Fund grant allocation (Round 6). UNITAID and its partners are currently in discussion regarding the possibility of establishing a co-payment mechanism through the Affordable Medicine Facility for malaria (AMFm) to increase access to ACTs.

FIGHTING TUBERCULOSIS

ESTIMATED NUMBERS OF
NEW CASES, 2006



Tuberculosis is an airborne infectious disease that is preventable and curable. People ill with TB bacteria in their lungs can infect others when they cough. Nearly nine million new cases of TB were estimated to have occurred globally in 2005. If TB disease is detected early and fully treated, people with the disease quickly become non-infectious and eventually cured. Multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), HIV-associated TB, and weak health systems are major challenges. UNITAID is supporting the control of TB by helping to ensure that:

- First-line treatments are always accessible and available in countries;
- Children have access to appropriate paediatric formulations to cure TB; and
- Treatments for multi-drug resistant TB are available and affordable in countries.

First-line treatments against tuberculosis – transitional grants and rotating stockpiles

In collaboration with the Stop TB Partnership's Global Drug Facility (GDF), UNITAID is using transitional grants to minimize the risk of drugs temporarily becoming unavailable – a situation known as a «stock-out». By establishing strategic rotating stockpiles of drugs, lead times for drug deliveries and the overall treatment costs have been reduced. This has also led to prices of anti-TB drugs being held in check in the short-term (2007/2008) and opens up the prospect of price reductions in the medium-term (2009).

58 RECIPIENT COUNTRIES FROM UNITAID FUNDS AGAINST TUBERCULOSIS



Source: World Health Organization, 2008

UNITAID funding against tuberculosis, 2007

■ Recipient countries
 ■ No data

- | | |
|---------------|------------------------|
| AFRO | EURO |
| Benin | Azerbaijan |
| Burkina Faso | Bosnia and Herzegovina |
| Cape Verde | Belarus |
| Cameroon | Bulgaria |
| Congo | Georgia |
| Cote d'Ivoire | Kyrgyzstan |
| DRC | Kazakhstan |
| Gambia | Moldova |
| Guinea | Tajikistan |
| Kenya | Uzbekistan |
| Lesotho | |
| Madagascar | EMRO |
| Malawi | Afghanistan |
| Mali | Djibouti |
| Mauritania | Egypt |
| Mozambique | Iraq |
| Niger | Lebanon |
| Nigeria | Pakistan |
| Rwanda | Syrian Arab Republic |
| Somalia | Yemen |
| Tanzania | WPRO |
| Togo | Cambodia |
| Uganda | Lao |
| Zambia | Philippines |
| | Vietnam |
| SEARO | AMRO |
| Bangladesh | Dominican Rep. |
| Bhutan | Guatemala |
| India | Haiti |
| Indonesia | |
| Myanmar | |
| Nepal | |
| Sri Lanka | |
| Timor-Leste | |

Development of new child-appropriate treatment formulations for children under four and providing appropriate strength paediatric drugs for children under Age 15

In January 2007, UNITAID provided financial support to the Global Drug Facility (GDF) of the Stop TB Partnership for the provision of appropriate-strength paediatric drugs for children under age 15 and to ensure the development of new child-friendly formulations for infants under age 5. A total supply of 180,000 anti-tuberculosis treatments for children in 35 countries was provided in 2007.

The Global Drug Facility has been able to pool its procurement activity, with the financial support of UNITAID, in order to generate significant price reductions for paediatric anti-tuberculosis drugs. UNITAID's funds have contributed to expand the supply of paediatric anti-tuberculosis drugs to approximately 600,000 children in an estimated 40 countries. These drugs will be supplied over a 3-year-period (2008-2010).

Treatments against multi-drug resistant tuberculosis (MDR-TB Scale-up Initiative)

Working together with the Stop TB Partnership, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and WHO, UNITAID is helping to increase the access and affordability of quality-assured second-line anti-tuberculosis drugs for use in MDR-TB control. By providing funding through the GDF, UNITAID would make it possible to procure and supply an estimated 4,716 patient treatments to MDR programmes in 17 countries by the end of 2011.

Good results have already been achieved. A rotating stockpile production process has been established; joint activities with the WHO drug prequalification programme continue; and competitive prices for drugs and treatments have been achieved through direct negotiation.



DEFINING FUTURE PROJECTS

The UNITAID Secretariat, as requested by the Board, embarked on a process to formalize the procedures for submitting funding requests. As a result, Pilot Guidelines for the Submission of Project Proposals and Pilot Guidelines for the Submission of Concept Notes were developed, to be further refined on the basis of lessons learnt drawn from the first round of submissions. An invitation to submit full proposals was issued to present partners and a public call for the submission of concept notes was published.

Pilot Guidelines for the Submission of Project Proposals

The pilot procedures outlined for the submission of funding proposals and decision by the Board represent a refined process. This is designed to explore any appropriate innovative approach to improve market diversification and make quality and more appropriate drug formulations available more rapidly and at the lowest possible price in countries.

To ensure a rigorous and transparent review and approval of funding proposals, all proposals must be presented using the Proposal Template drawn up to render the assessment more just and expedient.

The review process includes a screening by the UNITAID Secretariat and technical assessment by an Interim Expert Advisory Group, made up of independent experts in HIV/AIDS, malaria and TB, in public health and market dynamics. The proposals are assessed according to criteria set out in an evaluation sheet. On the basis of recommendations emanating from the review process as to technical soundness, consistency with UNITAID's strategy and other relevant factors, the Board will make its decision.

Pilot Guidelines for the Submission of Concept Notes

These pilot Guidelines have been drafted in response to UNITAID's wish to expand its range of partners and niche interventions to enlarge the implementation of its current strategy and to leverage its added value through innovative approaches and new ideas for additional projects. These Guidelines have been introduced to increase the scope of UNITAID's current programmes and to broaden its collaborative partnerships and are designed to encourage the exploration of novel approaches or different operating models to impact the market, increase the affordability of critical drugs and address other significant health challenges in line with UNITAID objectives.

The approval process of concept notes includes a review by the Secretariat, and may include a technical assessment by a small group of experts, before being presented to the Board.

FUNDING

Bill Clinton: «Even those who don't like taxes are not reluctant to pay a contribution for a good cause.»

Finding new and innovative funding

To fulfil its mission, UNITAID makes use of sustainable, predictable and additional funding to help generate a steady demand for drugs and diagnostics. By doing this it significantly changes the way the market for those drugs operates, leading to reductions in prices and increases in availability, quality and supply in countries. By guaranteeing sustainable predictable revenue for the purchase of drugs, UNITAID plays an important role in influencing the market.

We are able to do this because all of our contributors are committed to providing us with sustainable, predictable and additional funding, either through the solidarity contribution on airline tickets or through multi-year budgetary contributions.

In the spotlight: the solidarity contribution on airline tickets

One of the most innovative proposals designed to bring new funding for the achievement of the Millennium Development Goals was the implementation of a solidarity contribution on airline tickets, more commonly called 'air ticket tax'. This was chosen as an

economically neutral tool which is feasible to implement at the national level and well-suited to mobilizing predictable resources to provide sustainable access to medicines. Each country decides what rate to introduce and what it will apply to, for example all flights or only international flights; all classes or only business class etc. All countries are invited to confirm their intention to allocate the proceeds of the levy to UNITAID. Chile, France, Guinea, Mauritius, Niger and the Republic of Korea have implemented such a contribution, and other countries are preparing its implementation in 2008.

The solidarity contribution on airline tickets is a simple and effective mechanism that has no negative economic impact.

For example, in spite of the implementation of a tax on air tickets in France on 1 July 2006, Air France passenger traffic, per the latest budget Report from the French Parliament, has increased in 2006 and 2007 by more than 5%.



RESOLUTION

adopted by the General Assembly of the United Nations (20 December 2006):

“Recognizing the value of developing innovative sources of financing from various sources on a public, private, domestic and external basis to increase and supplement traditional sources of financing. Welcoming the contribution to the mobilization of resources for development through innovative financing initiatives taken by groups of Member States (including the International Drug Purchase Facility-UNITAID).”

The French case for the ‘air ticket tax’

The solidarity contribution on airline tickets came into force on 1 July 2006. France has opted for a progressive mechanism based on destination and class. In 2007, 90% of the tax product has been dedicated to UNITAID (€160 million).

| | Economy class | Business/first class |
|------------------------|----------------------------|----------------------|
| National flight | 1€ | 10€ |
| Intra-European flight* | } 70% of the flights 1€ | 10€ |
| International flight | 4€ | 40€ |



An aircraft with 300 passengers on board leaving from Paris will cover the treatment for 1 person with multi drug resistant tuberculosis, which is very expensive (approx \$ 4.000)

Impact of the air tickets levy: an example

| Tax received on each ticket by UNITAID (in France) | Economy class | First class or business |
|--|---|--|
| Flight in France or in Europe | 1€ ANTIMALARIAL TREATMENT FOR 2 CHILDREN ex: flight Paris - Berlin | 10€ |
| International flight | 4€ | 40 € 1 HIV-positive child under treatment for 1 year ex: flight Paris - Dakar |

CONTRIBUTORS

UNITAID:

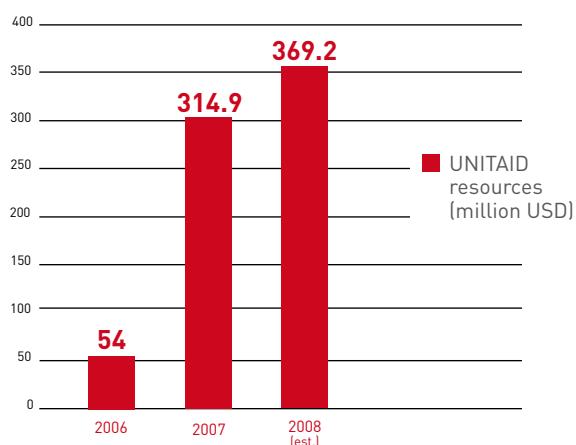
All members, all contributors, all equal

UNITAID has already demonstrated in its first year that it is an important part of the global response to the huge economic damage, social disintegration and political instability that HIV/AIDS, malaria and tuberculosis cause across the world.

But through the unique way we are funded we also have the opportunity to be the key tool of global solidarity when it comes to combating these diseases, bringing down the traditional barriers between «donor» and «beneficiary» countries.

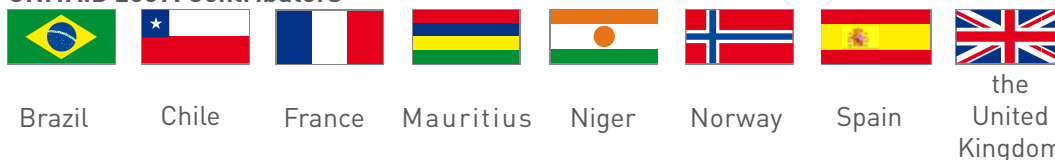
All UNITAID member states are encouraged to contribute to financing its operations in due proportion of their respective wealth. In 2007, 19 African countries have joined and pledged to commit funds to UNITAID. Mauritius and Niger have already taken the lead by making contributions in 2007.

**UNITAID funding:
Picking up**



BILL & MELINDA GATES foundation

UNITAID 2007: Contributors



«UNITAID IS SOMETHING FANTASTIC!»
Bill Gates



The way UNITAID funds can be used is very specific. Money is restricted exclusively to financing the purchase and supply of high quality drugs, diagnostics and related commodities including all reasonable costs for quality assurance, shipping, insurance and related procurement management. However, UNITAID funds may not be used to finance operating costs or to pay for administrative expenses that are covered by our partners. In 2007, UNITAID worked with a small number of well-recognized partners (see table) who played a key role in UNITAID activities. Building on the experiences of the last year, UNITAID has published pilot guidelines in January 2008 to better inform existing and potential partners on what working with UNITAID involves. UNITAID remains keen to diversify its collaborative partnerships and welcomes proposals for new market niches and invites the submission of Concept Notes.

UNITAID funding: additional only

UNITAID funding should not replace, divert or substitute existing resources. As stated in its constitution, UNITAID aims to support national and international efforts, and to complement the role and commitments of existing international institutions and national Governments. Programmes which receive UNITAID funding therefore need to enhance existing programmes or demonstrate added value.

Partners, not countries

Countries themselves cannot apply directly for UNITAID funding. UNITAID works through its partners to provide drugs, diagnostics and treatment to those in need.

UNITAID and the Global Fund: a special partnership»

UNITAID responded to a request from the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria (GF) for US\$52.5 million to purchase drugs under its funding Round 6, Phase 1. It has been agreed that US\$8.7 million of UNITAID funds will be used exclusively to finance second line ARVs; US\$21.5 million will be used to buy ACTs; US\$10.3 million for the purchase of MDR-TB treatments; and US\$12.0 million will be spent on paediatric ARVs. The Global Fund allocations to beneficiary countries are consistent with UNITAID eligibility criteria (at least 85% to low-income countries).

UNITAID'S PARTNERS



UNITAID AND THE WORLD HEALTH ORGANIZATION (WHO)

«For me, one of the most encouraging trends in public health today is the power of commitment to unleash the best of human ingenuity. Let me give just one example -. UNITAID. This facility for purchasing drugs draws funds primarily from a levy on airline tickets. This is the kind of hard-nosed pragmatism that gets results in public health.»

(Dr. Chan, opening the 122nd WHO Executive Board Session in Geneva on 21 January 2008)

WHO – UNITAID’s host

In line with the Memorandum of Understanding signed on 19 September 2006, the World Health Organization (WHO) serves as UNITAID’s trustee and also hosts its Secretariat. WHO was a natural choice as a parent for UNITAID, given its internationally agreed role to coordinate action in the field of health. WHO offers UNITAID a strategic platform from which to operate, as well as provides its legal identity and important administrative and technical support. Although UNITAID’s Secretariat does not constitute a separate legal entity within WHO, it does enjoy a large degree of autonomy, and it is free to take a flexible approach to fulfilling its missions. Use of WHO’s legal, financial and administrative services provides an added assurance to the proper use of UNITAID’s resources, while generating an administrative cost.

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

UNITAID’s positioning within WHO also demonstrates why its secretariat is and intends to remain lean.

The thinking behind UNITAID’s creation was not to create more bureaucracy or more competition with existing organizations. UNITAID is designed to be flexible in order to maximise the impact it has on the market through innovative approaches and providing the missing link between these sectors. The secretariat is responsible for managing the day-to-day operations of UNITAID and for coordinating its partners’ activities. It also liaises with contributors, Board members, partners and commercial organizations and is able to rapidly consult and communicate with WHO. UNITAID’s Executive Secretary acts as the chief executive officer of UNITAID, providing the overall management and leadership to the secretariat and takes responsibility for the day-to-day administration, direction and guidance of its work.

The act of limiting operational costs implies that it spends most of its funds for programme recipients and not management of programmes.

WHO – UNITAID’s partner

UNITAID works in collaboration with WHO technical units, and relies on WHO guidelines for managing the control of diseases, but the area where UNITAID and WHO work most closely is on the drug prequalification programme.

THE WHO PREQUALIFICATION PROGRAMME

The World Health Organization (WHO) established its Prequalification Programme in 2001. The purpose of the programme is to increase access to medicines that meet unified standards of acceptable quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis. From the outset, the Programme was supported by UNAIDS, UNICEF, UNFPA and the World Bank as a concrete contribution to the United Nations priority goal of addressing widespread diseases in countries with limited access to quality medicines.

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 assesses working procedures for compliance with WHO Good Manufacturing Practices (GMP). The assessment teams evaluating the products and manufacturers include experts from some of the national regulatory authorities (e.g. countries of the European Union, Canada and Switzerland). These teams ensure that high-quality, international standards are respected, and work with regulators from the countries where the medicines will be used to make sure that the process and results are at all times transparent and trusted by the end-users.

The Prequalification Programme does not intend to replace national regulatory authorities or national authorization systems for the importation of medicines. Prequalification draws on the expertise of some of the best national regulatory authorities to provide a list of prequalified products that comply with unified international standards.

The list of prequalified medicinal products produced by the Programme is used principally by United Nations agencies — including UNAIDS and UNICEF — to guide their procurement decisions. The list has however become a vital tool for any organization involved in the bulk purchase of medicines, both at national and international levels.

UNITAID

Support for the prequalification of drugs

After an initial contribution of US\$ 1 million in 2006, UNITAID has made a follow-up contribution of US\$6 million in 2007 to support the WHO Prequalification Programme. This funding is to facilitate the Programme's ability to rapidly process pharmaceutical company applications for prequalification of potentially highly effective new drugs against HIV/AIDS (paediatric and second-line), tuberculosis (first-line and MDR-TB) and malaria (ACTs), and support testing and sampling of these drugs in countries.

UNITAID support to the WHO Prequalification Programme in 2007 resulted in 21 new prequalified drugs and maintenance of the list of 180 prequalified products.

International laboratories will conduct sampling and analysis to determine the quality of the drugs provided to beneficiary countries through UNITAID funding. Testing and sampling is conducted with national regulatory authorities and involves the participation of some local laboratories to develop indigenous capacity. It is expected that in the short term, some national quality-control laboratories in countries will themselves be able to implement sampling and testing activities that are currently organized by the WHO Prequalification Programme.

FUTURE DEVELOPMENTS

Developing a brand new initiative such as UNITAID has its challenges. One of the central challenges faced by UNITAID is identifying the right models and mechanisms to achieve the full market impact potential for its funds, to support the «right» activities. UNITAID must have guiding principles and a framework in place for proposal review, to ensure that it is capable of responding to rapid changes in the market with innovative approaches. By developing pilot guidelines for proposals, UNITAID has just taken one more step towards the achievement of this objective.

To achieve long-term and continuous global health impact, UNITAID must also be responsive to changing market needs. This may include phasing into and out of particular market niches quickly, which is another key challenge. When UNITAID identifies new markets where its resources may be better utilized and therefore needs to phase out activities in other market niches, it will rely on other key contributors and organizations to step in. Those other organizations will need to continue to provide funds and support, and therefore provide a continuity guarantee for countries. But UNITAID can only phase into and out of markets with the support of strategic long-term financing partners like the Global Fund. UNITAID therefore depends on other global public health players to provide the funding required to support the gradual and planned decrease of UNITAID resources in a given drug niche.

Another challenge is that UNITAID's funds must be truly additional on many levels. This includes ensuring that funding provided to UNITAID by contributors does not lead to decreases in other forms of development assistance for health, and that funds provided to implementing organisations do not displace their own funding for programs. The fact that most of UNITAID funding comes from truly innovative sources of financing such as solidarity contribution on air tickets is an important guarantee against this risk.

This leads to the overarching challenge of finding UNITAID's place in the global health financing landscape. It requires us to define the nature of our relationships and identify areas of complementary activity between UNITAID and its peer organisations, primarily the Global Fund.

As UNITAID enters its second operational year, opportunities to expand towards new niches and address new needs multiply. This is a strategic challenge for such a young organization, and it calls for a deeper cooperation between member governments and partner organizations. If the missions expands, so must the funding. It will also require a profound capacity-building effort, both at the global, regional and country levels.



A

A young child in a white and brown striped shirt is visible on the left side of the page, looking towards the camera. The background is a field of tall, dry grass with a simple house visible in the distance under a bright sky.

FINANCIAL STATEMENTS

NOVEMBER 2006 - DECEMBER 2007

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KEY PERFORMANCE INDICATORS P.46

ACCOUNTS

«At least 85 % of UNITAID funds dedicated to purchase commodities should be spent on low-income countries.»

UNITAID Constitution, Section 5.

This criteria has been met in 2007:

84.16 % of UNITAID funds have been spent in low-income countries, 13.36 % for lower-middle-income countries and 2.48 % for upper-middle-income countries

REVENUES

UNITAID November 2006 - December 2007 revenues

▪ (million USD) 2006-07

| | Total |
|------------------|---------|
| Brazil | 16.145 |
| Chile | 5.333 |
| France | 268.354 |
| Norway | 21.624 |
| UK | 26.490 |
| Gates Foundation | 10.000 |
| Mauritius | 0.324 |
| Spain | 20.435 |
| Niger | 0.032 |
| Total | 368.889 |
| Interests | 5.200 |

COMMITMENTS

UNITAID November 2006- December 2007 fund commitment to programs

▪ (million USD) 2006-07

| | Total |
|---------------------------------------|-------|
| Paediatric ARV | 35.9 |
| 2 nd line ARV | 35.9 |
| ACT Liberia Burundi | 1.3 |
| ACT scale up | 15.6 |
| Paediatric TB | 5.7 |
| MDR TB | 20.8 |
| WHO prequalification | 7.0 |
| Global Fund Round 6 | 52.5 |
| PMTCT | 20.9 |
| First line anti TB Drug initiative | 26.8 |
| Total commitment | 222.4 |

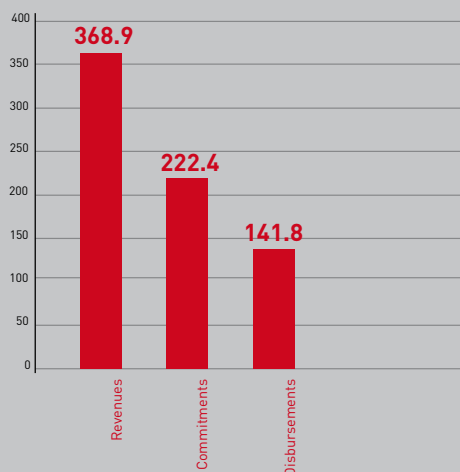
DISBURSEMENTS

UNITAID November 2006- December 2007 fund disbursement to programs

▪ (million USD) 2006-07

| | Total |
|---------------------------------------|-------|
| Paediatric ARV | 35.9 |
| 2 nd line ARV | 35.9 |
| ACT Liberia Burundi | 1.3 |
| ACT scale up | 15.6 |
| Paediatric TB | 5.7 |
| MDR TB | 7.0 |
| WHO prequalification | 7.0 |
| PMTCT | 6.5 |
| First line anti TB Drug initiative | 26.9 |
| Total disbursement | 141.8 |

Infography: showing revenues/ commitments/disbursements



A "LEAN SECRETARIAT"

UNITAID's Constitution (Section 4) states that UNITAID «will operate in a cost-efficient manner with a lean secretariat, keeping overhead down to dedicate its resources to the overall mission and achievement of its results». With operating costs as low as 1.75 % of its confirmed contributions, this objective was achieved in 2007.

OPERATING COSTS

UNITAID November 2006- December 2007

| | '000 US\$ |
|--|-----------|
| Secretariat salary cost | 1,540 |
| Specific operating costs | 1,143 |
| Of which: | |
| External expertise | 329 |
| Communication, website | 58 |
| Travel (Secretariat) | 216 |
| Travel (EB & Cons. Forum members) | 247 |
| Equipment, meetings | 192 |
| Miscellaneous | 101 |
| WHO administrative, financial, fiduciary, facility support and other operating costs | 3,781 |
| Of which ¹ | |
| WHO administrative fixed fee | 291 |
| WHO administrative percentage-based fees | 3,230 |
| WHO extra legal support ² | 210 |
| WHO extra internal audit | 50 |
| Total cost | 6,464 |
| As % of all UNITAID confirmed contributions | 1.75 % |

¹ These costs include the following services provided by WHO to directly support the work of UNITAID: office space, utilities, accounting services, IT and telecommunications support, Trust Fund management, procurement-related services, travel administration, salary and entitlement administration, human resources services, medical services and staff health insurance, security and staff services, routine internal, external audit, fees related to programme implementation work by WHO and administration of the Trust Fund.

² These additional amounts exceed routine WHO services and are directly attributed to UNITAID requirements.

2007 PERFORMANCE

UNITAID AND ITS KEY PERFORMANCE INDICATORS

1. Achievements:

Overall

- Total actual contributions to UNITAID for 2007, received from its members as of 31st December 2007 amounted to 313.95 M\$, that is 95.1% of the expected 2007 objective (330 M\$).
- 13 agreements, representing all Board approved actions for 2007, were signed in 2007.
- Commitments and disbursements meet UNITAID's eligibility criteria (see attached table).
- Operating expenses have been kept low

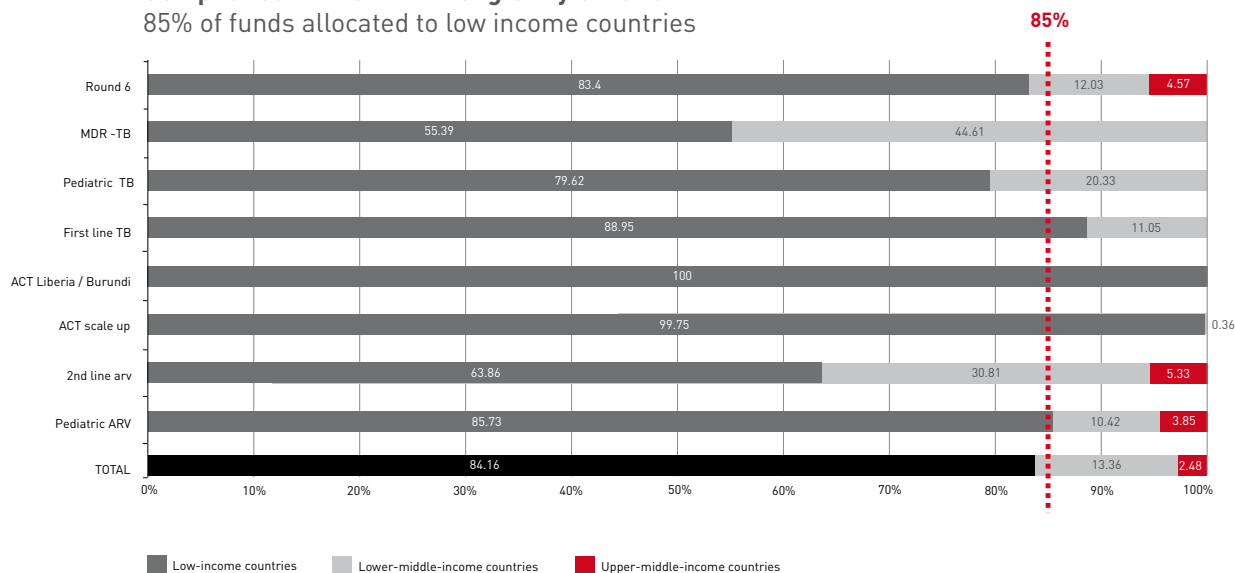
Niche Specific indicators

- A new FDC product for Paediatric ARV has been introduced and is now available in 25 of the 38 beneficiary countries.
- An average price reduction of 40% on paediatric ARV drugs has been achieved.
- A 23 % price reduction in low income countries and 49% in middle income countries has been achieved for Second line ARV.
- For the period 1st January-31 November 2007, 102,000 children (of which 62,000 previously untreated) received paediatric ARV treatment in 38 beneficiary countries;
- 70,900 new patients in 26 countries received second line ARV treatment [source: CHAI]
- 1.3 million doses of ACT have been delivered in Burundi and Liberia to deal with a stock out emergency.
- TB drugs to treat children have been delivered to selected high burden countries.

2. Challenges:

- Refine UNITAID's strategy through a consolidated strategic plan and to communicate it to the widest possible audience.
- UNITAID should decide on a timeframe for the independent evaluation of its programs as planned in its Constitution
- The Secretariat has experienced difficulties in filling the vacancies, and it has suffered chronic understaffing. This must be urgently addressed, in accordance with the UNITAID strategy.
- More standardized reporting and measurement tools are being developed to help the Secretariat better measure delivery and performance and to ensure consistency of data and reports provided by partners.
- Implementation of the MOUs signed at the end of the year will start in 2008 instead of 2007(PMTCT, ACT scale up, Round 6).
- The road map with the Global Fund is expected for 2008. A proposal from the two Secretariats was prepared in February 2008.
- In December 2007, UNITAID started to implement the Partnership Policy presented to the Board in early December, with the development of a clean, consistent, streamlined, transparent system and procedure for eliciting, appraising and ranking proposals and making recommendations to the Board.

Compliance with UNITAID eligibility criteria
85% of funds allocated to low income countries







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**World Health
Organization**

**UNITAID is hosted and
administered by the
World Health Organization**