Executive Board
12th Session
8-9 June 2010
Geneva, Switzerland

Agenda Item 9

Update on Operations

Report on implementation of projects approved by the Board

a. **HIV**

b. **TB**

c. **Malaria**

d. **Transversal**

Documentation

1. **Project Update HIV niche (Pediatric ARV, Second line ARV, PMTCT and ESTHERAID)**

2. **Project Update TB niche (Pediatric TB, First-line TB, MDR-TB diagnostics, MDR-TB scale-up initiative including an update on the status of development on the Strategic Revolving Fund)**

3. **Project Update Malaria niche (ACT scale-up, LLINs 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 EB12 Session, 8-9 June 2010

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 2009	4 May 2007 to 30 September 2011	305,799,000	223,970,038	184,287,244
PMTCT	10 December 2007 to June 2010	75,666,955	70,958,030	40,292,474
ESTHERAID, Phase 1	3 years project for which only phase 1 approved; July 2, 2009 - March 1, 2010	EURO 321,106 (estimated USD 451,626)	EURO 321,106 (estimated USD 451,626)(MoU Budget)	451,626 (USD equivalent of EURO 321,106 at the time of transaction)
Total for ongoing		618,058,775	529,921,251	408,774,092
EB APPROVED AND PENDING MOU				
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		15,498,374		
Total Cumulative:		633,557,149	529,921,251	375,649,886

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 portfolio. Furthermore, the EB has approved *the 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.*

MOUs

The UNITAID EB approved commitment ceiling of USD 633,557,149 have materialized into MOUs, with a net disbursement commitment of USD 529,921,251. 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 prevention and treatment of HIV/AIDS in children and adults as well as technical support to strengthen national health capacities.

Outlook

The Second Line ARV project, implemented in partnership with CHAI, will continue through 2011. In 2009, the project supported 24 beneficiary countries. By end 2009, nine countries have confirmed that they could transition to alternative funding starting in 2010. The EB has approved "bridge funding" for 2010-2011 to allow for a smooth transition to alternative and more sustainable funding sources. The project's market impact on price has seen encouraging indications: the 2009 supplier selection yielded price reductions for primary suppliers across all seven second-line ARV products and saw the entry of 4 newly eligible suppliers of second-line ARV formulations, including one formulation that had previously been sole-sourced. Further price reduction is expected with the introduction of atazanavir (ATV) and heat-stable ritonavir (RTV) which may become available in countries in September 2010.

For the Paediatric HIV/AIDS project, an additional budget ceiling of US$ 76,888,274 for 2010 was approved in December 2009 by EB 11, and later, in January 2010, additional support to Haiti was approved (USD 1,016,132). It is expected that a request for the project to be extended beyond 2010 to allow for a smooth transition of treatments to sustainable funding sources would be submitted to EB12 for the Board's consideration. The selection processes of approximately 40 pediatric first and second line antiretroviral and 18 opportunistic infection medicines for 2010 are being concluded, and their outcomes are expected to be made available by UNITAID and CHAI shortly in April.

Progress in the PMTCT niche has been made within main areas of intervention, thereby contributing to ultimately reaching the objectives set. Progress in the expansion of the facility-based coverage of PMTCT programmes, as well as the number of pregnant women reached by PMTCT interventions has been identified. Implementation of the Nutrition and Expansion Components, for which legal agreements were signed in July 2009, has begun and a funding request to cover a transition period for the First Component, which ended December 2009, was submitted to EB11 and is being followed up on in accordance with Board and expert guidance.

The Phase 1 of the ESTHERAID project started on the 2nd of July 2009. To-date, Phase I is being finalized. The assessment of the Benin, one of the 5 participant countries, has been submitted to UNITAID, and a MoU is being negotiated. It is expected that all proposals be submitted to UNITAID by the end of May 2010.

An initiative to scale up access to viral load monitoring tests in countries is being negotiated with UNITAID, WHO, CHAI and PASCAL with a view of submitting a proposal to the EB 13 in December 2010.

PROJECT TITLE: UNITAID-CHAI PAEDIATRIC HIV/AIDS PROJECT

Key Partner(s):	**Clinton HIV/AIDS Initiative (CHAI)**
Project Start Date:	**1 November 2006**
Project Duration:	**2006 - 2010**
Updates for the Period Ending:	**June 2009 (Financial updates up to January 2010)**

The 2009 Annual Report submission is pending and some procurement and programmatic data provided in this document has not been modified since EB11. Consolidated 2009 information will be provided to the Board in it 13th meeting in November 2010.

Section of the Board Update		Updates
XI	Financial and Procurement	The main objective of the project is to reduce the prices of medicines and increase the availability of quality assured manufacturers and products. ▪ An additional budget ceiling of US$ 76,888,274 for 2010 was approved in December 2009 by EB 11. In 14 January 2010, CHAI requested UNITAID to provide additional support to Haiti. Following electronic consultation, the Board approved the allocation of an additional amount of US$1,050,532 to support the inclusion of Haiti in the Project, thereby raising the total approved amount to **US$77,938,806** for 40 specified low and middle income countries. An amendment to the agreement was concluded in 11 February 2010. ▪ The first disbursement of the 2010 budget, of **US$ 37,779,000** was made on 31 March 2010 upon the UNITAID approval of the 2009 financial reports. ▪ It is expected that a request for the project to be extended beyond 2010 to allow for a smooth transition of treatments to sustainable funding sources would be submitted to EB12 for the Board's consideration. ▪ The selection processes of approximately 40 pediatric first and second line antiretroviral and 18 opportunistic infection medicines for 2010 are being concluded, and their outcomes are expected to be made available by UNITAID and CHAI shortly.
XII	Reporting Schedule	The Annual Report (for the period January 2009 to 31 December 2009) is due 30 April 2010. The Semi-annual Report, covering the period of January 2010 to June 2010 is due 5 August 2010.
XIII.	Project Progress	As of June 2009, UNITAID was funding 226,309 paediatric treatments. Of these, 30,582 were new treatments initiated between January and June 2009. Price reductions of an average of 5% from 2008 were achieved in a supplier selection process carried out in March 2009, and new suppliers are providing more adapted paediatric formulations, including FDCs. CHAI has offered paediatric FDCs to all Project beneficiaries, and through June 30, 2009, d4T and AZT-based paediatric FDCs (both dual and triple) have been ordered for 30 of the beneficiary countries. CHAI has committed over US$13.6 million cumulatively since the start of the programs, including US$3.5 million during January to June 2009 towards the purchase of paediatric FDCs. In the second quarter of 2009, Matrix received WHO Prequalification for AZT+3TC 60/30mg. The proportion of generic suppliers in primary or secondary positions has

Section of the Board Update		Updates
		increased from 75% in 2007 to 84% in 2009. New data will be available in early April, upon conclusion of the 2010 ARV and OI medicines tenders.
XV.	Issues and/or Lessons Learnt (Information of June 2009 reported to EB11)	**a. Monitoring and Evaluation:** Measuring patient numbers and patient retention continue to pose a challenge. As of the writing of this report, eleven countries have not reported monthly data for June 2009, namely Botswana, Burundi, Cameroon, Cote d'Ivoire, Guyana, Liberia, Mali, Nigeria, OECS, Senegal and Togo due to the lag time in the monitoring and evaluation systems. Significant efforts are being made to improve data collection and improve focus on retention, which CHAI anticipates may mitigate some of the loss. CHAI's advocacy on retention is aimed at countries to address retention, and help drive the implementation of practical, effective solutions. Some of the interventions aimed at reducing patient loss between testing and enrolment in treatment include SMS Printer Pilots, Early Infant Diagnosis ("EID") Service Reviews, and Exposed Infant Register/Improved Early Infant Tracking. **b. Inability to meet targets:** The failure to meet the original targets of additional children on treatment has been attributed in part to overly ambitious or inconsistent target setting and a loss to follow up of children tested or initiated on treatment. As countries improve their forecasting methodologies, numbers are updated and revised. In June 2009, the end-2009 target was revised from 67,580 to 65,025. This revision was due to updated expectations from select countries including: 1. Lesotho dramatically revised their estimates down from 1,261 to 500 due to the adoption of a new methodology of counting patients on treatment. Lesotho now only includes children alive and on treatment whereas in the past they were also including treatment initiations; 2. Liberia, Namibia, Malawi, Mozambique, Rwanda and Togo each estimate fewer patients than previously targeted; **c. Product Quality Concerns:** During 2009, beneficiary countries registered concerns regarding four products whereupon CHAI conducted investigations to diagnose and rectify the issues. 1. Ranbaxy Efavirenz 200mg - Uganda reported that upon opening sealed packages of EFV 200mg manufactured by Ranbaxy, approximately 10-20% of the capsules were broken. Investigations concluded that the probable cause of broken capsules was product mishandling after delivery. The product is being recalled and replaced with EFV 200mg from other suppliers. 2. Cipla Triomune and Lamivir - There were several reports of de-lamination, or splitting of the tablets, in bottles of Cipla's Triomune Baby. These products have previously been reported by some patients to be easily split horizontally. This prompted Cipla to add a score line to the tablets to encourage patients to break the tablet vertically in order to ensure proper dosing. As a result of these de-lamination issues, CHAI tested the products for friability in India at SGS. Friability is designed to identify issues with de-lamination and it is believed that post-delivery handling is the likely cause for this de-lamination. In the meantime, CHAI remains alert to the problem. 3. Ranbaxy's ddI 25mg - Ranbaxy's ddI 25mg did not pass SGS testing, failing the 3-minute disintegration test set forth by IP specifications. Prior batches have disintegrated in less than 3 minutes and passed SGS testing. Because Ranbaxy is the sole supplier CHAI had to procure these formulations from the only other eligible supplier, BMS. Both ddI 25mg and ddI 50mg have been included on the WHO PQ Expression of Interest ("EOI") list. to encourage

Section of the Board Update		Updates
		generic suppliers to seek SRA-approval for these formulations **d. Sustainability and transition:** CHAI has initiated negotiations with donors, in anticipation to plan for the transition after December 2010. Potential funding sources for some countries and the support necessary to access these funds were identified. A coordinator has been appointed by CHAI to manage the process. However, the global economic crisis has resulted in constraints in availability of funding from other donors. CHAI continues to work with countries on the preparation of their Global Fund proposals to improve their chances of success. **e. Coordination and transition:** The Coordinated Procurement Planning (CPP) for HIV/AIDS, represented by key donors (UNITAID, GFATM, PEPFAR, World Bank) and WHO, with support of Supply Chain Management System (SCMS) has provided a framework to improve and strengthen country-level coordination for the planning and procurement of HIV/AIDS related commodities. The CPP has monitored the transition, in close coordination from CHAI, to assure that countries and donors are capable to integrate UNITAID-related achievements into national systems or alternative funding sources.

PROJECT TITLE: SECOND LINE ARV Project

Key Partner(s):	**The Clinton HIV/AIDS Initiative (CHAI)**
Project Start Date:	**5 May 2007**
Project Duration:	**May 2007 - September 2010**
Updates for the Period Ending:	**31 March 2010**

Section of the Board Update		**Updates**
XI.	Financial and Procurement	Prior to EB10 approval, the allocated amount was US$ 145,468,038 for the period of 2007-2009, and had been fully disbursed as of 30 May 2009. EB10 approved an additional ceiling amount of US$ 120,410,000 for this project for 2010-2011. In addition, EB10 approved that the payment of up to US$ 17,120,706, originally due to be disbursed in Quarter 1 2010 to be disbursed in Quarter 4 2009 to harmonize the project budget year with the UNITAID fiscal year. The 2010 MoU was signed in 9 December 2009. • Of the additional MoU obligated amount of US$78,502,000, the first of three disbursements of US$ 5,695,000 was made in December 2009. The request for the second installment of US$ 33,124,206 was approved by the Secretariat in 7 May, and the total amount disbursed within the 2010 budget is now US$ 38,819,206. The third and final disbursement for 2010 is expected to be within a maximum of US$ 29,963,764. • The selection process of the 2010 ARV suppliers has been concluded in April 2010. A second supplier selection process was conducted in April to select Atazanavir (ATV) and heat-stable ritonavir (RTV) suppliers. The Expert Advisory Group (ERP) conducted a risk assessment of the non-prequalified formulations and raised objection to the proposed procurement of all 3 atazanavir formulations. The ERP comments were sent to manufacturers, through CHAI, for clarification. The funding of these 3 formulations will be held pending until a subsequent assessment is conducted or the products are prequalified. The ERP had no objection to HS ritonavir 100mg, and this product is now eligible for funding under the project. CHAI estimates that these products will enable to reduce the price of a priority regimen to as low as US$ 500 per patient per year in 2010-2011.
XII	Reporting Schedule	• The submission of the Annual Report, covering the period of 1 January through 31 December 2009, originally due 16 March 2010, has been delayed, and was received on 30 April. Its assessment is being finalized by the Secretariat. • A semi-annual report is rescheduled for 30 July 2010.
XIII.	Project Progress (as of January 2010)	**<u>Support Provided</u>** In 2009, the Project provided over US $63-million in support to 25 beneficiary countries. This resulted in the procurement of antiretrovirals for an estimated 67,490 second-line patients across all countries as well as an additional 49,834 first-line tenofovir regimen patients in Uganda and Zambia. **<u>Transition to Alternative Funding Sources</u>** As of October 2009, nine countries have confirmed alternative funding starting in 2010. One additional country has confirmed alternative funding after UNITAID Bridge Funding of three months, and another two countries may require up to six months of UNITAID Bridge Funding. Three of the remaining thirteen beneficiary countries were successful in their Global Fund Round 9 proposals and an additional country received Category 2b approval. Though a

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		source for transition has been identified for these countries they will require Bridge Funding to account for the delay in disbursements. For the remaining nine countries, UNITAID Bridge Funding will likely be required through end-2010 and possibly into 2011 as alternative funding sources are identified and secured. CHAI has recently finalized a report with country details on the transition and a copy was submitted to the Secretariat for its continued follow up. **Suppliers and Drug Formulations** The 2009 supplier selection process yielded price reductions for primary suppliers across all seven second-line ARV products in 2009. The 2009 supplier selection process saw the entry of four newly eligible suppliers of second-line ARV formulations, including one formulation that had previously been sole-sourced. Since the 2008 tender, there have been ten new stringent regulatory agency (SRA) approvals covering all seven formulations in the Project. Six out of seven products now have two or more SRA-approved suppliers.
XV.	Issues and/or Lessons Learnt	**Transition to Alternative Funding Sources (February 2010 CHAI Project Update)** The current economic environment is a significant factor contributing to the uncertainty regarding transition for thirteen beneficiary countries as many country budgets for health programs are flat-lining or decreasing. Another factor is 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; several of these beneficiary countries are facing delays with Global Fund Round 8 grants or uncertainty regarding the commitments of in-country partners. Other factors – including rapid scale-up, earlier initiation of treatment, and increased need for more costly second-line treatment – have also added increased pressure to country budgets. The Coordinated Procurement Planning (CPP) for HIV/AIDS, represented by key donors (UNITAID, GFATM, PEPFAR, World Bank) and WHO, with support of Supply Chain Management System (SCMS) has provided a framework to improve and strengthen country-level coordination for the planning and procurement of HIV/AIDS related commodities. The CPP has monitored the transition, in close coordination from CHAI, to assure that countries and donors are capable to integrate UNITAID-related achievements into national systems or alternative funding sources. **The following report was provided to EB 11 in December 2009** • CHAI has identified two issues related to the supply of atazanavir (ATV) and ritonavir (RTV): a) Ministries of Health are reluctant to incorporate ATV/r in into their guidelines until the product becomes available through UNITAID support; and b) CHAI expects that countries transitioning to PEPFAR or the Global Fund support after the end of the Project will be hesitant to incorporate ATV/r into their protocols until it receives WHO or FDA approval. Currently, when an antiretroviral is available through a single pre-qualified source, or there are no pre-qualified sources, it becomes eligible for procurement under the condition that a complete dossier of such a product is submitted by the supplier for pre-qualification by WHO or a stringent regulatory agency. As a result, CHAI anticipates a delay in the uptake of ATV/r, and initial orders may be low, thereby limiting its ability to negotiate volume-based price reductions. • Transition of tenofovir formulations supplied to Uganda and Zambia to other sources of funding in 2010 is currently not assured. CHAI will work closely with each country to help in their attempts to secure transition funding commitments

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		from longer-term funding sources. Closer collaboration between CHAI and alternative funding sources, with UNITAID support, is required • CHAI has reported that since the beginning of the Project, it has experienced difficulty in obtaining accurate forecasts from beneficiary countries, due in 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 (ARV) treatment centers that prescribe the ARVs and the central medical stores that place order requisitions with CHAI, making it difficult to calculate consumption and create accurate forecasts at the central level. A third difficulty in forecasting that is specific to second line is the uncertainty surrounding the actual rates of second-line migration. This uncertainty is driven by the fact that second-line programs are still relatively new, that historical migration rate data is generally not available, and that many countries are experiencing difficulty diagnosing treatment failure in the absence of viral load diagnostic capabilities. Though CHAI has a limited ability to improve upon data tracking capabilities, it supports quantification exercises every quarter before each round of pooled orders is placed, with Ministries of Health and local stakeholders, and in particular with SCMS in PEPFAR countries. Efforts have also been made by CHAI to improve forecast at the central level, and include a high-level check of all order quantities, collaboration with SCMS to harmonize forecasting activities in countries and supply chain training to teach supply chain best practices to country teams. • Some beneficiary countries have recently been experiencing shortages of first-line ARVs (e.g. Zimbabwe, Uganda and Togo). In these situations, there is a risk that patients may be treated with second-line or pediatric ARVs when stocks of first-line ARVs have been depleted. The provision of second-line ARVs, when first-line ARVs are insufficiently available, poses significant public health challenges, as unnecessary use of second-line ARVs may exacerbate resistance and will considerably increase long-term costs. In addition, patients that are eligible for second-line treatment may face restricted access if the products which have been procured for them are being consumed by other patient populations.

PROJECT TITLE: PMTCT INITIATIVE (I COMPONENT)

Key Partner(s):	**UNICEF and WHO**
Project Start Date:	**10 December 2007**
Project Duration:	**10 December 2007 - June 2010**
Updates for the Period Ending:	**31 December 2009**[1]

Section of the Board Update		**Updates**
XI.	Financial and Procurement	Total disbursements to date: **US$ 20,838,432** (100% of total approved budget as per MoA). The total approved budget as per MoA for this project amounts to US$ 20,838,432. This amount is within the ceiling the Board committed to: US$ 20,839,506. The main objective of this Project is to accelerate the Prevention of Mother-to-Child Transmission (PMTCT) and to scale up linkages to paediatric HIV care and treatment
XII	Reporting Schedule	On December 10th 2007 UNITAID, UNICEF and WHO finalized and signed the Memorandum of Agreement (MoA) for the UNITAID Initiative for 2007- 2009 for eight participating countries: Burkina Faso, Cameroon, Cote d'Ivoire, India, Malawi, Rwanda, Tanzania, Zambia; hereinafter referred to as the "UNITAID PMTCT Initiative" (PMTCT I). The 2nd Annual Report and progress update (for the period 1 January 2009 to 31 December 2009) was received by the Secretariat 15 February 2010 in a timely manner. It is currently being assessed by the Secretariat. It is not linked to any disbursement request and marks the end of the Project Component. The final report on closure of the PMTCT project is scheduled approximately end June 2010. Year 1 of the PMTCT I project ended on 31 December 2008, and Year 2 of the project ended on 31 December 2009. The 2nd Annual Report highlights implementation progress made in the eight countries according to provisions in the Project Plan as per the MoA.
XIII.	Project Progress	Some key achievements during this reporting period are: 1. *Treatments* The UNITAID funds that were committed for Year 2 of project implementation provided HIV-related drug and diagnostic commodities for the eight countries, which contributed to: • 1,486,539 HIV rapid tests for pregnant women (149% of the original targets for the 2nd year) • 158,865 more efficacious ARV treatments for PMTCT pregnant women living with HIV (136% of original target) • 25,305 HAART treatment for eligible pregnant women(148% of the original target) • 319,650 CD4 tests for pregnant women living with HIV(291 of the target) • 50,973 CTX preventive treatments for pregnant women (72% of the original target) • 35,075 CTX preventive treatments for HIV-exposed infants up to 6 months of age (75% of original target) and 35,244 CTX treatments for children born to mothers living with HIV up to the age of 2 years (68% of target). • 29,568 PCR tests for HIV-exposed infants (comprising 40% of the original target for the 2nd year). Overall, in all eight countries, there has been significant demonstrated significant progress in

[1] The progress presented herein corresponds to progress made for the reporting period, i.e. 1 January 2009-31 December, 2009 an is not cumulative since the beginning of the Project Component in 2007

		both service and population-based coverage of PMTCT services since 2007. 2. UNITAID -funded commodities were key in shifting PMTCT programmes from single-dose to more efficacious ARV regimens in Rwanda and UNITAID funding support has accelerated the transition from single-dose to combination regimens in Malawi. 3. In Burkina Faso, Cameroon, Malawi, Rwanda and Tanzania (the countries for which data on total needs of the programme was available) it was estimated that procurement funded by UNITAID represented 24% of the national needs for AZT; 100% of the country needs for CD4 reagents to assess treatment eligibility; 98% needs for HAART commodities for eligible pregnant women; and 24% of needs for PCR reagents for Early Infant Diagnosis (EID) in 2008. Estimates as to UNITAID's contribution to the national needs for 2009 will be available upon finalization of the 2009 country-level data. 4. During 2009, 90 Purchase Orders have been issued by UNICEF for a total of 355 individual item lines. 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. 5. *Availability & Quality* The number of sources of ARVs suitable for paediatric use prequalified by WHO or US FDA-approved increased from 41 in 2008 to 53 in 2009. ▪ Zidovudine 300mg tablets and lamivudine 150mg tablets for intrapartum period identified. ▪ PMTCT presentations of Nevirapine syrup in 10ml and 20 ml bottles and Cotrimoxzole in 120mg dispersible tablets in blister packs were also made available. 6. *Cost savings & price reduction* Pricing for most of the PMTCT commodities have maintained the downwards trend into 2009 as initially observed in the 2nd Interim Report, with cost savings of between 10% and 41% observed for 9 products over 2009. ▪ The progress towards price reduction is especially significant for bundles containing reagents and consumables for CD4, PCR and DBS collection where volume discounts have yielded continued savings from Year 1 into Year 2. ▪ Similarly, the average price paid per Rapid Diagnostic Test has continued to yield savings in Year 2 (approximately 14% lower than its baseline). ▪ The trend for ARVs however experienced fluctuations in 2009, with notable reductions (ranging from 1 to 21%) in select fixed dose combinations required for maternal interventions. It is important to highlight the price trend in Nevirapine 200mg, Zidovudine 300mg and Zidovudine 300mg +Lamivudine 150mg tablets considering that the bulk of these products have been supplied in blister packs, which are more costly to manufacture, but easier to use by patients. 7. *Delivery* 91% of orders arrived in country either on time or prior to the estimated arrival date. 80% of the items included in Year 2 purchase orders that have been shipped were delivered with lead times less than the 8-10 week target.
XV.	Issues and/or Lessons Learnt	The reduced quantities of PCR testing reagents and Co-trimoxazole (CTX) supplies were a result of improved coordination and planning at country level amongst in-country partners. The Clinton HIV/AIDS Initiative has been an important partner and has been supporting the procurement of Paediatric ARVs, some CTX and PCR commodities. Similarly PEPFAR is also supporting procurement of maternal CTX. Thus UNICEF, to avoid overlap with partners in country, has been adjusting its annual procurement plans based on actual needs and has supported the establishment of and/or operationalisation of national coordination mechanisms on PMTCT.

		The Secretariat shall follow up on evaluation of costs and shipping times for AIR and SEA delivery to be conducted during the first half of 2010 by UNICEF to determine opportunities for alternative delivery mechanisms. With regards UNICEF's ongoing efforts to stimulate the market of syrups and solutions for ARV treatment in children, the number of suppliers of Paediatric formulations (i.e., Zidovudine syrup), volatility around the active pharmaceutical ingredient and market size remains insufficient to create economies of scale and competition to enable lower prices. Regarding the Mother Baby Pack (MBP) in November 2009, the external packaging was field tested in Malawi, Rwanda and Zambia to assess the suitability and acceptability of the design and packaging of the Pack amongst the varied levels of end users (i.e., national PMTCT working groups, pregnant women and local health workers). Feedback from this initial field testing phase have been used to refine the pack's external packaging; and further content of the MBP revisited following WHO's "Rapid Advice: on the use of antiretroviral drugs for treating pregnant women and preventing HIV Infection in infants. India: In 2009, UNICEF, NACO and WHO developed a plan for implementation in centres covering 20% of the positive pregnant women receiving ARV prophylaxis. Based on the lessons learned the regimens will be scaled up to other parts of the country. Furthermore, based on the evaluation of Roche DNA PCR test kits by the National AIDS Research Institute, NACO decided to use the Roche kits for testing exposed children in the country in a research mode and also to initiate the process of getting an approval from the Drug Controller General of India (DCGI) for diagnostic use. An extension request for this PMTCT I Project Component was submitted to EB11, but no Board decision was made pending decision as to prioritization and available resources with the Board. Bearing in mind also the PRC recommendations (1-2 days workshop to clarify on lessons leant), it should be noted that the transition funding request would be for a maximum duration of one year during which UNICEF and WHO would have to develop their plan for transitioning to other funding sources. Hence a re-submission of the proposal was developed by UNICEF amounts of US$ 28,799,353 and sent on 11 May 2010 for extension of the PMTCT I project amended as per advice from the Board to cover one year of support and to include transition plans for the countries in the project. Moreover, consultations are also ongoing to establish the transition plans for the other countries supported by the PMTCT II Project, and it is expected that the update in the plans for all countries will be included in the periodic reports to UNITAID. UNICEF also incorporated updated information related to market impact. The Secretariat anticipates that this extension would be harmonized with the PMTCT II and Nutrition projects under the existing M&E framework. The timelines for reporting and disbursement would also be aligned.

PROJECT TITLE: PMTCT NUTRITION

Key Partner(s):	**UNICEF and WHO**
Project Start Date:	**31 July 2009**
Project Duration:	**31 July 2009 - September 2011**
Updates for the Period Ending:	**31 December 2009**

Section of the Board Update		**Updates**
XI.	Financial and Procurement	Total disbursement to date total **US$ 2,291,284**. The total approved budget as per MoU for this project amounts to US$ 4,510,847. The ceiling budget as per Board Resolution amounts to US$ 4,764,228. As per disbursement schedule of the MoU, the second payment of US$ 2,219,563 to cover Year 2 is foreseen after approval of the satisfactory 1st Programmatic Report. The overall project objective is to: To accelerate nutritional care for pregnant and lactating women and children linked to PMTCT: to address nutritional problems that impact negatively on PMTCT outcomes
XII	Reporting Schedule	On 31 July 2009, UNITAID signed the MOU for the Nutrition Initiative for the "Acceleration of Prevention of Mother-to-Child Transmission (PMTCT) and Scale up of Linkages to Paediatric HIV Care and Treatment for 2009- 2011" for the four participating countries (Malawi, Rwanda, Tanzania, Zambia); referred to as the "UNITAID Nutrition Initiative". The 1st Annual Programmatic Report (for the period 31 July 2009 to 31 December 2009) was received by the Secretariat in a timely manner on 15 February 2010.
XIII.	Project Progress	In the first five months of the Nutrition Initiative, two of the four countries (Malawi and Tanzania) have finalized their country forecasts and submitted their initial requests for RUTF and diagnostic (HmoCue) commodities. The first shipments of these requested commodities are due to arrive in the second half of Year 1. The financial report shows actual expenditure of only USD33, 708. This is due to that fact that not all expenditures for Year 1 have been incurred by 31 December 2009 and only when all invoices have been received, will UNICEF be in a position to report. From country-allocation estimates related to product expenditure, USD1, 659,313 has been provided to countries. Some countries have received funding for PMTCT commodities from non-UNITAID sources and therefore the resulting requests for use of UNITAID funding have shifted. The updated forecasts will be presented in the 1st interim report due in August 2010. It is noted that during the reporting period, no purchase orders were placed nor deliveries made. Some key achievements during this reporting period are: 1. Two new RUTF products were approved by UNICEF. One manufactured by Tabatchnick (USA), the other by Insta (Kenya). LTAs were issued with these two suppliers. 2. One new African RUTF manufacture (DRC) was approved for local procurement.
XV.	Issues and/or Lessons Learnt	As per Letter of Amendment, UNICEF had also committed to providing UNITAID with an update as to efforts to reduce delivery costs by January. UNICEF provides technical assistance to the two RUTF companies in Malawi to comply

		with the international standards by taking the samples for certification. In Rwanda, UNICEF supported the MoH in the identification of potential local manufacturers of RUTF (CSB) for the 2009 emergency plan to eliminate malnutrition. However, it is worth noting that neither of these manufacturers is approved by UNICEF or WHO. In Tanzania, Industrial Revelation, together with Nutriset is supporting development of the local food industry capacity (Power Foods) to manufacture RUTF. Continuous efforts have been made to identify alternative sources of affordable and quality anaemia diagnostic devices. At present, it has been found that HemoCue is the product that best addresses the needs of programmes in developing countries.

PROJECT TITLE: PMTCT EXPANSION (II COMPONENT)

Key Partner(s):	**UNICEF and WHO**
Project Start Date:	**31 July 2009**
Project Duration:	**31 July 2009 - September 2011**
Updates For the Period Ending:	**31 December 2009**

Section of the Board Update		Updates
XI.	Financial and Procurement	Total disbursements to date **US$ 18,223,990**. The total approved budget as per MoU for this project amounts to US 46,679,993. The ceiling budget as per Board Resolution amounts to US$ 50,009,221. As per disbursement schedule of the MoU, the 2nd payment of US$ 28,446,003 to cover Year 2 is has been requested after approval of the 1st Programmatic Report. The overall objective of this Project is to contribute to the acceleration of the global scale up of PMTCT programmes by influencing market prices for HIV commodities towards lower prices and by improving availability, affordability, forecasting, procurement and supply chain management of drug and diagnostic commodities.
XII	Reporting Schedule	On 31 July 2009 UNITAID, UNICEF and WHO signed the legal agreement for the Expansion Initiative for the Acceleration of Prevention of Mother-to-Child Transmission (PMTCT) and Scale up of Linkages to Paediatric HIV Care and Treatment for 2009-2011 for the nine participating countries (Central African Republic, China, Haiti, Lesotho, Myanmar, Nigeria, Swaziland, Uganda, Zimbabwe). The 1st Annual Programmatic Report (for the period 31 July 2009 to 31 December 2009) was received by the Secretariat 15 February 2010 and considered satisfactory.
XIII.	Project Progress	Some key achievements during this reporting period are: 1. *Treatments* The treatment commodities procured for the nine countries so far during Year 1 of the Initiative are: • 1,845,971 HIV rapid tests for pregnant women (47% of the target for the 1st year) • 82,860 more efficacious ARV treatments for PMTCT pregnant women living with HIV (60% of Year 1 target) • 21,213 HAART treatments for eligible pregnant women (114% of the Year 1 target) • 56,400 CD4 tests for pregnant women living with HIV (61% of the target) • 63,340 CTX preventive treatments for HIV positive mothers (280% of the target) • 16,690 CTX preventive treatments for HIV-exposed infants up to the age of 2 years (74% of target). • Finally 13,608 PCR tests for HIV-exposed infants, comprising 12% of the original target for the 1st year. All countries, except Zimbabwe have implemented more efficacious regimens for PMTCT. However, more support is needed to transition PMTCT programmes from single dose-NVP to more efficacious regimens in China, Myanmar, Nigeria, Uganda and Zimbabwe. 2. Following the signature of the MoA, UNICEF Country Offices, Supply Division and Programme Division have intensified dialogue with national governments and in-country partners (such as PEPFAR and CHAI) to finalize country-specific commodity forecasts so as to initiate the procurement of the PMTCT programme commodities.

		3. In the first five months of the PMTCT II Initiative, seven of the countries have finalized their country forecasts and submitted their initial requests for HIV-related medicines and diagnostic commodities including China, Haiti, Lesotho, Myanmar, Swaziland, Uganda and Zimbabwe. The first shipments of commodities within the present reporting period have occurred in Swaziland, Uganda and Zimbabwe. 4. *Delivery lead-times* Since the commencement of the PMTCT II until 31st December 2009, 22 Purchase Orders have been issued by UNICEF for a total of 115 individual item lines. During the reporting period, 92% of the orders arrived in country either on-time or prior to the estimated arrival date. The lead time ranged from 8 to 10 weeks. 5. *Price containment and reduction* Price reductions observed for the ARV formulations have exceeded the 5% target as established in the Project Plan to between 8% and 25% Similarly, the average price of the HIV rapid diagnostic test kits has not only been contained – as targeted - but also further reduced. Such savings are attributed to the Determine HIV test kit the RDT with the highest volumes procured under the two PMTCT Initiatives. 6. *Availability of better adapted and more user-friendly products* The total number of Paediatric ARV products WHO prequalified and/or US FDA- approved source has increased from 41 in 2008 to 53 by the end of 2009.
XV.	Issues and/or Lessons Learnt	As per Letter of Amendment, UNICEF had also committed to providing UNITAID with an update as to efforts to reduce delivery costs and shipping times for AIR and SEA delivery to determine opportunities for alternative delivery mechanisms. Reminders were given to UNICEF that this would be expected in February, but it has yet to be received. As of 31st December 2009, UNICEF maintains long term arrangements (LTAs) with a total of 16 ARV suppliers, covering a total of 66 finished products (including both generic and originator products). UNITAID shall follow up that UNICEF continuing its efforts to identify suitable commodities for use in PMTCT programmes. Tenders for suitable blister pack presentations and customized presentations of all medicines are required for PMTCT interventions and resulted in the identification of Zidovudine 300mg tablets and Lamivudine 150mg tablets for the intrapartum period that would improve the current portfolio of PMTCT ARV products. In addition, the availability of two commodities suitable for PMTCT presentations was also identified: Nevirapine syrup in 10ml and 20ml bottles and Co-trimoxazole 120mg dispersible tablets in blister packs. A second phase of field testing with the complete Mother Baby Pack (MBP, content and packaging) is expected to commence in Q1 2010. This second phase will solicit evidence about the effectiveness of the MBP in increasing PMTCT coverage in selected districts and in reducing stock-outs of medicines in local health facilities. The Secretariat shall follow up on UNICEF conducting in the first half of 2010 an evaluation of costs and shipping times for AIR and SEA delivery to determine opportunities for alternative delivery mechanisms.

PROJECT TITLE: ESTHER PROJECT

Key Partner(s):	**Ensemble pour une Solidarite Therapeutique Hospitaliere en Reseau (ESTHERAID)**
Project Start Date:	**2 July 2009**
Project Duration:	**3 years**
Updates for the Period Ending:	**31 March 2010**

Section of the Board Update		**Updates**
XI.	Financial and Procurement	Total disbursement to date: **US$ 451,625.88** against Phase 1 The total approved budget ceiling for this Project US$15,950,000 Subsequent to the Board approval of funding commitment, it was agreed that the project would be implemented in 2 phases: a) Phase 1: Preliminary Evaluation and Planning; and b) Phase 2: Operation and Implementation. Below is the agreed budget allocation for these two phases: **Phase 1**: Euro 321,106 (estimated to be equivalent to US$ 451,625.88) disbursed in 15 July 2009 **Phase 2:** US$ 15,498,374.12 (estimated on the basis of total US$ commitment minus Phase 1 US$ budget) Phase 2 budget and disbursement schedule will be negotiated on the basis of the expected outputs of Phase 1, which includes a proposed Phase 2 workplan that presents the individual country plans and corresponding country budgets. The objective of the project is to ease and safeguard the availability of ARV treatment and its good management for people living with HIV/AIDS.
XII	Reporting Schedule	Project reporting schedule to be defined in the draft MoU. The first report was expected at the end of Phase 1 which was due on the 2nd March 2010. A preliminary report on Benin was submitted in 22 December 2009, and report on the other 4 countries is pending. The final country proposals are expected to be submitted to UNITAID by the end of May 2010.
XIII.	Project Progress	• In January 2010 the first country assessment report (Benin) was completed and submitted to the Secretariat. The estimated budget amount for Benin is E$ 1.4 million • Two in-person follow up meetings in Geneva and Paris, and one teleconference were held with UNITAID and ESTHER to develop the draft MoU - A draft MoU and 3-year budget have been reviewed and adjustments are being made by ESTHER - A project plan for the Benin component, including targets, indicators, baselines and milestones, is being prepared and is anticipated to be submitted in April 2010. - It has been agreed that disbursement against this Project activity will be made on a phased approach, upon conclusion of individual project plans and budget to be Annexed to the MoU. The Benin component is expected to be the first one to be signed and receive a disbursement. • Update on the Progress made on other Phase 1 countries:

Section of the Board Update		Updates
		1. Burkina Faso: Estheraid assessment conducted in February 2010 2. Central African Republic: Estheraid assessment conducted in February 2010 3. Mali: Estheraid assessment conducted in November 2009. A 2-day workshop is scheduled for early April to finalize the proposal 4. Cameroun: Estheraid assessment planned for 5-16 April 2010
XV.	Issues and/or Lessons Learnt	• Meeting timelines for the initiation of project in countries involves reaching an agreement with the national authorities, which could result in delays in project start-up

OVERVIEW OF UNITAID TB PORTFOLIO

Reported to the EB 12 Meeting, June 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 to date 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
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 2011	26,129,987	26,129,900	19,582,000
MDR TB Scale-Up Initiative	July 2007- December 2011	37,662,000	37,661,066	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 PENDING MoU		
MDR-TB Acceleration of Access Initiative: Strategic Revolving Fund	Pending estimated start date - Q3 2010 - End of 2013	22,232,201[1]		
MDR TB Scale-Up Initiative (inclusion of India)	2009-2012	16,384,000[3]		
UNITAID Project Support for Narrowing the Gap: Expanding and accelerating access to diagnostics for patients at risk of multi-drug resistant tuberculosis (Expand-TB)	December 2008 - December 2013	61,482,085[4]		
Total		213, 793,049[5]	113,377,899	87,197,631

EB approved commitments

[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 currently being finalized into formal Legal Agreement.

[3] Project development put on hold due to lack of funding available to formalize project agreements between September 2009- mid January 2010

[4] See above footnote

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

At present, the UNITAID Executive Board (EB) has approved a total ceiling budget of US$ 213,792,962 for 8[2] projects under the Tuberculosis portfolio. Three Legal Agreements are pending with a total monetary value of US$100,098,286

MOUs

Five Legal Agreements have been signed, for a total budget of US$ 113,377,899. The Projects approved (US$77,866,085) at the May 2009 Executive Board are currently under development. The target for signature by all Parties is by the June 2010.

Completed project

N/A

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 became with UNITAID support a unique source for the provision of quality-assured pediatric products in line with both WHO's childhood TB treatment recommendations for formulations, dosages and presentations of these drugs, and WHO's quality assurance requirements. Price reductions have been achieved within a range of 10-30% for four key Paediatric products in 2009 and a second manufacturer has been secured to supply RHZ 60/30/150mg pending the implementation of the new WHO Paediatric treatment guidelines.

A request for budget extension recommended by the UNITAID IEAG was submitted for consideration by the EB11. This funding proposal was noted by the EB11 but not accepted due to lack of available funding. It is anticipated that this funding proposal will be resubmitted for consideration at the EB12[6].

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.

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.

[2] See footnote 1
[6] Total funding request US$33,456,483. Component 1: US$2,207,486: to increase the funding (due to the new treatment dosage) to facilitate the completion of the current UNITAID Project Support until December 2011. Component 2 (US$31,248,997): for the expansion of current agreement to facilitate 2nd round of 3 year grant for 58 countries.
[7] 18 of the 19 countries to date
[8] Until December 2011

Diagnostics:

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 74,000 MDR-TB patients or 15% of the world's total will be covered with diagnostic services and treated through the MDR-TB Acceleration of Access Initiative - Strategic Rotating Stockpile.

Medicines:
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 2009 no MDR-TB countries experienced stock-outs. Delivery lead times through the use of the SRS continue to be reduced from 60 to 39 days in 2009.

Outlook

Project implementation is slightly delayed across the TB niche although achievements have been demonstrated. The financing to the TB niche has increased twofold in the last 18 months. The challenge is to finalize the project plans and legal agreements for the three remaining grants by the Quarter 2 of 2010 in light of the availability of funding.

PROJECT TITLE: PROJECT SUPPORT FOR PEDIATRIC TB PROJECT

Key Partner(s):	**The Stop TB Partnership's Global Drug Facility**
Project Start Date:	**15 January 2007**
Project Duration:	**15 January 2007 - 31 December 2011**
Updates for the Period Ending:	**January-December 2009**

Section of the Board Update		**Updates**
XI.	Financial and Procurement	Total disbursements to-date: **US$ 9,624,301**[9]. The total approved budget ceiling for this Project US$11,603,952. In December 2009 (EB11) the Stop TB Partnership's Global Drug Facility 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. The two main Project objectives: A. To provide appropriate-strength Paediatric drugs for approximately 750,176 children under the age of 15 by the end of 2011 B. To ensure the development of new child-friendly formulations for infants under 4, in at least 58 countries by the end of 2011.
XII	Reporting Schedule	The 3rd Annual Programmatic and Financial Report (for the period 1 January to 31 December 2009) was due the 15th March 2010, was submitted and deemed satisfactory.
XIII.	Project Progress	Progress towards meeting the overall objective of supplying a cumulative total of 750,176 paediatric patient treatments by 2011 is on track. Some Key achievements during this reporting period are: 1. By the end of December 2009 a cumulative total of 668,109[10] quality assured paediatric anti-TB medicines were delivered in 56 countries. 2. The cumulative number of countries approved for funding by the GDF TRC as of 31 December 2009 was 58, achieving the Project target of 58 countries approved for receiving UNITAID funded paediatric anti-TB medicines. 3. Price reduction for four (4) key paediatric products has been achieved through negotiations between 10-30% 4. Average manufacturing lead times have been further reduced from 105 days (in 2008) to 87days per order in 2009. 5. A total of 3 Paediatric TB drugs have been pre- qualified by the WHO PQ Programme of which 2 (Rifampicin + Isoniazid mg (60/30) and Rifampicin + Isoniazid + Pyrazinamide mg

[9] 85% of total Project budget disbursed to date
[10] Curative 285,634 and Preventive 382'475

		(60/30/150) both in bulk packaging) were pre-qualified in the first quarter of 2009. 6. A second manufacturer has been secured for RHZ 60/30/150mg and RH 60/30mg blister packaging - currently being used by the GDF pending the implementation of new paediatric treatment guidelines is possible. 8. At least two manufacturers for five (out of the seven) quality assured paediatric formulations is available. In comparison to 2008 when only one manufacturer was available.
XV.	Issues and/or Lessons Learnt	<u>Planned Changes in the Programme:</u> The 2nd Annual Programmatic and Financial Report anticipates the following changes that could impact on the UNITAID Project Support: • The new dosage guidelines for paediatric TB drugs were published by WHO in Q4 2009. This has had an impact on the current strategy for supplying paediatric drugs in beneficiary programmes. The GDF has undertaken preparatory steps to face this upcoming challenge/opportunity in close collaboration with WHO Prequalification Programme and the WHO Stop TB Department. • At the end of Q4 2009 the UNITAID Secretariat requested the GDF to provide a status of the financial implications of the WHO recommended dosage on the current Project. In February 2010 the GDF submitted a Memorandum (Shortfall for the 2006-2011 UNITAID/GDF Paediatric TB Project) informing the Secretariat that for the remainder of the initial Project implementation the anticipated shortfall in funding amounted to US$3,557,798. • To facilitate the continuation of activities and treatments the GDF requested the release of the Cost Fluctuation Buffer to cover drug cost for the continuation of treatment in addition to the scheduled April 2010 disbursement (US$313,796). This request has been approved by the Secretariat and funding has been released in line with the current Board approved and Legal Agreement budget ceiling, based on the justification and rationale received by the Partners • The funding request recommended by the IEAG for funding at the EB11 will be resubmitted for Board consideration at the upcoming EB12. <u>Issues and/or Lessons Learnt:</u> (i) GDF has reported for the first time (March 2009) the number of TB child contacts and related prophylaxis treatments delivered for the beneficiaries. Therefore previous patient treatments numbers provided were capturing solely the number of curative treatments delivered. Reporting on both preventive and curative treatments was rectified retroactively in Progress updates during 2009. (ii) There is a need for the development of a transition strategy both for Component 1 (current Project cycle ending in 2011) and Component 2 (expansion until 2014), if approved by the EB12.

PROJECT TITLE: PROJECT SUPPORT FOR FIRST-LINE ANTI-TB DRUGS INITIATIVE

Key Partner(s):	**The Stop TB Partnership's Global Drug Facility**
Project Start Date:	**7 September 2007**
Project Duration:	**7 September 2007 - end April 2009**
Updates for the Period Ending:	**January -December 2009**

Section of the Board Update		**Updates**
XI	Financial and Procurement	The 2nd and final disbursement, amounting to US$ 4,382,700 was made on the 4th of February 2008. This brings the total disbursements to-date to **US$ 26,840,725**, which is 100% of total budget. A no cost extension (to 31st December 2011) 1st Amendment to the Letter of Agreement was signed by all parties in December 2009. The key objectives for the no cost extension of this Project is as follows: i) To facilitate the delivery of consignments under the Transitional Grants for two of the 19 countries and; ii) 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 (SRS).
XII	Reporting Schedule	The Annual Programmatic and Financial Report (for the period 01 January 2009 to 31 December 2009) was submitted and deemed satisfactory.
XIII.	Project Progress	The project implementation is on track. Some Key achievements during this reporting period are: 1. The total number of patient treatments delivered as of December 2009 is 785,080 out of the adjusted total cumulative target to be achieved by December 2009 of 786,843[11]. i) All 19 countries first-line TB drugs had been ordered on time to avoid stock-outs and ensure sufficient in-country stocks until anti-TB drugs paid for from new funding sources (predominantly Global Fund grants) are received between 2008 and 2009. ii) By the end of December 2009 18 of the 19 countries had successfully transitioned from UNITAID funded first-line TB drugs to other donor support: ▪ 11 countries transitioned from UNITAID support to the Global Fund ▪ 3 countries have transitioned to their own governmental budget support ▪ 1 country has transitioned with World Bank funding using GDF direct procurement Three countries were not able to secure alternative donor funding and have requested another grant support from the GDF. At the end of December 2009 one country[12] has not effectively transitioned from UNITAID support. 2. As of December 2009, 4 top priority first-line TB drugs (4FDC (RHZE), 3FDC (RHE) and

[11] Adjusted overall treatment target due to changes in total patient treatments supplied in Bangladesh
[12] Cote d'Ivoire

		2FDC R150/H75) and Pyrazinamide 400mg tablets were pre-qualified which brings the total number of pre-qualified drugs to nine, out of the 16 priority first-line products identified for pre-qualification. 3. The continuation of the SRS has demonstrated clear benefits for the recipient countries: • During 2009 no country experienced stock-outs in at least two key FDCs[13] products • Average lead time for all orders using the stockpile in 2009 was 41.5 days - no baseline data was reported previously. • The Lead time for orders using stockpile for urgent or emergency order during 2009 was 29.4 days from a reported 63 days in 2008. • Suppliers fulfilling their contractual obligations. • Delays due to comprehensive procurement process minimized. • Suppliers' finite production capacity for urgent orders. • Out of specification findings do not lead to delays - The SRS has ensured that this has not led to delays in order processing. 4. The project continues to successfully achieve the short-term objective of cost containment of under US$20 per treatment. The average treatment cost for a 6 month course of treatment is US$18.65[14] and US$34.95[15] 5. By the end of December 2009 the GDF had provided manufactures with quarterly forecasts for both Grant and Direct Procurement orders. The forecasts have contributed to improved resource planning by manufacturers and better response to need.
XV.	Issues and/or Lessons Learnt	(i) Changes to the management and functioning of the SRS occurred in Q4 2009 based on efforts to streamline procedures to increase effectiveness and efficiency by improving delivery lead times and adapt to changes in the TB drug market environment. Notwithstanding the demonstrated benefits of the SRS, there are some challenges in its implementation: • Suboptimal shelf-life of drugs - some drugs only have a 24 month shelf life which translates to meaning that after 6 months they have already reached the minimum shelf-life requirement for shipment to countries. • Urgent orders for high burden countries tend to be large and can rapidly deplete existing stocks (ii) In order to continue the containment of first-line drug prices, UNITAID will continue to explore options, in line with the UNITAID Strategy[16] and UNITAID TB Strategic Orientation[17,] for new actions to help stabilize the market for key first-line APIs, improving the quality of API suppliers and reducing API prices. (iii) An analysis of the impact of UNITAID's investment, used as a 'Bridge financing mechanism, for the 19 transitional grants will be done in conjunction with the development of a UNITAID policy on Transition.

[13] RHZE and RH 150/75
[14] Cat I & III - 2(RHZE)/4(RH)
[15] Cat. II- 2S (RHZE)/1(RHZE)/5(RHE)
[16] EB11 Board approved
[17] EB7 Resolution number 1

PROJECT TITLE: UNITAID PROJECT SUPPORT FOR NARROWING THE GAP: EXPANDING AND ACCELERATING ACCESS TO DIAGNOSTICS FOR PATIENTS AT RISK OF MULTI-DRUG RESISTANT TUBERCULOSIS (MDR-TB)

Key Partner(s):	**WHO's Global Laboratory Initiative, Foundation for Innovative New Diagnostics, The Stop TB Partnership's Global Drug Facility**
Project Start Date:	**16 January 2009**
Project Duration:	**16 January 2009 - 31 December 2011**
Updates for the Period Ending:	**January-December 2009**

Section of the Board Update		**Updates**
XI.	Financial and Procurement	Total disbursements to-date total **US$19,582,000**[18]. The total approved budget ceiling for this Project US$87,561,985 In May 2009 (EB10) the Board approved an additional US$61,482,085 for this Project. The US$61,482,085 was principally premised upon: funding within an extended timeframe to expand the Project with 11 countries (i.e. 27 countries in total) aimed at identifying an estimated 56,000 additional 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 Due to funding availability the drafting of a revised Project Plan was 'put on hold' by UNITAID until funding was made available in January 2010. The 1st Amendment to this Memorandum of Understanding will be signed by all Parties in May 2010. The two main Project objectives: A. To expand and accelerate access to modern TB diagnostic technologies; B. 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 C. 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
XII	Reporting Schedule	The 1st Annual Programmatic and Financial Report (for the period 1 January to 31 December 2009) was received by UNITAID, 15th March 2010 and was considered satisfactory.
XIII.	Project Progress	Some Key achievements during this reporting period are: 1. By the end of December 2009 activities were initiated in varying stages in a total of 12 countries instead of the initially planned 6 for 2009. 2. Diagnostic equipment and services are fully functional in the initial reference laboratories established in Ethiopia, Cote d'Ivoire, Uzbekistan and Lesotho. 3. Price reductions of 80% for reagents have been achieved in Q3 2009

[18] 75% of total current Project budget (US$26,129,900) disbursed to date

		4. 2 new additional suppliers have been identified for rapid speciation and one new supplier has been identified for Line Probe Assay 5. Drug Resistance Survey is ongoing, initiated by NRL/CDC in the countries where Diagnostics services have begun. This has resulted in initial reporting of MDR-TB cases in Ethiopia and Lesotho 6. Yearly negotiations with existing manufacturers occurred in Q4 2009 and price negotiations and long term agreements are in discussions with 2 suppliers. 7. A framework for a prequalification process for TB diagnostics has been initiated in 2009
XV.	Issues and/or Lessons Learnt	i) Access to second-line TB drugs: With the anticipated increase in the number of MDR-TB patients diagnosed through this Project, it will be essential to ensure that the required amount of second-line drugs, along with correct logistic conditions will be available for newly diagnosed patients. In this regard UNITAID might be requested to provide further funding support to ensure that this will happen[19]. In addition close collaboration of the GLI, FIND and GLC initiative will occur to mitigate the risk of Diagnostics outpacing MDR-TB control efforts. ii) Country delays in infrastructure upgrade, policy implementation: To mitigate this risk a MoU between the Ministries of Health and FIND will be signed to ensure the securing of country ownership, intensive long-term technical support with in-country consultant oversight, integrated laboratory approach.

[19] Through UNITAID innovative investment in the Strategic Rotating Stockpile or Strategic Revolving Fund mechanisms within the TB niche.

PROJECT TITLE: i) MDR-TB Scale-Up Initiative
ii) MDR-TB Acceleration of Access Initiative - Strategic Rotating Stockpile (SRS)[20]

i)

Key Partner(s):	**The Stop TB Partnership's Global Drug Facility, The Green Light Committee, and the Global Fund to Fight AIDS, Tuberculosis and Malaria**
Project Start Date:	**25 July 2007**
Project Duration:	**25 July 2007 - end July 2011**
Updates for the Period Ending:	**January - December 2009**

ii)

Key Partner(s):	**The Stop TB Partnership's Global Drug Facility**
Project Start Date:	**18 November 2008**
Project Duration:	**18 November 2008 - end December 2011**
Updates for the Period Ending:	**January - December 2009**

Section of the Board Update		**Updates**
XI.	Financial and Procurement	i) **MDR-TB Scale-up Initiative**: Total disbursement to-date is **US$ 21,565,302[21]** The May 2009 the Board approved an additional funding (US$16,384,000) support to this Project making the total approved budget ceiling for this Project US$54,046,000. This additional funding is premised upon expanding coverage to India[22] by supplying a total of 9,850 patient treatments between 2010-2012. This 2nd Amendment is anticipated to be signed by all parties in May 2010. The main Project objectives: D. Scale-up the number of patients accessing and receiving second-line anti-TB treatment; E. Decrease drug delivery lead times and prevent stock-outs; F. Increase the number of quality manufacturers and products; and G. Ensure cost-containment per treatment by 31 December 2011 and subject to a sufficient number of quality assured sources being available H. Achieve price reductions of 5-25% for key second-line anti-TB drugs by 31 December 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. ii) **MDR-TB Acceleration of Access Initiative: Strategic Rotating Stockpile (SRS)**: Total disbursement to-date is **US$9,585,303[23]** The total approved budget ceiling for this Project US$ 33,690,000. This is the 2nd component of the MDR-TB Acceleration of Access April 2008 EB7 Board approved resolution. The 1st component is has been reviewed by the UNITAID Administration and Finance Unit, and

20 The Secretariat reported in the EB9 that the augmented Strategic Rotating Stockpile will be reported as part of the MDR-TB Scale-up Initiative Progress updates to the Board in accordance with the Legal Agreement requirements signed between UNITAID and the Stop TB Partnership in November 2008. The Project strongly complements the original MDR-TB Scale-Up Initiative in which a SRS of 800 was established.

21 57% of total current Project budget (US$37,661,066) disbursed to date
22 India has the largest TB burden of any country globally accounting for one-fifth of the total global incident cases of TB
23 84% of total project budget (US$11,457,799) disbursed to date

		project plan development is in its final stages. The April 2008 Board approved funding of the augmentation of the Strategic Rotating Stockpile (additional 5,000 patient treatments) within the framework of the ' *MDR-TB Scale-Up Acceleration and Access Initiative - Strategic Rotating Stockpile*. This component of the April 2008, Board approval was signed by all parties in November 2008. The main Project objectives: The SRS Project has three broad objectives to support more rapid scale up MDR-TB treatment than would otherwise been possible and enable all GLC approved programmes/project and GF MDR-TB grantees. I. Accelerate scale-up of the number of patients accessing and receiving second line anti-TB treatment through a decrease in drug delivery lead times J. Increase the number of quality manufacturers and products K. Achieve price reductions for key second-line anti-TB drugs by 2011 This Project is intended to strongly complement the original UNITAID funded MDR-TB Scale-up Initiative and further enhance its objectives.
XII	Reporting Schedule	i) **MDR-TB Scale-up Initiative:** The 2nd Annual Programmatic and Financial Report (for the period 01 January 2009 to 31 December 2009) was submitted by the Partners and deemed satisfactory. ii) **MDR-TB Acceleration of Access Initiative: Strategic Rotating Stockpile (SRS):** The 1st Annual Programmatic and Financial Report was submitted by the Partners and deemed satisfactory.
XIII.	Project Progress	i) **MDR-TB Scale-up Initiative:** Key achievements 1. The 2009 patient treatment target is 2920 which should make the total cumulative number of patient treatment delivered by December 2009 to 4593[24]. In 2009 2004 patient treatments were delivered. To date the cumulative total number of patient treatments delivered is 3133. In 2009 13 countries had patient treatments delivered of the 12 countries during 2009 that had placed orders. 2. 5 additional suppliers have been sourced out for the 11 key MDR products and 3 suppliers for 5 of the key XDR products[25] 3. During 2009 two[26] new second-line anti-TB drugs were prequalified. In addition 13[27] new dossiers were submitted to WHO PQP. 4. A decision was taken by UNITAID and the GDF that based on the outcome of the EOI conducted between Q4 2008/Q1 2009 that a tender process in 2009 to determine prices and product supply awards was premature. Instead a Price Negotiation Task Force was established of which UNITAID is a member. To date the Price Negotiations Task Force negotiations has resulted in 3 of the 10 identified manufacturers committing to provide fixed prices for up to 24 months, and 2 have committed to fixed prices for 12 months.

[24] Anticipated deviation of 30% for UNITAID treatment target as initial targets where based on 2007 estimations.
[25] All second-line anti-TB medicines approved through GDF interim review quality risk assessment would have to follow prequalification process during a 12 month period after awarding contract are established.
[26] Cycloserine and Para-amino salicylate sodium
[27] An additional 6 from the EB11 reported 7 dossier submissions

		5. Average lead times have been reduced from 113 days to 100 days by the end of 2009. ii) **MDR-TB Acceleration of Access Initiative: Strategic Rotating Stockpile (SRS):** Key achievements <u>ii) Augmentation of the Strategic Rotating Stockpile</u>: ▪ By April 2009 countries were receiving orders from the augmented SRS. ▪ During 2009 1. 39 countries had used the SRS 2. 20 orders used the SRS for urgent requests 3. 15 countries need the SRS for urgent requests 4. The average lead time for orders using the SRS for urgent requests was 39 days **5. No Stock outs were reported for MDR-TB countries**
XV.	Issues and/or Lessons Learnt	i) The project's implementation has brought to light: a) some issues surrounding the lack of tenders to date for second-line drugs; and b) the duplication of quality assurance processes by the procurement agent and the WHO prequalification Programme. These issues are being monitored by the Secretariat and will be reported on actions taken between the Partner and the Secretariat to address these challenges. <u>ii) Strategic Rotating Stockpile:</u> The SRS although clear challenges in the efficiency of the functioning are noted, **the SRS continues to be a crucial tool** in enabling countries to have timely emergency supplies of quality assured drugs in the event of unexpected shortages. ▪ The augmentation of a fully functional stockpile has experienced systematic delays in the SRS being able to be 100% available or in rotation of the agreed target (set for June 2009). ▪ The GDF has reported during 2009 continued challenges in manufacturing capacity for some key products and its effect on access and procurement efficiency for key second-line products[28]. It is noted that the GDF has attempted to mitigate these risks by engaging and negotiating with Industry in identifying potential suppliers for key products. The Secretariat continues to note these key project risk factors and is currently in discussions with the GDF and WHO/STB to mitigate these risks. <u>Shortfall in the supply of Capreomycin from Eli Lilly and its impact on</u> ensuring key MDR-TB products are in constant rotation within the SRS<u>:</u> • In the EB9 and 10 it was reported that Eli Lilly would increase its quota of Capreomycin to a total of 1,420,000 million vials. In December 2009 1,100,000 vials were delivered. A difference of 300,000 of the agreed amount of vials. This shortfall is anticipated to be delivered in the 1st and 2nd Q of 2010. However this has posed a problem for the building up of the stockpile. <u>iii) Methodology for reporting on 'Patient treatments delivered':</u> It is recognized that in an effort to respond to this indicator, an extrapolation has been done based on the quantities of medicines delivered in the UNITAID countries. The methodology used is recommended by the Green Light Committee. It is noted the limitations in translating quantities of medicines delivered into number of patient treated **will not reflect the number of patients treated in each country** as per the set targets due to the following: • MDR-TB treatment faces many changes in treatment regimens due to resistance pattern and delays in receiving DST results.

[28] Amikacin, Moxifloxacin, Kanamycin and PAS Acid

		• Other factors affecting the patient treatment data and subsequently the consumption of delivered medicines (i.e. defaulted patients: 12%, died patients: 8%; failed patients: 4%) the percentages based on the Green Light Committee coverage 2000-2008 • For TB patient cohort data is collected at global level annually. 2008 enrolment data is available and 2009 data will be available in mid 2010. <u>iv) Treatment of extensively drug-resistant TB (XDR-TB):</u> In the updated indicative list of MDR-TB drugs group 5 medicines (Clofazimine (100mg capsules); Amoxicillin (500mg)/Clavulanate (125mg); and Linezolid (600mg tablets) have been added to the list of Drugs as per WHO treatment guidelines and in line with the Green Light Committee's mission to prevent the development of acquired resistance to MDR-TB drugs, especially in relation to XDR-TB, by ensuring that the second-line drugs (including group 5 drugs) are used properly. The group 5 drugs are not funded by UNITAID, but is noted that in order to have an impact these group 5 drugs need to be funded in the future either by UNITAID or alternative financing sources.

PROJECTS WITH PENDING LEGAL AGREEMENTS

MDR-TB ACCELERATION OF ACCESS INITIATIVE: STRATEGIC REVOLVING FUND

- Board approval in **April 2008**[29] of Strategic Rotating Stockpile and Strategic Revolving Fund[30]
- Decision[31] 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 **Jan. 2009**
- Several meetings were held between GDF and WHO Legal from **Feb - 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
- **May 2010**: The inclusion of financial indicators to mitigate the risk of this mechanism are being developed in collaboration with the Finance and Administrative Team
- **June 2010**: Project to be finalized into a formal legal agreement

[29] EB7 Resolution 3: Budget ceiling US$33,690,000
[30] Project Name: *Multi-Drug Resistant (MDR)-TB Scale-up and Acceleration of Access: 2008-2011*
[31] UNITAID, UNITAID Legal Representatives and the Stop TB Partnership's Global Drug Facility

OVERVIEW OF UNITAID MALARIA PORTFOLIO

Reported to the EB 12 Meeting, June 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	49,194,226	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	July 2009 to June 2011	9,280,400	9,280,400	9,280,400	9,280,400	
AMFm	June 2010 to July 2012	130,000,000	130,000,000	130,000,000	65,000,000	
Total		328,752,723	315,274,252	299,055,421	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 roll over of target deliveries for South Sudan, from Year 2 to Year 3 and/or Year 4 has been agreed in principle among the partners. Upon finalization of this planned rollover, the budget estimate currently presented under the column "Latest Approved Revised Budget" is expected to increase slightly to reflect the funds corresponding to the rescheduling of deliveries.

Note c for Accelerating Scale up of LLINs: UNICEF has reported full delivery of 20 million LLINs at the actual cost of US$ 92,856,982.77. Return of unused project funds to the UNITAID Secretariat is under discussion.

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.

MOUs

The UNITAID EB approved commitment ceiling have materialized into five MoUs, with a total MOU value of US$315.274 million. Fine tuning in the course of negotiation of the MOUs and subsequent implementation experience have resulted to agreed changes in targets and more refined price estimates. As of March 2010, the sum of the revised budgets for the malaria portfolio is US$ 299.055 million. Disbursements to-date is USD 220.948 million.

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.

Ongoing projects

UNITAID's ongoing projects under the malaria portfolio address the areas of prevention, treatment and artermisia supply management.

Through the Accelerating Scale up of LLINs project, which officially started in February 2009, the targeted delivery of 20 million WHOPES (WHO Pesticide Evaluation Scheme) recommended LLINs has been achieved. Beneficiary countries are: Angola, Congo-Brazzaville, Central African Republic, DRC, Guinea, Nigeria, Sudan, and Zimbabwe.

For the ACT Scale up, the UNICEF procurement and delivery report as of 10 March 2010 reflected that 15.16 million ACT treatments were delivered to the beneficiary countries as of December 2009. 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 PO issue date and arrival dates were shortened

The Assured Artemisinin Supply System project aims to increase the global production of Artemisinin by 40 metric tonnes in two years and to stabilize the Artemisinin market by providing revolving credit fund and promoting reasonable pricing of Artemisinin. During the reporting period: a) two loan applications for US$4 million with a production target of 20 MT of Artemisinin from China-based extractors reached final stages of negotiations; and b) one loan application from a Madagascar-based extractor has reached final stage of approval, with fund disbursement expected by the end of March 2010.

All the nine countries (including Zanzibar) that have confirmed their participation in the AMFm Phase-I are currently completing the amendments of the host grant by including all AMFm activities related to supporting interventions. This process was expected to be completed in May 2010.

The Global Fund has concluded Master Supply Agreements have been completed in mid-April 2010 with four manufacturers and negotiation with two other manufacturers is in progress. All

manufacturers have agreed to reduce the private sector price to the negotiated public sector price. The First-Line Buyer agreement with licensed ACT importers and distributors operating in the AMFm countries that are eligible to access the co-payment fund is also expected to be completed by May/June 2010. The completion of these essential actions will enable the delivery of the AMFm co-paid ACTs to start by August 2010.

Outlook

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.

The A2S2 project is on track in terms of completing contractual agreements with Artemisinin extractors. It is expected that, given the predictable needs ahead, the market environment would be stabilized. Barring unexpected climatic or other biological factors that may affect the planned cultivation of Artemisia annually, there are no identified potential hurdles that may adversely affect the expected achievements of the project.

The lack of consensus in the AMFm Ad Hoc Committee (AHC) on the issues of procurement of Fixed Dose Combination (FDCs) of ACTs, low investment on RDTs and the lack of prequalified Dihydroartemisinininin-Piperaquine (DHA-P) for Cambodia are some of the main outstanding issues that require timely resolution.

In an effort to address these problems, the AHC has proposed to incentivize FDC ACTs by offering a higher copayment level than what is paid for the co-blistered presentations. The AHC has also appealed to all partners to support efforts to increase access to diagnostics including the use of Rapid Diagnostic Tests (RDTs). To ensure availability of life saving drugs for Cambodia where the problem of Artemisinin resistance has been reported, the Global Fund Market Dynamics Committee (MDC) has recommended temporary approval for the procurement of DHA-P.

Synergies between the ongoing projects provide UNITAID with a real potential to achieve an impact that could far outweigh the individual results of these projects.

PROJECT TITLE: ACT SCALE UP

Key Partner(s):	**The Global Fund; UNICEF**
Project Start Date:	**4 December 2007**
Project Duration:	**December 2007 - August 2011**
Updates for the Period Ending:	**31 December 2009**

Section of the Board Update		Updates
XI	Financial and Procurement	The project's main objective is to scale up ACT treatments for malaria control and treatment, decrease the drug delivery lead times and prevent stock-outs and increase the number of quality manufacturers and products. Two remittances were originally scheduled for 2009. However, only the remittance scheduled for April was made. Remittance scheduled for October was not made - due to the reprogramming of target deliveries; the balances with UNICEF could still adequately cover the projected procurement. After taking into account the decreased treatment targets, price adjustments and savings from the first years of implementation, the budget is currently estimated at approximately US$49.2 million, representing a significant budget reduction of approximately US$16.2 million. *Note: The roll over of target deliveries for South Sudan, from Year 2 to Year 3 and/or Year 4 has been agreed in principle among the partners. Upon finalization of this planned rollover, the current budget estimate of US$49.2 million is expected to increase slightly to reflect the funds corresponding to the rescheduling of deliveries.* Based on the above mentioned latest budget estimate and remittance schedule, 83% of the funds scheduled for remittance have been disbursed.
XII	Reporting Schedule	The *3rd Interim Progress Report*, for the period July 2009 to 31 December 2009, was received on time (31st of March 2010).
XIII.	Programme Progress	<u>Treatment Targets</u> The UNITAID Board has been informed in prior reporting periods that the overall treatment target has decreased to 43,317,760 (decrease of 3,698,400 from the target stated in the MoU) due to North Sudan's decision to cut short its participation in the project. The treatment targets remain the same at 43,317,760 with changes in annual programme of deliveries due to the following: 1. Madagascar PSI: roll over of 2,019,893 treatment targets from Year 2 to Years 3 and 4 (1,220,000 and 799,893 respectively) 2. Zambia CHAZ: roll over of 1,234,479 ACT treatments from Year 2 to Year 3 3. Ethiopia: roll over of 5,100,031 ACT treatments from Year 2 to Years 3 and 4 (2,309,000 and 2,791,031 respectively) The delivery schedule before and after the above rollovers is shown below:

Section of the Board Update		Updates

	Cumulative ACT Treatment Targets (in million treatments)			
	Dec 2007 to June 2008	**July 2008 to June 2009**	**July 2009 to June 2010**	**July 2010 to June 2010**
As reported to EB11 (December 2009)	4.27	23.4	35.9	43.3
As of March 2010	4.27	15.09	32.3	43.3

Deliveries

The UNICEF procurement and delivery report (dated March 2010) reflected that 17.08 million ACT treatments were delivered to the beneficiary countries as of January 2010, of which deliveries to Cambodia, Indonesia and North Sudan covered the full targets. An additional 1.8 million treatments have been ordered and were awaiting delivery to the countries.

A total of 60 orders with corresponding deliveries were reported: 35 for 2008 and 25 for 2009. Delays in some deliveries were reported. Nevertheless, overall improvements, computed on the basis of simple averages, were observed:

a. ACT treatments arrived in country ahead of planned arrival date:
   - by a simple average of 4 days for POs issued in 2008; and
   - By a simple average of 19 days for POs issued in 2009.

b. Shorter lead time between PO issue date and arrival date:
   - POs issued in 2008: simple average of 100 days
   - POs issued in 2009: simple average of 71 days

Below are average delivery data per manufacturer:

Supplier	Simple Average of Actual Arrival Date Minus Planned Arrival Date		Simple Average of Actual Arrival Date Minus PO Issue Date	
	2008	**2009**	**2008**	**2009**
Activa Pharmaceuticals (FZC)	17.0		99.0	
Cipla Ltd.	-10.0	-21.0	81.0	101.0
Guilin Pharmaceutical Co., Ltd	-47.0	-36.5	29.0	73.0
Ipca Laboratories Limited	-29.0		110.4	
Novartis Pharma AG	8.3	-15.8	74.0	60.5
Strides Arcolab Limited	10.8	8.0	231.0	102.0

Note 1: Column headings refer to the years in which the POs were issued

Note 2: In relation to Actual Arrival Date Minus Planned Arrival Date
negative number of days: ACT treatments were delivered ahead of planned arrival date
positive number of days: ACT treatments were delivered after planned arrival date

Prequalification

This project contributes towards stimulating the submission of dossiers for WHO Prequalification programme. In 2009, 3 ACTs were reported to have been prequalified by WHO. Thus, cumulatively from the signing of this project's MoU in December 2007, nine additional ACT products have been prequalified, of which 8 are FDCs. Of the 9, 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

Section of the Board Update		Updates
		and transportation. Buffer Stock UNICEF clause on stockpile maintenance provides that it is the suppliers' responsibility to maintain buffer stock, which includes rotating the stock so that acceptable remaining shelf life (above 80%) is always available. It was reported that there were no emergency requests that required utilization of the stockpile. Procurement A new joint WHO-UNICEF competitive bidding exercise for ACTs was reported to have been launched in March 2009, with a total of 30 companies having been invited to offer their products. 13 companies submitted valid bids; of these 8 were awarded contracts. All of these 8 manufacturers have previously held UNICEF LTAs for ACTs. Although the 2009 tender exercise did not expand the supplier base, an expansion in the range of acceptable formulations and pack sizes was reported. UNICEF's standard solicitation method is a Request for Proposals, which gives bidders enough flexibility to offer products that may still be under the last stages of development. The offer is kept on file, ready to be used if the product becomes prequalified by WHO. This approach allowed UNICEF to quickly establish an agreement for the new FDC artesunate+amodiquine tablets as soon as the product were found acceptable by WHO in November 2008. It is reported that pooled procurement and competition for reduced pricing, healthy market development ad sustainability are some of the pillars of UNICEF's ACT procurement strategy. Pricing Following the tender exercise conducted in March 2009, and in conjunction with the rollover of target delivery dates for the 3 countries mentioned above, UNICEF has submitted a revised budget, which indicates a project savings of approximately US$16.2 million. It is to be noted that the budget and consequent savings will need to be revised in conjunction with the proposed roll over for South Sudan. Prices as well as timing of deliveries for this project are available in the UNICEF website (http://www.unicef.org/supply/index_42657.html).
XV.	Issues and/or Lessons Learnt	The project deliveries are to be coursed through 11 Global Fund participating grants in 8 countries. In order to reflect the Additionality from the UNITAID funding support, a re-negotiation of the targets of each of the eleven grants had to be done and the increased targets are to be documented through Implementation Letters between the Global Fund and the Principal Recipients (PRs). This renegotiation of targets is a prerequisite to the delivery of UNITAID funded treatments for the participating grants. The renegotiation process has encountered delays – among the reasons reported are: a) delay in the signing of the project MoU; and b) internal Global Fund processes (review for Phase 2, grant consolidation, rolling continuation channel). The UNITAID Secretariat has also observed a lack of understanding, on the part of one PR, of the required processes prior to ordering UNITAID funded treatments. The required processes have been clarified with the said PR. A number of grants reached their end dates with UNITAID funded treatments only partially delivered or not yet delivered.

Section of the Board Update		Updates
		Due to the delays encountered, some participating grants reached their end dates before full delivery of targets could be made. This has prompted the Global Fund to identify other eligible Global Fund grants that could absorb the UNITAID funded treatments, which have been presented to the UNITAID Secretariat. These have been positively considered by the Secretariat after receiving Global Fund confirmation of absorptive capacity and conformity with the UNITAID principle of Additionality, as well as advice from WHO LEG. The consultation process between the partners and the PRs has been time consuming, as was the process of documenting the agreements reached. Drawing on the lessons learned, the partners have agreed on a standardized set of information and processes for logging requested changes. With legal inputs and guidance, the partners have also agreed to simplify the documentation process, for decisions reached, through the use of a *Project Logbook*. Keeping a balance between adequate details and brevity/expediency was an overriding concern in the negotiations over the Project Logbook. Initiated in August 2009, the Project Logbook is now in the process of finalization.

PROJECT TITLE: ACCELERATING SCALE-UP OF LONG LASTING INSECTICIDE TREATED NETS (LLINS)

Key Partner(s):	**UNICEF**
Project Start Date:	**25 February 2009**
Project Duration:	**25 February 2009 - 31 December 2010**
Updates for the Period Ending:	**15 March 2010**

Section of the Board Update		**Updates**
XI.	Financial and Procurement	Total disbursements to-date **US$109, 246,140** The total approved budget ceiling for this Project: US$109,246,140 The primary objective of the project is to procure and deliver 20 million WHOPES (WHO Pesticide Evaluation Scheme) recommended LLINs to eight endemic countries in Africa namely: Angola, Congo-Brazzaville, Central African Republic, DRC, Guinea, Nigeria, Sudan, and Zimbabwe. The tendering process employed was through a Request for Proposals (RFP) from eligible suppliers. The time lapse from issuing of the RFP to signing of Long-Term Agreements (LTAs) with the selected suppliers was 19 weeks. A total of 20 million LLINs have been delivered to the beneficiary countries in 9 months (14 April 2009 to 17 January 2010) through 64 procurement orders. The target lead-time of 12 weeks from order to delivery was achieved for 80% of the deliveries. The actual supply value paid for 20 million LLINs is US$92,856,982.77. This is less than the planned budget by US$3.82 million (4%). To assess the impact of the project on price reduction, further data collection and analysis would be required. The comparison will be done based on median price paid per each type of LLIN through this project with the baseline median price.
XII	Reporting Schedule	The annual programmatic, procurement and financial report covering the period from 25 February 2009 to 15 March 2010 was received by the UNITAID Secretariat on 18 March 2010.
XIII.	Project Progress	Procurement and delivery of 20 million WHOPES recommended LLINs have been fully achieved. The impact of the project in-terms of price reduction and stabilizing the market of LLINs needs further data collection and analysis. This is expected to be completed prior to the next UNITAID Board meeting. Some of the key achievements during the reporting period also include: a) Procurement and delivery of the LLINs was completed on schedule. Only the last batch of 3000,000 delivered to Nigeria were delayed by two weeks. (target delivery date=Q4 of 2009; Actual=17 January 2010) b) The target lead-time for delivery of 12 weeks was achieved in 51 out of 64 (80%) purchase orders. c) During the implementation period, three new LLIN products obtained WHOPES recommendations (permanent 2.5, and Permanent 3 and DawaPlus): This brings the total number of WHOPES recommended LLINs to 8 (August 2009). d) Thus far 7.6 million LLINs (38%) have been distributed to households. Distribution of the LLINs is completed in two countries (Guinea and Zimbabwe) while Sudan and Nigeria have completed 58% and 54% respectively. Distribution of the last batch of 2.9 million LLINs in Nigeria will be completed in May 2010. e) A total of US$3.8 million has been saved from the planned supply value for LLINs. The repayment of this fund to UNITAID is under discussion. f) The funds required to complete distribution of LLINs to households (US$23 million) has now been fully mobilized by UNICEF and other partners and distribution of LLINs is on-going in all countries.

XV.	Issues and/or Lessons Learnt	Planned Changes in the Programme: 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 (DRC) and road access during rainy seasons in Sudan (Southern program). Despite these delays, most activities are on track as per the details indicated in the MoU and project plan. Issues and/or Lessons Learnt: The need to ensure availability of optimal storage capacity and adequate funding to support in-country distribution of LLINs are the two most important lessons learnt during the implementation period.

PROJECT TITLE: ASSURED ARTEMISININ SUPPLY SYSTEM (A2S2)

Key Partner(s):	**i+solutions**
Project Start Date:	**06 July 2009**
Project Duration:	**06 July 2009 - 30 June 2011**
Updates for the Period Ending:	**March 2010**

Section of the Board Update		**Updates**
XI.	Financial and Procurement	Total disbursements to-date **US$ 9,280,400.** The total approved budget ceiling for this Project US$87,561,985 The project aims to provide revolving credit fund to artemisinin extractors to support their engagement in the business and their contributions to increase availability of quality artemisinin required to meet the ACT needs for 2011 - 2012. An estimated US$8.16 million of the Project fund will be recovered from the loans and paid back to UNITAID by the end of the implementation period. A total amount of US$880,400 (9.5%) will be used to strengthen the artemisinin market intelligence and to support project management activities. An annual loss of 2% of the project fund, due to poor performance of individual loans, is estimated by Triodos Bank that manages the project fund. The project has no procurement component.
XII	Reporting Schedule	The 2nd periodic project progress report covering the period from September 2009 to March 2010 was on time (18 March 2010).
XIII.	Project Progress	The project aims to increase the global production of Artemisinin by 40 Metric Tones in two years and to stabilize the Artemisinin market by providing a revolving credit fund and promoting reasonable pricing of artemisinin. Only Artemisinin extractors who have legal contracts with ACT manufacturers whose product are prequalified by WHO are eligible to access the credit fund. The key project achievements during the reporting period are: a) Two loan applications from Artemisinin extractors based in China are in the final stage of assessment for approval before the end of March 2010. The loan value for the two applications is US$4 million with a production target of 20 MT of Artemisinin, b) One loan application submitted by an extractor based in Madagascar is in the final stage of approval and fund disbursement before the end of March 2010. c) The project has launched (October 2009) a project website http://www.a2s2.org and dashboard accessible to the public to foster transparency and information sharing.
XV.	Issues and/or Lessons Learnt	Planned Changes in the Programme: The lengthy process for Chinese extractors to obtain approval for loans in foreign currency and its implication on timely concluding loan agreements before the planting season was identified as a major implementation hurdle. The loan administration fee of 2.5% that will be paid by the borrowers has also been identified as a potentially discouraging factor to borrowers. Based on these observations and the recommendation of the Mumbai Artemisinin Conference (October 2009), the A2S2 project management proposed the following actions, a) To provide loans to extractors in local currency (Yaun) through a bank based in China, b) To hedge the credit fund in China at a cost of 2.5% to prevent currency loss due to exchange fluctuation in USD and Yaun. c) To waive the loan administration fee of 2.5% and charge it from the A2S2 project

		fund. Based on the continue project implementation and based on i+solutions' projections, which indicated that the funds to be reimbursed to UNITAID maybe the same or slightly lower (US$8.16 million), the above proposed actions were agreed by the UNITAID Secretariat. Issues and/or Lessons Learnt: The suitability of the banking operations for such loans in each of the countries where the artemisinin extractors are based was not well understood in advance. This resulted in implementation delays and extra efforts to modify the loan structure. Due to the sensitive nature of the Artemisinin market, information on the price of artemisinin and inventory data of Artemisinin stock remains confidential. The confidentiality agreements that will be signed between the A2S2 project and the ACT manufacturers, API formulators and extractors is believed to build confidence and partnership among the partners to confidently share their data and promote responsible use.

OVERVIEW OF UNITAID TRANSVERSAL PORTFOLIO

Reported to the EB 12 Meeting, June 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 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 transversal projects on prequalification are progressing well. Mixed results for the niches covered under the UNITAID Support for Global Fund Round 6 have been reported.

The *Prequalification Medicines Programme* continued to grow from strength to strength, having resulted to more prequalified products for HIV/AIDS, TB and malaria during the period, as well as the prequalification of one Quality Control Laboratory. The Programme actively provided

supporting interventions to activity areas that, collectively, would help expedite the prequalification process: training for regulators and manufacturers in Asia, Africa and Europe; technical assistance to manufacturers in the areas of GMP upgrading of pharmaceutical production; compliance with good manufacturing practice (GMP) and good laboratory practice; assessment of corrective measures and capacity to meet prequalification requirements; and meeting prequalification requirements; piloting of a collaborative procedure for facilitating registration of prequalified medicines in East Africa.

The *Quality Assurance of Diagnostics* started in March 2009. The work plan for the initial stage of this project includes activities to ensure that the work scheduling reflects UNITAID priorities, to incentivize manufacturers of priority diagnostics to apply for prequalification and if appropriate submit a product dossier track, establish evaluation protocols and development of guidelines. WHO/DTL requested a review of the disbursement schedule and the October 2009 disbursement has been adjusted and postponed for 1 June 2010 in the amount of US$ 2.7 million.

The *UNITAID Support for Global Fund Round 6, Phase 1* supports the procurement of drugs for Phase 1 of Global Fund Round 6 grants. It was reported that as of end December 2009, 14 out of participating 43 (count includes Mozambique, which has opted out of the project) grants have fully met the cumulative targets under the project. Significant achievements against cumulative year 2 targets were reported for: a) Pediatric ARV (97.56%); b) 2nd Line ARV (92.32%); and MDR TB (93.72%). Slow progress was reported for ACTs, which was attributed to: delayed arrival of ACTs in Guinea, suspension of grant disbursement for Mali and Mauritania following the Global Fund Office of Inspector General's investigation; and lower malaria prevalence in Djibouti.

Outlook

As recorded in the project MOU for the *UNITAID Support to Round 6 Phase 1*, it was envisaged that the project would reach completion by mid 2010. The recently reported project developments point towards the need to clarify: a) the implications of the consolidation of some Round 6 grants with Round 8; if the 13 grants that are expected to continue would still be under Phase 1; and status of the "frozen" grants.

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. The Global Fund 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. Necessary actions in line with MOU provision will be undertaken upon receipt of formal request from the Global Fund for extension of UNITAID support to participating Round 6 Phase 1 grants graduating to Phase 2.

Plans for technical assistance and workshops that are in place for the *Prequalification Medicines Programme* suggest that UNITAID can look forward to further strengthening: The Programme will extend its in-country sampling and testing upon receipt of information from UNITAID regarding which countries are supplied with UNITAID-funded medicines. Since September 2009 the WHO Expert Review Panel (ERP) has also been providing support to UNITAID in deciding on the eligibility, for UNITAID support, of antiretrovirals that are being assessed for prequalification. The ERP has met for the second time to assess the quality of antiretrovirals, which CHAI has recommended for procurement on behalf of the Pediatric and Second Line HIV/AIDS Projects in 2010.

PROJECT TITLE: UNITAID PROJECT SUPPORT FOR QUALITY ASSURANCE OF MEDICINES, 2009-2012 – WHO PREQUALIFICATION OF MEDICINES PROGRAMME (PQP)

Key Partner(s):	**WHO/PQ Programme**
Project Start Date:	**14 December 2006**
Project Duration:	**December 2006 - December 2012**
Updates for the Period Ending:	**15 March 2010**[32]

Section of the Board Update		**Updates**
XI.	Financial and Procurement	Total disbursements to-date: **US$ 15,000,000**. The total approved budget ceiling for this Project: US$47million The overall goal of the Project is to improve the quality of medicines supplied through UNITAID and other international procurement agencies.
XII	Reporting Schedule	**The 3rd Annual Programmatic and Financial report for the period 1 January to 31 December 2009 due for the 15th March 2010 was received 12 May 2010.**
XIII.	Project Progress	Some key achievements during this reporting period (2009) are: - prequalified a record number of medicines (44 products): PQP firsts included generic lopinavir/ritonavir and generic tenofovir, both of which are UNITAID priority products ***For HIV/AIDS*** ▪ Abacavir + lamivudine – Tablets 60 mg + 30 mg – Matrix Laboratories Ltd ▪ Lamivudine + nevirapine + zidovudine – Tablets 30 mg + 50 mg + 60 mg – Matrix Laboratories Ltd ▪ Tenofovir disoproxil fumarate – Tablets 300 mg – Matrix Laboratories Ltd ▪ Tenofovir disoproxil fumarate – Tablets 300 mg –Ranbaxy Laboratories Ltd ▪ Tenofovir disoproxil fumarate – Tablets 300 mg –Cipla Ltd. ▪ Abacavir - Tablets 60mg - Matrix Laboratories Ltd ▪ Lopinavir+Ritonavir- Tablets 200mg+50mg-Matrix Laboratories Ltd ▪ Lopinavir+Ritonavir-Tablets 100mg+25mg-Matrix Laboratories Ltd ***For malaria:*** ▪ Artemether + lumefantrine –Tablets 20 mg + 120 mg – Ipca Laboratories Ltd ▪ Artemether + lumefantrine –Tablets 20 mg + 120 mg – Ipca Laboratories Ltd ▪ Artemether + lumefantrine –Tablets 20 mg + 120 mg – Cipla Ltd ▪ Artemether + lumefantrine – Dispersible Tablets 20 mg + 120 mg – Novartis Pharma ***For TB:*** ▪ Cycloserine capsules 250 mg capsules: TB166 (Aspen Pharmacare Limited) ▪ Isoniazid + Pyrazinamide + Rifampicin 30 mg + 150 mg + 60 mg tablets: TB180 (Macleods Pharmaceuticals Limited) ▪ Isoniazid + Rifampicin tablets 30 mg + 60 mg tablets: TB181 (Macleods Pharmaceuticals Limited).

[32] Preliminary update based on ad-hoc information received by the Partner in the absence of the formal submission of the 2009 Annual Programmatic and Financial Report

- Isoniazid/Rifampicin-60mg/60mg- Dispersible tablets (Macleods Pharmaceuticals Ltd - India, TB182
- Pyrazinamide 400mg tablets Micro Labs Limited- India TB171
- Pyrazinamide 500mg tablets Micro Labs Limited- India TB172
- Para-aminosalicylate sodium - 60% w/w-Delayed release granules - Macleods Pharmaceuticals Ltd- India - TB156

Other achievements:

- prequalified 3 quality control laboratories (QCLs)
- organized 12 and co-organized 5 capacity-building courses for staff of national medicines regulatory authorities (NMRAs) from resource-limited countries and pharmaceutical manufacturers
- provided scientific advice and technical assistance to manufacturers aimed at improvement of the quality of their products
- finalized the guideline on the requalification of prequalified products (which was subsequently adopted during the 44th meeting of WHO's Expert Committee on Specifications for Pharmaceutical Preparations, in October 2009)
- contributed to the development of WHO pharmaceutical guidelines and standards, to promote medicines quality assurance globally
- provided technical advice and support to numerous parties and partners, including WHO procurement units, WHO disease-oriented programs, UNITAID and the Global Fund to Fights AIDS, Tuberculosis and Malaria (GFATM), regarding quality assurance of medicines in general and specific product groups and individual products in particular
- together with the WHO country office in China launched a project to improve the quality of TB medicines produced in China.

2. **Prequalification of active pharmaceutical ingredients (APIs)**
Prequalification of APIs has not yet started, however, due to lack of resources (mainly inspectors) and other priorities. It should also be noted that the other major donor to PQP during 2009 specifically requested that its funds not be used for covering staff costs relating to an API inspector.

The procedure for prequalifying Active Pharmaceutical Ingredients (API) has been by the 43rd Expert Committee on Specifications for Pharmaceutical Preparations in October 2008 and this was approved by WHO's Legal Counsel and published in WHO's Technical Report Series (as No. 953).

3. **Re-assessment and maintenance of list of prequalified medicines**
All prequalified products are monitored to check that the quality, safety and efficacy of products are being maintained. Applicants are therefore obliged to report any changes (variations) made to their prequalified product. In 2009, 381 variations were assessed, as opposed to 252 in 2008.

4. **Regulatory and production capacity building**
PQP organized 12 training courses (compared to 11 in 2008) and co-organized 5 training workshops (compared to 4 in 2008) with other partners. In 2009, these workshops involved nearly 800 participants. Training on general or specific technical issues was given to manufacturers, and to NMRA and QCL staff, as well as an introduction and/or update on PQP requirements and services.

5. **Technical support to selected manufacturers**
In 2009, PQP organized technical assistance missions to 8 pharmaceutical manufacturers in 5 countries (China, Egypt, Kenya, Russia and Thailand) and 2 technical assistance missions to national QCLs in Tanzania and Tunisia. The technical assistance was provided in the form of

		an audit, advice on development of an improvement plan, and training in technical or regulatory areas. Follow-up missions are also planned to support implementation of improvement plans. 6. **Global norms and standards needed for prequalification** In October 2009, the 44th Expert Committee on Specifications for Pharmaceutical Preparations adopted and recommended for use of new standard and guidelines of relevance to the Prequalification Program of Medicines. Three monographs for HIV/AIDS, TB and malaria were also adopted for inclusion in *The International Pharmacopoeia* 7. **Collection of key efficacy data and safety data, and development of innovative regulatory mechanisms** Preparations were made for review by the WHO Advisory Committee on Safety of Medicinal Products of pharmacovigilance plans for WHO-prequalified products. This will include review of safety issues relating to prequalified artesunate amodiaquine products. The PQP assessment team pays careful attention to review of risk management plans for innovator products in particular. 8. **In-country sampling and testing of medicines supplied by UNITAID** In the pilot phase in 2008, a total of 378 samples from 203 different batches were collected. It focused on 26 products from 24 manufacturers in Kenya, Tanzania, Uganda and Zambia. The products included Paediatric ARVs, co-trimoxazole (i.e. sulfamethoxazole + trimethoprim combination) and 2nd-line ARVs. Although not clinically significant, three samples failed due to non-compliance with international pharmaceutical norms and standards. In 2009, similar sampling and testing activities were conducted for antimalarials in selected African countries, and also initiated for anti-TB medicines collected in Armenia, Azerbaijan, Belarus, Kazakhstan, Ukraine and Uzbekistan, but were not focused on UNITAID-purchased products. Quality testing of medicines supplied by UNITAID will be organized upon receipt of information regarding medicines and sites to be sampled. 9. **Capacity building and prequalification of medicine QCLs** In 2009, three additional medicines QCLs (1 in Kenya, 2 in Singapore) were prequalified bringing the total number by the end of the year to 11. In 2008, 6 QLCs were prequalified. Additional 29 centers are working towards becoming prequalified. Two technical assistance missions were organized to national QCLs in Tanzania and 1 to Tunisia. 10. **Communications and advocacy** Efforts to ensure effective communication with stakeholders and to raise the profile of PQP, in the WHO regions, and globally, were maintained, for example through participation in a ministerial-level meeting on multidrug resistance in (Beijing, April), in the UNITAID implementers meeting (Nairobi, October), in the Second African Medicines Regulators Conference (Maputo, November), in the Global Fund Consultative Meeting with Manufacturers (Kuala Lumpur, November), in the International GMP Inspectors Summit: Building on International Cooperation and Collaboration (Washington, November), and through organization of a seminar with European manufacturers and European Union (EU) holders of marketing authorizations (Copenhagen, November). A brief annual report for 2009 was included in the WHO Drug Information Bulletin Vol. 24 No. 1 2010 and posted on the PQP web site. A combined annual report for 2009/advocacy report is in preparation, incorporating the new house style for PQP information products.
XV.	Issues and/or Lessons Learnt	**Planned changes in PQP** - PQP has contracted a consultant to revise the PQP IT System. This activity planned to be completed in 2010 will help identify how best to enhance its IT system. - Some activities of the PQP projects are under financed while others activities have earmarked fund beyond the required amount. WHO-PQP has requested adjustment and is currently under discussion. **Issues and/or lessons learnt**

		▪ Currently, PQP lacks sufficient inspection capacity to undertake all the inspections required in 2010. Efforts are ongoing to speed-up recruitment of inspectors.

PROJECT TITLE: UNITAID PROJECT SUPPORT FOR QUALITY ASSURANCE OF MEDICINES, 2009-2012 – WHO PREQUALIFICATION OF MEDICINES PROGRAMME (PQP)

Key Partner(s):	**WHO/PQ Programme**
Project Start Date:	**14 December 2006**
Project Duration:	**December 2006 - December 2012**
Updates for the Period Ending:	**15 March 2010**[33]

Section of the Board Update		**Updates**
XI.	Financial and Procurement	Total disbursements to-date: **US$ 15,000,000**. The total approved budget ceiling for this Project: US$47million The overall goal of the Project is to improve the quality of medicines supplied through UNITAID and other international procurement agencies.
XII	Reporting Schedule	**The 3rd Annual Programmatic and Financial report (for the period 1 January to 31 December 2009), was due the 15th March 2010. This Report has not been received by the Secretariat however ad-hoc data has been provided to facilitate reporting to the PSC.**
XIII.	Project Progress	Some key achievements during this reporting period are: **1. Prequalification of UNITAID priority medicines -** the following UNITAID priority medicines have been prequalified during 2009: *For HIV:* ▪ Abacavir + lamivudine – Tablets 60 mg + 30 mg – Matrix Laboratories Ltd ▪ Lamivudine + nevirapine + zidovudine – Tablets 30 mg + 50 mg + 60 mg – Matrix Laboratories Ltd ▪ Tenofovir disoproxil fumarate – Tablets 300 mg – Matrix Laboratories Ltd ▪ Tenofovir disoproxil fumarate – Tablets 300 mg –Ranbaxy Laboratories Ltd ▪ Abacavir - Tablets 60mg - Matrix Laboratories Ltd ▪ Lopinavir+Ritonavir- Tablets 200mg+50mg-Matrix Laboratories Ltd ▪ Lopinavir+Ritonavir-Tablets 100mg+25mg-Matrix Laboratories Ltd *For malaria:* ▪ Artemether + lumefantrine –Tablets 20 mg + 120 mg – Ipca Laboratories Ltd *For TB:* ▪ Cycloserine capsules 250 mg capsules: TB166 (Aspen Pharmacare Limited) ▪ Isoniazid + Pyrazinamide + Rifampicin 30 mg + 150 mg + 60 mg tablets: TB180 (Macleods Pharmaceuticals Limited) ▪ Isoniazid + Rifampicin tablets 30 mg + 60 mg tablets: TB181 (Macleods Pharmaceuticals Limited). ▪ Isoniazid/Rifampicin-60mg/60mg- Dispersible tablets (Macleods Pharmaceuticals Ltd - India, TB182

[33] Preliminary update based on ad-hoc information received by the Partner in the absence of the formal submission of the 2009 Annual Programmatic and Financial Report

- Pyrazinamide 400mg tablets Micro Labs Limited- India TB171
- Pyrazinamide 500mg tablets Micro Labs Limited- India TB172
- Para-aminosalicylate sodium - 60% w/w-Delayed release granules - Macleods Pharmaceuticals Ltd- India - TB156

2. **Prequalification of active pharmaceutical ingredients (APIs)**

In October 2008, the 43rd Expert Committee on Specifications for Pharmaceutical Preparations endorsed the new procedure for prequalification of APIs. The procedure has since been approved (in 2009) by WHO's Legal Counsel and has been published WHO's Technical Report Series (Annex 4 of TR953). However, hiring of additional staff to carry out prequalification activities for APIs continues to be delayed due to WHO administrative issues and difficulty in finding suitably qualified individuals.

3. **Re-assessment and maintenance of list of prequalified medicines**

The draft guideline on the requalification of prequalified products was adopted during the 44th meeting of WHO's Expert Committee on Specifications for Pharmaceutical Preparations, held in October 2009.

4. **Regulatory and production capacity building**

- 6 trainings for regulators and manufacturers has been organized by PQP since the beginning of October 2009 and co-organized 3 other events
- inspectors from developed countries participated in inspections as WHO co-inspectors. Inspectors from China, India, Namibia, Tanzania and Uganda participated as observers in inspections carried out in China, India, Tanzania, South Africa and Uganda.
- PQP appointed 1 rotational assessor. An assessor from Tanzania will join PQP for June to August, to be followed by an assessor from Zambia, who will join PQP for September to November.

5. **Technical support to selected manufacturers**

During this reporting period, technical assistance was provided on GMP upgrading of pharmaceutical production to a manufacturer in Thailand, on compliance with good manufacturing practice (GMP) and good laboratory practice to a manufacturer in Egypt, on assessment of corrective measures and capacity to meet prequalification requirements to a manufacturer in China and on capacity to meet prequalification requirements to a manufacturer in Indonesia. Technical assistance is currently being prepared for 2 manufacturers in India, 1 in Morocco and 1 in Nigeria.

6. **Global norms and standards needed for prequalification**

In October 2009, the 44th Expert Committee on Specifications for Pharmaceutical Preparations adopted and recommended for use 7 norms and standards.

- 3 monographs for HIV/AIDS, TB and malaria were adopted for inclusion in *The International Pharmacopoeia*

7. **Collection of key efficacy data and safety data, and development of innovative regulatory mechanisms**

A collaborative procedure for facilitating registration of prequalified medicines in East Africa was piloted in March 2010. The overall aim is to identify a framework for joint evaluation of dossiers and inspections of medicine manufacturing sites, and to ensure that these assessments are integrated into national decision-making processes.

Two assessors each from 3 East African Community (EAC) countries (Kenya, Tanzania and Uganda) and 6 WHO assessors jointly assessed 2 product dossiers submitted by a

manufacturer. Future joint assessment sessions will be held in the EAC region.

8. **In-country sampling and testing of medicines supplied by UNITAID**

The results of pilot phase activities carried out in Kenya, Tanzania, Uganda and Zambia, focusing on Paediatric fixed-dose combination antiretrovirals (ARVs), co-trimoxazole and second-line ARVs were finalized. Of the 378 samples collected and tested, only 3 failed quality testing. Although failure was due to non-compliance with international pharmaceutical norms and standards, none was life-threatening for patients. The results underscore that, provided procurement and distribution practices are sound, medicines prequalified by PQP can be viewed with confidence by health workers and patients alike. PQP will extend its in-country sampling and testing upon receipt of information from UNITAID regarding which countries are supplied with UNITAID-funded medicines.

9. **Capacity building and prequalification of medicine QCLs**

During the reporting period, 1 QCL was prequalified, as follows:

- 10 February 2010 – K.A.B.S. Laboratories Inc., Quebec, Canada.

Technical assistance was provided early in 2010 to a QCL in Burkina Faso on compliance with good practices for national pharmaceutical control laboratories.

An interregional seminar on pharmaceutical quality control laboratories, to be held in cooperation with the WHO Collaborating Centre at the North-West University, Potchefstroom, South Africa, is planned for November 2010.

10. **Communications and advocacy**

- The Fifth Consultative Stakeholder Meeting for UN Prequalification of Diagnostics, Medicines and Vaccines was held on 11 February 2009. Programme overviews were given by the 3 prequalification programmes during the morning session. During the afternoon session, key stakeholders presented their perspective on WHO prequalification activities and the ways in which these contribute to achievement of their own objectives.
- Efforts to ensure effective communication with stakeholders and to raise the profile of PQP in the WHO regions are being maintained, e.g. through participation in the Global Fund Consultative Meeting with Manufacturers in Kuala Lumpur in November 2009 and in the International GMP Inspectors Summit: Building on International Cooperation and Collaboration in Washington, 2009, and organization of a seminar with European manufacturers and European Union (EU) holders of marketing authorizations in Copenhagen, Denmark in November 2009. The seminar focused mainly on how generic manufacturers in the EU Member States could be more actively involved in international donor funded procurement. Information was provided about the Prequalification Programme and abridged procedures for holders of marketing authorizations granted in the EU or by other stringent regulatory authorities worldwide.
- A survey of manufacturers is being developed as part of PQP's efforts to improve its level of service and optimize its use of resources.

11. **Prequalification assessment and inspection statistics (cumulative figures)**

Dossier assessment	*2009*	*2008*
Assessment sessions in Copenhagen	7	7
Total number of assessment days	46	35
Total number of assessment reports	732	998*
Assessment reports on HIV/AIDS products	494	593
Assessment reports on TB products	100	208
Assessment reports on malaria products	115	133
Inspections		
Manufacturing sites of finished product manufacturers	27	27

		Manufacturing sites of active pharmaceutical ingredients	11	7
		Contract research organizations	14	10
		Pharmaceutical quality control laboratories	10	6
		* including on reproductive health and influenza products, and including "supporting reports", e.g. report on an API included in a product, or on a dossier to be cancelled.		
XV.	Issues and/or Lessons Learnt	**Planned changes in PQP** ▪ PQP has contracted a consultant to identify how best to enhance its IT systems. This includes determining whether the current system can be adapted to common use within PQP or whether a new solution must be sought. This activity is scheduled for completion during 2010. **Issues and/or lessons learnt** ▪ WHO's recruitment procedures continue to prove cumbersome and to slow recruitment of urgently needed inspectors. Currently, PQP lacks sufficient inspection capacity to undertake all the inspections required in 2010.		

PROJECT TITLE: ROUND 6

Key Partner(s):	**The Global Fund**
Project Start Date:	**21 December 2007**
Project Duration:	**December 2007 - June 2010**
Updates for the Period Ending:	**31 December 2009**

Section of the Board Update		**Updates**
XI.	Financial and Procurement	The project's primary objective is 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. 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, the total disbursement to-date, **US$ 38,691,956,** represents **100%** of project funding. The Global Fund reported a cumulative procurement value of US$15.5 million for the period March 2007 to June 2009. However, some of this procurement is still under discussion between the two Secretariats. During the reporting period covering July-December 2009, 19 PRs reported procurement of UNITAID funded pharmaceutical products through the Global Fund PQR. The total reported procurement spending for the period July to December 2009 is $10,992,530 and is broken down by treatment niche as follows: pediatric and 2nd line ARVs: $8,481,721; ACTs : $1,232,139; and MDR-TB 2nd line drugs: $1,278,670. ***The compilation of cumulative procurement is under discussion with the Global Fund.***
XII	Reporting Schedule	The *3rd Annual Progress Report* (for the period ending 31 December 2009) was received on the 30th of March 2010.
XIII.	Programme Progress	<u>Results</u> It was reported that as of end December 2009, significant achievements against cumulative year 2 targets have been achieved for: a) Pediatric ARV (97.56%); b) 2nd Line ARV (92.32%); and MDR TB (93.72%). **Cumulative Year 2 Targets / Yr 2 Results / % Result to Target** Pediatric ARV: 29,592 / 28,870 / 97.56% 2nd Line ARV: 8,099 / 7,477 / 92.32% MDR TB: 3,298 / 3,091 / 93.72% ACT: 11,213,096 / 2,055,927 / 18.34% The implementation rate for ACTs is particularly low. Among the reasons cited by the Global Fund for the low implementation rate for ACTs 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 <u>Overall Decrease in Treatment Targets</u> 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). The net

<table>
<tr><th colspan="2">Section of the Board Update</th><th>Updates</th></tr>
<tr><td></td><td></td><td>
decrease is due to lowered targets for China and increased target for Guinea. The UNITAID Secretariat will follow up with the Global Fund regarding the reasons and the financial implications of these revisions.

<u>Participating Grants, Status of Results and Indicative Outlook</u>

<table>
<tr><th></th><th colspan="4">Number of Participating Grants</th><th></th></tr>
<tr><th></th><th colspan="2">HIV/AIDS</th><th rowspan="2">MDR TB</th><th rowspan="2">ACT</th><th rowspan="2">Total</th></tr>
<tr><th></th><th>2nd Line</th><th>Pediatric</th></tr>
<tr><td>Cumulative Yr2 Target Fully Met</td><td>3</td><td>3</td><td>5</td><td>3</td><td>14</td></tr>
<tr><td>Will continue</td><td>3</td><td>1</td><td>5</td><td>4</td><td>13</td></tr>
<tr><td>Intends to Apply For Extension</td><td></td><td>2</td><td>7</td><td>4</td><td>13</td></tr>
<tr><td>Frozen - with OIG</td><td></td><td></td><td></td><td>2</td><td>2</td></tr>
<tr><td>Opted out</td><td>1</td><td></td><td></td><td></td><td>1</td></tr>
<tr><td>Total</td><td>7</td><td>6</td><td>17</td><td>13</td><td>43</td></tr>
<tr><td colspan="6">Notes:
Laos participating grant is not counted under Pediatric ARVs as the same grant participates in 2nd Line
Mozambique participating grant (opted out) is not counted under Pediatric ARVs as the same grant opted out of 2nd Line</td></tr>
</table>

As summarized above, there are 43 Round 6 Global Fund grants that are participating in this project. Out of the 43:

14 were reported to have fully met the cumulative targets under the project
2 grants were reported to have been consolidated with Round 8
13 grants with a total combined remaining target delivery of 5,317,387 results are expected to continue
13 grants with a total combined remaining target delivery of 1,231,093 results are about to (or have reached) Phase 2 and the Global Fund had informally indicated the intention to request for extension of support to Phase 2, but no formal request has been submitted.
2 grants with a total combined remaining target delivery of 2,705,329 results 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.

The range of follow up actions being done by the UNITAID Secretariat includes:

Consultation/seeking of legal advice and review of implications of the consolidation of some grants with Round 8, as the MOU covers Round 6 Phase 1
Clarification if the 13 grants that are expected to continue would still be under Phase 1
follow up the status of the “frozen" grants

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. Necessary actions in line with MOU provision will be undertaken upon receipt of formal request from the Global Fund for extension of UNITAID support to participating Round 6 Phase 1 grants that have graduated to Phase 2.
</td></tr>
<tr><td>XV.</td><td>Issues and/or Lessons Learnt</td><td>
<u>Need for Timely Reporting</u>
The UNITAID Support for Round 6, Phase 1 is expected to reach completion by mid 2010. However, the programmatic data for the period ending December 2009 is expected to be submitted to the UNITAID Secretariat only by the 31st of March 2010. This means that the UNITAID Secretariat programme issues, if any, would come to the attention of the UNITAID Secretariat just 3 months prior to the expected end date of the project, thus leaving hardly any window for implementation adjustments, much less proactive project management. Future MOU negotiations should bear in mind the need for more frequent and more timely reporting.
</td></tr>
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Section of the Board Update		Updates
		Products Procured As were the case with prior submissions, the latest procurement report included products not specified previously in the project proposal or MOU. For future projects, oversight and monitoring could be facilitated if more clearly defined product lists and procedures for updating the list of eligible products could be incorporated into the MOUs. Processes for Closing Down the Project Bearing in mind that procurement which does not meet the criteria set out in Exhibit 3 of the MOU will not be attributed to UNITAID Project Support, the UNITAID Secretariat requested the Global Fund to indicate the QA criteria that were applied in determining the reported procurement. The Global Fund has informally indicated that they intend to positively respond to this request. One of the biggest activities relating to the formal closure of the project would be the determination of the amount of Unexpended UNITAID Funding Support, if any. The project's MOU has recognized key constraints that could complicate this process. UNITAID Secretariat and the Global Fund are in discussion on how to address these.