Executive Board
13th Session
10-11 November 2010
WHO Geneva, Switzerland

Agenda Item 12.1

Project Overview:

1. HIV
2. TB
3. Malaria
4. Transversal

Annex:

1. Project Update HIV niche (Pediatric ARV, Second line ARV, PMTCT and ESTERAID)
2. Project Update TB niche (Pediatric TB, First-line Anti-TB drugs, MDR-TB Diagnostics (EXPAND-TB), MDR-TB scale-up initiative, MDR-TB Acceleration of Access Initiative: Strategic Rotating Stockpile and update on the status of the Strategic Revolving Fund)
3. Project Update Malaria niche (ACT scale-up, LLINs, AMFm and A2S2)
4. Project Update Transversal (Quality Assurance of Diagnostics, Prequalification of Medicines Programme and UNITAID Support to Round 6 Phase 1)

For Information ☒ For Review & Advice ☐ For Endorsement ☐

OVERVIEW OF UNITAID HIV PORTFOLIO

Reported to the EB13 Session

HIV Portfolio at a Glance

Project Title	Project Duration	EB Approved Project Budget Ceiling in US$	MoU Amount or Latest Approved Revised Budget in US$	Project Funds Disbursed to-date in US$
ONGOING				
Paediatric HIV/AIDS	1 November 2006 to 31 December 2010	236,141,194	234,541,557	183,742,748
UNITAID-CHAI Second Line HIV/AIDS Project	4 May 2007 to 30 September 2011	305,799,000	223,970,038	212,298,650
PMTCT	10 December 2007 to June 2010	75,666,955	72 029 272	72 029 272[1]
ESTHERAID, Phase 1	3 years project for which only phase 1 approved: 2 July 2009 to 1 March 2010	EURO 321,106 (estimated USD 451,626)	EURO 321,106 (estimated USD 451,626)	451,626 (USD equivalent of EURO 321,106 at the time of transaction)
Total for ongoing		589,259,422	530,992,493	468,516,593
EB APPROVED AND PENDING MOU				
PMTCT 1 extension	1 year	28,799,353		
ESTHERAID, Phase 2	3 years project for which only phase 1 approved: MoU for Phase 2 to be developed and approved upon completion of Phase 1	Balance after deduction of MoU amount for Phase 1 from the approved ceiling of USD 15,950,000 for two phases, estimated as USD 15,498,374 for Phase 2		
Total for EB Approved and pending MoU		44,297,727		
Total Cumulative:		633,557,149	530,992,493	468,516,593

[1] Unspent balance of $1,071,231 of PMTCT 1 Project has been reimbursed to UNITAID. This can be attributed to both unspent cost fluctuation buffer and savings through price reductions.

EB approved commitments

The UNITAID Executive Board (EB) has approved a total commitment ceiling of USD 633,557,149 million for projects under the HIV/AIDS portfolio. Furthermore, following the completion of Phase I of the ESTHERAID project, the EB has approved the balance (after deduction of the MoU amount for Phase 1 from the approved ceiling of USD 15,950,000) for phase II, estimated as USD 15,498,374.

An amount of USD 28,799,353 has been approved by the Board for the PMTCT 1 extension. The MoU for this project has not (at the time of writing) been signed yet and so is not reflected in the disbursement commitment total described above.

MOUs

The UNITAID EB approved commitment ceiling of USD 633,557,149 have materialized into MOUs, with a net disbursement commitment of USD 530,992,493. Fine tuning in the course of negotiation of the MOUs and subsequent implementation experience have resulted to agreed changes in targets and more refined price estimates.

Ongoing projects

UNITAID's ongoing HIV/AIDS projects address the areas of care, treatment and prevention of HIV/AIDS for children and adults as well as technical support to strengthen national health capacities. More recently the UNITAID Board approved support to improve the quality of medicines and the supply chain management in a few African countries.

In general de HIV/AIDS Projects are on track and producing the expected public health, and market impact results. For example, the PMTCT projects, with UNICEF, are implementing a detailed transition strategy for PMTCT 1 to ensure that ongoing funding is available for country programs without any interruption of treatment.

Outlook

The Second Line ARV project, implemented in partnership with CHAI, will continue through 2011. In 2009, this project supported 24 beneficiary countries. The EB10 has approved "Bridge Funding" for 2010-2011 (USD 120,410,000) to allow for a transition to alternative and more sustainable funding sources. The project's market impact on price has seen encouraging indications: the first six months of 2010 saw the entry of 5 newly eligible suppliers of second-line formulations. Seven out of nine products now have two or more SRA-approved suppliers, and in June 2010, single formulations of atazanavir (ATV) and ritonavir (RTV) were added to the Project further reducing the price of second line regimens.

For the Pediatric HIV/AIDS project, an additional budget ceiling of US$ 76,888,274 for 2010 was approved in December 2009 by EB11, and later, in January 2010, additional support to Haiti was approved (USD 1,016,132). The EB12 gave the "Green Light Status" for the *Pediatric HIV/AIDS Treatment Project Proposal* (2011-2012) up to US$83,787,650 for 2011 (EB Resolution n° 11). CHAI submitted a *Transitional Operational Plan* and a revised budget that after the review of the IEAG/PRC will be submitted to the EB13 for its consideration. According to the semi-annual report (January- June 2010), the Project is supporting 276,874 children, of which: 25,836 are new children in treatment for 2010, and 251,038 are children continuing treatment. In addition, monitoring and diagnostic tests, RUTF (read-to-use therapeutic food) for severe acute malnutrition and co-trimoxazole for prophylaxis of opportunistic infections are being provided. The March 2010 supplier selection saw the addition of 5 newly eligible suppliers and 5 new SRA approved suppliers of ARVs purchased under the Project.

Progress in the PMTCT niche has been made within main areas of intervention, thereby contributing to ultimately reaching the objectives set. All eight countries have demonstrated

an increase in uptake of HIV testing with UNICEF hitting 108% of its target for test kits being procured. Similarly there has been an increase in the percentage of pregnant women receiving ARVs in all eight countries with UNICEF hitting 120% of its target for HIV+ pregnant women receiving more efficacious ARVs for PMTCT and 135% of the target for HIV+ pregnant women receiving ARVs for their own health. There has also been a 21% decrease in the price of test kits, reduction in the prices of 4 ARVs ranging from 9 to 25%, reduction in the price of two co-trimoxazole products 28 and 35% respectively and reduction in the price of two bundles by 1 and 13%.

Funding for the PMTCT 1 (one year extension) has been approved by the Board and will enable UNICEF to work with Country Programs to secure sustainable sources of funding for ongoing PMTCT activity without treatment interruption.

The Phase 1 of the ESTHERAID project started on the 2nd of July 2009 and is now complete. Operational plans for Phase II have been drawn up and a signed MoU is imminent.

Two proposals to scale up access to viral load monitoring tests in developing countries have been submitted to UNITAID by WHO and PASCAL. After a technical review of the PRC, the proposals will be submitted to the EB13 for its consideration. An unsolicited proposal aimed at bringing to market and implementing two innovative point-of-care testing platforms developed specifically for the developing countries for early infant diagnosis and treatment monitoring has also been received and will be assessed by the ERP.

OVERVIEW OF UNITAID TB PORTFOLIO

Reported to the PSC Meeting, October 2010

TB Portfolio at a Glance

Project Title	Project Duration	EB Approved project budget ceiling in US$	MoU or Latest approved revised budget in US$	Project funds disbursed as of 01 October 2010 in US$
		Ongoing		
Project Support for Paediatric TB Project	January 2007-December 2011	11,603,952	11,288,409	9,624, 301
Project Support for First-Line Anti-TB Drugs Initiative	September 2007 - December 2011	26,841,025	26,840,725	26,840,725
EXPAND-TB Supported by UNITAID (Project Support for Narrowing the Gap: Expanding and accelerating access to diagnostics for patients at risk of multi-drug resistant tuberculosis (MDR-TB)	December 2008 - December 2013	87,612,072	87,562,000	37,553,128
MDR TB Scale-Up Initiative	July 2007-December 2012	54,046,000	54,045,321	21,565,302
MDR TB Acceleration of Access Initiative: Strategic Rotating Stockpile	November 2008-December 2011	11,457,799[2]	11,457,799	9,585,303
		EB approved and pending MoU[3]		
MDR-TB Acceleration of Access Initiative: Strategic Revolving Fund	Pending estimated start date - Q3 2010 - End of 2015	22,232,201[1]		
Project Support for Paediatric TB Project	Q42010-2011	2,207,486		
Total		216,000,535[4]	191,194,254	105,168,759[5]

[2] Original Project (EB7 Res No 3) *MDR-TB Scale-up and Acceleration of Access: 2008-2011* (US$33,690,000) consisted of 2 distinct components i) Strategic Rotating Stockpile (SRS) ii) Strategic Revolving Fund (SRF). Due to the complexity of the SRF component a decision was taken by the Secretariat and the Partners that the 1st component will be formalized into a Letter of Agreement (November 2008) prior to the 2nd Component is estimated to be signed by all Parties October 2010

[3] Project agreements to be signed by end of October 2010

[4] Total excludes US$10.3million for the GF Round 6 MDR-TB component

[5] Approximately 49% of the EB approved TB niche budget ceiling disbursed as of 1st October 2010

EB approved commitments

At present, the UNITAID Executive Board (EB) has approved a total ceiling budget of US$ 216 million for six[2] projects under the Tuberculosis portfolio. Two Legal Agreements are pending with a total monetary value of US$24,439,687.

MOUs

Five Legal Agreements have been signed, for a total budget of US$ 191 million. The Projects approved EB7 and EB12 are targeted for signature by all Parties is by the end of October 2010.

Completed project

Three of the seven projects are currently in the "sunset period"[6] of the Project lifecycle. UNITAID is currently actively engaged with the Partners in the development of a framework for the phase out of UNITAID support.

Ongoing projects

1. **Pediatric anti-TB Medicines** - *access to appropriately formulated Paediatric anti-TB drugs.* In the 58 countries approved by the Technical Review Committee, GDF still remains due to UNITAID support a unique source for the provision of quality-assured pediatric products. WHO will publish *The new Rapid Advice on Treatment of Tuberculosis in Children* in December 2010. Work has already begun by the WHO Essential Medicines Programme who have contracted Purdue University to determine what is a feasible FDCs for manufacturers, taking into consideration the amount of Pyrazinamide required. The outcome of these discussions will facilitate the formal engagement with industry in the development of the new FDCs as recommended by WHO.

A funding request for first-line drugs to treat Paediatric Tuberculosis based on the newly recommended dosage by WHO has been submitted to the UNITAID Proposal Review Committee. Pending approval by the UNITAID Proposal Review Committee this funding request may be presented at the upcoming EB13 for consideration for funding as a priority niche.

2. **First-Line anti-TB Medicines** - *Cost containment, Price reduction and increased access to First Line anti-TB drugs.* The project has facilitated the transitioning of grants to alternative funding sources[7]. In addition, the project continues to successfully maintain its short-term objective of cost containment of less than US$ 20 per treatment for a 6 month daily treatment regimen.

The Strategic Rotating Stockpile - the main objective of the 2009 no-cost extension[8] continues its operation towards achieving the goal of reduction of lead times and overall treatment costs.

The Strategic Rotating Stockpile has demonstrated its effectiveness in substantially reducing lead times. Lead time for freshly produced stock is approximately 15-19 weeks whereas the lead time for drugs on stock is approximately 4-8 weeks allowing for rapid response to urgent or emergency situations.

Without a stockpile, costs could increase for urgent and emergency orders due to the need to ship by air which can account for 20-30% of procurement costs - compared to the standard of 2-3% for sea. Another limitation that is mitigated by the stockpile is the finite manufacturing

[2] See footnote 1
[6] Estimated 23 months left for project implementation and phase out of UNITAID support
[7] 18 of the 19 countries to date
[8] Until December 2011

capacity of suppliers who may not be able to accommodate multiple urgent and standard orders at the same time. The stockpile allows urgent orders to be services without causing interruptions to standard orders.

With its proven effectiveness in reducing lead times, cost containment and responsiveness to emergency situations, it is important that the stockpile be continued beyond the current end date of the UNITAID Project Support for First-Line Anti-TB Drugs Initiative Project.

3. **MDR-TB** - *Linking Diagnostics with Medicines* In the area of second-line anti-TB UNITAID, through its Partners has, successfully linked the need to diagnose before treating.

Diagnostics (EXPAND-TB):

The overall objective of expanding access to new diagnostics technologies in countries is to enhance capacity for diagnose and enable the treatment of more patients. It is expected that 129,000 MDR-TB patients will be covered with diagnostic services and treated through the MDR-TB Acceleration of Access Initiative - Strategic Rotating Stockpile.

During the first 18 months of the project, a wide range of activities was initiated in 18 of the 27 countries including the crucial components of laboratory needs assessment and preparedness, upgrade of infrastructure, and training of staff. Technology transfer has subsequently started, paving the way for accelerated patient diagnosis and eventual routine surveillance of drug resistance at country level. The EXPAND-TB has full ownership by the Ministers of Health of the recipient countries and works on a model of best practices, learning-by-doing and optimizing resources for laboratory strengthening at country level.

At the WHO 10th Strategic and Technical Advisory Group STAG-TB) for TB meeting, the Xpert MDT/RIF technology was endorsed by the WHO STAG-TB. The STAG-TB recommends that WHO support the global update of this new technology which will diagnose patients in 100 minutes. In addition the STAG-TB recognizing the transforming potential of the Xpert MTB/RIF on the TB public health landscape acknowledged the solid evidence base to support widespread use of Xpert MTB/RIF for detection of TB and Rifampicin resistance. The WHO STAG-TB encouraged donors and funding agencies to facilitate the global uptake of Xpert MTB/RIF through the public health services or other mechanisms that explicitly promote access by the poor.

Medicines:

It is recognized that building a solid supplier base will contribute to the market dynamics within this niche. Due to the limited number of quality manufacturers of MDR-TB drugs, GDF has developed a market allocation algorithm which will be implemented by the Procurement Agent as of January 2011. It is anticipated that this will enhance market interest among suppliers as well as encourage pre-qualification of key second-line anti-TB drugs. A UNITAID initiated coordination meeting between the Global Fund, the GDF, the Green Light Committee and Partners on the EXPAND-TB supported by UNITAID project has facilitated greater coordination of activities and linkages between stakeholders within the MDR-TB niche

In addition the WHO/STB has established a Task Force on MDR-TB Scale-Up : "*Supply and Procurement Function*". A proposal for an *Advance Purchase Commitment* for key MDR-TB Drugs is currently being developed by WHO/STB. The proposal may be submitted to UNITAID for consideration to finance in 2011.

The augmentation of the Strategic Rotating Stockpile (SRS) to improve and accelerate the servicing to patients enrolled under GLC approved programmes/projects and the GF MDR-TB grantees; is successfully underway and serves to avert the risk of stock-outs. In September 2010, the Partners submitted a request for extension of the MDR-TB Acceleration of Access Initiative: Strategic Rotating Stockpile until 2015.

Outlook

The principle utility of the SRS both for first and second line anti-TB drugs may evolve based on the current market conditions. Direct investment in key areas such as the Active Pharmaceutical Ingredient and also direct engagement and negotiation with Manufacturers will be required to ensure the achievement of UNITAID investment within the TB niche.

The key challenges impact across the TB niche:

- The mapping of the API market and improving the market dynamics is crucial as this is one of the key determinants impacting on the price and availability of TB medicines
- The improvement of forecasting methods and tools
- Pro-actively encourage submissions of dossiers for drugs with few- pre-qualified suppliers

UNITAID is currently working the Partners in an attempt to mitigate these risk (specific provided in the Project updates).

OVERVIEW OF UNITAID MALARIA PORTFOLIO

Reported to the PSC Meeting, 21 October 2010

Malaria Portfolio at a Glance

Project Title	Project Duration	EB Approved Budget Ceiling in US$	MOU Amount in US$	Latest Approved Revised Budget in US$	Project Funds Disbursed to-date In US$	Notes
COMPLETED						
ACT Scale Up for Liberia and Burundi	March 2007 to 31 December 2007	1,334,755	1,334,655	1,334,655	964,402	*note a*
ONGOING						
ACT Scale Up	4 December 2007 to end of August 2011	78,887,568	65,413,057	51,659,815	36,457,859	*note b*
Accelerating Scale up of LLINs	24 February 2009 to March 2010	109,250,000	109,246,140	109,246,140	109,246,140	*note c*
Assured Artemisinin Supply System - A2S2	July 2009 to June 2011	9,280,400	9,280,400	9,280,400	9,280,400	
Affordable Medicines for Malaria - AMFm	November 2009 to April 2012	130,000,000	130,000,000	130,000,000	130,000,000	
Total		**328,752,723**	**315,274,252**	**301,521,010**	**220,948,801**	

Note-a for ACT Scale up for Liberia and Burundi: This project has been successfully completed and was officially closed in June 2008. The amount presented under the column "Project Funds Disbursed to date" is net of the project savings of US$ 370,253 which has been returned by UNICEF to the UNITAID Secretariat.

Note-b for ACT Scale Up: The Latest Approved Revised Budget as presented in this table reflects agreed project adjustments as of July 2010.

Note-c for Accelerating Scale up of LLINs: UNICEF has reported full delivery of 20 million LLINs with a total project cost of US$ 92,856,982.77. The unexpended project fund in favor of UNITAID of US$8,408,423.79 has been reimbursed to UNITAID on the 17th of August 2010.

1. EB approved commitments

To-date, the UNITAID Executive Board (EB) has approved a total commitment ceiling of USD 328.752 million for 5 projects under the malaria portfolio.

2. MOUs

The UNITAID EB approved commitment ceiling have materialized into five MOUs, with a total MOU value of US$315.274 million. Fine tuning in the course of negotiation of the MOUs and subsequent implementation experience have resulted to agreed changes in targets and more refined price estimates. As of July 2010, the sum of the revised budgets for the malaria portfolio is US$ 301.521 million. Disbursements to-date is US$ 220.948 million.

3. Completed project

As previously reported to the UNITAID Board, the project *ACT Scale up for Burundi and Liberia* has been successfully implemented and closed in 2008, having delivered the total target of 1.4 million ACT treatments.

4. Ongoing projects

UNITAID's three ongoing projects address the areas of prevention, treatment and Artemisinin Supply services. The overall progress of the project and outlook is summarized below.

a) ACT-Scale Up

For the *ACT Scale up*, the online UNICEF procurement and delivery data as of September 2010 reflected that a total of 24.07 million ACT treatments were delivered to the beneficiary countries as of July 2010 and another 4.23 million are expected to arrive in the participating countries by October 2010. Although delays in some deliveries were reported, overall data indicate that on average, ACT treatments arrived in country ahead of planned arrival date and lead times between procurement order issuance dates and arrival dates were shortened.

b) Accelerating Scale-up of Long Lasting Insecticide Treated Nets (LLINs)

The *Accelerating Scale up of LLINs* project was launched in February 2009 with a delivery target of 20 million WHOPES (WHO Pesticide Evaluation Scheme) recommended LLINs to eight beneficiary countries, namely: Angola, Congo-Brazzaville, Central African Republic, DRC, Guinea, Nigeria, Sudan, and Zimbabwe. Procurement and delivery of the 20 million LLINs to beneficiary countries was completed in January 2010 one month ahead of schedule.

The target lead-time for delivery of less than 12 weeks was achieved for 51 out of 64 (80%) of the purchase orders. Distribution of the LLINs to households has also been in good progress. As at August 2010, a total of 18.8 million LLINs (94.1%) have been distributed to households. The remaining 1.2 million LLINs will be distributed before the end of the year in Central African Republic and Nigeria.

The median price of LLINs procured through this project was US$4.36 for small LLIN 180x160x150; US$4.62 for large LLINs 190cmx180cmx150cm and US$6.21 for conical LLINs. Compared to the baseline median prices in 2007, of US$ 4.47, US$4.96 and US$7.51, the percent price reduction achieved through this project is 2.5% 6.9% and 17.3% respectively.

c) Affordable Medicines for Malaria - AMFm

Amendment and signing of the AMFm host grant scheduled to be finalized in May 2010 has been completed in most of the participating countries while the process in still ongoing in Nigeria, Uganda and Zanzibar.

Achievements of the AMFm in attaining the planned objectives are to be assessed through an independent evaluation. To facilitate the evaluation baseline and end point data will be collected through contracted firms. For the independent evaluation, a consortium led by Macro International Incorporated in collaboration with the London School of Hygiene and Tropical Medicine has been contracted in March 2010. The baseline data collection contract was awarded to three entities: Drugs for Neglected Disease *initiative* (DND*i*), Centre de Recherché pour le Développement Humain and Population Service International.

In addition to the grant amendment and the data collection and evaluation contracts, Master Supply Agreement (MSA) has been concluded with six ACT manufacturers and first line buyer undertakings have been co-signed by a total of 64 first-line buyers (61 private for profit; 2 public and 1 not-for-profit). As of the 23rd of July 9 eligible orders for 4,064,200 treatments worth US$4,401,482 had been received from Ghana (7 order) and Kenya (2 order). The first AMFm co-paid ACTs have been delivered to Kenya in August 2010.

d) Assured Artemisinin Supply Services

The A2S2 project was launched in July 2009 with a primary objective of securing 40 metric ton (MT) of artemisinin in two years. The artemisinin production through this project is additional to the 73-100

MT of artemisinin produced annually and the combined production is expected to meet the ACT need for 2010 and 2011. As of August 2010, the project has secured contracts for the production of 6 MT of artemisinin with the extractor Innovexx-Bionexx and ACT Cipla in Madagascar and Novartis and Beijing Gingko Group based in China for 10 MT. This attains 40% of the target additional artemisinin of 40MT. In addition to the concluded contracts, there are currently ongoing negotiations to secure additional 16 MT which are expected to be concluded before the end of 2010.

The time spent on the preparatory activities and negotiations to conclude contractual agreements was longer than expected. This was mainly due to the financial regulations in China that prohibit direct loan in foreign currency to artemisinin extractors that required setting-up alternative options. In the third quarter of 2010, significant progress in securing loan agreements with artemisinin extractors has been achieved, and delivery of the artemisinin and loan repayment is expected to commence in early 2011.

5. Outlook

a) ACT-Scale Up

Considerable progress has been achieved through the ACT Scale up project. However, start up deliveries in some of the Global Fund participating grants have given rise to the need for revisions to participating grants' implementation duration and delivery schedules. The UNITAID Secretariat is in discussion with the project partners to expedite the revisions.

b) Accelerating Scale-up of LLINs

The project is estimated to have contributed to increasing the household coverage with LLINs in the recipient countries by on average 18%. The LLIN price reduction attained of 2.6 to 17% is also remarkable. The service life of LLINs varies from 3-5 years depending on the conditions of use. Based on this assumption, the service period of the LLINs distributed through this project is estimated to end in the coming 2-3 years. The need to maintain and progressively increase the LLIN coverage to attain high levels therefore will be the main issue of concern if replacement and new distributions are not made according to the need. The price reduction attained through this project may not be sustained as this will mainly be governed by the market conditions. Therefore, to ensure stable market and high LLIN coverage, the need to continue mobilizing the required resource through concerted effort with other partners should be strengthened.

c) Assured Artemisinin Supply Services - A2S2

The A2S2 project is on track in terms of completing contractual agreements with Artemisinin extractors. Thus far loan agreements for 16 metric tonne (MT) of artemisinin have already been secured and a loan agreement for additional 16 MT is expected to be concluded before the end of 2010. The impact of the project on the overall supply and demand for artemisinin is likely to be influenced by the global demand for ACTs. In situations where the demand for ACTs is high, the price of artemisinin is likely to increase if the supply fails to cope-up with the need. Contrary to this, if the demand for ACT decline, business engaged in Artemisia growing and artemisinin extraction may shift their business. This scenario is also likely to create supply shortage and a potential price hike. The endeavor for semi-synthetic artemisinin and the prospects of achieving this breakthrough by the end of 2012 is likely to influence the overall picture of the market of artemisinin and ACTs.

d) Affordable medicines for malaria - AMFm

The first batches of AMFm co-paid ACTs have started arriving in participating countries. The AMFm will be evaluated through an independent mechanism one after the start of arrival of AMFm co-paid ACTs in the countries. The evaluation findings will determine the next phase of the program and the decision whether to go for global scale-up, redesign or drop the program altogether.

Although the outcomes of Phase-I of the AMFm are yet to be determined, some of the actions currently implemented are already contradicting the expectations. This is mainly related to the use of co-blistered antimalarial drugs and the lack of adequate support for Rapid Diagnostic Tests (RDTs). The use of co-blistered presentation while the same ACTs formulations are available in Fixed Dose Combinations (FDC) presentation is not an ideal approach for large scale-distribution.

The high price of malaria Rapid Diagnostic Tests (RDTs) is also likely to discourage treatment based on diagnosis. This will enhance overconsumption of ACTs as treatment will tend to be based on clinical symptoms. Therefore, factors that may potentially diminish the expected achievements of the AMFm should be prevented.

OVERVIEW OF UNITAID TRANSVERSAL PORTFOLIO

Reported to the PSC Meeting, 20 October 2010

Transversal Portfolio at a Glance

Project Title	Project Duration	EB Approved Budget Ceiling in US$	MOU Amount in US$	Latest Approved Revised Budget in US$	Project Funds Disbursed to-date In US$	Notes
Quality Assurance of Diagnostics	March 2009 to February 2013	7,500,000	7,500,000	7,500,000	1,000,000	
Prequalification of Medicines Programme	December 2006 to December 2012	47,000,000	47,000,000	47,000,000	15,000,000	
UNITAID Support to Round 6, Phase 1	21 December 2007 to June 2010	52,500,000	52,471,914	38,691,956	38,691,956	
Total		**107,000,000**	**106,971,914**	**93,191,956**	**54,691,956**	**note a**

Note a for UNITAID Support to Round 6, Phase 1: The lower budget was due to the decision of Mozambique to opt out of the project.

EB approved commitments

To-date, the UNITAID Executive Board (EB) has approved a total commitment ceiling of USD 107 million for 3 projects under the transversal portfolio.

MOUs

All the transversal projects approved by the UNITAID EB have materialized into MOUs, for which the initial total combined disbursement commitments corresponded almost fully with the EB approved budget ceiling of USD 107 million.

However, the amount of USD 13.8 million of the Global Fund Round 6 Project was held in a suspense account pending confirmation of the additionality for the ARV 2nd Line and Paediatric budgets earmarked for Mozambique. The Global Fund subsequently decided to not avail of this funding allocation and thus the MOU commitment has correspondingly decreased.

Ongoing projects

The UNITAID supported project for Medicines Prequalification is showing good progress while the progress of the Diagnostics Prequalification project has been relatively slow. Mixed results for the niches covered under the UNITAID Support for Global Fund Round 6 have been reported.

The *Prequalification of Medicines Programme* is actively providing support that would help expedite the prequalification process of medicines for HIV/AIDS, Tuberculosis and Malaria. The number of product dossier received since the start of the UNITAID support has more than doubled. Thus far 93 product dossiers have been received of which 25 (31%) products have been prequalified and evaluation of the remaining 64 (69%) dossier is in progress. In the period from January to June 2010 alone, six generic products and 1 innovator product (Norvir HA491) of which 5 for HIV/AIDS and 2 products for Tuberculosis received from

applicants in India and Germany have been prequalified. The number of prequalified Medicines Quality Control Laboratories has also increased over the reporting period.

The focus in during the project implementation period will be on hastening the prequalification process for UNITAID priority medicines and prequalification of Active Pharmaceutical Ingredient (API) and in-country sampling and testing of quality of medicines supplied by UNITIAD.

The *Quality Assurance of Diagnostics* started in March 2009. The project has completed most of the activities and processes required to initiate product dossier evaluation and prequalification. To date a total of 18 product dossier are under review and applicants of 21 other diagnostic products identified as UNITAID priority have been invited to submit their application with complete product dossier.

Some of the major achievements of the project included: completion of the Prequalification of Diagnostics Business plan for 2009-2013, setting-up of formal prioritization criteria for the evaluation of diagnostics and evaluation protocol for rapid diagnostic tests, CD4 and Virological methods of diagnosis. With the recruitment of additional staff expected to be completed before the end of 2010, the pace of implementation of the project is expected to speed up prequalification of more diagnostic products for HIV and Malaria.

The *UNITAID Support for Global Fund Round 6, Phase 1* funds the procurement of medicines for Phase 1 of Global Fund Round 6 grants. Although the project has reached official completion in June 2010, a number of participating grants have yet to achieve their full targets.

The MOU for this UNITAID project allows for Unexpended UNITAID Project Support to be applied for the purchase of drugs in Phase 2, subject to the UNITAID's assessment of the project in meeting its objectives and subsequent approval by the UNITAID Board. Although the Global Fund has initially reported that 13 out of the 43 participating grants have reached or about to reach Phase 2, and signalled the intention to request for continued participation on the project, the specification of which grants are being requested for extension is currently under discussion.

Project Update HIV niche:

Pediatric ARV
Second line ARV
PMTCT
ESTERAID

SEMI-ANNUAL REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I. Reporting Period: 1 November 2006 to 30 June 2010

II. Disease: HIV/AIDS

III. Niche: Pediatric ARV

IV. Project Name: UNITAID Funded Pediatric HIV/AIDS Treatment Project

V. Key Partner: Clinton Health Access Initiative (CHAI)

VI. Timeframe for Support: November 2006 to December 2010

VII. Start Date: 1 November 2006

VIII. Total Amount Approved: US$ 236.1 million for the period of 2006-2010:
2006-2007: US $ 35.9 million
2008: US$ 58.6 million
2009: US$ 63.7 million
2010: US$ 77.9 million

IX. Money Holder: Clinton Health Access Initiative (CHAI)

X. Procurement Agent:

- Pediatric ARV: IDA (International Dispensary Association) Foundation
- Diagnostics products and read-to-use therapeutic food (RUTF): CHAI

XI. FINANCIAL AND PROCUREMENT

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER RE
Project Agreement after the signature of the agreement 25 January 2007	US $ 2,500,000	20 Feb 2007	US $ 2,500,000	UNITAID disbursed US$ 35.9 million to CHAI in 2007 for the procurement and supply of paediatric ARVs, diagnostics, co-trimoxazole and RUTF. An amendment to the procurement project signed in August 2007 resulted in an updated disbursement schedule and timeline for submission of quarterly reports.
01 Mar 2007	US $ 1,725,000	22 June 2007	US $ 1,725,000	Disbursements for March and April 2007 were finalized after reaching agreement on the revised project budget.
01 Apr 2007	US $ 1,725,000	22 June 2007	US $ 1,725,000	
Procurement Agreement 10 days after the signature of the agreement on 25 January 2007	US $ 6,600,000	9 February 07	US $ 6,600,000	
01 Mar 2007	US $ 5,000,000	22 June 2007	US $ 5,000,000	
01 Apr 2007	US $ 4,600,000	22 June 2007	US $ 4,600,000	
01 Sep 2007	US $ 6,875,000	9 Oct 2007	US $ 6,875,000	
01 Dec 2007	US $ 6,875,000	19 Dec 2007	US $ 6,875,000	
10 Jan 2008	US $ 14,633,000	10 Jan 2008	US $ 14,633,000	
5 May 2008	US $ 28,000,000	6 May 2008	US $ 28,000,000	

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER RE
9 Aug 2008	US $ 15,297,000	24 Dec 2008	US$ 9,500,000	The actual amount disbursed was less than scheduled following the subtraction of uncommitted funds on hand (US$6,624,316), and interest earned during the year (US$743,571).
15 Mar 2009	US$ 31,865,000	9 Apr 2009	US$ 24,497,113	The actual amount disbursed was less than scheduled following the subtraction of uncommitted funds on hand US$6,624,316 and interest earned during the year US$743,571.
7 Sep 2009	US$ 31,865,000	15 Oct 2009	US$ 33,433,635	CHAI miscalculated the total of 2008 uncommitted funds in the April request for disbursement which resulted in an under disbursement of US$ 1,568.365.
5 Feb 2010	US$ 38,490,779	31 March 2010	US$ 37,779,000	The actual carry over funds as reported by the partner is US$1,190.485 as opposed to the estimated US$957,249 that was used for estimating the remittance schedule. Taking this into account, the amount requested is US$37,779,000, which is lower than the amount that appears in the 2010 Agreement remittance schedule.
3 September 2010	US$ 38,490,778	Pending approval		The disbursement request was received on 15 September and is currently being processed by the Secretariat. The partner has requested US$35,570,000.
TOTAL	**US$234,541,557**	**TOTAL AMOUNT DISBURSED: US$ 183,742,748** **PERCENT DISBURSED: 78%**		

REPORTING SCHEDULE **(report type, period covered, date)**		**REPORTS RECEIVED** **(report type, period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
Interim Progress Report covering Nov 2006 - Apr 2007	17 May 2007	17 May 2007	CHAI submitted interim activity and financial reports covering Nov 2006 - Apr 2007, and adjustments submitted in 5 Jun 2007	The final report was considered satisfactory and approved by the UNITAID Secretariat. This was followed by the disbursement of US$ 13,050,000 as provided for in the project and procurement agreements.
Interim activity and financial reports, covering May-July 2007	20 Aug 2007	20 Aug 2007	CHAI submitted interim activity and financial reports covering May-July 2007	After the approval of this report, it was approved the disbursement of US$ 6,875,000, on 9 Oct 2007 which included US$ 200,000 of procurement support to CHAI.
Interim activity and financial reports, covering August-October 2007	15 Nov 2007	15 Nov 2007	CHAI submitted interim activity and financial reports covering Aug-Oct 2007	The approval of this report triggered the final 2007 disbursement of US$ 6,875,000 on 19 December 2007, which included US$ 200,000 of procurement support to CHAI.
Annual Report covering Nov2006-Dec 2007	15 April 2008	15 April 2008	CHAI submitted an Annual Report covering Nov 2006-Dec 2007	
Interim activity and financial reports, covering January-March 2008	15 April 2008	15 April 2008	CHAI submitted interim activity and financial reports covering January-March	The approval of this report triggered the disbursement of US$ 28,000,000 on 6 May 2008

REPORTING SCHEDULE **(report type, period covered, date)**		**REPORTS RECEIVED** **(report type, period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
			2008	
Interim activity and financial reports, covering April-June 2008	19 July 2008	31 July 2008	CHAI submitted interim activity and financial reports covering April-June 2008	The approval of this report would have triggered the disbursement of US$ 15,297,000. However, based on disbursements to date (83% of the budget) and spending to date (only 2 of the 4 planned quarterly orders were placed), CHAI did not request for a disbursement.
Interim activity and financial reports, covering July-Sept 2008	15 Oct 2008	First Submitted 28 Oct 2008, then revised and re-submitted 25 Nov 08	CHAI submitted interim activity and financial reports covering July - Sept 2008	The approval of this report and request triggered the disbursement of US$9,500,000 in December 2008 after taking into account cash on hand. This was the final disbursement of the 2008 budget.
Interim activity and financial reports, covering Oct-Dec 2008	15 Jan 2009			The activities for this period were covered in the Annual Report
Annual Report 1 Jan 2008 to 31 Dec 2008	15 April 2009	1 May 2009	CHAI submitted an Annual Report covering January 2008-December 2008	The approval of this report triggered the disbursement of US$24,497,113 as the first tranche of the 2009 budget.
Semi-Annual Report 1 Jan 2009 to 30 Jun 2009	31 Aug 2009	22 Sept 2009		The approval of this report triggered the disbursement of US$33,433,635 as the second tranche of the 2009 budget.

REPORTING SCHEDULE **(report type, period covered, date)**		**REPORTS RECEIVED** **(report type, period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
Annual Report 1 Jan 2009 to 31 Dec 2009	15 April 2010	26 May 2010	CHAI submitted a Semi-Annual Report covering January 2009-December 2009	
Semi-Annual Report January 1 2010-30 June 2010	13 Sep 2010	13 Sep 2010	CHAI submitted a Semi-Annual Report covering January 2010-June 2010	The approval of this report would trigger the 2nd disbursement of the 2010 budget.

XII. PROJECT PROGRESS

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate)		YEARLY TARGETS (additional targets funded by UNITAID)				ACTUAL TARGETS REACHED TO DATE[9]	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	**Year**	**2007**	**2008**	**2009**	**2010**		
Scaling up the access to Paediatric ARVs to reach children in 40 countries	78,135	2006	140,000 100,000 new treatments; and 40,000 continued treatments	232,000 cumulative 95,000 new treatments; and 137,000 continued treatments	297,000 cumulative 65,025 new treatments; and 232,000 continued treatments	330,822 cumulative 70,070 new treatments and 260,752 continued treatments	276,874 cumulative (June 2010) 25,836 new treatments (2010); and 251,038 continued treatments	33 beneficiaries' countries have access to FDCs. $7.6 million have been spent on FDC purchases in the first half of budget year 2010.
Achieve price reductions of ARVs and diagnostics								**ARVs**: A supplier selection process in March 2010 price reductions ranging from 2-10% from 2009 prices resulting in an overall price reduction of up to 80% on leading paediatric regimens in low income countries since the start of the project.

[9] Please note that targets are yearly and hence may not always be reported on a semi-annual basis.

					Diagnostics: Current CHAI pricing starts at about $7.00per DNA PCR test, significantly below the benchmark of $18.00 per test.
Decrease drug delivery lead time					Cumulative weighted average lead time (number of days between the date of the purchase order and the date of invoice) for 2010 pediatric ARVs manufacturers: Abbott: 62 Strides: 64 Macleods: 66 Cipla Ltd: 77 Hetero: 78 Boehringer: 90 Aurobindo: 110 Merck: 120 BMS: 123 Matrix: 150 GSK: 210 The weighted average by number of purchase orders of the above manufacturer lead times is 104 days, which leaves significant room for improvement to the target mean of 84 days. In some instances, lead times are longer than the target because of the recipient country's requested delivery date.
Increase the number of					During the Reporting Period, there were an additional 12 new

quality manufacturers and products, and in particular, of fixed dose combinations (FDCs)					stringent regulatory authorities (SRA) approvals of UNITAID-funded ARVs. For example, the March 2010 supplier selection process saw the addition of five newly eligible suppliers and five new SRA approved suppliers of ARVs purchased under the Project.

XIII. OVERALL ASSESSMENT OF PERFORMANCE

Objectives
The objectives of the 2010 Project are:

(i) To scale up the access to Paediatric ARVs and related key commodities to increase the number of patients receiving treatment for HIV/AIDS in developing countries;

(ii) Influence market dynamics to achieve price reductions to increase the affordability of critical quality products;

(iii) Stimulate an increase in the number of quality assured manufacturers and products;

(iv) Decrease product delivery lead times;

(v) Encourage prequalification of approved manufacturers and products; and

(vi) Apply appropriate procurement strategies to develop a healthy market that favours competition and sustainability, with reductions in prices.

Availability: New suppliers are providing more adapted paediatric formulations, including FDCs.

Pricing. As of April 2010, ARV prices have been reduced cumulatively, from 2006 levels, by up to 80% in low-income countries. A price list is made available to the public through UNITAID website, and the WHO Global Price Reporting Mechanism (GPRM) website. Price reductions ranging from 2%-10% compared to 2009 prices were achieved in a supplier selection process carried out in March 2010.

Timeliness of deliveries. According to the 2010 Semi-Annual report, lead times for ARV deliveries in country vary and on average the weighted average mean of manufacturer lead times was 104day. In some instances, lead times are longer than the target because of the recipient country's requested delivery date. Nonetheless, the wide variability of lead times across manufacturers creates challenges in managing the supply chain.

Quality assurance. ARVs are procured under UNITAID's quality assurance criteria, which prioritizes prequalified products and includes at a minimum, GMP (Good Manufacturing Practices) standards, and the submission of a complete dossier for prequalification. Co-trimoxazole meets UNITAID quality assurance requirements - i.e. these are produced in an international GMP compliant site. Diagnostic and monitoring tests and RUTF also meet UNITAID's specific quality assurance criteria for these products. IDA conducts quality assurance and control in three manners: (1) laboratory retests; (2) pre-shipment inspections (PSI); and (3) dossier evaluations. The frequency of testing will depend on the regulatory status of the product. For generic suppliers, in 2010, 20% of batches were tested for products that have been WHO-prequalified or FDA-approved, and 100% of batches were tested for all other products. In June 2010, CHAI signed an agreement with Abbott, the largest branded supplier to the Second-Line Project, covering re-testing procedures. According to the agreement, randomly assigned batches of Aluvia (LPV/r) 200/50mg will be tested monthly at a third party laboratory. It was also conducted some quality control on orders placed with suppliers prior to IDA assuming procurement responsibilities, and the delivery and testing of these orders are completed.

Number of Children on Treatment. According to the semi-annual report (January- June 2010), the Project is supporting 276,874 children, of which: 25,836 are new children in treatment for 2010, and 251,038 are children continuing treatment. In addition, monitoring and diagnostic tests, RUTF for severe acute malnutrition and co-trimoxazole for prophylaxis of opportunistic infections are being provided.

To date, d4T and AZT-based paediatric FDCs (both dual and triple) have been ordered for 33 beneficiaries' countries. In 2010, particular progress with regards to FDCs was reported in Haiti and China:

- Upon adding Haiti to the Project in 2010, paediatric FDCs was procured on behalf of Haiti for the first time; and
- After years of advocacy, the government of China began procuring FDCs. FDC orders for China will be placed during the second half of 2010.

XIV. PLANNED CHANGES IN THE PROJECT, IF ANY

While reports to date indicate some progress regarding transition, key areas are also noted where additional support will be needed to ensure that transition is achieved. According to CHAI's report the following steps had been taken:

(i) Conducting workshops for program managers with a focus on in-depth technical support and information exchange around transition;

(ii) Identifying priority areas within each country's selected criteria, where there is a risk that children would fall off treatment or critical services would stop without UNITAID support in 2011;
(iii) Developing additional tools to support teams in transferring technical capacity and management responsibilities to partners, such as an audit tool for sample transport networks.

XV. ISSUES AND/OR LESSONS LEARNT

Positioning to Achieve Program Objectives: By June 2010, the Project has achieved approximately 37% of the 2010 target of 70,000 patients. The implementing partner remains confident that the specific goals of the program for 2010 relating to market impact will be met, with new price reductions achieved and newly eligible and SRA-approved suppliers joining the market in 2010.

Transition to Procurement Agent: As of 1 September 2009, IDA Foundation assumed responsibilities for procurement of pediatric ARVs and opportunist infection drugs. CHAI recently completed its first year of partnership with IDA and will soon complete its 5th order cycle together.

Product Quality Concerns: In May 2010, India registered concerns regarding one product – Matrix's pediatric AZT FDC. Broken tablets of AZT+3TC+NVP 60/30/50mg were discovered upon opening select bottles. Matrix's dispersible pediatric FDC, AZT+3TC+NVP 60/30/50mg, was WHO prequalified in Q4 2009. CHAI has been procuring this product since September 2008 and has distributed over 700K packs to 28 countries without any issues. This was the first batch delivered to India and the bottles were being stored at 35°-40°C, well above the recommended storage temperature of less than 30°C.

This incident is classified as "Class 3 Minor", as defined in *CHAI's Drug Quality Control Incident Management Policy*, acknowledged by UNITAID and attached to the 2010 Pediatrics Procurement Agreement. CHAI took the following steps:

- To ensure that patients know not to take broken pills, CHAI asked India's National AIDS Control Organisation (NACO) to replace broken pills prior to dispensing pediatric AZT-FDCs to patients. Sites in India were reminded to store the product under the appropriate storage conditions (less than 30°C). CHAI's India team also asked patients to return any broken pills to the clinic in order to assess if breakage is an ongoing issue.

- Upon follow up with Matrix, they noted that broken tablets were reported in 4-5 bottles intended for Thailand. Matrix confirmed that they do not use cotton in packaging their product. In addition, Matrix found a few broken tablets in the reserve samples of batch number 1022502. Matrix's response to the situation was that broken tablets are not unexpected due to the fact that the tablets are uncoated. Matrix also claimed that broken tablets could result from improper handling during transit. However, CHAI noted that the reserve samples, which presumably have been handled properly, also contained broken tablets and it is waiting response from Matrix regarding their limits for minor and major tablet

defects and the number of broken tablets found in the reserve samples. They were also asked to check reserve samples from three other batches for breakage.

- The tablets breaking in reserve samples at Matrix imply that batch number 1022502 is susceptible to breakage. CHAI will not procure any additional quantities of batch number 1022502. Any bottles from this batch that are still in the field will be distributed to patients once broken tablets are removed from the bottles.

- CHAI is considering requesting that Matrix use more appropriate packaging (cotton) to limit breakage. Furthermore, friability testing was added to the test pattern for this product going forward. With input from Matrix, CHAI has set a limit for friability on this formulation.

Transition: The current economic environment and the global health financing architecture — in which commodity funding is typically concentrated between 1-2 funding sources and where gaps between grants can lead to funding shortfalls —, are factors that are limiting the possibilities of some countries, such as Uganda, Zambia and Zimbabwe, to transition to other donors. Other factors, including rapid scale-up and recent guideline revisions to put patients on treatment earlier, add pressure to country budgets. In light of these issues, the transition to other funding sources this year may be problematic for some countries. Some countries have not yet secured alternative funding for commodities and will rely on Global Fund Round 10 to do so, the outcome of which is still uncertain. Taking into consideration these resources constraints and other issues, the EB12 gave the "Green Light Status" for the *Pediatric HIV/AIDS Treatment Project Proposal*, extension for 2011-2012 up to US$83,787,650 for 2011.

Partner Contribution and Collaboration: The Secretariat has been supporting the coordination of the transition with CHAI and major donors, including in the Coordinated Procurement Planning (CPP) initiative, which includes the Global Fund, PEPFAR, WHO, UNICEF, UNAIDS and World Bank. The CPP has facilitated the collection and sharing of information to allow countries and donors to assess the risk of treatment interruption due to gaps or delays in international funding. CHAI has been invited and contributed with the sharing of data collected at the local level. This mechanism has been useful to improve planning for the transition among donors at the central level.

CHAI global teams have been supporting countries in shaping work-plans and troubleshooting areas that present particular challenges for transition. The vast majority of the programmatic work is transitioning to government partners, with overall coordination from the national HIV/AIDS coordinating body in-country. Where governments do not have sufficient funds to support programming on their own, activities have frequently been written into Global Fund proposals. While the first choice of transition partner is always the national government, the implementing partner has also pursued other transition sources in cases where other partners play an integral role in technical support to the national program. Some of the examples are: transitioning procurement and supply chain to Supply Chain Management System (SCMS) — a PEPFAR implementing partner —, where SCMS is the lead partner in commodity management; and transitioning National Reference Lab programmatic support to the US Centers for Disease Control and Prevention (CDC), where CDC plays a lead role in laboratory support.

SEMI-ANNUAL REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I. **Reporting Period**: 8 May 2007 to 30 2010

II. **Disease:** HIV/AIDS

III. **Niche:** Second-Line Adult ARV

IV. **Project Name**: UNITAID-CHAI Second-Line HIV/AIDS Project

V. **Key Partner:** Clinton Health Access Initiative (CHAI).

VI. **Timeframe for Support:** 4 May 2007 to 30 September 2011

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VII. **Start Date:** 4 May 2007

VIII. **Total Amount Approved: USD 305,799,000** (ceiling project budget for expenditures through September 2011)

2007: USD 45,000,000
2008: USD 64.400,000
2009: USD 75,989,000
2010-2011: US$ 120,410,000 (Q4 2009-Q3 2011)

IX. **Money Holder:** Clinton Health Access Initiative (CHAI)

X. **Procurement Agent:** IDA (International Dispensary Association) Foundation.

XI. FINANCIAL AND PROCUREMENT

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
After the signature of the agreement (which was on 4 May 2007)	US$ 16,200,000	18 May 2007	US$ 16,200,000	
1 July 2007	US$ 19,700,000	6 August 2007	US$ 19,700,000	In 2007 UNITAID disbursed US$ 35.9 million, of the US$ 45 million approved by the Board, for the procurement of Second-line ARVs.
17 March 2008	US$ 18,926,752	17 March 2008	US$ 18,926,752	Disbursement processed as scheduled
5 June 2008	US$ 31,298,137	5 June 2008	US$ 31,298,137	Disbursement processed as scheduled
22 December 2008	US$ 37,995,000	22 Dec 2008	US$ 37,995,000	Disbursement processed as scheduled
30 May 2009	US$ 21,348,149	11 June 2009	US $21,348,149	In addition to this amount, a carry over of US$ $14,059,851 was added to the Project budget as the result of: 1) Interest earned in 2008: $ 909,843 2) Uncommitted 2008 Funds: $13,150,008
November 2009	US$ 5,695,000	15 Dec 2009	US$ 5,695,000	
15 March 2010	US$ 33,124,206	14 April 2010	US$ 33,124,206	
31 August 2010	US$39,682,794	6 October 2010	US$ 28,000,000	For the 2010 Project UNITAID has approved a ceiling budget of US$78,502,000 which is inclusive of US$9,719,030 being carried over from 2009. The first disbursement of US$5,695,000 was made in Dec 2009, and the remainder of US$63,087,970 was scheduled to be disbursed in two installments: in 26 February, and in 31 August 2010. The amount of the third installment could be up to US$39,682,794, but the partner requested US$ 28,005,703.
TOTAL SCHEDULED	**US$ 223,970,038**	**TOTAL DISBURSED:**	**US$ 212,298,650**	
		PERCENT DISBURSED: 94%		

REPORTING SCHEDULE **(report type, period covered, date)**		**REPORTS RECEIVED** **(report type, period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
Interim Progress Report	15 June 2007	Interim Progress Report for May-June 2007	4 July 2007	The final report was considered satisfactory and approved by the secretariat, which triggered the second disbursement of US$ 19.7 million in August 2007.
Interim activity and financial reports	15 September 2007	15 Nov 2007, covering July-October 2007	Activity and Financial reports	The postponement of the submission date of the report was due to a request from CHAI, to which UNITAID Secretariat agreed. The report was considered satisfactory.
Interim activity and financial report	15 Dec 2007	19 Feb 2008, covering Nov 2007-Jan 2008	Activity and Financial reports	The report was considered satisfactory and approved by the Secretariat, which triggered the disbursement of US$ 18.9 million in March 2008. A disbursement prior to March 2008 was not necessary due to the carry-over of uncommitted funds from 2007.
Semi-Annual Activity and Financial Report	5 June 2008	22 May 2008, covering Feb-April 2009	Semi-Annual Report	The report was considered satisfactory and approved by the Secretariat, which triggered the disbursement of US$ 31,298,137 in June 2008 which was the second and last disbursement of the 2008 budget.
Annual Report	10 March 2009	10 March 2009 (Jan-Dec 2008)	Annual Report with reconciled budget	
Semi-Annual Report	31 July 2009	20 Aug 2009 (Jan-June 2009)	Semi-Annual Report	The delay in the report submission was due to the finalization of the revised price reporting methodology.
Annual Report	31 Dec 2009	3 May 2010 (Jan-Dec 2009)	Annual Report	
Semi-Annual Activity and Financial Report	30 July 2010	3 Aug 2010 (Jan-June 2010)	Semi-Annual Report	

XII. PROJECT PROGRESS

KEY OBJECTIVES / ACTIVITIES	BASELINE (if appropriate) Before UNITAID funding		CUMULATIVE YEARLY TARGETS				ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	**Year**	**2007**	**2008**	**2009**	**2010 (as of June 2010)**		
Scale up of second line treatments			40,000	100,000	67,490	62,967	85,888	Actual patient numbers are not apparently recorded in all countries as many countries do not distinguish between adults on different regimens. CHAI estimates the number of patient treated with UNITAID-funded commodities based on commodities ordered, stock levels and the pace and size of replacement orders.
Influence market dynamics to further reduce the price of priority second line ARV regimens	US$ 664	2008			US$ 579 (price achieved for TDF/3tc+ LPV/r)		US$ 396 (price achieved for TDF/3tc+ATV /r)	- No specific target was set for prices, but CHAI expected to achieve US$ 500 by the end of the year. - In June 2010, single formulations of atazanavir and ritonavir were added to the Project and first orders are being placed. - The introduction of atazanavir and ritonavir allowed for further price reduction in the regimen, which is now available for US$ 396 pppy, or US$ 104 pppy below the expected price.
Scale up first line treatment in three countries				80,000	49,834	48,000	39,900	Tenofovir formulations are being provided to Uganda and Zambia in 2009 and 2010 for first-line regimens. Namibia received support for tenofovir formulations for first line therapy only until 2008, when this support was transitioned to alternative funding sources

XIII. OVERALL ASSESSMENT OF PERFORMANCE

Project objectives. (i) to scale up the access to Second-Line ARVs to increase the number of patients receiving treatment for HIV/AIDS in developing countries; (ii) influence market dynamics to achieve price reductions to increase the affordability of critical quality products; (iii) stimulate an increase in the number of quality assured manufacturers and products; (iv) decrease product delivery lead times; (v) encourage prequalification of approved manufacturers and products; and (vi) apply appropriate procurement strategies to develop a healthy market that favors competition and sustainability, with reductions in prices.

Availability: The first six months of 2010 saw the entry of 5 newly eligible suppliers of second-line formulations. Seven out of nine products now have 2 or more SRA-approved suppliers.

Pricing. In 2009, the lowest price of a prioritized second line ARV regimen was US$ 579 (TDF/3TC+LPV/r) for low income countries. The lowest price in 2010 decreased below the US$ 400 with the introduction of atazanavir e ritonavir and are regimen is now available for US$ 396 (TDF/3TC+ATV/r) pppy in low income countries.

Quality: (TDF/3TC+ATV/r). IDA conducts quality assurance and control in three manners: (1) laboratory retests, (2) pre-shipment inspections (PSI) and (3) dossier evaluations. The frequency of testing will depend on the regulatory status of the product. For generic suppliers, in 2010, 20% of batches were tested for products that have been WHO-prequalified or FDA-approved, and 100% of batches were tested for all other products. In 2010, CHAI will begin testing branded suppliers in addition to generic suppliers. In June 2010, an agreement was signed with Abbott, CHAI's largest branded supplier to the Second-Line Project, covering re-testing procedures. Randomly assigned batches of Aluvia (LPV/r) 200/50mg will be tested monthly at a third party laboratory, to meet CHAI's requirement of 20% batch testing. In May 2010 CHAI investigated one incidence in Zambia of a patient who experienced increased virological levels after switching from the Abbott/Gilead version of LPV/r+TDF/FTC to the same versions made by Matrix during Directly Observed Therapy (a process whereby a physician gives the patient his medicine every night and assures 100% perfect adherence). A full administrative and laboratory investigation was conducted and the batches used to treat the patient were found to meet all specifications. CHAI only supplied these batches to Zambia. CHAI and IDA continue to monitor the situation for further problems.

Delivery: According to the Semi-Annual Report (January-June 2010) the estimated number of patients receiving second-line ARVs by June 2010 were 62,967; and the estimated number of patients receiving first-line ARVs was 48,000. Initially, the treatment target for the Project involved only second line treatments and it was expected that 40,000 people would be receiving ARVs. Later in 2008 the Project also allowed for the supply of tenofovir formulations for first line regimens as recommended by WHO. This updated recommendation from WHO has been incorporated in the national guidelines of three participating countries (Namibia, Uganda and Zambia). Namibia received support until 2008 — when this support was transitioned to alternative funding sources — and since then only Uganda and Zambia have been receiving first line treatment.

XIV. PLANNED CHANGES IN THE PROJECT, if any

No major changes are anticipated for 2010. A mid-year review is being scheduled and it will include planning for the 2011 project amendment.

XV. ISSUES AND/OR LESSONS LEARNT

a. Transition to other Donors. As previously noted, some countries — such as Cambodia, Cameron, Haiti, Nigeria, and Uganda — have not yet secured alternative funding for second-line commodities and will rely on Global Fund Round 10 to do so (the outcome of which is uncertain). However, even among the countries that have secured alternative funding — such as Mali —, some have noted that the funding they will use to procure Second-Line ARVs has not been disbursed in a timely fashion. UNITAID has been coordinating the transition, particularly with CHAI, Global Fund and PEPFAR to exchange information on the transition and follow up on the countries which represent a higher risk.

b. Introduction of ATV/r: Atazanavir/ritonavir (ATV/r) is an attractive protease inhibitor (PI) option because the formulation is clinically comparable to, if not slightly better than, lopinavir/ritonavir (LPV/r) and is expected to be 40-60% less expensive than LPV/r in the long-term. ATV/r is also preferable for patient adherence since it is dosed with one pill once daily, versus LPV/r, which is dosed with two pills twice daily. For these reasons, it is an important goal of the Project to facilitate the introduction and scale-up of ATV/r before the Project comes to a close. This support will cover the three formulations: a) the heat-stable ATV/r FDC; b) the co-pack of TDF/3TC + ATV single + RTV heat-stable single; and c) the single formulations of ATV and heat-stable RTV. Currently only the single formulations are available.

Three manufacturers of ATV and one of RTV submitted a dossier for pre-qualification. The Expert Review Panel (ERP) assessed three of them, and approved them for procurement. An ATV manufacturer opted to submit a dossier during the forth ERP session for the Global Fund, and its outcome is pending. First orders for both formulations have been placed in September.

c. Accuracy of Forecasts and Patient Data. Since the beginning of the Project, CHAI has experienced difficulty in obtaining forecasts and actual patient figures with a high degree of accuracy from some beneficiary countries, due in large part to the fact that most beneficiary counties lack formal systems to track patient and drug consumption data. In addition, there is often deficient communication between the antiretroviral therapy (ART) centers that prescribe the treatment and the central medical stores that place order requisitions with CHAI, making it difficult to calculate consumption data and create accurate forecasts at the central level. A third difficulty in forecasting that is specific to second-line ARVs is the uncertainty surrounding the actual rates of migration from first-line to second-line. This uncertainty is driven by the fact that 1) second-line programs are still relatively new in many countries, 2) historical migration data is generally not available, and 3) many countries are experiencing difficulty diagnosing treatment failure in the absence of viral load diagnostic capabilities. Efforts to improve forecasting in the areas of CHAI expertise have been made

through involvement in quantification exercises in most countries; work with the Supply Chain Management System (SCMS) to harmonize forecasting activities; strengthening of efforts to train procurement analysts and directly support in-country forecasting; improvements to its ARV forecasting tool; and centrally, seeking to conduct high-level checks of all forecasts and order quantities to ensure consistency with existing patient estimates and reasonable second-line migration rates.

SEMI-ANNUAL REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I.	**Reporting Period:**	1 Jan 2009 - 31 Dec 2009[10] ; 1 June 2010 - 31 May 2010
II.	**Disease:**	HIV/AIDS
III.	**Niche:**	Prevention of Mother to Child Transmission of HIV (PMTCT)
IV.	**Project Name**	**1st PMTCT Component[11]:** Acceleration of Prevention of Mother-to-Child Transmission (PMTCT) and Scale-up of Linkages to Paediatric HIV Care and Treatment
V.	**Key Partners:**	United Nations Children's Fund (UNICEF) and World Health Organization (WHO)
VI.	**Timeframe for Support:**	**PMTCT 1:** 10 December 2007 to June 2010 approximately **PMTCT 1 extension:** June 2010 to June 2011
VII.	**Start Date:**	Dec 2007
VIII.	***Total Amount Approved*:**	*US$ 20 838 432 (PMTCT 1)* *US$ 28,799,353 (PMTCT 1 extension)* **US$ 49,637,785** (combined total)
IX.	**Money Holder:**	UNICEF
X.	**Procurement Agent:**	UNICEF

[10] PMTCT 1, Second Annual Report February 2010
[11] Eight (8) beneficiary countries

XI. FINANCIAL AND PROCUREMENT[12]

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount)		REASONS FOR ANY DEVIATION AND/OR ANY OTH
1st disbursement within 10 days of 10 December 2007 (last signature date of MoA)	US $ 6,475,722	26 Dec 2007	US $ 6,475,721	Disbursement took place nine working days after receipt of the signed MoA from the last partner to sign.
2nd disbursement15 October, 2008	US $ 7,262,248	8 Jan 2009	US $ 7,262,247	Disbursement was dependent on approval of the 1st Interim Progress Report, submitted to UNITAID on July 15th. The Interim Progress Report was approved only following clarifications received from UNICEF. The delay in disbursement was due to clarifications needed on the report and delays in internal financial processes.
3rd disbursement 15 Apr 2009	US $ 7,100,452	1 July 2009	US $ 7,100,464	Disbursement was dependent on approval of the 1st Annual Progress Report, submitted to UNITAID on February 15th. The Annual Report was approved only following clarifications received from UNICEF. The delay in disbursement was due to clarifications needed on the report and delays in processing by UNITAID Finance.
		Total	**US$20,838,432**[13]	Unspent balance of $1,071,231 has been reimbursed to UNITAID. This can be attributed to both unspent cost fluctuation buffer and savings through price reductions.
		% Disbursed	100%	

[12] Note that at the time of writing this report, PMTCT 1 Extension project plan (including the disbursement schedule) had not been drawn up yet.
[13] The Project budget as per MoU was US$20,838,432, which is within the ceiling amount of the Board Resolution at US$20,893,506.

REPORTING SCHEDULE **(report type, period covered, date)**		**REPORTS RECEIVED** **(report type, period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
1st Interim Progress Report	15 Jul 2008	July 15th 2008	From Dec 26th 2007 until May 31st 2008	Request for clarification was made by UNITAID on August 27th. UNICEF provided answers to the questions posed on September 19th, 2008. With the additional clarifications provided, and on the condition that detailed information on the Mother-and-Baby Pack be provided as part of the development of the Extension and that the M&E issues be addressed as part of this process, UNITAID approved the report.
1st Annual Programmatic, Procurement and Financial Report	15 Feb 2009	15 Feb 2009	From Jan 1st 2008 until December 31st 2008	The Report was submitted in a timely manner. Clarifications were requested and subsequently provided.
2nd Interim Progress Report	15 Aug 2009	26 Aug 2009	From January 1st until June 30th 2009	The partners requested an extension of the submission time. This was granted. Clarifications on the report have been requested.
2nd Annual Programmatic, Procurement and Financial Report	15 Feb 2010	15 Feb 2010	Jan 1 2009-Dec 31 2009	The report was submitted on time as per the schedule.
Final Project and Financial Report	90 days after settlement of all obligations (target date June 2010)	N/A	N/A	

XII. PROJECT PROGRESS

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate) Before UNITAID funding		CUMULATIVE YEARLY TARGETS			ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year	2007	2008	2009		
Accelerate the scale-up of provider-initiated HIV testing and counseling in antenatal, maternity and postpartum services		2007	The 2-year Project is for 2008-2009 (inclusive).	761,021 women tested	1,701,436 women tested	1,851,049 test kits procured by UNITAID funds for screening and confirmation of HIV	All eight countries demonstrated an increased uptake of HIV testing among pregnant women between 2007 and 2008, on average from 14% in 2007 to 21% in 2008. With the exception of India, as its strategy is not to test all women because of its HIV epidemic typology, the testing rate in pregnant women for the seven remaining countries was 50%. As of June 2009, more than 70% of antenatal care (ANC) services in Rwanda, Tanzania and Zambia; 80% of ANC services in Burkina and Cameroon and over 90% of ANC facilities in Malawi were providing HIV testing and ARVs for PMTCT.
Reduce the proportion of infants born with HIV through the		2007		51,303 HIV+ pregnant women receiving	168,484 HIV+ pregnant women receiving	202,629 HIV+ pregnant received ARVs for PMTCT	The percentage of pregnant women receiving ARVs in the eight countries increased by 20% between 2007 and 2008. In Malawi, Rwanda and Tanzania all proportionately have more

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate) Before UNITAID funding		CUMULATIVE YEARLY TARGETS			ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
provision of more efficacious ARV regimens to women				more efficacious ARVs for PMTCT	more efficacious ARVs for PMTCT		HIV positive pregnant women receiving ARVs than the global average. Cote d'Ivoire demonstrated significant progress in expansion of maternal ARV coverage from 12% in 2007 to 34% in 2008. Further, all PMTCT sites in Burkina Faso, Cote d'Ivoire and Rwanda are providing more efficacious regimens for PMTCT.
Accelerate early access of young HIV-infected infants to paediatric ART treatment through optimized identification strategies, such as Early Infant Diagnosis (EID)		2007		33,715 HIV-exposed infants accessing PCR testing at 6 weeks	107,712 HIV-exposed infants accessing PCR testing at 6 weeks	2009: 37,632 HIV-exposed infants received PCR-test	The reduced quantity of PCR testing (relative to projections) was a result of improved coordination and planning at a country level among in-country partners.
Reduce morbidity and mortality among HIV-infected pregnant		2007		Co-trimoxazole to 28,231 HIV+women	Co-trimoxazole to 99,466 HIV+ mothers	2009: Co-trimoxazole to 99,775 HIV+ mothers	

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate) Before UNITAID funding		CUMULATIVE YEARLY TARGETS			ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
women, mothers and their infants though the provision of co-trimoxazole prophylaxis for the prevention of opportunistic infections.				24,850 HIV-exposed infants receiving co-trimoxazole at 3 months if PCR-tested 19,652 HIV-exposed infants receiving co-trimoxazole at 2years	71,563 HIV-exposed infants receiving co-trimoxazole at 3 months if PCR-tested 51,511 HIV-exposed infants receiving co-trimoxazole at 2years	56,641 HIV-exposed infants received co-trimoxazole at 3 months 48,864 HIV-exposed infants received co-trimoxazole at 2 years	
Increase access to ART for eligible HIV-infected women.		2007		ART to 5,972 HIV+ pregnant women	ART to 23,062 HIV+ pregnant women	31,253 HIV + pregnant women given ART	All the countries are increasingly providing more efficacious regimens to pregnant women living with HIV; in Rwanda it is widely acknowledged that UNITAID funded commodities were key in shifting PMTCT programs from single-dose to more efficacious ARV regimens. Similarly, UNITAID funding support has accelerated the transition from single-dose to combinations regimens in Malawi. By the end of

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate) Before UNITAID funding		CUMULATIVE YEARLY TARGETS			ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
							2008, more than 99% of services were offering single-dose NVP only, while by the end of ,Q2 2009 20% of the PMTCT sites were providing combination regimens.
Achieve continuous supply of suitable, high-quality PMTCT medicines, diagnostics and other commodities at the best possible price and facilitate price reduction.				1 new product suitable for use in PMTCT pre-qualified by WHO	2 new products suitable for use in PMTCT pre-qualified by WHO	19 sources of Pediatric ARVs obtained necessary approvals for prequalification (WHO and/or FDA-approved). The average price paid per Rapid Diagnostic Test has dropped by 14%. These savings are attributed to the pricing of the Determine HIV test kit, the RDT, with the highest volumes procured under the PMTCT Initiative. The reductions in ARV prices ranged from 1 to 21% in select fixed done combinations required for maternal interventions. It is important to highlight the price trend in Nervirapine 200mg, Zidovudine 300mg and Zidovudine 300mg+Lamivudine 150mg tablets considering that the bulk of these products have been supplied in blister packs. While such presentation is more	The progress towards price reduction is especially significant for those bundles containing reagents and consumables for CD4, PCR and DBS collection where volume discounts have yielded continued savings from Year 1 into Year 2. The reason for the increase in the price of co-trimoxazole was that there was an increase in price of a component ingredient (Sulfamethoxazole). The increase in the price of Nevirapine was due to the fact that the drugs were bought in blister packs instead of in bottles that had been budgeted for.

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate) Before UNITAID funding		CUMULATIVE YEARLY TARGETS			ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
						costly to manufacture, blister packs present a comparative advantage when dispensed in resource-limited settings and provide patients with easy to use packages. The price of certain products like Nevirapine 200mg and co-trimoxazole 120mg went up by 1 and 17% respectively. Cost-savings of between 1% to 41% were made on 8 products.	

XIII. OVERALL ASSESSMENT

General

- PMTCT 1 has been had all of its disbursements made. A one year extension to PMTCT 1 has been granted by the board to facilitate the procurement of commodities while UNICEF support national programmes in finding alternative sources of funding while avoiding any interruption of treatment.
- While UNITAID has not directly funded the development of the Mother-Baby Pack, this innovation is of particular interest to UNITAID as it represents a commodity that UNITAID beneficiary countries are likely to purchase during it's piloting (later in 2010) and subsequent rollout.
- The Mother-Baby Pack developed by UNICEF and partners contains the antiretroviral drugs and the prophylactic antibiotic co-trimoxazole, needed to protect the health of one mother living with HIV and her baby. The Mother-Baby Pack will

facilitate increased access to more efficacious ARV prophylactic regimens in line with Option A of the WHO 2009 guidelines, and will streamline the procurement and supply management.

Availability

- All eight countries have demonstrated an increase in uptake of HIV testing with UNICEF hitting 108% of its target for test kits being procured.
- There has been an increase in the percentage of pregnant women receiving ARVs in all eight countries with UNICEF hitting 120% of its target for HIV+ pregnant women receiving more efficacious ARVs for PMTCT and 135% of the target for HIV+ pregnant women receiving ARVs for their own health.
- Co-trimoxazole was given to 100% of the targeted number of HIV+ mothers, 79% of exposed infants at 3 months and 94% of exposed infants at 2 years.
- As of June 2009, more than 70% of antenatal care (ANC) services in Rwanda, Tanzania and Zambia; 80% of ANC services in Burkina Cameroon and over 90% of ANC facilities in Malawi were providing HIV testing and ARVs for PMTCT

Price

- Progress towards price reduction is especially significant for those bundles containing reagents and consumables for CD4, PCR and DBS collection where volume discounts have yielded continued savings from year 1 to year 2
- With regards UNICEF's ongoing efforts to stimulate the market of syrups and solutions for ARV treatment in children, market size remains insufficient to create economies of scale and competition to enable lower prices.
- Competitive international tendering for ARVs continues to be primary mechanism for UNICEF to ensure price containment (i.e., best value for money). Reducing the price of ART therapy remains a priority; however, for most ARVs there are fewer opportunities to lower prices, particularly as prices level near those that manufacturers can bear. Price reductions (and consequential cost savings) in the future may be achievable where the overall manufacturing costs of ARVs (i.e., cost of active ingredients) are in turn reduced

Quality

- In Rwanda it is widely acknowledged that UNITAID funded commodities were key in shifting PMTCT programmes from single dose to more efficacious ARV regimens
- Similarly, UNITAID funding support has accelerated the transition from single-dose to combinations regimens in Malawi. By the end of 2008, more than 99% of services were offering single-dose NVP only, while by the end of Q2 2009 20% of the PMTCT sites were providing combination regimens.

Delivery

- 91% of products that were shipped arrived in country either on time or prior to the estimated arrival date.
- For those products that were shipped within the reporting period, 91% of the orders arrived in country either on-time or prior to the estimated arrival date. 9% of the ordered items encountered delays attributed to supplier performance. 80% of the items included in Year 2 purchase orders that have been shipped were delivered with lead times less than 8-10 weeks. From those that had longer lead times, approximately half of the items had been included in a Purchase Order with deliberate long lead times (staggered deliveries requested by the countries) and would reflect good planning and not a delay in the supply chain.

XIV. PLANNED CHANGES IN THE PROJECT, if any

- PMTCT 1 has been extended for a one year period to facilitate the procurement of commodities while UNICEF supports national programs in finding alternative sources of funding and avoiding any interruption of treatment. UNICEF has developed a transition strategy and will be working with national programs and relevant stakeholders during the extension period to allow for a smooth transition. An agreement with UNICEF is expected to be signed by early November.
- Contingent on successful field testing, the Mother Baby Pack will be made available to countries during the extension period.
- A mid-term review of the PMTCT project will be undertaken during the extension period to evaluate impact of the project.

XV. ISSUES AND/OR LESSONS

Challenges/constraints:

- In-country coordination remains a challenge for sharing information on PMTCT supplies and identifying supply-related bottlenecks. Quantification and forecasting poses challenges in the expanded in-country partnership landscape, aggravated by the lack of real time data on consumption. Efforts have been made to improve this at the central level, such as in Cameroon where the partners working in PMTCT engaged in a meeting, as a result of which ‘the coordination of supplies has improved’; in Rwanda, all partners involved in the procurement of HIV drugs and diagnostics meet regularly, as is the case in Malawi and Tanzania. In Zambia, the improved coordination has led to reduced stock outs in 2008. UNICEF is

moreover developing standardised PSM tools for joint annual and multi-year planning, harmonised with existing mechanisms used by the different partners.

- Inability of some countries to cover the storage and distribution costs for the SCM. Moreover, costs associated with transportation of laboratory specimens and the transmission of results for PCR testing remains a challenge in Cote d'Ivoire. UNICEF has initiated a micro-planning process at district level in response to this with the aim of starting implementation before 2010 and UNICEF and WHO have been continuously involved in the country-level dialogue and coordination mechanisms to integrate UNITAID within national PSM plans.
- The existing tools and systems for M&E at the country level allow only annual reporting of the programmatic indicators.
- End-user monitoring and reporting for UNITAID commodities is not always feasible since the products are included into the overall national pool of the PMTCT commodities.
- Delay in the development of Mother and Baby Pack (MBP): It was expected to be made available by December 2008. However, production of the MBP is presently underway and expected to be introduced in Q4 2010 in Kenya, Cameroon, Lesotho and Zambia.
- India: The Government has decided to introduce more efficacious regimens in centres with good infrastructure and then to scale up based on experience.
- Referrals from PMTCT sites to settings where CD4 testing and HAART is available (Malawi, Cote d'Ivoire).

Lessons learnt:

- The need at a late stage in the project for UNICEF to develop a viable transition strategy highlights the need to include a detailed transitions strategy as part of the original project plan in future projects.
- Integration of the UNITAID Project into already existing systems is critical to ensure timely availability of drugs and supplies
- Working with partners and other funding institutions, country programs must ensure effective supply chain management of commodities purchased using UNITAID funds. For examples transportation of laboratory specimens and the transmission of results for PCR testing remains a challenge in Cote d'Ivoire.
- Forecasting for UNITAID commodities needs to be considered when carrying out country quantification, forecasting and procurement plan at the beginning of the year, with engagement of all partners. The UNICEF country offices have established strong relations with partners, and quantification mechanisms are firmly in place and standardized PSM tools for joint annual and multi-year planning, harmonized with existing mechanisms used by the different partners are under development.

- In Rwanda, Malawi, Tanzania and Zambia all partners involved in the procurement of HIV drugs and diagnostics meet regularly. In Zambia, the improved coordination has led to reduced stock outs in 2008. This kind of activity represents a best practice and should be encouraged in places that it does not exist.

Validation of Tool:

- The UNITAID Validation Tool process will be initiated after the signature of the MoU to delineate the organizational capabilities of UNICEF to implement the project.

SEMI-ANNUAL REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I.	**Reporting Period:**	31 July 2009 - 30 June 2010
II.	**Disease:**	HIV/AIDS
III.	**Niche:**	Prevention of Mother to Child Transmission of HIV (PMTCT)
IV.	**Project Name:**	**PMTCT/Expansion Component:** Acceleration of Implementation of Comprehensive PMTCT Services in the Era of Access of HIV Care and Treatment[14] (PMTCT2)
V.	**Key Partners:**	United Nations Children's Fund (UNICEF) and World Health Organization (WHO)
VI.	**Timeframe for Support:**	**PMTCT/Expansion Component:** 31 July 2009 to June 2011 approximately
VII.	**Start Date:**	July 2009
VIII.	**Total Amount Approved:**	US$ 50,009,221
IX.	**Money Holder:**	UNICEF
X.	**Procurement Agent:**	UNICEF

[14] Extends the Ist Component to a further nine (9) countries

XI. FINANCIAL AND REPORTING

DISBURSEMENT SCHEDULE (date, amount)		**DISBURSEMENTS MADE (date, amount)**		**REASONS FOR ANY DEVIATION AND/OR ANY OT**
1st disbursement within 10 working days of 31 July 2009 (last signature date of MoA)	US$ 18,233,990	14 Aug 2009	US$ 18,233,990	Disbursement took place nine working days after receipt of the signed MoA from the last partner to sign.
2nd disbursement15 March, 2010	US$28,446,003	20 Jul 2010	US$28,446,003	Disbursement was dependent on the approval of the 1st Interim report. The delay in disbursement was due to clarifications that were needed.
		Total	US$ 46,679,993	
		% Disbursed	100%	

REPORTING SCHEDULE (report type, period covered, date)		**REPORTS RECEIVED (report type, period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
1st Annual Programmatic Report	15 Feb 2010	15 Feb 2010	31 July-31 December 2009	Report received as per schedule.
1st Interim Progress Report	15 Aug 2010	18 August 2010	1 Jan 2010-30 June 2010	Report received in a timely manner as per schedule. UNITAID is currently evaluating the report.
2nd Annual Programmatic, Procurement and Financial Report	15 Feb 2011	N/A	1 Jan 2010-31 Dec 2010	

XII. PROGRAMME PROGRESS

KEY OBJECTIVES/ ACTIVITIES	BASELINE		CUMULATIVE YEARLY TARGETS		ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year	2009	2010		
Accelerate the scale-up of provider-initiated testing and counseling in antenatal maternity and postpartum services			3,900,001 rapid diagnostic tests for pregnant women	4,907,588 rapid diagnostic tests for pregnant women	3,834,004 rapid test of pregnant women	Note that the figures for targets reached reported in this report represent those achieved during the first year of activity July 31st 2009- June 30 2010 and should be compared with the cumulative target figures in the first (2009) column.
Reduce the proportion of infants born with HIV through the provision of more efficacious ARV regimens to women			137,463 more efficacious ARV treatments for PMTCT	179,384 more efficacious ARV treatments for PMTCT	321,277 more efficacious ARV treatments for PMTCT	
Accelerate early access of young HIV-infected infants to paediatric ART treatment through optimized identification such as EID[15] strategies,			115,400 DBS/PCR tests for infants born to HIV+ women	225,054 DBS/PCR tests for infants born to HIV+ women	13,536 DBS/PCR tests for infants born to HIV+ women.	
Reduce morbidity and mortality among HIV-infected pregnant women, mothers and their infants through the provision of co-trimoxazole prophylaxis for the prevention of opportunistic infections			22,632 co-trimoxazole treatment for HIV+ mothers 22,693 co-trimoxazole treatment for	31,419 co-trimoxazole treatment for HIV+ mothers 40,921 co-trimoxazole treatment for infants	97,316 co-trimoxazole treatment for HIV+ mothers 40,124 co-trimoxazole treatment for infants	

[15] Early Infant Diagnosis

KEY OBJECTIVES/ ACTIVITIES	BASELINE		CUMULATIVE YEARLY TARGETS		ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
			infants			
Increase access to ART for eligible HIV-infected women			91,913 CD4 tests for ART eligibility 18,546 ART treatment to HIV+ pregnant women for their own health	130,098 CD4 tests for ART eligibility 29,221 ART treatment to HIV+ pregnant women for their own health	337,750 CD4 tests for ART eligibility 24,269 ART treatment to HIV+ pregnant women for their own health	
Achieve continuous supply of suitable high-quality PMTCT medicines, diagnostics and other commodities at the best possible price and facilitate price reduction			Mother-and –Baby Pack field-tested by Q4 2009	Availability of 1 additional better-adapted and more user-friendly commodity for use in PMTCT programmes, including EID	The development of the Mother Baby Pack is ongoing. To-date the packaging has been field tested but the MBP itself has not. It is scheduled to be field tested in Q4 2010. There has been a 21% decrease in the price of test kits; reduction in the prices of 4 ARVs (Nevirapine 200mg tabs/PAC-60; ZDV+3TC+NVP 300+150+200mg tabs/PAC-60; ZDV+3TC 300+150mg tabs/PAC-60; Zidovudine 300mg tabs/PAC-60) ranging from 9 to 25%; reduction in the price of one dispensing device (Dispenser and Tipcap box/100) by 17%; reduction in the price of two co-trimoxazole products (Sulfameth+trimeth 400+80mg tabs/PAC-500; Sulfameth+trimeth 800+160mg tabs/PAC-100) by 28 and 35% and reduction in the prices of two bundles (E1 List for 200 CD4/FACSCounts test; E@ List for	The field testing of the MBP has been divided into the testing of the packaging (which has taken place) and the testing of the product itself (which is currently ongoing). The revised WHO recommendations for PMTCT have resulted in delays in the appropriate development of these products. I

KEY OBJECTIVES/ ACTIVITIES	BASELINE		CUMULATIVE YEARLY TARGETS		ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
					200 CD4/Cyflow test)by 1 and 13% respectively.	

XIII. OVERALL ASSESSMENT

Availability

- In all nine countries, there has been a concerted effort to improve coordination of forecasting among all implementing partners of PMTCT programs to create national forecasts for PMTCT commodities.
- In country coordination with partners such as CHAI, and PEPFAR allowed the programs to respond to rapidly changing environments, capacity constraints, available stocks, planned shipments, the plans and policies of various agencies as well as the diverse funding sources to ensure that there was sufficient funding to cover targeted needs.

Price

- UNICEF sees market competition as a continued enabler for effective price control thus supports the acceleration of new suppliers and cost effective formulations in the market. Better demand information made available, together with spot-price and performance-based allocation of orders, are key in achieving price reductions and increased availability , while remaining fair and transparent.
- During the reporting period, the volumes purchased through the UNITAID PMTCT II Initiative have contributed to production efficiencies and increased competition which has exceeded the 5% price reduction target as established in the Project Plan (Annex 3) for ARV formulations.
- The average price of the HIV rapid diagnostic test kits has not only been contained (as targeted) but also further reduced.
- With regards to UNICEF's ongoing efforts to stimulate the market for syrups and solutions for ARV treatment in children, the number of suppliers of paediatric formulations (Zidovudine syrup), volatility around the active pharmaceutical ingredient and market size remains insufficient to create economies of scale and competition to enable lower prices.
- Progress towards price reduction overall has been achieved as Year 1 average prices fall below baseline budgeted prices. The LTA's established by UNICEF for the commodities under the PMTCT II Initiative have benefited from the tender processes (and pooled volumes) that had previously been launched under the PMTCT I initiative.

Quality

- The price reductions of up to 25% for Nevirapine 200mg, Zidovudine 300mg, Zidovudine 300mg+, Lamivudine 150mg and the triple FDC ZDV+3TC+NVP tables supplied in blister packs as this represents a comparative advantage when dispensed in resource limited settings and provides patients with an easy to use package.

Delivery

- Since the commencement of the PMTCT II Initiative 99 Purchase Orders have been issued by UNICEF for a total of 406 individual item lines.

- For those products that were shipped within the reporting period, 91% of the orders arrived in country either on time or prior to the estimated arrival date. 53 of the PO lines not yet delivered are those attributed to China.
- 84% of the items that have been shipped during the reporting period were delivered with lead times of less than 8-10 weeks.

XIV. PLANNED CHANGES IN THE PROJECT, if any

- The UNITAID Validation Tool will be employed to assess the organizational capabilities of UNICEF to implement the project.

XV. ISSUES AND/OR LESSONS

- By sharing information, the in-country partners have been able to enhance their coordination and take concrete actions to ensure product availability. In particular, the Year 1 forecasting exercise of the PMTCT Expansion Initiative engaged frequent reviews and adjustments to quantification (based on actual consumption) and so prevented a number of ARV drugs and diagnostics from expiring in country.

SEMI-ANNUAL REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I.	**Reporting Period:**	31st July 2009 - 30 June 2010
II.	**Disease:**	HIV/AIDS
III.	**Niche:**	Prevention of Mother to Child Transmission of HIV (PMTCT)
IV.	**Project Name:**	**PMTCT/Nutrition Component[16]:** Acceleration of Nutritional Care of Pregnant and Lactating Women and Children linked to PMTCT
V.	**Key Partners:**	United Nations Children's Fund (UNICEF) and World Health Organization (WHO)
VI.	**Timeframe for Support:**	**PMTCT/Nutrition Component:** 31 July 2009 to June 2011 approximately
VII.	**Start Date:**	Jul 2009
VIII.	**Total Amount Approved:**	US$ 4,764,228
IX.	**Money Holder:**	UNICEF
X.	**Procurement Agent:**	UNICEF

[16] Nutrition component (RUTF and Hemoglobin tests for anaemia diagnosis) for 4 of the PMTCT1 beneficiary countries.

XI. FINANCIAL AND REPORTING

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount)		REASONS FOR ANY DEVIATION AND/OR ANY OTH
1st disbursement within 10 working days of 31 July 2009 (last signature date of MoA)	US$2,291,284	14 Aug 2009	US$2,291,284	Disbursement took place nine working days after receipt of the signed MoA from the last partner to sign.
2nd disbursement 15 March, 2010	US$ 2,219,563	20 July 2010	US$ 2,219,563	Disbursement was dependent on the approval of the 1st Interim report. The delay in disbursement was due to clarifications that were needed.
		Total	US$ 4,510,847	
		% Disbursed	100%	

REPORTING SCHEDULE (report type, period covered, date)		REPORTS RECEIVED (report type, period covered, date)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
1st Annual Programmatic Report	15 Feb 2010	15 Feb 2010	31 July-31 December 2009	Report submitted as per schedule
1st Interim Progress Report	15 Aug 2010	18 August 2010	1 Jan 2010-30 June 2010	Report received in a timely manner as per schedule. UNITAID is currently evaluating the report.
2nd Annual Programmatic, Procurement and Financial Report	15 Feb 2011	N/A	1 Jan 2010-31 Dec 2010	

XII. PROJECT PROGRESS

KEY OBJECTIVES/ ACTIVITIES	BASELINE		CUMULATIVE YEARLY TARGETS		ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year	2009	2010		
Inclusion of nutrition interventions as part of PMTCT and HIV care and treatment interventions to improve maternal and child health outcomes			All four countries to have finalized their country forecasts and submit requests for RUTF and diagnostic commodities		At the end of the 1st year all four countries had finalized their country forecasts and submitted requests for RUTF and diagnostic commodities	
Reduced morbidity and mortality among pregnant women through targeted diagnosis (for anaemia using HemoCue)			241,738 pregnant women tested for anemia	634,226 pregnant women tested for anemia	Data pending	Reporting on targets is pulled from National databases which are analysed annually. This data has not been included in the 2009 reporting as delivers have only taken place in 2010 (delays have been due to late orders and long shipping times as many of these products are shipped by sea)
Reduced morbidity and mortality among pregnant women through targeted nutritional care (RUTF for SAM[17] HIV+ pregnant women)			1,780 HIV + pregnant women treated with RUTF	5,180 HIV + pregnant women treated with RUTF	Data pending	
Reduced morbidity and mortality among children through targeted diagnosis (for anaemia using HemoCue)			40,800 children tested for anemia	98,800 children tested for anemia	Data pending	
Reduced morbidity and mortality among children			7,200 HIV exposed children treated	19,200 HIV exposed children treated with	10,557 HIV exposed children were treated with	

[17] Severely acutely malnourished

KEY OBJECTIVES/ ACTIVITIES	BASELINE		CUMULATIVE YEARLY TARGETS		ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
through targeted nutritional care (RUTF for SAM[18] children)			with RUTF	RUTF	RUTF between Jan-March 2010 Period and 29,071 were treated between Jan-Jun 2009.	
Availability of suitable RUTF and anaemia related products at the best possible price			3 additional RUTF products approved by July 2009	3 additional product dossiers approved by January 2010	2 new RUTF products approved by UNICEF in the first 6 months of the initiative	One product manufactured by Tabatchnick, located in the USA and the other product manufactured by Insta, located in Kenya.
Incentivising new manufacturers			2 LTAs signed with new local manufacturers	3 LTA signed with new local manufacturers	1 new Long Term Arrangement for the global supply of RUTF was established with Compact India 1 new African RUTF manufacturer was approved for the local procurement within the reporting period, JB/Tanaka Foods located in Madagascar.	Compacts product "eeZee paste" is compliant with UNICEF's RUTF technical requirements and therefore could be supplied to UNICEF country programmes.
Price containment and price reduction				Price reduction of at least 5% for two products by Dec 2010	Therapeutic spread sachet 92g/CAR-150 reduced in price by 7% in first year compared with budget. Similarly two Hb tests were reduced by 6% and 1% respectively while one went up by 1%	UNICEF aims to achieve price reductions during the reporting period, however, it is dependent on the pace at which suppliers meet UNICEF's quality assurance criteria, among other factors. At present, the RUTF market continues to remain limited to seven suppliers that meet requisite quality standards.

[18] Severely acutely malnourished

XIII. OVERALL ASSESSMENT

Availability

- UNICEF was able to procure 11,949 therapeutic spread sachet and 822,400 Hb tests.

Price

- RUTF: Budgeted price was US$ 59.34 (92kg/CAR) and actual weighted average price was US$ 55.47, which represents a 7% reduction in price achieved during the reporting period.
- The HemoCue bundles containing reagents and consumables have yielded savings in Year 1:
  - **List E6**: 200Hb tests with HC 301 went from a budgeted price of USD 220.00 to an actual average weighted price of USD 206.52 representing a 6% reduction.
  - **List E7**: 200Hb tests with HC 201+ went from a budgeted price of USD 220.00 to an actual average weighted price of USD 218.14, representing a 1% reduction in price.
  - **List E5**: Starter set Hb testing HC 301 however went up in price from a budgeted USD 585.85 to an actual average weighted price of USD 611.97, representing an increase of 4%.
- Although the individual items, such as the microcuvettes used to collect blood samples to measure haemoglobin (Hb) concentration and the HemoCue photometer, specified in these bundles were budgeted for based on past procurement of such products, procurement in Year 1 derives savings where these products are clustered with awarded suppliers.

Delivery

- In the first year of the Initiative, 17 orders were issued by UNICEF for a total of 50 individual products.
- Countries have since inception of the Nutrition Initiative been advised to estimate all RUTF and diagnostic needs for the following six and or twelve months for each respective program year to allow for adequate planning with manufactures and ensure timely delivery of products as per the Project Plan (Annex 2). Orders have therefore been placed with staggered delivery dates throughout the year, aligned with country requirements.
- 81% of deliveries had lead times less than 8-10 weeks from PO issued to FCA delivery
- 87% of orders arrived in country either on time or prior to the estimated arrival date.
- 13% of the ordered items encountered delays attributed to supplier performance.

XIV. PLANNED CHANGES IN THE PROJECT, if any

No changes are anticipated at the moment.

XV. ISSUES AND/OR LESSONS

- Better demand information made available, together with spot-price and performance-based allocation of orders, are key in achieving price reductions and increased availability, while remaining fair and transparent.

SEMI-ANNUAL REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I. Reporting Period: Dec 2009 to August 2010

II. Disease: HIV/AIDS

III. Niche: HIV/AIDS

IV. Project Name: Safeguarding Availability of ARV Treatment

V. Key Partner: Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau (ESTHERAID)

VI. Timeframe for Support: 3 years
8 months for Phase 1

VII. Start Date: 2 July 2009

VIII. Total Amount Approved: US$ 15,950,000

Note: Subsequent to the Board approval of funding commitment, it was agreed that the project would be pursued in 2 phases: a) Phase 1: Preliminary Evaluation and Planning; and b) Phase 2: Operation and Implementation. Below is the agreed budget allocation for these two phases:

Phase 1: Euro 321,106 (estimated to be equivalent to US$ 451,625.88)
Phase 2: US$ 15,498,374.12 (estimated on the basis of total US$ commitment minus Phase 1 US$ budget)

IX. Money Holder: ESTHER

X. Procurement Agent: Not applicable

XI. FINANCIAL AND PROCUREMENT – Phase 1 (Preliminary Evaluation and Planning Phase)

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
12 July 2009	US$ 451,625.88	15 July 2009	US$ 451,625.88	This was the disbursement for Phase I. The Phase II disbursement schedule will be agreed upon signing of the MoU for Phase II.
		TOTAL AMOUNT DISBURSED: US$ 451,625.88 **PERCENTAGE DISBURSED:** 100 %		

REPORTING SCHEDULE (date, report type, period covered		REPORTS RECEIVED	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
Final Report on Phase 1	No later than 8 months after the start date (March 2009)	All five country reports including the results of Phase I and operational plans for	Project delays until now have been for numerous reasons including 1) changes in key staff at ESTHER who were responsible for the projects management; 2) unexpected complexity in terms of obtaining official approval from partners, including Ministries of Health; and 3) prolonged engagement between UNITAID and ESTHER in finalizing project success indicators and financial modalities.

REPORTING SCHEDULE (date, report type, period covered		REPORTS RECEIVED	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
		Phase II were submitted by 30 September 2010.	

XII. PROJECT PROGRESS (NOT APPLICABLE AT THIS STAGE)

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate)		YEARLY TARGETS 2009	ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year			
Improve procurement and supply management for inputs all the way to treatment sites			Number of months without stock-outs for tracer drugs, measured in a sample of peripheral care centres		Note that these outputs are preliminary and will be measured during Phase II of the respective country projects and they may change with the development of the project plan.
			Delivery time in days after orders for tracer drugs, measured in a sample of peripheral care centres		

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate)		YEARLY TARGETS 2009	ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	**Year**			
Optimise the use of inputs by raising the quality of practice in patient diagnosis, treatment and monitoring			Number of cases of early detection among children in care centres with PCR equipment		
			Rate of early detection among children compared with total number		
			Number of CD4 counts in treatment centres with counters		
			Percentage of prescribers trained in good prescription practice		
			Percentage of stakeholders trained in therapeutic education		
			Percentage of sick children receiving nutritional aid		
			Percentage of staff in treatment centres trained in detecting		

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate)		YEARLY TARGETS 2009	ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	**Year**			
			tuberculosis		
			Percentage of staff in tuberculosis control centres trained in detecting HIV		
			Number of detected patients with multiresistant tuberculosis		
Strengthen monitoring systems for care and ARV access programmes in order to improve the reliability of quantification of needs for inputs used in HIV/AIDS control			Percentage of treatment centres using patient care monitoring tools (adults and children)		
			Size of case loads recorded by the monitoring system at care sites and centrally		

XIII. OVERALL ASSESSMENT OF PERFORMANCE

UNITAID is working with ESTHER to finalize phase I of this project and to draw up project plans and an MOU to cover phase II of the project. To-date, three in-person follow up meetings in Geneva and Paris and two teleconferences have been held with a view to progressing this project.

The operational plans for Phase II for all five countries are an improvement on earlier versions and now include a detailed log frame for activities going forward. While this project has been taken some time to get going, the secretariat is confident that the operational implementation of the project will unfold as planned and within the set timeframes established.

The UNITAID Validation Tool is currently being employed to assess the organizational capabilities of ESTHER to implement the project. Stage I, desk review, of ESTHER's financial, operation and governance capabilities has been concluded by the Secretariat. Stage II related to ESTHER self assessment is ongoing and will be finalized by 15 October.

XIV. PLANNED CHANGES IN THE PROJECT, if any

Not applicable at this point as Phase II is yet to commence.

XV. ISSUES AND/OR LESSONS LEARNT

The challenges faced in this project include the coordination of standardized reporting across the 5 countries. The lesson learned on this project so far is that where clear and unambiguous guidelines are provided, ESTHER has responded with good documentation of the activities and plans. Keeping open and regular lines of communication between ESTHER and UNITAID will be important as this project is implemented.

Provisional work plan for EATHERAID

	September				October				November					December				2011
	6th	13th	20th	27	4th	11th	18th	25th	1st	8th	15th	22nd	29th	6th	13th	20th	27th	
ESTHER submits Phase II operational plans																		
Telecon with ESTHER to discuss project plan																		
Draft project plan																		
Draft MoU																		
Comment on draft (UNITAID)																		
Teleconference and ESTHER make changes																		
Sign MoU																		
Disbursement																		
Implementation by ESTHER																		
Ongoing M&E																		
Bianual Progress Report																		
Annual Progress Report																		

= ongoing processes

Project Update TB niche:

Pediatric TB

First-line Anti-TB drugs

MDR-TB Diagnostics (EXPAND-TB)

MDR-TB scale-up initiative

MDR-TB Acceleration of Access Initiative: Strategic Rotating

Stockpile Update on the status of the Strategic Revolving Fund

SEMI-ANNUAL REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I. Reporting Period: January - June 2010[19]

II. Disease: TB

III. Niche: Paediatric TB

IV. Project Name: UNITAID Project Support for Paediatric TB Project

V. Key Partners: Global Drug Facility (GDF)

VI. Timeframe for Support: 12 January 2007 to 31 December 2011

The original Letter of Agreement (LOA) was signed 12 January 2007 a one year timeframe. In December 2007, the Letter of Agreement was amended to reflect a no-cost extension of timeframe from 31 December 2007 to 31 December 2010, as the substantial cost savings achieved under the Project allowed for a higher treatment target.

The July 2008 UNITAID Board Meeting approved an additional funding support (US$5,938,952) in order to increase the number of countries and patient treatments - The duration of the Project was extended to the end of 2011.

In June 2010 the UNITAID Board approved an additional funding support (US$2,207,486). This increase in funding was to address the shortfall in funding from September 2010- December 2011. The Project agreement is currently under development.

VII. Start Date: 15 January 2007[20]

VIII. Total Amount Approved: US$13,495,895[21]

IX. Money Holder: GDF

X. Procurement Agent: The Letter of Agreement states that the procurement and delivery of drugs funded with UNITAID support will be the responsibility of the GDF selected Procurement Agent. The procurement Agent selected for the project is Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ), under GDF oversight.

XI. FINANCIAL AND PROCUREMENT

[19] Ad hoc reporting
[20] Coinciding with the date of receipt of the contribution
[21] This includes the EB12 budget ceiling.

DISBURSEMENT SCHEDULE [22] (date, amount)		**DISBURSEMENTS MADE (date, amount)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
Upon signature of Letter of Agreement	US$ 864,000	15 January 2007	US$ 864,000	
Second disbursement 15th February 2007	US$ 4,801,000	26 September 2007	US$ 4,801,000	Evidence as to the satisfactory completion of all conditions to the second disbursement of funds was awaited prior to disbursement. The interim progress report was received by the Secretariat June 2007.
Upon signature of 2nd Amendment[23] to the letter of Agreement	US$3,959,301	28 January 2009	US$ 3,959,301	
April 2010	US$ 313,796	30 October 2010		Late submission of Financial reporting. In addition to additional request by UNITAID for a cash reconciliation report.
Earmarked payment retained by UNITAID	US$1,350,312	30 October 2010		Release of cost fluctuation buffer due 30th October 2010
	US$ 11,288,409[24]	**TOTAL AMOUNT DISBURSED: US$ 9,624,301** **PERCENT DISBURSED: 85%**		

[22] This disbursement schedule does not yet reflect the additional budget of US$ 5,938,952 that was recently approved by the EB meeting in July 2008. This additional budget will be documented through an Amendment to the LOA, and such amendment is still under discussion with the GDF.
[23] First Amendment was a no cost extension for the project lifecycle and expanding the coverage
[24] This total is not reflective of EB12 budget ceiling. The project agreement is currently under development.

REPORTING SCHEDULE **(report type, period covered**		**REPORTS RECEIVED** **(date, report type, period covered)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
April 2007	Interim progress report (covering Q4/2006 and Q1/2007)[25]	June 2007	Interim progress report Q4/2006, Q1/2007 and Q2/2007	The delay in reporting was due to initial implementation bottlenecks encountered at the outset of the project.
End of January 2008	1st Annual Programmatic Report: Interim Financial statement of income and expenditures (covering 2007 activities)	May 2008	1st Annual Programmatic Report January - December 2007: Interim Financial statement of income and expenditures, covering activities for same the period	The Partner requested an extended deadline for the submission of the 1st Annual Report. This was approved by the Secretariat. The Annual Report was deemed satisfactory by the Secretariat
15 March 2009	2nd Annual Programmatic and Financial Report	April 2009		The Annual Report was deemed satisfactory by the Secretariat.
15 October 2009	Interim Progress Report	October 2009		The Interim Report was deemed satisfactory by the Secretariat
15 March 2010	3rd Annual Programmatic and Financial Report	March 2010		The Secretariat is currently finalizing its assessment of the Annual Report submitted.
15 October 2010	Interim Progress Report			
15 March 2011	4th Annual Programmatic and Financial Report			
15 October 2011	Interim Progress Report			
90 days after settlement of all obligations				

[25] As stated in the original Letter of Agreement (LoA)

XII. PROJECT PROGRESS

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate)		CUMULATIVE YEARLY TARGETS					ACTUAL TARGETS REACHED TO DATE[26]	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year	Year 2007	Year 2008	Year 2009	Year 2010	Year 2011		
Secure prices (US$) annually for paediatric drugs.[27]	13	2006	10.63 Per treatment	<=10.63 Per treatment	< =10.63 Per treatment	<= 10.63 Per treatment			
Paediatric patient treatments supplied	0	2006	150,000	300,000	450,000	600,000	750,176	782,865	Between January - June 42,336 curative and 80,767 preventive treatments have been delivered Delayed deliveries were due to the temporary suspension of GDF's sole supplier of blister strip fixed dose combinations (FDCs)
Number of GDF Technical Review Committee (TRC) countries approved to be served under this agreement.	14	2006	20	40	40	58	N/A	58	By December 2009, the Stop TB Partnership's Technical Review Committee had approved all beneficiary countries
Development of pre-qualified appropriate	0	2006	>1	>1	>1	>1	1	5[28]	In anticipation of the formal release of the new treatment guidelines for paediatric TB, dossiers for the current paediatric formulations were not submitted to the WHO Prequalification Programme.

[26] Please note that targets are yearly and hence may not always be reported on a semi-annual basis.
[27] Prices secured for 4 products (appropriate strength Paediatric Fixed-dose combinations (FDCs) and single formulations) from 3 suppliers based on provisional quality assurance process.
[28] Based on the original recommended strengths.

strength paediatric drug fixed dose combination - (FDC)									
Reduction in delivery lead times (number of days)	N/A	2006	60	< 60	<60	<60	57	N/A	Delivery lead time is the time it takes for a manufactured product to go from manufacturer to country.
Reduction in manufacturing lead times (number of days)	N/A	2006	120	< 120	< 120	< 120	111	76	The average lead time from order placement to first delivery in country has been reduced by 11 days from the average lead time reported for the calendar year 2009.

XIII. OVERALL ASSESSMENT OF PERFORMANCE

The project has two main objectives[29]:

To provide appropriate-strength Paediatric drugs for approximately 750,176 children under the age of 15 by the end of 2011
To ensure the development of new child-friendly formulations for infants under 4, in at least 58 countries by the end of 2011.

As of June 2010 a cumulative total of 762,865 (of which 321,208 curative treatments and 461,657 are preventive treatments) were delivered. The project has surpassed its original treatment target of supply 750,176 paediatric treatments by 2011.

Since the Project inception in Q42006 until 30 June 2010, 16 of the 58 countries have completed their 3 year grants for which orders have been partially or totally delivered.

[29] In July 2008 UNITAID Board Meeting approved an increased budget ceiling for this project. The patient treatments increased by 150,175, bringing the total to 750,175 in an additional 18 countries (total number of countries 58) by 2011. The additional targets and extended duration of the project will be reflected in the next update to the Board, after the finalization of the Amendment to the existing LOA.

In parallel to the publication of the WHO treatment guidelines and the determination of the ideal FDC - WHO and the Stop TB Partnership, incentivized by UNITAID support through GDF grants to countries have implemented a series of workshops and trainings to prepare national TB programmes for uptake of the new WHO recommendations. The below is the following schedule of workshops to date:

Country	Status	Event title	Organizing body	Schedule
Papua New Guinea	Postponed	Pediatric Network Meeting	NTP	Tbd
Cambodia	Planned	TA for childhood TB (evaluation)	WHO/WPRO	Jan-11
Niger	Confirmed	Workshop and follow up on extra pulmonary TB management cases, on pediatrics TB cases management and co infection TB HIV manage	GIP Esther	Oct-10
Bangladesh	Confirmed	Development of training manuals on Childhood TB	WHO	Sep-10
Rwanda	Confirmed	Best practices in TB control regional meeting	The Union	Aug-10
Malawi	Confirmed	Childhood	The Union	Jun-10
Switzerland	Completed	Childhood TB Sub-Group meeting	WHO/HQ	Oct-09
Cambodia	Completed	Childhood TB National Guidelines	WHO/WPRO	Sep-09
Myanmar	Confirmed	Mission on Childhood TB	WHO/SEARO	Apr-09

Phase out of UNITAID support - As requested by UNITAID in 2009, the GDF was requested to implement activities to Phase out its current UNITAID support (ending in December 2011). As of September 2009, the GDF opened access to purchase Paediatric medicines through its Direct Procurement (DP) Service to prepare for the phase out of UNITAID support and allow countries continued access to quality assured low cost drugs through alternative funding sources. In Quarter 1 of 2010, 3 countries[30] have concluded their UNITAID funded support and have been able to identify an alternate source of funding whilst using the GDF Direct Procurement service to sustain the gains (and continuity of treatments) achieved through UNITAID investment in this nascent market.

XIV. PLANNED CHANGES IN THE PROJECT, if any

The WHO Stop TB Department has been developing the clinical guidelines for the new WHO recommended dosage for children. "*The Rapid Advice on Treatment of Tuberculosis in Children*" will be published by December 2010. Interim guidance for the new evidence based treatment pending the publication of these guidelines has been developed by the WHO Department of Essential Medicines in collaboration with the WHO Stop TB Department and the GDF. These interim guidelines introduced in September 2009 are currently being used by the GDF within the framework of the UNITAID funded Project.

At the EB11 the GDF submitted a funding request (*Paediatric Tuberculosis extension*) for an additional amount of US$33,456,483 from 2011-2014. The additional amount was principally premised upon expanding and scaling up the current UNITAID funded Project via aggregated demand and pooled procurement, thereby positively shaping market dynamics. The EB11 Board noted the IAEG recommendation to accept this Proposal if funding was available. The Executive Board did not adopt the draft resolution (UNITAID/EB11/2009/R13) since confirmed funding was not available. The Board however noted the favourable recommendation of the IEAG.

[30] Djibouti, Pakistan and Cambodia

Subsequently the GDF submitted a twofold (*Component 1 and Component 2*) financial expansion request for the EB12. Component 1[31] was recommended for funding by the Executive Board. The project's Third Amendment to the Letter of Agreement is currently being developed and will reflect the June 2010 UNITAID Board Resolution Component 2 although recommended by the Interim Expert Advisory Group was not considered for funding in view of current funding constraints. It was recommended that the GDF resubmit Component 2 to the Executive Board for its consideration during its EB13 session.

In September 2010, the GDF submitted to the UNITAID Secretariat a funding request which is currently being reviewed by the UNITAID Proposal Review Committee.

XV. ISSUES AND/OR LESSONS LEARNT

A prerequisite to ensure **continuity** of paediatric anti-TB treatment is the **ability to provide continued business stimulus to manufacturers** - in particular to those, who have already invested in a relatively small/limited market of products that will gradually phase out of demand - in order to develop the market for paediatric formulations further.

The **provision of sustainable funding** would provide positive incentives for the manufacturers to invest in the development of the new formulations. Due to the current relatively limited size of the market of importance is the strategy plan to continue engaging manufacturers to commit to the required investments.

The publication of "***The Rapid Advice on Treatment of Tuberculosis in Children***" and the availability of appropriate FDC are paramount to countries' adoption of these new WHO recommendations. Without these key leverages, no countries can reasonably be expected to adopt these new guidelines pending official WHO directions. It is evident that countries are waiting for both the publication of the official guidelines and the availability of appropriately formulated FDCs to engage in the long and costly process of adapting their national guidelines.

[31] The funding request was premised on the recent change in the WHO recommended treatment guidelines. The key objectives were to ensure continuity of treatment for a total of 750,176 children by 2011, to address the shortfall in funding from September 2010-December 2011 due to the costs associated with the implementation of the new WHO recommended dosage for children and to positively impact Paediatric TB drug market dynamics through improvements in price and quality and the development of child-friendly formulations.

SEMI-ANNUAL REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I. Reporting Period: January - June 2010[32]

II. Disease: TB

III. Niche: First-Line TB

IV. Project Name: UNITAID Project Support for First-Line Anti-TB Drugs Initiative

V. Key Partners: Global Drug Facility (GDF)

VI. Timeframe for Support: 2007 – 2011[33]

The Letter of Agreement was signed on the 7th of September 2007. A no cost extension to the Project was signed by all Parties December 2009. The no cost extension was principally premised upon ensuring that countries can benefit from the Stockpile while they improve their drug management capacity to a point where they will no longer require urgent deliveries from the Strategic Rotating Stockpile The Letter of Agreement will remain in effect until such time as all the drugs procured under Project for recipients of transitional grants have been satisfactorily delivered, the Strategic Rotating Stockpile is fully operational and UNITAID has accepted the final programmatic and financial reports submitted to UNITAID by GDF.

VII. Start Date: 7 September 2007

VIII. Total Amount Approved: US$ 26,841,025

IX. Money Holder: GDF

X. Procurement Agent: The Letter of Agreement states that the procurement and delivery of drugs funded with UNITAID support will be the responsibility of the GDF selected Procurement Agent. The Procurement Agent selected for the project[34] is Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ), under GDF oversight.

[32] Ad hoc reporting.

[33] The MOU reflected the expectation that all deliveries would be completed on or about 31 December 2008. The GDF submitted a request for Amendment to this Project to the Secretariat in December 2008 to extend this Project into 2009 to facilitate the delivery of consignments under the Transitional Grants for some countries

[34] In July 2009 the Procurement Agent was changed from GTZ to Partnership for Supply Chain Management (PFSCM). The contract was not extended beyond the initial 12 months.

XI. FINANCIAL AND PROCUREMENT

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
Within 10 days of last signature of Letter of Agreement (21 September 2007)	US$ 22,458,025	21 September 2007	US$ 22,458,025	
Balance of payment based on approval of Interim Progress Report (15th January 2008)	US$ 4,382,700	4 February 2008	US$ 4,382,700	The second and final disbursement was scheduled to be paid on 15 January 2008. However, payment was made on 4 February 2008 to accommodate internal Secretariat review of progress report.
		TOTAL AMOUNT DISBURSED: **US$ 26,840,725** **PERCENT DISBURSED: 100 %**		

REPORTING SCHEDULE **(date, report type, period covered**		**REPORTS RECEIVED** **(date, report type, period covered**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
1st Interim progress report 07 September - 31 November 2007	31 December 2007	Received 21 December 2007	07 September - 31 November 2007	Report deemed satisfactory by the Secretariat
2nd Interim progress report December 2007- 30 June 2008	30 July 2008	Received 4th September 2008	January - June 2008	The Partner requested for a delayed submission of the 2nd Interim report. This was requested so that the Partner could begin initiating work on the July Board Approved Projects. This request was approved by the Secretariat.
Annual programmatic and financial report 01 January - 31 December 2008	31 March 2009	Received 1st April 2010	01 January - December 2009	The progress was reported to the EB12.
3rd Interim Progress Report January - June 2009	15 October 2010			
Annual programmatic and financial report January - December 2009	15 March 2011			
4th Interim Progress Report January - June 2010	15 October 2011			
Annual programmatic and financial report January - December 2010	15 March 2012			
Final Project and financial Report	90 days after settlement of all obligations	Not yet due		

XII. PROJECT PROGRESS

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate)		CUMULATIVE YEARLY TARGETS	ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year	Year 2007-2011		
Patient treatments to be supplied	0	2007	866,273	786,843[35]	Total number of patient treatments delivered to date.
Beneficiary countries	0	2007	19	19	As of June 2010 all 19 countries first-line TB drugs have been ordered, supplied and delivered.
Establishment of a Strategic Rotating Stockpile	0	2007	380,000 Treatment courses for emergency orders	100%	The size of the stockpile due to price increase facilitates the servicing of an estimated 220,000 patient treatments
Reduction in delivery lead times (months)	4-6	2007	1-3	46.5 days	Average lead time for all orders using stockpile
Achieve cost containment (US$ per treatment)	17.88[36]	2007	< 20[37]	13.86	Price weighted by 2009 order volumes have decreased on average
Achieve price stabilization and price reduction by 2009[38]	0	2007	N/A[39]	N/A	The long term objective of price reduction remains not achievable due to an increase in cost of the active pharmaceutical ingredient (API) of the main first line anti-TB drugs.
Prequalification of first-line drugs	5[40]	2007	16[41]	13	4 additional drugs have been prequalified
Increased number of eligible generic suppliers competing for GDF business	1	2007	3[42]	3	5 generic competing drugs have 5 suppliers

[35] As of June 30th 2008
[36] Short-term objective of cost containment at or below US$20.
[37] Short-term objective of cost containment at or below US$20 for Category 1 treatment with standardized, WHO recommended FDCs meeting GDF quality assurance standards
[38] Achieving price reduction by 2009 is dependent on increasing the number of generic suppliers in the market.
[39] Specific target not set for 2009
[40] Out of the 16 priority first-line products identified for pre-qualification, 5 have been prequalified
[41] This includes the 5 existing pre-qualified products out of the 16 priority first-line product identified for pre-qualification
[42] 3 suppliers for each of the 3 products

XIII. OVERALL ASSESSMENT OF PERFORMANCE

The project originally had three main objectives to ensure country access to high-quality first-line anti-TB drugs and to positively impact TB market dynamics to increase the affordability of first-line anti-TB drugs:

A. Through Transitional Grants: minimize the risk of stock-outs and therefore drug resistance among countries that will face a gap in drug supply between the end of a GDF grant and the beginning of a planned future source of funding for first-line anti-TB drugs;
B. Through Strategic Rotating Stockpile(s): reduce lead times and overall treatment costs for drug deliveries by reducing the ratio of expensive freight/emergency orders to non-expensive freight/urgent orders.
C. Through Transitional Grants and Strategic Rotating Stockpile(s): (a) achieve cost containment of anti-TB drugs in the short-term by strengthening GDF purchasing power in its Q3/Q4 2007 tender and (b) achieve price stabilization and potential price reductions in the medium term (2009) since catalysis of prequalification of first-line anti-TB drugs, and with the development of a larger competitive pool of pre-qualified first line anti-TB drug manufacturers, is expected to occur as a result of UNITAID's contribution to the maintenance of a sustainable market and aggregated demand via GDF for first-line anti-TB drugs.

The key objectives of the no cost extension signed in December 2009 are:

D. To facilitate the delivery of consignments under the Transitional Grants for two of the 19 countries
E. To ensure that countries can benefit from the Stockpile while they improve their drug management capacity to a point where they will no longer require urgent deliveries from the Strategic Rotating Stockpile

The project implementation is on track. GDF continues to minimize the risk of stock-outs for first-line TB drugs and ensures sufficient in-country stocks until anti-TB drugs paid from new funding sources (predominantly Global Fund grants) are received in 2008 and Q4 2010. . As reported in EB12 Board update one of the 19 countries had not effectively transitioned from UNITAID support to support from the Global Fund, however this is expected in Q4 2010.

The Strategic Rotating Stockpile continues to demonstrate prove its effectiveness in reducing lead times, cost containment and responsiveness to emergency situations. The Strategic Rotating Stockpile has offset delays in countries unable to receive their deliveries hence avoiding treatment disruption. In addition it has also mitigated such risks related to the finite manufacturing capacity of supplies that may not be able to accommodate multiple urgent and standard orders at the same time. The lead time for drugs on stock is approximately 4-8 weeks allowing for rapid response to urgent or emergency situations in comparison to the lead time for freshly produced stock which is approximately 15-19 weeks?

XIV. PLANNED CHANGES IN THE PROJECT, if any

One of the objectives of this Project was to establish Strategic Rotating Stockpile (SRS) facilities. Two Options[43] were identified to be tested by GDF. Option I was chosen to be implemented. Option I was assessed in the fourth quarter of 2008 and GDF reserved the right to implement Option II as an alternative if Option I proved to be unsuccessful. The success of Option I relies predominantly on GDF suppliers fulfilling their contractual obligation to hold and rotate the required percentages of stocks. Effective July 2008, monthly audits of stock levels are being conducted by GDF's independently contracted inspection agency, Intertek. In GDF's annual report for 2008 and 2009, GDF provided an update of the progress made in implementing the SRS under this system of tighter control and oversight as well as an indication of whether a strategic decision to substitute Option I for Option II would need to be made.

The GDF is developing an expanded Rapid Response Facility. This Facility is integrally linked to the existence of a Stockpile. GDF is currently performing further analyses to determine the most effective structure for the stockpile. This analysis will be finalized by the end of 2010. Currently there are three principle options under consideration by the GDF to be further discussed with UNITAID:

F. ***Based on current mode***l: maintain stocks of key drugs with suppliers, at their premises at no cost to GDF, up to agreed levels (maximum 20% of anticipated annual volume). Additional stocks beyond such levels can be maintained on specific request, subject to pre-payment by GDF.
G. Utilizing a consolidation warehouse of the Freight Forwarder or a central warehouse managed by the Procurement Agent
H. Making use of regional drug warehouses and distribution centres

[43] Option I: Requires that manufacturers that were contracted via Long Term Agreements (LTAs) in January 2008 hold a fixed percentage (5, 10 or 15 % depending on the product) of certain priority products while still remaining legal owners of the stock. Option II: requires the competitive selection and contracting of a qualified, independent agent to manage a Stockpile of priority products.

The current model is presently the most economical option. If this Option is chosen it is envisioned that it will maintain a constant minimum stockpile level, supplemented by a flexible portion depending on the orders in the pipeline over a 3-6 month timeframe.

Once an Option is selected for future implementation of the Stockpile, GDF will submit no later than December 2010, a, funding Proposal for the continuation of the Stockpile Component.

XV. ISSUES AND/OR LESSONS LEARNT

Key issues are as follows:

Several lessons regarding the effectiveness of the Strategic Rotating Stockpile have been learned to date and relevant processes and actions have been taken to address these:

1. Basing stock levels on historic data has proven inefficient: Demand patterns changes much be accommodated by the stock management system, Required stock levels are therefore now to be based on the forecast of actual requirements
2. Stock levels are calculated on a dynamic and flexible basis: They vary according to the forecasted upcoming demand. Holding fixed level stocks has proven inefficient and uneconomical since it can lead to high stock levels at times of low demand and insufficient stock levels at times of high demand. The risk of the shelf-life of stocks falling below acceptable limits is high.
3. Since it is the Procurement Agent that is responsible for the daily running of the stock management system, it is imperative that the PA has access to all relevant information. The Procurement Agent has therefore been given access to draft orders in the GDF Order Management System. This has been of great value when operating a dynamic stock management system.

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SEMI-ANNUAL REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I. Reporting Period: January - June 2010[44]

II. Disease: TB

III. Niche: MDR-TB Diagnostics

IV. Project Name: EXPAND-TB supported by UNITAID

V. Key Partners: Global Laboratory Initiative (GLI), Foundation for New Innovative Diagnostics (FIND) and the Global Drug Facility (GDF)

VI. Timeframe for Support: 10 December 2008 to 31 December 2013

The Initial Memorandum of Understanding (MoU) was signed 12 December 2008. In May 2009 the UNITAID Board approved additional funding support (US$61,482,085). This was additional funding and extension of the project lifecycle to 2013, was principally premised upon: to cover 11 additional countries (i.e. 27 countries in total) aimed at identifying an estimated 56,000 patients with MDR-TB in priority settings (i.e. 129,000 in total) thereby achieving a significant impact on the global gap in scaling up access to diagnosis of such patients.

VII. Start Date: 16 January 2009[45]

VIII. Total Amount Approved: US$ 87,562,000

IX. Money Holder: Stop TB Partnership Trust Fund and FIND

X. Procurement Agent: The Memorandum of Understanding states that the procurement and delivery of diagnostics funded with UNITAID support will be the responsibility of the GDF/FIND selected Procurement Agent. The Procurement Agent selected for the project is Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ), under GDF oversight.

[44] Ad hoc reporting -
[45] Coinciding with the date of receipt of the contribution by partners.

XI. FINANCIAL AND PROCUREMENT

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
Upon signature of MoU	US$ 8,123,200	16 January 2009	US$ 8,123,200	
Second disbursement 30th June 2009	US$11,458,800	August 2009	US$11,458,800	
Third disbursement 28th May 2010	US$ 17,971,128	15th June 2010	US$17,971,128	
Fourth disbursement 15th October 2011	US$ 24,137,720	N/A		
Fifth disbursement 15th October 2012	US$ 10,476,851	N/A		
	US$87,562,000	**TOTAL AMOUNT DISBURSED: US$ 37,553,128** **PERCENT DISBURSED: 43%**		

REPORTING SCHEDULE (report type, period covered		**REPORTS RECEIVED** (date, report type, period covered		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
15 March 2009	Inception Report (covering activities during December 2008-28 February 2009)	15 March 2009	Inception Report	The report was deemed satisfactory by the Secretariat
01 October 2009	1st Interim Progress Report	1 October 2009	1st Interim Progress Report	The Report was deemed satisfactory by the Secretariat
15 March 2010	1st Annual Programmatic and Financial Report (covering 2009 activities)	15 March 2010	1st Annual Programmatic and Financial Report	The Report was deemed satisfactory by the Secretariat
01 October 2010	2nd Interim Progress Report			
15 March 2011	2nd Annual Programmatic and Financial Report			
01 October 2011	3rd Interim Progress Report			
15 March 2012	3rd Annual Programmatic and Financial Report			

REPORTING SCHEDULE **(report type, period covered**		**REPORTS RECEIVED** **(date, report type, period covered**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
01 October 2012	4th Interim Progress Report			
15 March 2013	4th Annual Programmatic and Financial Report			
90 days after settlement of all obligations	Final Project and Financial Report			

XII. PROJECT PROGRESS

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate)		CUMULATIVE YEARLY TARGETS					ACTUAL TARGETS REACHED TO DATE[46]	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year	Year 2009	Year 2010	Year 2011	Year 2012	Year 2013		
Beneficiary country selection process	0	2008	6	18	3	N/A	N/A	21	This represents the total number of beneficiary countries selected for access to diagnostics
Agreement signed with Health Authorities of Beneficiary Programs by WHO Stop TB Partnership and/or the GF as applicable	2	2008	2	13[47]	16	16	3	16	16 Agreements have been signed. Consisting of both Category 1 and 2 countries
On-site assessment of TB laboratory networks and selection of laboratory sites	3	2008	6	18	3	N/A	N/A	12	On-site assessment has been completed for 8 countries
Renovation and upgrade of selected sites	1	2008	6	18	3	N/A	N/A	18	Sites are assessed and renovated depending on existing infrastructure

[46] Please note that targets are yearly and hence may not always be reported on a semi-annual basis.
[47] A total of 3 countries Agreements to be signed Q2 2009, 10 additional country Agreements to be signed by Q4 2009

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate)		CUMULATIVE YEARLY TARGETS					ACTUAL TARGETS REACHED TO DATE[46]	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year	Year 2009	Year 2010	Year 2011	Year 2012	Year 2013		
Achieve price reduction by 2010	50%[48] 78%[49]	2008	50 78	< 50 < 78	10[50]	10	50%[51] 78%[52]	US$1.85 [53]	The starting price range for reagents is US$2.20 - US$11.25. Price reduction of Liquid culture diagnostics by 80% of the full private sector price has been achieved in this reporting period
Delivery of diagnostics to beneficiary countries	0	2008	0	4	13	16	103	4	New TB diagnostics services have been implemented and first deliveries of diagnostics have been
Stimulate the increase in the number of manufacturers	6[54]	2008	> 6	9[55]	12	12	6	3	To date 8 manufacturers exist for each category of TB diagnosis.

[48] Initial starting price negotiated by FIND for UNITAID Project for equipment
[49] Initial starting price negotiated by FIND for UNITAID Project for reagents
[50] Cost per patient diagnosis at least 10% lower than baseline initial negotiated price
[51] Initial starting price negotiated by FIND for UNITAID Project for equipment
[52] Initial starting price negotiated by FIND for UNITAID Project for reagents
[53] Price reduction achieved specifically for the MGIT tube
[54] 2 manufacturers for each category of TB diagnosis
[55] 3 new additional manufacturers identified across all product categories by Q3 2009

XIII. OVERALL ASSESSMENT OF PERFORMANCE

Through this project, funding from UNITAID to make modern diagnostics available will be a key component in establishing a sustainable impact on the detection and management of MDR-TB. The goals of this Project are:

I. To expand and accelerate access to modern TB diagnostic technologies;
J. Impact market dynamics to leverage price reductions for diagnostic tools, instruments, reagents, and supplies and stimulate a greater number of suppliers of modern TB diagnostics; and
K. Improve case detection and management of TB and MDR-TB by deploying all reasonable efforts to ensure the TB diagnostic tools supplied are taken up and properly used by National TB Control Programmes

The project will also aim to stimulate the increase in the number of quality assured diagnostics - i.e. facilitate the creation of new markets for diagnostic tools through the establishment of new, quality-assured laboratories in the 16 countries which are prepared to absorb the new TB diagnostics

Progress towards meeting the overall objective of supplying new diagnostics technologies in 27countries by 2013 is on track. It is expected that 129,000 MDR-TB patients, will be covered through this project and treated through the UNITAID Project Support to the MDR-TB Acceleration of Access Initiative - Strategic Rotating Stockpile.

Some key achievements have been demonstrated after 18 months of implementation of this project:

1. Two additional suppliers have been identified and Long Term Agreements have been signed with these suppliers[56]

2. Sixteen of the 27 countries have been approved for the supply of new TB diagnostic equipment, consumables and other essential supplies

3. One additional TB Laboratory (Myanmar[57]) has been inaugurated in July meaning that Myanmar can now diagnose the country's own MDR-TB cases.

XIV. PLANNED CHANGES IN THE PROJECT, if any

At the WHO 10th Strategic Technical and Advisory Group (STAG-TB) held in October 2010, the use of a new diagnostic tool, the Xpert MTB/RIF was recommended to WHO for global roll out of this new technology revolutionary technology which can diagnose in 100 minutes. UNITAID is currently having discussions regarding the price implications of this new technology and how Donors and Partners can investment in this global scale up based on their respective added value.

XV. ISSUES AND/OR LESSONS LEARNT

During Project implementation it has been noted that the success in country implementation of the EXPAND-TB Project is highly dependent on local political commitments and in country Partner collaboration and involvement.

[56] BD and Hani
[57] National Reference Laboratory in Yangon and the Regional laboratory at Mandalay

SEMI-ANNUAL REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I. Reporting Period: January - June 2010[58]

II. Disease: TB

III. Niche: MDR- TB

IV. Project Name:
a) MDR TB Scale-Up Initiative
b) MDR-TB Acceleration of Access Initiative

V. Key Partners:
a) Green Light Committee (GLC), the Global Drug Facility (GDF) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF)
b) Stop TB Partnership's Global Drug Facility

VI. Timeframe for Support:
a) 25 July 2007 to 2012
b) November 2008-December 2011

a) The Memorandum of Arrangement (MOA) was signed 25th July 2007, making this the project's start date. To date there have been two Amendments to the MoA. The last Amendment signed August 2010 has extended the duration of this project until 2012. The MOA will remain in effect until such time as all the drugs procured under the Project have been satisfactorily delivered and until acceptance by UNITAID of the final programmatic and financial reports submitted to UNITAID by GDF.

VII. Start Date: 25 July 2007

VIII. Total Amount Approved:
a) US$ 54,046,319
b) US$11,457,799

IX. Money Holder: a) and b) GDF

X. Procurement Agent: IDA Foundation

[58] Ad hoc reporting

XI. FINANCIAL AND PROCUREMENT

A.

DISBURSEMENT SCHEDULE[59] (date, amount)		DISBURSEMENTS MADE (date, amount)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
8 August (which is 10 days of last signature of Memorandum of Arrangement between Parties)	US$ 7,090,000	2nd August 2007	US$ 7,090,000	
15 April 2008	US$ 2,482,500	N/A	N/A	No disbursement request was submitted
15 October 2008	US$ 2,482,500			A disbursement request for a total of US$4,965,000 was submitted to the Secretariat on the 16th of October 2008. This amount is the sum of the scheduled disbursement for the 15th of April 2008[60] (US$2,482,500) and 15th October 2008 (US$2,482,500).
6 July 2009	US$ 9,510,302	6th July 2009	US$ 9,510,302	Report deemed satisfactory
30 August 2010	US$ 18,480,646			Cash reconciliation financial report requested from UNITAID received from Partner 28th September 2010. Report currently under review by UNITAID
30 November 2011	US$ 8,902,547			
Earmarked payment retained by UNITAID	US$ 5,096,826			Cost fluctuation buffer to be retained by UNITAID and only disbursed in whole or part upon request by GDF on one or more occasions during the Project lifetime based on sound written justification
	US$ 54,046,000	**TOTAL AMOUNT DISBURSED: US$ 21,565,302** **PERCENT DISBURSED: 40%**		

[59] This disbursement schedule does not yet reflect the additional budget US$16,842,000 that was approved by the EB meeting of July 2008. This additional budget will be documented through an Amendment to the MoA, and such amendment is still under discussion with the GDF/GLC/GF.

B.

DISBURSEMENT SCHEDULE[61] (date, amount)		**DISBURSEMENTS MADE (date, amount)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
8 November 2008 (which is 10 days of last signature of Memorandum of Arrangement between Parties)	US$ 9,585,303	8 November 2008	US$ 9,585,303	
30 June 2009	US$ 432,043			Disbursement was not made due to lack of evidence of need. A decision was taken by UNITAID to assessment the progress to be reported in the Annual Programmatic and Financial Report and if deemed satisfactory at that time this disbursement will be made in conjunction with the June 2010 disbursement
30 June 2010	US$ 432,043			The Partners are currently assessing the efficiency of the Stockpile pending the finalization of this assessment the Partners stated that the pending disbursement of 2009 in addition to the 2010 is currently not required.
Earmarked payment retained by UNITAID	US$ 1,008,410			Cost fluctuation buffer to be retained by UNITAID and only disbursed in whole or part upon request by GDF on one or more occasions during the Project lifetime based on sound written justification
	11,457,799	**TOTAL AMOUNT DISBURSED: US$9,585,303** **PERCENT DISBURSED: 84%**		

[61] This disbursement schedule does not yet reflect the additional budget US$16,842,000 that was recently approved by the EB meeting July 2008. This additional budget will be documented through an Amendment to the MoA, and such amendment is still under discussion with the GDF/GLC/GF.

REPORTING SCHEDULE[62] **(date, report type, period covered**		**REPORTS RECEIVED** **(date, report type, Period covered**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
1st Interim progress report July - November 2007	20 December 2007	21 December 2007	1st Interim progress report	Report was deemed satisfactory by the Secretariat.
1st Annual programmatic and financial report January – December 2007	31 March 2008	See Reasons for any deviation and or any other remarks		The MoA came into effect in July 2007. GDF submitted a 1st Interim Progress Report with an uncertified financial statement in December 2007, covering July to December 2007. The period covered by this 1st Interim Progress Report, taking into account the actual start date of the project, covered the same period as would have been covered in the Annual programmatic and financial report. Due to the aforementioned reason, the 1st Annual programmatic and financial report was not submitted. However, an Addendum to the interim report and certified financial statement were submitted. The Addendum to the interim report provided complimentary technical confirmation and served as an update to the 1st Interim Progress Report.
Interim progress report. January – June 2008	30 September 2008	15 October 2008	2nd Interim progress report	Report deemed satisfactory
Annual programmatic and financial report January – December 2008	15 March 2009	April 2009	1st Annual Programmatic and Financial Report	Report deemed satisfactory
Interim progress report January – June 2009	15 October 2009	October 2009		Financial assessment to be done in conjunction with assessment of 2nd Annual Report
Annual programmatic and financial report January – December 2009	31 March 2010	31 March 2010		Progress achieved was reported at the EB12
Interim progress report January – June 2010	15 October 2010			
Annual programmatic and financial report January – December 2010	15 March 2011			
Interim progress January - June 2011	15 October 2011			
Annual Programmatic and Financial	15 March 2012			

[62] Reporting reflective of MDR-TB Scale-Up Initiative and MDR-TB Acceleration of Access Initiative: Strategic Rotating Stockpile effective 15th October 2009

REPORTING SCHEDULE[62] **(date, report type, period covered**		**REPORTS RECEIVED** **(date, report type, Period covered**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
January - December 2011				
Interim Progress January- June 2012	15 October 2012			
Final Project and Financial Report.	90 days after settlement of all obligations and activities commenced prior to the completion of the project			

XII. PROJECT PROGRESS[63]

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate)		CUMULATIVE YEARLY TARGETS					ACTUAL TARGETS REACHED TO DATE[64]	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Yr	Year 1 2008-2009	Year 2 2009	Year 3 2010	Year 4 2011	Year 5 2012		
Patient treatments delivered	0[65]	2007	3,133	2,920	3,957	5,596	15,606	3,499	The projected target of patients to be treated by end of 2012 is 15,606. The increase in total delivery target is due to the inclusion of India which alone totals 9,850 patient treatments. Delivery of treatments to India will begin November 2010 In this reporting period 407 patient treatments were delivered in 5 of the 17 countries.
Decrease drug delivery lead times (months) and prevent stock-outs (via a Rotating Stockpile)	4- 6[66]	2007	1-3	1-3	1-3	1-3	1-3	29 days	In this reporting period the average lead time has decreased by 10 days in comparison to the average lead time reported in June 2009
Creation of Rotating Stockpile	0	2007	800[67]	5,800[68]	800	800	800	100%[69]	The Stockpile consists of the equivalent of 5,800 patient treatments which is held in the warehouse of GDF's second-line anti-TB drug Procurement Agent (IDA).
Number of Green	0	2007	15	17	18	18	18	18	

[63] Reporting reflective of MDR-TB Scale-Up Initiative and MDR-TB Acceleration of Access Initiative: Strategic Rotating Stockpile effective 15th October 2009

[64] Please note that targets are yearly and hence may not always be reported on a semi-annual basis.
[65] With respect to UNITAID funding of second-line treatments
[66] Standard delivery leads time for drug delivery.
[67] The Rotating Stockpile was created to supply an estimated 800 patient treatments. The April 2008 Board Approved Project 'MDR-TB Scale-up Acceleration and Access Initiative' endorsed an augmentation of the existing MDR-TB Rotating Stockpile to service an additional 5,000 patient treatments, which will have an impact on this Project. The augmented Strategic Rotating Stockpile is expected to accelerate services for newly enrolled patients under GLC approved country projects/programmes. The increased coverage of the Rotating Stockpile will be reflected in the next update to the Board, after the relevant legal document is finalized.
[68] Fully operational zed Q3 2009
[69] Fully functioning and servicing orders from countries

KEY OBJECTIVES/ ACTIVITIES	BASELINE (if appropriate)		CUMULATIVE YEARLY TARGETS					ACTUAL TARGETS REACHED TO DATE[64]	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Yr	Year 1 2008-2009	Year 2 2009	Year 3 2010	Year 4 2011	Year 5 2012		
Light Committee (GLC) beneficiary countries approved to be served under this agreement.									
Increase the number of pre-qualified drugs	1	2007	>1	>1	>1	>1	>1	5	No new second-line drugs were prequalified in this reporting period. In this reporting period 12 dossiers were submitted to WHO PQ Programme and are currently under assessment. Various actions were taken in 2009 to increase the number of number of quality manufacturers and products. The outcome of these actions will be reported in EB14.
Achieve price reductions of up to 5-20% for second-line anti-TB drugs by 2010	0	2007	N/A	N/A	N/A	up to 20%	Up to 25%	N/A	Reducing price is based on increasing the number of eligible pre-qualified manufacturers approved by the WHO PQ Programme.
Competitive prices (US$) secured via direct negotiation.	0	2007	N/A	N/A	N/A	N/A	N/A	Yes	As reported in EB12, the Price Negotiation Task Force established by the GDF has resulted in 4 of the 11 manufacturers committing to provide fixed prices for up to 24 months. A further 4 have committed to fixed prices for 12 months and 3 committed to fixed prices for 2010.

XIII. OVERALL ASSESSMENT OF PERFORMANCE

A. The project has four main objectives:

L. Scale-up the number of patients accessing and receiving second-line anti-TB treatment;
M. Decrease drug delivery lead times and prevent stock-outs;
N. Increase the number of quality manufacturers and products; and
O. Ensure cost containment per treatment by 2012 and
P. Achieve price reductions[70] of 5-25% for second-line anti-TB drugs by 2012.

A. The SRS project has three broad objectives:

Q. Accelerate scale-up of the number of patients accessing and receiving second-line anti-TB treatment through a decrease in drug delivery lead times
R. Increase the number of quality manufacturers and products
S. Achieve price reductions for key second-line anti-Tb drugs by 2011

In addition to the above objectives, this Project will help to reinforce the effectiveness of HIV actions by countering the threat of HIV/MDR-TB co-infection.

The Project continues to gain momentum, despite some delays in project start up in 2007. Six of the 18 countries have achieved their target or will achieve their target by Q1 2011. In August 2009 UNITAID, the GDF the Green Light Committee and the Global Fund signed an Amendment to this Project Agreement to include India.

Some key achievements to-date includes:

Countries continue to access the Strategic Rotating Stockpile for the purposes of enrolling new patients and continuing treatment of already enrolled patients. In this reporting period 35 countries (including GF grantees who have GLC approval) benefited from the Strategic Rotating Stockpile. In addition to the Strategic Rotating Stockpile being used to fulfill urgent orders, the SRS was used to complete 34 standard orders to ensure timely delivery and to rotate the stock with respect to shelf-life.

XIV. PLANNED CHANGES IN THE PROJECT, if any

The SRS project set up has passed the mid point of its 3-year timeframe. The statistics of the last 18 months, i.e. from the point the when the stockpile was physically augmented with an additional 5000 treatments, has proven the effectiveness of the SRS to substantially decrease lead times for urgent deliveries and alongside the MDR-TB Scale Up Initiative, to stimulate the market for MDR-TB drugs. Nevertheless, the full potential of the SRS is yet to be fully realized. In September 2010, the GDF submitted to UNITAID a request for additional financing of this mechanism. This request will be presented at the next UNITAID Board (EB14), if recommended by the UNITAID Proposal Review Committee.

GDF envisions a redesign of the SRS both conceptually and in terms of volume to include all MDR-TB Drugs procured by the countries for scale up, as per GLC recommendations. **The plan is to use the stockpile not only for urgent orders and completion of standard orders, but to shift to serving all orders with standard requirements from the stockpile to further meet the country requested lead-times and to accelerate the scale-up.** With the envisioned changes and given the substantial share in the total supply of MDR-TB drugs the SRS will have, it could become an increasingly powerful instrument to stimulate and shape the market of quality-assured MDR-TB drugs.

In addition the WHO/STB has established a Task Force on MDR-TB Scale-Up: Supply and Procurement Function. A proposal for an Advance Purchase Commitment for key MDR-TB Drugs is currently being developed by WHO/STB and the Stop TB Partnership

[70] Subject to a sufficient number of quality assured sources being available for key second-line anti-TB drugs

XV. ISSUES AND/OR LESSONS LEARNT

Key issues and lessons learnt are as follows:

Significant treatment scale-up in the MDR-TB niche and further positive impact on market dynamics cannot be solved by financing of second-line drugs alone – such scale-up is greatly constrained by a lack of diagnostic capacity at country level. The MDR-TB Diagnostics Proposal (EXPAND-TB) that was approved by the UNITAID Board is one of the Projects intended to help address this challenge. In addition greater investment and engagement with manufacturers is required.

The capacity of manufacturers is a limiting factor for procurement, thus creating the risk that not all orders could be procured. Therefore it is important to ensure that credible short to mid-term forecasts are available for existing suppliers and to widen the pool of eligible suppliers so that capacity barrier is eliminated.

GDF is proactively working to identify potential new suppliers in order to eliminate the risk of capacity restrictions and promote the WHO Prequalification of Medicines Program (PQP) as a major requirement of sourcing of quality drugs through the GDF. As a result, a new potential supplier of Kanamycin sent in the files for Kanamycin product to WHO PQP in August 2010, and a new supplier of Cycloserine is expecting WHO PQP GMP inspection in November 2010.

PROJECT WITH PENDING LEGAL AGREEMENTS

MDR-TB ACCELERATION OF ACCESS INITIATIVE: STRATEGIC REVOLVING FUND

- Board approval in **April 2008**[71] of Strategic Rotating Stockpile and Strategic Revolving Fund[72]
- Decision[73] in **June 2008** to prepare two separate Project Plans for the two initiatives and to prioritize the one for SRS (since it was an expansion of an existing 800 patient treatment stock that was already in high demand and since the SRF was a new and complex undertaking)
- **Q3/Q4 2008** dedicated to development and completion of SRS (agreement signed in November 2008); in parallel discussions initiated with UNICEF and the PAHO Strategic Fund Office to accumulate lessons learned from similar initiatives and also validate risk assumptions for the SRF. This process of information gathering including obtaining indicative SOPs, Agreement templates with countries was concluded end 2008.
- A first draft of the Project Plan was then submitted to WHO Legal by GDF in late **January 2009**
- Several meetings were held between GDF and WHO Legal from **February and March 2009** on the draft plan.
- In **May 2009** the 1st draft of the Strategic Revolving Fund Project plan was submitted for UNITAID review
- **July 2009**: A revised Plan (2nd draft) was submitted to UNITAID based on UNITAID's initial feedback and review
- **August 2009**: The 3rd draft was submitted to UNITAID. A decision was taken by UNITAID to submit to the IEAG for a review of the 3rd draft of the Project Plan
- **October 2009**: The outcome of the IEAG's review - request for clarification and recommendations were submitted to the GDF.
- **February 2010**: The 4th draft Project Plan taking into consideration the recommendations of the IEAG was submitted to UNITAID by the GDF
- **March 2010**: A **financial analysis** of the feasibility/capacity of the implementation of the Strategic Revolving Fund is being conducted by the UNITAID Finance and Administrative Team The outcome of this analysis[74] will determine the next actionable steps of this pending Project.
- **End June - August 2010:** Refinement of Project plan and negotiation on the terms and conditions of the Legal Framework
- **September 2010:** Finalization of the Project Plan and terms and conditions of Legal Framework.

The Project is currently under negotiation.

[71] EB7 Resolution 3: Budget ceiling US$33,690,000
[72] Project Name: *Multi-Drug Resistant (MDR)-TB Scale-up and Acceleration of Access: 2008-2011*
[73] UNITAID, UNITAID Legal Representatives and the Stop TB Partnership's Global Drug Facility
[74] Anticipated to be completed in June 2010

Project Update Malaria niche:

ACT scale-up

LLINs

AMFm

A2S2

SEMI-ANNUAL REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I. Reporting Period: 4 December 2007 to 31 December 2009 (based on official report received), with additional updates based on: a) project developments discussed directly with the UNITAID Secretariat; and b) UNICEF's web-based order status report.

II. Disease: Malaria

III. Niche: ACT

IV. Project Name: ACT Scale-up Initiative

V. Key Partners: The Global Fund to Fight HIV/AIDS, TB and Malaria (The Global Fund) and United Nations Children's Fund (UNICEF)

VI. Timeframe for Support: From 4 December 2007 to approximately end of August 2011

The last signature for the Memorandum of Understanding (MOU) was secured on 4 December 2007, making this the project's start date (section 5.1 of MOU). The MOU will remain in effect until such time that all the drugs procured under the project have been satisfactorily delivered and until final acceptance by UNITAID of the Final Programmatic, Procurement and Financial reports submitted to UNITAID by UNICEF and the Global Fund.

VII. Start Date: 4 December 2007

VIII. Total Amount Approved: US $ 78,887,568 (budget ceiling)
The UNITAID Board's commitment originally covered agreed upon targets of 68,021,416 additional treatments for UNITAID funding support. However, as a result of further assessment by the Global Fund, the estimated treatment numbers for this project were reduced to 47,016,160 for the period 2007 to 2011. The revised treatment target was estimated to cost US$ 65,413,057. These were the budgets and targets reflected in the signed MOU.

Subsequent to the signing of the MOU, the adjustments to the project's target deliveries and timelines have resulted to a lower treatment target of 43,329,731.

After taking into account the more recent price adjustments, savings from the first years of implementation and adjustments in country targets, the budget has been revised to US$ 51,659,815 of July 2010.

IX. Money Holder: UNICEF

X. Procurement Agent: UNICEF

XI. FINANCIAL AND PROCUREMENT

DISBURSEMENT SCHEDULE[i] (date, amount)		**DISBURSEMENTS MADE (date, amount)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
On or before 14 Dec 2007	US $ 15,601,173	6 Dec 2007	US $ 15,601,173	There was neither deviation in amount nor timeline
15 April 2008[ii]	US $ 9,128,683	15 April 2008	US $ 9,128,683	There was neither deviation in amount nor timeline
15 October 2008	US $ 4,644,698	19 Dec 2008	US $ 4,644,698	The official disbursement request was received on the 12th of November 2008.
15-Apr-09	US$ 7,083,305.46	9 July 2009	US $ 7,083,305.46	The requested disbursement was processed after receipt of the finalized report, which was submitted on the 5th of June 2009
15-Oct-09	No disbursement	No disbursement	No disbursement	Due to reprogramming of target deliveries, fund remittance was not required in October 2009.
15 April 2010	No disbursement	No disbursement	No disbursement	Due to reprogramming of target deliveries, fund remittance was not required in April 2010.
15 October 2010	US $ 5,553,011			The amount cited (US$ 5,553,011) is still under discussion with UNICEF and Global Fund and may be revised, in accordance with the outcome of the discussions.
15 April 2011				

DISBURSEMENT SCHEDULE[i] (date, amount)		DISBURSEMENTS MADE (date, amount)	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
		TOTAL AMOUNT DISBURSED: US$ 36,457,859.46 **PERCENT DISBURSED: 71 % (of US$ 51,659,815)**	*The scheduled disbursements as presented in this table are as per latest discussions with UNICEF. Note that this schedule takes into account the funds carried over from previous periods, which are expected to be deducted from the last scheduled disbursement – thus, the sum of the scheduled disbursements at this stage is lower than the total revised budget.*

REPORTING SCHEDULE (report type, period covered, date)		REPORTS RECEIVED (report type, period covered, date)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
1st Interim Progress Report 4 December 2007 to 31 December 2008	31 March 2008	1st Interim Progress Report 4 December 2007 to 31 December 2008	31 March 2008	The report was submitted on time and met the information requirements as specified in the MOU.
1st Annual Programmatic, Procurement and Financial Report 4 December 2007 to 30 June 2008	30 September 2008	1st Annual Programmatic, Procurement and Financial Report 4 December 2007 to 30 June 2008	15 September 2008	The report was submitted on time and met the information requirements as specified in the MOU.
2nd Interim Progress Report July 2008 to 31 December 2008	31 March 2009	2nd Interim Progress Report July 2008 to 31 December 2008	5 June 2009	The initial report was submitted on the 31st of March 2009. Clarifications and the final version were submitted on the 5th of June 2009.
2nd Annual Programmatic, Procurement and Financial Report 1 July 2008 to 30 June 2009	30 September 2009	2nd Annual Programmatic, Procurement and Financial Report 1 July 2008 to 30 June 2009	30 September 2009	The report was received on time and met the information requirements.

REPORTING SCHEDULE (report type, period covered, date)		**REPORTS RECEIVED (report type, period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
3rd Interim Progress Report 1 July 2009 to 31 December 2009	31 March 2010	3rd Interim Progress Report 1 July 2009 to 31 December 2009	31 March 2010	The report was received on time. Additional programmatic details in response to UNITAID request are expected to be provided in the next report.
3rd Annual Programmatic, Procurement and Financial Report 1 July 2009 to 30 June 2010	30 September 2010	30 September 2010	30 September 2010	The timeline for finalization of project updates to the PSC precluded reporting on the basis of the 3rd Annual Programmatic, Procurement and Financial Report.
4th Interim Progress Report 1 July 2010 to 31 December 2010	31 March 2011			
Final Project and Financial Report 4 December 2004 up to the end of the project	Due 90 days after settlement of all obligations			

XII. PROJECT PROGRESS

KEY OBJECTIVES / ACTIVITIES	BASELINE (if appropriate) Before UNITAID funding		CUMULATIVE YEARLY TARGETS [iii] [iv] (additional targets as a result of UNITAID funding, targets are in the form of ACT products requested by Global Fund PRs)				ACTUAL TARGETS REACHED TO DATE [v]	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year	Calendar Year 2008	Calendar Year 2009	Calendar Year 2010	Calendar Year 2011		
Scale up the number of patients accessing and receiving ACT treatment	Approximately 52 million treatments [vi]	By the end of all Global Fund grants that are included in the project	9.7 million treatments	24.1 million treatments	39.9 million treatments	43.3 million treatments	The delivered quantities of UNITAID funded treatments are not required to be reported distinctly from the total delivered quantities.	For the reporting period ending December 2009, the combined result (combination across grants and combination of UNITAID and Global Fund supported treatments) is **20,380,148** people treated. These results were reported by Cambodia, Ghana, Indonesia, Madagascar, North Sudan, and Zambia. The ACT Scale Up procurement and delivery report on the UNICEF website (dated September 2010) indicated that: a. As of the period ending 2009, a total of **15.16 million** UNITAID funded treatments have been delivered to the participating countries. b. As of July 2010, a total of **24.07 million** UNITAID funded ACTs have been delivered to countries and **another 4.23 million** are expected to arrive in the participating countries by October 2010.

<table>
<tr><th rowspan="2">KEY OBJECTIVES / ACTIVITIES</th><th colspan="2">BASELINE (if appropriate) Before UNITAID funding</th><th colspan="4">CUMULATIVE YEARLY TARGETS [iii] [iv] (additional targets as a result of UNITAID funding, targets are in the form of ACT products requested by Global Fund PRs)</th><th rowspan="2">ACTUAL TARGETS REACHED TO DATE [v]</th><th rowspan="2">REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS</th></tr>
<tr><th>Value</th><th>Year</th><th>Dec 2007 to June 2008</th><th>July 2008 to June 2009</th><th>July 2009 to June 2010</th><th>July 2010 to June 2011</th></tr>
<tr><td>Decrease the delivery time and prevent stock outs</td><td>Average standard delivery time from placement of Purchase Order until CIP (carriage and insurance paid to) delivery at port of entry: between 8-10 weeks

Additional 4 weeks (approximately) to be added to the delivery time for products that are selected for random testing according to Global Fund Quality Control policy (Ci and Cii category)</td><td>2007</td><td>No numerical targets were set</td><td>No numerical targets were set</td><td>No numerical targets were set</td><td>No numerical targets were set</td><td></td><td>The ACT Scale Up procurement and delivery report on the UNICEF website (dated September 2010) reflected a total of 85 orders, with average lead time for 2010 showing improvements over 2009. The average lead time per supplier, computed as arrival date less the PO order date are:

(Box 1)
<table>
<tr><th>Supplier</th><th>2008</th><th>2009</th><th>2010</th><th>Overall Average</th></tr>
<tr><td>Activa</td><td>81</td><td>114</td><td></td><td>98</td></tr>
<tr><td>Cipla</td><td></td><td>93</td><td>46</td><td>76</td></tr>
<tr><td>Guilin</td><td>28</td><td>74</td><td></td><td>54</td></tr>
<tr><td>Ipca Lab</td><td>45</td><td>268</td><td></td><td>109</td></tr>
<tr><td>Novartis</td><td>72</td><td>54</td><td>71</td><td>66</td></tr>
<tr><td>Strides</td><td>154</td><td>302</td><td>100</td><td>202</td></tr>
<tr><td>Overall Average</td><td>69</td><td>102</td><td>67</td><td>81</td></tr>
</table></td></tr>
</table>

KEY OBJECTIVES / ACTIVITIES	BASELINE (if appropriate) Before UNITAID funding		CUMULATIVE YEARLY TARGETS [iii] [iv] (additional targets as a result of UNITAID funding, targets are in the form of ACT products requested by Global Fund PRs)				ACTUAL TARGETS REACHED TO DATE [v]	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	**Year**	**Dec 2007 to June 2008**	**July 2008 to June 2009**	**July 2009 to June 2010**	**July 2010 to June 2011**		
Increase the number of quality manufacturers and products	2 prequalified ACTs	2007	No numerical targets were set	No numerical targets were set	No numerical targets were set	No numerical targets were set	9 as of end 2009	The WHO Prequalification website indicates that from the signing of this project's MoU in December 2007, nine additional ACT products have been prequalified, of which 8 are FDCs. Of these, four are for Artemether-Lumefantrine tablets, which are particularly significant in light of the high project demand for this treatment combination (i.e., Mozambique, Zambia, and Ethiopia). In addition, one such FDC of Artemether-Lumefantrine 20mg+120mg formulation (Novartis Pharma) has been made available in dispersible tablets, which, among others, presents a comparative advantage over the non-dispersible tablets in ease of oral consumption, storage and transportation. *Note: The PQ data cited in this section reflects the additional Prequalified ACTs in the global market, which may not have the same reporting criteria for the UNITAID funded PQ project, which is limited to those that were facilitated with UNITAD funding.*

XIII. OVERALL ASSESSMENT OF PERFORMANCE

The project has four objectives relating to the scale up ACT treatments for malaria control and to positively impact market dynamics to increase the affordability of ACTs. The project is progressing steadily, albeit with demonstrated delays, as presented below. The delivery of UNITAID funded treatments is being coursed through Global Fund grants, thus achieving synergies with other programme components supported by the Global Fund. Under this project's MOU, UNICEF has committed to country level activities that complement the UNITAID funded treatments.

AVAILABILITY
Objective: Scale Up the Number of Patients Accessing and Receiving ACT Treatment

UNITAID's contribution of additional ACT treatments are implemented and tracked through the Global Fund's grant infrastructure by amending existing Global Fund grants agreements and treatment targets with Principal Recipients to include UNITAID funded treatments.

Results

In the report submitted on March 2010, the Global Fund reported **20,380,148** people treated for the period ending December 2009 representing combined results of UNITAID and Global Fund supported treatments. These results were reported for Cambodia, Ghana, Indonesia, Madagascar, and North Sudan, and Zambia. UNICEF, as Procurement Agent for the project, maintains a web-based order and delivery information for this project. The data as of September 2010 indicate that: a) as of end December 2009, a total of 15.16 **million** UNITAID funded treatments have been delivered to the participating countries; and b) as of July 2010, **24.07 million** UNITAID funded ACTs have been delivered to countries and **another 4.23 million** are expected to arrive in the participating countries by October 2010.

Treatment targets

As of end 2009, nine (out of the eleven[vii]) participating grants have been amended to reflect UNITAID support, with the intention of treating 52,693,078 people overall [viii] representing an increase of 28,697,228 from previous grant targets.

As of end December 2009, grants for the following countries had yet to be amended to incorporate UNITAID-funded ACTs: South Sudan and Ethiopia. Subsequently, the Global Fund provided UNITAID Secretariat with the signed Implementation Letter for Ethiopia, dated 13 April 2010. No update regarding the signing of the Implementation Letter for South Sudan has been received to-date.

Progress and performance of participating programs in implementing ACT treatments

Overall performance of Global Fund grants: The Global Fund evaluation process classifies grant performance in four categories: excellent performance (rated A), adequate performance (B1), inadequate performance (B2-rated) or unacceptable performance (C-rated). 2 of the 11 participating grants have not yet been amended and therefore their ratings were not reported and 1 reached completion date in 2008. It was reported that for the period ending December 2009, the 8 actively participating grants received Global Fund ratings of : A1 (1 grant); B1 (4 grants); and B2 (3 grants).

DELIVERY
Objective: Decrease the Drug Delivery Lead Times and Prevent Stock-Outs

UNICEF has secured an agreement with its suppliers, which requires these suppliers to maintain buffer stock and to rotate the stock so that acceptable remaining shelf life (above 80%) is always available. To date, there have been no emergency requests received from countries which required stockpile utilization. The UNICEF clause on stockpile maintenance has continued to contribute to shorter lead times at the time of order confirmation, as it implies that finished product manufacturers increase their buffer stocks of Active Pharmaceutical Ingredients (APIs) and packaging materials, and factor in higher quantities for production planning (finished product).

Box 1 (Section 12 above) indicates improved delivery times over orders placed in 2009.

QUALITY
Objective: Increase the Number of Quality Manufacturers and Products

From the signing of the MOU in December 2007, nine additional ACT products have been prequalified, of which 8 are FDCs. Of these, four are for Artemether-Lumefantrine tablets, which are particularly significant in light of the high project demand for this treatment combination (i.e., Mozambique, Zambia, and Ethiopia). In addition, one such FDC of Artemether-Lumefantrine 20mg+120mg formulation (Novartis Pharma) has been made available in dispersible tablets, which, among others, presents a comparative advantage over the non-dispersible tablets in ease of oral consumption, storage and transportation.

UNICEF shares with WHO (Global Malaria Programme) periodic updates on the actual procurement of ACTs, along with the expected demand, in order to facilitate production planning and sourcing of raw materials/APIs. Better demand information made available, together with spot-price and performance-based allocation of orders, are key in achieving price reductions and increased availability, while remaining fair and transparent.

As part of UNICEF strategy of pursuing all options to expand access to essential medicines, the invitation to bid was extended to a total of 30 manufacturers under the 2009 joint WHO-UNICEF RFP (closed on 24th March 2009), while clearly prioritizing products that have obtained full prequalification approval. It was reported that 13 companies submitted valid proposals - of these, eight were awarded contracts: Africasoins SAS; Ajanta Pharma; Cipla; Dafra Pharma GmbH; Guilin; Ipca Laboratories Limited; Novartis; and Strides Arcolab.

XIV. PLANNED CHANGES IN THE PROGRAMME, if any

It is to be recalled that the following changes to the project have been previously reported:

a. decrease in overall treatment targets on account of North Sudan
b. revision of budget from US $ 65,413,057 into US$ 54,214,397 as a result of the price adjustments and the reduction of treatment targets for North Sudan
c. roll over of treatment targets and budgets for Cambodia, South Sudan, Zambia, Ethiopia and North Sudan
d. acceleration of delivery of treatments for Mozambique

In addition to the above, the following changes have also taken place:

a. Madagascar Population Services International, PSI
    i. Original participating grant reached completion date and unused allocations were absorbed into Round 7 grant also managed by the same PR (PSI)
    ii. Year 3 treatment targets were partially rolled over to Year 4
    iii. treatment allocation for Madagascar PSI was changed from co-blisters to FDCs

b. Ethiopia delivery schedule was rolled over from Year 3 to Year 4

c. Zambia (Churches Health Association of Zambia, CHAZ)

i. Original participating grant reached completion date and unused allocations were absorbed into Round 7 grant also managed by the same PR (CHAZ)
ii. Cash disbursements to Zambia MOH grant were frozen and a planned change of PR to UNDP was announced. Global Fund clarified that the delivery of UNITAID funded ACTs was not interrupted in line with its continuation of treatment policy
iii. Change in target age group for Zambia MOH grant – from ages 6 and 12 to ages 18 and 24
iv. Partial acceleration of delivery schedule for Zambia MOH grant from Year 4 to Year 3

d. Ghana gave up its allocation of 1,575,000 treatments

e. North Sudan absorbed the 1,575,000 treatments given up by Ghana, which helped alleviate North Sudan's treatment gap

In spite of the above changes, the overall target treatments remained within the EB approved ceiling. The resulting financial impact of the differences in treatment regimens across the grants was also well within the EB approved ceiling.

The UNITAID EB has required that the second year funding and beyond to be calculated on the basis of potential new price agreements and as a result of an increased purchasing power or market impact of the 2007 orders. In line with this, and in consideration of the abovementioned changes and taking into account the results of the 2009 Joint UNICEF-WHO tender process, an updated budget has been submitted and approved.

XV. ISSUES AND/OR LESSONS LEARNT

Linkage with AMFm

The ACT Scale Up project three participating countries that are also covered under the AMFm. UNITAID has discussed these with the Global Fund with a view to avoiding overlaps.

Time Lag

Time lag between arrival of medicines in-country and LFA reporting of results achieved (patients treated) have been observed and Global Fund's response regarding contributory factors as well as implications on the reckoning of results achieved per grant are awaited.

Implications on Delivery and Project's End Date

As aforementioned, the delivery of some treatments were shifted from older grants to Round 7 grants. Taking absorptive capacity into account, the UNITAID funded ACTs could not be fully scheduled within Round 7 Phase 1. While delivery under Round 7 Phase 2 is not discounted, it has to be borne in mind that graduating to Phase 2 would be dependent on the performance under Phase 1. There is therefore a possibility that the UNITAID funded treatments would not be fully delivered by August 2011 (the anticipated end date as per MOU). The possibility of a request for extension has been informally raised by the Global Fund.

Importance of complementary reporting

This project supports eleven Global Fund grants. Overall progress requires consolidating the individual reports for these grants, which have their respective implementation and reporting arrangements. Since these grants have their individual timelines and reporting cut off periods, there is a possibility that progress already achieved may not have been included in the overall progress reported to UNITAID. Additionally, the achievements reported through the Global Fund cover both the Global Fund and UNITAID funded components. The order data that UNICEF provides in its website provides an important source of more updated information and also allows for specific monitoring of UNITAID funded ACTs.

UNITAID funded ACTs not fully integrated into the participating Global Fund grants

In the discussions leading up to the finalization of the MOU for this project, and in the context of UNITAID's principle of additionality, UNITAID communicated its expectation that the ACT treatment targets for the participating grants would be increased by as much treatments that are to be funded by UNITAID. However, this had not been the case. The Global Fund clarified that it did not share this understanding and expectation, citing the negotiation processes between the Global Fund FPMs and PRs on setting grant treatment targets, as described in the earlier section of this report. The Global Fund further clarified that the ACT procurement funds and UNITAID’s maximum contribution for ACTs are taken into account when setting revised treatment targets. However, the FPM’s primary focus is to set a feasible and practical target for implementation. The Global Fund does not require the PRs to order all of UNITAID’s contribution nor reflect this maximum amount in grant agreements.

END NOTES

[1] The disbursements for April 2008 was in consideration of the acceleration of delivery of ACTs for Mozambique, as agreed upon in April 2008. The projected disbursement for October 2008 was in consideration of the revised budget as of October 2008, taking into account the decreased treatment targets for North Sudan and other price adjustments. The projected disbursements from April 2009 onwards are in consideration of prior year balances that were re-programmed.

[1] While both the UNITAID Board and the Global Fund emphasize the importance of the sustainability of funding, the UNITAID Board has conditioned funding commitment and disbursements for 2008 and beyond as being "subject to evidence of need and on demonstration of the Principal Recipient's satisfactory performance, as assessed and reported under Global Fund's results based funding policies and procedures ". Consequently, the MOU provides that continuation of UNITAID-funded ACT support is subject to evidence of need, technical soundness, evidence of progress for the realization of project objectives and submission of technical and financial reports (ref section 3.2.2, page 5/40 of MOU).

[1] The additional targets as a result of UNITAID funding are in the form of ACT products requested by Global Fund Principal Recipients (PRs). The numerical targets in this table are as they appear in the MOU. However, it is to be noted that the project is being implemented through the Global Fund architecture, under which these figures were expected to represent a ceiling as opposed to a target. The Global Fund indicated that it is not their intention to make the PRs request their full allocation unless it is feasible for implementation.

[1] The targets presented in this report reflect the roll overs approved since and adjustments, in target allocations and deliveries, as of July 2010 . Comparative table of original, revised and projected yearly targets as per most recent roll over request is presented below:

	Cumulative Targets (in million ACTs)			
	Quantity Year 1 (Q4 07-Jun08)	**Quantity Year 2 (Jul08-Jun09)**	**Quantity Year 3 (Jul09-Jun10)**	**Quantity Year 4 (Jul10 Q1 11)**
Original yearly targets (per MOU)	10.1	22.5	33.9	47.0
Revised yearly targets after revisions approved as of July 2010	4.3	15.1	33.1	43.3

The net decrease in cumulative targets is attributed to the lowered overall targets for North Sudan. In addition to the lowered targets for North Sudan, the other approved changes in delivery schedules pertain to:

a. deferment of target delivery dates (ie, from one project year to later project years) for the following: Cambodia, North Sudan, South Sudan, Zambia, and Ethiopia)
b. acceleration of target delivery dates for Mozambique
c. swap of unused allocation of Ghana, to the favor of North Sudan

[1] Targets are yearly and hence may not always be reported on a semi-annual basis. The target treatment deliveries as reflected in the signed MOUs are based on project years (ie, July to June). In light of the UNITAID Secretariat's aim of standardization of reporting of results, the project year targets have been converted into calendar year targets through pro-rata calculation as discussed with the implementing partners. See endnote iv for the targets per project year.

[1] As computed by the Global Fund on the basis of the originally indicated participating grants. Previously recorded baseline data was 165 million treatments, as provided by the Global Fund. The Global Fund subsequently clarified that this included erroneous treatment targets for Mozambique, South Sudan, Zambia and Ethiopia. Mozambique and Zambia's use of ACT is new to scale-up and previous targets for these countries and South Sudan included treatments targets using non-ACT products and should not have been included. Ethiopia's current treatments targets were erroneously reported by the PR in the invitation to participate.

[1] Including the participating grant for Indonesia which has reached the end of the grant lifetime.

[1] The 2nd Annual Report (dated September 2009, for the period ending June 2009) indicated a revised treatment target of 54,067,244 people, In March 2010, a revised treatment target of 52,693,078 was reported. The decrease was attributed to the revised treatment targets for Madagascar PSI and Cambodia grants (ref: 3rd Interim Report (for the period ending December 2009).

INTERIM REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I.	**Reporting Period:**	March 2010 - September 2010
II.	**Disease:**	Malaria
III.	**Niche:**	Long Lasting Insecticide Treated Nets (LLINs)
IV.	**Project Name:**	Accelerating Scale-up of Long Lasting Insecticide Treated Nets (LLINs)
V.	**Key Partners:**	United Nations Children's Fund (UNICEF)
VI.	**Timeframe for Support:**	From 25 February 2009 to December 2010
VII.	**Start Date:**	25 February 2009
VIII.	**Total Amount Approved:**	US $109,246,140
IX.	**Money Holder:**	United Nations Children's Fund (UNICEF)
X.	**Procurement Agent:**	United Nations Children's Fund (UNICEF)

XI. FINANCIAL AND PROCUREMENT

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
On or before 25 February 2009	US $ 55,000,000	25 Feb. 2009	US $ 55,000,000	There was no deviation.
On or before 27 March 2009	US $ 54,246,140	20 Mar. 2009	US $ 54,246,140	The fund transfer date was advanced by one week as the transaction process was completed on time.
		TOTAL AMOUNT DISBURSED: US$ 109,246,140 (100%) **UNEXPENDED BALANCE REIMBURSED TO UNITAID US$ 8,408,423.79**		The target number of 20 million LLINs has been achieved. The unexpended project fund saved from the price reduction was reimbursed to UNITAID on the 17th of August 2010.

REPORTING SCHEDULE (report type, period covered, date)		REPORTS RECEIVED (report type, Period covered, date)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
1st Interim Progress Report 25 Feb. to 30 Aug. 2009	30 Aug. 2009	1st Interim Progress Report 25 February to 30 August 2009	31 August 2009	The report was submitted on time and met the information requirements as specified in the MOU.
Annual programmatic, procurement and financial 25 Feb. 2009 to 15 Mar. 2010	15 Mar. 2010	2nd Interim Progress Report 25 Feb. 2009 to 15 Mar. 2010	15 March 2010	The annual programmatic and financial report was received on-time. At the time of reporting, 20 million LLINs had been delivered to the beneficiary countries.
Extraordinary Report Requested by UNITAID	7 September 2010	Progress update	10 Sep. 2010	The final project report is due for the end of December 2010. UNITAID Secretariat requested an

REPORTING SCHEDULE **(report type, period covered, date)**		**REPORTS RECEIVED** **(report type, Period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
March to September 2010		15 Mar. - 7 Sept. 2010		extraordinary report covering the period from March to September 2010 to track status of distribution of the LLINs to beneficiary households.

XII. PROGRAMME PROGRESS

KEY OBJECTIVES/ ACTIVITIES	BASELINE (Before UNITAID funding)		Annual Project Target (LLINs in 2009)	ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year			
To increase access to insecticide-treated mosquito nets for the prevention of malaria in eight countries in sub-Saharan Africa	15.1million[75]	2008	20 million	20 million	Procurement and delivery of 20 million LLINs has been completed in March 2010 one month before the scheduled date of completion of the delivery.
To reduce global market price of quality Long-Lasting Insecticide treated nets (LLIN) (median price)[76]	US$4.47 US$4.96 US$7.51	2007	5-20% price reduction	2.5 to 17.3% US$4.36 US$4.62 US$6.21	For budgeting purposes, a weighted average price of US$ 4.93. The price reduction achieved, however, is presented based on median prices for each type of LLIN.
To shorten delivery lead-time of LLINs to beneficiary countries from the current average of 16 weeks to less than 12 weeks	0	2008	80%	80%	The 20 million LLINs were delivered through 64 orders of which 51 (80%) deliveries were completed in less than 12 weeks.

[75] The baseline value of fully funded LLINs in 2008 obtained from the project plan doesn't include contributions from DFID, US-PMI and GF Round 8 support.
[76] The price of LLINs varies by size and shape. The prices indicated are for small, large and conical LLIN.

XIII. OVERALL ASSESSMENT OF PERFORMANCE

Procurement and delivery of 20 million WHOPES recommended LLINs has been fully completed in January 2010. The impact of the project in-terms of price reduction and stabilizing the market of LLINs needs further data collection and analysis.
Some of the key achievements during the reporting period also include:

a) During the implementation period, three new LLIN products obtained WHOPES recommendations bringing the total number to eight as of August 2009. The new products are Permanet 2.5, and Permanent 3 and DawaPlus. It is believed that the LLIN project has created a motivating factor to expedite evaluation of LLIN products.
b) Compared to the baseline median LLIN price in 2007 of US$ 4.47 for small LLINs, US$4.96 for large LLINs and US$7.51 for conical LLINs, price reduction of 2.5% 6.9% and 17.3% respectively has been achieved through this project and this is closer to the targeted price reduction of 5-20%.
c) Procurement and delivery of the LLINs to beneficiary countries was completed one month ahead of schedule. The target lead-time for delivery of 12 weeks was achieved for 51 out of 64 (80%) of the purchase orders.
d) As at August 2010 a total of 18.8 million LLINs (94.1%) have been distributed to households. The remaining 1.2 million LLINs will be distributed in Central African Republic and Nigeria before the end of 2010. The number of LLINs distributed to households by country is presented in the following table

No.	Country	LLINs Delivered	LLINs distributed to Households	Date of distribution	Remark
1	Angola	850,000	850,000 (100%)	September 2010	
2	Central African Republic	1,100,000	258,298 (23.5%)	July 2010	The remaining 841,702 LLINs (76.5%) will be distributed before the end of 2010.
3	Congo- Brazzaville	470,000	470,000 (100%)	April 2010.	
4	Democratic Republic of Congo	5,500,000	5.5 million	May 2010	
5	Guinea-Conakry	1,300,000	1.3 million (100%)	November 2009	
6	Nigeria	6,500,000	6.2 million (95%)	August 2010	The remaining 339,350 (5.2%) will be distributed before the end of 2010
7	Sudan (Southern)	2,250,000	2.25 million (100%)	May 2010	
8	Sudan (Northern)	1,600,000	1.6 million (100%)	March 2010	
9	Zimbabwe	430,000	430,000 (100%)	November 2009	
Total		20,000,000	18,818,948 (94.1%)		

e) The funds required to conduct distribution of LLINs to households (US$23 million) has been fully mobilized by UNICEF and other partners.

Objective 1: To increase access to insecticide-treated mosquito nets for the prevention of malaria in eight countries in sub-Saharan Africa

The baseline value of fully funded number of LLINs in the project countries in 2008 is estimated around 15.1 million. This covered on average 34% (range 14% to 66%) of the target beneficiary households in the project countries. The additional 20 million LLINs that are being delivered through the UNITAID supported project are expected to increase the mean coverage to 54% (range 2 to 100%) by Q1 of 2011. The projected contribution of this project towards achieving RBM targets of universal coverage of LLINs by 2010 is significant, however, determining the actual increase in coverage requires data generated through surveys.

Objective 2: To reduce global market price of quality Long-Lasting Insecticide treated nets (LLIN) through injection of secured funding and support to market stabilization

The median price of LLINs procured through the UNITAID project was US$4.36 for small LLIN 180x160x150); US$4.62 for large LLINs 190cmx180cmx150cm, and US$6.21 for conical LLINs. Compared to the baseline prices in 2007 of US$ 4.47, US$4.96 and US$7.51, respectively, the percent price reduction achieved through this project is 2.5% 6.9% and 17.3% respectively. The weighted average price per LLIN considered for budgeting purposes at the start of the project of US$4.93 was higher than the US$4.88 baseline price in 2007. As a result of the higher budget estimate and the price reduction achieved, a total of US$8,408,423.798.4 of the project fund has been saved and fully reimbursed to UNITAID on the 17th of August 2010. This project has achieved a clear price reduction as the median prices paid through this project are lower than the baseline price in 2007. However, the factors that contributed to the price reduction and stability of the reduction achieved requires further analysis based on the final project report and data that will be received by the end of December 2010.

In an effort to ensure continuing engagement by manufacturers to produce WHOPES (WHO Pesticide Evaluation Scheme) recommended products, UNICEF conducted a joint discussion with manufacturers before the start of the project in October 2008. Following the consultation and the launch of the UNITAID supported LLIN project, more products entered the WHOPES evaluation scheme that resulted in WHOPES granting interim[77] recommendation for three new LLIN products, i.e. Permanet 2.5 and Permanet 3.0, in January 2009 and the Dawa Plus 2.0 LLIN in August 2009.

XIV. PLANNED CHANGES IN THE PROJECT, if any

During the project implementation, however, delays in LLIN delivery to countries have been reported due to changes of delivery points made to ensure optimal warehousing in the Democratic Republic of Congo (DRC) and to overcome road access problems during the rainy seasons in Southern Sudan.

[77] A recommendation or interim recommendation concerning a specific product means that the World Health Organization has evaluated that product in laboratory and field trials and that the product was found to meet the criteria and requirements of the World Health Organization. For long-lasting insecticidal mosquito nets (LNs), the World Health Organization may – pending the completion of long-term studies that may be required to fully evaluate such LNs and subject to certain conditions being met – issue an interim recommendation for the use of such LNs for malaria prevention and control. Ref. Report of the Twelfth WHOPES working group meeting. Available from http://whqlibdoc.who.int/hq/2009/WHO_HTM_NTD_WHOPES_2009_1_eng.pdf

Despite these delays reported at the early stage of the project, the overall timing of delivery of LLIN to countries of less than 12 weeks was achieved for 80% of the deliveries.

XV. ISSUES AND/OR LESSONS LEARNT

Inadequate warehouse space, poor road access and delay in mobilizing the fund required to support LLINs distribution to households were the major problems encountered during implementation of the project. The storage problems and road access was mainly seen in the Democratic Republic of Congo and Southern Sudan. The need to ensure availability of optimal storage capacity, synchronizing timing of transport before the rainy season and securing adequate funding for operational cost well before the full start of such projects were the lessons learnt.

INTERIM REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I.	**Reporting Period:**	March 2010 - August 2010
II.	**Disease:**	Malaria
III.	**Niche:**	Artemisinin supply
IV.	**Project Name:**	Assured Artemisinin Supply System (A2S2)
V.	**Key Partners:**	i+solutions, FSC Development Service International, AEDES/OTECI and Triodos Sustainable Trade Fund
VI.	**Timeframe for Support:**	2 July 2009 to 30 June 2011
VII.	**Start Date:**	2 July 2009
VIII.	**Total Amount Approved:**	US$ 9,280,400
IX.	**Money Holder:**	i+solutions and Triodos Sustainable Trade Fund
X.	**Procurement Agent:**	The project has no procurement component.

XI. FINANCIAL AND PROCUREMENT

DISBURSEMENT SCHEDULE (date, amount)		**DISBURSEMENTS MADE (date, amount)**		**REASONS FOR ANY DEVIATION AND /OR ANY OTHER REMARKS**
On or before 27 July 2009	US$9,280,400	20 July 2009	US$ 9,280,400	There was no change in the amount or schedule of disbursement of fund for this project.
		TOTAL AMOUNT DISBURSED: US$ 9,280,400 **PERCENT DISBURSED: 100 %**		

REPORTING SCHEDULE (report type, period covered, date)		**REPORTS RECEIVED (report type, period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
1st Interim Progress Report July 2009 to 30 Sep. 2009	30 Sep. 2009	1st Interim Progress Report July 2009 to Sept. 2009	14 Sep. 2009	The report for this period was received two weeks ahead of time at the request of the Secretariat due to the felt need to confirm timely commencement of the project activities.
2nd Interim Progress Report Oct. 2009 to March 2010	31 March 2010	2nd Interim Progress Report October to March 2010	18 March 2010	
3rd Annual Financial Report April 2010 to August 2010	31 August 2010	3rd Interim Progress Report April 2010 - August 2010	14 Sep. 2010	

XII. PROJECT PROGRESS

KEY OBJECTIVES/ ACTIVITIES	BASELINE		CUMULATIVE YEARLY TARGETS		ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year	Year I (July 09 to June 10)	Year II July 10 to June 11)		
Expansion of Artemisinin supply to help meet the ACT needs in 2010 and 2011, through a revolving Artemisinin Pre- Finance Facility to artemisinin extractors selected by eligible ACT manufacturers,	73 to 100 MT (Metric ton)	2009 - 2010	10 Metric ton	40 Metric ton	16 MT	- 6 MT with CIPLA – Innovexx-Bionexx in Madagascar - 10 MT with Novartis and BGG in China - Discussion is currently ongoing with 4 other extractors for 16 MT of artemisinin.
Setting on-line data sharing and information on the actual artemisinin supply situation to enhancing transparency and market-responsiveness.	1	Jan. 2009	1	1	1	A web based data sharing and information communication system has been set-up. Visit http://www.a2s2.org/
Contribution to the realization of a stable artemisinin supply market through fair pricing	US$180	2004 - 2009	US$350	US$350	No data	The price of artemisinin has been highly fluctuating from USD 300/kg in 2004 to USD1, 100 in 2005 and USD180 in 2009. Data on the current price is not yet available.

XIII. OVERALL ASSESSMENT OF PERFORMANCE

The A2S2 project was launched in July 2009 with a primary objective of securing 40 metric ton (MT) of artemisinin in two years. The artemisinin production through this project is additional to the 73-100 MT of artemisinin produced annually and the combined production is expected to meet the ACT need for 2010 and 2011. The first half of the project year was mainly devoted to completing preparatory activities including development of standard operating procedures (SOP), convening preliminary discussions with Artemisinin Extractors and ACT manufacturers and setting-up a web based dashboard for information and data sharing.

The standard operating procedures and confidentiality agreements for data sharing with ACT manufacturers have been completed and a web site (http://www.a2s2.org) to publish and share project data has been launched in October 2009. Based on the agreed procedures, preliminary assessment and discussions for tri-partite contractual loan agreements with ACT manufacturers and artemisinin extractors have been initiated. As of August 2010, the project had secured contracts for the production of 6.2 MT of artemisinin with the artemisinin extractor Innovexx-Bionexx and ACT the manufacturer Cipla in Madagascar for 6 MT and Novartis and the artemisinin extractor Beijing Gingko Group based in China for 10 MT. This attains 40% of the target additional artemisinin of 40MT. In addition to this, there are currently ongoing negotiations to secure additional 16 MT and are expected to be completed before the end of 2010.

The time spent on the preparatory activities and negotiations to conclude contractual agreements was longer than expected. This was mainly due to the financial regulations in China that prohibit direct loan in foreign currency to artemisinin extractors. China is one of the largest producers of artemisinin where an estimated 70% of the global artemisinin is produced. Delivery of the artemisinin and loan repayment is expected to commence in the first half of 2011.

Objective 1: Expansion of Artemisinin supply to help meet the ACT needs in 2010/11, through a revolving Artemisinin Pre- Finance Facility to artemisinin extractors selected by eligible ACT suppliers

To achieve the additional production of 40 MT of artemisinin, extractors based in countries with the potential to support the required supply, namely: China, Madagascar, Kenya, Vietnam and Uganda have been visited by the project management team members. Following completion of preliminary visits and assessments, discussions to conclude loan agreements were convened with eligible extractors and ACT manufacturers who expressed interest in the A2S2 facility. Despite the time required to conduct capacity assessment of extractors and the need to explore alternative approaches to overcome financial regulatory hurdles, the status of completion of contractual agreements was relatively progressive. The status of the negotiations and contractual agreements in the countries visited is summarized below.

1) China

The A2S2 project management team carried extensive discussion with Novartis and the Artemisinin extractors, Beijing Gingko Group (BGG) and Xieli that resulted in two agreements for 20 MT of artemisinin with a loan value of US$4 million. However, due to the limited experience of the small artemisinin extraction companies in handling their export businesses and Chinese financial regulation that prevent approval of loan to extractors in foreign currency or a loan in the local currency with a guarantee in foreign currency, the agreements were not concluded on time. As a result of this and the delay in sorting alternative options, Xieli decided to seek financial support from other sources while the loan agreement with Novartis and BGG for 10 MT of artemisinin with a loan value of US$2 million was concluded through a special arrangement involving Novartis. Further detail on the new arrangement is presented below under XIV - planned changes in the program.

In addition to the 10 MT agreement secured with Novartis and BGG, currently the project is investigating lending opportunities for the Chinese extractor PIDI based in Hong Kong, in collaboration with the ACT manufacturers Cipla and Ipca for 3.2 MT and 3 MT of artemisinin, respectively.

2) Madagascar

A contract for 6MT of artemisinin with Innovexx-Bionexx and Cipla was concluded in February 2010. The loan value of US$1.2 million for this contract has been fully transferred to the extractor. Inspection of the Innovexx-Bionexx plantations, extraction and purification facilities has been completed. Based on the inspection findings, the A2S2 project is mobilizing additional support from EDL in the United Kingdom to provide guidance and technical support to Innovexx-Bionexx on its artemisinin purification process.

3) Vietnam

The major artemisinin extractors in Vietnam including Hung Thinh Ltd have been contacted by the A2S2 project management team members. Hung Thinh supplies artemisinin to local dealers and has never contracted directly with major ACT manufacturers. This is mainly due to the low bank interest rates and availability of local market for artemisinin that made the A2S2 project loan less attractive. Through ongoing contacts with Cipla in India, A2S2 has now initiated a contract for 1-2MT of artemisinin to be supplied by Hung Thinh to Cipla before the end of 2010. This action is expected to progressively reduce the amount of artemisinin reaching manufacturers of artemisinin mono-therapies or low quality treatments. In addition to this, process is ongoing to complete loan agreement with another artemisinin extractor, Vedic, for the supply of 2MT in 2010 and 6MT in

2011 to Strides Limited that produces artemether injections. At this stage there are no other eligible artemisinin extractors based in Vietnam that have applied to access the A2S2 project loan.

4) East Africa

a. Kenya

The East African Botanicals (EABL) based in Kenya is one of the major artemisinin extractors the region. The extractor has had investment problems that could not allow them to carry purification of artemisinin. As a result of this the Artemisia planted in the first quarter of 2010 was quite limited. The A2S2 project management after discussing with EABL has concluded that EABL needs to establish the set-up for the purification technology which requires higher investment than what could be provided from the A2S2 project. Based on the advice, EABL is working to finalizing arrangements to set-up the purification technology and has already started discussions with Sanofi, Cipla and Ipca in preparation to access the A2S2 project fund.

b. Uganda

Afro Alpine, an extractor based in Uganda partnering with Cipla has limited artemisinin supply capacity with the total volume in 2010 of about 500kg. The extractor is now planning to increase its production capacity and has indicated interest to discuss and secure A2S2 project loan. The A2S2 project management has accepted the request and will conduct further discussions with the company.

Objective 2: Collection and on-line sharing of market intelligence on the actual artemisinin supply situation, enhancing transparency and market-responsiveness

The A2S2 project data sharing dashboard is available on the project website (www.a2s2.org). Data collection and entry on supply volume of artemisinin and prices is work in progress. The market data collection will be done through online questionnaires. The dashboard is set-up to capture data by region, namely: China, Vietnam, Africa and Others. The first data collected from China in March 2010 and Madagascar in May 2010 is currently being processed and additional data from Vietnam is currently entered and processed. The market intelligence data for these regions will be posted on the website upon completion of the validation process.

Objective 3: Contribution to the realization of a stable artemisinin supply market at fair prices

The project aims to stabilize the artemisinin market by promoting conditions for fair pricing. The project is in its early stage of implementation and more concrete data relating to the price of artemisinin is not yet available.

XIV. PLANNED CHANGES IN THE PROJECT, if any

Due to local financial regulations and lack of experience of artemisinin extractors based in China in handling their export business, concluding loan agreements on time was not possible. The loan administration fee of 2.5% imposed on borrowers, on top of the interest rate of 5.6%, has also been identified as a potentially discouraging factor to borrowers as the combined fee results in a higher payment than what the local market offers.

Based on these observations and the recommendation from the Mumbai Artemisinin Conference held in October 2009, the A2S2 project management team submitted a proposal to UNITAID to modify the loan structure. The proposed modification included:

a) To waive the loan administration fee of 2.5% payable to the Bank by charging the cost from the A2S2 project fund,
b) To provide loan for extractors based in China in local currency (Yaun) through a bank based in China and hedge the fund at a cost of 2.5% to prevent currency loss due to exchange fluctuations.

After examining the possible implications of the proposed changes and the need to secure the most needed supply of artemisinin, UNITAID in consultation with WHO/LEGAL and the A2S2 project management approved the proposed changes to the loan structure. The proposed loan structure was confirmed to have no effect on the total amount of project fund expected to be reimbursed to UNITAID by the end of the project.

However, before the modified loan structure could be implemented, a new financial regulation in China imposed in July 2010 further restricted approval of loans to extractors in foreign currency or a loan in local currency guaranteed with foreign currency. As a result of this change, two contracts arranged between Novartis and Beijing Gingko and Xieli for 20 MT of artemisinin with a loan value of US$4 million were delayed. To overcome the problem, the A2S2 project management team proposed an alternative option that could allow providing the loan to Novartis to facilitate transfer and payment of the fund to the extractors (BGG and Xieli) through its logistic subsidiary (ChinaCHem) based in China. The project management team also requested to waive the loan interest for ease of management and charge the borrower a 2.5% fee instead to compensate for the interest.

UNITAID and WHO/Legal, although aware that the proposed loan arrangement is within the framework of the tripartite agreement, expressed serious concern over the implications and consequences of providing the loan directly to Novartis. After examining the pros and cons of the proposed arrangement through a series of consultations with WHO Legal, the project management team and the WHO/Global Malaria Program, approving the request under a special circumstance was recommended in order not to miss the much needed artemisinin supply. By the time this decision was reached, Xieli dropped out from the arrangement in search for other sources of funding while the Novartis-BGG loan for US$2 million for the production of 10 MT was concluded.

XV. ISSUES AND/OR LESSONS LEARNT

The idea of establishing a loan facility for artemisinin extractors was one of the recommendation of the artemisinin conference convened in Guilin, China in October 2008. However, the mode of operation of the proposed loan facility and the suitability of the banking operations in handing the service in the artemisinin producing countries was not fully assessed. This resulted in implementation delays and extra efforts to modify the loan structure originally presented in the proposal.

Due to the sensitive nature of the Artemisinin market, information on the price of artemisinin and inventory data of Artemisinin stock has never been readily available. The confidentiality agreements reached between the A2S2 project and the ACT manufacturers, artemisinin extractors and API formulators is believed to build confidence and partnership that will contribute to improving better information and data sharing.

INTERIM REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I.	**Reporting Period:**	December 2009 - April 2010[78]
II.	**Disease:**	Malaria
III.	**Niche:**	Artemisinin Based Combination Therapies (ACTs)
IV.	**Project Name:**	Affordable Medicines for Malaria - AMFm
V.	**Key Partners:**	The Global Fund
VI.	**Timeframe for Support:**	November 2009 to April 2012
VII.	**Start Date:**	02 November 2009
VIII.	**Total Amount Approved:**	US$130 million
IX.	**Money Holder:**	The Global Fund to Fight AIDS, Tuberculosis and Malaria
X.	**Procurement Agent:**	The Global Fund to Fight AIDS, Tuberculosis and Malaria

[78] Annex 1. Additiona information has been received from the AMFm Ad hoc Committee (AHC) Chair on the 30th of July 2010)

XI. FINANCIAL AND PROCUREMENT

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
On or before 19 November 2009	US $ 65,000,000	18 Nov. 2009	US $ 65,000,000	There was no deviation.
On or before 30 April 2009	US $ 65,000,000	21 Sep. 2010	US $65,000,000	The second disbursement was delayed pending clarification from The Global Fund (TGF) on MOU required clarifications related to the conditions for UNITAID funding commitment. These include: 1. Programmatic and financial implication due to country (ies) ceasing to participate in the AMFm (MOU Article 5.2) 2. Justification on the use of funds that will no longer be needed due to the cessation of participation of a country(ies) in the AMFm and savings from the UNITAID funded ACT Scale-up project (Article 5.6), in which two AMFm countries, Cambodia and Madagascar, are participating. The MOU required clarification was received from TGF on the 27th of July 2010[79]. According to the clarification, the revised co-payment fund estimated range for Phase-I excluding Rwanda has changed from US$216-US$220 to US$208 to US$212 million. UNITAID upon receiving the clarifications has officially requested TGF for these issues to be discussed during the AHC meeting in October 2010 in order to obtain clarification on the use of the funds.

[79] Annex 2 TGF - Clarification with Revised ACT Need Forecast and saving from the ACT Scale-up Project, July 2010

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount)	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
		TOTAL AMOUNT DISBURSED: US$ 130,000,000 **PERCENT DISBURSED: 100 %**	

REPORTING SCHEDULE (report type, period covered, date)		REPORTS RECEIVED (report type, Period covered, date)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
AMFm Ad Hoc Committee (AHC)[80] Report November 2009	November 2009	AHC report submitted to the 20th TGF Board November 2009	9 Nov. 2009	The last signature in the MOU between UNITAID and TGF was on 02 November 2009. This marks the official start date of the cooperation.
AHC Report December 2009 - April 2010	April 2010	AHC report submitted to the 21st TGF Board	28 Apr. 2010	In addition to the regular AHC report, an update on the status of implementation of the AMFm was received from the AHC Chair[81].

[80] AMFm implementation progress update is submitted to UNITAID and other partners on semi-annual basis through the AHC reports. The semi-annual reporting of the AHC is aligned to the timing of TGF's Board meeting.

[81] Annex 1. Additional information has been received from the AMFm Ad hoc Committee (AHC) Chair on the 30th of July 2010)

XII. PROJECT PROGRESS[82]

KEY OBJECTIVES/ ACTIVITIES	BASELINE		Project Target	TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year			
To increase Affordability of ACT: - Proportion of outlets in rural/urban areas that have quality assured ACTs in stock at the time of survey, - Number and percent of outlets in rural/urban areas, with no reported stock-outs of nationally recommended antimalarial drugs lasting more than 1 week at any time during the past 1 month.					*See footnote*
To increase availability of quality assured ACTs - Median cost to patients of a full course of treatment (adult/child) with ACTs in rural/urban outlets - Median cost to patients of a full course of [monotherapy/ other anti-malarial] (adult/child) in rural/urban outlets - Cumulative percentage mark-up between retail median price of a full course of treatment with quality assured ACTs (adults) and wholesaler median price					
Increase use of quality assured ACTs - Proportion of children with fever in the past two weeks who received ACTs - Proportion of households in poor areas with one or more inhabitants with fever in the past 2 weeks treated with ACT					
Increase market share of quality assured ACTs,					

[82] The AMFm progress monitoring and evaluation parameter values are not yet determined. Baseline data will be collected to determine the M&E parameter values through contracted firms. Three agencies, namely: Drugs for Neglected Disease *initiative* (DND*i*), Centre de Recherché pour le Développement Humain and Population Service International have been awarded the contract to conduct the baseline surveys. For the independent evaluation, a consortium led by Macro International Incorporated in collaboration with the London School of Hygiene and Tropical Medicine have been awarded the contract in March 2010. Findings and recommendation of the independent evaluation will be completed in early 2012.

KEY OBJECTIVES/ ACTIVITIES	BASELINE		Project Target	TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year			
- Proportion of quality assured ACTs sold or distributed in the last week via outlets across sectors in rural/urban areas					

XIII. OVERALL ASSESSMENT OF PERFORMANCE

The AMFm host grant amendment and signing scheduled to be finalized in May 2010 has been completed in most of the participating countries. while the process in still ongoing in Nigeria, Uganda and Zanzibar. The contracts to conduct baseline and end point data collection and independent evaluation have also been awarded to the selected firms. In addition to the grant signing and awarding of the contracts for baseline data collection and evaluation contracts, the following major tasks have been accomplished.

1. Pre-testing of the AMFm logo to ensure appropriateness for the local context,

2. Master Supply Agreement (MSA) concluded with six ACT manufacturers. The manufactures include: Ajanta Pharma, Cipla, Guilin, Ipca, Novartis and Sanofi-Aventis.

3. First line buyer undertakings have been co-signed by a total of 64 first-line buyers (61 private for profit; 2 public and 1 not-for-profit).

4. As at the 23rd of July 2010 a total of nine eligible orders for 4,064,200 treatments worth US$4,401,482 have been received from Ghana (7 orders) and Kenya (2 orders). The first AMFm co-paid ACTs have been delivered to Kenya in August 2010.

XIV. PLANNED CHANGES IN THE PROJECT, if any

Due to the delay in the start of the actual AMFm Phase-I activities in the countries, The Global Fund Secretariat has requested the AMFm Ad hoc Committee (AHC) to shift the timeline of implementation so that the evaluation and report to the Board would take 6 to 12 months later than the original timeline.

The AHC members having agreed to the request,[83] had asked the TGF to prepare a briefing note and justification on the cost of shifting the timeline due to delays in the implementation for further discussion and recommendation during the upcoming AHC meeting that will convene in Geneva, 18-19 October 2010.

XV. ISSUES AND/OR LESSONS LEARNT

TGF Secretariat has started receiving and approving ACT orders from eligible first-line buyers. However, there are still some critical issues that need to be addressed. Some of the major issues the UNITAID Secretariat would like to raise in the upcoming AHC meeting include the following:

- A product marketing and communication material is still work in progress. As ACTs have started arriving in the countries (e.g. Kenya, August 2010), finalization and dissemination of the material requires speedy implementation in order to ensure consumer awareness.
- Despite the WHO recommendation to use fixed dose combination (FDC) ACTs, some orders approved by TGF to date included co-blistered antimalarial drugs. The use of loose co-blistered presentation, while the same ACTs are available in FDC presentation is not an ideal approach for large scale-distribution. Therefore, this needs prompt attention and decision to halt procurement of co-blistered anti-malarial drugs.
- The high price of malaria Rapid Diagnostic Tests (RDTs) is likely to discourage treatment based on diagnosis. This will enhance overconsumption of ACTs as treatment will tend to rely on clinical diagnosis. A workshop on the economics of parasitological confirmation of malaria convened in Geneva highlighted the need to address implementation, operations research and policy analysis required to ensure universal access for malaria diagnosis. However, further practical interventions towards its implementation and as to which organizations should be responsible for either coordinating, developing detailed plans, or carrying out these recommendations was not discussed during the meeting and this requires follow-up action.[84].
- The current practice of ACT dispensing in the private sector of the AMFm countries is a mix of Over-The-Counter (OTC) and on prescription basis. This is likely to create variable access for ACTs and requires further engagement with the AMFm countries to assess the limitations of the dispensing approaches and to recommend actions that can ensure ease of access for ACTs.

[83] Annex 3. AHC Vice Chair email communication.
[84] Full report of the meeting is available in the UNITAID Secretariat.

Annex 1. AHC Chair Update

Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria

Affordable Medicines Facility-malaria (AMFm)

AMFm Ad Hoc Committee Chair's Update
[30July 2010]

Overview

We would like to update you on the following 4 items:

- Completion of MSAs
- Status of Grant Amendments
- First-Line Buyer Undertakings
- Orders Placed

1. Completion of Master Supply Agreements

The Global Fund and six manufacturers of quality-assured malaria drugs have finalized Master Supply Agreements for AMFm Phase 1. The six manufacturers are: Ajanta Pharma, Cipla, Guilin, Ipca, Novartis and Sanofi-aventis. All six pharmaceutical companies meet the Global Fund's quality assurance criteria for supplying artemisinin-based combination therapies (ACTs) to first-line buyers under the AMFm. Other ACTs manufacturers will be able to participate in the AMFm, provided that they meet the Global Fund's quality assurance policy.

Under the agreements, private importers will now pay up to 80% less than they did in 2008-2009 for ACTs, bringing the factory gate prices paid by private sector buyers down to the same level as for public sector buyers. The AMFm will then subsidize purchases made by all eligible first-line buyers, all of whom have signed an undertaking to pass the benefit of low prices down the supply chain, thereby enabling the roughly 60% of malaria patients who obtain treatment in private shops to obtain the most effective treatments at affordable prices.

A press release on this topic is available online at:

http://www.theglobalfund.org/en/pressreleases/?pr=pr_100714

2. Status of Grant Amendments

Countries and signature status as of 29 July 2010

Grant amendments signed by the Global Fund Secretariat and the Country

Cambodia
Ghana
Kenya
Madagascar
Niger

Grant amendment signed by the Global Fund Secretariat, signature by country expected within days

Tanzania (mainland)

Works in progress (stages and status vary by country) and yet to be signed by the Global Fund Secretariat

Nigeria
Uganda
Zanzibar

3. First Line Buyers by Country

As of 23 July, 64 first-line buyers have co-signed First-Line Buyer Undertakings.

Table 1 - First-Line Buyer distribution by country and sector

Buyer Country	Private-for-profit	Public	Not-for-profit	Total
Cambodia	0	0	0	0
Ghana	18	1	0	19
Kenya	6	0	0	6
Madagascar	6	0	0	6
Niger	1	1	1	3
Nigeria	21	0	0	21
Tanzania	2	0	0	2
Uganda	4	0	0	4
Zanzibar	2	0	0	2
International	1	0	0	1
Total	**61**	**2**	**1**	**64**

4. Orders Received

As of 23 July, 9 eligible orders had been received for 4,064,200 treatments totaling US$ 4,401,482.

Table 2 - Orders received

Country	Buyer	Manufacturer	ACT	Number of Treatments	Delivery Expected
Ghana	Neo Pharma	Ajanta	A/L	245,000	August
Ghana	Vicdoris	Guilin	AS+AQ	100,000	August
Ghana	Guilin	Guilin	AS+AQ	100,000	September
Ghana	East Cantonments Pharmacy	Ipca	A/L	453,600	October
Ghana	Far East Mercantile Limited	Guilin	AS+AQ	162,000	August - September
Ghana	Leptap Pharmaceuticals	Cipla	A/L	1,000,000	November
Ghana	Spintex Chemists	Ipca	A/L	250,000	December
Kenya	Harleys Ltd	Ajanta	A/L	1,300,000	August - September
Kenya	Sai Pharmaceuticals	Ipca	A/L	453,600	October

The Secretariat will soon post on the Global Fund's external website regular updates of the lists of first-line buyers and orders received. This will make it possible for all interested parties, including Committee members, to access the information with ease.

Annex 2 - TGF Clarification with Revised ACT Need Forecast and saving from the ACT Scale-up Project, July 2010

From: Olusoji Adeyi [Olusoji.Adeyi@theglobalfund.org]
Sent: 27 July 2010 16:01
To: Duneton, Philippe; Bermudez, Jorge Antonio Zepeda
Cc: de Leon, Imelda Iral; Yohannes, Ambachew Medhin; Fabienne Jouberton; Humberto Laudares; Lloyd Matowe; Melisse Murray; Andrew Freeman
Subject: RE: Follow up on meeting of June 29: UNITAID - Global Fund Cooperation on the AMFm
Attachments: 100616-AMFm Revised Forecast Estimates for UNITAID-Final-CLEAN.DOC

Dear Philippe,

Please allow me to begin by thanking UNITAID for supporting the AMFm. We also appreciate your contributions to the oversight of AMFm Phase 1 through the AMFm Ad Hoc Committee.

We would like to provide you with the following information on AMFm Phase 1 and UNITAID supported initiatives. This is further to communications between Dr. Jorge Bermudez and Professor Michel Kazatchkine. It is also further to our meeting at your offices on 29 June.

1.) Context

According to the Memorandum of Understanding (MoU), the second tranche of co-payment funding was due by 30 April 2010. At our meeting on 29 June, the UNITAID Secretariat acknowledged that the information requested by UNITAID is not a precondition for disbursement of funds that are over-due. We also understood that UNITAID was requesting the information for its internal process. We are providing the information below and in the attachment.

Considering that the provision of this information is not a pre-condition for disbursement of the delayed funds, we would be most grateful if the disbursement of US$65 million is made without further delay.

2.) Rwanda withdrawal from AMFm Phase 1

Please find attached the document outlining revised forecast estimates following the withdrawal of Rwanda from Phase 1. This is the same document that we handed over at our meeting at your offices on 29 June.

3.) AMFm Phase 1 Applications

We thought it might be useful to outline what was required of an applicant in their AMFm Phase 1 application.

The application form enabled applicant countries to apply for:

- The ability for eligible first-line buyers in the applicant's country to buy co-paid ACTs through the AMFm
- Funding for supporting interventions for AMFm

Where funds permitted, applicants could also propose additional ACT procurement in the public sector and additional ACT-related activities to strengthen the health system.

date of September 2009.

- The PR is currently ordering 65,561 ACTs which are scheduled to arrive on 6 September 2010.
- Therefore, 57,590 UNITAID funded ACTs remain to be ordered by the PR.

5.2.2. AMFm

- Cambodia proposed its R6 Malaria Grant as the 'host' grant for AMFm Phase 1. The R6 Malaria Grant had no savings.
- Cambodia has signed its grant amendment.
- We do not anticipate any orders in the short to medium term as there is not currently an ACT (DHA-PPQ) that meets Global Fund Quality Assurance standards.

5.3. MADAGASCAR

5.3.1. UNITAID Support (PSI)

- 2,019,893 UNITAID funded ACTs have been allocated to the grant
- 300,000 ACTs were delivered on 15 January 2010.
- 709,947 ACTs were ordered on 1 July 2010 and are due to be delivered to the country from August 2010 to January 2011 according to the Drug Disbursement request.
- Therefore, there are still 1,009,946 ACTs due to be ordered by the end of 2011.
- The UNITAID ACT Scale Up in Madagascar, through PSI, focuses on the delivery of highly subsidized ACTs to children at community level.

5.3.2. UNITAID Support (UGP)

- The grant is under Phase 2 review process. The CCM will decide on whether the country will take the 2.3 million UNITAID funded ACTs by September 2010.

5.3.3. AMFm

- For AMFm Phase 1 a grant agreement has been signed with a new PR, Salama, the central procurement entity for essential drugs and medical equipment. Six private-for-profit buyers have registered as First-Line Buyers.

In closing, let me once again thank UNITAID for the visionary support. Noting that the requested information is not a condition for disbursement of the delayed payment of Tranche 2 (US$ 65 million), we look forward to receiving soon the confirmation of payment.

Best regards,

Soji

Dr. Olusoji Adeyi
Director
Affordable Medicines Facility-malaria (AMFm)

The Global Fund to Fight AIDS, Tuberculosis and Malaria
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AMFm countries were asked to provide in their applications estimates of the savings that will be gained from ACT budgets in their country's existing Global Fund malaria grants, through purchasing ACTs at the lower AMFm price. This should take into account future planned procurement. Applicants were not requested to include ACTs received from other donors as they clearly could not be reprogrammed for savings.

Applicants were not required to provide countrywide ACT forecast information in their application; it is understood that private sector wholesalers will place their orders based on their understanding of relevant market forces in their area of operation, which cannot be planned in the same fashion as traditional public sector procurement.

The AMFm applications from Ghana, Cambodia and Madagascar are available for review on the Global Fund website.

4.) Use of Savings

From article 5.6 of the Memorandum of Understanding:

"UNITAID is currently providing funding support for a scale-up of ACTs in three potential AMFm Phase 1 beneficiary countries: Cambodia, Ghana and Madagascar. If these three countries participate in AMFm Phase 1, then there are likely to be significant savings under the UNITAID ACT Scale-Up Initiative. The Parties will, together with UNICEF, endeavor to agree on the use of such savings".

UNITAID funded ACTs, as outlined below, may result in reduced demand for ACTs under AMFm Phase 1 in Cambodia and Madagascar. As per Article 5.6 of the Memorandum of Understanding we are ready to work with UNITAID and UNICEF to identify any consequent savings. We would like to note that *it is not possible to know ex-ante* what the reduced demand will be and therefore what any level of savings would be. The UNITAID-led work on demand forecasting will be an essential element in quantifying predicted demand. Establishing accurate levels of demand and therefore the level of savings will only be possible ex-post.

5.) UNITAID funded ACT projects and AMFm

5.1. GHANA

5.1.1.UNITAID Support
- The final delivery of UNITAID funded ACTs to Ghana was on 21 January 2009.
- According to the March 2010 report, the combined treatment target of 9,517,222 was achieved.
- The Ghana CCM confirmed on 30 April 2010 that the country will not request the remaining 1.575 million ACTs from UNITAID.

5.1.2. AMFm
- Ghana signed its grant amendment in July. .

5.2. CAMBODIA

5.2.1. UNITAID Support
- 419,001 UNITAID funded ACTs have been allocated to the grant (123,151 under Round 6 Phase 1 Initiative, 295,850 under ACT Scale-up Initiative)
- The PR (MoH) ordered 295,850 ACTs under ACT scale-up initiative in early 2009 with an arrival

2010-09-14

Affordable Medicines Facility-malaria (AMFm) Phase 1

Estimates and Projections of ACT demand and co-payment costs

Updates Prepared for UNITAID

Updated 15 June 2010

1. Purpose

This note was prepared in response to a request made by UNITAID on May 10, 2010, regarding revised estimates and projections of ACTs that take into consideration Rwanda's withdrawal from the AMFm. It builds on a revised approximate forecast update of 26 October 2009 that was prepared for the AMFm Ad Hoc Committee (AHC) which took into account the Technical Review Panel (TRP) recommendations for funding.

2. Prior work and context

A forecast of ACT demand under AMFm Phase 1 was presented to the Global Fund Board at its Eighteenth meeting. Based on this forecast, resources required to fund co-payments for the full AMFm Phase 1 period were estimated at US$ 225-233 million. This forecast was developed by UNITAID with McKinsey & Company, the Clinton HIV/AIDS Initiative (CHAI), MIT Zaragoza and Dalberg Global Development Advisors.

Since the initial forecast was done, all eligible applicants submitted applications to AMFm Phase 1. The TRP reviewed these applications[1] and recommended that ten of the twelve applicants be funded. Applications received from Benin and Senegal were not recommended for funding by the TRP. In response to a request from the AMFm Ad Hoc Committee during its meeting on 1-2 October 2009, the Secretariat developed an approximate updated forecast, taking into consideration the number of countries for which AMFm Phase 1 applications were recommended for funding by the TRP. The AHC requested this rough approximation while planning for a more refined estimate that will be developed after about six months of implementation.

Subsequent to the 26 October 2009 update, Rwanda withdrew from participation in Phase 1 of the AMFm, and the Global Fund Secretariat has been asked to provide a revised estimated forecast that takes this event into account.

In line with the AHC Committee decision of its meeting in October 2009, UNITAID has issued a request for proposals (RFP) for ACT demand forecasting services in view of establishing that will produce a more refined estimate that will be developed after about six months of implementation. The outcome of this demand forecasting exercise, once completed, will provide essential demand data that the AMFm can use for revised estimates of co-payment needs and that UNITAID needs for resource optimization.

[1] Applications were received for AMFm Phase 1 from the following twelve (12) applicants: Benin, Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Rwanda, Senegal, Tanzania, Uganda and Zanzibar.

3. Methods used in this forecasting exercise

The following was deemed an acceptable approach to estimating the revised upper and lower end of co-payment cost *ad interim*, given the plans for a refined estimate to be produced by a demand forecasting exercise commissioned by UNITAID.[2]

- Detailed calculations and explicit assumptions are available to the Global Fund Secretariat from the Dalberg work, which resulted in an estimated ACT demand of 289 million doses and US$ 233 co-payment cost for all Phase 1 eligible applicants for the two-year duration of Phase 1. This represents the upper end of the US$ 225-233 million estimate presented to the Board. To account for the TRP recommendations, the country-specific contributions of Benin and Senegal to the ACT demand (approximately 16 million doses) were removed from the Dalberg estimates.

- **To account for Rwanda's decision to not participate in Phase 1 of the AMFm, the country-specific contribution of Rwanda to the ACT demand (approximately 5.2 million doses) have been removed from the Dalberg estimates.**

- Regarding the lower end of the estimate presented to the Board (i.e., US$ 225 million), it was the McKinsey methodology that provided this figure. The country-specific data used by McKinsey for the forecasting exercise are currently not available to the Global Fund Secretariat. As a result, the same percentage reduction that results from adjusting the Dalberg estimates for the upper end of the estimate was applied to the lower end of the estimate as well.

- **To account for Rwanda's decision to not participate in Phase 1 of the AMFm, the same percentage reduction that results from adjusting the Dalberg estimates for the upper end of the estimate were applied to the lower end of the estimate as well.**

4. Results of the revised forecast

Removing ACT demand for Benin and Senegal from the Dalberg Phase 1 estimates resulted in a drop from 289 million ACT doses to 273 million doses. This resulted in a corresponding total ACT co-payment upper end cost estimate of US$ 220 million required for the countries that were recommended for funding by the TRP to participate in Phase 1 of the AMFm, per the Dalberg Methodology. **After removing the estimated ACT demand for Rwanda from the Dalberg Phase 1 estimates, this results in a drop from 273 million ACT doses to 268 million doses. This revised figure results in a corresponding total ACT co-payment upper end cost estimate of US$ 216 million required for participating countries, without Rwanda.**

[2] The refined estimates will be subjected to thorough checks (of methods and numbers) during the detailed exercise that UNITAID is commissioning.

Table 1: AMFm Phase 1 estimated ACT demand and co-payment cost for all eligible applicants and those recommended for funding by the Technical Review Panel

	Dalberg Methodology		
	All eligible applicants	All TRP recommended applicants	All TRP recommended applicants, without Rwanda
Total ACT demand (million doses)	289	273	268
Total ACT co-payment cost (US$ million)	233	220	216

Thus, as a result of the TRP recommendations, the upper end of the revised co-payment forecast need dropped from US$ 233 million to US$ 220 million for the two-year period after removing Benin and Senegal. This represents a 5.6% reduction. When the same 5.6% reduction is applied to the McKinsey US$ 225 million figure, this resulted in a revised lower end estimate of US$ 212 million. The revised estimated co-payment needed thus changed from US$ 225-233 million to US$ 212-220 million.

After removing Rwanda from this estimate, the upper end of the revised co-payment forecast need drops from US$ 220 million to US$ 216 million for the two-year period. This represents a 1.8% reduction. When the same 1.8% reduction is applied to the revised McKinsey US$ 212 million figure, this results in a revised lower end estimate of US$ 208 million. The revised estimated co-payment need after removing Rwanda's contribution to the estimates thus changes from US$ 212-220 million to US$ 208-216 million.

5. Limitations

These estimates are indicative, not definitive. The following limitations are acknowledged and should be considered in interpreting this approximate revised forecast:

- The only revision undertaken at this time was to remove the estimates for Benin, Senegal and Rwanda from the previously completed forecast. Therefore, the limitations of the Dalberg methodology still apply; the forthcoming work commissioned by UNITAID will provide opportunities for extensive revisions of methods as appropriate.
- Methodologies used by Dalberg and the other forecasting organizations employ assumptions for which certain data are not presently available (for example: initial uptake of co-paid ACTs across countries and sectors, which ACT formulations purchased, etc...). After six months of implementation, more refined estimates and projections will be prepared, with the advantage of new information on realized demand and actual co-payments per formulation and weight pack, among other factors.

6. Next phase of the work

In line with a decision of the AMFm Ad Hoc Committee to produce more refined estimates after approximately 6 months of implementation, UNITAID has issued an RFP for ACT demand forecasting services. This exercise, when completed, is expected to produce more refined forecasts that will inform both UNITAID's and the Global Fund's decision making process.

Annex 3. AHC Vice Chair email Communication

From: Kirsten Myhr [mailto:myhr@online.no]
Sent: 19 August 2010 09:28
To: 'Olusoji Adeyi'; 'Andrew Freeman'; 'Melisse Murray'; 'Esther Otieno'
Cc: 'Leslie Ramsammy'; 'V Walford'; 'Alexandra Farnum'; 'Fr?d?ric Goyet'; Duneton, Philippe; 'Giancarlo Majori'; 'Louis Da Gama'; 'Rajendra Maharaj'; Van Erps, Jan Frans Jozef; Spinaci, Sergio; 'Joanne Carter'; 'Pani Obengui'; 'Anna Thompson Quaye'

Subject: Costing an extension / shifting timeline - AHC decision

The AHC agrees with the suggestion put to us by the Secretariat that the Secretariat prepares a briefing note on the cost of shifting timeline due to delays in the implementation of AMFm (so that the evaluation and report to the Board would take place 6 or 12 months later).

The AHC expects the additional costs to be limited since the expenditure on ACTs and supporting interventions will be delayed and those funds can be carried forward. The briefing note will provide useful information for the AHC discussion in October, when we will look at progress so far in implementation at country level.

The AHC would not recommend costing a longer extension of the AMFm at this stage. There is unlikely to be funding committed for an extension until AMFm starts to show it is reaching milestones and delivering some results and there is no new information on which to base the cost projections.

We are hopeful that the operational research which the Secretariat and others are supporting will provide useful information for the decision at the end of Phase 1. This includes findings on how far the AMFm and supporting interventions are reaching communities and what works to increase demand and access. And the success metrics to be decided upon will include a picture of what success is expected to look like after e.g. five years in each country with three scenarios for uptake (slow, middle, fast).

The AHC expects the Secretariat's briefing note to the October meeting to include advantages and disadvantages of delays and to cover also implications beyond financial, e.g. quality.

Seven members replied and all supported this decision.

Kirsten Myhr
Vice chair

Project Update Transversal:

Quality Assurance of Diagnostics
Prequalification of Medicines Programme
UNITAID Support to Round 6 Phase 1

INTERIM REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I.	**Reporting Period:**	15 May 2010 - 1 October 2010
II.	**Disease:**	HIV/AIDS and Malaria
III.	**Niche:**	Transversal **(**Diagnostics for HIV/AIDS and Malaria)
IV.	**Project Name:**	UNITAID Support for Quality Assurance of Diagnostics
V.	**Key Partners:**	WHO, Diagnostics and Laboratory Technology (WHO/DLT)
VI.	**Timeframe for Support:**	March 2009 to March 2013
VII.	**Start Date:**	23 March 2009
VIII.	**Total Amount Approved:**	US $ 7,500,000
IX.	**Money Holder:**	World Health Organization
X.	**Procurement Agent:**	The project has no procurement component.

XI. FINANCIAL AND PROCUREMENT

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
March 2009	US $ 1, 000,000	March 2009	US $ 1,000,000	
1 June 2010	US $ 2,200,000			Disbursement postponed at the request of WHO/DLT. More information is presented under XIV- Planned Changes.
		TOTAL AMOUNT DISBURSED: US$ 1,000,000 **PERCENT DISBURSED: 13.3 %**		

REPORTING SCHEDULE (report type, period covered, date)		REPORTS RECEIVED (report type, Period covered, date)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
1st interim progress report March 2009 to October 2009	1 Oct. 2009	1st interim progress report	30 Sep. 2009	
Annual project and financial report March 2009 to March 2010	15 Mar. 2010	1st annual project and financial report	10 June 2010	Submission of the annual report was delayed to complete inclusion request for amendment of activity and budget allocation.
2nd interim progress report March 2010 to September	1 Oct. 2010	2nd interim progress report	1 October 2010	

REPORTING SCHEDULE **(report type, period covered, date)**		**REPORTS RECEIVED** **(report type, Period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
2010				

XII. PROJECT PROGRESS

KEY OBJECTIVES/ ACTIVITIES	BASELINE (Before UNITAID funding)		PROJECT TARGET	ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year			
Prequalification of UNITAID priority diagnostics for HIV/AIDS and malaria	0	2008	50 - HIV rapid tests = 21 - Malaria rapid tests =21 - CD4 methods= 4 - Virological Methods=4	0	Initial review processes of 18 product dossiers are currently under review and their prequalification status expected to be determined by the end of November 2010[85].
Facilitate review of applications for the development of appropriate diagnostics by incentivizing manufacturers,	0	2008	120	51	Of the 51 product documents received, 21 (41%) have been accepted and manufacturers invited to submit complete dossier for formal evaluation.
Number of countries and manufacturers who participated in regulatory capacity building for diagnostics	0	2008	5	4	Process started in four of the five priority countries.
Number of countries and manufacturers participating in regulatory capacity building in post-market surveillance of diagnostics	0	2008	5	0	Process started in 3 (60%) of the priority countries. Frequent request by some countries to postpone the mission has been a major implementation problem. To avoid such problems, WHO/DLT may decide to consider other priority countries.

[85] . From the total of 76 products dossier received, 28 products have been classified as UNITAID priority products. Accordingly, applicants have been officially invited to submit complete product dossier for assessment. The dossier currently under review include nine (9) HIV rapid tests, seven (7) malaria rapid tests and two (2) CD4 tests.

XIII. OVERALL ASSESSMENT OF PERFORMANCE

There are no prequalified diagnostic products through the UNITAID support to this project, yet. However, most of the activities and processes required to initiate the dossier review and prequalification process has been in good progress. To date 18 product dossier are under review and applicants of 21 other diagnostic products that have been identified as UNITAID priority have been invited to submit their application with complete product dossier. Some of the major project achievements made since the launch of the project include the following:

1. The DLT Prequalification of Diagnostics Business Plan 2009-2013 completed.
2. Formal prioritization criteria for diagnostics evaluation developed and approved by the interagency group at the Infection Prevention and Control (IPC) meeting in April 2009.
3. Evaluation protocols for rapid diagnostics, CD 4 and Virological methods finalized and contractual process initiated to conduct evaluation of the tool.

XIV. PLANNED CHANGES IN THE PROGRAMME, if any

WHO/DLT reported availability unutilized fund from the first UNITAID disbursement and simultaneous funding for related activities received from the Bill and Melinda Gates Foundation. Due to this and the departure of two staff members from the unit that resulted in delayed implementation of project activities, WHO/DLT requested to postpone transfer of the second disbursement.

The next disbursement of US$2.2 million will be completed in early 2011 upon review and approval of the financial report and itemized justification for the requested disbursement.

XV. ISSUES AND/OR LESSONS LEARNT

The issue of understaffing and availability of multiple funding for similar or related project activities have been identified as the most critical problems that resulted in delayed implementation of planned activities of the project. WHO/DLT is working to get the required staff on board by early 2011 and the UNITAID Secretariat will facilitate transfer of the required fund up on confirmation of receipt of all the required.

INTERIM REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I.	**Reporting Period:**	1 January 2010 to 30 June 2010
II.	**Disease:**	HIV/AIDS, Tuberculosis and Malaria
III.	**Niche:**	Transversal (Medicines for HIV/AIDS, Tuberculosis and Malaria)
IV.	**Project Name:**	UNITAID Project Support for Quality Assurance of Medicines
V.	**Key Partners:**	WHO Medicines Prequalification Program (WHO/PQP)
VI.	**Timeframe for Support:**	January 2007 to December 2012
VII.	**Start Date:**	1 January 2007
VIII.	**Total Amount Approved:**	US $ 47 million
IX.	**Money Holder:**	World Health Organization (WHO)
X.	**Procurement Agent:**	The Project has no procurement component.

XI. FINANCIAL AND PROCUREMENT

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount, US$)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
Up to Jan. 2009	US$ 15,000,000	- Dec. 2006 - Mar. 2007 - Sep. 2008 - Jan. 2009	1,000,000 2,500,000 3,500,000 8,000,000	As per the MOUs signed between WHO and UNITAID in December 2006, March 2007 and December 2008
15 October 2009	US$2,000,000			WHO/PQP has submitted financial expenditure report and request for the next disbursement of US$7 million. The disbursement will be effected upon completion of assessment of the financial expenditure report and justification for the request to ensure preparation for timely utilization of the fund.
15 June 2010	US$5,000,000			Same as above
15 October 2010	US$5,000,000			Not due
		TOTAL AMOUNT DISBURSED: US$ 15,000,000 **PERCENT DISBURSED: 32 %**		

REPORTING SCHEDULE **(report type, period covered, date)**		**REPORTS RECEIVED** **(report type, Period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
2008 Annual Report Jan. to Dec. 2008	15 Mar. 2009	2008 Annual Report Jan. to Dec. 2008	22 July 2009	Reporting has generally been late on average by 7 weeks mainly for administrative reasons. WHO/PQP is working to fill existing positions and this is expected to improve reporting timeliness.
Interim Progress Report 1 Jan. to 30. Jun. 2009	15 Aug. 2009	Interim Progress Report 1 Jan. to 30. Jun. 2009	12 October 2009	Same as above…
2009 Annual Report Jan. to Dec. 2009	15 Mar. 2010	2009 Annual Report Jan. to Dec. 2009	12 May 2010	Same as above…
Interim Progress Report 1 Jan. to 30. Jun. 2010	15 Aug. 2010	Interim Progress Report 1 Jan. to 30. Jun. 2010	31 Aug. 2010	Report received on time.

XII. PROJECT PROGRESS

KEY OBJECTIVES/ ACTIVITIES	BASELINE (Before UNITAID funding)		PROJECT TARGET	ACTUAL TARGETS REACHED TO DATE	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year			
Decrease lead-time between receipt of a complete dossier for a finished product to pre-qualification (median)	36 months	2006	24 months	28 months (2009) 18 months (2010)	The actual time lapse range was 1-97 months (8 years)
Increase the number of prequalified products in UNITAID priority area	14	2007	40	25	The total number of prequalified products from 1 January 2007 to June 2010 in indicated in Table 1 below.
Re-assessment and maintenance of the list prequalified medicines and products	300	2007	350	646	381 products reassessed in 2009 and 265 during the first half of 2010. Compared to 2009, the total achievement in the first half of 2010 is 70%.
Increase inspection and prequalification of API manufacturers	0	2009	2	0	This deliverable was not attained due to lack of experts on board.
Build capacity and prequalification of medicines quality control laboratories	1	2007	4	6	- Three in 2009 (2 in Singapore and 1 in Kenya) - Six (first nine months of 2010) in Bolivia, Canada, Peru, Ukraine and Uruguay.
Expand in-country sampling and testing of medicines supplied by UNITAID	20 batches in 6 countries	2007	400 batches from 12-15 countries	0	Preparatory activities completed to start country sampling in the first quarter of 2011.

XIII. OVERALL ASSESSMENT OF PERFORMANCE

The UNITAID projects support for the Medicines Prequalification Program agreed in three MOUs is US$47 million of which US$15 million (32%) has been disbursed. Before the commencement of the UNITAID support for the program, a total of 38 product dossiers were under review. The number of product dossier received since the start of the UNITAID support has more than doubled. Thus far 93 product dossiers have been received of which 25 (31%) products have been prequalified and evaluation of the remaining 64 (69%) dossier is in progress. In the period from January to June 2010 alone, six generic products and 1 innovator product (Norvir HA491) received from applicants in India and Germany have been prequalified. The prequalified medicines are five ARVs and two anti-tuberculosis formulations. The table below summarizes the overall progress of the product dossier assessment and prequalification status.

Table 1. Status of Dossier Submission and Assessment for UNITAID Priority Medicines January 2007 - June 2010

Product	Number of Product Dossier		
	Received	Assessment Started	Product Prequalified
Second-line antiretroviral	29	29	11
Pediatric antiretroviral	6	6	4
1st line anti-tuberculosis products	14	13	1
2nd line anti-tuberculosis products	14	13	0
Pediatric anti-tuberculosis products	10	10	4
Antimalarial	20	18	5
	93	89	25

WHO/PQP has also been performing activities required to maintain and update the list of prequalified medicines. Accordingly, re-assessment of 265 variations received in the first half of 2010 has been completed. The variations assessed in the reporting period are nearly 70% compared to the 381 products re-assessed in 2009. The variations assessed were mainly related to additional new source for Active Pharmaceutical Ingredient (API), specification and test procedure change for API and Finished Pharmaceutical Product specific(FPP), change in packaging material and size and changes in API and FPP manufacturing site and process.

During the reporting period and additional information received in the third quarter of 2010, a total of six Quality Control Laboratories have been prequalified in Ukraine (two laboratories), Peru (1), Uruguay (1), Bolivia (1) and Canada (1) bringing the total number of prequalified Quality Control Laboratories through the project to nine. In the area of regulatory capacity building, eight training session with an average of 53 participants have been completed and technical support provided to four manufacturers two each in China and India.

The overall project implementation progress in terms of product dossier assessment, prequalification of Quality Control Laboratories and assessment of variations of prequalified products is in good progress. However, activities related to the prequalification of Active Pharmaceutical Ingredient (API) and in-country sampling and testing of quality of medicines supplied by UNITIAD is still work in progress. WHO/PQP is currently working with European Directorate for the Quality of Medicines and Health Care (EDQM) to complete an agreement for joint inspection and exchange of relevant information. The ongoing process to complete recruitment of experts which is expected to be completed in early 2011 is also expected to strengthen the implementation pace of the project.

XIV. PLANNED CHANGES IN THE PROJECT, if any

The project fund utilization pace compared to the planned disbursement stands at 32%. This is mainly due to delay in the recruitment of expert that resulted in non-utilization of the corresponding budget for salary. WHO/PQP has also identified the need to amend budget allocation to ensure adequate funding per activity. Following completion of review of the financial expenditure report and fully itemized justification, the next disbursement of US$7 million will be completed in the early 2011.

XV. ISSUES AND/OR LESSONS LEARNT

The project needs to hasten implementation of activities related to the prequalification of Active Pharmaceutical Ingredients (API) prequalification, shorten time to completion of dossier assessment, quality control of medicines procured through UNITAID support and inspection of manufacturing site.

The median number of days for the completion of assessment of dossier shows considerable variability. The delay on the part of the applicants in providing additional information required to complete dossier assessment has been identified as one of the major problems contributing to the overall delay. WHO/PQP, through the annual meeting with manufacturers is trying to address such issues.

The need expedite recruitment of experts is also one of the most important administrative issues identified. The recruitment of additional qualified staff in expected to be completed in the first quarter of 2011 and this is expected hasten implementation of the projects activities as per the project plan.

SEMI-ANNUAL REPORTING ON PROGRESS OF APPROVED PROJECTS, OPERATIONS

I. Reporting Period: March 2007 [ix] to 30 June 2010

II. Disease: HIV/AIDS, TB and Malaria

III. Niche: 2nd line ARV, Paediatric ARV, ACT, and MDR TB

IV. Project Name: UNITAID Support for Global Fund Round 6, Phase 1

V. Key Partner: Global Fund to Fight HIV/AIDS, TB and Malaria (Global Fund)

VI. Timeframe for Support: 21 December 2007 to June 2010
(please note that the Global Fund has submitted a request to use, for Phase 2, this project's Unexpended UNITAID Project Support)

VII. Start Date: 21 December 2007 **(see end note i)**

VIII. Total Amount Approved: US$ 52.5 million (Paediatric ARV US$ 11.9 million, 2nd Line ARV US$ 8.7 million, ACT US$ 21.5, and MDR-TB US$ 10.3 million)

The Global Fund's decision to not avail of the financial support for Mozambique has resulted to the following reduction of budget for the respective components: US$ 6.45 for Paediatric ARV; and US$7.3 for 2nd Line ARVs. With this reduction, the budget was reduced to **US$ 38.7 million.**

IX. Money Holder: Global Fund (subject to its trust fund arrangements)

X. Procurement Agent: The MOU provides that the procurement and delivery of drugs funded with UNITAID support will be the responsibility of the Principal Recipients (PRs) of the respective Round 6 grants (ref 4.1). In the case of MDR-TB control, the Global Fund reported that it had sent a written communication to PRs of UNITAID-funded Round 6 TB grants to encourage them to request that payment for the purchase and supply of second-line anti-TB drugs be made by direct disbursement from the Global Fund to the Global Drug Facility (GDF) to minimize transaction costs.

XI. FINANCIAL AND PROCUREMENT

DISBURSEMENT SCHEDULE (date, amount)		DISBURSEMENTS MADE (date, amount)		REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
Within 10 days of 21 December 2007	US$ 38,691,956	24 January 2008	US$ 38,691,956	The MOU provides that prior to payment/disbursement, WHO/UNITAID shall execute and deliver to the World Bank a contribution agreement in the form customarily required by the World Bank. Securing another round of signatures for the finalization of this contribution agreement caused a slight delay in disbursement.
upon fulfilment of conditions described in 4.5.2 for the determination of UNITAID Project Support for Mozambique	US$ 13,779,958	Not disbursed		In relation to UNITAID funding for paediatric and 2nd line ARVs for Mozambique, information obtained by the UNITAID Secretariat suggested funding overlap for Mozambique. The likely risk of duplicate funding was considered to be significant and a provision for withholding remittance of funds for these niches, amounting to US$ 13,779,958, was incorporated into the project's MOU. Through a letter dated 19 March 2009, UNITAID was informed by the Global Fund that Mozambique requested the very small amount of US$851 for the procurement of ARVs under the Round 6. The Global Fund indicated that it considered it best not to avail of UNITAID's offer of financial support for Mozambique's procurement of paediatric ARVs under the Round 6. UNITAID's total financial commitment under the MOU for *UNITAID Support for Global Fund Round 6, Phase 1* is US$ 52,471,914. The amount of US$ 38,691,956 was remitted in January 2008. With the Global Fund's decision to not avail of the financial support for Mozambique, UNITAID has fully fulfilled its financial responsibilities for this project. Thus, it can be considered that **100%** of funds for this project has been remitted.
		TOTAL AMOUNT DISBURSED: US$ 38,691,956 **PERCENT DISBURSED: 100 %**		

REPORTING SCHEDULE [x] [xi] **(report type, period covered, date)**		**REPORTS RECEIVED (report type, period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
Semi-annual project and procurement update 1 March to 31 Dec 07 (see end note i)	31 March 2008	1st Semi-annual project and procurement update 1 March to 31 Dec 07	8 April 2008	The information requirement for the report was met except for the omission of the names of the PRs and Phase 1 Starting Date. This is not a cause for concern as this information was provided in the other reports and can be easily cross-referenced.
1st Annual Programmatic Reports 1 March to 31 Dec 07(see end note i)	31 March 2008	1st Annual Programmatic Report 1 March to 31 Dec 07	8 April 2008	The information requirement for the report was met. However, The information that was provided was quite limited due to the relatively short period covered by the report. The Global Fund reported that for 38 of the 42[xii] participating grants the report deadline has not yet passed as of the reporting period or the Global Fund was not expecting progress to be reported on the treatment indicator. Twenty-two grants had not passed the reporting deadline after the first disbursement of funds and 16 had not planned to treat people within the reporting period (and so have not reported against treatment targets). Four grants reported progress towards treatment targets.
1st Annual Financial Reports 1 March to 31 Dec 07(see end note i)	31 March 2008	1st Annual Financial Reports 1 March to 31 Dec 07	8 April 2008	The total consolidated period that is covered by the Progress Update and Disbursement Reports (PUDRs) was omitted, but this is not a cause for concern since this data can be easily inferred from the report. Although minimal procurement of drugs was reported and it was acknowledged that procurement of drugs for some grants were not expected at the initial stages of the grants, it was reported that UNITAID funds have been fully disbursed (zero undisbursed balance). Although this does not meet the practical information requirements of the UNITAID Secretariat, it is acknowledged that the computation was in line with the MOU provision for reckoning the disbursements.
Semi-annual project and procurement update 1 January to 30 June 2008	30 September 2008	2nd Semi-annual project and procurement update 1 January to 30 June 2008	19 September 2008	Due to the early stage of the participating grants, most PRs had not planned to procure or were just initiating procurement activities within the reporting period. However, 11 out of 43 PRs have reported procurement of medicines in UNITAID niches within the reporting period. This represents 25% of all participating grants.
Semi-annual project and procurement update	31 March 2009	3rd Semi-annual project and procurement update	31 March 2009	The report was received on time. The report covered the agreed scope and time period for reporting.

REPORTING SCHEDULE [x] [xi] **(report type, period covered, date)**		**REPORTS RECEIVED (report type, period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
1 July to 1 December 2008		1 July to 1 December 2008		
2nd Annual Programmatic Report 1 January to 31 December 2008	31 March 2009	2nd Annual Programmatic Report 1 January to 31 December 2008	31 March 2009	The report was received on time. The report covered the agreed scope and time period for reporting.
2nd Annual Financial Reports 1 January to 31 December 2008	31 March 2009	2nd Annual Financial Reports 1 January to 31 December 2008	31 March 2009	The report was received on time. The report covered the agreed scope and time period for reporting.
Semi-annual project and procurement update 1 January to 30 June 2009	30 September 2009	4th Semi-annual project and procurement update 1 January 2009 to 30 June 2009	24 September 2009	The report was submitted ahead of 30 September 2009 upon the request of UNITAID Secretariat, in order to facilitate preparation of report to the UNITAID Board.
Semi-annual project and procurement update 1 July to 1 December 2009	31 March 2010	Semi-annual project and procurement update 1 July to 1 December 2009	31 March 2010	The report was received on time. The report covered the agreed scope and time period for reporting.
3rd Annual Programmatic Report 1 January to 31 December 2009	31 March 2010	3rd Annual Programmatic Report 1 January to 31 December 2009	31 March 2010	The report was received on time. The report covered the agreed scope and time period for reporting.
3rd Annual Financial Reports 1 January to 31 December 2009	31 March 2010	3rd Annual Financial Reports 1 January to 31 December 2009	31 March 2010	The report was received on time. The report covered the agreed scope and time period for reporting.
Final Programmatic Report From last day of most recent reporting period to the completion of the project	Within 90 days after completion of the project	Final Programmatic Report	30 September 2010	The report was received on time. Additional data/analysis will be submitted to support the request to use, for Phase 2, the project's Unexpended Funds.

REPORTING SCHEDULE [x] [xi] **(report type, period covered, date)**		**REPORTS RECEIVED** **(report type, period covered, date)**		**REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS**
Final Financial Report As of completion date of the project	Within 90 days after completion of project	Final Financial Report	30 September 2010	The report was received on time. Discussions on the computation of the Unexpended Balance are still ongoing.

XII. PROGRAMME PROGRESS

KEY OBJECTIVES/ ACTIVITIES	BASELINE [v] (if appropriate)		CUMULATIVE YEARLY TARGETS [vi]		ACTUAL TARGETS REACHED TO DATE [vii]	REASONS FOR ANY DEVIATION AND/OR ANY OTHER REMARKS
	Value	Year	Year 1	Year 2		
Paediatric ARV			13,671	29,592[xiii]	28,870	The Global Fund reported that the total intended target per UNITAID reporting period (as specified in Progress Update and Disbursement Requests) is 29,584. Clarification regarding the difference between the targets specified in the MOU and *Total Intended Targets per UNITAID Reporting Period* has yet to be received.
2nd line ARV			5,539	8,099[xiv]	7,477	The Global Fund reported that the total intended target per UNITAID reporting period (as specified in Progress Update and Disbursement Requests) is 7,269. Clarification regarding the difference between the targets specified in the MOU and *Total Intended Targets per UNITAID Reporting Period* has yet to be received.
ACT			5,057,431	11,190,095[xv]	2,055,927	The Global Fund reported that the total intended target per UNITAID reporting period (as specified in Progress Update and Disbursement Requests) is 9,860,992. Clarification regarding the difference between the targets specified in the MOU and *Total Intended Targets per UNITAID Reporting Period* has yet to be received.
MDR TB			1,232	3,298	3,091	The Global Fund reported that the total intended target per UNITAID reporting period (as specified in Progress Update and Disbursement Requests) is 3,262. Clarification regarding the difference between the targets specified in the MOU and *Total Intended Targets per UNITAID Reporting Period* has yet to be received.
Support price reductions of high quality drugs for HIV/AIDS, MDRTB and malaria in national treatment programs through efforts to facilitate the use of a reference price mechanism and pooled procurement			No numerical targets	No numerical targets		Global Fund had indicated that due to time lag in PR reporting, the some procurement have been omitted in the prior procurement reports submitted to-date. In its Final Report, the Global Fund reported that the price dynamics data for the period 2007 to 2010 were inconclusive in analysing the attainment of this objective.

XIII. OVERALL ASSESSMENT OF PERFORMANCE

The project has two objectives to scale up access to treatment and to positively impact market dynamics to increase the affordability of drugs for the treatment of HIV/AIDS, multi-drug resistant tuberculosis and malaria:

a. increase the number of patients accessing and receiving treatment for HIV/AIDS, multi-drug resistant tuberculosis and malaria;
b. support price reductions of high quality drugs for HIV/AIDS, multi-drug resistant tuberculosis and malaria in national treatment programs through efforts to facilitate the use of a reference price mechanism and pooled procurement

PROGRAMMATIC RESULTS

Delivery of Treatments

As shown by the table below, significant achievements against cumulative targets have been reported for all niches except ACTs.

Niche	Treatment Target Yr 2 (per Final Report)	Actual Result to date (as specified by LFA)	% Result to Targets per Final Report
Pediatric ARV	29,592	30,052	102%
2nd Line ARV	8,099	7,477	92%
ACT	11,190,095	2,650,652	24%
MDR-TB	3,298	3,168	96%

Among the reasons cited for the low implementation rate are:

- delayed arrival of ACTs in Guinea
- suspension of grant disbursement for Mali and Mauritania following the Global Fund Office of Inspector General's investigation
- lower malaria prevalence in Djibouti

There are 43 Round 6 Global Fund grants that are participating in this project. The Final Report indicated that out of the 43:

- 1 (Mozambique) has opted out of the project
- 14 [xvi] were reported to have fully met the cumulative targets under the project; of which:
  - 3 are for Pediatric ARV
  - 3 are for 2nd Line ARV
  - 3 are for ACTs
  - 5 are for MDR-TB
- 28 grants have not yet fully achieved targets; of which
  - 2 grants with a total combined remaining target delivery of 2,542,337 were reported to have been "frozen" and are under investigation by the Office of Inspector General. Disbursements to these grants were reported to have been suspended
  - 26 **(see endnote viii)** will be analysed on a grant-by-grant basis, with a view to reaching agreement on way forward, including possibility of no-cost extension, close-out, and/or reimbursement of unused funds. The analysis is expected to build on targets achieved to date and the outlook for further possible achievements before the end of the Global Fund grants.

Eligibility Criteria

As of June 2010, the World Bank income classification for nine participating countries has been revised. Belarus, Bulgaria Kazakhstan, Namibia and Serbia were reclassified from Lower Middle Income Countries to Upper Middle Income Countries while Bhutan, Cote d'Ivoire, India and Moldova were reclassified from Low Income Countries into Lower Middle Income Countries.

UNITAID's constitution provides that " *No more than 5% of UNITAID funds dedicated to purchase commodities should be spent on upper middle income countries (UMICs) with priority given to those with a high disease prevalence, subject to these countries providing co-financing for their projects as to 20% in year 1 rising to 40% in year 5"*.

However, the Global Fund indicates that the country's income level are determined at the time of the call for proposals and a change in income level of the country during the period of the grant would not result in the imposition of new or additional cost-sharing requirements for that grant.

PROCUREMENT

For the period March 2007 to 31 December 2009, it was observed that a number of Principal Recipients did not report procurement data but reported treatment progress. While noting that the GF Price Reporting Mechanism is not meant to account for all procurement under the project, it is

nevertheless understood from the MOU that PRs are required to provide procurement data before further disbursements of funds are made by the Global Fund. UNITAID has requested for an update on actions taken in relation to PRs' non reporting of procurement data.

A recurrent observation made by UNITAID Secretariat on the Round 6 reports has been in relation to the reported procurement of drugs which are not specifically listed in Exhibit 2 of the MOU. To address this observation, the Global Fund had introduced a new "Yes/No" column to indicate compliance with QA requirements. However, the UNITAID Secretariat has requested that the specific QA criteria that were met by the procured items be specified instead of a "Yes" entry. Discussions regarding this topic are ongoing.

In its Final Report for the period ending June 2010, the Global Fund indicated that 33 PRs reported procurement of pharmaceutical products with a total value of US$33,421,219.7, broken down per niche into:

	Reported Procurement (Final Report)
Paediatric ARVs	6,762,369
2nd Line ARVs	13,286,345
ACT	6,590,254
MDR TB	6,422,252
Total	**33,061,220**

The procurement report is yet to be evaluated at the UNITAID Secretariat.

XIV. PLANNED CHANGES IN THE PROJECT, if any

1. Completion of the Project

With the lapse of the project's completion date of June 2010, the UNITAID Secretariat has notified the Global Fund that the project, including all the participating grants, is considered to have officially reached completion.

2. Request for Use, for Phase 2, of Unexpended Funds

Subject to assessment, the project's MOU has a provision for the use, for Phase 2, of the project's Unexpended UNITAID Project Support. After the lapse of the project completion date, the Global Fund submitted a formal request to draw upon this provision for the following participating grants:

Paediatric ARV:	Burkina Faso and Serbia
ACT:	Cambodia, Bangladesh, Guinea Bissau and Namibia
MDRTB:	Benin, Bhutan, Egypt, Rwanda, Sri Lanka, Syrian Arab Republic and Viet Nam

The Global Fund has been requested to submit the estimated Unexpended UNITAID Project Support as well as relevant programmatic information to support the required assessment attendant to the requested use of unexpended funds.

3. Implications of the Two Grants under Investigation by the Global Fund Office of the Inspector General (OIG)

The Annual Report for 2009 indicated that the ACT grants for Mali and Mauritania were "frozen" and disbursements were suspended.

The UNITAID Secretariat is in consultation with the Global Fund regarding the possible implication of the OIG investigation of the two ACT grants (Mauritania and Mali). The updates made available to-date by the Global Fund (see below) on this issue suggests that some financial resources might be refunded, but expectations along this line will need to bear in mind the Global Fund policy on continuation of life-saving and/or essential treatments.

a. Mauritania

The Principal Recipient for the participating Round 6 grant is UNDP. According to the Progress Report submitted by the Office of the Inspector General (OIG) to the 21st Board Meeting of the Global Fund, was alerted by the UNDP Office of Audit and Investigation (OAI) to widespread evidence of fabricated documents in supporting material provided by sub-recipients over a five and a half year period, which were discovered during a regular UNDP audit. Supporting the UNDP investigators, the OIG deployed its team of investigators. The investigation confirmed systematic fraud by the sub-recipients in the Global Fund grants administered by the UNDP.

The OIG also reported that the work to quantify the value of the loss to the Global Fund has not yet been completed. Once the final loss figure is calculated, the OIG will:

1. discuss appropriate recovery action with the Global Fund Secretariat
2. discuss with the UNDP's (as the project's Principal Recipient) Office of Audit and Investigation the process of formally referring the evidence to the Mauritanian authorities for criminal investigation and prosecution of those responsible

It is to be noted that the *Progress Report* indicated that Mauritania had returned funds to the Global Fund Trustee as a result of a similar/related case.

b. Mali

According to the Progress Report submitted by the Office of the Inspector General (OIG) to the 21st Board Meeting of the Global Fund, the fraudulent and unjustified use of Global Fund grant funds were confirmed by the OIG in November 2009. This resulted to the arrest of the Accountant responsible for the administration of grants at Mali's Ministry of Health, along with the Secretary General and the Register for the Ministry.

The OIG report indicated that preliminary indications from the ongoing OIG investigation are that the fraudulent and unjustified use of funds are systematic rather than isolated and involves a large portion of the supporting documentation. At the time of reporting to the Global Fund Board, the amount attributable to the fraud had not yet been quantified.

It was reported that the OIG has met with the Investigating Judge to discuss the modalities of referring further and more specific evidence. At the conclusion of the investigation, comprehensive evidence will be provided to the authorities for the criminal investigation and prosecution of those responsible.

In a separate but related event, the French Cours de Comptes, which is tasked with the overall review of use of the airline taxes, visited Mali as part of its review. The visit brought to fore the possibility of stock out situation in light of the GF decision to suspend disbursements. The UNITAID Chair and the UNITAID Secretariat Executive Secretary have conveyed the situation and the need for urgent solution to the GF Board and the GF Executive Director, respectively. The GF Executive Director has subsequently clarified that GF had been informed by the LFA that there was no imminent risk of disruption of medicines in Mali.

Unpaid bills for ACTs, dating back to 2009, were also brought to the attention of the Cours de Comptes. The account to charge for these bills would need to be sorted out, taking into consideration the parameters of the MOU, and bearing in mind that the UNITAID financial support for this project has been fully remitted to GF.

4. Other changes that have taken place

a. As of 2009, the World Bank income classification for nine participating countries has been revised.

b. A net increase from the MOU specific targets has been reported, summarized below. Details are provided in the end notes:

	Targets per MOU	Less Quantities Earmarked for Mozambique	Targets after deducting quantities earmarked for Mozambique	Total Targets reported in Final Report	Difference
Paediatric ARVs	194,561	165,000	29,561	29,592	31
2nd line ARVs	172,465	165,000	7,465	8,099	634
ACTs	11,173,036		11,173,036	11,190,095	17,059
MDR TB	3,298		3,298	3,298	
	11,543,360	**330,000**	**11,213,360**	**11,231,084**	**17,724**

c. Under a separate project, UNITAID was informed of a change in MDR TB regimen in line with GLC recommendations - e.g. the substitution of Moxifloxacin for Levofloxacin and Levofloxacin for Ofloxacin. UNITAID has requested clarification as to whether this change in regimen is expected to affect the MDR TB component of the Round 6 project.

XV. ISSUES AND/OR LESSONS LEARNT

Issues and/or lessons were learned even as the MOU was being negotiated and these have been reported to the UNITAID Board during its meeting in April 2008.

Also discussed in earlier submissions to the UNITAID Board and/or prior sections of this report are concerns relating to: a) financial implications arising from the project's reporting limitations; and b) procurement; and c) changes in income classification of participating countries.

The project's reporting limitations has precluded the UNITAID Secretariat to independently estimate the project's Unexpended UNITAID Project Support. As recognized in the MOU, its estimation is dependent on the reporting to be done by the Global Fund. The Global Fund is a trusted partner and there is no reason to doubt its representations. However, due diligence and planning on the part of the UNITAID Secretariat could have been better served had the MOU provided for the regular submission of more robust and more comprehensive information.

The recent development regarding the OIG investigation of the ACT grants for Mali and Mauritania underscore the need for appropriate risk management/mitigation provisions in UNITAID's project MOUs in case similar events arise.

END NOTES

[i] The disbursements for April 2008 was in consideration of the acceleration of delivery of ACTs for Mozambique, as agreed upon in April 2008. The projected disbursement for October 2008 was in consideration of the revised budget as of October 2008, taking into account the decreased treatment targets for North Sudan and other price adjustments. The projected disbursements from April 2009 onwards are in consideration of prior year balances that were re-programmed.

[ii] While both the UNITAID Board and the Global Fund emphasize the importance of the sustainability of funding, the UNITAID Board has conditioned funding commitment and disbursements for 2008 and beyond as being "subject to evidence of need and on demonstration of the Principal Recipient's satisfactory performance, as assessed and reported under Global Fund's results based funding policies and procedures ". Consequently, the MOU provides that continuation of UNITAID-funded ACT support is subject to evidence of need, technical soundness, evidence of progress for the realization of project objectives and submission of technical and financial reports (ref section 3.2.2, page 5/40 of MOU).

[iii] The additional targets as a result of UNITAID funding are in the form of ACT products requested by Global Fund Principal Recipients (PRs). The numerical targets in this table are as they appear in the MOU. However, it is to be noted that the project is being implemented through the Global Fund architecture, under which these figures were expected to represent a ceiling as opposed to a target. The Global Fund indicated that it is not their intention to make the PRs request their full allocation unless it is feasible for implementation.

[iv] The targets presented in this report reflect the roll overs approved since and adjustments, in target allocations and deliveries, as of July 2010 . Comparative table of original, revised and projected yearly targets as per most recent roll over request is presented below:

	Cumulative Targets (in million ACTs)			
	Quantity Year 1 (Q4 07-Jun08)	**Quantity Year 2 (Jul08-Jun09)**	**Quantity Year 3 (Jul09-Jun10)**	**Quantity Year 4 (Jul10 Q1 11)**
Original yearly targets (per MOU)	10.1	22.5	33.9	47.0
Revised yearly targets after revisions approved as of July 2010	4.3	15.1	33.1	43.3

The net decrease in cumulative targets is attributed to the lowered overall targets for North Sudan. In addition to the lowered targets for North Sudan, the other approved changes in delivery schedules pertain to:

a. deferment of target delivery dates (ie, from one project year to later project years) for the following: Cambodia, North Sudan, South Sudan, Zambia, and Ethiopia)
b. acceleration of target delivery dates for Mozambique
c. swap of unused allocation of Ghana, to the favor of North Sudan

[v] Targets are yearly and hence may not always be reported on a semi-annual basis. The target treatment deliveries as reflected in the signed MOUs are based on project years (ie, July to June). In light of the UNITAID Secretariat's aim of standardization of reporting of results, the project year targets have been converted into calendar year targets through pro-rata calculation as discussed with the implementing partners. See endnote iv for the targets per project year.

[vi] As computed by the Global Fund on the basis of the originally indicated participating grants. Previously recorded baseline data was 165 million treatments, as provided by the Global Fund. The Global Fund subsequently clarified that this included erroneous treatment targets for Mozambique, South Sudan, Zambia and Ethiopia. Mozambique and Zambia's use of ACT is new to scale-up and previous targets for these countries and South Sudan included treatments targets using non-ACT products and should not have been included. Ethiopia's current treatments targets were erroneously reported by the PR in the invitation to participate.

[vii] Including the participating grant for Indonesia which has reached the end of the grant lifetime.

[viii] The 2nd Annual Report (dated September 2009, for the period ending June 2009) indicated a revised treatment target of 54,067,244 people, In March 2010, a revised treatment target of 52,693,078 was reported. The decrease was attributed to the revised treatment targets for Madagascar PSI and Cambodia grants (ref: 3rd Interim Report (for the period ending December 2009).

[ix] The last signature for the Memorandum of Understanding (MOU) was secured on 21 December 2007, making this the project's start date (section 5.1 of MOU). However, the MOU allowed for reporting from March 2007 in light of the Global Fund disbursements of UNITAID attributable funds for participating Global Fund Round 6 grants commencing in March 2007.

[x] The MOU provides that the reports will provide data per grant and collated for each treatment niche and for the initiative as a whole

[xi] Each Global Fund grant operates on different timelines. Therefore each grant will report programmatic results at a different time.

[V] The Global Fund confirmed that the estimated treatment targets for each niche during Phase 1 of Round 6 as set out in the MOU represent an additional number of patients under treatment in relation to those currently being treated under Global Fund grants. However, UNITAID does not have the data for pre-UNITAID treatment numbers or pre-Global Fund baseline. The yearly targets represent additional treatments to be delivered to patients but may not be additional patients since some patients need to be maintained on treatment.

[vi] The project supports the procurement for drugs for Round 6 grants during Phase 1, which comprises the period covering the first 2 years of the grant (after the first disbursement of grant funds) and any subsequent extension period of up to six months. Start dates of the Global Fund grants will be specific to each grant and not all grants will start in 2007. Thus, while the UNITAID project started in 2007, it is anticipated that the completion of the project will occur on or about June 2010.

The report for the period ending December 2009 indicated a revised total target of 11,254,085 treatment targets across the niches, representing a net decrease of 7,587 treatment targets from that which was reported for the period ending December 2008 (11,261,672). Lowered targets for China and increased target for Guinea were observed. Clarification is awaited..

[vii] Targets are yearly and may not always be reported on semi-annual basis. It was been subsequently clarified that the targets presented under Year 2 of the MOU are cumulative and the targets presented in this report have been accordingly adjusted.

[xiii] The Cumulative Year 2 target per MOU, after deducting Mozambique, was 29,561. The financial implication of the net increase of 31 has yet to be clarified by the Global Fund. The net increase is due to:

	Target in MOU	Reported Target	Increase/ Decrease
Serbia	0	8	8
Laos	790	0	-790
Guinea	6037	6850	813
Net Increase			**31**

[xiv] The Cumulative Year 2 target per MOU, after deducting Mozambique, was 7,465. The financial implication of the net increase of 634 has yet to be clarified by the Global Fund. The net increase is due to:

	Target in MOU	Reported Target	Increase/ Decrease
Laos	790	1,424	**634**

[xv] The Cumulative Year 2 target per MOU was 11,173,036. The financial implication of the net decrease of 40,060 has yet to be clarified by the Global Fund. The net increase is due to:

	Target in MOU	Reported Target	Increase/ Decrease
Cambodia	123,151	148,602	25,451
China	78,400	70,000	-8,400
Mali	2,687,868	2,687,876	8
Net increase			**17,059**

[xvi] The text report indicated that 15 have fully achieved the targets but the supporting data indicates that 14 have fully achieved targets. Assuming that 15 grants having fully achieved targets, 25 remaining grants are to be subjected to grant-by-grant analysis to determine the way forward. This number (25) may change to 26, depending on the resolution of the discrepancy, which is under discussion with the Global Fund.