16th Executive Board
12-13 June 2012
WHO Headquarters, EB Room
Geneva, Switzerland

Agenda Item 9.1

Report on implementation of projects approved by the Board

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

Draft UNITAID Top 10 Achievements 2011[1]

1. UNITAID-CHAI placed over 65,000 new children on treatment in 2011, **increasing the global coverage of children in need of ART to 25%.** UNITAID-CHAI supports over 400,000 children on ARV treatment using optimal AZT-based paediatric FDCs.

2. A leading paediatric ARV[2] costs US$130 per patient per year today instead of US$ 252 in 2006, contributing to the overall **price reductions of 80%** achieved by the UNITAID-CHAI partnership.

3. The UNITAID-CHAI 2nd Line project facilitated access to **ATV/r FDC**, the first heat-stable alternative to LPV/r. **ATV/r FDC costs US$300 per patient per year**, **25% less than LPV/r** and it reduces the pill burden for patients to one pill per day instead of 4 per day for LPV/r.

4. **Stock outs of ARVs avoided** in Benin and Mali through improved coordination within countries and with major global funders[3].

5. **13 low-income, high-burden TB countries now have fully functioning laboratories** using state-of-the-art Line Probe Assay tests to detect patients with MDR-TB.

6. **1,098,959 curative and preventive anti-TB treatments,** cumulatively through end of 2011, provided for children in 57 countries.

7. **Generic manufacturers supply 84% of all ARVs, 73% of all ACTs and 100% of all anti-TB medicines** purchased with UNITAID's funds.

8. **151 million ACTs** delivered to consumers[4], through support to the Affordable Medicines Facility for Malaria (GFATM)

9. **Reduced ACT cost: only between US$0.33 and US$ 1.31 per treatment** (as opposed to US$ 8 to US$10 per treatment).

10. 45 products prequalified**, including 20 UNITAID priority medicines and 10 diagnostic tests.**

[1] The Key Performance Indicator Report 2011will be available on 30 June 2012. After 30 June 2012, the Board will be asked to approved the 2011 report by electronic vote.
[2] AZT + 3TC + NVP (300mg+ 150mg +200mg)
[3] Through ESTHERAID and the Coordinated Procurement Planning Initiative with GFATM, PEPFAR, UNICEF, WHO and SCMS.
[4] From GFATM annual report (provided May 2012) to UNITAID on the AMFm

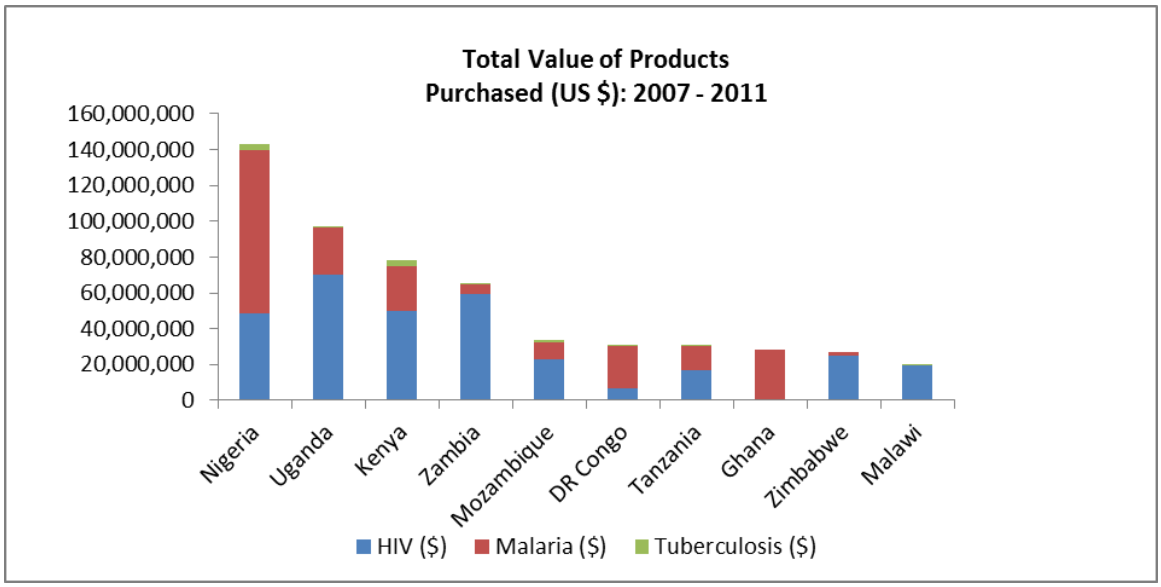
1. Operations update-High level view of the Portfolios

Operations manage a wide range of projects divided into 4 specific areas. These are HIV/AIDS, TB, Malaria and Cross-cutting projects. Cross-cutting projects are projects that provide medicines and related products for more than one of the three disease areas, including support to the WHO Prequalification programmes for medicines and diagnostics. The total MoU value (US$) across the entire UNITAID portfolio is 1.3 Billion. This is broken down by disease area portfolio as follows:

- HIV/AIDS-US$ 729 million;
- TB- US$ 196 million;
- Malaria-US$ 315 million; and
- Cross-cutting- US$ 100 million.

UNITAID operates differently from any other Global Public Health funding initiative. Our interventions are targeted at the very best products to test, treat and prevent the three diseases and our impact is measured by how our interventions have improved access to these products in the poorest countries by generating sustainable price reductions for important, state-of-the-art tests and treatments. One way of doing this is to open the market for medicines up to quality assured generic manufacturers. Partner reports to the Operations team show that the Indian generic manufacturers accounted for 100% of all anti-TB medicines bought with its funds. Generic manufacturers contributed in a similar way for paediatric and 2nd line ARVs with 84% of all funded medicines being generic products. Likewise, 73% of ACTs to treat malaria came from generic manufacturers.
UNITAID's focus on low and middle income countries is unique. The majority of UNITAID's project funding goes to projects being implemented in high burden African countries. As Figure 1 shows, UNITAID provides funds mainly for HIV/AIDS and malaria in Sub-Saharan Africa. The distribution of the investment across the three diseases in Africa is 58% for HIV/AIDS, 39% for Malaria and 3% for TB. Operations also tracks the monies spent in countries by World Bank income group within each disease-based project and across its portfolio as a whole. Approximately 84% of UNITAID's funding benefits low income countries with a further 13% invested in low middle income countries and only 3% in upper middle income countries. For HIV/AIDS products, 88% of all funding goes to low income countries with low middle income and upper middle income receiving 8 and 5% respectively. TB products are dived between both low and low middle income countries with low income countries receiving 66% of the value of monies spent and low middle income countries receiving 32%. The low middle income countries receiving support through UNITAID funded products have the highest TB burdens in the world. Only 2% of TB funds go to upper middle income countries. For malaria, the monies are spent only in malaria endemic countries, 80% of which are low income countries and 20% are low middle income countries.

Figure 1 Top 10 Sub-Saharan African countries benefiting from UNITAID's investments



2. Consolidation of programmatic information by the Operations Team

This document provides an update on UNITAID-funded projects and their achievements for the 2011 annual reporting cycle. The purpose of the document is to highlight new developments and key challenges in the current projects and to provide an update to the project assessments made for the time period from January to June 2011 and provided at EB 15. These assessments are made using the UNITAID 6 "traffic-light" performance scores illustrated in Annex 1. These scores summarize financial and programmatic performance to provide a high-level overview of project performance.

Implementing partners reports are received twice a year, in September/October and March/April/May. At this point, we have received and reviewed all of the 18 project reports for the full 2011 calendar year. A complete reconciliation of facts and figures for the 2011 calendar year will be consolidated in the Key Performance Indicators Report 2011 that will be final on 30 June 2012. This report will be approved by EB members by electronic vote, and subsequently made available on the UNITAID website (www.unitaid.eu). The project-specific operations updates are available as Annex 1 of this document. These updates include a project performance score for 2011, highlights (achievements or challenges) identified for each project and "next steps" that each implementing partner is taking in conjunction with the UNITAID Secretariat to move the project forward in 2012.

The Operations team has focused on the reasons behind project performance that is "on track", "delayed" or "poor". A lesson learnt from project planning, and reinforced by the mid-term evaluations, is that the projects should be:

- Realistic in scope;
- Implemented by partners who are able to report the information needed to track achievements systematically;
- Responsive to implementing the results of evaluations; and

- Adjusted regularly to the changing conditions of both the markets for products and the global public health landscape.

Where projects have performed poorly, it has been observed that partners have not had the capacity or expertise to re-direct the project to a successful conclusion, once changes have occurred requiring modification to the project plan.

3. Status of UNITAID's projects

UNITAID currently supports 18 projects, in various stages of project implementation. They 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, population and product market to achieve their intended impact with time-limited financial support from UNITAID. Table 1 summarizes a selection of key UNITAID-supported projects highlighting the market intervention and public health benefit of each. In addition, Table 3 presents a snapshot of project performance, assessed through partner annual reports to Operations for the year ending 31 December 2011. Full project details are provided in Annex 1.

External mid-term reviews of 8 of the projects have been completed and the UNITAID Operations team has worked with partners to implement the recommendations of these reviews. A complete summary of the mid-term reviews was presented to PSC 7 and a summary by project is available from the Secretariat. Full reports are also available from the Secretariat upon demand.

Six projects finished on 31 December 20115. End of project reviews of newly completed projects are being implemented to make sure that lessons learnt from project implementation are fully integrated into the planning and management of future UNITAID projects. One project, Provision of Long lasting insecticide treated nets to high burden malaria countries (UNICEF) ended in 2010 and the external end of project evaluation is expected from Dalberg by the end of June 2012. Another project, PMTCT-I, II &III with UNICEF, is currently being evaluated by the Euro Health Group (EHG).

In addition to the usual project management and reporting challenges with existing implementing partners, 4 new projects have been added to the Operations Portfolio in March 2012.
The UNITAID Executive Board approved funding for the following projects:

- Implementation of CD4 and viral load testing with MSF;
- Accelerating Access to innovative point of care HIV diagnostics with CHAI/UNICEF;
- Creating a private sector market for RDT for Malaria with PSI; and
- Sustainable quality control for malaria RDTs with FIND.

[5] See table 2 for a summary of these projects, transition steps and actions being taken by Operations.

The Operations team has benefited from the expertise of the three new Portfolio Managers who took up their posts in early 2012, just in time to participate in the review of the new proposals for projects focused on diagnostic technologies for the three diseases. The Operations team is now working with the new implementing partners to finalize project plans and contractual agreements to begin these projects in 2012.

4. Up-date on transition of UNITAID funded projects

UNITAID continues to monitor the transition of its projects to other sources of donor funding in order to secure its market achievements. This is particularly challenging given the funding constraints that many global public health funding bodies are facing. Given the challenging economic times, interventions that increase competitiveness in the market place and decrease overall prices are of paramount importance. Throughout the grant life-cycle, grant sustainability should be evaluated to ensure that if a grant is going to transition to a stakeholder, patients continue to receive treatment, the market is sustainable and adequate financing is available. It is critical to engage implementing partners and country leadership with structured and relevant communications to ensure lasting project sustainability after UNITAID market gains are achieved. The Operations team has focused on understanding the implications of grant sustainability at a project and country level by working with implementing partners to mitigate risks and discuss transition priorities. Detailed transition information has been collected and is not only being pro-actively monitored by Operations, but also being incorporated into all of the new projects where applicable.

Table 1 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

TABLE 2. UNITAID completed projects with end of project evaluations due in 2012

Project name	Transition status	Actions
2nd line HIV/AIDS treatments - **CHAI**	Monitoring transitioned countries	"No cost" extension of US$8,100,000 to cover emergencies
PMTCT I, II, III **UNICEF**	Completed	Data to be reconciled External end of project evaluation started by EHG
1st line anti TB drugs **GDF**	Completed	Final report and external end of project evaluation to be started
Paediatric TB project **GDF**	"No cost" extension for 2012	Unspent funds to be used to complete treatment delivery
ACT Scale up project **UNICEF, GFATM (7 countries)**	Project closing	Unspent funds used to cover ACT shortfalls; project to be closed
Provision of Long lasting insecticide treated nets (LLINs) to high burden malaria countries **UNICEF (9 countries)**	Closed	Dalberg has started external end of project review. Review will be complete by end of June 2012
Support to Round 6 **GFATM**	Completed	Reconciliation of expenditures and procurement

TABLE 3. Summary of UNITAID projects with performance update

HIV	TB	Malaria	Cross cutting
1. Paediatric HIV/AIDS treatment program **CHAI**	8. First line anti TB drugs initiative **GDF**	13. Artemisia supply project **i+Solutions**	16. Support to Round 6 **GFATM**
2. 2nd line Adult HIV/AIDS treatment program **CHAI**	9. MDR TB scale up **GDF**	14. AMFm **GFATM**	17. Support for quality assurance of medicines **WHO**
3. PMTCT I **UNICEF**	10. MDR TB acceleration of access initiative: SRS **GDF**	15. ACT Scale up project **UNICEF, GFATM**	18. Support for quality assurance of diagnostics **WHO**
4. PMTCT II expansion **UNICEF**	11. Paediatric TB project **GDF**		
5. PMTCT III nutritional support **UNICEF**	12. Expand MDR TB diagnostics **FIND, GLI, GDF**		
6. Support to SCM in West Africa **ESTHER**			
7. Medicines Patent Pool **MPP Foundation**			

5. HIV/AIDS Portfolio

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 ended 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. 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. Operations is involved in specific Secretariat led projects with Partners and other stakeholders to face the challenge of transition.

For the 2nd Line Adult ARV medicines project with CHAI transition plans have been disrupted for some countries by the cancellation of the Global Fund round 11 which they planned to use for 2nd Line Adult ARV support6. CHAI was granted a no-cost extension to allow any un-spent 2011 funds to carry over into 2012 to support these countries.
The PMTCT projects have now ended. UNITAID has commissioned Euro Health Group to perform an end of project evaluation of these projects. This evaluation is now under way and expected to be completed by September 2012.

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, continue to progress according to the objectives defined by their project plans; however challenges remain. For example, the Paediatric ARV project struggles to maintain a healthy, competitive market for paediatric because there are many recommended formulations and a declining number of patients, thanks to PMTCT programmes in high burden countries. In 2011, the number of manufacturers entering the market to make new and existing formulations improved from the 2010 results and prices have remained stable with some specific products achieving reductions of up to 8%. The project continues to scale up the use of PCR tests to diagnose infants early. This achievement combined with better forecasting and improved pooling of orders, is working towards a more stable paediatric ARV market over the longer term. UNITAID and CHAI are working on transition of this

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

project to other funding sources through the Paediatric ARV Procurement Working group7 and a dedicated transition team supported by UNITAID.

UNITAID continues to face the challenge of making sure that the products that it supports 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 all 5 countries are now participating in the project. An initial assessment of supply chain management and regional and central medical stores led to the identification of shortages of key ARVs and diagnostic reagents. ESTHER was able to provide details of these shortages to the Coordinated Procurement Planning initiative (World Bank, GFATM, UNITAID, UNICEF, PEPFAR, WHO, SCMS) to facilitate some immediate, short term supplies for the affected countries.

6. Malaria Portfolio

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 (3 are child-adapted formulations) prequalified through the WHO Prequalification programme funded by UNITAID. 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, Artemisinin8 in the face of rising demand.

UNITAID currently supports one project related to this market challenge, the Affordable Medicines for Malaria facility (AMFm, GFATM). Two other projects, the Assure Artemisinin supply project (A2S2, with i + Solutions) and the ACT Scale up (UNICEF and GFATM) are in the process of closing. In the case of the ACT scale up project, this involves using unspent monies to make sure that beneficiary countries do not have supply shortages for ACTs. The ACT scale up project has delivered 56 million ACTs to 8 high burden countries since its start in 2007. UNICEF, GFATM and the UNITAID Secretariat are now reconciling the data and ensuring that the external end of project evaluation can be delivered quickly.
For A2S2, close out of the project involves monitoring repayment of outstanding loans and delivery of Artemisinin from extractors to manufacturers of ACTs. UNITAID is making arrangements to ensure continuation of project activities with minimal operational cost until complete repayment of existing loans and full delivery of projected artemisinin. This is expected to be completed by April 2013 in accordance with the decision made at EB 15 during the special session on diagnostics.

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 151

[7] UNITAID, Supply Chain Management Systems (SCMS), UNICEF, CHAI, GFATM.
[8] 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.

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 a proposal to UNITAID requesting US$50 million in additional contributions to cover the remaining period of phase 1 of the project. This request was approved by the Executive Board and the Secretariat is in the process of finalizing a contractual agreement with GFATM for this additional contribution. UNITAID as a member of the new AMFm Working Group of the GFATM will actively participate in the governance of the AMFm. An independent external evaluation by a GFATM selected team is expected by mid-2012.

7. Tuberculosis Portfolio

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 785,080 first line patient treatments were delivered to 19 countries who were facing stock outs of these critical medicines. All funds were allocated to treatments and the project has ended.
- 1,098,959 treatments[9] for children were delivered to 57 countries.
- 4 key paediatric products showed initial price reductions of almost 30%[10].
- 10,492 2nd line treatments were delivered to 15 high TB burden countries since the start of the MDR-TB project. The SRS continues to service emergency and urgent orders for treatment.
- New laboratory infrastructure and transfer of technology is established in 21 out of 27 target countries to support MDR-TB diagnosis.

9 Represents both curative and preventive TB treatments for children.

10 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.

- 13 project countries are routinely detecting MDR TB using state-of- the-art laboratory infrastructure and 11,000 MDR-TB patients have been diagnosed in these countries (a three-fold increase since 2010).

Two of these projects, first line TB treatment support (GDF) and the paediatric TB project (GDF) ended on 31 December 2011. A third, the MDR-TB scale up (GDF) will end on 31 December 2012. UNITAID is expecting a final project report from the first line project in July 2012 and an external end of project evaluation will be initiated shortly afterwards. For the paediatric TB project, GDF is developing a detailed transition plan to support countries requiring continued support for paediatric TB treatments. In addition, a Letter of Intent has been submitted to UNITAID in May 2012 proposing interventions to address market shortcomings.
The MDR-TB diagnosis project (FIND/GLI) has responded to 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. A catch up plan has been initiated by FIND for the project. A decision on whether to revise this project's diagnostics portfolio to include Gene Xpert MTB/RIF is being made for select project countries.

8. 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. Since 2007, 55 UNITAID priority medicines have been prequalified[11] by PQP medicines. 2011 also saw 10 UNITAID priority diagnostics prequalified[12].

9. Conclusions

Project updates presented in Annex 1 include highlights (achievements or challenges) identified for each project and "next steps" in project management. Reconciled and analysed project data is being to produce the Key Performance Indicators Report for 2011 which will be available on 30 June 2012.

The Operations team is now almost[13] at full capacity with 3 new Portfolio Managers taking up their posts by early 2012. The team is involved in the management of on-going projects and also the development of new projects plans and contractual agreements for successful submissions to the call for proposals for diagnostics.

[11] 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)
[12] 8 HIV and 2 malaria
[13] The TB Technical Officer position remains unfilled.

Annex 1: Project updates, June 2012

Key to assessment of projects[14]

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.	

[14] The colored dots represent a summary of programmatic and financial assessments of each project by the Operations and Finance and Administration teams.

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 30 June 2012)
Updates for the Period Ending: 31 December 2011

Updates **Operational Performance: Poor performance**[15]	
Project description	The project aims to support production of 40 metric tons (MT) of additional artemisinin, the key ingredient in artemisinin combination therapy (ACT) by providing revolving loan and technical support to artemisinin extractors and to establish a market intelligence system to improve information in the artemisinin market.
Finance	• MOU amount (as of 30 June 2011): US$ 9,280,400 (fully disbursed) • 2011 budget: US$ 0 • Actual expense: US$ 0 • Budget implementation 0%

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):
	  • Beijing-Gingko, China, 3.2 MT (59%)
	  • Vidic, Vietnam, 1.64MT (31%)
	  • 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	• The projected amount of artemisinin that will be delivered is less than the contracted volume; the main reasons include: a) Side selling of Artemisia leaves by farmers in China to competitors, Beijing-Gingko's difficulties due to loss of a key partner in Japan; b) Low levels of planning of Artemisia in Vietnam due to adverse weather conditions; c) Delays in the introduction of artemisinin purification process by Bionexx in Madagascar; and d) Artemisinin price remains unpredictable and highly fluctuating between US$ 600 and 900 per kilogram in 2011.

[15] Project achievements fell short of targets (40 Metric tons delivered to ACT manufacturers) in original project plan agreed between partner and UNITAID.

Next steps for the project	• I+solutions' proposal for a two-year cost extension of the project was rejected by the UNITAID Board at EB15, special session, March 2012. • UNITAID is making arrangements to ensure continuation of project activities with minimal operational cost until complete repayment of existing loans and full delivery of projected artemisinin, expected to be completed by April 2013. • To support market intelligence and information sharing among stakeholders, UNITAID may consider supporting the 2012 Artemisinin Conference.

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 (extension approved until the end of 2012 with additional UNITAID support of US$50 million)**
Updates for the Period Ending: 31 December 2011	

Updates **Operational Performance: ○ Unable to assess at this time[16]**	
Project description	The AMFm Phase 1 pilot project aims to: increase the availability**,** affordability, market share and access to ACTs by poor and rural communities and children through the private and public channels through a co-funding subsidy mechanism.
Finance	• 1st MOU amount (as of 30 December 2011): US$ 130 million (disbursed in 2009) • Actual expense: 0 • Budget implementation 0%
Achievements	• Co-payment for 168,552,491 ACT treatments worth U$ 169,749,345 approved; 8.4% of the total budget was paid for freight and insurance • Of the total approved ACT treatments, 151,783,868 (90%) have been delivered to eligible first-line buyers in the public sector (34%), private for-profit sector (62%) and private not-for-profit sector (4.3%) • 75% of ACT delivered were procured from generic manufacturers • On average 53% of the ACTs delivered were formulations for children
Challenges for the reporting period	• UNITAID has supported BCG and associates to make regular global and AMFm-specific ACT demand forecasts. The forecast report for 2012 is publically available at http://www.unitaid.eu/actforecasting • At the current high rate of approval of co-payments, there is a high risk of the AMFm facing a shortfall of co-payment funds before the end of 2012. The US$ 10 million per month ceiling set for co-payment approvals must be tightly monitored and enforced in order to avoid a shortfall. • The Master Supply Agreement between AMFm and the ACT manufacturers that was signed in April 2012 leaves unchanged the maximum AMFm co-payment. This means that any manufacturer ACT price increase will be met by the first-line buyers and those increases are likely to be paid by end users.
Next steps for the project	• The amendment to the MOU between UNITAID and the GF for Board-approved support for an additional US$50 million for AMFm Phase 1 will be completed. • UNITAID as a member of the new AMFm Working Group of the Global Fund will continue its active participation in the governance of the AMFm. • The Independent Evaluation report is due in mid-2012.

[16] Awaiting external evaluation of phase 1 commissioned by GFATM and available mid-2012.

PROJECT TITLE: Second-Line ARV Project

Key Partner(s): Clinton Health Access Initiative (CHAI)
Project Duration: May 2007-December 2012[17]
Updates for the Period Ending: 31 December 2011

Updates **Operational Performance:**  **Minor delays**	
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	• MoU amount: USD 299,651,000 • 2011 budget: USD 47,000,000 • 2011 actual expenses: USD 22,526,000 • Budget implementation: 48% (remainder of budget is used to support 7 countries into 2012)
Achievements	• In 2011, the project supported 15[18] of the original 25[19] beneficiary countries. • An estimated 65,690 patients received 2nd line[20] in 2011 • Price reductions of approximately 27% achieved compared to 2010 prevailing prices of the leading 2L ARV formulation. This contributed to the budget savings for the project and facilitated support to countries unable to transition by the end of 2011. • 6 newly eligible and SRA approved formulations were added in the 2011 supplier selection process • 11 countries ordered ATV and h/s Ritonavir singles available in 2010. • 5 countries ordered the newly available ATV/r FDC. • 18 of 25 countries completed transition from the project by the end of 2011.
Challenges for the reporting period	• Transitioning the remaining 7 countries remains a challenge due to GFATM funding delays. This explains the minor delays associated with this project.
Next steps for the project	• UNITAID and CHAI have a transition strategy for the remaining seven countries. This involves finding sufficient funding to continue procurement of 2nd line commodities, providing technical capacity for forecasting, procurement, and supply chain management and timely access to high-quality products at affordable and sustainable prices on the global market.

17 A no cost extension of one year (January to December 2012) was granted to this project, including the following countries: Burundi, Cameroon, Democratic Republic of Congo, Haiti, Mozambique, Uganda, and Zimbabwe.
[18] Benin, Burundi, Cameroon, Chad, Democratic Republic of Congo, Haiti, India, Kenya, Mali, Mozambique, Nigeria, Togo, Uganda, Zambia, and Zimbabwe
[19] The project started in 2007 with the following countries: 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
[20] Support for Tenofovir as a first line treatment was also provided to Uganda and Zambia through this project

PROJECT TITLE: Paediatric HIV/AIDS Project

Key Partner(s): Clinton Health Access Initiative (CHAI) **Project Duration: November 2006-December 2012** **Updates for the Period Ending: 31 December 2011**

Updates **Operational Performance:**  **On track**	
Project description	The primary goal of the Project in 2011 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
Finance	• MoU amount: USD 318,883,000 • 2011 budget: USD 81,117,000 • 2011 actual expenses: USD 33,906,000 • Budget implementation: 42% (for paid commitments only)
Achievements	• The project supported 25 countries in the 2011 budget year[21]. • The project reported over 65,000 new children on treatment in the end of 2011 (cumulative is 390,000 new children). • The supplier selection process for 2011 concluded with price reductions of up to 8% compared to 2010 prices, amounting to an overall price reduction of over 80% on leading pediatric ARV regimens since the start of the project[22]. • 98% of the patients benefiting from the project are now on fixed-dose combinations. • 344,168 PRC tests were run in 2011 (cumulative 8,112,747). • Establishment of the Paediatric Procurement ARV Working Group with the objective of managing the transition process towards sustainable, coordinated procurement of paediatric ARVs[23].
Challenges for the reporting period	• Transition to alternative funding remains a challenge and the developments with the GFATM cancellation of Round 11 and possible cuts to previous grants. • Some countries are still facing challenges to guarantee alternative funding sources and/or timely disbursement.
Next steps for the project	• The UNITAID Board approved an extension of the Pediatric ARV Project with a budget of US$ 62,800,000[24]. • On-going work with the Pediatric Procurement ARV Working Group.

[21] 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

[22] 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

[23] The following organizations are part of the Working Group: UNITAID, Global Fund, CHAI, UNICEF, MSF, PFSCM/VPP, and SCMS/PEPFAR

[24] The following 17 countries will be part of the Project in 2012: Botswana; Burkina Faso; Cameroon; Cote d'Ivoire; Democratic Republic of Congo; Ethiopia; Haiti; India; Kenya; Malawi; Mozambique; Nigeria; Swaziland; Tanzania; Uganda; Zambia; and Zimbabwe

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

Key Partner(s): UNICEF and WHO
Projects Duration: December 2007 – December 2011
Updates for the Period Ending: 31 December 2011

Updates **Operational Performance: PMTCT I**  **May not meet all objectives**[25] **PMTCT II and III**  **Poor performance**[26]	
Project description	These three projects contributed to the acceleration of PMTCT activities and the linkages of PMTCT to paediatric care in seventeen countries[27] and provided nutritional support, including diagnostics within four of these countries[28].
Finance	• MoU amount: USD 98,793,000 • 2011 budget: USD 28,799,000 • Actual expenses: USD 23,592,000 • Budget implementation: USD 82%
Achievements	• All three PMTCT projects have now been finalized. UNICEF will be providing UNITAID with Final Reports in 2012 that will include cumulative treatments delivered over the project timeframes as well as a reflection on the market impact of these projects. • Of particular note during 2011 was 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 was slower than expected due to poor planning as well as political unrest (i.e. Cote d'Ivoire). • Complexity of institutional procedures and the regulatory framework has impeded the implementation of the project in China
Next steps for the project	• UNICEF will submit final reports for the PMTCT projects in 2012 • An End of Project external evaluation has started with Euro Health Group (EHG).

[25] Products were delivered to beneficiary countries but Mother and Baby Pack was not delivered in an appropriate package for countries to use.
[26] Product delivery was delayed and actual targets for delivery did not meet the expectations of the original project plan.
[27] Burkina Faso, Malawi, Rwanda, Cote d'Ivoire, India, Tanzania, Zambia, Cameroon, CAR, China, Haiti, Lesotho, Myanmar, Nigeria, Swaziland, Uganda and Zimbabew
28 Malawi, Rwanda, Tanzania and Zambia

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: 31 December 2011

Updates **Operational Performance: Poor performance**[29]	
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 Global Fund grants in Round 6, Phase 1.
Finance	• MOU amount (as of 30 June 2011): US$ 38,691,956 • 2011 budget: US$ 0 • Actual expense: US$ 0 • Budget implementation 0%
Achievements	• 74% of targeted treatments were delivered in 24 grants and 80% in 7 grants • By the end of 2010, the project had delivered: - 31,197 paediatric ARV treatments - 2,650,652 ACT treatments - 3,223 MDR TB treatments • The UNITAID support through the Global Fund has helped to strengthen existing country procurement activities without creating new processes
Challenges for the reporting period	• A summary report on the status of procurement and delivery medicines to participating countries was received in May 2011; however, UNITAID requests for reconciled project reports were not delivered as expected by the end of December 2011 • The Global Fund requested and was granted a no cost extension for the project; however, the Global Fund has not yet fully complied with the MOU reporting requirements
Next steps for the project	• In April 2012, the Global Fund submitted to UNITAID a programme update and reinvestment proposal for the remaining funds for Round 6, Phase 1. The proposal requests the use the remaining balance of US$ 9,289,561 to procure medicines to treat 2,334 MDR-TB cases in Belarus, Pakistan, Vietnam and Ethiopia. This request is under consideration by UNITAID. • UNITAID will continue to work with the Global Fund fully reconcile project programmatic and financial reporting. • UNITAID will commission an external independent end-of-project review in 2012.

[29] Product delivery did not correspond to targets originally planned by partners and UNITAID.

PROJECT TITLE: EXPANDx-TB: New Diagnostics Scale-up for MDR-TB

Key Partner(s): WHO-STOP TB, Foundation for Innovative New Diagnostics (FIND) and the Global Drug Facility (GDF)
Project Duration: January 2009 – December 2013
Updates for the Period Ending: 31 December 2011

Overall Operational Performance: **Delayed**	
Project description	The Project aims to provide laboratory infrastructure, training and new diagnostic tests to build a market for advanced MDR TB diagnosis, resulting in more rapid and accurate testing, thereby enabling increased and more appropriate treatment.
Finance	▪ MoU Amount: US$ 89,612,000 ▪ 2011 Budget: US$ 10,210,000 ▪ 2011 Expenses: US$ 0 ▪ % Budget implementation: 0%
Achievements	▪ New Laboratory infrastructure and successful technology transfer established in 21 out of 27 countries. ▪ 58 of targeted 105 laboratories successfully established. ▪ 13 project countries are routinely diagnosing MDR TB. ▪ ~11,000 MDR-TB patients diagnosed in 13 countries, representing a three-fold increase compared with 2010.
Challenges for the reporting period	• Speed of project roll-out, including a lack of expenses in 2011, is sub-optimal and this is why the project is considered to be delayed. ▪ A project "catch-up" plan has been developed for the remaining two years (2012-2013) to ensure that as many as possible of the original project deliverables can be realized by end 2013.
Next steps for the project	▪ Close monitoring of the catch-up plan by the UNITAID Secretariat. ▪ Decision on whether to revise project diagnostics portfolio to include Gene Xpert MTB/RIF in place of further investment in central/regional reference laboratory capacity in select project countries.

PROJECT TITLE: MDR-TB Scale-up Initiative and Strategic Rotating Stockpile

Key Partner(s): Global Drug Facility (GDF), Green light Committee and the Global Fund
Project Duration: July 2007 – December 2012
Updates for the Period Ending: 31 December 2011

Overall Operational Performance:  **Minor delays**	
Project description	The Project aims to scale up access to treatment for MDR-TB by improving affordability, number and quality of products and facilitating faster delivery lead times.
Finance	MDR-TB Scale-up: ▪ MoU Amount: US$ US$ 55,667,000 ▪ 2011 Budget: US$ 10,300,000 ▪ 2011 Expenses: US$ 14,420,000 ▪ % Budget implementation: 140% (budget adjusted because of error in cost of 2nd line treatment made by GDF) Strategic Rotating Stockpile: ▪ MoU Amount: US$ 11,802,000 ▪ 2011 Budget: US$ 1,039,000 ▪ 2011 Expenses: US$ 0 ▪ % Budget implementation: 0%
Achievements	▪ In 2011, 6,568 2nd line TB treatments were delivered to 15 high burden countries (Project cumulative total of 10,492, representing 67% of project target). ▪ 15 additional MDR-TB products meeting international quality assurance standards were secured for supply. ▪ The Strategic Rotating Stockpile (SRS) continued to service urgent and emergency country orders (although average lead times did increase compared to 2010).
Challenges for the reporting period	▪ Increase in average delivery lead-times from SRS. ▪ Despite increase in number of available products and new Long Term Supply Agreements, there is continued supply insecurity and/or lack of competition for approx. half of the recommended MDR-TB medicines (1 or fewer suppliers for ~50% of required MDR-TB medicines). ▪ Uncertain funding for MDR TB products at the end of the project (2012) means that several countries may be at risk of MDR-TB treatment shortfalls. As MDR TB diagnosis is improved and scaled-up (e.g. with the introduction of Gene Xpert MTB/RIF), greater supply security will be required.
Next steps for the project	▪ The project partners are developing a detailed transition plan to quantify the needs of countries requiring MDR-TB treatment support beyond 2012. ▪ GDF and partners have submitted a Letter of Intent to UNITAID in response to open call that closed in May 2012, which proposes new interventions for UNITAID and others in this niche, designed to improve access to and availability of quality assured MDR-TB medicines.

PROJECT TITLE: Paediatric TB

Key Partner(s): Global Drug Facility (GDF)
Project Duration: January 2007 – December 2012
Updates for the Period Ending: 31 December 2011

Overall Operational Performance:  **May not meet all objectives**[30]	
Project description	The Project aims to create a market for better adapted paediatric TB medicines to treat children with TB.
Finance	▪ MoU Amount: US$ 11,627,000 ▪ 2011 Budget: US$ 0M ▪ 2011 Expenses: US$ 0 ▪ % Budget implementation: 0%
Achievements	▪ 146,736 paediatric treatments (curative and preventive) provided to 21 countries in 2011 (Project cumulative total of 1,098,959 paediatric treatments 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. ▪ 16 quality assured products consisting of both blister and bulk packaging are now available.
Challenges for the reporting period	▪ 7 national programmes stocked out of paediatric TB medicines in 2011 due to non-availability of a key injectable product, payment delays, poor national planning and supplier delays. Specific corrective actions were taken to address the stock-outs/avoid a recurrence by GDF and the relevant National Programme. ▪ A major challenge for this entire niche remains the absence of: paediatric fixed-dose combinations that are optimally formulated so that they are stable and in line with revised WHO dosing recommendations; population pharmacokinetic studies to enable regulatory submission; sufficient market sizing data and information on treatment and consumption patterns/preferences.
Next steps for the project	▪ A detailed transition plan to address the needs of countries needing paediatric treatment support beyond 2012 is required. ▪ The transition plan needs to be linked to initiatives to address the market shortcomings of this TB niche as outlined above, so that a treatment bridge, and with it a supplier presence in this market space, is maintained until new formulations are available. A Letter of Intent has been submitted to UNITAID in response to the open call that closed in May 2012, proposing interventions to address these market shortcomings.

[30] Treatment guidelines for Paediatric TB changed and market achievements may not be met as a result of these changes.

PROJECT TITLE: First-line TB

Key Partner(s): Global Drug Facility (GDF) **Project Duration:** September 2007 – December 2011 **Updates for the Period Ending:** 31 December 2011

Overall Operational Performance:  **Project did not meet an objective**[31]	
Project description	The Project aimed to prevent treatment interruption for first line TB medicines for countries transitioning to Global Fund support.
Finance	▪ MoU Amount: US$ 27,646,000 ▪ 2011 Budget: US$ 0M ▪ 2011 Expenses: US$ 0 ▪ % Budget implementation: 0%
Achievements	▪ 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 31 December 2011).
Challenges for the reporting period	▪ Not applicable
Next steps for the project	▪ End-of-project report due in Q2 2012 ▪ External end-of-project evaluation to be conducted in 2012

[31] The strategic rotating stockpile objective of this project was ultimately not implemented as originally envisioned. The funds disbursed for this objective were 'used' by GDF as a supply guarantee to encourage suppliers to hold strategic stocks rather than to purchase and independently operate a strategic stockpile. These funds will be returned to UNITAID.

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 until December 2011)
Updates for the Period Ending: 31 December 2011

Updates **Operational Performance: May not meet all objectives**[32]	
Project description	The ACT Scale-Up project was initiated to provide 47,016,160 high quality ACT treatments to eight countries[33]. The project covers 11 grants chosen by the GFATM Secretariat.
Finance	• MOU amount (as of June 2011): US$ 65,413,057 • 2011 budget: US$ 10,000 • Actual expense: US$ 3,230 • Budget implementation: 32%
Achievements	• A total of 236,256 ACT treatments were delivered in 2011. • By the end of 2011, a cumulative total of 31,587,847 ACT treatments worth a total of US$ 37,935,121 (including freight and insurance) were delivered to eight countries. • Procurement efficiency was improved in terms of lead-time for ACT delivery to countries and there were no reported ACT stock outs from the participating countries.
Challenges for the reporting period	• There have been project reporting delays as well as inconsistencies in reporting that remain unresolved. The GFATM and UNICEF are making efforts to address gaps in reporting on the number and nature of ACT treatments delivered per grant, funds expended and number of people treated. • The GFATM and UNICEF submitted a request for project extension and the release of additional funds. UNITAID rejected the proposal because of persistent implementation delays and the lack of clear quantification of ACT need and country absorptive capacity. • The GFATM and UNICEF have not yet reported to UNITAID on the actions taken to deal with the project-procured ACTs that expired in Madagascar (destruction and costs).
Next steps for the project	• UNITAID agreed to use the remaining project funds (US$ 1,752,998) to deliver ACT treatments under three participating grants in Madagascar and Zambia. • The Global Fund and UNICEF will provide UNITAID with the outstanding reports and data reconciliation and an end of project report.

[32] Project was originally to supply 47,016,160 high quality ACT treatments to eight countries
[33] Ghana, Cambodia, Madagascar, Mozambique, Sudan (North and South, at time of agreement, this was one country), Indonesia, Zambia and Ethiopia.

PROJECT TITLE: ESTHERAID Project - HIV/AIDS - ARV paediatric and second line ARVs

Key Partner(s): ESTHER (Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau
Project Duration: Project duration: 2008-2013
Updates for the Period Ending: 31 December 2011

Updates **Operational Performance:**  **On track**	
Project description	This project contributes to improving supply chain management from national central medical stores to treatment centers in 5 West African countries[34] by improving logistic information systems and patient monitoring systems. The project supports the efforts of treatment centers to improve treatment choices and ensure that UNITAID supplied products are received and used.
Finance	MoU amount: USD 14,681,000 2011 budget: USD 6,600,000 2011 actual expenses: USD 4,041,000 Budget implementation: 61% (due to delays in finding suitable technical assistance)
Achievements	• Assessments of medical stores completed and results used to align the project with the national strategic plan priorities in all countries. • Information systems for patients monitoring systems are place for all five countries. • Benin and Burkina Faso have established official mechanisms to improve forecasting, quantification and monitoring of medical supplies through National Committees and a Procurement Coordination. • The process for twinning of the respective selected ESTHERAID project treatment centers with centers in France has been completed. • ESTHER has trained medical practitioners on paediatric HIV and developed an "e-learning" tool in pediatric care, www.estherformation.fr
Challenges for the reporting period	• An initial assessment of supply chain management and regional and central medical stores led to the identification of shortages of key ARVs and diagnostic reagents. ESTHER was able to provide details of these shortages to the Coordinated Procurement Planning initiative[35] to facilitate short term supplies for the affected countries. • All of ESTHER activities in Mali have been suspended due to the coup d'état. ESTHER national coordination team's activities are limited to essentials and no new agreement will be signed or any new funds engaged.
Next steps for the project	• The 5 countries of this project need to be supported to manage supply to treatment centers to lower stock out occurrence. • Capacity building on treatment optimization will continue.

[34] Benin, Burkina Faso, Central African Republic, Cameroon and Mali
[35] World Bank, GFATM, UNITAID, UNICEF, PEPFAR, WHO, SCMS

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: 31 December 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, 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 • 2011 budget: USD 20,030,000 • 2011 actual expenses: USD 14,727,000 • Budget implementation: 74%
Achievements	• 35 products (20 UNITAID priority products) prequalified in 2011 • 8 APIs prequalified • 6 quality control laboratories prequalified • 90 manufacturing sites, contract research organizations and QCLs inspected • Training for approximately 400 regulatory participants, more than 100 QCL participants and over 900 manufacturing company participants
Challenges for the reporting period	• Many formulations included on the current invitations to manufacturers to submit an Expression of Interest for which no products have been prequalified • PQ is still functioning without a programme manager • Experts who can undertake inspections of QCLs are in short supply
Next steps for the project	• UNITAID is working with PQ on procedures for accelerating the approval of prequalified products • PQ plans to create a network of QCLs that are already working with PQ and who can undertake mutual audits, aimed at helping participating QCLs to identify any corrective actions needed, before a WHO inspection is scheduled

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: 31 December 2012**

Updates **Operational Performance:** **Minor Delays**	
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[36].
Finance	• MoU amount: USD 8,475,000 • 2011 budget: USD 4,464,000 • 2011 actual expenses: USD 3,221,000 • Budget implementation: 72%
Achievements	• 15 new applications for UNITAID priority products submitted for prequalification in 2011 (10 HIV and 5 malaria) • 10 UNITAID priority products were prequalified in 2011 (8 HIV, 2 malaria) – up from only 1 product in 2010 • Implementation of "fast track" procedure • 19 UNITAID priority products production processes were inspected • 7 lab assessments for HIV tests were completed • Meeting held to increase knowledge for regulatory capabilities in East Africa with regard to in-vitro diagnostics
Challenges for the reporting period	• Poor quality dossiers submitted for evaluation resulting in labor intensive "back and forth" with applicants • Companies providing false information about the real production site of products resulting in additional inspections needed
Next steps for the project	• The UNITAID Secretariat is working with PQ diagnostics to improve reporting processes • Training for manufactures to improve the quality of dossiers submitted • Improve communication with companies regarding information required for applications • Replace lost staff compliment (1 additional inspector and 1 additional technical officer)

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