15th Executive Board
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Quai d'Orsay
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Agenda Item 8.1

Operations Update

For Information ☒ **For Review & Advice** ☐ **For Decision** ☐

List of acronyms and abbreviations

ACT	Artemisinin-based combination therapy
AIDS	Acquired Immune Deficiency Syndrome
AMFm	Affordable Medicines Facility for malaria
API	Active Pharmaceutical Ingredient
ART	Antiretroviral treatment
ARV	Antiretroviral drug
ATV	Atazanavir
AZT	Azidothymidine (Zidovudine)
CHAI	Clinton Health Access Initiative
DFID	Department for International Development (UK)
FDC	Fixed-dose combination
FIND	Foundation for Innovative New Diagnostics
GDF	Global Drug Facility (Stop TB Partnership)
GFATM	The Global Fund to Fight AIDS, TB and Malaria
GMP	Good Manufacturing Practice (WHO)
HIV	Human Immunodeficiency Virus
LLIN	Long-Lasting Insecticide-Treated bed Net
MDR-TB	Multi-drug resistant TB
PMTCT	Prevention of Mother-to-Child Transmission (of HIV)
PRC	Project Review Committee
RUTF	Ready-to-use therapeutic food
r	Ritonavir
SRA	Stringent Regulatory Authority
SRS	Strategic Rotating Stockpile
TB	Tuberculosis
TDF	Tenofovir
UN	United Nations
UNICEF	United Nations Children's Fund
UNITAID	United Nations International Drug Purchase Facility
WHO	World Health Organization

Summary of impact for selected UNITAID projects

PROJECT	MARKET INTERVENTION	PUBLIC HEALTH
2nd line ARVs (HIV/AIDS)	• Price negotiation and product procurement (with CHAI); • Support to WHO/UN prequalification programme	More patients treated with quality 2nd line medicines at lower prices
Paediatric ARVs (HIV/AIDS)		More patients started on treatment with quality assured child adapted formulations (including FDCs)
PMTCT HIV	Provision products for PMTCT to integrated programmes in high burden HIV countries to stop the spread of HIV to children (with UNICEF).	Integrated testing, treatment and support to HIV positive pregnant women and their infants
ESTHERAID	Technical support and training in supply chain management for ARVs and HIV tests	Improved patient care at monitored treatment sites
1st line TB	1st line medicines procured and delivered to prevent stock outs in countries awaiting additional external funds.	Prevent development of resistant TB by providing patients with uninterrupted quality medicines.
Expand TB diagnostics	Provide laboratory infrastructure, training and new tests to build a market for State of the Art MDR TB testing	Testing for MDR TB is quicker and more efficient so people can be treated faster to stop the spread of MDR TB
MDR-TB Scale up	• Increase number of quality assured manufacturers to stabilize the market; • Support to WHO/UN prequalification programme; • Support strategic rotating stock pile to facilitate immediate patient treatment.	Increase patient access to quality treatments and enable patients with MDR strains to be immediately initiated on medication to prevent spread of MDR TB.
ACT Scale up	• Product procurement; • Support to WHO/UN prequalification programme	More patients have better access to ACT to treat malaria. ACTs replace monotherapy, delaying the development of resistance to Artemisinin
Affordable medicines for malaria facility (AMFm)	Reduce prices to end user purchasers of ACTs by providing subsidized ACTs to the private sector	More people can afford ACTs so that these replace ineffective treatments leading to better patient outcomes

1. Background

This document summarizes UNITAID-funded achievements based on partner reports for the time period from January to June 2011. Implementing partners reports are received twice a year, in September/October and March/April. At this point, we have received and validated project reports for the first half of 2011. A complete reconciliation of facts and figures for the 2011 calendar year will be reported at the June Executive Board meeting in 2012 as part of the Key Performance Indicators Report 2011. This report will be available on 30 June 2012.

The remainder of this report provides a brief update on relevant actions since the release of the Key performance Indicator Report 2010 on 30 June 2011. More comprehensive Operations updates are available as Annex 1 of this document.

2. Operations

UNITAID currently supports 17 projects (Table 1) which share the overall objectives of increased access to efficacious, safe products that are affordable and sustainably priced available in sufficient quantities and delivered within reasonable timeframes. They use the tools appropriate to their target disease and specific product market to achieve their intended impact with time-limited financial support from UNITAID. External mid term reviews of 7 projects have been completed and UNITAID is working with partners to implement specific reviewer recommendations summarized in Annex 2.

Two projects have been completed[1] and a further 6 are scheduled to finish on 31 December 2011[2]. UNITAID continues to monitor the transition of its projects to other sources of donor funding in order secure its market achievements (see

1 Provision of ACTs to Liberia and Burundi to prevent stock outs (UNICEF, WHO); Provision of LLINs to countries to prevent stock outs (UNICEF).

2 Support to GFATM Round 6, ACT Scale up (UNICEF, GFATM) First line anti TB drugs initiative (GDF), Paediatric TB medicines project (GDF), CHAI 2nd Line ARV project and Prevention of Mother to Child Transmission of HIV (PMTCT-I, UNICEF).

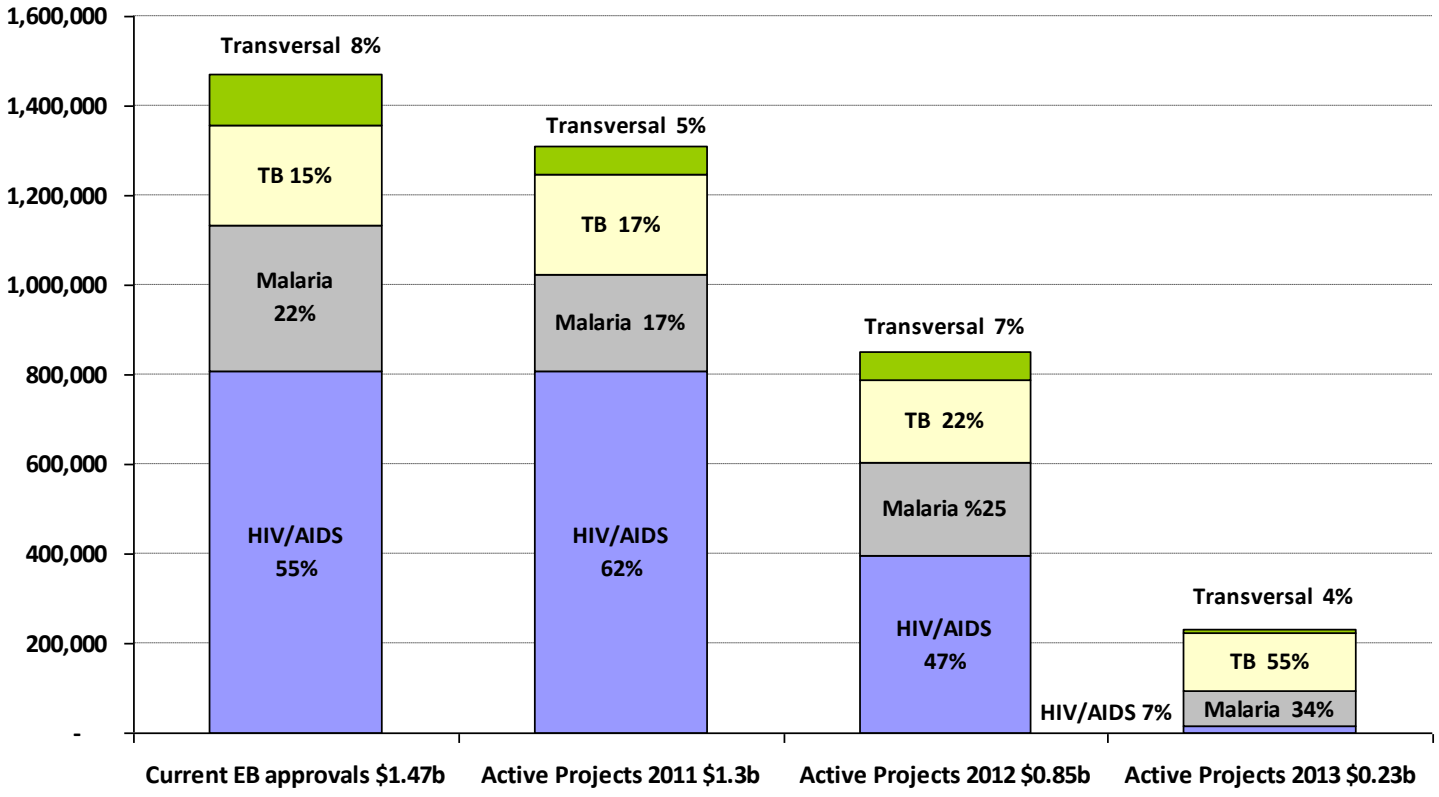
Annex 3). The evolution of UNITAID's funding portfolio (Figure 1) shows that UNITAID has the resources to invest in new projects and to re-shape, if necessary, existing grants.

End of project reviews are being implemented to make sure that lessons learnt from project implementation are fully integrated into the planning and management of future UNITAID projects.

Table 1. List of UNITAID funded projects, partners and monies (US$, '000) allocated to each disease area as of November 2011.

	HIV	TB	Malaria	Cross cutting
	Paediatric HIV/AIDS treatment program (CHAI)	First line anti TB drugs initiative (GDF)	Artemisia Supply project (i+Solutions)	Support to Round 6, phase 1 (GFATM)
	2nd line Adult HIV/AIDS treatment Program (CHAI)	MDR TB Scale up (GDF)	Affordable medicines for malaria facility (AMFm) (GFATM)	Support for quality assurance of medicines (WHO)
	Prevention of Mother to Child Transmission of HIV(PMTCT-I) (UNICEF)	MDR TB Acceleration of Access initiative: Strategic Rotating stockpile (GDF)	ACT Scale up project (UNICEF, GFATM)	Support for quality assurance of diagnostics (WHO)
	Prevention of Mother to Child Transmission of HIV, expansion (PMTCT-II) (UNICEF)	Paediatric TB project (GDF)		
	Nutritional support to prevention of mother to Child Transmission of HIV, (PMTCT-III) (UNICEF)	Expand MDR TB diagnostics(FIND, GLI, GDF)		
	Support to supply chain management of HIV medicines and diagnostics in West Africa (ESTHER)			
Total '000 (%)	**806,273 (55)**	**328,753 (22)**	**222,470 (15)**	**114,085 (8)**

Figure 1. Evolution of the current project portfolio 2011-2013, without any new Board approved projects



3. HIV/AIDS

UNITAID support to projects that target the markets for HIV tests, anti-retrovirals and related products has improved treatment access through lower prices, better product availability and integrated care programmes for children and pregnant women. Now there are specific challenges related to sustaining these achievements over the longer term. Two projects that focus on interventions in the HIV/AIDS market are scheduled to come to an end in December 2011. These projects are the CHAI 2nd Line Adult ARV project and the UNICEF Prevention of Mother to Child Transmission of HIV/AIDS project and transition of the project achievements is uncertain at this time due to the financial constraints of many global public health funding agencies. The main challenges that UNITAID faces as these projects conclude are:

- Maintaining price reductions achieved for the standard second line Adult ARV regimens and passing these price improvements on to all purchasers of 2nd Line medicines.
- Continued on time product delivery for prevention of mother to child HIV transmission (PMTCT) programmes trying to integrate testing, prevention and care of pregnant women and their infants in countries facing a high burden of HIV/AIDS; and
- Successful transition of projects, with market improvements, to country and GFATM funding.

Transition to other funding sources is an important barrier to completion of these projects.

For the 2nd Line Adult ARV medicines project with CHAI, most countries are on track to move to other funding sources but transition plans have been disrupted for some by the cancellation of the Global Fund round 11 which they planned to use for 2nd Line Adult ARV support[3]. CHAI is requesting a no-cost extension to allow any un-spent 2011 funds to carry over into 2012 to support these countries.

For the PMTCT project, implementation has been slower than expected and

[3] Burundi, Cameroon, DR Congo, Mozambique, Uganda and Zimbabwe.

delivery of products will require a no-cost extension from UNITAID. The "in-country" programmatic support to countries to find alternative sources of funding for PMTCT products has also been delayed and will also require a no-cost extension.

For the two continuing projects, Paediatric ARV medicines project with CHAI and Support to supply chain management of HIV medicines and diagnostics in West Africa with ESTHER work towards meeting project objectives continues. For the Paediatric ARV project, maintaining a healthy, competitive market for paediatric ARVs is difficult because there are many recommended formulations and a declining number of patients, thanks to PMTCT programmes in high burden countries. The number of manufacturers entering the market to make new and existing formulations is less than expected and this has limited the prices reductions to specific ARVs. However, the project has dramatically increased the use of PCR tests to diagnose infants early and combined with better forecasting and improved pooling of orders, this may help to stabilize the paediatric ARV market longer term. UNITAID and CHAI are working on transition of this project to other funding sources through the Paediatric ARV Procurement Working group[4] and a dedicated transition team supported by UNITAID.

One of the key challenges that UNITAID faces is making sure that the products that it supports through partners reach people in need. The planning for delivery of tests and medicines to treatment centres requires the technical support of specialized medicine management practices. Through ESTHER, UNITAID is providing this needed technical support to improve supply chain management of its products in 5 West African countries. This work started in 2011 and we are waiting for results from its annual report due in March 2012.

The key challenges in each project area are summarized in the table below along with project achievements and next steps for UNITAID.

[4] UNITAID, Supply Chain Management Systems (SCMS), UNICEF, CHAI, GFATM.

Key challenges, achievements and actions in HIV/AIDS

HIV/AIDS		
CHALLENGES	**ACHIEVEMENTS-2011**	**NEXT STEPS**
Maintaining a healthy, competitive market for paediatric ARVs	• Scale up of PCR testing to diagnose HIV positive infants early[5]. • 8% further price reductions[6] on key paediatric ARVs on latest negotiation with suppliers (March 2011). • A leading paediatric AZT-based fixed dose combination treatment[7] costs US$130 per patient per year today instead of US$ 252 in 2006.	• Continued scale of early infant diagnosis with PCR testing; • Improved forecasting and order pooling; • transition of CHAI paediatric ARV project to other funding sources through a dedicated transition team supported by UNITAID
Transferring price reductions achieved for the standard second line anti-retroviral (ARV) regimens to other purchasers.	• Leading 2nd Line regimen[8] costs US$527 per patient per year today instead of US$1500 as in 2006. • Development of a stable Atazanavir/ritonavir FDC[9] which will reduce the cost of the leading 2nd line regimen to less than US$400 per patient per year.	• No-cost extension to CHAI to allow any unspent 2011 funds to carry over into 2012 to support countries which will not transition to other sources to buy these medicines. • Procurement of ATV/r as it becomes available to the ARV market; • Close monitoring of country-level transition plans.
Continued on time product delivery for prevention of mother to child HIV transmission (PMTCT) programmes.	• HIV testing of over 8 million pregnant women in 8 countries. • Treatment of HIV+ pregnant women with effective ARVs. • Increased access to testing and opportunistic infection medicines for infants at risk of HIV	• No-cost extension is required to support countries to complete planned activities for their PMTCT programmes.
Verify that the HIV tests and treatments that UNITAID supports reach people in need	• ESTHERAID is providing needed technical support to improve supply chain management of its UNITAID supplied HIV products in 5 West African countries.	• The project started in 2011 and annual report will be available in March 2011. • Follow up on country-level implementation of the project; • Propose a monitoring system that tracks the progress of medicines through the supply chain.

[5] Over 84,000 PCR tests run in beneficiary countries in 2011.
[6] From 2010 prices, this amounts to an overall price reduction of 80% across all paediatric formulations since 2006.
[7] AZT + 3TC + NVP (300mg+ 150mg +200mg)
[8] Generic TDF +3TC (300mg + 300 mg) & LPV/r (200 mg + 50 mg) in 2010.
[9] This will be a possible replacement for LPV/r in the regimen containing TDF + 3TC (or FTC). CHAI estimates ATV/r will cost up to 60% less than LPV/r, when it becomes available on the market . It has been recently approved by the FDA and the WHO Prequalification programme.

4. Malaria

UNITAID's interventions in the market for effective malaria medicines (ACTs) have led to considerable change since 2006 when there was only one manufacturer of an ACT co-blistered formulation. To date there are several generic manufacturers making ACTs and 8 of these products are fixed dose combinations (FDCs) prequalified through the WHO Prequalification programme funded by UNITAID. However the market for anti-malarials remains private sector driven, and end users can and do pay a high price for ACTs as opposed to cheaper but ineffective anti-malarials. The challenge for the market remains to quickly replace ineffective anti-malarial medicines with ACTs by making them affordable for end users and at the same time, stabilizing the price of the active ingredient of ACTs, Artemisinin[10] in the face of rising demand.. UNITAID currently supports 3 projects related to this market challenge, the ACT Scale up (UNICEF and GFATM), the Affordable Medicines for Malaria facility (AMFm, GFATM) and the Assure Artemisinin supply project (A2S2, with i + Solutions).

The ACT scale up project has delivered 29 million ACTs to 8 high burden countries since its start in 2007. The project is scheduled to end at the end of 2011. However, the project has suffered some implementation delays and the GFATM will submit a formal request for a no-cost extension until 2013 to complete deliveries and all 3 grants[11] to purchase their planned treatments.

The AMFm objective is to significantly reduce the price of ACTs paid by end-users through a subsidy mechanism to the private sector. The project has delivered over 46 million ACTs to first line buyers in countries. Prices have fallen for end users from US$8 to 10 to around US$0.33 to1.32 per treatment in some countries. However, orders from first line buyers have significantly exceeded the modeled demand forecast for the product and as a result, GFATM have submitted

[10] At this moment, the active ingredient in ACTs, Artemisinin, is extracted from the *Artemisia* plant. The process of growing the plant, harvesting and extracting the Artemisinin takes around 18 months.
[11] Madagascar, South Sudan and Zambia.

a proposal to UNITAID requesting US$50 million in additional contributions to cover the remaining period of phase 1 of the project. This request has been reviewed by the UNITAID PRC and is for decision at EB15.
The A2S2 project provides loans to artemisinin extractors through tri-partite agreements between the artemisinin extractor, a prequalified ACT manufacturer and i+Solutions. The aim is to make the buying of *Artemisia* more predictable to encourage growers to produce the plant and to encourage extractors to sell the extracted artemisinin to quality assured manufacturers of ACTs. The project aims to secure 40 Metric Tons of Artemisinin, representing almost 30% of the global market. To date agreements have been made with extractors to supply 44 MT but only 4 MT have been delivered to manufacturers. Because of delays in negotiating loans and product prices, i+ Solutions are requesting a project extension. This has been reviewed by the UNITAID PRC and i+ Solutions is now working to clarify their process for negotiating loans with extractors to address PRC concerns.

The key challenges in each malaria-related project are summarized in the table below along with project achievements and UNITAID's next steps.

Key challenges and achievements in malaria

Malaria		
CHALLENGE	**ACHIEVEMENTS-2011**	**NEXT STEPS**
To replace ineffective anti-malaria medicines with ACTs, the only remaining effective treatment for malaria.	• ACT scale up delivered 29.1 million ACTs to 8 high burden countries. • 8 FDC ACTs prequalified from multiple manufacturers. Three of these were for child-adapted ACTs; important because over 50% of malaria cases are children. • Delivery lead times for ACTs to countries reduced through use of existing GFATM programmes in countries.	• The GFATM has indicated its intention to submit a formal request for no-cost extension to 2013 in order to allow the 3 grants to purchase planned amounts of ACTs. • Delivery of products purchased through the project is continuing for some grants. UNITAID continues to monitor the procurement and delivery of these products through UNICEF.
Predominately private sector market for anti-malarial medicines means that patients pay high prices for ACTs.	• 46,247,222 ACTs delivered to first line buyers in the private sector through AMFm. • Consumers are now paying between US$0.33 and US$ 1.32 per ACT treatment down from US$8 to US$10 per treatment. • Market size doubled for 2010-2011 with a number of generic manufacturers making quality ACTs.	• GFATM has submitted a proposal to UNITAID requesting and additional US$50 million to complete phase 1 of the project due to demand being greater than forecasted. • Orders for co-paid ACTs will be tightly managed to save an estimated US$40 million until additional donor funding is secured. Priority for co-payments will be given to paediatric formulations and pack sizes.
Stabilize the price of Artemisinin and secure the production of this biological product as demand for ACTs rises.	• I+ Solutions has delivered 3.93 MT of artemisinin to ACT manufacturers. • A total of US$1.37 million in loans has been paid back to the project.	• Monitor delivery of promised Artemisinin from extractors to manufacturers; • Monitor loan repayments from extractors to Triodos Bank. • Request for project extension received from i+ Solution has been reviewed by PRC.

5. Tuberculosis

UNITAID support to the Global Drug Facility of the Stop TB Partnership (GDF) continues to try and stabilize the markets for treatment and detection of multi

drug resistant (MDR)-TB and TB medicines for children. The global market size for UNITAID- supported medicines and diagnostics is small. There are an estimated 500,000 cases of MDR-TB and almost 50,000 case detections (smear positive) of TB in children annually. The low volume of products needed means that manufacturers are unwilling to invest in new, better formulated, products and prices remain high. In addition, for most anti- TB medicines, the rising costs of active pharmaceutical ingredients and oil for the manufacturing process has increased the price of patient treatments. Price reductions for medicines will be realized over a longer timeframe than anticipated. Improvements in speed and ease of case detection, supply chain management and better treatment options will lead to a more predictable demand which manufacturers can respond to by investing in the production of these medicines.

Despite difficult market conditions, UNITAID-funded projects have had some success in delivery of first line TB medicines, paediatric treatments, MDR-TB treatment scale up and diagnosis using state of the art technologies. Highlights include:

- Over 785,000 patient treatments were delivered to 19 countries who were facing stock outs of these critical medicines due to gaps in TB medicine funding.
- Over 900,000 treatments[12] for children were delivered to 57 countries.
- 4 key paediatric products showed initial price reductions of almost 30%[13].
- A Strategic Rotating Stockpile (SRS) of 5,800 patient treatments is improving treatment delivery time for urgent country orders with treatments delivered within 30 days of orders place instead of over 100 days in the absence of an SRS.
- 8 project countries are routinely detecting MDR TB using State of the Art laboratory infrastructure and advanced laboratory tests that speed up the time to diagnosis and treatment.

12 Represents both curative and preventive TB treatments for children.

13 A change in WHO treatment guidelines for children with TB means that more of these products are needed to treat the same number of children, unfortunately increasing the overall cost of treatment for children.

Two of these projects, first line TB treatment support (GDF) and the paediatric TB project (GDF) will end in December 2011. A third, the MDR-TB scale up (GDF), will end in December 2012. All three of these projects are requesting a no-cost extension to continue delivery of ordered treatments[14] or to propose new model for completion of unachieved project objectives[15]. The MDR-TB diagnosis project (FIND/GLI) will follow the recommendations of the UNITAID-initiated external mid term review which proposed actions to increase the speed of roll out and adoption of new laboratories and technologies in participating countries to realign the project with its original timeline.

The key challenges in each TB-related project are summarized in the table below along with project achievements and UNITAID's next steps.

14 Continue delivery into 2012 for the paediatric TB project and through 2013 for the MDR-TB Scale up.

15 GDF may request a no-cost extension and propose a new model for the SRS, including for high volume first line medicines. This is an ongoing discussion between UNITAID and GDF and is subject to an invitation by UNITAID for a detailed concept note.

Key challenges and achievements in TB

TB		
CHALLENGE	**ACHIEVEMENTS-2011**	**NEXT STEPS**
Avoid treatment interruption for first line TB medicines for countries awaiting GFATM funding	• 785,080 treatments for 19 countries. • All of the funds allocated to purchase treatments in this project have been used and the project has been completed (as of December 2011).	• The project will end as on 31 December 2011 after which an external end of project evaluation will be done.
Create a market for better adapted paediatric TB medicines to treat children with TB	• Over 915,000 paediatric treatments (curative and preventive) provided to 57 countries. • Initial price reductions of almost 30% for 4 key products achieved between 2008 and 2010 but eroded due to change in WHO treatment guidelines for children with TB. • 13 products consisting of both blister and bulk packaging are now available.	• No-cost extension requested by GDF to use unspent funds and complete planned activities. • GDF and WHO are drafting a new proposal to facilitate treatment of children with newly developed anti-TB formulations based on revised guidelines.
Scale up access to treatment for MDR TB by improving price, number and quality of products and facilitating faster delivery lead times	• 7,184 2nd line TB treatments delivered to 14 high burden countries. • Strategic Rotating Stockpile (SRS) created to improve treatment delivery time for urgent country orders. • SRS lead times for urgent orders reduced to around 30 days in 2010 down from approximately 110 days in 2007.	• No-cost extension requested to revise and continue the SRS. • Implement and monitor a detailed transition plan to address the needs of countries needing 2nd Line treatment support beyond 2012.
Scale up detection of MDR TB through development of better laboratories and state of the art tests.	• New Laboratory infrastructure and successful technology transfer established in 18 countries[16]. • 8 project countries[17] are routinely diagnosing MDR TB.	• Increase the speed of project roll out and adoption of new technology in participating countries. • Monitor partner scale up of diagnostic activities in countries now that initial infrastructure and training phase has been completed.

16 Azerbaijan, Cameroon, Cote d'Ivoire, Djibouti, Ethiopia, Georgia, Haiti, India, Kenya, Kyrgyzstan, Lesotho, Moldova, Myanmar, Senegal, Swaziland, Tanzania, Uganda, Uzbekistan

17 Ethiopia, Georgia, Haiti, India, Lesotho, Myanmar, Uganda, Uzbekistan

6. Prequalification of medicines and diagnostics related to UNITAID's strategic priorities in HIV/AIDS, TB and malaria

Across the UN system, procurement of medicines, diagnostics and some related products is subject to stringent regulatory conditions. UNITAID provides financial support to partners to buy only from manufacturers who have stringent national regulatory authority (SRNA) approval or WHO/UN prequalification status and who comply with Good Manufacturing Practice (GMP) standards established by the World Health Organization. To ensure that there are an increasing number of generic manufacturers who can supply these products, UNITAID provides the primary financial support to the WHO/UN Prequalification programme for medicines and diagnostics for HIV, TB and malaria.

The WHO/UN Prequalification programme works to increase the number of new, quality manufacturers of pre-existing medicines and to facilitate the timely introduction of new quality assured medicines, including FDCs and paediatric formulations across all disease and product areas. UNITAID support ensures that all implementing partners can negotiate with a wide range quality assured manufacturers (generic and local) and negotiate favourable long-term agreements with quality suppliers of medicines, diagnostics and related products. UNITAID also supports prequalification of priority diagnostics tests to improve the rational use of the medicines through better and timelier detection of disease.

Both prequalification of medicines and diagnostics have faced special challenges in engaging with manufacturers and encouraging the submission of dossiers because the process is a voluntary one. Manufacturers are reluctant to spend money and time on a process that does not necessarily translate into more orders from purchasers for their products. UNITAID can do more to advertise its quality assurance policy to reinforce the need for prequalification as a mechanism to ensure that quality products are purchased by implementing partners that it funds.

Although both projects have been slow to start up, they have over the past year made good progress and are continuing to improve the rate of prequalification of medicines and diagnostics. To date, 41 UNITAID priority medicines have been prequalified[18] by PQP medicines (since 2007). The first diagnostic test (a rapid test for malaria) was prequalified last year and 15 more rapid tests are in the final stages of prequalification.

The key challenges in both prequalification projects are summarized in the table below along with project achievements and UNITAID's next steps for the projects.

Key challenges and achievements in prequalification

Prequalification of medicines and diagnostics		
CHALLENGE	**ACHIEVEMENTS-2011**	**NEXT STEPS**
Increase the number of new, quality manufacturers of pre-existing medicines and to facilitate the timely introduction of new quality assured medicines, including FDCs and paediatric formulations	• 6 finished pharmaceutical products prequalified[19]. • 3 active pharmaceutical ingredients (API) for ACTs to treat malaria prequalified. • Inspection of 38 manufacturing sites completed. • 3 new quality control laboratories prequalified.	• Implementation of external mid term review recommendations with UNITAID. • Review of UNITAID priority medicines list to provide support to PQP on strategic priorities for prequalification. • PQP will start a programme of field sampling and testing of UNITAID funded products
Improve the ability to accurately detect and treat disease by providing quality diagnostic tests that can be used in low income settings	• 1 rapid diagnostic test for malaria was prequalified in 2010. • 15 new rapid diagnostic tests are in the final stage of prequalification.	• Reporting is expected on the 15 rapid tests in final stage of prequalification by end of December 2011. • An external mid term review of the project is planned for early 2012. • WHO/DLT will submit a request to replace some of the pilot countries participating in the project.

[18] 24 for HIV (19 2nd line & 5 paediatric), 10 anti-TB (3 first line & 3 2nd line & 4 adult) and 7 ACTs (3 paediatric &4 adult)

[19] 4 for HIV, 2 for TB

7. Conclusions

The directed, strategic approach demonstrated by UNITAID through the achievements documented here is what makes UNITAID unique in the public health funding arena. The continued success of UNITAID depends on future strategic decisions about the priorities for funding, good project planning and management. The Operations report provides information on the implementation of projects funded by the UNITAID Board. It highlights the successes, challenges and provides actions and next steps for the Board to consider. Through this mechanism, UNITAID can continue to contribute to supporting global public health achievements through focused market interventions delivered on time to low and middle income countries.

Annex 1: Project updates, December 2011

Key to assessment of projects

Performance score	Interpretation	Indication
On track	Project performing according to project plan with milestones and targets reached or on track to be reached within timeframe of contractual agreement with UNITAID.	
Minor delays	Project off to a slower than expected start or is experiencing unforeseen but resolvable delays.	
Delayed	Project delayed due to technical difficulties but is still expected to deliver on milestones and targets within the timeframe of the agreement with UNITAID.	
May not meet all objectives	Project will meet some but not all objectives by the end of the contractual agreement with UNITAID.	
Poor Performance	Project performance does not meet the requirements as set out in contractual agreement with UNITAID.	
Unable to assess	Not enough information is available at the time of reporting or the project environment is too uncertain to make an assessment about if the project will meet its milestones and targets.	

PROJECT TITLE: Pediatric HIV/AIDS Project

Key Partner: Clinton Health Access Initiative (CHAI) **Project Duration: November 2006 - December 2011** **Updates for the Period Ending: 30 June 2011**

Updates **Operational Performance:** On track	
Project description	The goal of the Project in 2011 is to maintain on-going access to pediatric ARVs, diagnostic bundles and related components. The project is also increasing the sustainability of the pediatric marketplace through the use of supplier selection techniques that increase the number of quality assured paediatric products and reduce their prices.
Finance	• Board ceiling: US$ 380,058,000 • MoU amount (as of 30 June 2011): US$ 315,883,000 • 2011 Disbursement: US$10,963,000 • Cumulative Disbursement (as of 30 June 2011): US$ 225,510,000
Achievements	• The Project currently supports 25 beneficiary countries[20], down from 40 in 2010. 14 countries in the Project are expected to transition to alternative funding sources by the end of 2011 (Annex 1). • The supplier selection process concluded in March 2011. CHAI achieved price reductions of up to 8% compared to 2010 prices on key Pediatric ARV formulations, amounting to an overall price reduction of over 80% since the start of the Project.[21] • 19 countries procured fixed dose combinations (FDCs) through June 30th 2011. Approximately 97% of the patients benefiting from the Project are now on FDCs[22]. • An additional 2 newly eligible and SRA approved formulations were available in the 2011 supplier selection process compared with the same selection in 2010. • 86,045 PCR tests to diagnose infants with HIV were run in countries in Q1 2011. This reflects CHAI's support to country programmes and represents 123% of the quarterly benchmark for 2011.[23]
Challenges for the reporting period	• Transition to alternative funding for treatment of children is a challenge. Delay of GFATM Round 11 grant proposals adds to the risk of treatment interruption for several countries[24]. CHAI is

[20] Angola; Benin; Botswana; Burkina Faso; Burundi; Cameroon; Cote D'Ivoire; Democratic Republic of Congo; Ethiopia; Haiti; India; Kenya; Lesotho; Malawi; Mali; Mozambique; Nigeria; Senegal; Swaziland; Tanzania; Togo; Uganda; Vietnam; Zambia; and Zimbabwe.

[21] This calculation averages the reductions achieved on AZT+3TC+NVP and d4T+3TC+NVP, based on a comparison of the 2011 UNITAID pricing vs. the average LI 2006 syrup pricing from the GPRM.

[22] Compared with, 85% in 2010, 69% in 2009, and 48% in 2008.

[23] CHAI's most recent reporting on diagnostic access was for end-Q1.

[24] These countries are Malawi, Swaziland, Uganda, and Zimbabwe. The budget of these four countries in 2012, just for ARVs is US$ 16,000,000, but the full budget (including ARVs, Diagnostics, OI drugs, and RUTF) is US$31,398,000.

	submitting a proposal for 2012 that will be discussed at EB15 to avoid these risks.
Next steps for the project	• UNITAID and CHAI established a "Transition Team" in 2011. To facilitate transition decisions, a “Paediatric ARV Procurement Working Group” has been created and will include the GFATM, UNICEF, CHAI, Supply Chain Management Systems (SCMS) and UNITAID. • An external mid-term review and an independent procurement and financial review are underway. The results will be submitted to the Secretariat before the end of 2011. • CHAI has commissioned an external review of the performance of its procurement agent, IDA Foundation. The UNITAID, CHAI and IDA will discuss the recommendations implement them as necessary.

Transition Plans for Countries Included in 2012 Pediatric Project

Country	Transition Status and 2012 Plans
Burundi	Burundi is expected to transition to a Global Fund Round 8 Phase 2 grant in early- to mid-2012. Burundi will need significant technical assistance for ARV quantification to secure the Phase 2 disbursement, which has a moderate risk of delays.
Cameroon	Cameroon was slated for transition to Global Fund Round 10 and MOH funds, but is facing significant funding gaps from both sources in 2012. CHAI will be assessing opportunities for savings within the Round 10 grant and seeking additional funding sources.
Cote d'Ivoire	Cote d'Ivoire is expected to transition to Global Fund Round 9 funds, but has a high level of uncertainty regarding the timing and adequacy of funds due to political instability. CHAI will be reengaging with partners to map the transition timeline.
Democratic Republic of the Congo (DRC)	The DRC is expected to transition to Global Fund Round 8 Phase 2 funds in 2012. However, Phase 1 of the grant is currently frozen, leading to high risk of delays in Phase 2 disbursement. Substantial technical support will be needed to move Phase 2 forward.
Malawi	Malawi has highly constrained funding sources for ARVs and limited prospects for transition sources.
Mozambique	Mozambique secured a Global Fund Round 9 grant to support ARVs, but has had chronic challenges with grant disbursements, with the result that Round 9 is indefinitely on hold. CHAI will be assessing opportunities to support grant implementation.
Nigeria	Nigeria's FMOH will be gradually increasing its support for the ARV budget; however, the funding levels in 2012 remain uncertain. CHAI is supporting national budget planning to incorporate transition costs.
Swaziland	Swaziland is facing major funding gaps due to constraints in MOH budgets, which were intended to take over the pediatric ARV needs from 2012.
Tanzania	Tanzania will transition to a Global Fund Round 8 Phase 2 grant in mid-2012. Tanzania will require light technical assistance for Phase 2, and faces moderate risk of delays in grant disbursement.
Uganda	Uganda is facing substantial funding gaps in 2012, with limited new funding prospects.
Zimbabwe	Zimbabwe was slated to transition to a Global Fund Round 8 Phase 2 grant, but regimen shifts and dramatic scale-up have overstretched the available Phase 2 funds.

PROJECT TITLE: Second-Line ARV Project

Key Partner(s): Clinton Health Access Initiative (CHAI)
Project Duration: May 2007- December 2011
Updates for the Period Ending: 30 June 2011

Updates
Operational Performance: On track

Project description	The objective of the Second-Line Project in 2011 is to ensure ongoing access to second-line ARVs through the use of supplier selection techniques that increase the number of quality assured second-line products and reduce their prices.
Finance	• Board ceiling: US$ 305,799,000 • MOU amount (as of 30 June 2011): US$299,651,000 • 2011 Disbursement: US$6,600,000 • Cumulative Disbursement (as of 30 June 2011): US$219,426,000
Achievements	• 15 of the 25 countries in the Second-line Project have transitioned to alternative funding sources.[25] • CHAI achieved price reductions of 27% on leading 2L ARVs compared to 2010 prices during its supplier selection process concluded in March 2011. • Since the launch of Atazanavir and heat stable Ritonavir singles in 2010, 11 countries have accessed these ARV formulations. A co-pack of Atazanavir, heat stable Ritonavir, TDF and 3TC is under review by WHO PQP. • The 2011 supplier selection process saw the addition of 6 newly eligible and SRA approved formulations.
Challenges for the reporting period	• UNITAID support to the Second-Line Project is scheduled to end in December 2011. Most countries are on track for transition to alternative funding by the end of 2011 (see Annex). However, some countries are facing delays in signing their grants with the Global Fund.[26]
Next steps for the project	• CHAI will be presenting to the Secretariat a request for a no-cost extension, allowing any unspent 2011 funds to carry over into 2012. CHAI expects to be able to reduce, but not fully eliminate, the risks inherent in the funding transition process by working with the beneficiary countries and donors as well as requesting a no-cost extension in 2012. • An external mid-term review and an independent procurement and financial review are under way. The results of these reviews will be submitted to the Secretariat before the end of 2011. • CHAI has commissioned an external review of the performance of its procurement agent for the project, IDA Foundation. UNITAID, CHAI and IDA will discuss the recommendations and implement them as necessary.

[25] This includes five countries that transitioned out in the first half of 2011: Benin, Chad, Kenya, Mali, and Togo. The remaining 10 countries all have plans in place to transition out of the Project by the end of 2011: Burundi, Cameroon, Democratic Republic of Congo, Haiti, India, Mozambique, Nigeria, Uganda, Zambia, and Zimbabwe.
[26] Burundi, Cameroon, DR Congo, Mozambique, Uganda, and Zimbabwe.

Second-Line Project: 2012 Transition Status and Plans

Country	Transition Risk	Transition Funding Source	Can face problem signing the grant. Why?	2011 ARV Budget US$
Burundi	Medium Risk	Global Fund Round 8 Phase 2	Grant is due for signing in March 2012 with moderate risk of delays due to negotiation and budgeting process.	$951,138
Cameroon	High Risk	Global Fund Round 10/MOH	Cameroon faces risk both from potential delays with grant signing and sufficiency of R10 and MOH funds.	$4,569,422
DR Congo	High Risk	Global Fund Round 8 Phase 2	Grant is due for signing in March 2012 with high risk of delays because of grant performance ratings [Phase 1 is currently frozen].	$2,086,554
Haiti	Low Risk	Global Fund Round 1/PEPFAR		$549,250
India	Low Risk	Global Fund Round 4/MOH		$4,778,926
Mozambique	High Risk	Global Fund Round 9/PEPFAR	Mozambique's Round 9 grant is currently frozen, and with PEPFAR flat lining Mozambique could face significant ARV funding gaps in 2012.	$2,596,689
Nigeria	Low Risk	Global Fund Round 9/PEPFAR		$10,752,534
Uganda	Medium Risk	Global Fund Round 7/PEPFAR	Grant negotiations for Round 7 Phase 2 may be prolonged and Uganda faces risk of funding gap even after R7 disbursement.	$7,915,434
Zambia	Low Risk	Global Fund Round 10		$4,248,114
Zimbabwe	Medium Risk	Global Fund Round 8 Phase 2	Grant is due for signing in March 2012 with moderate risk of delays due to negotiation and budgeting process.	$1,083,689

The risk assessment prepared by CHAI is based on CHAI's current understanding (considering discussions with the donors and the beneficiary countries) of the threats posed by both funding constraints and disbursement timelines to each country's transition plan. To take a conservative approach, CHAI is assuming the following to describe the challenges faced by these 10 countries in 2012:

- **Low-risk.** 4 countries should not require emergency orders in 2012: Haiti, India, Nigeria, and Zambia
- **Medium-risk**. 3 countries may require one emergency order in 2012: Burundi, Uganda, and Zimbabwe
- **High-risk**. 3 countries may require two emergency orders in 2012: Cameroon, DR Congo, and Mozambique

PROJECT TITLE: ESTHERAID

Key Partner(s): ESTHER
Project Duration: July 2009 – July 2013
Updates for the Period Ending: 30 June 2011

Updates **Operational Performance:** Minor delays	
Project description	This project contributes to improving supply chain management from national central medical stores to treatment centers in 5 West African countries[27] by improving logistic information systems and patient monitoring systems. The project also supports the efforts of treatment centers to improve treatment choices by making sure that UNITAID supplied tests and treatments are received and used.
Finance	• Board ceiling: US$ 15,950,000 • MOU amount (as of 30 June 2011): US$ 14,681,000 • 2011 Disbursement: US$ 4,041,000 • Cumulative Disbursement (as of 30 June 2011): US$ 4,493,000
Achievements	• The project has been launched in all five countries. • Planning workshops have been held in all five countries. • ESTHER and the Coordinated Procurement Planning initiative (CPP)[28] are sharing information on supply chains and stock outs for the five participating countries to better align product support to these countries.
Challenges for the reporting period	• Identifying national program contacts has been challenging because many national programs were previously supported by GFATM grants that have now ended. UNITAID is working with ESTHER to anticipate this type of obstacle to full project implementation and to minimize risks of delay where possible. • Stock-outs in Benin and Burkina Faso have made project implementation at the hospital level slower than expected. • There was a delay in the launch of the project in CAR due to civil unrest following country elections. The project has now been launched and is progressing.
Next steps for the project	• Finalize contracts and approve year one work plans with implementing partners in CAR and Mali • Publication of baseline data collected in Phase I of the ESTHERAID project is under-way, pending approval from all countries.

[27] Benin, Burkina Faso, Central African Republic, Cameroon and Mali.
[28] Comprised of PEPFAR, the World Bank, GFATM, UNITAID and WHO

PROJECT TITLE: Acceleration of PMTCT and Scale up of Linkage to Paediatric HIV Care and Treatment (PMTCT I extension)

Key Partner(s): UNICEF and WHO
Project Duration: January 2011 – December 2011
Updates for the Period Ending: 30 June 2011

Updates **Operational Performance:** 🔴 **Poor performance**	
Project description	The project contributes to the acceleration of PMTCT activities and the linkages of PMTCT to paediatric care in eight countries[29]. This 'extension' year was granted at the end of 2010 to allow partners to work with country programmes to identify alternative sources of funding for PMTCT products for the future.
Finance	• Board ceiling: US$ 49,693,000 • MoU amount (as of 30 June 2011): US$ 47,602,000 • 2011 Disbursement: US$ 26, 764,000 • Cumulative Disbursement (as of 30 June 2011): US$ 43,424,000
Achievements	• Delivery of PMTCT products continues to the countries in the project but with significant delays. • Of particular note is the progress made by Rwanda, Malawi, and Zambia towards project targets for PMTCT products including, HIV tests for pregnant women, ARVs being given to HIV + women for prophylaxis, CD4 tests provision, and HIV tests for infants born to HIV + women.
Challenges for the reporting period	• Implementation in countries has been slower than expected due to poor planning as well as political unrest (i.e. Cote d'Ivoire). • For Tanzania, identification of gaps in PMTCT commodities in Central Medical Stores and those that are in the pipeline has been an ongoing issue. These gaps have been identified and a full request for the entire budget allocated to Tanzania was submitted to UNICEF in June 2011.
Next steps for the project	• This project is due to end in Dec 2011. However, UNICEF and WHO have submitted LogFrames with budgets to UNITAID for 'in-country' work that was needed to support countries to transition to alternative sources of funding. These plans are under review. • In-country work may require a no-cost extension for implementation, if a sufficiently robust LogFrame and budget for these activities is provided by UNICEF and WHO. • An End of Project Review is planned for all of the PMTCT projects in 2012

[29] Burkina Faso, Malawi, Rwanda, Cote d'Ivoire, India, Tanzania, Zambia and Cameroon.

PROJECT TITLE: Affordable Medicines for Malaria (AMFm)

Key Partner(s): The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria
Project Duration: November 2009 - April 2012
Updates for the Period Ending: 30 June 2011

Updates **Operational Performance: ○ Unable to assess at this time**	
Project description	The AMFm objective is to significantly reduce the price for ACT treatments paid by end-users through a subsidy mechanism to the private sector. This is essential to increasing access to effective ACTs and to delaying development of resistance to artemisinin. AMFm Phase I is currently implemented through nine programs in eight countries.[30]
Finance	• Board ceiling: US$130,000,000 • MOU amount (as of 30 June 2011): US$130,000,000 • 2011 Disbursement: US$0[31] • Cumulative Disbursement (as of 30 June 2011): US$130,000,000 • Performance by the Partner against budget (%): Not applicable.[32]
Achievements	• Co-payment for 110,335,560 ACT treatments worth U$112,535,892.87 has been approved. Only 8.4% of the total budget was paid for freight and insurance. • Of the total ACT treatment approved, 46,247,222 (42%) worth U$46,247,222 have been delivered to first line buyers in countries.
Challenges for the reporting period	• ACT demand forecast is based on limited data and requires continuous updating based on new data inputs and methodological modifications. UNITAID and the GFATM are working with the BCG consortium to improve forecasting. • The AMFm orders by private-sector first-line buyers are likely to exceed the modeled demand forecast by 23 million ACT treatments in 2011. This calls for more refined demand forecast estimates and stringent order approval. • GFATM estimates that an additional U$124 million is needed for the co-payment fund to cover the remaining period of Phase I.
Next steps for the project	• Levers for managing orders for AMFm co-paid ACTs will be implemented with the aim of saving an estimated US$40 million until additional donor funding is secured. Among these will be to give priority to pediatric formulations and pack sizes. • GFATM has submitted a proposal to UNITAID requesting U$50 million in additional contributions[33]. • End of project independent evaluation will be conducted as scheduled by GFATM

[30] Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania and Uganda.
[31] Not expected in 2011
[32] In the first half of 2011, a total of US$49,200,314 was spent for the 46,247,222 ACT treatments delivered to countries. This is charged from the pooled AMFm fund provided by UNITAID, DFID and Gates Foundation.
[33] A request has been made to the UK for an additional US$70 million.

	(mid-2012). • GFATM governance reform has advised that the current ad-hoc committees be dissolved and that the responsibility of AMFm oversight be taken on by the Market Dynamics Advisory Group. UNITAID will consult with GFATM to ensure that it has a continued role in the governance of AMFm.

PROJECT TITLE: Assured Artemisinin Supply Service (A2S2)

Key Partner(s): i+Solutions, Triodos
Project Duration: July 2009 - June 2011 (no cost extension granted until the 31 December 2011)
Updates for the Period Ending: 30 June 2011

Updates **Operational Performance:** 🔴 **Poor performance**	
Project description	The project supports production of additional Artemisia (40 MT) in order to contribute to stabilizing the price of Artemisinin, the key ingredient in Artemisinin Combination Therapy (ACT). The project provides loans to artemisinin extractors through tri-partite agreements between the artemisinin extractor, a prequalified ACT manufacturer and i+Solutions.
Finance	• Board ceiling: US$9,280,400 • MOU amount (as of 30 June 2011): US$ 9,280,400 • 2011 Disbursement: US$0 • Cumulative Disbursement (as of 30 June 2011): US$ 9,280,400 • Performance by the Partner against budget: 74% of operational cost (U$880,400) and 46% of revolving loan fund (U$8,400,000)
Achievements	• **T**wo loan agreements to supply additional 18MT of artemisinin completed with Vedic-ABE and Bionexx – Innovexx. • Technical support to facilitate sales agreement for 18.5MT additional artemisinin provided to Mediplantex and Hung Thinh based in Vietnam, AfroAlpine (Uganda) and Xieli (China). • Dissemination of market intelligence through dedicated newsletter and website. • Delivery of 3.93 MT of artemisinin to ACT manufacturers. • A total of US$1.37 million in loans has been paid back to the project.
Challenges for the reporting period	• Loan agreements are subject to local financial regulations. If these change, it can delay loans at crucial planting and harvesting times, as demonstrated in China in 2010. UNITAID and i+ Solutions are discussing ways of increasing the flexibility of loan agreements to make them consistent with national regulations. • Beijing Gingko has delivered 3MT (out of the agreed 10MT) to Novartis as per their contractual arrangement. However, the extractor has signaled that it is unable to meet the remaining delivery volume of 7MT to Novartis at the agreed price due to an increase in the price for leaves. Beijing-Gingko has repaid U$980,000 of the loan fund with U$1,020,000 still outstanding. Discussions are under way to ensure that the outstanding loan is

	repaid within a reasonable time period.
Next steps for the project	• Preparations for the 6th Artemisinin Conference that will convene in Hanoi, Vietnam 2 - 3 November 2011 in progress. • A mid term review of the project has been completed and UNITAID is working with i+ Solutions to implement the recommendations. • Request for project extension has been received and submitted to UNIATID PRC for review.

PROJECT TITLE: ACT Scale-up

Key Partner(s): The Global Fund to Fight AIDS, TB and Malaria and UNICEF
Project Duration: December 2007 to June 2010 (with no-cost extension to December 2011)
Updates for the Period Ending: 30 June 2011

Updates **Operational Performance: May not meet all objectives**	
Project description	The ACT Scale-up project was initiated to provide 47,016,160 high quality ACT treatments to seven countries[34]. The project covers 11 programs chosen because of their participation in the Global Fund round grants.
Finance	• Board Ceiling: US$78,887,568 • MOU amount (as of June 2011): US 65,413,057 • 2011 Disbursement[35]: US$0 • Cumulative disbursements (as of June 2011): US$36,613,871.19 • Performance by the partner against budget (%): 81%
Achievements	• 29.1 million ACT treatments delivered to 8 high burden malaria countries. • Procurement lead times significantly reduced and no stock outs of ACTs reported from countries.
Challenges for the reporting period	• Implementation delays mean that remaining ACTs should be delivered to programmes by end of December 2011. UNITAID is in contact with UNICEF to ensure that this is on track. • Linking provision of ACTs to programmes with number of patients treated remains a challenge because of the GFATM's aggregate reports. UNITAID is expecting confirmation from the GFATM that an estimated numbers of patients treated can be provided for the end of project report. • The GFATM has informed UNITAID of the expiry of 500,000 ACT treatments delivered to UGP-CRESAN in Madagascar. UNITAID has requested a full report on the circumstances of this failure[36].
Next steps for the project	• Engage in further discussion with the GFATM to align type of data and performance assessment in line with the terms stated in the agreement,

[34]Ghana, Cambodia, Madagascar, Mozambique, Sudan (North and South, at time of agreement, this was one country), Indonesia, Zambia and Ethiopia.
[35]UNICEF had submitted a request for disbursement in 2010, but UNITAID Secretariat decided to not remit the requested funds as the remaining cash balance with UNICEF could fully cover the projected procurement.
[36]Including a shared approach to destroying of expired stock and future plans for the project in the USP-CRESAN programme.

	• An external project mid-term review has been completed. UNITAID is working with UNICEF and GFATM to implement findings. • The GFATM has indicated its intention to submit a formal request for no-cost extension to 2013 in order to allow the 3 grants (Madagascar PSI, South Sudan and Zambia MOH) to use their treatment targets.

PROJECT TITLE: First Line Anti-TB Drugs Initiative

Key Partner(s): STOP TB Partnership Global Drug Facility
Project Duration: September 2007 – December 2011
Updates for the Period Ending: 30 June 2011

Updates **Operational Performance:** 🟠 **May not meet all objectives**	
Project description	This project supports first line TB drugs to minimize the risk of stock-outs while country programmes secure alternative funding sources (mostly GFTAM) following the ending of GDF grants. A second component of the project is to establish a strategic rotating stockpile (SRS) to reduce product delivery lead times and overall treatment costs.
Finance	• Board ceiling: US$ 27,646,000 • MOU amount (as of 30 June 2011): US$ 27,646,000 • 2011 Disbursement: US$ 0 • Cumulative Disbursement (as of 30 June 2011): US$ 27,646,000
Achievements	• All 19 countries have received the treatment targets set out in the MOU between UNITAID and GDF. • All of the funds allocated to purchase treatments in this project have been used and the project has been completed (as of December 2011).
Challenges for the reporting period	• Price containment has been a challenge due to an increase in the costs of API[37] and a lack of competition for some key products. To obtain better prices in this situation, GDF is consolidating orders and will issue requests for quotations for specific (consolidated) volumes. • SRS has not been implemented in this project. UNITAID and GDF are discussing the future of the stockpile to better understand why the model used has not worked. None of the US$8 million allocated to the stockpile has been used. GDF has asked to re-program these funds into an alternative stockpile model that includes all high volume anti-TB medicines warehoused in a strategic location that reflects manufacturing base as well as the countries in need.
Next steps for the project	• The project will end as on 31 December 2011 after which an external end of project evaluation will be done. • GDF may request a no-cost extension and propose a new model for the SRS. This is an ongoing discussion between UNITAID and GDF and is subject to an invitation by UNITAID for a detailed concept note.

[37] For example, Rifampicin is highly dependent on the cost of oil needed for manufacture and this has increased over the time period of the project.

PROJECT TITLE: EXPANDx TB (MDR-TB Diagnostics)

Key Partner(s): WHO's Global Laboratory Initiative, Foundation for Innovative New Diagnostics, The STOP TB Partnership, the Global Drug Facility
Project Duration: January 2009 – December 2013
Updates for the Period Ending: 30 June 2011

Updates **Operational Performance: Delayed**	
Project description	The project accelerates access to MDR TB diagnosis by introducing new and rapid technologies and laboratory service together with the necessary know-how for technology transfer. The intention is to identify an estimated 119,000 MDR TB patients in 27 countries and enable appropriate treatment of these patients.
Finance	• Board ceiling: US$ 89,663,000 • MOU amount (as of 30 June 2011): US$ 89,612,000 • 2011 Disbursement: US$ 0 • Cumulative Disbursement (as of 30 June 2011): US$ 38,216,000
Achievements	• New Laboratory infrastructure and successful technology transfer established in 18 countries[38]. • 8 project countries[39] are routinely diagnosing MDR TB. • One additional MOU was signed with a National Health Authority[40]. • MOU's with three countries[41] were under review during the reporting period (and have subsequently been signed)
Challenges for the reporting period	• Speed of adoption of new MDR-TB diagnostic technologies in countries is dependent on the baseline laboratory systems preparedness in the countries. FIND and GDF are working with countries to identify bottlenecks to building better laboratories.
Next steps for the project	• FIND and GDF to actively pursue new country-level partnerships to address laboratory system preparedness to increase the speed of roll out and adoption of new technology. • FIND and GDF to continue to work with country programmes to ensure that the remaining 5 MoUs with project countries are signed. This will help to secure appropriate political commitment for roll out and adoption of new technologies. • Revisit MOU and LogFrame with FIND and GDF to take into account the recommendations of the external mid term review. This will include a 'catch-up' plan to speed up the rate of project implementation and revised programmatic and financial reporting.

[38] Azerbaijan, Cameroon, Cote d'Ivoire, Djibouti, Ethiopia, Georgia, Haiti, India, Kenya, Kyrgyzstan, Lesotho, Moldova, Myanmar, Senegal, Swaziland, Tanzania, Uganda, Uzbekistan
[39] Ethiopia, Georgia, Haiti, India, Lesotho, Myanmar, Uganda, Uzbekistan
[40] Viet Nam
[41] Belarus, Kazakhstan, Indonesia

PROJECT TITLE: MDR-TB Scale-Up Initiative and the Strategic Rotating Stockpile (SRS)

Key Partner(s): STOP TB Partnership Global Drug Facility, the Green Light Committee and the Global Fund to Fight AIDS, TB and Malaria
Project Duration: July 2007 – December 2012
Updates for the Period Ending: 30 June 2011

Updates **Operational Performance:** **Delayed**	
Project description	This project intends to increase the number of patients accessing quality 2nd line anti-TB medicines by improving price, number and quality of products and facilitating faster delivery lead times through a strategic rotating stockpile.
Finance	• Board ceiling: US$ 55,667,000 (MDR Scale-Up) • MOU amount (as of 30 June 2011): US$ 55,667,000 (MDR Scale-Up) • 2011 Disbursement: US$ 0 (MDR Scale-Up) • Cumulative Disbursement (as of 30 June 2011): US$ 34,518 (MDR Scale-Up) • Board ceiling: US$ 11,802,000,000 (SRS) • MOU amount (as of 30 June): US$ 11,802,000 (SRS) • 2011 Disbursement: US$ 0 (SRS) • Cumulative Disbursement: US$ 9,873,000 (SRS)
Achievements	• Treatment delivery is on track according to project country targets. • The number of Long Term Agreements (LTAs) is increasing in accordance with the project targets. • SRS lead times for urgent orders are below the target of 2 months (median lead time from SRS is 31 days) • Stockpile usage is above the target of 60% per year. It is currently operating at 68% per month. This, however, is reflecting overall usage and not just the usage for urgent orders.
Challenges for the reporting period	• Uncertain funding for MDR TB products at the end of the project (2012) means that many countries may be at risk of having shortfall in MDR-TB treatments. As we scale up MDR TB diagnosis, we will require treatment of newly detected cases, requiring more supply security. UNITAID and GDF are developing a detailed transition plan for MDR-TB treatments. • Some products have seen a significant increase in price[42]. Future price reductions are dependant on WHO and Countries ensuring that patients are put onto treatment and that treatment volumes are consolidated. A minimum of 30,000 patient treatments per year

[42] Capreomycin has gone from $4 per ampoule to $8 (following technology transfer from Eli Lilly who subsidized the price of the product to Akorn.

	is needed in the public sector in order to achieve significant price reductions[43]. In 2010, GDF procured 10,700 treatments. Focus will be on India with a scale up plan anticipating 30,000 patients on treatment by 2015 • The SRS was intended be used to facilitate emergency orders only. It is however being used for off-cycle orders and may represent a disincentive to countries to improve their forecasting. UNITAID and GDF are working to revise the existing stockpile model to better link it to improved country forecasting.
Next steps for the project	• Revise the stockpile model, providing incentives for countries to improve their forecasting, supply chain management and ordering processes. • Develop a detailed transition plan that addresses the need for predictable funding after 2012. • Revisit project plan and MOU following the external mid-term review.

[43] CHAI estimate, 2011.

PROJECT TITLE: Paediatric TB Project

Key Partner(s): STOP TB Partnership Global Drug Facility **Project Duration: January 2007 – December 2011** **Updates for the Period Ending: 30 June 2011**

Updates **Operational Performance:** ● **May not meet all objectives**	
Project description	This project has provided 750,000 paediatric treatments to 57 countries and aims to foster the development of child-friendly formulations of TB treatments for children under-5 years of age.
Finance	• Board ceiling: US$ 14,226,000 • MOU amount (as of 30 June 2011): US$ 11,627,000 • 2011 Disbursement: US$ 0 • Cumulative Disbursement (as of 30 June 2011): US$ 11,627,000
Achievements	• All planned treatments have been supplied to 57 countries.
Challenges for the reporting period	• WHO new dosage guidelines mean that existing formulations are not adequate for paediatric treatment. • Due to the uncertainty in paediatric dosage guidelines between 1999 and 2008 and the new WHO recommendations, it has been difficult to provide incentives to manufacturers to make the new formulations required for this market.
Next steps for the project	• This project ends in December 2011. • An external, end of project evaluation is planned following the close of the project. • A consortium including the WHO Essential Medicines Programme, GDF and WHO Prequalification are preparing a plan for supporting paediatric treatment that takes into account that this is a nascent market (new formulations) and there is a need for ongoing treatment while new formulations are being developed.

PROJECT TITLE: UNITAID Project Support for Quality Assurance of Medicines

Key Partner(s): WHO/Medicines Prequalification Programme
Project Duration: December 2006 - December 2012
Updates for the Period Ending: 30 June 2011

Updates **Operational Performance:** Minor delays	
Project description	The Medicines Quality Assurance project aims to increase the number of prequalified UNITAID priority medicines for HIV/AIDS, Tuberculosis and Malaria. In addition to increasing the number of prequalified products, the project contributes to: • Increasing capacity in production of quality of priority medicines, • Facilitating the development of national regulatory processes and promote capacity building for quality control of medicines in recipient countries, and • Accelerating testing of the quality of medicines to ensure quality for the end-user.
Finance	• Board ceiling: US$53,110,000 • MOU amount (as of 30 June 2011): U$53,110,000 • 2011 Disbursement: US$6,577,585 • Cumulative Disbursement (as of 30 June 2011): U$ 23,730,000 • Performance by the Partner against budget (%): 116.4%[44]
Achievements	• Inspection of 38 manufacturing sites completed. • 6 finished pharmaceutical products prequalified[45]. • 3 active pharmaceutical ingredients (API) for ACTs to treat malaria prequalified. • 3 new quality control laboratories prequalified.
Challenges for the reporting period	• The median number of days from submission of dossiers to prequalification of products remains high but is decreasing[46]. • Sustainable funding for prequalification of medicines is a challenge. UNITAID and WHO are exploring the possibility of using a fee for service arrangement with manufacturers to provide a more sustainable revenue base for this important area in the future.
Next steps for the project	• An external mid term review of this project has been completed. UNITAID and WHO are working on implementing the recommendations of this review. • Prequalification will start a programme of field sampling and testing of UNITAID funded products as agreed in the MoU.

[44] Cumulative budget
[45] 4 for HIV, 2 for TB
[46] The median time for the reporting period was 593 days, still short of the target lead-time of 547 days.

PROJECT TITLE: UNITAID Project Support for Quality Assurance of Diagnostics

Key Partner(s): WHO Diagnostics and Laboratory Technology **Project Duration: March 2009 - February 2013** **Updates for the Period Ending: 30 June 2011**

Updates **Operational Performance: Delayed**	
Project description	The project intends to increase the number of quality assured tools to diagnose and monitor treatment for HIV/AIDS and malaria. The project also provides support to strengthen regulatory capacity and post marketing surveillance of diagnostic tests in five pilot countries[47].
Finance	• Board ceiling: US$7,500,000 • MOU amount (as of 30 June 2011): U$7,500,000 • 2011 Disbursement: US$0 • Cumulative Disbursement (as of 30 June 2011): U$1,130,000
Achievements	• Manufacturing sites for 11 new diagnostic products are being inspected now, with completion expected by end of 2011. • Re-inspection of 4 product applications is currently underway. • A plan to speed up the prequalification of 15 diagnostic products has been implemented with completion expected by end of 2011.
Challenges for the reporting period	• Processing of product dossier assessments has been slow due to staff shortages. WHO is working to improve the staff-hiring situation to facilitate the assessments. • Submissions of sub-standard dossiers and manufacturing practices slow down the prequalification process. Efforts are ongoing to address the problem in coordination with manufacturers. • Strengthening capacities in some of the pilot countries has been delayed due to local problems.
Next steps for the project	• An external mid term review of the project is planned for early 2012. • A list of prequalified products is expected from the project by December 2011. • WHO/DLT will submit a request to replace some of the pilot countries participating in the project due to political challenges,

[47] Burkina Faso, China, Cote d'Ivoire, Tanzania and South Africa.

PROJECT TITLE: UNITAID Support for Global Fund Round 6, Phase I

Key Partner(s): The Global Fund to fight AIDS, TB and Malaria **Project Duration: December 2007 - June 2010** **Updates for the Period Ending: 30 June 2011**

Updates **Operational Performance:**  **Poor performance**	
Project description	The project intends to scale up access to treatment and to improve affordability of medicines for the treatment of HIV/AIDS, MDR-TB and malaria through the Global Fund grants in Round 6, Phase 1.
Finance	• Board ceiling: US$52,500,000 • MOU amount (as of 30 June 2011): US$38,691,956 • 2011 disbursement: US$0 • Cumulative disbursements (as of 30 June 2011) : US$38,691,956 • Performance by the partner against budget (%): no specific information was received from The Global Fund.
Achievements	At the end of 2010, the project had supplied: – 31,197 paediatric ARV treatments, – 2,650652 ACT treatments, and – 3,223 treatments for MDR TB. • Channelling monies through the GFATM system has helped to strengthen existing country procurement activities without creating new processes.
Challenges for the reporting period	• Procurement report and computation of remaining unspent funds is still incomplete. UNITAID has requested that the GFATM report on these issues by the end of December 2011. • The Global Fund has requested no cost extension for the project. This is expected to allow reconciliation of information on funds spent and procurement achieved for the Project.
Next steps for the project	• Continue working with The Global Fund to finalize reconciliation of expenditure and procurement accomplishments, • An external end of project review is expected to start in early 2012.

Annex 2. Recommendations of external mid-term reviews for UNITAID-funded projects.

Projects & external reviewers

✓WHO/UN Support to the Prequalification of Medicines Programme- AEDES

Recommendations

Pre-qualification of medicines

✓Provide detailed financial review, including supporting information

✓Improve activities of capacity building for both regulators and manufacturers.

✓UNITAID to provide adequate project management support for follow up with prequalification programme.

✓ Develop clear project plan using Logical Framework Approach.

Projects & external reviewers

✓i+ Solutions Assured Artemisinin Supply Systems project (A2S2) - Dalberg

✓UNICEF/GFATM ACT Scale up- Swiss Tropical Institute of Public Health

Recommendations

A2S2

✓Extend reach of pre-financing facility by identifying local lenders and transitioning funding to them.

✓Standardize market intelligence and make it useful to UNITAID and other market players.

✓Improve project reporting and management.

✓ Define "transition" indicators for when intervention will no longer be needed.

ACT Scale up

✓Channel funds through a more efficient implementation arrangement than with GFATM.

✓Develop risk management plan for the project.

✓Partners to report on interest earned and to reallocate this to the project or deduct from next disbursement.

✓Changes in grant implementation at GFATM to be tracked better.

Projects & external reviewers

✓FIND/GLI/GDF EXPAND TB Diagnostics-Swiss Tropical Institute for Public Health

✓GDF/GLC MDR-TB Treatment Scale up with rotating stockpiles for MDR-TB and 1st Line TB medicines- Swiss Tropical Institute for Public Health

Recommendations

Expand TB diagnostics

✓Produce "catch-up" plan to speed up rate of project implementation.

✓Coordinate with donors and GLC to ensure that MDR TB treatments are available in countries scaling up diagnosis.

✓ Develop and implement final programmatic and financial templates based on Logical Framework Approach.

MDR-TB Scale up and Rotating Stockpiles

✓Consolidate volumes for MDR-TB medicines to help manufacturers in production planning.

✓Revised stockpile model, providing incentives for countries to improve their forecasting, supply chain management and ordering processes.

✓Develop detailed transition plan that addressed need for predictable funding after 2012.

✓Up date agreements with clearly defined performance indicators using Logical Framework Approach.

Projects & external reviewers

✓CHAI 2nd Line ARV project- Swiss Tropical Institute for Public Health

✓CHAI paediatric ARV project- Swiss Tropical Institute for Public Health (expected December 2011)

✓UNICEF PMTCT-1 project- Swiss Tropical Institute for Public Health

Recommendations

CHAI 2nd Line ARV project

✓Explore negotiated ceiling prices with manufacturers.

✓Report on project synergies between UNITAID project and in-country activities.

✓Improve project reporting, including a reliability rating on patient numbers provided to UNITAID.

✓ Develop and implement a risk management plan (including drug theft and poor storage conditions).

UNICEF PMTCT-1

✓Improve project specific forecasting through improved connections to national government agencies and in-country planners.

✓Report on interest earned by UNICEF with UNITAID's funds.

✓Clarify status of Mother and baby pack as part of UNITAID's funding

✓Develop risk management plan for the project.

Annex 3. Status of UNITAID funded project transition to December 2011.

Project	Status	Actions
Paediatric ARVs CHAI Ends 2012	• GFAMT funding only for essential services to on-going programmes until 2014 • Delays expected for round 10. Additional bridge funding may be required for at least 6 months for those countries reliant on transitioning to round 10 • Consolidated demand for paediatric ARVs and coordinated price negotiation needs to be maintained	• The Sustainability Working Group[48] meet regularly to address funding and market challenges for these products • CHAI is updating a detailed analysis of anticipated funding challenges and timelines • A meeting with partners (CHAI, GFATM) and country programmes to discuss funding and market challenges will be held in Dakar, Jan 25th -27th 2012 • UNITAID will monitor forecasted funding needs and market risks throughout 2012
2nd Line ARV CHAI Ends 2011	• Delays expected for round 10, increasing the uncertainty of first disbursement from GFATM	• A no-cost extension request has been agreed to address any delay in disbursement of GFATM funds
PMTCT UNICEF Ends 2011	• Alternative sources of funding are in place for UNITAID supported products	• A no cost extension is needed to complete activities in the current grant
ESTHERAID ESTHER Ends 2013	• No additional funding support is expected from UNITAID at the end of this project	• ESTHER has been asked to develop a detailed hand-over (exit) strategy
AMFm GFATM Ends 2012	• Phase I of this project is not completed • The future of the AMFm is yet to be determined pending the findings of an independent evaluation and GFATM board	• A cost extension request for US$ 50 million has been submitted • A plan to transition to Phase II is being developed by RBM and GFATM
A2S2 I + Solutions Ends 2011	• Identify and engage local lenders that can support Artemisinin extractors in providing technical and financial support before the end of UNITAID support	• Request for project extension for 2012 has been reviewed by PRC

[48] UNITAID, CHAI and GFATM

ACT Scale-up GFATM Ends 2011	• Deliveries are continuing into 2012 for some countries	• No-cost extension requested into 2013 to allow the 3 grants to purchase planned amounts of ACTs
TB 1st Line GDF Ends 2011	• This project has met its objectives	• Project closure at the end of 2011
EXPANDx TB FIND Ends 2013	• No transition problems are anticipated	• No actions are required at this point
MDR Scale-up GDF Ends 2012	• Scale up of MDR TB diagnostics will outpace countries capacity to treat MDR TB	• UNITAID is working with GDF to better understand the funding and market risks going into 2013
Paediatric TB GDF Ends 2011	• Changes to the WHO guidelines for paediatric dosages have increased the cost of treatment	• A no cost extension into 2012 will allow GDF to use unspent funds and complete planned activities • A new project proposal to address the need for new formulations will be presented by GDF/WHO in early 2012
Round 6 GFATM Ends 2011	• Deliveries are continuing into 2012	• A no cost extension requested into 2012 to deliver treatments to some grants