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Agenda Item 15_r1

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
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

Background

This document summarizes UNITAID-funded achievements based on Implementer reports for the time period from January to June 2012. Implementers 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 2012. A complete reconciliation of facts and figures for the 2012 calendar year will be reported at the June Executive Board meeting in 2012 as part of the Key Performance Indicators Report 2012. This report will be available on 30 June 2013.

The remainder of this report provides a brief update on relevant actions since the release of the Key performance Indicator Report 2011 on 30 June 2012. More comprehensive overview of specific projects is available as Annex 1 of this document.

Operations

Update on current active UNITAID projects

UNITAID currently supports 14 grants (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. The disease area distribution of the financial resources approved by UNITAID's Board for project funding is shown in Figure 1.

End of project evaluations of 2 UNICEF grants (PMTCT and LLINS) were completed in 2012. UNITAID will use the lessons learnt and recommendations produced from these evaluations to inform the management of the new projects that will start in December 2012.

Update on new projects approved by the Executive Board in 2012

The UNITAID call for proposals in the area of diagnostic tests for HIV, TB and malaria was successful in 2012 with seven projects receiving approval from UNITAID's Executive Board. The approved projects represent a number of new areas for UNITAID, including:

- Operational research activities;
- New point –of –care diagnostic products, some of which are not currently available for purchase;
- A set of new Implementers; and
- New procurement models and practices.

Implementation of these types of projects has required Implementers to do additional preparatory work in countries, with manufacturers and with UNITAID to facilitate a smooth start to the projects. The challenges faced by Implementers and UNITAID to initiate projects in the area of diagnostics include:

- Some products have not yet come to market, making it difficult to plan procurement and predict how the market will develop once they are available for purchase;
- Quality assurance standards have not yet been developed for all types of diagnostic tests and policies and practices need to be developed to ensure safe use of these tests;
- Country-specific implementation plans have taken time to develop because of the new and unfamiliar technology;
- Coordination between Implementers who are doing similar activities in the same countries has taken time to facilitate but is vital to ensuring appropriate, coordinated and sustained up take of the tests by countries;
- New procurement models have had to be developed to ensure that markets stay open to new competitors who may not be ready to enter the market for another year or more; and

- Detailed project plans were required to capture the needs and risks of complex projects with many different and inter-related components.

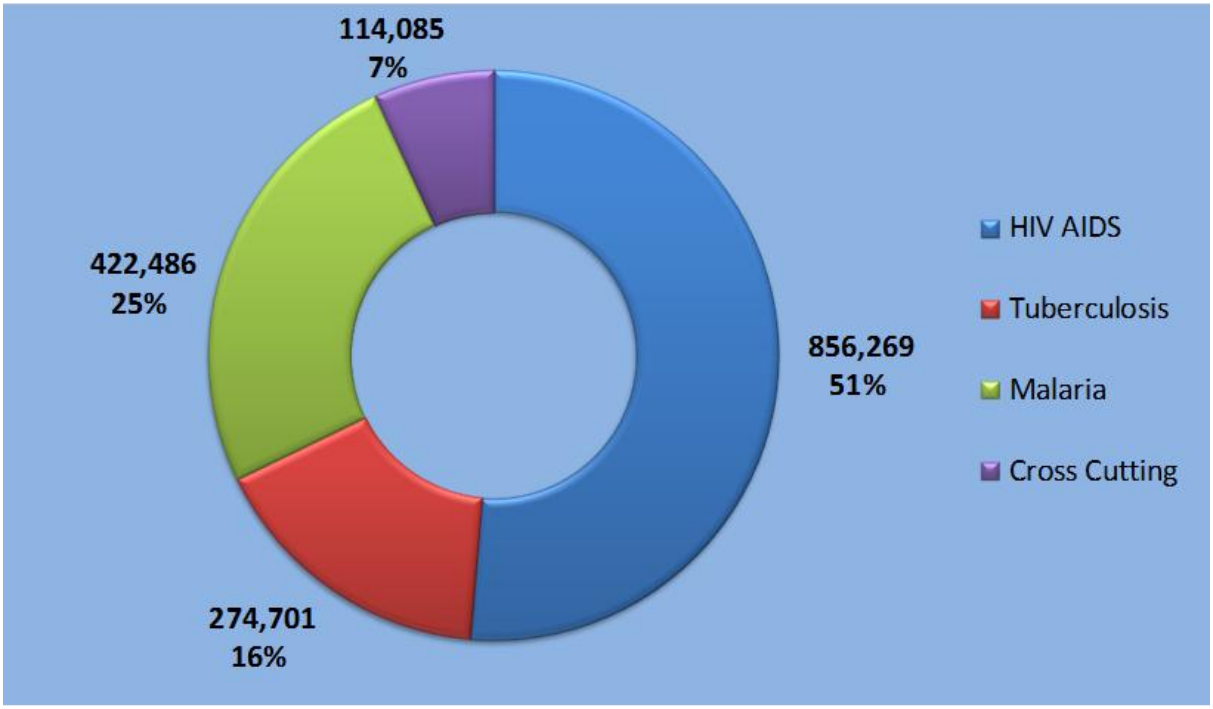
Annex 2 describes the specific challenges, actions taken by the Implementers and UNITAID and next steps to facilitate the signing of contractual agreements for seven EB-approved projects in 2012 and two other projects (A2S2 and AMFm) which received EB approved project extensions.

Table 1. List of active UNITAID funded grants and Implementers as of November 2012.

	HIV	TB	Malaria	Cross cutting
	Paediatric HIV/AIDS treatment program (CHAI)	MDR TB Scale up (GDF)	Artemisia Supply project (i+Solutions)	Support to Round 6, phase 1 (GFATM)
	2nd line Adult HIV/AIDS treatment Program (CHAI)	MDR TB Acceleration of Access initiative: Strategic Rotating stockpile (GDF)	Affordable medicines for malaria facility (AMFm) (GFATM)	Support for quality assurance of medicines (WHO)
	Support to supply chain management of HIV medicines and diagnostics in West Africa (ESTHER)	Paediatric TB project (GDF)	ACT Scale up project (UNICEF, GFATM)	Support for quality assurance of diagnostics (WHO)
	Support to Coordinated Procurement Planning (CPP) Initiative (SCMS)	Expand MDR TB diagnostics (FIND, GLI, GDF)		

Figure 1. The Board has approved US$ 1.667 Billion worth of funding proposals from 2006 to June 2012 for grants[1]. This figure shows how these funds (in '000 US$) have been distributed across the three diseases.

Distribution of Board approved funding since 2006



[1] Excluding the Medicines Patent Pool

1. HIV/AIDS

UNITAID supported the markets for HIV tests, anti-retrovirals and related products and improved treatment access through lower prices, better product availability and integrated care programmes for children and pregnant women. Now there are challenges related to sustaining these achievements, especially ARVs for children living with HIV, over the longer term.

Challenges

The CHAI/UNITAID Paediatric ARV project has suffered delays. Five countries[2] have not yet secured transition funding for paediatric ARVs for 2013 and beyond. Generic manufacturers are not entering the market for new and existing formulations as expected for two main reasons: 1) too many recommended formulations have led to a fragmented market and 2) a declining number of patients is expected in the longer term. The market changes, including price reductions, generated by the project are not sustainable over the longer term and transitioning the project to alternative sources of funding is necessary to support the nascent paediatric ARV market.

UNITAID and CHAI, through the Paediatric ARV Procurement Working group[3] are working on transition of this project to other sources of funding. One potential source of transition funding, the GFATM, informed UNITAID that it was unable to commit to funding paediatric ARVs in Malawi, Mozambique and Uganda as these countries have already committed available GFATM funding to other health requirements. Nonetheless, GFATM agreed to support UNITAID's efforts in reaching out to other donors to address the current funding gaps.

CHAI has requested an extension to this project through 2013. An additional US$ 7 million may be needed to support treatment for children in high-risk countries through 2013.

[2] Malawi, Mozambique, Uganda, Swaziland, and Zimbabwe
[3] UNITAID, Supply Chain Management Systems (SCMS), UNICEF, CHAI, GFATM.

Another key challenge that UNITAID faces is making sure that the products that it supports through Implementers 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. In addition to this activity, UNITAID support to the Coordinated Procurement Planning Initiative is aimed at ensuring that countries at risk of stock-outs for key medicines and diagnostics for HIV, TB and malaria are monitored and any stock-outs are reported to the global public health community so that action can be taken.

Grant updates

The UNICEF Prevention of Mother to Child Transmission of HIV/AIDS project ended in December 2011. This project was the subject of an end of project evaluation in 2013. The evaluation will be made publically available on UNITAID's web-site (www.unitaid.eu).

The CHAI 2nd Line Adult ARV project received a no-cost extension for 2012 and ends on 31 December 2012. Complete transition by the end of 2012 of all 25 project countries is continuing as planned. UNITAID will commission and end of project evaluation in early 2013 to gather lessons learnt from its implementation, including lesson learnt from the successful transition process.

Three continuing projects, Paediatric ARV medicines project with CHAI, Support to supply chain management of HIV medicines and diagnostics in West Africa with ESTHER and Coordinate Procurement Planning Initiative with SCMS, are working towards achievement of their project objectives.

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

Key challenges, achievements and actions in HIV/AIDS

HIV/AIDS		
CHALLENGES	**ACHIEVEMENTS-2012**	**NEXT STEPS**
Maintaining a healthy, competitive market for paediatric ARVs	• 21,395 new children on ARV treatment and programme is on track to meet its target of 59,946 new children on treatment in 2012. • Price reductions of 19% achieved in March 2012 supplier selection process; • 35 out of 40 countries have secured transition funding for paediatric ARVs.	• CHAI has requested a project extension through 2013[4]. • UNITAID will continue working with the Global Fund[5], CHAI and other potential donors to assure a responsible transition of the remaining countries.
Transferring price reductions achieved for the standard second line anti-retroviral (ARV) regimens to other purchasers.	• 25 countries on track to transition to other funding sources for 2nd line ARVs • 2nd Line ARV market stabilized with new, improved formulations available (ATV/r)	• Close monitoring of country-level transition plans.
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.	• Follow up on country-level implementation of the project; • Propose a monitoring system that tracks the progress of medicines through the supply chain.
Monitor countries at risk of stock outs of essential ARVs and diagnostic tests	• Coordinated Procurement Planning initiative is developing an "early warning" system and web-based platform to alert the global public health community to countries at risk of stock outs.	• The Beta version of the web-based system will start testing by UNITAID and others in January 2013.

2. 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. The challenge for the market remains to quickly replace

[4] The request: Malawi, Mozambique, Uganda, Swaziland, and Zimbabwe.
[5] The GFATM informed UNITAID that GFATM was unable to commit to funding paediatric ARVs in Malawi, Mozambique, Uganda but agreed to support UNITAID's efforts in reaching out to other donors to address the current funding gaps.

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[6] 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).

Challenges

The GFATM requested an additional USD 40 million from UNITAID at the end of November 2012 to support ACT co-payments for AMFm Phase 1 pilot countries during the Global Fund Board Transitional Arrangements for AMFm during 2013 (GF/B27/DP4 September 2012). UNITAID has supported AMFm Phase 1 with grants of USD 130 million (EB9/2008/R9) and USD 50 million (EB15/2012/R7) in conjunction with complementary support from DFID and BMGF. In response to the request for additional funding in November 2012, DFID has already pledged GBP 36 million (approximately USD 57.2 million) for the 2013 Transition year. The Government of Canada and the BMGF are also being asked to contribute an additional USD 20 million each.

Under UNITAID support, the project has delivered over 46 million ACTs to first-line buyers in countries. The Independent Evaluation of the AMFm Phase 1 pilot showed that the project was successful in reducing prices of ACTs in the private sector (price per treatment for end users falling from USD 8 to 10 to USD 0.51 to 1.96 in some countries) and in increasing availability of quality assured ACTs in the private sector.

Grant updates

The ACT scale up project has delivered over 36 million ACTs to 8 high burden countries since its start in 2007. The project was scheduled to end at the end of 2011. However, the project has suffered some implementation delays and is

[6] 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.

continuing until the end of 2012 to support countries with ACT gaps. An end of project evaluation of will start in 2013.

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 5.37 MT have been delivered to manufacturers. Because of delays in negotiating loans and product prices, i+ Solutions requested a project extension which will come to an end in May 2013.
The key challenges in each malaria-related grants are summarized in the table below along with project achievements and UNITAID's next steps.

Key challenges and achievements in malaria

Malaria		
CHALLENGE	**ACHIEVEMENTS-2012**	**NEXT STEPS**
To replace ineffective anti-malaria medicines with ACTs, the only remaining effective treatment for malaria.	• ACT scale up delivered 36,135,545 ACTs to 8 high burden countries. • Delivery lead times for ACTs to countries reduced through use of existing GFATM programmes in countries.	• End of project evaluation expected in early 2013
Predominately private sector market for anti-malarial medicines means that patients pay high prices for ACTs.	• Success benchmarks met in 5 pilots of AMFm; • Prices paid for ACTs in private sector ranged from US$ 0.51 to 1.96, considerably decreased from the 8 to 10 US$ paid previously.	• GFATM has submitted a proposal to UNITAID requesting and additional US$40 million to transition to integration with GFATM grants. • AMFm model to be modified to include RDTs for malaria.
Stabilize the price of Artemisinin and secure the production of this biological product as demand for ACTs rises.	• I+ Solutions has delivered 5.37 MT of artemisinin to ACT manufacturers. • A total of US$2.7 million in loans has been paid back to the	• Monitor delivery of promised Artemisinin from extractors to manufacturers; • Monitor loan repayments

	project.	from extractors to Triodos Bank. • Monitor market intelligence reporting agreement with UNITAID.

3. 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.

Challenges

The global market size for UNITAID- supported medicines and diagnostics is small. The low volume of products needed means that manufacturers are unwilling to invest in new, better formulated, products and prices remain high. Price reductions for medicines will be realized over a longer timeframe than anticipated and several projects, including the Paediatric TB project, will require "no cost" extensions to support countries with treatment gaps until the end of 2013. 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.

Grant updates

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:

- All planned treatments for treating children with TB have been provided to 57 countries.
- 12,717 patient treatments have been delivered to 18 countries for the scale up of MDR-TB treatment initiative;
- 50 programme world-wide ordered MDR TB drugs from the stockpile to deal with emergencies and ensure optimal shelf-life of products;

- 21,787 MDR-TB patients have been diagnosed through EXPAND TB project in 19 project countries.

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

Key challenges and achievements in TB

TB		
CHALLENGE	**ACHIEVEMENTS-2012**	**NEXT STEPS**
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.	• No-cost extension requested by GDF to support countries with treatment gaps until 31 December 2013. • 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	• 12,717 2nd line TB treatments delivered to 18 high burden countries. • SRS lead times for urgent orders reduced to around 46 days in 2012 down from approximately 110 days in 2007.	• Countries in need of extended financial support for MDR-TB drugs into 2013 have been identified. • 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.	• 21,787 MDR-TB patients diagnosed in 19 countries; • 51 out of 97 laboratories have improved systems and equipment.	• Monitor partner scale up of diagnostic activities in countries. • Project is being amended to incorporate revised targets and include Xpert MTB Rif technology.

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

Challenges

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. Nonetheless, the number of applications from manufacturers for prequalification of UNITAID priority products doubled in 2012. This is encouraging but there remain too few prequalified formulations of some key medicines including, second-line TB medicines and paediatric anti-malarial medicines.

Grant updates

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. For example, 15 UNITAID priority diagnostic products have been prequalified to date. 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-2012**	**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	• 10 new UNITAID priority products were prequalified during the period from January to June 2012; • There has been a large increase in TB and malaria medicine dossiers submitted to the programme; • 15 APIs have been prequalified.	• New PQP programme manager appointed. • PQP will submit a new proposal for UNITAID funding totaling US$54 million over three years (2013-2015) for review at EB18 • PQP will submit a "no cost" extension to the current project to enable activities to continue with unspent funds in the project in 2013.
Improve the ability to accurately detect and treat disease by providing quality diagnostic tests that can be used in low income settings	• 15 UNITAID priority diagnostic products have been prequalified[7].	• DLT has submitted a cost extension request to the Dec. 4-5 Board for US$ 2M to cover the period March – Dec. 2013 • An external mid-term review of the project is starting in December 2012.

[7] Two malaria rapid diagnostic tests (RDTs), 4 HIV RDTs, 8 HIV viral load (VL) technologies and 1 CD4 technology

5. Conclusions

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. In this semi-annual report for 2012, we show improvements in grant performance over and above what was reported for 2011. 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 2012

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.	

Assessment of project programmatic performance uses 6-level scoring indicators to provide an overview of the project's performance according to the following criteria:

- Adherence to the project goals and outcomes;
- Timely delivery of project outputs;
- Management of risks and changes to the project;
- Results of mid-term reviews; and
- Management of project closure and transition.

Financial performance is reported to the Finance and Accountability Committee (Document UNITAID/FAC9/2012/1). Projects are rated according to the following factors:

- Budgetary planning and control;
- Cash management;
- Financial reporting;
- Risk awareness and management;
- Results of audits and reviews; and
- Collaboration and decision-making.

Financial performance of grants follows the same 6 level scoring indicators as programmatic performance of grants. However, the language describing the indicators has been modified to reflect the additional financial management actions that are taken for projects not performing in accordance to UNITAID standards.

PROJECT TITLE: Paediatric HIV/AIDS Project

Key Partner:	**Clinton Health Access Initiative (CHAI)**
Project Duration:	**November 2006 - December 2012**
Updates for the Period Ending:	**30 June 2012**

Updates **Operational Performance:** **Delayed**	
Project description	The goal of the Project is to maintain on-going access to paediatric ARVs, diagnostic bundles and related components. The project is also increasing the sustainability of the paediatric marketplace through the use of supplier selection techniques that increase the number of quality assured paediatric products and reduce their prices. The project is also working to identify long-term funding sources for paediatric ARVs and related commodities and support countries in securing these funds.
Finance	• Board ceiling: US$ 380,058,000 • MoU amount: US$ 315,883,000 • 2012 Disbursement: US$ 33,052,000 • Cumulative Disbursement (up to 2012): US$ 281,504,748
Achievements	• **35 of the 40 project countries**[8] have secured full funding and have received, or are in the process of receiving the necessary commodities for a full transition. • Suppliers were selected in March 2012, achieving price reductions of up to 19% compared to 2011 prices on key Pediatric ARV formulations.9 • 19 countries10 benefited from the project in 2012 with 21,39511 new children receiving treatment as of 30 June 2012.
Challenges for the reporting period	• Five countries (Malawi, Mozambique, Uganda, Swaziland, and Zimbabwe)planning to submit a proposal for GFATM Round 11 remain at high risk for transition funding in 2013 and beyond. • Since 2011, UNITAID, the GFATM and CHAI have been working through the Paediatric ARV Procurement Working Group to address continued funding support for pediatric patients in need of treatment. • The new funding model of the GFATM may be a barrier to some countries needing to seek additional funding to support paediatric treatments through grants from GFATM.
Next steps for the project	• CHAI has requested a project extension through 2013 • UNITAID will continue working with the Global Fund12, CHAI and other potential donors to assure a responsible transition of the remaining countries.

[8] Malawi, Mozambique, Uganda, Swaziland and Zimbabwe remain at high risk of not having continued support for paediatric ARVs.
[9] 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.
[10] Botswana; Burkina Faso; Cameroon; Cote D'Ivoire; Democratic Republic of Congo; Haiti; India; Kenya; Malawi, Mali; Mozambique; Nigeria; Senegal; Swaziland; Tanzania; Togo; Uganda; Zambia and Zimbabwe
[11] This represents over 35% of the 59,946 benchmark for new children on treatment in 2012 and the program is on-track to meet or surpass this benchmark by the end of the year.
[12] The GFATM informed UNITAID that GFATM was unable to commit to funding paediatric ARVs in Malawi, Mozambique, Uganda but agreed to support UNITAID's efforts in reaching out to other donors to address the current funding gaps.

PROJECT TITLE: Second-Line ARV Project

Key Partner: Clinton Health Access Initiative (CHAI) **Project Duration: May 2007-December 2012**[13] **Updates for the Period Ending: 30 June 2012**

Updates **Operational Performance:**  **On track**	
Project description	The objective of the Second-Line Project is to ensure on-going 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 (2012): US$ 299,651,000 • 2012 Disbursement: US$17,517,200 • Cumulative Disbursement (up to 2012): US$ 252,868,944
Achievements	• A "no cost extension for 2012 was granted to this project[14]. • CHAI covered all orders placed by the countries included in the 2012 project through the "no cost" extension. • Complete transition by the end of 2012 of all 25 countries[15] included in the project is continuing as planned. • The last 2nd line ARV orders will be placed in December 2012.
Challenges for the reporting period	• CHAI is working with Cameroon and Democratic Republic of Congo (DRC), to determine the status of their Global Fund grants and to cover any needs on-going into 2013 to prevent stock outs.
Next steps for the project	• A final project report will be submitted by CHAI in 2013 including the challenges and achievements of the project since its inception. • Lessons learned from a successful transition process will be publically disseminated. • An end of the project evaluation will be commissioned by UNITAID in early 2013.

13 No "cost-extension" was granted to this project for 2012.

14 The no-cost extension included the following countries facing risk of delays in their transition process: Cameroon, Haiti, Mozambique, Togo, Uganda, and Zimbabwe.

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

PROJECT TITLE: ESTHERAID

Key Partner : ESTHER (Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau)
Project Duration: January 2008-December 2013
Updates for the Period Ending: 30 June 2012

Updates **Operational Performance:**  **Minor delays**	
Project description	This project contributes to improving supply chain management from national central medical stores to treatment centres in 5 West African countries[16] by improving logistic information systems and patient monitoring systems. The project also supports the efforts of treatment centres 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 (2012): US$ 14,681,000 • 2012 Disbursement: US$ 2,385,093 • Cumulative Disbursement (up to 2012): US$ 6,426,463
Achievements	• Strategies to improve management, distribution and storage of medicines are now part of standard operating procedures in Benin and in the Central African Republic[17]. • A decentralization plan for paediatric care was implemented in Central African Republic and the referral process of infected children was created in Benin. • An improved sampling and result delivery systems is functional in Benin and Burkina Faso to promote optimal care for children and people with therapeutic (first line) failure. • Prescribing doctors from Central African Republic, Mali, Burkina Faso and Benin benefited from scholarships for diploma-based training on HIV prescribing and care. • The ESOPE software for clinical monitoring of people living with HIV is now installed in the treatment and care centers covered by the project in Benin, Mali, Burkina Faso and in Cameroon.
Challenges for the reporting period	• Cameroon and Mali are delayed in the programmatic implementation of the project. • The project in Mali has stalled due to internal conflict. A strategy to manage the work plan for Mali is under development.
Next steps for the project	• All ESTHERAID stakeholders are meeting to design a country-specific strategies to improve the implementation of the remaining project activities. • A mid-term review will be conducted starting in December 2012.

16 Benin, Burkina Faso, Central African Republic, Cameroon and Mali.

17 Results of an evaluation of the Central Medical Stores and of the Treatment and Care Centers in these countries led to significant changes in National policy for supply chain management of ARVs.

PROJECT TITLE: Support to the Coordinated Procurement Planning (CPP) Initiative

Key Partner: Supply Chain Management System (SCMS)
Project Duration: August 2012-August 2013
Updates for the Period Ending: 30 June 2012

Updates **Operational Performance:**  **On track**	
Project description	The Project aims to establish a common framework for understanding stock out risks, improving funding coordination and procurement and supply management of medicines for HIV/AIDS, TB and malaria. The financial contribution of UNITAID is to develop a publically accessible database and web-platform to improve information sharing between the CPP Members and to be more effective in preventing stock outs. Six countries are included in the initial phase of the project[18].
Finance	• MOU amount (2012): US$190,000 • 2012 Disbursement: US$120,000 • Cumulative Disbursement (up to 2012): US$ 120,000
Achievements	• UNITAID is participating in the monthly CPP meetings and it is part of the committee that reviews the status of countries at-risk of stock-outs of key ARVs. • Beta testing of the publically accessible information sharing platform (database) will begin in December 2012. • SOLTHIS (Solidarité Thérapeutique & Initiatives Contre le Sida) and SIAPS (Systems for Improved Access to Pharmaceuticals and Services Program) have joined the CPP Technical Working group and ESTHER will be formally invited to join the group. These additions increase the technical capacity of CPP better coordinate in-country procurement planning at the national level.
Challenges for the reporting period	• SCMS received the first disbursement from UNITAID later than expected.
Next steps for the project	• Launch of the interactive, publically available database to share information on stock-outs for ARVs in at risk countries is expected in January 2013. • CPP is developing a plan to provide assistance for better coordinated in-country procurement planning at the national level. This will involve conducting an assessment of existing coordination mechanisms.

18 Angola, Burkina Faso, Cameroon, Central African Republic, Mali, and Mozambique

PROJECT TITLE: Affordable Medicines for Malaria (AMFm)

Key Partner: The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria
Project Duration: 31 December 2012[19]
Updates for the Period Ending: 30 June 2012

Updates **Operational Performance:**  **On track**	
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.[20]
Finance	• Board ceiling: US$130,000,000 • MoU amount (as of December 2010): US$130,000,000 • Cumulative Disbursement (as of June 2012): US$130,000,000 • MoU amount for the Extension period (as of December 2012):US$ 50,000,000 • 2012 Disbursement: US$ 25,000,000
Achievements	• MOU signed for an extension of UNITAID support until 31 December 2012. • ACT and artemisinin demand forecasts published on a quarterly basis to update AMFm, donors, partners, industry and endemic countries about the status of global demand. • GFATM AMFm Working Group and SIIC recommendations concerning the future of AMFm were approved by the 28th GFATM. • Board Report of the Independent Evaluation of AMFm Phase 1 published in September 2012 (see summary below).
Challenges for the reporting period	• AMFm Phase 1 pilot countries are very concerned about the future availability of affordable ACTs in the face of uncertainty concerning AMFm and likely change in AMFm at the end of Phase 1 •
Next steps for the project	• Disburse the second amount of U$D 25 million for 2012 extension period of the AMFm. • UNITAID to decide on the request that was submitted by the GF on 08 November 2012 for a no-cost extension to extend the use of UNITAID additional funds for co-payment of ACTs until 31 March 2013. • Monitor timely submission of GF regular quarterly reports through the end of December 2012. • Review and disseminate the ACT demand forecast quarterly updates. • End of Phase 1 programmatic and financial reports to be submitted by GF by the end of December 2012.

The AMFm Phase 1 Independent Evaluation (IE) and GF Board Decision

1. **Major Findings of the IE**

- Success benchmarks were clearly met in 5 pilots for availability, 5 pilots for quality assured ACTs (QAACTs) price relative to the most popular antimalarial that is not a quality assured ACT, and 4 pilots for ACT market share.

19 UNITAID has received a request for a no-cost extension until 31 March 2012.

20 Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania and Uganda.

- The success benchmarks related to artemisinin monotherapy (AMT) price and market share were met in all pilots with sufficient AMTs in the market to make these benchmarks relevant. Even at baseline, market share for oral AMT was less than 4% in Ghana and less than 1% in the rest of the pilots. In Nigeria and Zanzibar, where oral AMT market share was somewhat higher at baseline, large and significant falls were observed.
- The price of co-paid QAACTs in the private for-profit sector at end-line was variable across pilots, ranging from USD 0.51 in Madagascar to USD 1.96 in Uganda. The median retail gross mark-up on co-paid QAACTs was less than 70% in all pilots, except Uganda (133%) and Zanzibar (100%).

2. Global Fund Board Decision (28th Session 15 November 2012, Geneva)

- Decides to integrate the Affordable Medicines Facility - malaria (AMFm) into core Global Fund grant management and financial processes, following an orderly transition period in 2013;
- Under the new, integrated model, eligible countries will be able to allocate funding from their core Global Fund grants and determine how the money should be spent; and
- Following an assessment by technical partners, the AMFm model may be further modified to include malaria rapid diagnostic tests (RDTs).

PROJECT TITLE: Assured Artemisinin Supply Service (A2S2)

Key Partner(s):	**i+solutions, Triodos**
Project Duration:	**July 2009 – May 2013**[21]
Updates for the Period Ending:	**30 June 2012**

Updates **Operational Performance:**  **Poor performance**	
Project description	The project supports the production of additional Artemisia (40 MT) 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 an artemisinin extractor, a prequalified ACT manufacturer and i+solutions
Finance	• Board ceiling: US$ 9,280,400 • MoU amount US$ 9,280,400 • 2012 Disbursement: none • Cumulative disbursement (as of December 2010): US$ 9,280,400[22]
Achievements	• Finalized agreements for the production of an additional 24.8 MT of artemisinin with four extractors; and approved loans of US$ 6.45 million • 5.37 MT of artemisinin delivered to ACT manufacturers; deliveries by extractor (Extractor, country, amount delivered (percentage of total delivered) as follows: 1)Beijing-Gingko, China, 3.2 MT (59%), 2)Vidic, Vietnam, 1.64MT (31%), 3) Bionexx, Madagascar, 525kg (10%) • A total of US$ 2.7 million (42%) of the total loan fund disbursed has been reimbursed to the project • Information on artemisinin production and artemisinin market intelligence disseminated through a dedicated newsletter and website.
Challenges for the reporting period	• Failure to report fully the market intelligence data to UNITAID as requested, citing commercial confidentiality. • Concluding loan agreement negotiations with Artemisinin extractors were lengthy and time consuming resulting the completion of few low volume contracts
Next steps for the project	• Market intelligence data reporting requirements, reporting format and frequency or reporting has been agreed under a confidentiality agreement • Follow-up with i+solutions to ensure delivery of contracted artemisinin to ACT manufacturers and to reimburse the loan fund to UNITAID. • Follow-up with i+solutions and Triodos Bank to effectively conclude the search and negotiation for social Investors who may continue to support a revolving loan fund for artemisinin extractors. • UNITAID to organize project financial audit and end of project evaluation.

21 Third no cost extension granted for the period from June 2012 to May 2013.

22 Last Project Year Budget: Operating cost from June 2009-July 2010 of USD 480,200; the loan fund of USD 8.4m goes across 2 years. As of November 2012, USD 5 million has been reimbursed to UNITAID.

Remaining balance and interest will be accounted for at the end of the project period

PROJECT TITLE: ACT Scale-Up

Key Partner(s): The Global Fund to Fight AIDS, TB and Malaria and UNICEF
Project Duration: December 2007-June 2010[23]
Updates for the Period Ending: 30 June 2012

Updates **Operational Performance:** ◯ **Unable to assess**	
Project description	The ACT Scale-up project was initiated to provide 47,016,160 high quality ACT treatments to seven countries[24]. 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 December 2010): US$ 65,413,057 • 2012 Disbursement: US$ 0 • Cumulative disbursements (up to December 2011): • US$ 39,844,131 •
Achievements	• 36, 135,545 ACT treatments delivered to 8 high burden malaria countries • Procurement lead times reduced.
Challenges for the reporting period	• Both Madagascar and Zambia have reported ACT stock-outs, indicating poor supply chain management by the project. • Reporting from the GFATM and UNICEF remains problematic – Figures reported by GFATM and UNICEF are not consistent, clear or understandable. • UNITAID expects the GFATM to report the estimated number of patients treated in the end-of-project report.
Next steps for the project	• Follow-up with the GATMF and UNICEF to ensure the timely submission of the end-of-project programmatic and financial reports. • UNITAID to request a detailed financial report and to transfer of unexpended funds. • Make arrangements for the independent end-of-project evaluation.

23 no-cost extension to December 2012 agreed

24 Ghana, Cambodia, Madagascar, Mozambique, Sudan (North and South, at time of agreement, this was one country), Indonesia, Zambia and Ethiopia.

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[25]
Updates for the Period Ending: 30 June 2012

Updates **Operational Performance:**  **Poor performance**	
Project description	This project aims to scale up access to treatment and to improve affordability of medicines for AIDS, MDR-TB and malaria through Global Fund grants in Round 6, Phase 1
Finance	• Board ceiling: USD 52,500,000 • MOU agreed amount: US$ 38,691,956 • Disbursement in 2012: US$ 0 • Cumulative disbursements (up to 2012) : US$ 38,691,956 • Estimated remaining balance of USD 11 million to be reimbursed to UNITAID
Achievements	• At the end of 2010, the project had supplied: ○ 31,197 paediatric ARV treatments ○ 2,650,652 ACT treatments ○ 3,223 treatments for MDR TB
Challenges for the reporting period	• Procurement report and computation of remaining unspent funds is still incomplete[26]. • Global Fund did not fulfill the UNITAID request to reconcile project data by the end of December 2011. • End-of-project programmatic and financial report is still pending.
Next steps for the project	• UNITAID to request the Global Fund to reimburse at least USD 11 million in unexpended project funds. • The Global Fund to submit end-of-project programmatic and financial report. • UNITAID to coordinate the end-of-project independent evaluation in the first quarter of 2013.

25 no-cost extension to 31 December 2012 under discussion

26 According to UNITAID records, the undisbursed project fund available in the account of the implementer is around US$11 million.

PROJECT TITLE: Paediatric TB project

Key Partner: Stop TB Partnership, Global Drug Facility **Project Duration: January 2007-December 2012** **Updates for the Period Ending: 30 June 2012**

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: US$ 11,603,952[27]. • Cumulative disbursement (up to 2012): US$ 11,626,950
Achievements	• All planned treatments have been provided to 57 countries.
Challenges for the reporting period	• Existing formulations are still not adequate for paediatric treatment. • New suppliers still need to be identified for the new dosage formulations and it has been difficult to provide incentives to manufacturers to make the new formulations required. • The cost reductions achieved have not been substantial during the project compared to baseline prices due to the absence of new dosage formulations.
Next steps for the project	• Out of the 57 countries supported by the project, 8 countries[28] will need additional financial support, amounting to a total of USD 1,379,500. This will be covered from the balance remaining at the end of 2012. • GDF has submitted a “no cost” extension request to support countries with treatment gaps until 31 December 2013.

27 In 2010 UNITAID’s 12th Executive Board approved an additional US$ 2,207,486 to support Paediatric TB project.

28 Macedonia, Niger, Nigeria, Sudan, South Sudan, Tajikistan, Somalia and Sri Lanka.

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 2012

Updates **Operational Performance:**  **On track**	
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	MDR TB Scale up Initiative and Strategic Rotating Stockpile: • Board ceiling: US$ 51,816,384 • Cumulative disbursement (up to 2012): US$ 48,937,671 Strategic Rotating Stockpile only: • Board ceiling: US$ 13,686,737 • MoU amount: US$ 13,686,737 • Cumulative disbursement(up to 2012): US$ 9,872,862
Achievements	MDR TB Scale up Initiative • **12,717 patient treatments have been delivered in 18 countries**[29]. • 100% of proposed treatments have been ordered. Strategic Rotating Stockpile: • 50 programmes world-wide ordered MDR-TB drugs from the stock-pile. Some of these were emergency orders, whereas few were ordered to ensure rotation of stocks and optimal shelf-life of drugs. • 11 countries accessed the emergency stock-pile during first half of 2012 (Emergency orders). • The median lead time for emergency orders delivery for the first half of 2012 was 46 days.
Challenges for the reporting period	• The SRS was intended to be used for emergency procurement, to prevent stock-outs. However due to sub-optimal forecasting purposes, countries are using the stock-pile for off-cycle orders. This may be a disincentive to countries, preventing them from improving their forecasting and supply chain management. • Changes in MDR-TB drug regimens decreased demand for some drugs[30] presenting challenges in delivery of these items to programmes that are still using them. •
Next steps for the project	• A detailed transition plan is being developed for the MDR-TB segment of this project. • Countries in need of extended financial support for MDR-TB drugs into 2013 have been identified. GDF may request a no-cost extension to UNITAID to support these countries.

29 81% of the total project target (15,606 patient treatments planned for delivery by December 2012)

30 Ofloxacin and Prothionamide

PROJECT TITLE: EXPAND$_x$ TB (MDR-TB Diagnostics)

Key Partner(s): Stop TB partnership, Global Drug Facility
Project Duration: : January 2009 – December 2013
Updates for the Period Ending: 30 June 2012

Updates **Operational Performance:**  **Minor delays**	
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: US$ 89,612,000 • 2012 Disbursement: US$ 0 • Cumulative disbursement (up to 2012): US$ 38,216,000
Achievements	• 51 out of 97 laboratories have been strengthened to deliver diagnostic services routinely. 15 additional laboratories are in the process of attaining the same status in 2013. • Five countries are in the laboratory strengthening phase. • **21,787 MDR-TB patients** have been diagnosed through EXPAND TB project in the 19 project countries, with about 50% of them being reported in the first half of 2012 alone. • The number of commodities delivered in the countries has increased exponentially and in the first half of 2012, 181 shipments worth USD 4,650,824 were delivered to 19 countries.
Challenges for the reporting period	• The number of targeted laboratories was reduced to 97 from the originally planned 105, in view of the consideration of changes in National laboratory plans and the introduction of a new diagnostic method (Xpert MTB Rif) in some countries. Experience shows that laboratory capacity established under the EXPAND TB project will be critical to the successful use of Xpert MTB Rif in these countries because subsequent follow-up of MDR-TB cases can only be done after comprehensive laboratory strengthening and not by Xpert technology in isolation. • Due to inadequate progress on the project two countries, Zambia and DR Congo, were replaced by Rwanda and Mozambique.
Next steps for the project	• In 2013, it is anticipated that there will be a three-fold increase in the number of MDR-TB cases diagnosed in the 19 countries, achieving close to 95% or more of the project's target. • The project is being amended to incorporate a revision of targets so as to make them more realistic and to include Xpert MTB Rif in selected countries. • Along with the amendment, the project partners are also planning a no-cost extension of the project for one year in 2014. This extension will also assist in the transition of few countries which have challenges in funding continuity for laboratory services.

PROJECT TITLE: WHO Medicines Prequalification Programme (PQP)

Key Partner(s): WHO
Project Duration: December 2006 – December 2012
Updates for the Period Ending: 30 June 2012

Updates **Operational Performance:**  **On Track**	
Project description	The Medicines Quality Assurance project aims to increase the number of prequalified UNITAID priority medicines for HIV/AIDS, TB and malaria as well as 1) increasing capacity in production of quality medicines, 2) facilitating the development of national regulatory processes and 3) Accelerating testing of the quality of medicines
Finance	• MoU amount: USD 53,110,000 • 2012 budget: US$ 11,486,450 • 2012 actual expenses: US$ 6,216,728 •
Achievements	• A new PQP programme manager has been appointed. • Nearly double the number of applications for UNITAID priority products were received compared to same period in 2011 (January to June). • 10 new UNITAID priority products were prequalified (more than same period in 2011) bringing the total prequalified since 2009 to 119. • In 2012 there has been a large increase in TB and malaria medicines dossiers submitted to the programme. • 15 APIs have been prequalified with 8 APIs prequalified during this reporting period alone (January to June). • 23 assessors from 10 LICs, 9 of which are UNITAID supported countries, participated in 3 PQP dossier assessment sessions helping to build capacity.
Challenges for the reporting period	• Current invitations to manufacturers to submit an Expression of Interest for include many formulations for which no products have been prequalified. • There remain too few prequalified versions of second-line TB products and anti-malarial ACTs (paediatric products).
Next steps for the project	• PQP submitted a new proposal for UNITAID funding totaling US$ 54M over 3 years (2013-2015) for review at EB18. • PQP will submit a “no cost” extension to the current project to enable activities to continue with unspent funds in the project in 2013.

PROJECT TITLE: WHO Prequalification of Diagnostics Programme (PQP)

Key Partner(s): WHO
Project Duration: March 2009 – February 2013
Updates for the Period Ending: 30 June 2012

Updates **Operational Performance: ◯ Not able to assess**	
Project description	The project aims 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[31].
Finance	• MoU amount: US$ 8,475,000 • 2012 budget: US$ 3,400,000 • 2012 actual expenses: US$ 1,151,601
Achievements	• 15 UNITAID priority diagnostic products have been prequalified[32]. • An additional 5-7 products (1-3 HIV RDTs, 2 CD4 technologies and 2 HIV VL technologies) are expected to be prequalified by end 2012.
Challenges for the reporting period	• Semi-annual report to UNITAID is significantly delayed. • Prequalification of an additional 6 products is currently on hold, due to quality concerns identified during the WHO PQ Dx assessment procedure. • A fast track procedure to accelerate the prequalification of priority diagnostics, in particular point-of care (POC) diagnostics, has not yet been established.
Next steps for the project	• DLT has submitted a cost extension request to the Dec. 4-5 Board for US$ 2M to cover the period March – Dec. 2013 to allow for (i) the successful completion of the current project; (ii) establish and implement a process to conditionally prequalify new and innovative POC diagnostics; and (iii) Improve readiness of manufacturers of innovative POC diagnostics for WHO prequalification.

31 Burkina Faso, China, Cote d'Ivoire, Tanzania and South Africa.

32 Two malaria rapid diagnostic tests (RDTs), 4 HIV RDTs, 8 HIV viral load (VL) technologies and 1 CD4 technology

Annex 2: Update on project proposals approved by the Executive Board in EB15 Special Session

Project	Challenges	Actions taken	Next steps
MSF: Implementation of CD4 and VL testing in decentralized, remote and resource-limited settings in MSF HIV programmes **EB15SS-Res.3**	• The project focuses on operational research which means that preparatory work in countries is needed start the project. • Not all of the expected diagnostic products are currently available for purchase in all countries. • MSF is a new partner using procurement practices that difer with the WHO/UN procurement model. • Suitable quality assurance procedures are not available for all of the diagnostic tests that will need to be purchased.	• All participating countries have letters of support for the project; • Laboratory-based and POC CD4 are now fully available. VL POC is expected in 2013-2014; • Procurement and supply mechanism agreed by UNITAID, WHO and MSF; • Quality assurance for these tests is based on ISO13485 and CE marked. The process will be reviewed as the market develops.	• Project plan and related documents finalized • Legal agreement drafted by UNITAID; awaiting MSF clearance • Signature of MOU and launch of the project expected for end of November 2012
FEI: OP-PERA **EB16-Res.4**	• Diagnostic product to be used as open polyvalent platforms has yet to formally enter the market for this project; • FEI sent a partial project plan that did not correspond to the EB approval or EB conditions for project approval;	• FEI participated in UTD webinar on the "Business case and commercialization strategy" to understand more about expectations for market entry. • UNITAID provided feedback to FEI on the process of project planning through visits and regular communications.	• Revised project plan under review
CHAI/UNICEF PoC HIV Project **EB15SS-Res.5**	• Only one PoC test is available for purchase at this time. Procurement policies were needed to deal with different scenarios for product availability in order to maintain the market for these tests;	• Procurement policies and procedures have been created to deal with different scenarios for product availability; • UNITAID met with all parties to clarify Board decision and budget;	• MoU awaiting clearance by CHAI/UNICEF; • Signature MOU expected for end of November 2012

	• Implementers did not provide a project plan and budget relating to EB approval of a 1 year project; • Country operational plans were limited and not connected to other external projects being done in the same countries; • CHAI and UNICEF did not clearly define their specific roles and responsibilities for the project overall and in-country;	• Project Plan format and legal structure of MoU has been agreed; • Project timeline, budget and M&E expectations clarified between all parties.	
PSI RDT Private Sector **EB15SS-Res.6**	• RDTs are not widely available in the private sector, where anti-malarials are purchased; • Project involves operational research and multiple in country sites using different implementation models; • Complex project requires a more detailed project plan; • Procurement model and plan has not been produced; • Transition and communication plans are missing.	• UNITAID, PSI, WHO & FIND convened a **Technical Consultation** in July to develop implementation model for project; • PSI revised project their proposal in September but it is still missing procurement, transition and communication elements; • UNITAID is working closely with PSI to finalize the project plan, LogFrame and budget	• PSI project plan, LogFrame and budget and associated documents are under review
FIND QC for RDTs **EB15SS-Res.4**	• Quality control for RDTs is a highly specialized area and requires specific expertise; • Project plan was not fully developed because the details of implementation were missing; • Delays in project documentation have occurred because of	• Specific expertise has been provided by WHO to FIND to facilitate project development; • UNITAID is working closely with FIND and WHO to finalize the project plan, LogFrame and budget.	• All project documentation completed by FIND and WHO; • MOU is being drafted by UNITAID and project will start in Q1 2013.

	staffing shortages with the Implementers (FIND & WHO).		
A2S2 **EB15SS-Res.9**	• Delays are reported in recovery of loan monies; • Delivery of artemisinin as contracted has taken longer than expected; • Transition of A2S2 revolving fund to other investors has required an extension • Orderly project closure	• i+solutions and UNITAID agreed on a final phase project plan including the production of market intelligence based on EB request; • Triodos is seeking interest from investors to transition the revolving loan fund from UNITAID; • Amendment to the MoU is being prepared to cover the additional time on this project.	• Final amendment to MOU signed; • Oversee project implementation and closure; • Carry out end-of-project evaluation.
AMFm **EB15-Res.7**	• UNITAID requires a stronger role in Governance of the AMFm project; • AMFm needs to fully articulate their financial position and need for funds to support the co-funding of ACTs in the private sector.	• MOU between UNITAID and GF signed in July and first tranche of USD 25 m disbursed; • Independent Evaluation results show overall positive results of the AMFm Phase 1; • GF Board extended AMFm Secretariat for an 2013 (GF is seeking additional support for ACT co-payment fund); • Disbursement request for second tranche of funding for 2012 is under process (November 2012)	• Disbursement request for second disbursement of Board-approved funding approved; • Consider GFATM no-cost extension request for 2013; • Work with GFATM to facilitate a responsible transition of AMFm in 2013 and beyond • GFTAM request for 2013 (40 millions) to be considered
TB Xpert project: Public health and market impact components.	• High price of TB Xpert platform and tests identified as a barrier to access in low-income	• Price reduction on TB Xpert secured on 06 April 2012 through agreements between	• Negotiations on the contract between UNITAID and

Public Health impact: 25.9 million USD for Xpert scale-up in 21 countries through Stop TB Dept, WHO and the Stop TB Partnership Market Impact component: Up to 4.1 million USD for buy-down payment to Cepheid to effect price reduction to 9.98 US dollars per cartridge (test) **EB16-Res.5**	markets; • Countries need to have ownership of the project to be facilitate uptake of TB Xpert technology into national TB programmes.	Cepheid and US Govt. UNITAID agreement with Cepheid is pending; • Reduced price available to 145 countries (in public sector) • For Xpert roll-out to 21 countries, Project Acceptance Letters have been received from most countries • Project agreement and project plan are being developed with good progress being made in the process.	Cepheid due started. Contract conclusion targeted for end November 2012 • Project Plan and MoU with WHO Stop TB Department and Stop TB Partnership for the Project roll-out completed and under review