UNITAID Executive Board meeting
18th Session
6 - 7 June 2013
WHO Headquarters, Salle A
Geneva, Switzerland

Agenda Item 13

Update on Operations 2012

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

BACKGROUND

This document summarizes UNITAID's Operational activities for 2012 and early 2013. It provides the PSC with an overview of UNITAID's active projects by portfolio (HIV, TB, Malaria and cross-cutting). It also describes actions taken to implement new projects.

UNITAID's annual results are presented in its Key Performance Indicator Report available on 30 June of each year for the preceding year. This cycle is aligned with UNITAID's project funding cycle where Implementers report to the Secretariat twice a year, in September/October and in March/April. The remainder of this report provides a brief update on relevant actions since the December 2012 EB 17. A comprehensive overview of specific projects is available in Annex 1. A review of actions taken to start new grants is in Annex 2.

UPDATE ON UNITAID PROJECTS

Twenty-two grants, one Special project[1] and one Secretariat initiative[2] (Table 1) are currently active. Five projects have ended. Three of these are the subject of end of project evaluations in 2013[3] and two are awaiting financial closure[4]. The distribution of UNITAID's Board approved funding by project type is shown in Figure 1. This shows the shift that UNITAID is making into diagnostic products for detecting HIV, TB and malaria in low resource settings, an under-resourced area, particularly in low income countries.

UNITAID is using a quality management system to manage its grants, special projects and Secretariat initiatives. This system seeks to improve performance through documented and implemented standard operating procedures. The processes currently being implemented are designed to provide protocols for portfolio teams to use to manage grants in a way that optimizes their chances for success.

[1] Medicines Patent Pool Foundation
[2] Coordinated procurement planning initiative (CPP) with PEPFAR/SCMS
[3] 2nd line adult ARV project (CHAI), ACT Scale up (UNICEF, GFATM), Support to round 6 phase 1 GFATM all closed on 31 December 2012. These projects are the subject of end of project evaluations in 2013.
[4] First Line anti-TB medicines and PMTCT (I, II, III)

Monitoring and evaluation supports the grant management process by working with Implementers to develop project-specific indicators that allow the grant's achievements, challenges and course corrections to be monitored over time. Complementary to this process are the independent, external evaluations performed at the mid-point of project implementation and again when a project ends. End of project evaluations of 2 UNICEF grants (PMTCT and LLINS) were completed in 2012. In addition, Mid-term reviews of two projects, ESTHERAID and WHO Prequalification of diagnostics, were started in late 2012 and completed early in 2013. The findings of these reviews will be presented to the Board in June 2013 and then be made available on the web at www.unitaid.eu/impact.

UPDATE ON ACTIONS TAKEN TO IMPLEMENT NEW PROJECTS

The standard operating procedure for Operations includes a rigorous pre-launch grant agreement development phase that clearly defines the project plan and timeline for implementation of the plan. This process provides UNITAID grants with a strong foundation because it uses a suite of robust project tools that support the development of a project. These tools are:

- Guidance on how to develop a comprehensive project plan;
- Support for using the Logical Framework Approach to project planning to develop strong indicators of achievement;
- Harmonized reporting templates for reporting both programmatic and financial results.

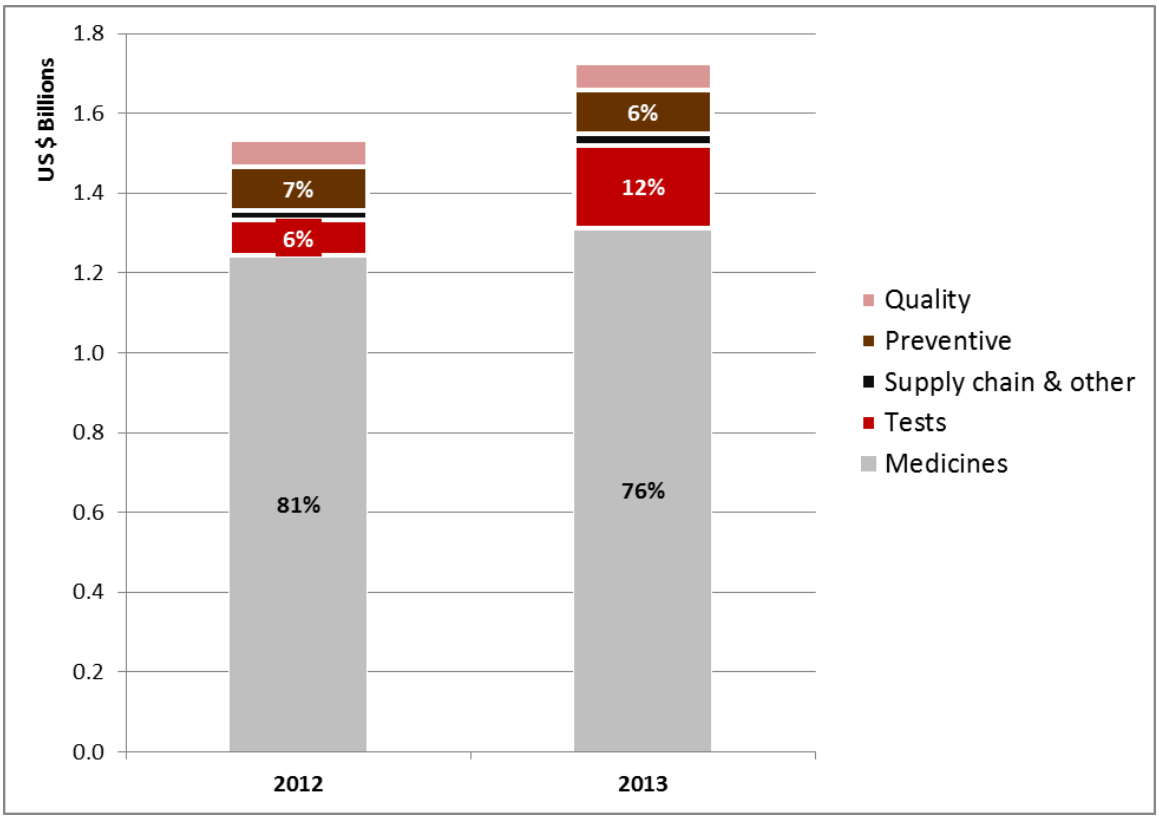
Seven projects received approval from UNITAID's Executive Board response to the call for proposals for projects to support diagnostic tools for HIV, TB and malaria in 2012. Annex 2 describes the actions taken by the Implementers and UNITAID and next steps to facilitate the signing of the remaining contractual agreements for the EB-approved projects. There are a number of other projects that received EB approved grant extensions at EB 17 and in early 2013. These include A2S2 (i+ Solutions), AMFm (GFATM), the paediatric ARV treatment project (CHAI), paediatric TB project (GDF) and MDR-TB scale up project (GDF and Stop TB partnership).

TABLE 1. LIST OF UNITAID FUNDED GRANTS (INCLUDING SPECIAL PROJECTS AND SECRETARIAT INITIATIVES) AND IMPLEMENTERS AS OF 23 APRIL 2013.

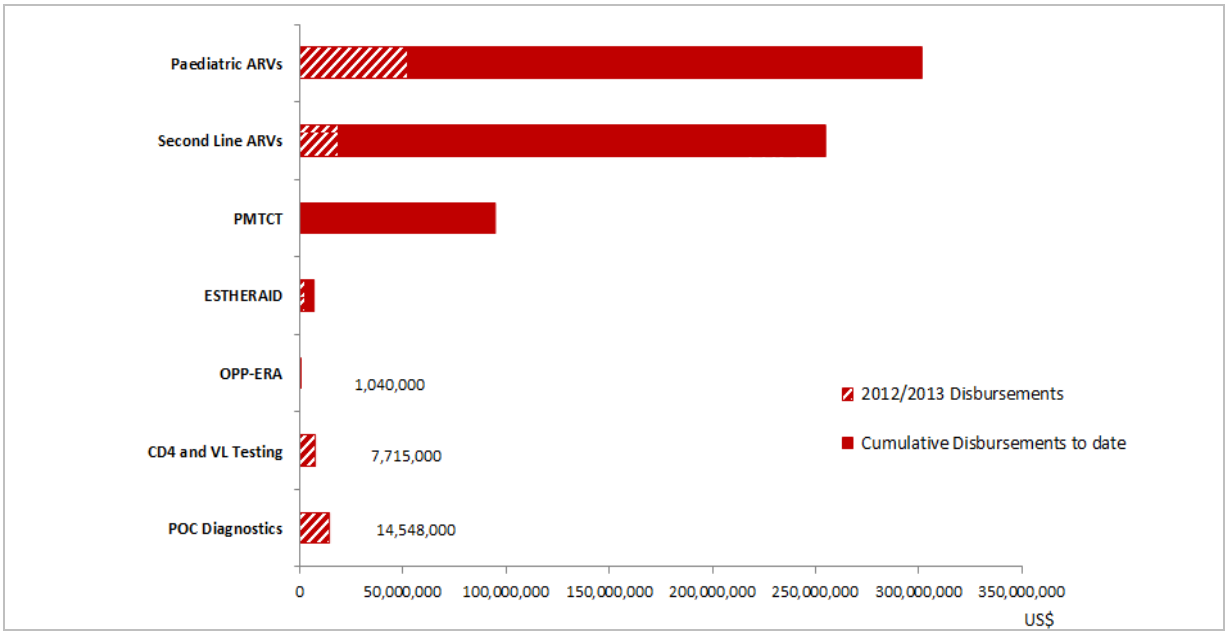
	HIV	TB	MALARIA	CROSS CUTTING
	2ND LINE ARV TREATMENT PROJECT (CHAI)[5]	FIRST LINE ANTI-TB MEDICINES[6]	ACT SCALE UP (UNICEF/GFATM)[7]	SUPPORT TO GF ROUND 6 (GFATM)[8]
	PAEDIATRIC HIV/AIDS TREATMENT PROGRAM (CHAI)	MDR TB SCALE UP (GDF)	ARTEMISIA SUPPLY PROJECT (I+SOLUTIONS)	SUPPORT FOR QUALITY ASSURANCE OF MEDICINES (WHO)
	SUPPORT TO PMTCT (I, II, II) (UNICEF)[9]	MDR TB ACCELERATION OF ACCESS INITIATIVE: STRATEGIC ROTATING STOCKPILE (GDF)	AFFORDABLE MEDICINES FOR MALARIA FACILITY (AMFM) (GFATM)	SUPPORT FOR QUALITY ASSURANCE OF DIAGNOSTICS (WHO)
	SUPPORT TO SUPPLY CHAIN MANAGEMENT OF HIV MEDICINES AND DIAGNOSTICS IN WEST AFRICA (ESTHER)	PAEDIATRIC TB PROJECT (GDF)	QUALITY CONTROL FOR MALARIA RAPID DIAGNOSTIC TESTS (FIND/WHO)	MEDICINES PATENT POOL[10]
	SUPPORT TO COORDINATED PROCUREMENT PLANNING (CPP) INITIATIVE (SCMS)[11]	EXPAND MDR TB DIAGNOSTICS (FIND, GLI, GDF)	CREATING A PRIVATE SECTOR MARKET FOR QA RDTS (PSI)	
	POINT OF CARE DIAGNOSTICS FOR HIV (CHAI/UNICEF)	SCALE UP ACCESS TO CONTEMPORARY DIAGNOSTICS (GENEEXPERT) (WHO/STOP TB)		
	POINT OF CARE DIAGNOSTICS FOR HIV (MSF)	SCALE UP ACCESS TO CONTEMPORARY DIAGNOSTICS (BUY DOWN) (CEPHEID)		
	OPEN POLYVALENT PLATFORMS FOR SUSTAINABLE AND QUALITY ACCESS TO VIRAL LOAD (FEI)			

[5] Ended 31 December 2012
[6] Ended 31 December 2011but UTD is awaiting reimbursement from GDF
[7] Ended 31 December 2012
[8] Ended 31 December 2012
[9] Ended 31 December 2011but UTD is awaiting reimbursement from UNICEF
[10] UNITAID Special Project
[11] Secretariat Initiative

FIGURE 1. DISTRIBUTION OF BOARD APPROVED FUNDING BY PROJECT TYPE.



1. HIV/AIDS: DISTRIBUTION OF DISBURSEMENTS ACROSS THE HIV PORTFOLIO CUMULATIVELY SINCE 2006 AND TO DATE.



At the end of 2012, UNITAID grants for PMTCT and adult 2nd Line ARVs transitioned to other sources of funding made possible by the extraordinary changes made in the markets for these products through UNITAID's funding. UNITAID funding continued for paediatric ARVs and for supporting supply chain management through ESTHERAID in west Africa. In addition, two projects that will open the point-of care diagnostic markets for HIV tests were started, one with CHAI/UNICEF at in November 2012 and the other with MSF shortly after in December 2012. Supporting point of care testing for HIV means that people living with HIV can be tested, treated and their treatment monitored more easily than ever before. Better health and survival of people living with HIV/AIDS will follow. These two projects show UNITAID's commitment to identifying areas in need of investment through market intelligence and filling these gaps with suitable projects developed to address a market challenge that has serious public health implications.

CHALLENGES & ACHIEVEMENTS

The CHAI/UNITAID Paediatric ARV project suffered delays in 2012 because five countries[12] did not secure transition funding for paediatric ARVs for 2013 and beyond. In response to this challenge, CHAI requested an extension of US$ 7 million to the project through 2013. UNITAID's Board agreed to this request at its 17th Executive Board meeting in December 2012 so that children living in high risk countries would not suffer treatment interruptions while alternative funding sources were being secured. UNITAID and CHAI, through the Paediatric ARV Procurement Working group[13] continue to seek transition partners for this project. One potential source of transition funding, the GFATM agreed to support UNITAID's efforts in reaching out to other donors to address the current funding gaps.

Another key challenge is making sure that the products that UNITAID 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. ESTHER and UNITAID are providing this technical support to improve supply chain management of its products in 5 West African countries through the project ESTHERAID. An independent external review of ESTHERAID ended in March 2013. The findings were that the project had provided substantial technical support to the five countries through technical training in managing the ordering, storing and prescription of key medicines and tests for HIV/AIDS. However, there have been some delays to the project which means that a no-cost extension will be requested from ESTHER to extend the project through 2014.

UNITAID's 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

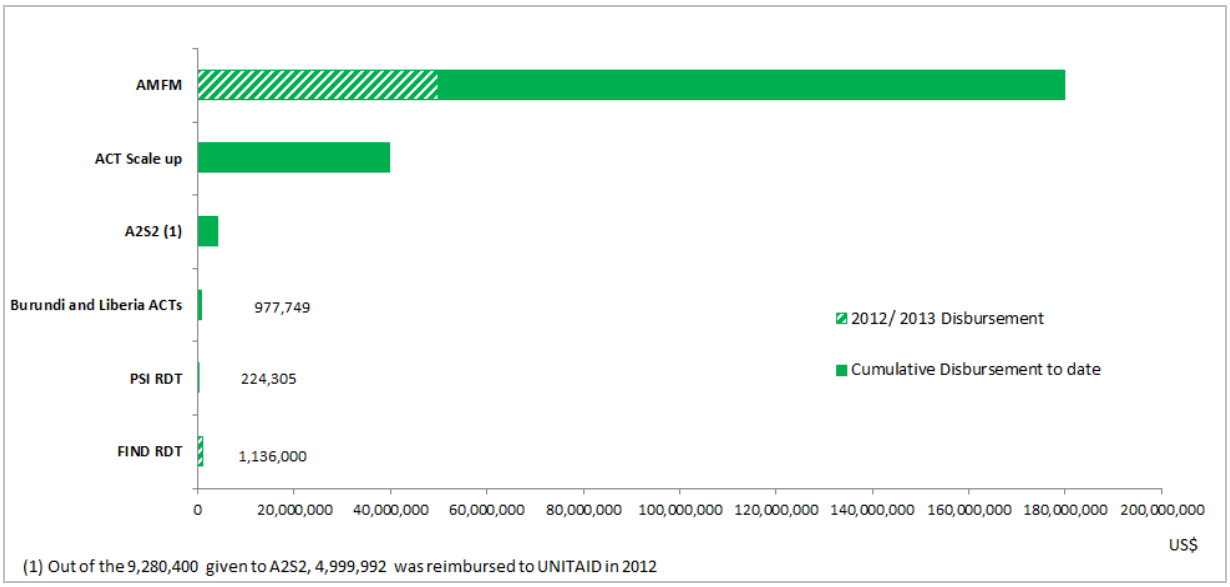
[12] Malawi, Mozambique, Uganda, Swaziland, and Zimbabwe
[13] UNITAID, Supply Chain Management Systems (SCMS), UNICEF, CHAI, GFATM.

global public health community so that action can be taken. Progress with this short term Secretariat initiative was made in 2012 and into 2013 with the launch of the Procurement Information Exchange (PIE) platform which will help all partners involved in the provision of ARVs and tests for HIV/AIDS to identify actual countries at-risk and provide timely intervention where necessary.

UPDATES ON NEW GRANTS

The Memorandum of Understanding (MoU) between CHAI, UNICEF and UNITAID for the project "accelerating access to diagnostic point of care (POC) diagnostic testing for HIV" was signed in December 2012. CHAI-UNICEF ended an "expression of interest"(EOI) exercise which is important for starting to procure optimal POC CD4 tests for the project countries in 2013. Agreement is pending on the most efficient procurement sources for diagnostic CD4, VL and EID commodities for routine use. Procurement should, nonetheless, start in mid-2013. The MOU between MSF and UNITAID was also signed in December 2012 for the MSF POC diagnostic tests project. The agreement was signed without a final procurement strategy and plan, both of which are expected shortly from MSF. UNITAID expects synergies between these two POC diagnostic testing projects and to maximize the benefit of both projects, a stakeholder meeting between CHAI/UNICEF, MSF, UNITAID and others working in the area of HIV POC testing will be held in 2013.

MALARIA: DISTRIBUTION OF DISBURSEMENTS ACROSS THE MALARIA PORTFOLIO CUMULATIVELY SINCE 2006 AND TO DATE.



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. However, the challenge for the market remains to quickly replace ineffective anti-malarial medicines with ACTs by making them affordable for end users and at the same time, stabilizing the price of the active ingredient of ACTs, Artemisinin[14] in the face of rising demand. UNITAID currently supports 2 projects related to this market challenge, the Affordable Medicines for Malaria facility (AMFm, GFATM) and the Assure Artemisinin supply project (A2S2, with i + Solutions). In 2012 UNITAID also supported the rational use of ACTs by focusing its investments on interventions to support rapid diagnostic tests for malaria. These are aimed at improving the rational use of ACTs by ensuring that only those who have malaria are treated with ACTs. The two projects that UNITAID is supporting are working to put quality RDTs in the private sector facilities where they are most needed.

[14] 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.

CHALLENGES

UNITAID has supported AMFm Phase 1 with grants of USD 180 million in conjunction with complementary support from DFID and BMGF. The latest disbursement of US $ 50 million was made in 2012. A total of 126,232,797 ACT treatments were delivered in 2012 alone, bringing the cumulative total to 283,735,930 treatments to date. The challenge remains to ensure that AMFm co-paid ACTs reach areas where they are most needed and that they are used in conjunction with rapid diagnostic tests for malaria where possible to provide the best patient outcomes and reduced resistance.

GRANT UPDATES

As per the Board decision15 of 26 February 2013, UNITAID will continue to support AMFm through 2013. An MoU was sent to GFATM on 18 April 2013 to start this process and the Secretariat is waiting for the agreement to be signed.

The ACT scale up project closed at the end of 2012. The selection process for the external end of project evaluator has finished and the evaluation will start mid-2013. The A2S2 project received a project extension in 2012. This extension will come to an end on the 31st May 2013. The selection process for the external end of project evaluator has finished and the evaluation will start mid-2013.

Two new project agreements were signed in early 2013, one with FIND[16] and the other with PSI and a consortium of partners[17]. Both of these projects are focused on building a private sector market for quality assured rapid diagnostic tests for malaria. Quality rapid diagnostic tests are an essential tool in the fight against malaria because they facilitate appropriate treatment with ACTs for malaria patients while eliminating unnecessary ACT use (for non-malarial fevers). ACT

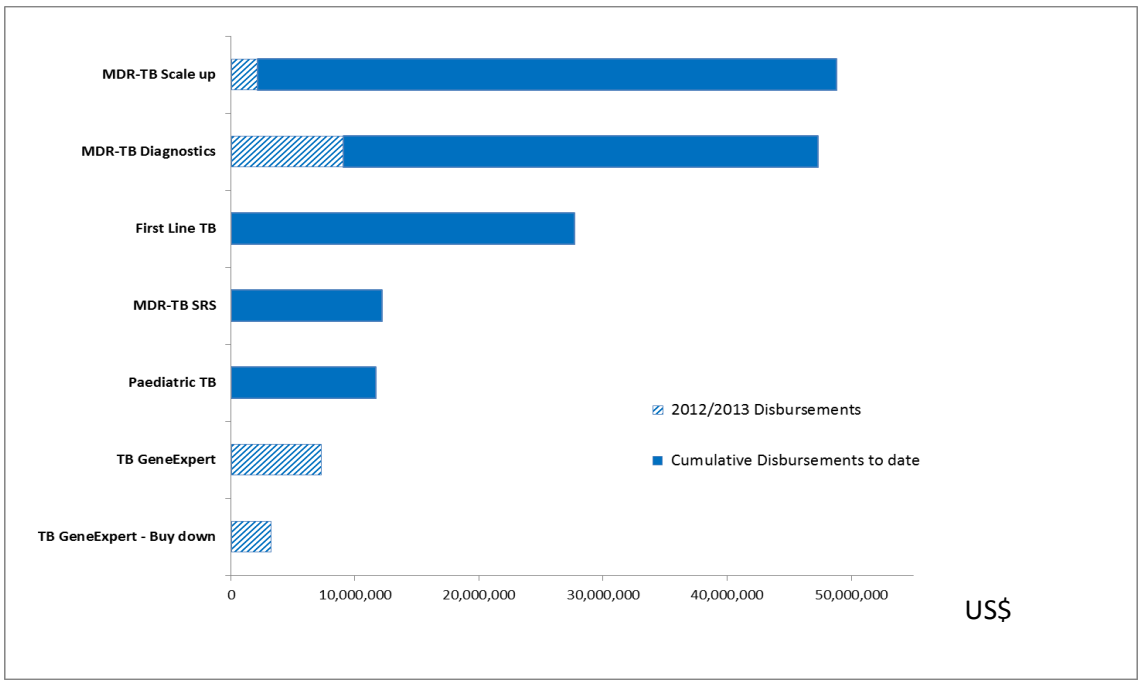
15 Resolution 1-2013-E

16 "Sustainable Global and National Quality Control for Malaria Rapid Diagnostic Tests", implemented in collaboration with WHO/GMP

17 "Creating a Private Sector Market for Quality-Assured RDTs in Malaria-Endemic Countries" implemented with Malaria Consortium, FIND and WHO/GMP.

use for non-malarial fevers, will not only be detrimental for the patient but may accelerate parasite resistance to artemisinin in the longer term. A new project that will be signed soon in 2013 will work on eliminating deaths from severe malaria by opening up the markets for quality injectable Artesunate and quality inter-rectal Artesunate to make sure that cases can be treated successfully even in rural and remote communities to prevent deaths and disability from severe malaria.

2. TUBERCULOSIS: DISTRIBUTION OF DISBURSEMENTS ACROSS THE TUBERCULOSIS PORTFOLIO CUMULATIVELY SINCE 2006 AND TO DATE.



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 MDR-TB and to make available more efficacious TB medicines for children. A new grant being signed soon in 2013 will support the creation of better formulated, quality assured medicines to treat children with TB.

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, required 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

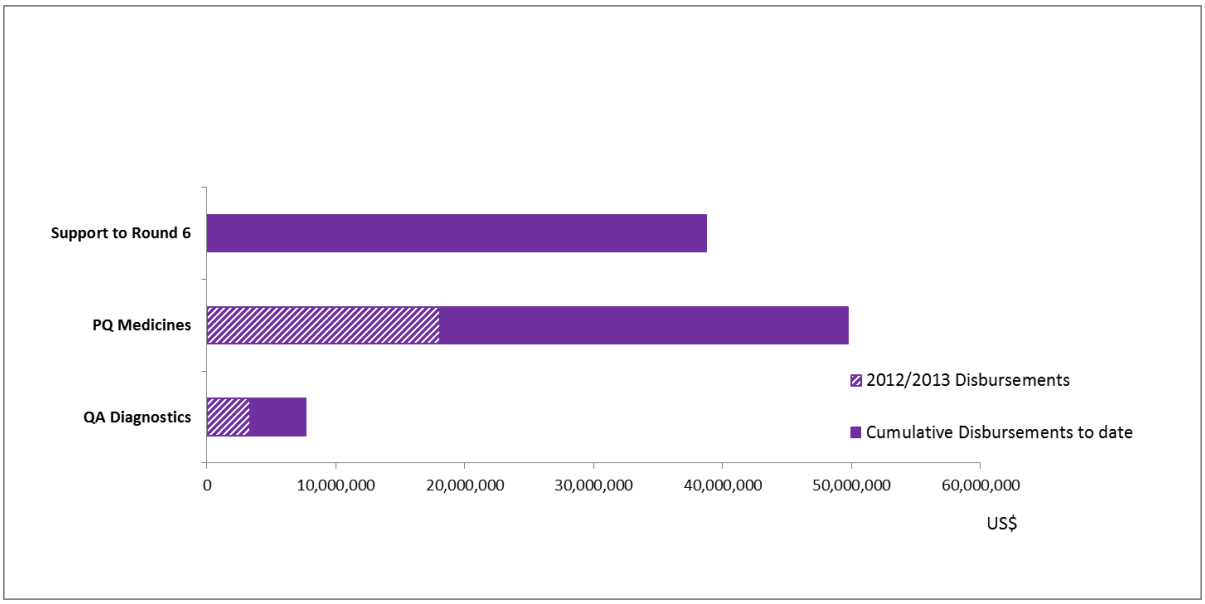
Despite difficult market conditions, UNITAID-funded projects have had some success in delivery of paediatric treatments, MDR-TB treatment scale up and diagnosis using state of the art technologies. Highlights include:

- 24 countries have moved into the routine detection and reporting phase of the expand MDR-TB diagnostic project, exceeding the project targets for detection of MDR-TB cases in 2012.
- 12 new products for treating MDR-TB became available for supply in 2012, expanding the GDF supply catalogue to a total of 54 medicines/manufacturers eligible for supply in 2012.
- 9,974 curative and 36,553 prophylaxis TB treatments for children were delivered in 2012, bringing the cumulative numbers since project inception to 463,504 curative treatments and 681,982 prophylaxis treatments.
- 21,787 MDR-TB patients have been diagnosed through EXPAND TB project in 19 project countries.
- 17 countries placed and received emergency orders from the MDR-TB strategic rotating stockpile.

UNITAID continues to work with the TB Alliance to start a grant that aims to increase and accelerate the availability of properly formulated, appropriately dosed international-standard paediatric TB medicines. This project will act as a

market catalyst and creator by facilitating adoption and uptake of improved paediatric TB medicines, and by making it appealing to manufacturers to produce medicines that address a major public health issue.

3. CROSS-CUTTING PROJECTS: DISTRIBUTION OF DISBURSEMENTS ACROSS THE CROSS-CUTTING PROJECTS PORTFOLIO CUMULATIVELY SINCE 2006 AND TO DATE.



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. Since UNITAID first started providing financial support to the Prequalification of medicines programme, the number of prequalified manufacturers of medicines for HIV, TB and malaria has doubled.

UNITAID also supports prequalification of priority diagnostics tests for HIV and malaria to improve the rational use of the medicines through better and timelier detection of disease.

CHALLENGES

Prequalification of medicines has in the past faced challenges in engaging with manufacturers and encouraging the submission of dossiers for prequalification of medicines. However, the recent proactive approach of PQP and the implementation of an accelerated approval of prequalified products has yielded improved results for PQP medicines with 34 finished products and 20 active pharmaceutical ingredients prequalified in 2012.

The Prequalification of diagnostics programme continues to face 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, an additional 7 diagnostic tests for HIV where prequalified in 2012, bringing the total number of prequalified diagnostic tests to 19 since 2009[18].

GRANT UPDATES

The Prequalification Programme for medicines has, over the past year, made good progress and are continuing to improve the rate of prequalification of medicines. The Secretariat is currently working with the PQP programme to develop a new proposal for continued UNITAID support for this critical activity.

The Prequalification Programme for diagnostics was the subject of an independent mid-term review[19] which was completed in early 2013 and will be presented to the PSC and Board. This review provided important recommendations designed to improve the performance of this grant. Implementation of these recommendations will require the support and actions of WHO senior management.

[18] 2 malaria rapid tests, 6 HIV rapid tests, 3 CD4 cell count HIV tests and 8 HIV viral load tests.
[19] By Euro Health Group

CONCLUSIONS

Performance of UNITAID's grants has improved over the past year and most of our active grants are on track. The newly Executive Board approved grants have also mainly progressed to signature in a timely manner and are being implemented as planned. The Secretariat is refining the performance rating for each project into one that combines key operational and financial indicators of performance.

The UNITAID Key Performance Indicator report, available on 30 June of each year, presents the fully reconciled data for the previous calendar year in a series of tables and figures. This information will also be on the UNITAID web-site at www.unitaid.eu/impact in the form of data visualizations and country profile sheets.

The Operations project updates in Annex 1 contain the preliminary information for each project and should be viewed as a preview of UNITAID's grant performance for 2012. Annex 2 presents an update on the newly approved and pending grants and Secretariat Initiatives. This is included because it shows the status of these grants and Secretariat Initiatives since the 17th Executive Board meeting.

ANNEX 1: OPERATIONS PROJECT UPDATES

EXPLANATION OF GRANT PERFORMANCE RATINGS FOR PROJECT UPDATES

Score	Meaning	Management action
	Robust	standard grant management processes apply as deliverables are on track
	Good	targeted grant management processes needed to address delays
	Acceptable	enhanced grant management processes needed to find solutions to delays
	Fair	escalated grant management processes required to guide the project back on track
	Poor	emergency grant management processes needed to salvage deliverables
	Unable to assess	Recently signed grant which has not been operating long enough to assess performance

SUMMARY OF GRANT PERFORMANCE RATINGS 2012

	Robust	Good	Acceptable	Fair	Poor	Unable to assess (new grants)	Total
HIV	4**	1				3	8
TB	2	2				2*	6
Malaria	1			1	1	4	7
Cross cutting		1	1	1			3
Total	7	4	1	2	1	9	24

***TB Xpert and Cepheid buy-down**
****includes CPP and MPP Foundation**

PROJECT TITLE: Assured Artemisinin Supply Services – A2S2

Key Partner : i+Solutions and Triodos Development Bank **Project Duration: July 2009 - June 2011**[20] **Updates for the Period Ending: 15 May 2013**

Updates **Operational 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	• MOU amount: US$ 9,280,400 • 2012 disbursement: US$ -4,999,992[21] • Cumulative Disbursement: US$ 4,280,408
Achievements	• A total of 2.38 MT of Artemisinin was delivered to ACT manufacturers in 2012. 7.89 MT of Artemisinin were delivered since the start of the project. • Four Artemisinin Extractors[22] were contracted to produce an additional 24 MT of Artemisinin. • Project information and market intelligence is publicly available on the updated project website (http://www.a2s2.org).
Strategic considerations for EB 18	• While 24 MT of Artemisinin (60% of target) was secured, only 7.89 MT of additional Artemisinin was delivered to ACT manufacturers (32% of the targeted amount[23]). • Completion of the loans and delivery of the contracted Artemisinin did not end on 31 May 2013. Outstanding loans are not expected to be re-paid until the end of January 2014. The EB may need to consider a no-cost extension for the project until the end of January 2014 to complete repayment of outstanding loans. • The Artemisinin market remains unstable because of the recent acceptance of semi-synthetic Artemisinin by WHO PQP. The EB may need to consider a proposal to: a) Stabilise the plant-derived Artemisinin market in the era of semi-synthetic Artemisinin b) Collect, analyse and report to UNITAID market intelligence related to the production of plant-derived Artemisinin.

[20] no cost extension granted until May 2013
[21] Represents loan replayments to UNITAID made during 2012.
[22] based in China, Vietnam, Madagascar and Mauritius
[23] due to (a) failure to honour contractual commitments (Chinese Artemisinin extractor Beijing Gingko); (b) adverse weather conditions (reduced yield from Vietnam); and (c) low extraction technical and financial capacity (Bionnexx/Innovexx, Madagascar, and Elysian Life Sciences).

PROJECT TITLE: ACT Scale-up

Key Partner : The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria **Project Duration: December 2007 to June 2010 (with no-cost extension to December 2011)** **Updates for the Period Ending: 15 May 2013**	
Updates **Operational Performance**	
Project description	The ACT Scale-up project was initiated to provide 47,016,160 high quality ACT treatments to eight countries[24]. The project covers 11 programmes chosen because of their participation in the GFATM round of grants.
Finance	• MOU amount (2012): US$ 65,413,057 • 2012 Disbursement: US$ 0 • Cumulative Disbursement (up to December 201): US$ 39,844,131
Achievements	• 36 million ACT treatments delivered to 8 high burden malaria countries • Procurement lead times reduced • No stock outs of ACTs reported from countries during the project implementation period
Strategic considerations for EB 18	• The number of people treated in relation to the total number ACT treatments delivered per year per country remains unresolved due to aggregate reporting by the GFATM. • For some countries, ACT quantification appears not to have been based on disease burden, absorptive capacity or historic use, resulting in drug expiry[25]. • ACT delivery under three GFATM grants, namely Madagascar PSI, Zambia CHAZ and Zambia MOH, have been delayed. The GFATM and UNICEF requested a no-cost extension of the project until the end of 2013 to allow delivery of the remaining ACTs to Madagascar and Zambia. This was not accepted by UNITAID because the dates for the completion of ACT deliveries to those countries was long-overdue. • Outstanding programmatic reporting and accounting needs to be finalised and agreed by UNITAID. There remains a difference between the GFATM reports, the UNICEF reports and the information reported by these agencies to UNITAID for the project. • End of project evaluation external evaluator has been chosen and will start soon. • As this and other ACT projects are closing, the EB may need to consider soliciting new project proposals to support malaria treatment with ACTs.

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

25 For example, in Madagascar where 500,000 ACT treatments delivered to UGP-CRESAN expired and had to be destroyed.

PROJECT TITLE: Affordable Medicines Facility – Malaria

Key Partner : The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria **Project Duration: November 2009 - December 2013** **Updates for the Period Ending: 15 May 2013**

Updates **Operational Performance:** 	
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 is currently implemented through nine programs in eight countries[26].
Finance	• MOU amount (2012): US$ 180,000,000 • 2012 Disbursement: US$ 50,000,000 • Cumulative Disbursement (up to 2012): US$ 180,000,000
Achievements	• A total of 126,232,797 ACT treatments was delivered in 2012. • A cumulative total of 283,735,930 ACT treatments was delivered through the project from July 2010 to December 2012. • Procurement under AMFm was efficient and delivery lead-times for AMFm co-paid ACTs to countries were low.
Strategic considerations for EB 18	• Maintain stringent screening and approval processes for ACT orders from the private-sector first-line buyers in beneficiary countries. • Inform and encourage beneficiary countries to ensure that AMFm co-paid ACTs reach areas where they are most needed and that they are used in conjunction with diagnostic tests wherever possible. • Inform and encourage countries to ensure that the price paid by patients and caregivers for AMFm co-paid ACTs is as low as possible. • **Transition update**: Tanzania and Ghana have both allocated routine GF grant resources to support the provision of subsidized ACTs to the private sector. However, at this time, there are no clear transition plans for other countries, especially for the major AMFm countries of Nigeria and Uganda. • UNITAID support for this project will be completed by the end of 2013. The EB may need to consider soliciting project proposals to support malaria treatment with ACTs including for the private sector.

[26] Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania and Uganda.

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

Key Partner : The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria **Project Duration: July 2009 - June 2011**[27] **Updates for the Period Ending: 15 May 2013**

Updates **Operational Performance:** 	
Project description	This project aims to scale-up access to and availability of quality assured medicines for the treatment of HIV/AIDS, Tuberculosis and Malaria through Global Fund Round 6, Phase 1 for 42 grants in 37 countries.
Finance	• MOU amount: US$ 38,691,956 • 2012 Disbursement: US$ 0 • Cumulative Disbursement: US$ 38,691,956 • Estimated unexpended balance in GF custody: US$ 11,000,000
Achievements	At the end of 2011, the project had delivered the following quantities of treatments for HIV/AIDS, Tuberculosis and Malaria: • 31,197 paediatric ARV treatments • 2,650,652 ACT treatments • 3,223 treatments for MDR-TB
Strategic considerations for EB 18	• The GFATM did not submit the final programmatic and financial report for the project including the full accounting of unexpended project funds to be refunded to UNITAID in 2012. • In the context of the EB Resolution (No. 1 – 2013-e) to provide the remaining unexpended balance from the GF Round 6 project for the AMFm Transition Year 2013, UNITAID will reconcile the amount of project funds that remain unexpended and ensure that this amount is reimbursed to UNITAID. • UNITAID will agree with the Global Fund on the mechanism for the transfer of unexpended funds from the GF Round 6 project to the AMFm.

[27] no cost extension granted until May 2013

PROJECT TITLE: Creating a Private Sector Market for Quality-Assured RDTs in Malaria-Endemic Countries

Key Partner: Population Services International (PSI)
Project Duration: 12 April 2013-December 2015
Updates for the Period Ending: 15 May 2013

Updates **Operational Performance:** ◯	
Project description	PSI and the collaborating implementers, MC, FIND, and WHO/GMP, will stimulate the creation of a private sector market for malaria RDTs. The partnership will operate in five target countries[28] where the UNITAID-supported Affordable Medicines Facility-malaria (AMFm) has been implemented. The project is designed as a catalytic market intervention to develop methods and to learn and disseminate experience for introducing and scaling up access to malaria RDTs in the private sector.
Finance	• MOU amount: US$ 34,290,561 • 2012 Disbursement: US$ 0 •
Achievements	• Grant agreement signed 12 April 2013
Strategic considerations for EB 18	• This project is a collaboration of four partners: PSI, Malaria Consortium, FIND and WHO/GMP. PSI will coordinate the partnership and provide the reporting to UNITAID on the agreed performance indicators.

[28] Kenya, Madagascar, Nigeria, Tanzania (main land) and Uganda

PROJECT TITLE: Sustainable Global and National Quality Control for Malaria Rapid Diagnostic Tests

Key Partner: Foundation for Innovative and New Diagnostics (FIND) **Project Duration: 01 January 2013 -December 2017** **Updates for the Period Ending: 15 May 2013**

Updates **Operational Performance:** 	
Project description	The goal of this project is to establish sustainable standards to ensure quality malaria RDTs are increasingly used to support rationale treatment of malaria in endemic countries. FIND will coordinate implementation of the RDT product and lot testing services in collaboration with WHO/GMP. FIND and partners will establish and employ RDT quality control procedures and will develop and pilot the introduction of recombinant antigen-based evaluation panels.
Finance	• MOU amount: US$ 9,441,777 • 2012 Disbursement: US$ 0
Achievements	• Grant agreement signed 25 January 2013
Strategic considerations for EB 18	• FIND is coordinating implementation of this project with WHO/GMP. • The project is innovative because it will support the developments of recombinant antigen-based evaluation panels that will make quality assurance of tests easier and faster.

PROJECT TITLE: CHAI/UNITAID Second-line Adult Anti-retroviral (ARVs) treatments

Key Partner: Clinton Health Access Initiative (CHAI)
Project Duration: May 2007-December 2012
Updates for the Period Ending: 15 May 2013

Updates Operational Performance: 	
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[29].
Finance	• MOU amount (2012): US$ 299,650,557 • 2012 Disbursement: US$ 17,517,200 • Cumulative Disbursement: US$ 252,868,944
Achievements	• By the end of 2012 all 25 countries have secured other sources of funding for second-line ARVs. • A WHO-recommended, PI-based 2L regimen is now available at a price 78% lower than what was available for at the start of the project in Lower Income countries. • The 2012 selection process saw the addition of 2 newly eligible and SRA approved formulations over the same selection process in 2011. • There were an additional 4 new SRA approvals of UNITAID-funded ARVs, further increasing the number of high-quality ARVs available globally.
Strategic considerations for EB 18	• The Project closed its activities on 31 December 2012. The original date to end the Project was 31 December 2011, but a one year no-cost extension of US$ 8,000,000 was granted to the project. • CHAI and UNITAID recognize that there will always be potential issues affecting the supply of ARVs. CHAI and UNITAID will monitor post-transition progress of all former project countries through the participation in the Coordinated Procurement Planning (CPP) initiative.[30] Where CHAI has a country office or market coordination presence, CHAI also will informally monitor a country directly. • A final project report will be submitted by CHAI by July 2013 including the challenges and achievements of the Project since its inception. • A final audit of the grant will be commissioned by UNITAID in 2013. • Lessons learned from a successful transition process and achievements will be prepared and publically disseminated.

[29] The Project was implemented in 25 countries: Benin, Botswana, Burundi, Cambodia, Cameroon, Chad, Cote d'Ivoire, Democratic Republic of the Congo, Ethiopia, Ghana, Haiti, India, Kenya, Malawi, Mali, Mozambique, Namibia, Nigeria, Rwanda, Senegal, Tanzania, Togo, Uganda, Zambia, and Zimbabwe.
[30] See update on CPP project for details.

PROJECT TITLE: CHAI/UNITAID Paediatric HIV/AIDS Treatment Project

Key Partner: Clinton Health Access Initiative (CHAI)
Project Duration: November 2006-December 2013
Updates for the Period Ending: 15 May 2013

Updates Operational Performance: 	
Project description	The goal of the Project is to maintain on-going access to paediatric ARVs, diagnostics bundles and related commodities. 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 source for paediatric ARVs and related commodities and support countries in securing these funds.
Finance	• MOU amount: US$ 386,682,996 • 2012 Disbursement: US$ 17,517,200 • Cumulative Disbursement: US$ 292,504,748
Achievements	• 18 countries benefited from the project in 2012[31] with 203,427 new children placed on treatment. • By the end of 2012, 35 project countries have secured funding for transition. • Suppliers were selected in March 2012, achieving price reductions of up to 19% compared to 2011 on key Pediatric ARV formulations[32]. • CHAI has led a multi-country pediatric ARV optimization[33] effort to facilitate the procurement transition from UNITAID to other buyers while improving the quality of treatment for children with HIV. The concentration of optimal products has increased from 52% in 2010 to 82% in 2012.
Strategic considerations for EB 18	• Unspent monies from 2012 and a new commitment of US$ 8,000,000 from EB 17 will be used in 2013 to support countries in need. • Swaziland has secured funding for paediatric ARVs. The remaining four countries are at different application phases for the GFATM's New Funding Model with success not assured. • An extension of the Project into 2014 may be necessary if GFATM monies arrive after Q3 2013. A realistic budget for 2014 would be under US$25 million, providing GFATM monies arrive in time for orders to be placed in Q1 2014. • CHAI is resubmitting to EB18 the Innovation in Paediatric Market Access (IPMA) Proposal[34]. One of the objectives of the Proposal is to stabilize the supply of essential paediatric ARVs and tests.

[31] Benin, Botswana, Burkina Faso, Burundi, Cameroon, D R Congo, India, Malawi, Mali, Mozambique, Nigeria, Senegal, Swaziland, Tanzania, Togo, Uganda, Zambia, and Zimbabwe.

[32] 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.

[33] Paediatric product optimization is the process of reviewing and decreasing the number of products in a program to consolidate procurement around optimal formulations, especially FDCs. This work is critical for reducing fragmentation in the still-yet fragile pediatric ARV market in order to minimize supply risks and stabilize the market.

[34] Together with the Partnership for supply Chain Management

PROJECT TITLE: ESTHERAID: Facilitate and secure the availability of ARV treatments and their proper administration to people living with HIV/AIDS in five African countries

Key Partner : ESTHER (Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau)
Project Duration: January 2008 – December 2013
Updates for the Period Ending: 15 May 2013

Updates **Operational Performance:** 	
Project description	This project contributes to improving supply chain management from national central medical stores to treatment centers in 5 West African countries35 by improving logistic information systems and patient monitoring systems. The project also supports the efforts of treatment centers to improve treatment choices by making sure that UNITAID supplied tests and treatments are received and used.
Finance	• MOU amount (2012): US$ 14,680,988 • 2012 Disbursement: US$ 2,889,072 • Cumulative Disbursement: US$ 7,382,068
Achievements	• Significant impact has been observed on the numbers of patients getting access to pediatric and second line treatment at project sites. • Increased patient numbers initiated on treatment with quality-assured child-adapted formulations, including fixed-drug combinations (FDCs). • Training programs and the roll out of databases at peripheral treatment sites have had a strong and positive impact on the project contributing to project sustainability.
Strategic considerations for EB 18	• The Project is ending on 31 December 2013, but delays in achieving project objectives led to a request for a no-cost extension of the project to December 2014. ESTHER and UNITAID will formalize the one year no-cost extension to the project. • A mid-term project review was completed in early 2013 with recommendations that are being implemented for the no cost extension (including redistribution of activities and contingency plans for unforeseen events (e.g. coup d'état in Mali and the rebellion in the Central African Republic). • Third line drugs needs have been identified in 3 of the 5 project countries – Benin, Burkina Faso and Cameroon.

[35] Benin, Burkina Faso, Cameroon, Central African Republic and Mali.

PROJECT TITLE: Accelerating access to point of care (POC) HIV diagnostics (Dx)

Key Partners: Clinton Health Access Initiative (CHAI) and UNICEF **Project Duration: December 2012 – December 2013** **Updates for the Period Ending: 15 May 2013**

Updates **Operational Performance:** ◯	
Project description	The project intends to prepare the market for accelerated scale-up of POC HIV diagnostics including CD4, VL and EID by working with 7 high-volume early adopter countries[36] to prepare for rapid scale-up of POC Dx, while helping new suppliers through the regulatory and policy approval processes.
Finance	• MOU amount (2012): US$ 20,000,000 • 2012 Disbursement: US$ 14,548,000 • Cumulative Disbursement: US$ 14,548,000
Achievements	• The Memorandum of Understanding between CHAI, UNICEF and UNITAID was signed on 30 November 2012. • Drafts of the diagnostic quality policy, standards for successful evaluation and a coordination protocol for CHAI-UNICEF have been submitted to UNITAID and are under review. • An updated procurement plan has been submitted enabling CD4 POC Dx required to kick-start or roll-out to be supplied in project countries staring in late June. • All country operational plans have been completed and submitted to UNITAID.
Strategic considerations for EB 18	• UNITAID has requested that CHAI adapt its procurement strategy HIV POC Dx to take into account the new WHO HIV Treatment Guidelines to be published in July 2013 because these will have market implications for viral load (VL Dx) technologies. This will ensure a strategic approach to market shaping for both CD4 and VL Dx technologies. • UNITAID has requested that CHAI share the project market segmentation analysis for VL Dx, CD4 and EID, once completed. This will confirm the CD4 market footprint in the project countries and inform the strategic procurement and site selection of these Dx during scale-up under Phase 2. • The shift to VL Dx for routine monitoring could have funding implications for Phase 2 of the project to be submitted by CHAI for EB19 consideration i.e. require a higher budget ceiling than initially estimated in 2012. • The project offers an opportunity to leverage development of broader HIV, TB and Malaria strategic plans in the project countries through CHAI's work on developing national strategic plans for POC Dx scale-up. These will be needed for GFATM proposals under the new funding model. Effective transition from UTD funding to GFATM funding for CD4 POC would benefit from this synergy. • UNITAID will coordinate Stakeholder meetings between CHAI/UNICEF, MSF, London School of Hygiene and Tropical Medicine (LSHTM), FEI to maximize information sharing between UNITAID-funded projects working in the area of HIV POC.

[36] Ethiopia, Malawi, Mozambique, Kenya, Tanzania, Uganda and Zimbabwe

PROJECT TITLE: HIV diagnostics (Dx) (CD4 and Viral Load Testing)

Key Partner : Médecins Sans Frontières (MSF) **Project Duration: December 2012 – December 2015** **Updates for the Period Ending: 15 May 2013**

Updates **Operational Performance:** ◯	
Project description	MSF will engage in operational research on introduction of PoC and adapted laboratory-based monitoring to understand how, where and when PoC fits in the mix of laboratory services available in the health services. Eleven different MSF-supported HIV/AIDS programs in the seven project countries[1] will engage in complementary work to compare different strategies and identify the most feasible and affordable options for optimal deployment and use of diagnostic tests in given types of resource-constrained settings.
Finance	• MOU amount (2012): US$ 28,696,023 • 2012 Disbursement: US$ 0 • Cumulative Disbursement: US$ 7,715,000
Achievements	• The Memorandum of Understanding between MSF and UNITAID was signed on 25 December 2012.
Strategic considerations for EB 18	• While MoUs have been introduced to each country Government, expected delays have been flagged for Mozambique, South Africa and Uganda. This may mean a delay in implementation of the project in these countries. • Finalization of the procurement plan - a request from MSF to make regional and local purchases delayed the finalization of the Procurement Plan. The procurement plan for year 1 will be finalised by Q2 2013. This plan will be reviewed at the end of the first project year. • UNITAID will address international, regional and local purchasing from an overall policy perspective for all relevant projects in its Procurement and Supply Chain Management Framework to be presented for information to the FAC and PSC in November 2013. The Framework is intended to ensure a consistent, transparent, cost-effective, practical and strategic approach to procurement across projects engaged in procurement of UNITAID financed health products. • Stakeholder meetings to be formalized and coordinated by UNITAID between CHAI/UNICEF, MSF, London School of Hygiene and Tropical Medicine (LSHTM), FEI to maximize harmonization and information sharing between UNITAID-funded projects working in the area of HIV POC.

[1] Lesotho, Malawi, Mozambique, South Africa, Swaziland, Uganda and Zimbabwe

PROJECT TITLE: Open Polyvalent Platforms for Sustainable Access to Quality and Affordable Viral Load Testing in Resource Limited Settings

Key Partner: France Expertise International (FEI)
Project Duration: 01 March 2013 - 30 June 2014 (Phase I)
Updates for the Period Ending: 15 May 2013

Updates Operational Performance:	
Project description	The Project aims to improve access to viral load testing (VLT) and early infant diagnosis (EID) for adults and children living with HIV through the introduction of innovative Open Polyvalent Platforms (OPPs). During Phase I of the Project, the lead project implementer, France Expertise International (FEI), will work with other partners to develop a full Business Plan for scaled-up commercialization of VLT/OPP, prepare a proposal for the second phase of the Project, develop a procurement strategy and plan for the 4 project target countries[37] and commence deployment on OPPs in these countries.
Finance	• MOU amount (2012): US$ 2,400,000 • First Disbursement (March 2013): US$ 1,040,000
Achievements	• The Project MOU was signed on 12 February 2013 • Visits to the four project countries have been completed and a decision on site selection will be made by end June. • Visits to the project countries for procurement planning purposes (to discuss approach, clarify logistics and importation requirements etc.) were completed at the end of May.
Strategic considerations for EB 18	• A letter will be issued in early June inviting potential suppliers of OPPs (in additional to Biocentric and Quiagen) to express interest in supplying the Diagnostics. An information meeting is planned with interested suppliers around 09 July (date TBC). UNITAID will participate in the meeting as an observer. • A meeting is planned in Geneva between FEI and UNITAID to discuss preliminary findings of a baseline market study done on current dynamics, prices, suppliers and IP issues. • Delays in prequalification (PQ) of Biocentric's generic VL assay present a risk of delayed introduction of this product under the project. UNITAID is exploring other qualification options (see update on PQ Dx project). • Stakeholder meetings to be formalized and coordinated by UNITAID between CHAI/UNICEF, MSF, London School of Hygiene and Tropical Medicine (LSHTM), FEI to maximize harmonization and information sharing between UNITAID-funded projects working in the area of HIV POC.

[37] Cameroon, Cote d'Ivoire, Burundi and Guinea.

PROJECT TITLE: Support to the Coordinated Procurement Planning (CPP) Initiative[38]

Key Partner: Supply Chain Management System (SCMS) **Project Duration: August 2012-August 2013** **Updates for the Period Ending: 15 May 2013**

Updates Operational Performance: 	
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[39].
Finance	• MOU amount (2012): US$ 190,000 • 2012 Disbursement: US$ 127,000 • Cumulative Disbursement: US$ 127,000
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. • The CPP Web platform, now formally named the Procurement Information Exchange (PIE) has been completed and will help members to identify actual countries at-risk, and the types of advocacy needed to act on risks[40]. Data are accompanied by quantitative assessments of funding flows relative to needs and a brief qualitative assessment of potential risks. The site also hosts an ARV Supply Risk Assessment.
Strategic considerations for EB 18	• A no-cost extension is likely needed from August to December 2013 to allow for completion of the analysis of data collected in the PIE but more strategically, UTD should consider how this initiative may be formally aligned with, if approved by EB18, the CHAI-Global Fund IPMA proposal.

[38] This is a Secretariat Initiative.

[39] Angola, Burkina Faso, Cameroon, Central African Republic, Mali and Mozambique

[40] The Technical Secretariat will update the site on at least a bi-monthly basis with stock out information and funding needs, gaps and availability, by country.

PROJECT TITLE: UNITAID Project Support for Quality Assurance of Medicines

Key Partner: WHO Medicines Prequalification Programme **Project Duration: December 2006 - December 2013** **Updates for the Period Ending: 15 May 2013**

Updates **Operational Performance:** 	
Project description	The Medicines Quality Assurance project (WHO PQP) aims to increase the number of prequalified UNITAID priority medicines for HIV/AIDS, Tuberculosis and Malaria. The project also contributes to increasing capacity in production of quality of priority medicines, facilitating the development of national regulatory processes and promoting capacity building for quality control of medicines in recipient countries, and accelerating testing of the quality of medicines.
Finance	• MOU amount (2012): US$ 53,110,00041 • 2012 Disbursement: US$ 15,882,150 • Cumulative Disbursement: 47,559,574
Achievements	• Prequalification of 89 priority finished pharmaceutical products (FPPs) • Prequalification of 28 active pharmaceutical ingredients (APIs), all of which can be used for manufacturer of UNITAID priority products • Prequalification of 19 medicines quality control laboratories (QCLs), so that prequalified QCLs can now be found in all six WHO regions (see Figure 2) • PQP now has a modernized, computerized business processes and information management platform.
Strategic considerations for EB 18	• Funding and sustaining PQP activities are key challenges. Increasing amounts of time need to spent on "maintenance" activities such as requalification and re-inspection, to ensure that prequalification standards are maintained. Additional funding options are needed to sustain these activities in the longer term. • The WHO PQP proposal submitted to EB17 for new multi-year funding was not sufficiently robust because it was not fully aligned with UNITAID's new strategic plan. More details are needed about the proposed budget rationale, including confirmed and expected sources of co-funding. The proposal also requires a stronger section on sustainability planning. • How the new proposal is structured/scoped will depend very much on current reforms of WHO's Prequalification programmes and the outcome of the synergy meetings described below. • Synergy meetings between UNITAID and the Bill and Melinda Gates Foundation to discuss and align funding plans for WHO PQP after 2013 are underway. • WHO PQP plans to introduce fees for some of its services in 2013 (subject to approval from the WHO Director-General.) Care will have to be taken to ensure that these do not discourage manufacturers from submitting products for evaluation.

[41] Includes US$ 13,000,000 agreed by EB17 for the one year cost-extension for 2013

PROJECT TITLE: UNITAID Project Support for Quality Assurance of Diagnostics

Key Partner(s): WHO Diagnostics and Laboratory Technology Department
Project Duration: March 2009 - December 2013
Updates for the Period Ending: 15 May 2013

Updates Operational Performance:	
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[42].
Finance	• MOU amount: US$ 8,475,00043 • 2012 Disbursement: US$ 3,333,500 • Cumulative Disbursement: 7,684,000
Achievements	• The project cost-extension from March to December 2013 approved by EB17 was concluded as planned, including a significantly improved log frame and reporting templates. • A draft concept note on the Expert Review Panel (ERP) process to be established by DLT during the extension period in order to streamline/accelerate the prequalification of HIV POC diagnostics is under review. • The first voluntary male circumcision device (PrePex) is expected to be prequalified by DLT within Q2 2013.
Strategic considerations for EB 18	• UNITAID, the GFATM, BMGF and other stakeholders have requested WHO DLT to develop in 2013 an Expert Review Panel for Diagnostics (EPRD) process to streamline/accelerate the prequalification, in particular, of HIV POC Diagnostics. The GFATM wishes to lead the EPRD as it has done successfully for medicines. WHO DLT could play a hosting role. The pros and cons of such an arrangement are being considered by the key stakeholders. • Synergy meetings are underway between UNITAID, USG (PEPFAR, USAID, CDC) and the Bill and Melinda Gates Foundation to align efforts to accelerate prequalification of priority Dx and devices and discuss the comparative advantages of various players (CDC, WHO DLT) in a complementary manner. • WHO DLT will develop a new funding proposal for Prequalification of Diagnostics by for EB19. How the proposal is structured/scoped will depend very much on current reforms of WHO's Prequalification programmes and the outcome of the aforementioned synergy meetings and EPRD development process.

[42] Burkina Faso, China, Cote d'Ivoire, Tanzania and South Africa.
[43] US$ 2,000,000 was agreed by EB17 for the one year cost-extension for 2013

PROJECT TITLE: TBXpert Project, Scaling up access to contemporary diagnostics for tuberculosis (TB) with a focus on HIV-associated TB, drug-resistant TB and early TB case detection

Key Partner: WHO-STB, TBP[44] **Project Duration: 2013-2015** **Updates for the Period Ending: 15 May 2013**	
Updates **Operational Performance:** ◯	
Project description	The TBXpert Project will scale up TB diagnostic testing using state-of-the-art Xpert MTB/RIF, providing approximately 1.4 million Xpert MTB/RIF test cartridges and over 200 GeneXpert instruments for the rapid detection of TB and rifampicin resistance in 21[45] recipient. To ensure country absorptive capacity and effective use of the technology, the TBXpert project links a broad network of partners and existing initiatives for TB laboratory strengthening to expand access to vulnerable populations in the public and private sector.
Finance	• MOU amount (2012): US$ 4,100,000 • 2012 Disbursement: US$ 3,200,000 • Cumulative Disbursement: US$ 3,200,000
Achievements	• The grant agreement was signed on 28 January 2013. • UNITAID signed a buy-down agreement with Cepheid on 28 December 2012. The first payment has been made to Cepheid. • The first disbursement has been made to the implementers of the project. Orders are being placed for initial supplies to countries by end of quarter 2, 2013.
Strategic considerations for EB 18	• Cepheid reported some limitations to scale up of its manufacturing capacity, leading to back-log on supplies to countries with many only getting partial supplies. No orders have been delivered as of 08 May 2013. The situation is expected to be resolved from mid-2013 when Cepheid's newly commissioned manufacturing units start up[46]. • UNITAID met with its partners of the Buy-down agreement, Cepheid and TBXpert Implementers, to find solutions to the short supply of cartridges during April 2013. A method for consolidating forecasts across all Implementers was finalized for the period starting from June 2013. The core committee set up to monitor forecasting will meet every month until the supply situation is stabilized, after which it will meet quarterly. • Countries are revising their targets[47] based on diagnostic algorithms and in-country needs, and availability of resources from other funders. • UNITAID may support similar products in this diagnostics landscape in a future call for proposals.

[44] TBXpert Project partners include IRD and ASLM. UNITAID has separate sub-agreements with these sub-implementers of the grant.
[45] Xpert Project countries are: Bangladesh, Belarus, Cambodia, Congo, Ethiopia, India, Indonesia, Kenya, Kyrgyzstan, Malawi, Mozambique, Myanmar, Nepal, Pakistan, Philippines, Moldova, Swaziland, Uganda, Tanzania, Uzbekistan, Viet Nam
[46] Large volume orders from non-project countries (India and China), may be prioritized at this time.
[47] Up to >20% of their original planned requirement of cartridges

PROJECT TITLE: EXPAND$_x$ TB (MDR-TB Diagnostics), Expanding and accelerating access to diagnostics for patients at risk of multi-drug resistant tuberculosis

Key Partner : FIND, GDF, WHO/GLI **Project Duration: 2010-2014** **Updates for the Period Ending: 15 May 2013**

Updates **Operational Performance:** 	
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 115,000 MDR TB patients in 27[48] countries to enable appropriate treatment of these patients.
Finance	• MOU amount (2012): US$ 89,612,000 • 2012 Disbursement: US$ 9,043,400 • Cumulative Disbursement : US$ 47,259,865
Achievements	• The project has accelerated its pace and the annual target and cumulative project targets for diagnosis of MDR-TB cases have been exceeded with 24,870 MDR-TB cases detected in 2012. • 24 countries have moved into the routine detection and reporting phase of the project. • 65 of expected 99 laboratories under this project are now routinely diagnosing and reporting MDR-TB cases.
Strategic considerations for EB 18	• The laboratory strengthening and capacity building components of this project was key to improving access to MDR-TB diagnostics. Improved laboratories have enabled many countries to incorporate TBXpert technologies as part of MDR-TB screening, leading to faster detection and treatment of the disease in low resource settings. • There have been long delays in obtaining permits for importation of goods in some countries. As a result, manufacturer delivery times to countries seem unacceptably long. The project will establish SOPs specific to countries for importation permits. These processes will be transferred to National Programmes during project transition. • The gap between diagnosing MDR-TB and treating MDR-TB remains a challenge in some countries. • The implementing partners are working with National TB Programmes, Ministries of Health, donors and others to develop sample referral systems, LIMS and equipment maintenance in the project countries. • A transition plan is expected later in 2013. Funding for FIND in TB is available only until the end of 2014 (supported by BMGF). GLI has become the lead Implementer of the project as a result.

[48] The EXPAND TB project countries are: Azerbaijan, Bangladesh, Belarus, Cameroon, Cote d'Ivoire, Djibouti, Ethiopia, Georgia, Haiti, India, Indonesia, Kazakhstan, Kenya, Kyrgyz republic, Lesotho, Mozambique, Myanmar, Peru, Republic of Moldova, Rwanda, Senegal, Swaziland, Tajikistan, Uganda, UR Tanzania, Uzbekistan, Viet Nam.

PROJECT TITLE: Multi-Drug Resistant (MDR)-TB Scale-up and Acceleration of Access Project

Key Partner : GDF **Project Duration: 01/01/2007 to 31/12/2013** **Updates for the Period Ending: 15 May 2013**

Updates **Operational Performance:** 	
Project description	The aim of this project (otherwise known as the MDR-TB Scale-up Initiative) is to scale-up access to quality assured anti-TB drugs to treat MDR-TB patients in eligible countries and positively impact the dynamics of the MDR-TB drug market.
Finance	• MOU amount (2012): US$ 53,371,575 • 2012 Disbursement: US$ 2,111,500 • Cumulative Disbursement: US$ 48,753,922
Achievements	• 5,395 patient treatments were delivered in 2012. 15,886 patient treatments have been delivered since the project began. • The GDF obtained bids from an unprecedented number of manufacturers of second and third-line anti-TB medicines[49]. • A total of 54 medicines/manufacturers were eligible for supply in the GDF 2012 catalogue. • A total of 12 new products became available for supply in 2012.
Strategic considerations for EB 18	• The project was granted an extension for one year during 2013 (as a no cost extension) to assist in the transition of 5 countries[50]. • Access to and affordability of MDR-TB medicines remains problematic. UNITAID may have to continue to support access to MDR-TB medicines using GDF as the Implementer because there are no other partners who have the mandate and capacity in this area. • However, more manufacturers are moving into the market for MDR-TB medicines. UNITAID's support for MDR-TB diagnostics has led to more people being diagnosed, providing incentives to market entry for generic manufacturers. • WHO is piloting the use of shorter duration regimens for MDR-TB. New medicines which are also more affordable are included in these regiments. UNITAID may support these regimens if they prove efficacious. • Reporting the number of patients receiving treatments from this project has been difficult because of the non-standard duration of the two treatment phases, one lasting 8 to 10 months with injectable medicines and the other continuing with non-injectable medicines for an additional 8 to 10 months.

[49] 19 in total
[50] The five countries transitioning in 2013 are Guinea, Kyrgyzstan, Kenya, Myanmar and Nepal.

PROJECT TITLE: MDR-TB SRS, Support for MDR TB Acceleration of Access Initiative: Strategic Rotating Stockpile

Key Partner: GDF **Project Duration: 2007-2013**[51] **Updates for the Period Ending: 15 May 2013**

Updates **Operational Performance:** 	
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	• MOU amount (2012): US$ 14,097,545 • 2012 Disbursement: US$ 0 • Cumulative Disbursement: US$ 12,168,111
Achievements	• 67 programmes ordered from the stockpile in 2012. • 17 countries placed and received emergency orders. • The median lead time for delivery of treatments to countries was 55 days in 2012. • The shortage of injectable drugs encountered in the first half of 2012 has been successfully managed and these treatments are now available.
Strategic considerations for EB 18	• The SRS is a successful model which has help to ensure availability of MDR-TB regimens. However, the per cent of time that the SRS was not fully stocked increased in 2012, suggesting that the stockpile is too small. In addition, case detection of MDR-TB is expected to increase in the near future, leading to concerns that the 5,800 treatments in the SRS are no longer sufficient. • GDF will convene a meeting with the Global Fund and partners during this quarter to further explore options for continuation of the SRS once the project concludes at the end of this year. It is unclear if a transition plan supported in part or solely by the Global Fund and/or other partners will be successful. This means that the relatively stable treatment delivery times supported by the current SRS may not be sustainable in the longer term and UNITAID may need to consider how to support this model in the future. • Ofloxacin is being replaced with Moxifloxacin in the Stock-pile. PASER is being replaced by PAS. GDF submitted a memo requesting permission to write-off expiring PASER. Additional changes to the composition of the SRS were also requested[52].

[51] A one year no-cost extension was granted to the project from 01 Jan 2013 to 31 Dec 2013, through EB resolution dated March 2013.

[52] Treatment guidelines have changed, resulting in two products no-longer in use, Ofloxacin and Prothionamide. These products will need to be phased out of the SRS.

PROJECT TITLE: Paediatric TB

Key Partner: GDF/STOP TB **Project Duration: 01/01/2007 to 31/12/2013** **Updates for the Period Ending: 15 May 2013**	
Updates **Operational Performance:** 	
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	• MOU amount (2012): US$ 13,143,830 • 2012 Disbursement: US$ 0 • Cumulative Disbursement (up to 2012): 11,626,950
Achievements	• In 2012, 9,974 curative and 36,553 prophylaxis treatments were delivered, bringing the cumulative numbers since project inception to respectively 463,504 and 681,982 treatments. • GDF extended LTAs with current suppliers until 31 December 2012. • New LTAs were initiated from 01 January 2013 and as a result, prices have remained stable for products for which GDF has LTAs with manufacturers.
Strategic considerations for EB 18	• The project was granted an extension for one year during 2013 for an amount of USD 1,472,833 USD to assist in the transition of 12 countries[53]. • Price reductions are not likely for the first line paediatric formulations now on the market. However, new quality medicines for children from the UNITAID-TB Alliance project may be available at lower prices, depending on the uptake of these products in high burden countries. • Once new, child-friendly medicines are available, UNITAID may play a role in improving access to these products in low resource settings. • New diagnostic products that facilitate the faster detection of children with TB are not currently available but could change the market for paediatric TB medicines, with more children being detected with TB providing incentives to generic manufacturers to enter the market.

[53] The twelve countries transitioning in 2013 are Afghanistan, Cambodia, Bangladesh, Pakistan, Somalia, Macedonia, Sri Lanka, DPR Korea, Sudan, South Sudan, Tanzania and Nigeria.

PROJECT TITLE: The Medicines Patent Pool Foundation

Key Partner: The Medicines Patent Pool (MPP) **Project Duration: 2010-2015** **Updates for the Period Ending: 15 May 2013**

Updates **Operational Performance:** 	
Project description	This project aims to bring down the prices of HIV medicines and facilitate development of better-adapted HIV medicines, such as fixed-dose combinations (FDCs) and special formulations for children, by creating a pool of relevant patents for licensing to generic manufacturers and product development partnerships.
Finance	• MOU amount: US$ 31,151,121 • 2012 Disbursement: US$ 5,975,982 • Cumulative Disbursement: US$ 10,774,878
Achievements	• License and sub-license agreements concluded covering 4 products, including Tenofovir (TDF), Emtricitabine (FTC), Elvitegravir (EVG) and Cobicistat (COBI), plus licenses for some patents on Darunavir. Negotiations in advanced stage at end 2012 with two other licensors. Sub-licenses with generics manufacturers covering between 60-80% of MPP portfolio concluded. • An Executive Board seat for civil society was added to the MPP Board. Two additional seats for civil society stakeholders added to MPP Expert Advisory Group. • A consultation with civil society stakeholders was held in November • No serious weaknesses were found in standard limited PricewaterhouseCoopers (PWC) audit to December 2011. Budget implementation rate reached 79% at the end of 2012. • Commenced planning for operational review covering activities through 2012. 6-month search for new Executive Director concluded successfully in Nov. 2012.
Strategic considerations for EB 18	• The license base is expanding to include new patent holding companies. • The new Executive Director (Greg Perry) took office in January 2013 and staff recruitment of 2 positions are proceeding in line with approved staffing plan. • Cooperation with operational review is on-going to understand strengths and weaknesses of the foundation. • Planning has started for relevant course adjustments to better facilitate achievement of the project's mission and objectives.

ANNEX 2: UPDATE ON NEW ACTIVE GRANTS, PENDING GRANTS & SECRETARIAT INITIATIVES APPROVED BY THE EXECUTIVE BOARD

NEW ACTIVE GRANTS	ACTIONS TAKEN	NEXT STEPS
MSF: IMPLEMENTATION OF CD4 AND VL TESTING IN DECENTRALIZED, EMOTE AND RESOURCE-LIMITED SETTINGS IN MSF HIV PROGRAMMES EB15SS-RES.3	MOU SIGNED 25/12/2012	PROCUREMENT PLAN APPROVED BY UNITAID
FEI: OP-PERA EB16-RES.4	MOU SIGNED 11/02/2013	INCEPTION REPORT EXPECTED SEPTEMBER 2013 REPORTING ON PROGRESS IN THE FIRST 6 MONTHS OF PROJECT IMPLEMENTATION
CHAI/UNICEF POC HIV PROJECT EB15SS-RES.5	MOU SIGNED 30/11/2013	PROJECT UNDERWAY
PSI RAPID DIAGNOSTIC TESTS IN THE PRIVATE SECTOR EB15SS-RES.6	MOU SIGNED 12/04/2013	PROJECT UNDERWAY
FIND QUALITY CONTROL FOR RDTS EB15SS-RES.4	MOU SIGNED 25/12/2013	PROJECT UNDERWAY
I+ SOLUTION A2S2 EB15SS-RES.9	BOARD APPROVED EXTENSION TO 31/05/2013	PROJECT ENDING 31/05/2013
AMFM EB15-RES.7	BOARD APPROVED EXTENSION TO 31/12/2013	PROJECT UNDERWAY
TB XPERT PROJECT: EB16-RES.5	MOU SIGNED 28/01/2013	PROJECT UNDERWAY

PENDING GRANTS	CHALLENGES	ACTIONS TAKEN	NEXT STEPS
TB ALLIANCE: PAEDIATRIC TB EB17-RES.11	• AGREEMENT ON INDIRECT COSTS IS NEEDED; • DISBURSEMENT SCHEDULE FOR INDUSTRY PARTNERS NEEDS AGREEMENT	FINAL PROJECT PLAN & BUDGET EXPECTED 08 MAY 2013;	LEGAL AGREEMENT FINALIZATION; SIGNATURE EXPECTED MAY 2013
DNDI: PAEDIATRIC HIV EB17-RES.7	NEW PROJECT TYPE REQUIRED REPORTING TEMPLATE ADAPTATIONS	ALL DOCUMENTATION PROVIDED BY DNDI	REPORTING TEMPLATES TO BE FINALIZED AND CONTRACTUAL AGREEMENT DRAWN UP BY MID-MAY 2013
MMV: IMPROVING SEVERE MALARIA EB17-RES.13	• PROCUREMENT AGENT SELECTION TOOK TIME; • RECTAL ARTESUNATE COMPONENT DEPENDED ON GETTING HISTORICAL RECORDS FROM WHO/TDR TO MMV	PROJECT PLAN DEVELOPMENT UNDERWAY	UNITAID WORKING CLOSELY WITH MMV TO FINALIZE PROJECT PLAN AND REPORTING TEMPLATES BY MAY 2013
LAWYERS COLLECTIVE: PREVENTING PATENT BARRIERS EB17-RES.9	AWAITING PROJECT PLAN	GUIDANCE PROVIDED TO IMPLEMENTER	MOU TO BE PRODUCED BY MID-MAY 2013
LSHTM: GLOBAL NETWORK TO IMPROVE ACCESS AND QUALITY OF HIV MONITORING EB17-RES.15	NONE	NONE	LEGAL AGREEMENT AND DISBURSEMENT EXPECTED BY END OF MAY 2013
PSI: ACTWATCH2 EB17-RES.12	PROJECT PLANNING INITIATION DELAYED	PLANNING HAS BEGUN AND PROJECT PLAN DEVELOPMENT UNDERWAY	AGREEMENT AND DISBURSEMENT EXPECTED AROUND LATE JUNE 2013

PENDING SECRETARIAT INITIATIVES	CHALLENGES	ACTIONS TAKEN	NEXT STEPS
WDI: MARKET DYNAMICS INFORMATION SERVICE	AWAITING 3RD VERSION OF PROJECT PLAN AND BUDGET	AS PER PRC RECOMMENDATION & BOARD DISCUSSION IN DECEMBER 2012, THE PROJECT WAS SUBMITTED TO WHO'S CRC WHICH HAS AGREED THAT UNITAID CAN PROCEED WITH THE INITIATIVE	UNDER DEVELOPMENT
IMS: MARKET INTELLIGENCE DATABASE	IMS OVER ANALYZING REQUIREMENTS FOR THE SYSTEM-DELAYS TIMELINE	AS PER PRC RECOMMENDATION & BOARD DISCUSSION IN DECEMBER 2012, THE PROJECT WAS SUBMITTED TO WHO'S CRC WHICH HAS AGREED THAT UNITAID CAN PROCEED WITH THE INITIATIVE	UNDER DEVELOPMENT