UNITAID

Background paper prepared for the

Working Group on Value for Money:
An Agenda for Global Health Funding Agencies

Global Health Policy Program
Center for Global Development

October 2012
Revised April 2013

http://www.cgdev.org/section/topics/global_health/working_groups/value_for_money.

UNITAID

Rachel Silverman
Under the direction of Victoria Fan and Amanda Glassman

Revised April 2013

Table of Contents

List of Acronyms and Abbreviations

ACT	Artemisinin-combination therapies
AGFP	Advisory Group on Funding Priorities
AMFm	Affordable Medicine Facility – malaria
ANRS	*Agence Nationale de Recherche sur la Sida*
ARV	Antiretroviral
CHAI	Clinton Health Access Initiative
DFID	United Kingdom Department for International Development
ESTHER	*Ensemble pour une Solidarite Therapeutique Hospitaliere En Reseau*
FDC	Fixed-dose combination drugs
FIND	Foundation for Innovative New Diagnostics
GDF	Global Drug Facility
Global Fund	The Global Fund to Fight AIDs, Tuberculosis, and Malaria
GPRM	Global Price Reporting Mechanism
HIV/AIDS	Human immunodeficiency virus/acquired immune deficiency syndrome
LMIC	Low and middle income countries
LLIN	Long-lasting insecticide nets
MDR-TB	Multi drug-resistant tuberculosis
MOU	Memorandum of understanding
MPP	Medicines Patent Pool
NGO	Non-governmental organization
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PMTCT	Prevention of mother to child transmission
PRC	Proposal Review Committee
R&D	Research and Development
RFP	Request for Proposals
TB	Tuberculosis
UNICEF	United Nations Children's Fund
UNITAID	*Tous Unis pour Aider*
WHO	World Health Organization

Part I: Funding History, Landscape, and Governance

Background

In 2004, two reports were released which assessed the potential of "innovative financing mechanisms" to address global inequality, particularly in the areas of health and hunger.

The first report, from Action against Hunger and Poverty, was released by its Technical Group on Innovative Financing Mechanisms in September 2004. The Technical Group had formed in support of the 2004 Geneva declaration, led by Brazil, Chile, France, and Spain, which urged full implementation of financial commitments to meet the Millennium Development Goals. The Group studied a range of potential new mechanisms for development finance that would promote stability of aid flows and galvanize financial resources. Accordingly, the report considered several options, including but not limited to taxation of financial transactions or the arms trade; decreasing transaction costs for foreign remittances; and voluntary programs to earn charitable contributions in lieu of typical credit card rewards programs, all of which were designed to provide "a predictable and continuous flow of resources over time, so that recipient nations could succeed in the pursuit of long-term development."[1]

The second report was commissioned by French President Jacques Chirac in November 2003, and publically released in December 2004. Known as the Landau Report, the report considered the feasibility and desirability of a prosperity tax on the rich to fight poverty and inequality.[2] While the report raised a number of concerns about the potential constraints and adverse effects of international taxation – for example, the limited legal framework and the risk that such mechanisms could ultimately detract from traditional bilateral aid – it also concluded that new funding streams could help overcome the limitations of the existing aid regime, including insufficient resources and aid volatility. In particular, the report concluded that "one crucial element [was] currently missing in the present development system: a resource that is both totally concessional and predictable." Among other ideas, the Landau Report proposed a tax on civil air transport as a potential mechanism to fill that gap, though it did not offer a strong endorsement.[3]

Following the release of the two reports, support gradually increased for the implementation of such initiatives, particularly among the countries which had been involved from the outset, and most notably in France and Brazil. In February 2005, Brazil, Chile, France, Germany and Spain released a joint statement endorsing innovative approaches to development financing, noting that a pilot project to tax air travel was currently under consideration.[4] Throughout that year, the French government lobbied internationally to garner support for a bulk drug purchasing program, which would be financed by a tax on plane tickets and called *Tous Unis pour Aider* (Everyone United to Help), or UNITAID for short..[5] In July 2006, prior to the

[1] Action against Hunger and Poverty (2004). *Report of the Technical Group on Innovative Financing Mechanisms*
[2] Douste-Blazy, Philippe, and Daniel Altman (2010). *Power in Numbers*. Public Affairs: New York.
[3] Groupe de travail sur les nouvelles contributions financieres internationales (2004). *Rapport a Monsieur Jacques Chirac, President de la Republique*. English Version.
[4] Governments of Brazil, Chile, France, Germany and Spain. (2005). "Joint Statement." Accessed March 18, 2012 at http://www.diplomatie.gouv.fr/en/IMG/pdf/Declaration_adoptee_le_11_fevrier_2005_a_Brasilia_par_les_membres_du_groupe_quadripartite_Bresil_Chili_Espagne_Allemagne_France.pdf
[5] Douste-Blazy, Philippe, and Daniel Altman (2010). *Power in Numbers*. Public Affairs: New York.

official launch of UNITAID, France unilaterally introduced its own levy on civil air travel, a precursor to UNITAID's international effort.[6]

Despite his extended advocacy for the development of innovative funding sources, founding president Philippe Douste-Blazy was originally unsure of how to best spend the new resources. According to Douste-Blazy's autobiography, a short meeting with President Bill Clinton in 2005 provided the genesis for UNITAID's focus areas and its market-based, commodity-driven approach:

> "[Clinton] had an answer to my question. 'I know what you have to do. You have to do, on a big scale, what I do with my foundation. You have to work on drugs to fight HIV/AIDS, malaria and tuberculosis…You have to say to the drug companies, I'm giving you money, not for one year, but for several years…How much do you agree to decrease the price[?]'"[7]

UNITAID was launched in September 2006 at the United Nations General Assembly by the governments of Brazil, Chile, France, Norway, and the United Kingdom.[8] By 2011, UNITAID was supported by 29 countries and the Gates Foundation; nine countries – France, Cameroon, Chile, the Democratic Republic of the Congo, Korea, Madagascar, Mali, Mauritius, and Niger – had implemented the air travel tax (Norway contributed a portion of its tax on carbon dioxide emissions),[9] and a majority of contributors were either low- or middle-income countries.[10] Notably, the U.S. has not pledged its support to UNITAID, reportedly objecting to the proposed tax on air travel.[11]

Structure and Governance

UNITAID is headquartered in Geneva, where it is hosted by the World Health Organization (WHO); however, UNITAID is not part of the WHO, and the WHO exercises only limited control over UNITAID's operations through its non-voting presence on the Executive Board. Though UNITAID was launched at the UN General Assembly, it is not an official UN Agency.

The organization is governed by its 12-member Executive Board, which is its chief decision-making body. The board is chaired by former French Foreign Minister and Minister for Health Philippe Douste-Blazy, and is comprised as follows:

- One member from each of the five founding countries (Brazil, Chile, France, Norway, and the United Kingdom), and Spain;
- One representative of African countries, selected by the African Union (currently Mauritius);
- One representative of Asian countries (currently Korea);
- Two representatives of relevant civil society networks (currently Esther Tallah of the Cameroon Coalition Against Malaria, and Kim Nichols of the African Services Committee);

---

[6] Bermudez, Jorge (2008). "UNITAID: Innovative Financing to Scale up Access to Medicines." Global Forum Update on Research for Health; Vol. 5: pp. 182-185.
[7] Douste-Blazy, Philippe, and Daniel Altman (2010). *Power in Numbers*. Public Affairs: New York
[8] *Ibid.*
[9] UNITAID. "How Innovative Financing Works." Accessed March 18, 2012 at http://www.unitaid.eu/en/about/innovative-financing-mainmenu-105/163
[10] Bermudez, Jorge (2008). "UNITAID: Innovative Financing to Scale up Access to Medicines." Global Forum Update on Research for Health; Vol. 5: pp. 182-185.
[11] Douste-Blazy, Philippe, and Daniel Altman (2010). *Power in Numbers*. Public Affairs: New York.

- One representative of the constituency of foundations (currently Girindre Beeharry of the Gates Foundation); and
- One representative of the World Health Organization (non-voting).[12]

In response to a request by the board, two committees were formed in November 2008. The first, a finance and administration committee, is chaired by the United Kingdom. The second committee is chaired by France and focuses on policy and strategy considerations.[13] The board is also responsive to the Consultative Forum, a broader group of donors, beneficiaries, and partners, which "provides feedback, recommendations, and advice for consideration by the Executive Board."[14]

The board delegates day-to-day operational responsibilities to the Secretariat, which has been led by Executive Director Denis Broun since September 2011.[15] Previously, Jorge Bermudez had held the post since its creation in 2007.[16] Given the size of UNITAID's budget and disbursements, the Secretariat is quite small (44 people).[17]

Finally, UNITAID's operations are guided by its formal constitution and official bylaws. UNITAID's current constitution, adopted by the Executive Board in July 2011, describes its principle mission as follows:

> "UNITAID's mission is to scale up access to treatment for HIV/AIDS, malaria and tuberculosis…by leveraging price reductions of quality drugs and diagnostics…and to accelerate the pace at which they are made available. To fulfill its mission, UNITAID will use sustainable, predictable and additional funding to help generate a steady demand for drugs and diagnostics, thereby significantly impacting market dynamics to reduce prices and increase availability and supply."[18]

According to its 2010-2012 strategy document, UNITAID is guided by twelve principles: innovation, effectiveness, leverage, global equity, a pro-public health approach to intellectual property, sustainability, additionality, complementarity, global impact, transparency, flexibility, and forward-looking, The organization has four main objectives:

1. Increase access to efficacious, safe products of assured quality that address public health problems.
2. Support adaptation of products targeting specific populations.
3. Ensure affordable and sustainably priced products.
4. Assure availability in sufficient quantities and timely delivery to patients.[19]

UNITAID is a funding agency; its projects are implemented by partners which are already active in country. However, UNITAID does not directly handle procurement or project implementation. UNITAID funds are

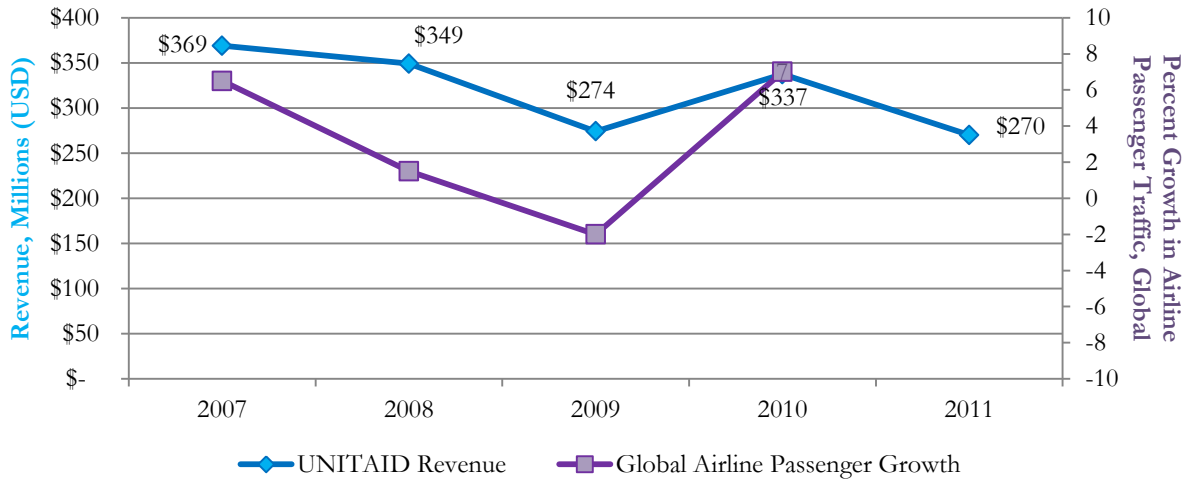
[12] UNITAID. "Executive Board" and "Members of the Executive Board." Accessed March 18, 2012 at http://www.unitaid.eu/en/governance-mainmenu-4/executive-board-mainmenu-33?task=view and http://www.unitaid.eu/en/governance-mainmenu-4/executive-board-mainmenu-33/164
[13] UNITAID. "Committees." Accessed March 18, 2012 at http://www.unitaid.eu/en/governance-mainmenu-4/working-groups-mainmenu-115
[14] UNITAID. "Consultative Forum." Accessed March 18, 2012 at http://www.unitaid.eu/en/governance-mainmenu-4/consultative-forum-mainmenu-63
[15] UNITAID (2011). "Denis Broun Appointed UNITAID Executive Director." Accessed March 18, 2012 at http://www.unitaid.eu/en/resources/news/354-denis-broun-appointed-unitaid-executive-director
[16] Douste-Blazy, Philippe, and Daniel Altman (2010). *Power in Numbers*. Public Affairs: New York.
[17] UNITAID. "Secretariat." Accessed March 18, 2012 at http://www.unitaid.eu/en/governance-mainmenu-4/secretariat-mainmenu-60
[18] UNITAID (2011). *UNITAID Constitution.*
[19] UNITAID (2009). *Strategy 2010-2012: Improving Global Markets to Address HIV/AIDS, Tuberculosis, and Malaria.*

exclusively earmarked for commodity purchases and supply chains, including shipping and procurement management. Implementing partners must find "extra funding sourced separately from other donors" to cover implementation and management.[20] UNITAID does not work directly with developing country governments or local civil society, instead preferring to fund a limited number of "programmatic partners,"[21] which are primarily multilaterals and large foundations.

Funding and Trends

Because UNITAID is funded primarily by a levy on airline tickets (approximately 60% of its funding)[22], its annual revenue has tracked closely with performance of the air travel sector, which is itself highly correlated with the global economy. Figure 1 shows UNITAID's revenue between its launch in 2006/2007 and 2011, the most recent year with available data. For comparison, the chart also includes a trend line for global airline passenger growth through 2010. For both indicators, a dip is observed in 2008/2009, with a recovery in 2010. A decline in UNITAID's revenue is again observed in 2011.

Figure 1: UNITAID Revenue and Global Airline Profitability, 2007-2011[23]



UNITAID's airline tax was designed to provide a steady, consistent funding mechanism and to limit volatility in global health aid flows. However, Figure 1 suggests a potential weakness of UNITAID's funding model. As a luxury good, air travel is highly vulnerability to economic fluctuations, such as during the 2008/2009 economic crisis. The fall in air traffic during that crisis appears to be correlated with a similar drop in UNITAID's revenue. Though the airline levy was intended to insulate UNITAID's funding from political considerations, it may also have limited the ability of the political process to act as a counter-cyclical, revenue-smoothing device. UNITAID's revenues fell 21% between 2008 and 2009; overall development assistance for health rose 3% during the same period.[24]

[20] UNITAID (2009). Strategy 2010-2012: Improving global markets to address HIV/AIDS, tuberculosis, and malaria.
[21] UNITAID (2011). UNITAID Constitution.
[22] UNITAID (2011). *UNITAID Annual Report 2011*.
[23] 2007 UNITAID revenue figure includes both 2006 and 2007. UNITAID data is taken from 2011 annual report; airline data is from the International Air Transport Association (IATA), via Centre for Aviation (2011), "IATA halves profit forecast for 2011l 78% weaker than 2010," accessed March 18, 2012 at http://www.centreforaviation.com/analysis/iata-halves-profit-forecast-for-2011-78-weaker-than-2010-52841
[24] IHME (2011). Financing Global Health 2011: Continued Growth as MDG Deadline Approaches. Seattle: University of Washington.

A closer look at revenue by donor also shows a contrast between UNITAID's funding rhetoric and reality (Table 1). While UNITAID often touts its broad support, including from developing country governments, France alone contributed 62% of UNITAID's cumulative revenue between 2006 and 2011, followed by the United Kingdom at 16%. Together, the high-income country donors and Gates Foundation were responsible for 95.8% of UNITAID's funding during that same period; LMICs, including founding members Brazil and Chile, have contributed less than 5% of the organization's total funding.

Table 1: Revenue by Donor (Thousands)[25]

Country/Donor	2011 Voluntary Contributions	Percent of Total, 2011	Cumulative Revenue, 2006-2011	Percent of Total, Cumulative
Bill and Melinda Gates Foundation	10,000	3.70%	50,000	3.13%
Brazil	-	0.00%	37,202	2.33%
Cameroon	1,018	0.38%	1,018	0.06%
Chile	2,282	0.84%	20,400	1.28%
Congo	1,090	0.40%	1,090	0.07%
Cyprus	488	0.18%	1,578	0.10%
France	144,251	53.38%	996,899	62.32%
Guinea	-	0.00%	49	0.00%
Luxembourg	611	0.23%	1,961	0.12%
Madagascar	12	0.00%	27	0.00%
Mali	526	0.19%	928	0.06%
Mauritius	1,937	0.72%	7,032	0.44%
Niger	-	0.00%	281	0.02%
Norway	18,761	6.94%	109,550	6.85%
Republic of Korea	7,000	2.59%	28,000	1.75%
Spain	-2,813	-1.04%	81,603	5.10%
United Kingdom	85,072	31.48%	262,088	16.38%
Total Revenue	270,235	1.00	1,599,706	1.00

Note: For highlighted countries, 100% of contributions are revenue earned through the levy on air travel.

To date, nine countries have adopted an airline tax, which represents 100% of their respective contributions to UNITAID. In addition, Norway's contribution is raised via a tax on carbon emissions, from which it contributes a portion of overall revenues. The remainder of UNITAID's funding has been raised via voluntary contributions from six country governments and the Bill and Melinda Gates Foundation.[26]

UNITAID has also investigated other innovative fundraising mechanisms. In 2008, UNITAID set up the Millennium Foundation, an independent organization intended to raise additional funds for UNITAID's programs. In 2010, the Millennium Foundation launched a pilot of MASSIVEGOOD, a web platform to enable voluntary micro-donations through travel booking services. The program was discontinued in November 2011; the Foundation's "Board [did] not see sufficient enough returns for such a micro philanthropy initiative in today's economic climate."[27]

[25] UNITAID (2011). *UNITAID Annual Report 2011.*
[26] UNITAID (2011). *UNITAID Annual Report 2011.*
[27] Millennium Foundation (2011). "Who We Are: MASSIVEGOOD." Accessed March 18, 2012 at http://www.massivegood.org/en_US/news-feed/432-new-direction-for-massivegood

Mission and Priority Activities

UNITAID focuses on increasing "access to treatment for HIV/AIDS, malaria, and tuberculosis," primarily by procuring large quantities of health commodities. Because its funding is considered to be "predictable" and thus immune from annual political fluctuations, UNITAID can make "long-term funding commitments" for bulk purchasing. Through this process, UNITAID attempts to "stimulate increased production" and "[create] economies of scale that drive prices down," a strategy which should theoretically lower prices for all buyers.[28]

UNITAID describes itself as having a "market-based" approach, serving three primary functions:

- "**Market catalyst:** identifying and facilitating adoption and uptake of new and superior health commodities;
- **Market creator:** providing incentives for manufacturers to produce otherwise unattractive products with low market demand but substantial public health benefits; and
- **Market 'fixer':** addressing market inefficiencies…contributing to low access of quality assured medicines, diagnostics, and preventative items."[29]

Accordingly, UNITAID works to "[identify] niche markets" which other donors have not addressed and where "where intervention is likely to have a tangible public health impact."[30] To date, UNITAID's focus areas for bulk, long-term purchasing have included pediatric and second-line AIDS treatment, artemisinin-combination therapies (ACTs) to treat malaria, long-lasting insecticide nets (LLINs) to prevent malaria transmission, and treatment for pediatric and multi drug-resistant tuberculosis (MDR-TB).[31] However, its goal of lowering prices may contradict its ambitions to promote the development of new medicines, as lower prices are likely to discourage private research and development.[32]

In December 2009, the Executive Board approved plans for the establishment of a patent pool as a new legal entity,[33] aiming to facilitate research and development for improved and more affordable HIV treatment.[34] The pool intends to address legal roadblocks preventing the repurposing and combination of existing medicines to create "fixed-dose combination" drugs (FDCs), primarily due to diffuse intellectual property rights over the relevant component drugs.[35] The Medicines Patent Pool (MPP) is supported by UNITAID under the terms of a five-year memorandum of understanding (MOU).[36] UNITAID describes its approach as follows:

> "The unique strategy of the MPP is to persuade patent-holders – companies, researchers, universities, and governments – to voluntarily license their patents to the Pool. The MPP then makes licenses to these patents available to qualified third parties, such as generic drug manufacturers, who then pay

[28] UNITAID. "UNITAID: Mission." Accessed March 18, 2012 at http://www.unitaid.eu/en/about/mission-mainmenu-89
[29] UNITAID. "How UNITAID Works in Markets. Accessed March 18, 2012 at http://www.unitaid.eu/en/about/market-approach
[30] UNITAID (2010). *UNITAID Annual Report 2010*.
[31] UNITAID. *UNITAID Annual Report 2010* and "Projects," Accessed March 18, 2012 at http://www.unitaid.eu/en/projects-mainmenu-3
[32] Van Gelder, Alec and Philip Stevens (2010). "What purpose UNITAID's Patent Pool?" International Policy Press. International Policy Network.
[33] UNITAID Executive Board (2009), "Patent Pool Implementation Plan."
[34] Medicines Patent Pool, "Mission." Accessed April 26, 2013 at http://www.medicinespatentpool.org/who-we-are2/mission/
[35] Van Gelder, Alec and Philip Stevens (2010). "What purpose UNITAID's Patent Pool?" International Policy Press. International Policy Network.
[36] Medicines Patent Pool Foundation. "UNITAID." Accessed April 26, 2013 at http://www.medicinespatentpool.org/who-we-are2/partners/

> appropriate royalties on the sale of the medicines. In this innovative way the MPP makes patents work for public health, with fair compensation for the pharmaceutical companies."[37]

Currently, the MPP has licensed patents from Gilead Sciences and the U.S. National Institutes of Health. As of mid-2012, it was in negotiations with several other patent-holders, including Boehringer-Ingelheim, Bristol-Myers Squibb, F. Hoffman-La Roche, and ViiV Healthcare. It had also licensed the available patents to three generic companies (Emcure Pharmaceuticals Limited, Aurobindo Pharma Limited, and MedChem).[38]

However, the patent pool has been criticized for devoting even greater resources to HIV/AIDS at the expense of underfunded diseases, and for focusing on commodity development rather than distribution and health systems constraints. One analysis by Van Gelder and Stevens (2010) termed it a "solution in search of a program," as "many Indian companies already produce dozens of such therapies for export, even without the permission of the rights-holder." They also worry that the patent pool might "crowd out the legitimate generic ventures that already exist," including direct voluntary licenses "for the manufacture of low-cost generic ARVs and FDCs."[39]

Proposal and Review Process

UNITAID is a funding agency; its projects are implemented by partners which are already active in-country.[40] According to its constitution, UNITAID does "not receive proposals directly from developing country governments or NGOs, but rather through the programmatic partners," i.e. a limited number of multilateral organizations and large foundations (described in detail below).

A page on UNITAID's website is dedicated to requests for proposals (RFP); however, no RFPs were open at the time of writing.[41] In 2010, an Advisory Group on Funding Priorities (AGFP) was established "to assist the Executive Board in identifying potential priority niches," which are to be the focus of RFPs.[42] According to UNITAID's 2010-2012 strategy, AGFP should base its recommendations for RFPs on designated Level 1 criteria (Appendix A).

At its March 2011 meeting, the Executive Board slightly revised its proposal process. The Board agreed that the four most important funding criteria were market impact in product area; public health impact in product area; value for money; and innovation. The amended RFP process would take place as follows:

1. "UNITAID Secretariat [uses] landscape analysis in the 3 disease and 3 product areas…to create a long list of potential funding opportunities;"
2. "Secretariat [develops] a shortlist of potential strategic using assessment of opportunities against UNITAID Strategy criteria, funding envelope, and analysis of opportunities against UNITAID portfolio principles…;"
3. AFFP recommends and "the Board selects and approves" strategic priorities or RFPs; and

[37] UNITAID (2011). *UNITAID in 2011*.
[38] Medicines Patent Pool. "Company Engagement." Accessed 26 April 2013 at http://www.medicinespatentpool.org/licensing/company-engagement/
[39] Van Gelder, Alec and Philip Stevens (2010). "What purpose UNITAID's Patent Pool?" International Policy Press. International Policy Network.
[40] UNITAID (2011). *UNITAID in 2011*.
[41] UNITAID. "Requests for Proposals (RFPs)." Accessed March 18, 2012 at http://www.unitaid.eu/en/about/requests-for-proposal-mainmenu-109
[42] UNITAID (2010). *UNITAID Annual Report 2010*.

4. "A call for proposals is then issued by the Secretariat around the Board-approved priority niche."[43]

UNITAID also accepts unsolicited letters of intent twice each year, a practice intended to "maintain UNITAID's ability to fund innovative proposals, and flexibility."[44]

Once UNITAID receives a funding request from its partners, the proposals are reviewed by a Proposal Review Committee (PRC), "composed of external experts in fields such as public health, market dynamics, health economics, supply chain management and intellectual property." The PRC is charged with "evaluating funding requests against UNITAID's strategic objective of achieving health outcomes through market impact, and making recommendations for Board consideration."[45] The PRC bases its evaluation on UNITAID's Level 2 funding criteria (Appendix A). Following the PRC's recommendation, and considering resource availability, the Executive Board makes a final decision on whether or not to fund a particular project.[46]

Despite the criteria outlined in UNITAID's 2010-2012 Strategy, the 2011 DFID Multilateral Aid Review criticized the funding process, noting that "UNITAID does not yet have a credible framework for choosing between and prioritizing which proposals are funded and which are not. A 'first come, first served' approach once resources are available and without prioritization has potential for significant opportunity costs and is a real weakness."[47]

The 2010-2012 Strategy also called for the creation of a "market intelligence information system" to monitor global markets for health commodities in UNITAID's focus areas. Such a system would help inform UNITAID's funding priorities. As of 2010, the project was under joint development by the Agence Nationale de Recherche sur le Sida (ANRS), the Foundation for Innovative New Diagnostics (FIND), and Boston University.[48] At the time of writing, the project's status is unclear; there is no indication that it remains active.

Following approval, UNITAID and the implementing partner engage directly with manufacturers to negotiate (1) a low price through bulk purchasing and (2) a commitment to timely production for the requisite commodities. Once negotiations are complete, "the partners purchase the products and supply them to countries through national partners which may include governments, NGOs and procurement agents."[49]

[43] UNITAID (2011). "Executive Board Retreat: Civil Society Delegations Communique." Accessed March 18, 2012 at http://unaidspcbngo.org/wp-content/uploads/2011/06/Civil-Society-Delegations-to-UNITAID-Communique-UNITAID-Board-Retreat..pdf
[44] *Ibid.*
[45] UNITAID. *UNITAID Annual Report 2010*.
[46] *Ibid.*
[47] Department for International Development (2011). "Multilateral Aid Review: Assessment of UNITAID."
[48] Child, Rachel (2011). "Operations and Market Dynamics." UNITAID. Accessed March 18, 2012 at http://www.slideshare.net/unitaid/unitaid-operations-report-to-eb13
[49] UNITAID. "Implementing Partners: Working Towards the Common Goal of Expanding Access to Health." Accessed March 18 2012 at http://www.unitaid.eu/en/projects-mainmenu-3/partners-mainmenu-123

Part 2: UNITAID's Expenditures

What Does UNITAID Fund?

As discussed above, UNITAID's mandate is to influence health product markets in HIV/AIDS, malaria, and tuberculosis, particularly for underserved markets such as pediatric drugs and second-line treatment. Accordingly, it exclusively funds programs which focus on access to quality medicines and diagnostics.

Per requirements in its constitution, UNITAID's funding for commodity purchases must be distributed as follows: at least 85% to low-income countries; under 10% to lower-middle income countries; and less than 5% to upper middle income countries. Upper middle income countries must also co-finance UNITAID contributions with government funds ("20% in year 1 rising to 40% in year five").[50] A full map of countries that benefit from UNITAID funding can be found in Appendix B (HIV/AIDS), Appendix C (malaria), and Appendix D (tuberculosis).

As of February 2011, 94 countries had benefitted from UNITAID funding. [51] The 2011 DFID Multilateral Aid Review noted that although "UNITAID does not directly support countries, the country pattern of its funding is reasonably aligned to burden of disease."[52]

Table 3 shows cumulative funding commitments by category at the close of 2011; each line indicates a single grant or program. UNITAID divides its funds between HIV/AIDS (52% of funding), malaria (25%), and tuberculosis (16%), plus a small selection of cross-cutting projects (7%).[53] Most UNITAID projects target underserved "niches" that are either expensive or otherwise unlikely to receive donor support, such as pediatric drugs and second-line treatment.

Table 2. Major UNITAID Interventions, 2006-2011[54]

UNITAID Intervention	Implementing Partner	Amount Committed
Market Catalyst		
Second-line ART HIV/AIDS Project	Clinton Health Access Initiative	$305,058,000
Long Lasting Insecticide Treated Nets (Project Completed December 2010)	UNICEF	$109,250,000
MDR-TB Scale-Up Initiative	The Global Fund	$55,667,000
Market Creator		
Pediatric HIV/AIDS Project	Clinton Health Access Initiative	$380,058,000
Affordable Medicines Facility for Malaria (AMFm)	The Global Fund	$180,000,000
ExpandX TB (MDR-TB Diagnostics)	Foundation for Innovative New Diagnostics	$89,663,000
Pediatric TB Project	Stop TB Partnership Global Drug Facility	$37,691,000
Market Fixer		
Support for Quality Assurance of Medicines (HIV/AIDS, malaria, TB)	World Health Organization	$53,110,000
MDR-TB Strategic Rotating Stockpile	Stop TB Partnership Global Drug Facility	$37,691,000
First Line Anti-TB Drugs Initiative	Stop TB Partnership Global Drug Facility	$27,646,000
ESTHERAID (Supply chain management)	ESTHER	$15,950,000
Unclear Category		

[50] UNITAID (2011). *UNITAID Constitution.*
[51] Department for International Development (2011). "Multilateral Aid Review: Assessment of UNITAID."
[52] Department for International Development (2011). "Multilateral Aid Review: Assessment of UNITAID."
[53] UNITAID (2011). Five years of innovation for better health. Annual Report 2011.
[54] UNITAID (2011). Annual Report 2011.

PMTCT	UNICEF	$104,466,000
ACT Scale-Up	The Global Fund	$78,888,000
Support for Global Fund Round 6	The Global Fund	$52,500,000

UNITAID employs a streamlined funding process; rather than managing many grants, it channels its funding through a small selection of large, international organizations. As of December 2011, UNITAID provided funding to ten partners:

- Clinton Health Access Initiative (CHAI)
- *Ensemble pour une Solidarite Therapeutique Hospitaliere En Reseau* (ESTHER)
- Foundation for Innovative New Diagnostics (FIND)
- Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria (Global Fund)
- i+ solutions
- Roll Back Malaria Partnership
- Stop TB Partnership
- Stop TB Partnership, Global Drug Facility (GDF)
- United Nations Children's Fund (UNICEF)
- World Health Organization

Of its partners, CHAI receives by far the most funding, accounting for about 44% of UNITAID's total cumulative commitments. Specifically, CHAI holds two agreements with UNITAID to receive pediatric and second-line ARVs. After CHAI, the Global Fund is the largest recipient, with about $368 million in UNITAID commitments; however, some of its projects have multiple prime partners, and it is not clear what proportion goes directly to the Global Fund. UNICEF is the third largest recipient with about $215 million; the same caveats apply. CHAI is the largest recipient for HIV/AIDS programs; the Global Fund is the largest recipient for malaria programs; and GDF is the largest recipient for TB programs.

UNITAID has collaborated extensively with the Global Fund, providing support on a number of projects. Between 2007 and 2010, UNITAID committed up to $38.7 million to supplement 42 Global Fund grants in 37 countries with funding for ACTs, pediatric and second-line ARVs, and treatment for MDR-TB.[55] The Global Fund also received support to scale up ACTs to treat malaria, including through the Affordable Medicine Facility – malaria (AMFm), which has received $180 million in UNITAID funding. The Global Fund is responsible for management of the AMFm, but UNITAID is represented on its Ad Hoc Committee.[56]

Market Impact

There is evidence to suggest that UNITAID's programs have helped build the markets for health commodities in its key niche areas, increasing the number of targeted products and reducing costs. However, those gains have not occurred across the board, nor can they be considered independent of other global health efforts, such as PEPFAR, the Global Fund, and the President's Malaria Initiative (PMI).

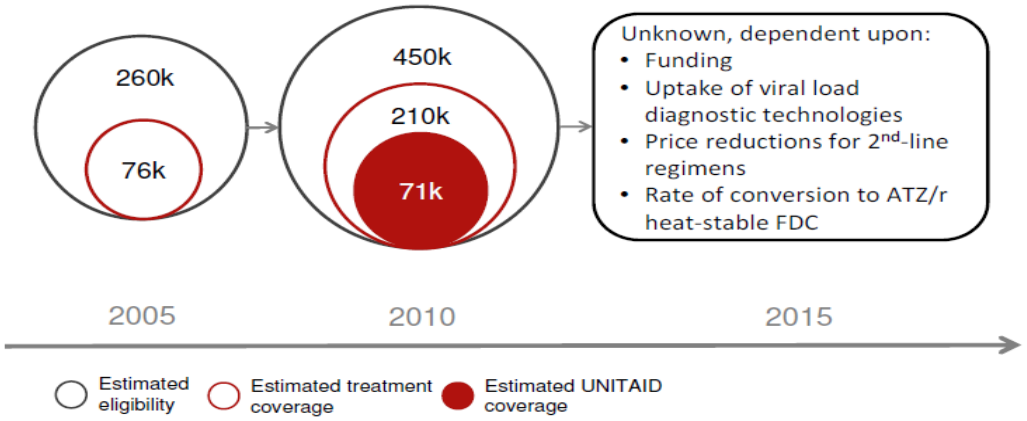
[55] UNITAID. "Support to Global Fund Round 6." Accessed March 18, 2012 at http://www.unitaid.eu/en/projects-mainmenu-3/cross-cutting-issues/support-to-global-fund-round-6-mainmenu-127

[56] World Health Organization and the Global Fund to Fight AIDS, Tuberculosis and Malaria (2009). "Memorandum of Understanding Concerning UNITAID Support for the Affordable Medicine Facility – Malaria." Accessed March 18, 2012 at http://www.unitaid.eu/images/operations/malaria/amfm/AMFm_MoU.pdf

Second-Line ARVs

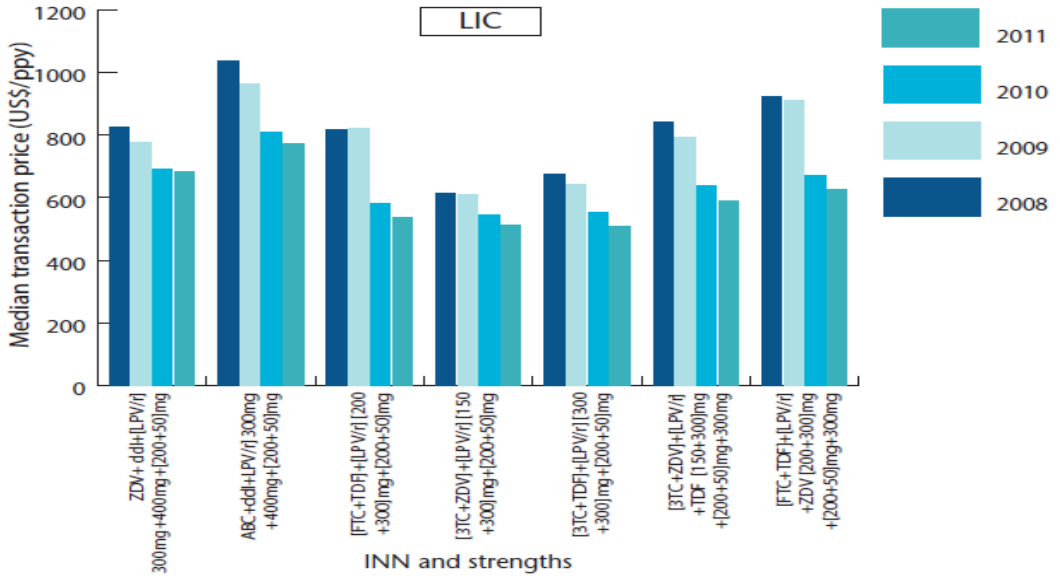
Between 2005 and 2010, total coverage of second-line treatment for HIV/AIDS almost tripled; by 2010, UNITAID-supplied ARVs were treating about one third of all second-line patients (Figure 2). The 2012 Medicines Landscape reports that "over the course of the project, UNITAID [achieved] price reductions of more than 50% for second-line ARVs."[57]

Figure 2: Market Evolution of Second-Line ARV[58]



Data from the WHO's global price reporting mechanism (GRPM) shows universal declines in the price of second-line ARVs between 2008 and 2011 in low income countries (Figure 3). However, it is impossible to know how much of the change can be credited to UNITAID, given the substantial increase in ARV provision by PEPFAR and the Global Fund during the same period.

Figure 3: Price Evolution for Second-Line ARVs in Low-Income Countries, 2008-2011[59]



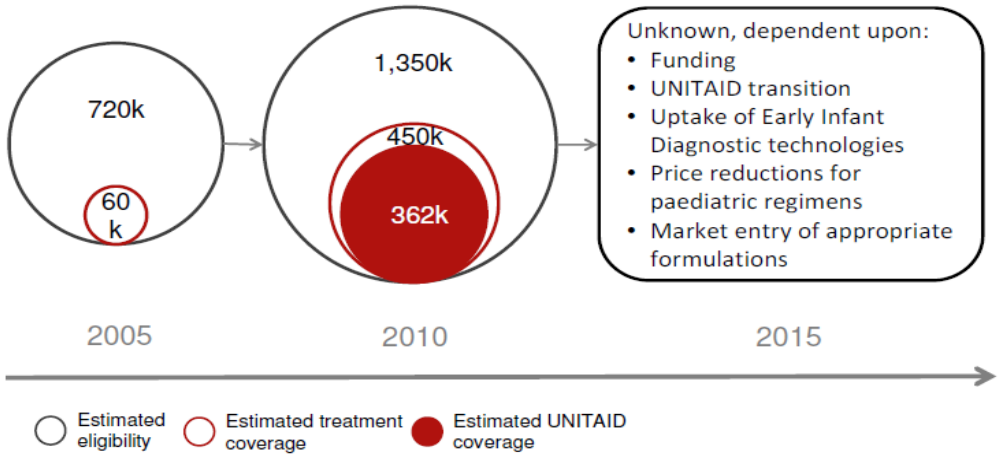
[57] UNITAID (2012). *HIV, Tuberculosis and Malaria Medicines Landscape: Progress Report on Emerging Issues and Potentital Opportunities to Improve Access.*
[58] *Ibid.*
[59] WHO AIDS Medicines and Diagnostic Services Global Price Reporting Mechanism (2011). "Transaction Prices for Antiretroviral Medicines and HIV Diagnostics from 2008 to July 2011." World Health Organization.

Pediatric ARVs

UNITAID has clearly played a major role in advancing the ARV market for pediatric patients, as described in its 2012 Medicines Landscape Progress Report:

> "In 2005, most pediatric ARVs were produced by innovator companies in single-component solid and liquid formulations. By 2010, there were five 2-in-1 and four 3-in-1 generic pediatric FDCs in solid and dispersible forms…During this time period, the number of children receiving treatment increased more than seven-fold with UNITAID accounting for 80% of children on treatment in 2010. Over the course of the project, UNITAID has achieved price reductions of 49%."[60]

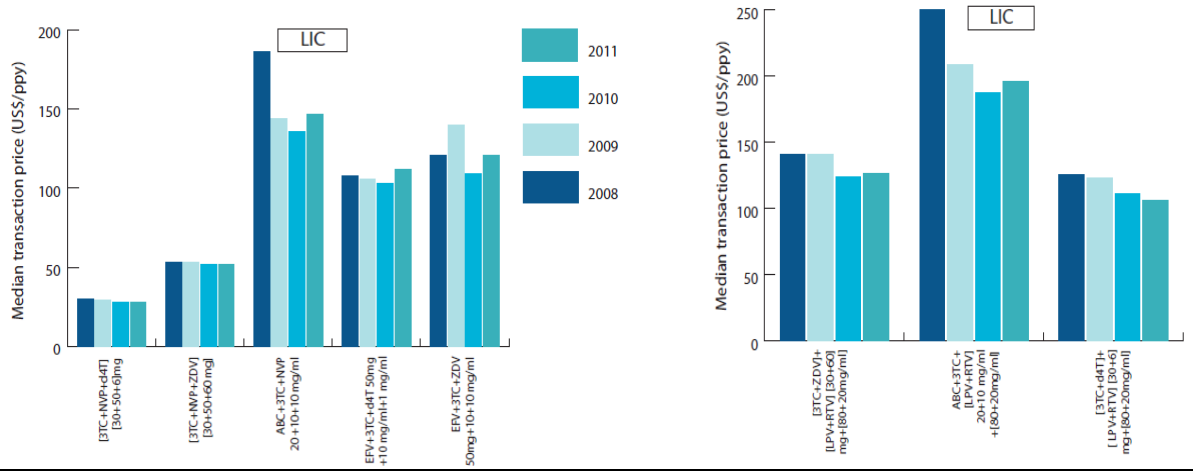
Figure 4: Market Evolution of Pediatric ARVs[61]



However, despite the clear role that UNITAID has played in *creating* a market for pediatric treatment, particularly in low-income countries, its impact on pricing remains ambiguous. According to GPRM data, the median price for pediatric first-line ARVs in low-income countries has flat-lined between 2008 and 2011, though there have been some minor price reductions for second-line drugs (Figure 5). It is also possible that UNITAID sparked significant price decreases between 2006 and 2008. UNITAID's 2011 annual report shows greater progress, claiming that prices have fallen more than 80% since 2006. One fixed-dose combination (AZT+3TC+NVP) is provided as an example; according to UNITAID, it cost $252 per patient-year in 2006, but only $130 as of 2011. No source is cited.[62]

[60] UNITAID (2012). *HIV, Tuberculosis and Malaria Medicines Landscape: Progress Report on Emerging Issues and Potential Opportunities to Improve Access*.
[61] *Ibid.*
[62] UNITAID (2012). "Five Years of Innovation for Better Health." UNITAID Annual Report 2011.

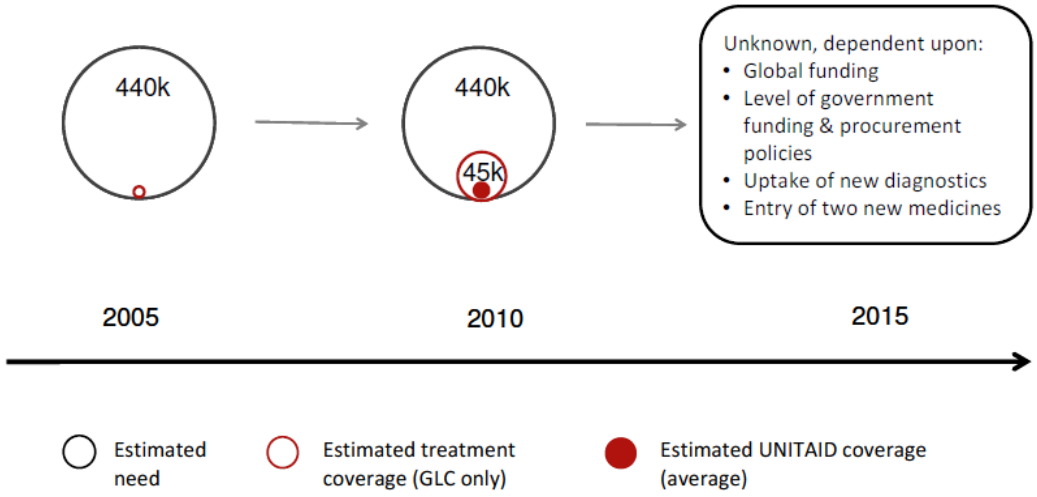
Figure 5: Price Evolution of First and Second Line Pediatric ARVs in Low-Income Countries[63]



Second-Line Tuberculosis Treatment

The market for second-line TB treatment remains small, expensive (costing up to $2,400 per course of treatment), and underserved, despite UNITAID's efforts.[64]

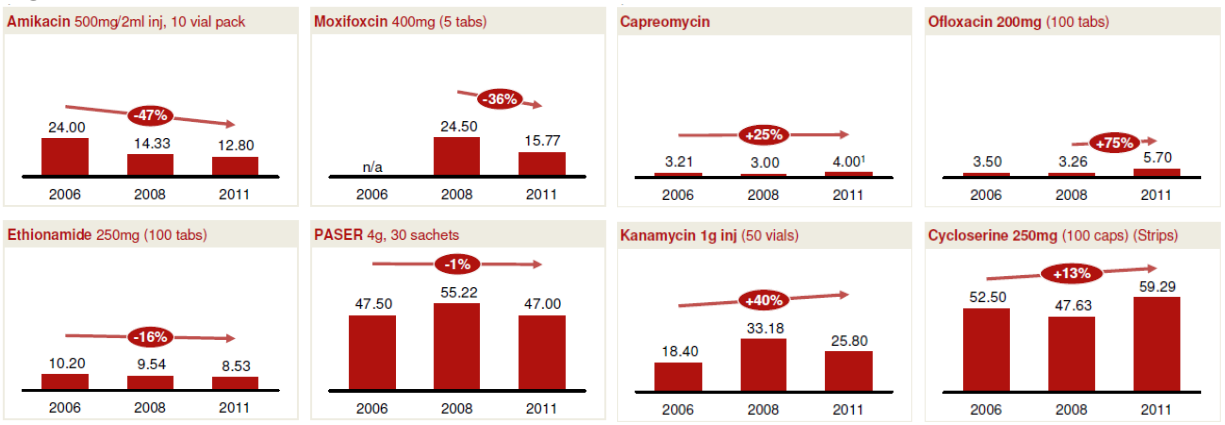
Figure 6: Market Evolution for Second-Line TB Medicines[65]



While the price of some second-line TB drugs has fallen by as much as 47% between 2006 and 2011 (Amikacin), others have risen substantially during the same period (Figure 7).

[63] WHO AIDS Medicines and Diagnostic Services Global Price Reporting Mechanism (2011). "Transaction Prices for Antiretroviral Medicines and HIV Diagnostics from 2008 to July 2011." World Health Organization.
[64] UNITAID (2012). *HIV, Tuberculosis and Malaria Medicines Landscape: Progress Report on Emerging Issues and Potential Opportunities to Improve Access.*
[65] *Ibid.*

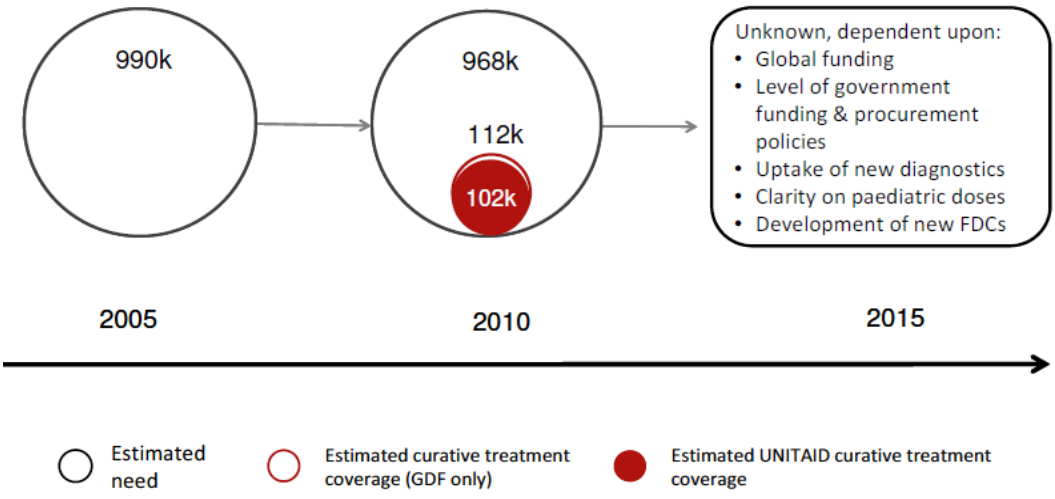
Figure 7: Price Evolution of Selected Second-Line TB Medicines, 2006-2011[66]



Pediatric Tuberculosis Treatment

UNITAID's demand for pediatric tuberculosis treatment appears to have had a significant effect. While the market appeared basically nonexistent in 2005, by 2010 there were 112,000 children receiving treatment, with UNITAID responsible for 102,000. However, UNITAID reports that 90% of need for pediatric TB treatment remains unmet.[67] It is unclear from UNITAID's reporting whether it has achieved price reductions in this area.

Figure 8: Market Evolution for Pediatric TB Medicines[68]

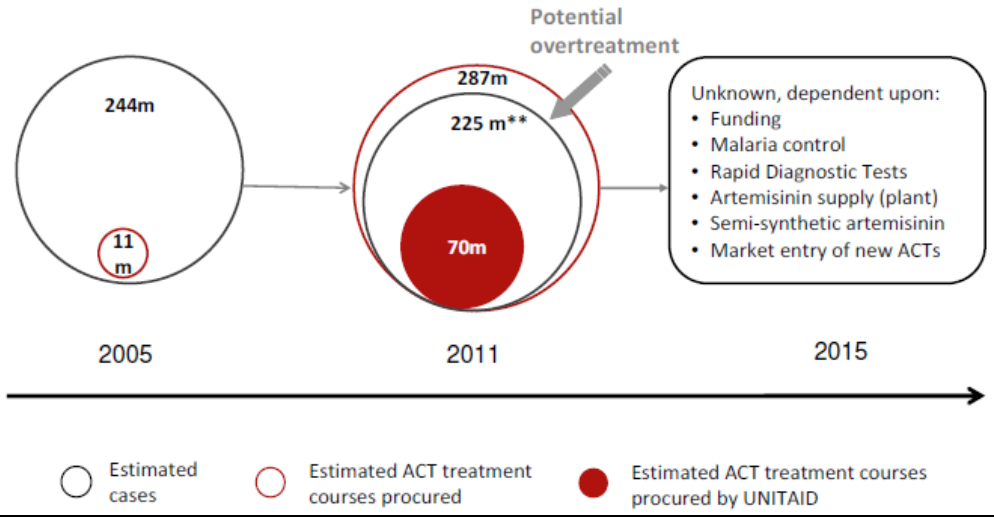


ACTs to Treat Malaria

The market for ACTs has grown substantially since UNITAID's entry. However, UNITAID cannot be solely responsible for any developments in this market, given the large procurement of ACTs by PMI and Global Fund programs.

[66] *Ibid.*
[67] *Ibid.*
[68] *Ibid.*

Figure 9: Market Evolution of ACTs[69]



Value for Money Considerations

UNITAID's approach "Value for Money" is quite different from other agencies in that it does not chiefly define its goals in terms of health impacts. Instead, UNITAID "measures its success based on its impact on the markets for medicines, diagnostics and related products."[70] UNITAID believes that a critical mass of public health problems is caused market shortcomings, which lead to low access to adequate treatment or diagnostics. UNITAID thus takes a market-based approach, where its projects are targeted as "market interventions" which aim to lower prices, improve quality, and incentivize manufacturer innovation and competition. In other words, UNITAID's Value for Money framework is based on three assumptions: (1) that "market shortcomings…result in the loss of life for the most vulnerable"; (2) that "time-limited projects" can "yield both short-term market impact (lower prices, better quality, improved formulations) and long-term sustainable impact, where manufacturers invest, innovate and compete"; and (3) that "the end result is an increased number of healthier people with access to quality products".[71] UNITAID aims to achieve value for money through technical efficiency by lowering prices or improving quality throughout the commodity market: "interventions are high value for money because UNITAID's market impact extends to all countries, not just those receiving direct UNITAID support."[72]

Some aspects of UNITAID's value for money are discussed below:

- **Allocative efficiency (countries)**: UNITAID does not fund programs directly at the country level; nonetheless, its constitution mandates that at least 85% of the funds channeled through its partners go to low-income countries. According to a 2011 DFID review, UNITAID's international funding allocation aligns well with the global distribution of disease burden.[73] Rather than focusing on a select

[69] *Ibid.*
[70] UNITAID (2011). Key performance indicators.
[71] UNITAID (2011). Five years of innovation for better health. Annual Report 2011.
[72] UNITAID (2012). Why UNITAID adopts a market-based approach. Accessed 6 September 2012 at http://www.unitaid.eu/about/market-approach
[73] Department for International Development (2011). "Multilateral Aid Review: Assessment of UNITAID."

group of countries, UNITAID funding is widely distributed; however, it is channeled through other organizations with established on-the-ground programs, which helps avoid the common pitfalls of micro-disbursement.

- **Allocative efficiency (programs and focus)**: With a majority of its resources going towards HIV/AIDS, UNITAID has been criticized for pouring additional funds into an already overfunded disease, particularly since it was founded after the Global Fund and PEPFAR.; van Gelder and Stevens (2010) note that "despite only causing around four percent of mortality in developing countries, HIV/AIDS currently consumes around 25 percent of all development aid for health," and "40 percent of all global health funding for R&D."[74] UNITAID argues that it addresses underserved niches within the HIV/AIDS sector, including pediatric and second-line drugs, which would otherwise be neglected. If effective, UNITAID's strategy to decrease drug prices would also spark cost savings across other donors' HIV/AIDS programs, creating greater value for money *because* such large amounts are currently spent on HIV/AIDS treatment.

- **Partnerships:** To avoid duplication and project proliferation, UNITAID funnels its resources through a limited number of implementing partners, which limits transactions costs.

- **Monitoring and Evaluation:** Because UNITAID primarily funds commodity procurement, there is limited range for impact evaluation. However, UNITAID does monitor some aspects of its grant performance, particularly for indicators related to outputs such as commodity-related service delivery and cooperation with ministries of health. As of 2010, there were plans to track the cumulative lives saved and life years gained by UNITAID supported commodities, but the methodology was still under development. UNITAID's primary evaluation focus is on achieving its desired market outcomes, as discussed below. To this end, it tracks a range of data, including market share, lead time for delivery of commodities, prices paid for commodities, the number of new manufacturers for priority products, and the number of new drugs approved for UNITAID's niche areas.[75] The most recent KPI report available is for 2010; a full list of UNITAID KPIs and reported progress thus far is included as Appendix F. Notably, there is no available data for a number of the indicators, as some methodologies and data sources were still under development.

  A five-year independent evaluation, released in January 2013, concludes that "UNITAID has validated its business model of identifying, selecting and funding market-shaping interventions carried out by implementing partners." However, it also finds that "UNITAID's project portfolio has performed unevenly in its achievement of market and health outcomes and in its treatment of sustainability.[76]

- **Performance-Based Funding:** UNITAID's unique design and mandate preclude most traditional strategies for performance-based funding. This is because UNITAID does not provide funding directly to recipient governments; nor does it seek to foster innovation in implementation beyond the basic delivery of health commodities.

[74] Van Gelder, Alec and Philip Stevens (2010). "What purpose UNITAID's Patent Pool?" International Policy Press. International Policy Network.
[75] UNITAID (2010). *Key Performance Indicators 2010*.
[76]ITAD (2012). UNITAID 5 Year Evaluation. Summary.

- **Effectiveness in Achieving Desired Market Outcomes:** There is substantial evidence to suggest that UNITAID's niche focus areas would be underserved by pharmaceutical companies and other donors if not for UNITAID's attention. Particularly for pediatric commodities, UNITAID has played a key role in increasing demand and sparking drug development. However, its record is mixed on achieving the desired price reductions, which may reflect the intrinsic tension between lower prices to increase access, and higher prices to increase R&D incentives. It is also possible that UNITAID's pooled procurement could distort markets by crowding out other manufacturers, thus reducing competition in the long term.[77]

- **Sustainability:** UNITAID intends to drive long-term market changes through time-limited, short-term market interventions. According to its model, "implementers assume the responsibility for ensuring that countries have successfully integrated the targeted products into their national health financing and procurement systems," and that sustained "domestic or external funding" is available to continue procurement.[78] The DFID multilateral aid review found that "there has been insufficient attention to sustainability once UNITAID support ends."[79]

[77] Waning, Brenda et al. (2010). "Intervening in Global Markets to Improve Access to HIV/AIDS Treatment: An Analysis of International Policies and the Dynamics of Global Antiretroviral Medicines Markets." Global Health; Vol. 6(9).
[78] UNITAID (2012). "Five Years of Innovation for Better Health." UNITAID Annual Report 2011.
[79] Department for International Development (2011). "Multilateral Aid Review: Assessment of UNITAID."

Appendix A: Funding Criteria for UNITAID Projects[80]

Level 1 Criteria

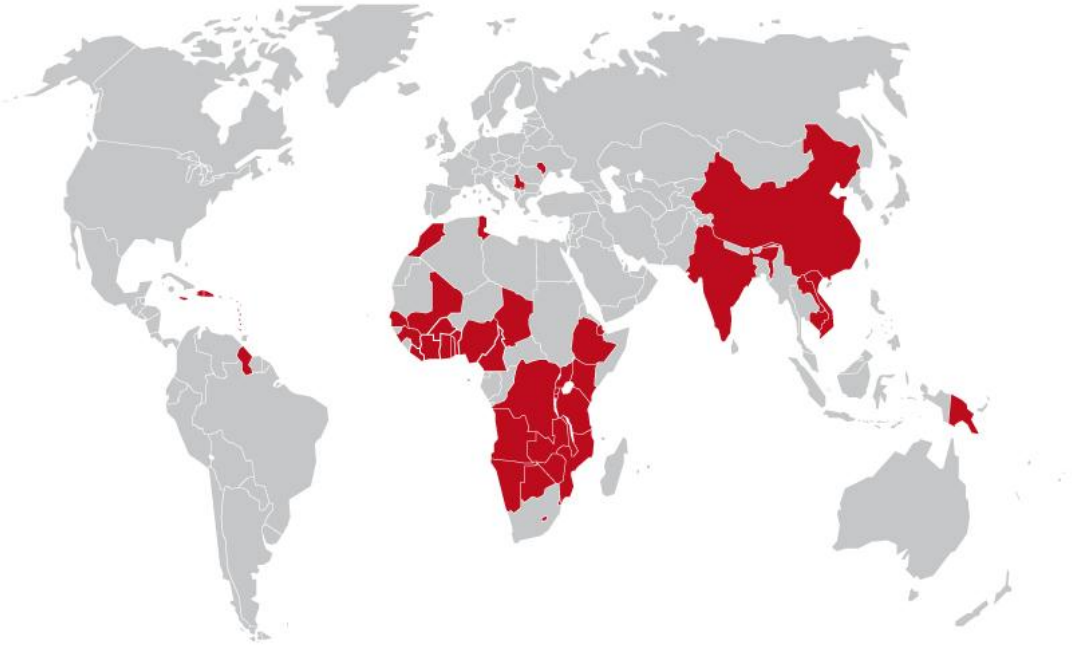
Criteria	Rating
1. Does it fit within UNITAID's mission and goals (Section 1)?	- Yes/No
2. What is the importance of the public health problem? - Scope/scale of problem? - Specific (vulnerable) populations? - Severity of problem?	- High/Medium/Low - Large/Medium/Small or specific number - e.g. pregnant women, children, rural population - Life-threatening, disabling, etc. or in DALYs
3. What is/are the priority market shortcomings in this niche? [Identify Market Shortcomings]	- Safe, efficacious and quality product - Adapted to target populations - Affordable and sustainable - Available[8]
4. What would be the public impact of resolving the market shortcomings? - Scope/scale of impact? - Specific (vulnerable) populations? - Depth of impact?	- High/Medium/Low - Will reduce #s affected by Large/Medium/Small or specific quantity - Will help children, etc - Life-saving, morbidity reducing, etc. or in DALYs
5. How feasible is it to resolve the market shortcomings?	- High/Medium/Low

[80] UNITAID (2009). *Strategy 2010-2012: Improving Global Markets to Address HIV/AIDS, Tuberculosis, and Malaria.*

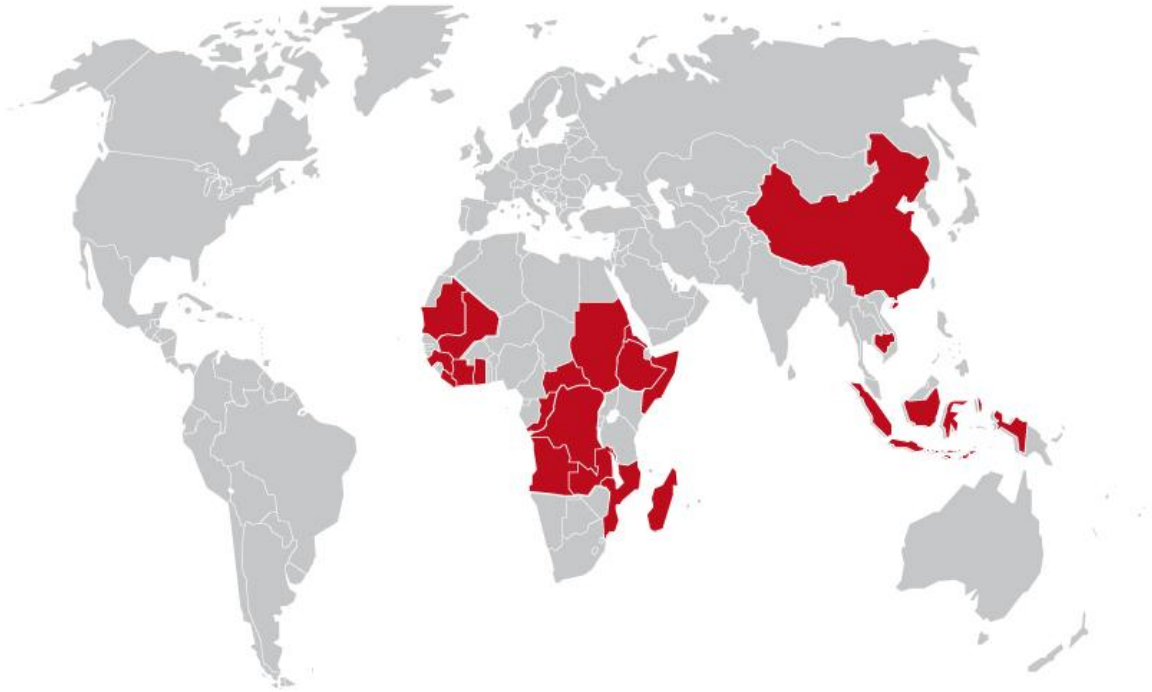
Level 2 Criteria

Criteria	Rating
1. Does it fit within UNITAID's mission and goals (Section 1)?	- Yes/No
2. What is the importance of the public health problem? - Scope/scale of problem? - Specific (vulnerable) populations? - Severity of problem?	- High/Medium/Low - Large/Medium/Small or specific number - e.g. pregnant women, children, rural population - Life-threatening, disabling, etc. or in DALYs
3. What is/are the priority objective(s)? [Identify Market Shortcomings]	- Safe, efficacious and quality product - Adapted to target populations - Affordable and sustainable - Available
4. To what extent does the project adhere to UNITAID's Guiding Principles?	- i.e. Innovative, Efficient Sustainable, Additional, Complementary, Global impact, Globally equitable, Pro-health approach to intellectual property, Transparent, Effective, Flexible, Forward-looking
5. Accurate identification of a plausible market shortcoming.	- High/Medium/Low
6. Plausibility of intervention having the expected market impact and leverage effect; confidence in quantitative market impact targets and announced leverage potential; post-grant sustainability of Market Impact.	- High/Medium/Low; Large/Medium/Small
7. Plausibility of intervention having the expected public health impact; confidence in quantitative public health targets	- High/Medium/Low, Large/Medium/Small
8 Importance of the desired public health impact: - -Scope/scale of impact? - Specific (vulnerable) populations? - Depth of impact?	- High/Medium/Low - Will reduce #s affected by Large/ Medium/Small or specific quantity - Will help children, etc - Life-saving, morbidity reducing, etc. or in DALYs
9. Quality of other proposal components: - Budget and Budget Narrative - Timeline - Monitoring and Evaluation Plan - Risks and risk mitigation - Transition Plan	 - High/Medium/Low - High/Medium/Low - High/Medium/Low - High/Medium/Low - High/Medium/Low
10. Value for money: - Projected health benefits per unit of UNITAID expenditure	- TBD

Appendix B: Countries (49) Benefitting from UNITAID Funding for HIV/AIDS[81]

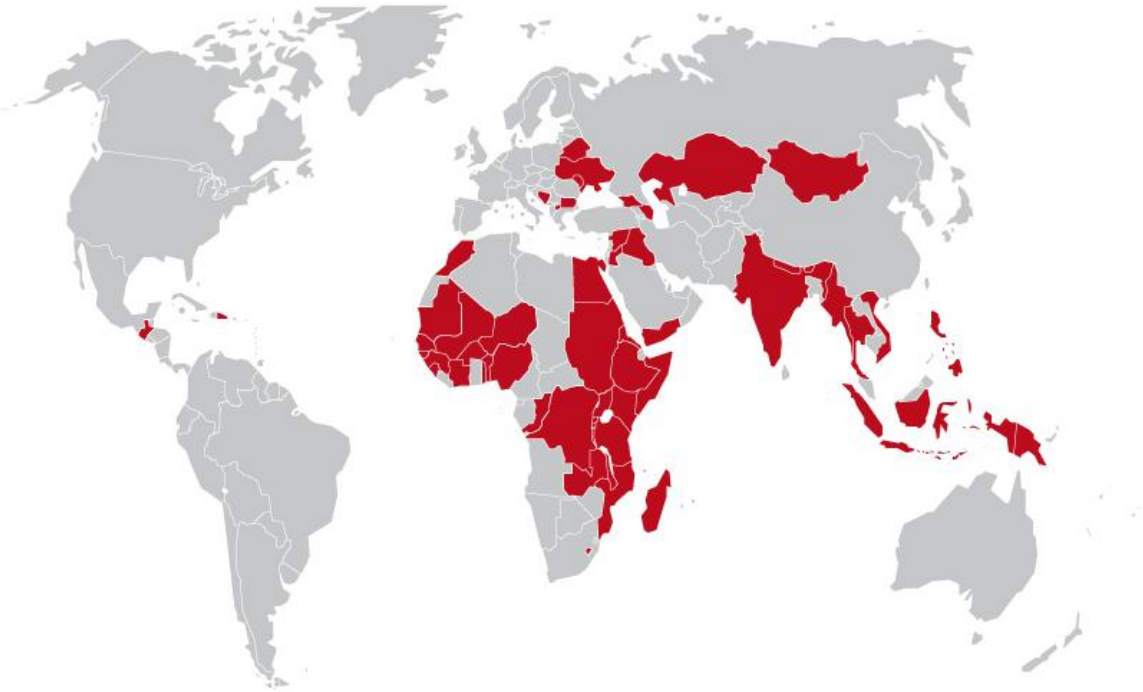


Appendix C: Countries (29) Benefitting from UNITAID Funding for Malaria[82]



[81] UNITAID (2010). "Countries Benefitting from HIV/AIDS Funding." Accessed March 18, 2012 at http://www.unitaid.eu/en/hivaids-projects
[82] UNITAID (2010). "Countries Benefitting from Malaria Funding." Accessed March 18, 2012 at http://www.unitaid.eu/en/malaria-projects

Appendix D: Countries (72) Benefitting from UNITAID Funding for Tuberculosis[83]



[83] UNITAID (2010). "Countries Benefitting from TB Funding." Accessed March 18, 2012 at http://www.unitaid.eu/en/tb-projects

Appendix E: Key UNITAID Challenges and Achievements, 2006-2009 (Self-Reported)[84]

HIV/AIDS		
CHALLENGES-2006	**UNITAID ACTIONS**	**ACHIEVEMENTS-2009**
• No child adapted ARV formulations; • Fixed dose combination (FDC) ARVs needed to promote adherence to treatment	• Create a market for paediatric ARVs by providing funds to CHAI to buy them • Encourage purchase and use of child-adapted fixed dose combinations.	• UNITAID funded projects provide 100% of the market for most paediatric ARVs[2]. • AZT-based paediatric FDCs (both dual and triple) provided to 30 low income countries; and • 84% of these products are provided by multiple generic suppliers.
Limited access to 2nd line medicines in low income countries	UNITAID provides funding to CHAI to buy quality 2nd line medicines from generic manufacturers at lowest prices through cost plus negotiations.	• UNITAID support represents 50% of the demand[3] for 2nd line ARVs. • The price of key regimens reduced by more than 50% from 2006 to 2009.[4]
Integrated approach to prevention of mother to child transmission of HIV (PMTCT) missing in low income countries	Support to UNICEF to integrate: • HIV testing of pregnant women, • Treatment of HIV+ pregnant women with effective ARVs; and • testing and opportunistic infection medicines for infants at risk of HIV	• First time support for integrated PMTCT of HIV. • Development of the Mother and Baby pack to provide basic medicines and support to HIV positive women and their infants to prevent transmission of HIV and assist with treatment in rural communities.
Increased patenting of medicines in low and middle income countries, making decreases in prices for future ARV formulations harder	In 2009, the UNITAID Executive Board supported the establishment of a legal entity to house the Medicines Patent Pool for ARVs with start-up funds from UNITAID.	The Patent Pool will become operational the second half of 2010

2 Except for Lopinavir/ritonavir, for which UNITAID provides 82% of the market volume.
3 Generic manufacturer accessible demand, excluding Argentina, Brazil, China and Mexico.
4 Tenofovir disoproxil fumarate + Lamivudine and Lopinavir/ low dose ritonavir (TDF +3TC & LPV/r) now available at US$561 per patient per year and Tenofovir disoproxil fumarate + emitricitabine and Lopinavir/low dose ritonavir (TDF + FTC & LPV/r) at US$582 per patient per year. Prices prior to UNITAID support to the market for these medicines were between US$1,105 and US$ 1,789, depending on the country procuring the products.

[84] UNITAID (2010). "Demonstrating UNITAID's Public Health and Market Impact.

Malaria		
CHALLENGE-2006	**UNITAID ACTION**	**ACHIEVEMENTS-2009**
To replace ineffective anti-malaria medicines with ACTs, the only remaining effective treatment for malaria. Only one manufacturer making ACTs in a co-blister (sub-optimal) formulation.	Provide funding to UNICEF and TGF for the scaling up of ACTs in high burden malaria countries. Encourage the production of fixed dose combination ACTs from multiple manufacturers.	• Over 19 million ACTs have been provided to high burden malaria countries since 2007. • 8 out of the 9 new ACTs prequalified (and from multiple manufacturers) since 2007 are fixed dose combination medicines, essential for adequate patient treatment.
Predominately private sector market for anti-malarials meaning that patients pay high prices for ACTs.	UNITAID supports the Affordable Medicines for Malaria Facility of TGF to provide subsidized ACTs to both the public and private sectors to facilitate lower prices to end users	• Countries for the AMFm pilot have been chosen and the facility is about to be launched; • Market size doubled for 2010-2011 with a number of manufacturers making quality ACTs
Stock outs of LLINs triggered by change in policy for provision of nets to households (2 per household)	UNITAID provides funding to UNICEF to buy 20 million LLINs in 2009 to prevent stock outs and facilitate time critical distribution	• 20 million LLINs are provided to high burden malaria countries in 2009, preventing stock outs and contributing to the number of LLINs needed by 2010; • UNITAID has supplied nearly 20% of the LLINs in high burden countries for 2009.

TB		
CHALLENGE-2006	**UNITAID ACTION**	**ACHIEVEMENTS-2009**
Stock outs expected for 1st line TB medicines for countries awaiting TGF round funding	• Provide 785,080 treatments for 19 countries through funding support to the Global Drug facility of the Stop TB Partnership. • Established rotating stock pile for first line TB medicines to increase supply security and avoid a repeat of this situation.	• Prevent patient treatment interruptions due to stock outs of medicines leading to less development of drug resistant TB strains. • Improve delivery time of medicines for newly detected TB patients
Create a market for better adapted paediatric TB medicines to treat children with TB	Funding support to GDF to provide 668,141 curative and preventive treatments for children.	Facilitated the development of 7 different paediatric formulations and 13 products consisting of both blister and bulk packaging are now available.
Scale up access to treatment for MDR TB	Provide MDR TB treatments to high burden TB countries and establish a strategic rotating stock pile of 5800 (24 month) MDR TB treatments to improve timely treatment of newly detected cases.	• Provision of over 6,000 MDR TB treatments (of 24 months duration), • Use of strategic rotating stockpiles to initiate patients on treatment quickly to prevent the spread of drug resistant TB.
Scale up detection of MDR TB through development of better laboratories and state of the art tests in low and middle income countries.	Support to the Foundation for Innovative Diagnostics (FIND), GDF and WHO to provide state of the art laboratory facilities and testing protocols to detect MDR TB.	Supported development of a fully functioning MDR-TB detection laboratory in Lesotho that is now using state-of-the-art Line Probe Assay tests to rapidly detect drug resistant TB

Appendix F: UNITAID Key Performance Indicators (2010)[85]

Indicator	Milestone 2010	2009	2010	trend
1. Monitoring the market: UNITAID has systems and reports in place to track the market for UNITAID target products	progress report started based on information collected in UNITAID's market Intelligence Information system	Market Intelligence Information System tender complete. Project teams selected.	Market Dynamics team being hired; landscape analyses started	Increasing
2. Percentage of UNITAID funded projects reporting to UNITAID annually on progress towards their well/defined transition plans.	100% of new projects report progress towards transition (where relevant to the project)	N/A	50%[3]	Increasing

Indicator	Milestone 2010	2009	2010	trend
1. Median prices paid for priority UNITAID medicines, diagnostics and related products reported by imple-menting partners to UNITAID's Market Intelligence Information System	At least 50% reduction from 2008 in median prices paid for key paediatric and 2nd line ARVs[5]	2nd line ARVs: 11% and 29% reductions on key 2nd line regimens[6] from 2008 to 2009 Paediatric ARVs: 8% price reduction for key AZT and ABC based fixed dose combinations[7] (cumulative change 2008-2009)	2nd line ARVs: A further 9% and 4% price reduction on key 2nd line regimens[8] from 2009 to 2010 (53% reduction cumulative 2008-2010) Paediatric ARVs: 39% price reduction for key AZT and ABC based fixed dose combinations from 2009 to 2010 (49% reduction cumulative 2008-2010) ACTs: AMFm negotiates 80% price reduction of private sector ACT prices.	Decreasing prices
2. # new manufactu-rers of priority UNITAID medicines, diagnostics and related products with products available for public procurement	At least 1 new market entrant with quality ARV participating in the CHAI supplier selection process	6 new ARV suppliers for 2nd line ARVs	ARVs: 12 new suppliers for 2nd line ARVs TB: 4 new suppliers of products in the GDF catalogue	Increasing
3. Proportion of products in each disease area showing same or lower price than previous 12 months	Proportion of products in each disease area showing same or lower prices than last 12 months	N/A	2nd line ARVs: 8 out of 9 medicines[9] showed decreasing prices. 1st line TB medicines (stockpile): 15 out of 16 products reduced or maintained prices from 2009.	N/A

[85] UNITAID (2010). *Key Performance Indicators 2010.*

Indicator	Milestone 2010	2009	2010	trend
1. # of priority UNITAID medicines and diagnostics prequalified annually by niche	1) # of medicines and diagnostics prequalified for HIV, TB and malaria reported to UNITAID in interim and annual reports; 2) Target for 2009 (7 for HIV, 7 for TB and 3 for malaria)	1) 18 UNITAID priority medicines prequalified out of a total of 44 medicines prequalified. 2) 10 ARVs, 3 ACTs and 5 anti-TB medicines prequalified[13]	1) 15 UNITAID priority medicines prequalified out of a total of 36 medicines prequalified. 2) 9 ARVs, 5 anti-TB and 1 malaria	Stable
2. Median number of days taken to prequalify a medicine	Less than 547 days for a medicine with a dossier submitted in 2010	736 days	663 days	Decreasing
3. Median number of days taken to prequalify a diagnostic test	Dossiers are assessed by the diagnostics team for first time in 2010	Diagnostic= N/A	15 days	One rapid test for malaria prequalified

Indicator	Milestone 2010	2009	2010	trend
1. Manufacturer lead times for key medicines and diagnostics reported to UNITAID annually by Implementing Partners.	Manufacturer lead times reported to UNITAID by implementing partners allow for comparisons across medicines and diagnostics manufacturers;	Table 4	Table 9	Meeting milestone
2. Number of stock-outs of UNITAID funded medicines to treat HIV, TB and malaria experienced by developing countries known and monitored by implementing partners and reported to UNITAID	1. Stockpile for MDR-TB medicines functioning at 5,800 treatments; 2. Buffer stock for ACTs in place for all UNICEF approved suppliers with LTAs	1. Strategic rotating stockpile reached 5,800 patient treatments for MDR-TB; 2. All 14 suppliers with LTAs to for UNICEF ACTs have buffer stocks in place; 3. 100% of LLINs distributed to 9 countries facing shortages in 2009.	1. The indicator has changed in 2011 and UNITAID is working with implementing partners to provide up to date country level reporting. 2. GDF reported a stock out of paediatric anti-TB medicines in Niger.	N/A

Indicator	Milestone 2010	2009	2010	trend
1. Implementing partners report the number of new paediatric-adapted products for treatment of a) HIV, b) TB and c) malaria.	All implementing partners report number of new paediatric-adapted products according to their project types and intended outcomes.	GDF reported 2 additional paediatric medicines in its catalogue for 2009;	a) HIV: no new; b) TB: 1 (Isoniazid) prequalified c) Malaria: no new	Stable
2. Number of fixed dose combination (FDC) treatments for a) 2nd line products and b) ACTs (malaria) to ensure better patient adherence to treatment.	All implementing partners report number of new fixed dose combination treatments according to their project types and intended outcomes.	8 out of 9 of the prequalified ACTs are FDCs	a) 2nd Line: Atazanavir & heat stable ritonavir available as a co-blister; b)ACTs: none	Stable

Indicator	Calculation notes	Milestone 2010	2009	2010	Trend
1. Per cent (%) Secretariat costs (US$) relative to direct project costs for funded projects (US$)	Secretariat costs exclude project specific expenses and expenses related to market dynamics; Implementing partners exclude Millennium Foundation and Medicines patent Pool.	Secretariat costs are less than 5% of annual direct project costs for funded projects	2.4%	3.5%	Increasing
2. Ratio of annual disbursements to UNITAID full time equivalent (FTE) staff members	Annual disbursements exclude Millennium Foundation and Medicines patent Pool	2010 sets the benchmark	N/A	US$ 6,473,829	N/A

Indicator	Calculation notes	Milestone 2010	2009	2010	Trend
1. Median time between Board approval of project for funding and first disbursement for all projects;	Includes new projects only	10% reduction from baseline	175	105	Decrease
2. Median time between Board approval and signing of agreements for all projects;	Includes Board approvals that have resulted in an agreement in reporting year	10% reduction from baseline	157	57	Decrease
3. Median time between signing of agreement and first disbursement for all projects;	Includes new projects which require first disbursements to start work	10% reduction from baseline	18	48	Increase

Indicator	Calculation notes	Milestone 2010	2009	2010	Trend
1. Per cent (%) of total budget spent by Secretariat annually (budget performance)	Uses an arithmetical formula using budget approved by the Board in its June meeting	At least 70% of the Board approved budget is spent by the Secretariat annually	64% of overall budget for 2009 spent by the Secretariat	66%	Increasing
2. Per cent (%) budget allocations per country income classifications (as designated by World Bank)	Calculated based on partner project spending annually	Low income: at least 85%; Lower middle income: less than 10%; Upper middle income: less than 5%	Low income: 87.2%; Lower middle income: 9.6%; Upper middle income: 3.2 %	Low income: 85.9 %, Lower middle income: 6.9 %; Upper Middle income: 7.6 %	Stable
3. Per cent (%) of actual expenses of implementing partners compared to the latest UNITAID approved budget for a financial year for each UNITAID funded project.	Only grants with annual budgets included here	Baseline is reported in 2010 report	N/A	85%	N/A

Indicator	Calculation notes	Milestone 2010	2009	2010	Trend
1. Rate of turnover for Professional positions	Percent of number of fixed term staff leaving annually/ by number of fixed term staff employed at 31 December of each year	Less than 10%	3.5%	6.7%	Increasing
2. Per cent (%) staff with learning and development plan in place and demonstrated progress towards implementing this plan annually.	based on WHO e-work system	100%	N/A	41%	Increasing
3. Per cent (%) of actual expenses of implementing partners compared to the latest UNITAID approved budget for a financial year for each UNITAID funded project.	based on WHO e-work system	100%	N/A	[15]	
4. Per cent of Professional posts filled by women	Percent of number of fixed term professional staff/ total number of professional fixed term staff	At least 50% of Professional posts filled by women	58%	57%	

Indicator	Calculation notes	Milestone 2010	2009	2010	Trend
1. Funds collected mid-year as per cent of funds collected annually	Includes only monies released from donors by 30 June in each calendar year.	25%	17%	25%	Increasing
2. Per cent (%) of donors who have contributed in previous year and who continue to contribute.	Calculated over two calendar years (i.e. 2009 for previous years contribution compared to 2010 for continued contributions)	75%	75%	75%	stable
3. Per cent (%) increase in number of new donors to UNITAID annually	Measured over the calendar year	10%	N/A	0%	Stable

Indicator	Calculation notes	Milestone 2010	2009	2010	Trend
1. Number of Board members who have gone through Board member training within the last 3 years.	Cannot be measured until plans for training are developed and approved.	Board member training process developed and implemented	N/A	None	N/A

Indicator	Notes on calculations	Milestone 2010	2009	2010[16]	Trend
1. Number of treatments delivered and estimated number of patients treated known for each project on an annual basis	These are estimates based on implementing partner reporting	100% of UNITAID-funded projects have partner verified worksheets describing the estimated patients treated by country available on the UNITAID web site and updated by Q2 of the following year	HIV: **over 600,000** ARV treatments delivered to 44 countries TB: **424,543** TB treatments delivered in 2009 to 64 countries Malaria: nearly **19 million** malaria treatments (ACTs) delivered to date for 16 countries **13.5 million** LLINs delivered to 8 countries in 2009	HIV: **over 700,000** ARV treatments delivered to 52 countries[17] TB: **over 250,000** TB treatments delivered in 2010 to 68 countries. Malaria: over **17.6 million** malaria treatments (ACTs delivered for 32 countries. **6.5 million** LLINs delivered to 1 country in 2010	Stable
2. Number of patients treated as percentage of number on treatments planned for the year as per national forecasts shared with Implementing Partners	These are calculations done by the Secretariat based on implementing partner reporting and contractual agreements for 2010	Partners report % of patients treated relative to number of planned treatments based on annual agreed forecasts with beneficiary country government.	N/A	Reported for HIV projects (paediatric, 2nd line and PMTCT)	

Indicator	Notes on calculations	Milestone 2010	2009[18]	2010[19]	Trend
Costs (US$) of treatments delivered known for each project on an annual basis	Provided by implementing partners in 2010 annual reports	100% of UNITAID-funded projects have partner verified worksheets describing the costs (US$) of patients treated by country available on the UNITAID web site and updated by Q2 of the following year	HIV: **US$285,649,351** spent on products delivered to countries. . TB: **US$ 46,502,271** spent on anti-TB medicines and diagnostics. Malaria: **US$ 247,649,174** spent by partners on Malaria actions.	HIV: **US$ 160 million.** TB: **US$ 32.2 million.** Malaria: **US$ 57 million**	In accordance with project plans

Indicator	Notes on calculations	Milestone 2010	2009	2010	Trend
1. Estimated number of lives saved as a result of UNITAID funded ARVs, anti-TB medicines and ACTs.	Methodology under development	1st analysis completed based on partner results for 2010	N/A	Consultant working on partner submitted data	N/A
2. Estimated number of life years gained as a result of UNITAID funded ARVs, anti-TB medicines and ACTs.	Methodology under development	1st analysis completed based on partner results for 2010	N/A	Consultant working on partner submitted data	N/A

Indicator	Baseline 2009	Milestone 2010	2009	2010	Trend
1. Per cent (%) of UNITAID funded projects that have a costing (US$) for operational costs and the sources of operational costs provided at the start of project funding.	N/A	Partners report source and amounts of operational costs to UNITAID annually	N/A	HIV: CHAI reports contributing US$ 13 million to complementary programmatic work in UNITAID funded countries Malaria: US$ 86 million are contributed by the UK (DFID) and the Gates Foundation for phase 1 of AMFm TB: FIND reports raising US$ 4.2 million funds for category 1 countries and US $1.3 million for category 2 countries	Increasing

Indicator	Baseline 2009	Milestone 2010	2009	2010	Trend
1. Per cent (%) of UNITAID implementing partners that have MoUs signed with all national governments before start of the project or within Q1 of the project start year.	All partners have a requirement for an MoU arrangement with national governments but only 25% sign all agreements before the start of the project or by Q1 of the project start year.	100% of new partners with new projects sign MoUs with beneficiary country national governments by Q1 of the project start year.	25%	81% [21]	Increasing