14th Executive Board
5-6 July 2011
Conference Centre Varembé,
Geneva, Switzerland

Agenda item 10

Update on operations

Report on implementation of projects approved by the Board

For Information ☒ **For Discussion** ☐ **For Decision** ☐

PROJECT TITLE: Second-Line ARV Project

Key Partner(s): Clinton Health Access Initiative (CHAI)
Project Duration: May 2007 - December 2011
Updates for the Period Ending: December 2010

Updates	
Goals and Objectives	**Goals** and **Objectives**: • To scale up the access to Second-Line ARVs to increase the number of patients receiving treatment for HIV/AIDS in developing countries • Influence market dynamics to achieve price reductions to increase the affordability of critical quality products • Stimulate an increase in the number of quality assured manufacturers and products • Decrease product delivery lead times • Encourage prequalification of approved manufacturers and products • Apply appropriate procurement strategies to develop a healthy market that favors competition and sustainability, with reductions in prices.
Finance	• Board ceiling: US$ 305,799,000 • MoU amount (as of December 2010): US$ 252,135,000 • 2010 Disbursement: US$ 61,124,206 • Cumulative Disbursement (as of December 2010): US$212,825,744 • Last Project Year Budget : US$ 77,938,806 • Performance by the Partner against budget : US$69,766,852 • Performance by the Partner against budget (%): 90%
Achievements	• Twenty-six countries have benefited from the UNITAID-supported second-line project[1] since the project started. • An estimated 113,892 patients received 2nd line[2] treatment via this Project in 2010. • 12 eligible suppliers of second-line formulations added to the Project in 2010. • The Second-Line Project currently represents an estimated 77% of second-line ARV demand in generic-accessible low and middle income countries[3]. • Seven out of nine products procured by CHAI in 2010 now have two or more Stringent Regulatory Authority (SRA) approved suppliers.

[1] Benin, Botswana, Burkina Faso, Burundi, Cambodia, Cameroon, Chad, Cote d'Ivoire, Democratic Republic of Congo, Ethiopia, Ghana, Haiti, India, Kenya, Malawi, Mali, Mozambique, Namibia, Nigeria, Rwanda, Senegal, Tanzania, Togo, Uganda, Zambia, and Zimbabwe
[2] Support for tenofovir as a first line treatment was also provided to Uganda and Zambia through this project.
[3] excluding Argentina, Brazil, China, Mexico, and South Africa

Project Progress	• The Procurement Agent for this Project is IDA Foundation. No contractual issues were reported to UNITAID. • The median price of medicines for adult major first-line regimens continued to decrease in low and middle-income countries between 2008 and 2010. Within that period, the median price of the most commonly prescribed 2nd line regimen for adults use[4] dropped by 32% from US$ 815 per patient treatment per year to US$ 558 ppy.
Challenges and actions taken	**Accuracy of forecasts and patient data:** CHAI has experienced difficulty in obtaining forecasts and actual patient figures from some beneficiary countries, because formal systems to track patient and drug consumption data do not exist in these countries. A lack of communication between health facilities where patients receive ART and central medical stores that place orders with CHAI contributes to difficulties with forecasting and planning. Procurement processes related to ARVs and other HIV commodities will be enhanced through the Coordinated Procurement Planning (CPP) Initiative. The CPP facilitates the collection and sharing of information to allow countries and donors to assess the risk of treatment interruption due to gaps or delays in funding. It was initiated by PEPFAR, USAID, UNITAID, the Global Fund and the World Bank. **Transition to Alternative Funding Sources:** Some countries were able to successfully transition to alternative funding sources[5]. Others are still facing difficulties to transition to alternative funding. UNITAID and CHAI are developing a transition strategy. The Secretariat has set up an internal working group to address transition in all projects. **Signature of MoU with beneficiary countries:** the majority of countries signed MoU with CHAI, but a few are still missing. The Secretariat is working with CHAI to ensure that countries sign MoUs prior to UNITAID support.
Next Steps for project	• In 2011, the Project is part of two reviews: a mid-term review, conducted by the Swiss Tropical and Public Health Institute; and a procurement and financial review, conducted by Price Waterhouse Coopers(PWC) • Collaborative work with the Global Fund, PEPFAR and beneficiary countries on transition is on-going. • In 2011, a review of IDA Foundation's performance will be conducted, and the recommendations will be discussed with CHAI and IDAF. CHAI is responsible to select the firm to conduct the review. It is part of the 2011 budget.
Implications for sustainability	CHAI and UNITAID are working together on transition and sustainability - a priority for this project in 2011 - including engagement from the Secretariat with the Global Fund, PEPFAR and other potential donors.

[4] TDF/FTC (300mg/200 mg) & LPV/r (200 mg + 50 mg)

[5] These include: Cambodia (GFATM); Cote d'Ivoire (PEPFAR); Ethiopia (GFATM); Ghana (GFATM and PEPFAR); Malawi (GFATM); Namibia (GFATM and MOH); Rwanda (GFATM and PEPFAR); Senegal (GFATM and MOH); and Tanzania (GFATM and PEPFAR).

PROJECT TITLE: Paediatric HIV/AIDS Project

Key Partner(s): Clinton Health Access Initiative (CHAI)
Project Duration: November 2006 - December 2012
Updates for the Period Ending: December 2010

Updates	
Goals and Objectives	**Goals** and **Objectives**: • To scale up the access to Paediatric ARVs and related key commodities to increase the number of patients receiving treatment for HIV/AIDS in developing countries[6] • Influence market dynamics to achieve price reductions to increase the affordability of critical quality products. • Stimulate an increase in the number of quality assured manufacturers and products • Decrease product delivery lead times • Encourage prequalification of approved manufacturers and products • Apply appropriate procurement strategies to develop a healthy market that favors competition and sustainability, with reduction in prices • Reach an additional 70,000 new children in 2010
Finance	• Board Ceiling: US$ 380,057,634 • MoU Amount (as of December 2010): 252,135,000 • Cumulative Disbursement (as of December 2010): US$ 214,546,748 • 2010 Disbursement: US$ 68,224,000 • Last Project Year Budget: US$77,938,806 • Performance by the Partner against budget : US$69,258,138 • Performance by the Partner against budget (%): 89%
Achievements	For 2010, the project : • Added an additional 70,059 children in 2010, totaling 331,532 children on treatment at the end of 2010. • Increased supply and reduced prices of diagnostic and monitoring tests for children. • Provided an integrated package of care for children with HIV/AIDS, including therapeutic food to remedy malnourishment. • EID (Early Infant Diagnosis) programs experienced a 30% increase in testing volumes globally compared to 2009.
Project Progress	• The supplier selection process concluded in March 2010 and CHAI achieved price reductions ranging from 2-10% compared to 2009 prices on many ARV formulations, amounting to an overall price reduction of 48% on leading Zidovudine and Abacavir-based pediatric ARV regimens cumulatively from 2008 to 2010. • The 2010 supplier selection process saw the addition of 3 newly eligible suppliers

[6] Angola; Benin; Botswana; Burkina Faso; Burundi; Cameroon; Cambodia; China; Cote D'Ivoire; Dominican Republic; Democratic Republic of Congo; Ethiopia; Guyana; Haiti; India; Jamaica; Kenya; Lesotho; Liberia; Malawi; Mali; Mozambique; Namibia; Nigeria; Organization of Eastern Caribbean States (Antigua & Barbuda, Dominica, Grenada, Saint Kitts & Nevis, Saint Lucia, Saint Vincent and the Grenadines); Papua New Guinea; Rwanda; Senegal; Swaziland; Tanzania; Togo; Uganda; Vietnam; Zambia; and Zimbabwe

	of ARVs and 3 new stringent regulatory authorities (SRA) approved suppliers of ARVs purchased under the Project. However, the number of suppliers per product remained the same because some suppliers exited the market in 2010.
Challenges and actions taken	**Transition to Alternative Funding Sources:** The challenge is to find additional support for this nascent market and secure the gains that have been made by UNITAID and CHAI in the face of manufacturer expectations of a declining market based on successes in prevention of mother to child transmission of HIV (PMTCT). CHAI and UNITAID are in discussions with both The Global Fund and PEPFAR to coordinate transition of this project . A full report on transition, including detailed information about where the countries are in terms of transitioning to alternative funding source will be submitted by CHAI to EB14.
Next Steps for project	• In 2011, The Project is part of two reviews: a mid-term review, conducted by the Swiss Tropical and Public Health Institute; and a procurement and financial review, conducted by Price Waterhouse Coopers(PWC) • Collaborative work with the Global Fund, PEPFAR and beneficiary countries on transition is on-going. • In 2011, a review of IDA Foundation's performance will be conducted, and the recommendations will be discussed with CHAI and IDAF. CHAI is responsible to select the firm to conduct the review. It is part of the 2011 budget.
Implications for sustainability	Once UNITAID support ends, the possibility of fragmentation could threaten market sustainability with some countries placing lower volume orders. The need for new products and better formulations could be hampered by the currently fragmented market. UNITAID and CHAI work on transition is focused on ensuring a sustainable market for Pediatric ARVs.

PROJECT TITLE: ESTHERAID

Key Partner(s): ESTHER
Project Duration: July 2009 - July 2013
Updates For The Period Ending: December 2010

Updates	
Goals and Objectives	**Goal**s: Contribute to extending the number of patients on pediatric and/or second line ARVs in HIV treatment centers in Benin, Burkina Faso, Central African Republic, Cameroon and Mali **Objectives**: • Improve the pediatric and/or second-line ARV supply management system from the central medical store • Optimize delivery by identifying, rationally treating and monitoring patients needing pediatric and/or second line ARVs • Improve logistic information systems and patient monitoring systems in countries
Finance	• Board ceiling : US$15,950,000 • MoU Amount as at 31/12/2010 : US$14,680,988 • 2010 Disbursement : US$0 • Cumulative disbursements as at December 2010 : US$451,626 • Last Project Year Budget (2010) : No budget for 2010 • Performance by the partner against budget : Not applicable • Performance by the Partner against budget (%): Not applicable Note: As the project was launched in Q1 of this year, the first financial report on spending is due in September 2011.
Achievements	• The projects have been launched in all of the countries and MoUs have been signed with the respective Ministries of Health. • Project planning workshops for the implementation of the project have been held with local stakeholders. • Local implementing partners have been identified and contracts with them have been prepared • Project Managers for each country have been recruited and trained. • Specific project outcomes, reported against the objectives of the project will be provided in the Semi-Annual Report in September 2011.
Project Progress	• The ESTHERAID project has been implemented in two phases. o Phase I (now complete) provided evaluations of the 5 countries. The evaluations highlighted barriers to access to UNITAID funded pediatric and 2nd Line ARVs in the targeted countries. The results of the evaluations are the basis of the Project Plans for Phase II and the data collected will provide the baseline for ongoing M&E of the project. o An MoU between UNITAID and ESTHER was signed in Dec 2010 for the second Phase of this project. Implementation has begun and a detailed report of outcomes is expected in September of this year.

Challenges and actions taken	**Benin :** UNITAID funded drugs (procured by CHAI) were detained at the airport in Benin in Q2 of 2011. A quality control assessment of the drugs was required before the drugs could be distributed to treatment centers as a result of the length of time that they were held at the airport. ESTHER worked closely with Benin and UNITAID to ensure that this quality control was done. The results were positive and all of the drugs except one qualified for distribution. **Central African Republic :** The launch of the ESTHERAID project was delayed in CAR due to national elections. The project was launched in CAR on the 17th June 2011.
Next Steps for project	• The first Semi-Annual Report will provide a basis for a detailed analysis of the projects progress and its contribution to UNITAIDs KPIs.
Implications for sustainability	The ESTHERAID project is expected to have a positive impact on transition and sustainability of pediatric and second line ARVs. The project will help UNITAID address 'in country' management of commodities procured through other projects. The ESTHERAID project is designed to improve the national Procurement and Supply Management capacities which will strengthen country supply chain management capacities.

PROJECT TITLE: Acceleration of PMTCT and Scale up of Linkages to Paediatric HIV Care and Treatment (PMTCT I)

Key Partner(s): UNICEF and WHO
Project Duration: December 2007- December 2009. A one year extension has been granted (January 2011 - December 2011)
Updates For The Period Ending: December 2010

Updates	
Goals and Objectives	**Goals:** The acceleration of Prevention of Maternal to Child Transmission of HIV (PMTCT) and the scale up of linkages to pediatric HIV care and treatment in Burkina Faso, Malawi, Rwanda, Cote d'Ivoire, India, Tanzania, Zambia and Cameroon **Objectives:** • Accelerate the scale-up of provider-initiated HIV testing and counseling in antenatal, maternity and postpartum services • Reduce the proportion of infants born with HIV through the provision of more efficacious ARV regimens, including ART, to women and their newborn. • Accelerate early access of young HIV-infected infants to paediatric ART through optimized identification strategies, such as Early Infant Diagnosis. • Reduce morbidity and mortality among HIV-infected pregnant women, mothers and their infants through the provision of co-trimoxazole prophylaxis for the prevention of opportunistic infections. • Increase access to ART for eligible HIV-infected women. • Achieve continuous supply of suitable, high-quality PMTCT medicines, diagnostics and other commodities at the best possible price and facilitate price reduction.
Finance	• Board Ceiling : US$49,692,859 • MoU Amount as of December 2010 : US47,602,092 • 2010 Disbursement: US$0 • Cumulative Disbursements (as of December 2010): US$19,831,957 • Last Project Year Budget (2010) : No budget for 2010 • Performance by the Partner against Budget : Not Applicable • Performance by the Partner against Budget (%) : Not Applicable
Achievements	• Treatments - ART for HIV positive pregnant women: 31,253 • Prevention - ARVs to prevent mother to child transmission: 197,247 • Prevention - Cotrimoxazole provided to HIV+ women: 99,774 • Prevention - Cotrimoxazole : 87,264 • Pregnant women HIV tests: 2,223,814 • HIV positive pregnant women CD4 tests : 361,850 • Tests-HIV for Early Infant Diagnosis : 37,632
Project Progress	• The original PMTCT 1 project was completed in 2009 and a final report is due later this year. • The PMTCT 1 extension will continue until the end of 2011. This extension was granted to enable UNICEF and WHO to work with country programs to identify alternative sources of funding going forwards. • The Amendment to the MoU that allows for the PMTCT I extension includes changes to the reporting format which will ensure that UNICEF reports more clearly to inform UNITAIDs KPIs

	• A Mid-Term-Review of this project is ongoing. • UNICEF has demonstrated strong internal management structures and extensive capabilities in the area of procurement.
Challenges and actions taken	**Transition:** This project ended in December 2009. "Bridge funding" was made available at the beginning of 2011 to enable UNICEF and country programs to identify sustainable and reliable sources of funding for PMTCT commodities going forwards. UNICEF and country programs were able to supply PMTCT related commodities during 2010 by using commodities procured during 2009 and by using country program and other sources of funding. **Mother Baby Pack:** Concerns were raised by "Aids Free World" (and others) in March 2011 as to the appropriateness and effectiveness of the Mother Baby Pack. At that point in time, the MBP had only been distributed in Kenya. UNICEF has suspended the distribution of the Mother Baby Pack and has established an External Technical Advisory Group to address the concerns raised. The expectation is that the concerns raised will be adequately addressed and that the MBP will be rolled out in the future. **Market Impact:** The impact of the PMTCT project on the demand for HIV-related products in general (over and above the demand within the context of PMTCT) has not been discussed or reported on in this project. UNITAID is working with UNICEF and the WHO to address this in future reports. **Virtual Elimination of MTCT:** UNICEF/WHO/UNAIDS have set the goal of virtual elimination of Maternal to Child Transmission of HIV (MTCT) by 2015. Market shortcomings may need to be mitigated if this goal is to be reached. UNITAID is working with UNICEF and WHO to identify and understand any market related issues that may need to be addressed towards elimination of MTCT.
Next Steps for project	• UNICEF will produce a final report in July 2011 that we expect will address both the public health and market dynamics impact of this project. • UNICEF will do a financial reconciliation of the PMTCT I project and return any unspent money. • The results of a Mid-Term-Review will provide recommendations for many of the programmatic issues related to this initiative. The implementation of the "extension" until December 2011 will be improved through this review. • UNICEF/WHO will report on progress made in the PMTCT extension in the Semi-Annual Report in September 2011, in particular on progress made in terms of securing alternative sources of funding for PMTCT products in the future.
Implications for sustainability	UNICEF and WHO are working with country programs to ensure that alternative source of funding are identified for the continuation and scaling up of national PMTCT programs. UNICEF and WHO are working with country programs to strengthen PSM capabilities in the context of scaling up PMTCT activities towards "virtual elimination by 2015"

PROJECT TITLE: PMTCT Expansion Component (PMTCT II)

Key Partner(s): UNICEF and WHO
Project Duration: July 2009 - July 2011
Updates For The Period Ending: December 2010

Updates	
Goals and Objectives	**Goals:** The acceleration of prevention of mother to child transmission of HIV (PMTCT) and Scale up of Linkages to Paediatric HIV Care and Treatment in 9 additional countries[7]. **Objectives:** • Accelerate the scale-up of provider-initiated HIV testing and counseling in antenatal, maternity and postpartum services • Reduce the proportion of infants born with HIV through the provision of more efficacious ARV regimens, including ART, to women and their new born. • Accelerate early access of young HIV-infected infants to paediatric ART treatment through optimized identification strategies, such as Early Infant Diagnosis. • Reduce morbidity and mortality among HIV-infected pregnant women, mothers and their infants through the provision of co-trimoxazole prophylaxis for the prevention of opportunistic infections. • Increase access to ART for eligible HIV-infected women. • Achieve continuous supply of suitable, high-quality PMTCT medicines, diagnostics and other commodities at the best possible price and facilitate price reduction.
Finance	• Board Ceiling : US$50,009,221 • MoU Amount as of December 2010 : US$46,679,993 • 2010 Disbursement : US$28,446,003 • Cumulative Disbursements as of December 2010 : US$46,679,993 • Last Project Year Budget : US$18,223,990 • Performance by the Partner against Budget for June 2009 - July 2010 : US$15,165,141 • Performance by the Partner against Budget for June 2009 - July 2010 (%) : 83%
Achievements	• Treatments- ART for HIV positive pregnant women : 33,624 • Prevention - ARVs to prevent mother to child transmission : 614,724 • Prevention - Cotrimoxazole provided to HIV+ women : 97,316 • Prevention- Cotrimoxazole : 40,124 • Pregnant women HIV tests : 5,787,864 • HIV positive pregnant women CD4 tests : 426,750 • Tests-HIV for Early Infant Diagnosis : 25,056
Project Progress	• The PMTCT II project ends as of July 2011. UNICEF and WHO have submitted a request to have this project extended for a year. This application will be considered by the UNITAID Board in July 2011. • A Mid-Term-Review of this project is ongoing. • UNICEF has demonstrated strong internal management structures and extensive capabilities in the area of procurement.

[7] Central African Republic, China, Haiti, Lesotho, Myanmar, Nigeria, Swaziland, Uganda, and Zimbabwe

Challenges and actions taken	**Transition:** Planning for the transition to alternative sources of funding for PMTCT related commodities started late. Most of the PMTCT II countries were not successful in their round 10 Global Fund applications. UNICEF/WHO have applied to UNITAID for a one year extension to the project to facilitate transition to alternative sources of funding. **Mother Baby Pack:** Concerns were been raised by "Aids Free World" (and others) in March 2011 as to the appropriateness and effectiveness of the Mother Baby Pack. At that point, the MBP had only been distributed in Kenya. UNICEF has suspended the distribution of the Mother Baby Pack and have established an External Technical Advisory Group to address the concerns raised. The expectation is that the concerns raised will be adequately addressed and that the MBP will be rolled out in the future. **Market impact:** The impact of the PMTCT project on the demand for HIV related products in general (over and above the demand with in the context of PMTCT) has not been discussed or reported on in this project at all, despite possibly being one of the most important outcomes. UNITAID is working with UNICEF and WHO to address this in future reports. **Virtual Elimination of MTCT:** UNICEF/WHO/UNAIDS have set the goal of virtual elimination of Maternal to Child Transmission of HIV (MTCT) by 2015. Market shortcomings may need to be mitigated if this goal is to be reached. UNITAID is working with UNICEF and WHO to identify and understand any market related issues that may need to be addressed towards elimination of MTCT.
Next Steps for project	• In the event that the UNCEF / WHO application for a 1 year extension to PMTCT II is successful, UNICEF / WHO will be asked to draft a Project Plan that includes an updated reporting format to ensure that the project reports its results in a way that informs UNITAID's key performance indicators (KPIs). • If its extension application is not successful, UNICEF will produce a final report that we expect will address both the public health and market dynamics impact of this project. • The results of a Mid-Term-Review will provide recommendations for the programmatic issues related to this initiative. It will also inform the management of the PMTCT II extension, if this application is successful.
Implications for sustainability	Most country programs supported by PMTCT II were not successful in their applications for Global Fund Round 10. UNICEF / WHO have submitted an application for an extension to PMTCT II for one year to facilitate transition to alternative sources of funding. UNICEF and WHO are working with country programs to strengthen PSM capabilities in the context of scaling up PMTCT activities towards "virtual elimination by 2015"

PROJECT TITLE: PMTCT Nutrition (PMTCT III)

Key Partner(s): UNICEF / WHO
Project Duration: July 2009 - July 2011
Updates For The Period Ending: December 2010

Updates	
Goals and Objectives	**Goals**: Prevention of maternal to child transmission of HIV, nutrition (PMTCT III) addresses the major nutritional problems associated with HIV in four of the PMTCT I countries[8] . **Objectives**: Address severe acute malnutrition (SAM) among: • HIV-infected pregnant women (screened for anaemia; anthropometry screening performed and if SAM, provided with RUTF); • HIV-uninfected pregnant women (screened for anaemia and if SAM, interventions as per national treatment guidelines); • HIV-exposed infants who are HIV-uninfected (screening for anaemia; anthropometry screening performed and if SAM, provided with RUTF); and • HIV-exposed infants who are HIV-infected (screening for anaemia; anthropometry screening performed and if SAM, provided with RUTF) identified through PMTCT services.
Finance	• Board Ceiling : US$4,764,228 • MoU Amount as of December 2010: US$4,510,847 • 2010 Disbursement : US$2,219,563 • Cumulative Disbursements (as of December 2010) : US$4,510,847 • Last Project Year Budget : US$2,291,284 • Performance by the Partner against Budget for June 2009 - July 2010 : US$2,175,525 • Performance by the Partner against Budget for June 2009 - July 2010 (%) : 95%
Achievements	• Prevention - RUTF : 74,603 severe and acute malnutrition cases treated with RUTF • RUTF for management of SAM cases linked to PMTCT and paediatric ART services has been associated with increased uptake of PMTCT and paediatric HIV care services and significant reductions in loss to follow up and Nutrition Commodities Supply Chain is now integrated into the national health commodities supply chain in Rwanda.
Project Progress	• During the second half of 2010 the four countries did not request RUTF and/or diagnostic commodities as they continued to use supplies previously ordered in Year 1 of the project or further exhausting existing stocks supplied by other in-country partners (i.e., PEPFAR, CHAI). • Although no commodity requests were received within the 1st half of Year 2, the price of RUTF remains comparable to its baseline price, as existing LTAs with Suppliers continue to apply into the second quarter of 2010. • During the 2010 a Request of Expression of Interest (EOI) for potential suppliers of

[8] Malawi, Rwanda, Tanzania and Zambia

	RUTF was published with a pre-bid conference held for potential suppliers in Copenhagen on 18 October 2010. The RFP was launched by UNICEF on 29 October 2010 soliciting proposals from 31 companies. Offers have since been received from 27 companies. The first LTAs were established early in 2011. • No new tenders for anaemia diagnostics devices were issued in 2010. • LTAs for the supply of HemoCue analyzers are in place and valid until the end of 2011.
Challenges and actions taken	**Rwanda:** notes a bottleneck related to M&E indicators: i) Nutrition indicators in National HMIS are currently not disaggregated by HIV status making it difficult to monitor progress in the PMTCT/nutrition program at national level. UNITAID is working with UNICEF to better understand and address this problem. **Tanzania**: It is challenging to coordinate among the various development partners supporting HIV and nutrition services[9] and alignment of supplies. UNITAID is working closely with the Coordinated Procurement Planning initiative to develop strategies to improve coordinated procurement.
Next Steps for project	• UNICEF / WHO have submitted an application to UNITAID for a one year extension to this project to facilitate transition to alternative sources of funding. • In the event that the application for an extension is successful, the UNITAID secretariat will work with UNICEF / WHO and establish an Amendment to the MoU that includes changes to the current reporting protocols to ensure that UNITAID receives data that informs reporting of UNITAID's key performance indicators (KPIs).
Implications for sustainability	In the context of UNICEF / WHO's plans to scale up PMTCT activity (and linkages to pediatric HIV care and treatment) towards virtual elimination by 2015, the provision of RUTF and the associated focus on nutritional care will have to be scaled up in parallel. UNICEF and WHO have hosted two meetings aimed at developing a framework for scale up of PMTCT in African countries that includes focus on nutritional components of care. There are other funding agents who are providing funds for RUTF[10] . UNICEF / WHO need to work closely with country programs to ensure that funding is coordinated and that PSM is carefully planned in this area. The fact that no procurement took place in 2010 with UNITAID money is an indication of poor demand forecasting in this area. Long terms sustainability in this area will require that this be addressed by the global community of donors and country authorities

[9] PEPFAR/CHAI/FANTA/Global Fund
[10] PEPFAR are funding countries that overlap with UNITAID countries.

PROJECT TITLE: Assured Artemisinin Supply Service (A2S2)

Key Partner(s): i+solutions
Project Duration: July 2009 - June 2011
Updates for the Period Ending: December 2010

Updates	
Goals and Objectives	**Goals:** To support the global production of sufficient Artemisia/Artemisinin to meet the expanded needs for ACTs, specifically following the introduction of the AMFm. **Objectives:** • Expansion of Artemisinin supply to help meet the ACT needs in 2010/11, through a revolving Artemisinin Pre- Finance Facility to artemisinin extractors selected by eligible ACT suppliers: The projects aims to support production of 40 Metric Ton of additional artemisinin in two years. • Collection and on-line sharing of market intelligence on the actual artemisinin supply situation, enhancing transparency and market-responsiveness. • Contribution to the development of a stable artemisinin supply market at fair prices.
Finance	• Board ceiling: US$9,280,400 • MoU amount (as of December 2010): US$ 9,280,400 • 2010 Disbursement: US$0 • Cumulative Disbursement (as of December 2010): US$9,280,400 • Last Project Year Budget: Operating cost from June 2009-July 2010 of $480,200. The loan fund of $8.4m goes across 2 years. • Performance by the Partner against budget: US$363,606 for operational cost and loan worth US$3.9 million. • Performance by the Partner against budget: 74% of operational cost and 46% of loan
Achievements	• As of the end of 2010, loan contracts for 26MT artemisinin (65% of the project target and 15% of the global market) have been approved. • The tripartite loan agreements concluded are with three extractors and three ACT manufacturers, namely: ▪ Artemisinin extractor Innovexx-Bionexx based in Madagascar with Cipla Ltd. ▪ Artemisinin extractor Benjing-Jinko based in China with Novartis, ▪ Artemisinin extractor Vedic Faxipan based in Vietnam with Sequent
Project Progress	Status of the loan contracts • Contract 1: Innovex-Bionexx and Cipla: The artemisinin extractor Innovex-Bionexx outsourced the extraction service to Extraction Technologies Limited (EDL) based in the UK. Due to raw material and extraction process delays, delivery of artemisinin and loan repayment has not yet started. • Contract 2: Beijing Ginko and Novartis: The artemisinin extractor Beijing Ginko has not started delivery of artemisinin to Novartis. Beijing Ginko allegedly sold the artemisinin at higher price to other buyers and UNITAID has requested the project management to provide further information and the actions that will be taken to

	resolve the problem. • Contract 3: Vidic and Strides: The contract between the artemisinin extractor Vidic based in Vietnam and Strides was concluded in September 2010 and artemisinin delivery and loan repayment is not yet due. • Negotiation for three loan agreements for an additional 24MT of artemisinin is ongoing. • The project has also facilitated contracts that do not involve A2S2 project loans between extractors and producers for 18MT of artemisinin. • **M**id-term evaluation of the project has been completed.
Challenges and actions taken	**Loan agreements:** Due to the involvement of tripartite agreements, completing the loan agreements was lengthy and time consuming. **Financial regulations**: Regulations in China restricted timely conclusion of loan agreements with artemisinin extractors. To overcome the problem, the project management agreed with Novartis for Novartis to channel the fund to the extractor **Market information:** Obtaining market information on the status of supply and price of artemisinin has been difficult due to confidentiality issues aimed at preventing company interests. UNITAID has requested the project management for more information and regular updates. **Delivery:** artemisinin delivery from one extractor has been delayed due to technical problems and lack of due diligence on the part of the extractor Bejing-Ginko. UNITAID has requested the project management to provide monthly update on the delivery status of artemisinin and loan repayment.
Next Steps for the project	Dalberg completed a mid term review of this project. The UNITAID Secretariat will follow-up with i+solutions to ensure implementation of the review recommendations.
Implications for sustainability	• Access for malaria treatment services in endemic countries is increasing through a number of global initiatives[11] and the demand for ACTs is likely to increase. • Endemic countries place orders for ACTs based on the amount of funds that they have secured and the pace at which these funds are made available to them. • ACT manufacturers plan production around forecasted ACT orders from endemic countries and donors. • The limited funding available to endemic countries and the ACT manufacturers production plan based on firm orders only creates an unpredictable demand and supply scenario. • The unpredictability in the ACT market also creates unpredictable supply and demand in the artemisinin market. • To prevent risk of shortfall of artemisinin and ACTs, therefore, engaging with all stakeholders is crucial.

[11] Including the UNITAID supported Affordable medicines for Malaria (AMFm) initiative.

PROJECT TITLE: ACT SCALE UP

Key Partner(s): The Global Fund; UNICEF
Project Duration: December 2007 to mid 2010
Updates for the Period Ending : December 2010

Updates	
Goals and Objectives	**Goals:** To scale up ACT treatment for malaria and to positively impact market dynamics to increase the affordability of ACTs. **Objectives:** • Scale up the number of patients accessing and receiving ACT treatment; • Decrease drug delivery lead times and prevent stock outs • Increase the number of quality manufacturers and products, and • Achieve continuous supply of high quality ACTs at the best possible price and facilitate price reductions
Finance	• Board Ceiling: US$78,887,568 • MOU amount (as of December 2010): US 65,413,057 • Disbursement in 2010: US$0 • Cumulative disbursements (as of December 2010): US$36,613,871.19 • Last Project Year Budget : US$21,336,351 • Performance by the Partner against budget : US$17,185,328 • Performance by the partner against budget (%): 81% Note: UNICEF had submitted a request for disbursement in 2010, but UNITAID Secretariat decided to not remit the requested funds as the remaining cash balance with UNICEF could fully cover the projected procurement.
Achievements	• ACT treatments delivered ▪ 2008-2010 (cumulative): 27,715,270 ACTs ▪ 2010: 12,553,840 ACTs • Buffer Stock/prevent stock outs: UNITAID is not aware of any stock out situations in country. • Quality Manufacturers and Products: For 2010, no additional oral ACT was prequalified although, artesunate powder for injection was prequalified.
Project Progress	Expected to complete the treatment deliveries in 2011, the project is lagging behind in terms of timeline. The Global Fund reported that as of December 2010, out of 12 participating grants: ▪ 4 have fully utilized their UNITAID allocations[12] ▪ 7 grants are in progress of implementing UNITAID funded ACTs[13] ▪ 1 grant (South Sudan) has not yet used its UNITAID funded ACTs Delays were due to: ▪ Delayed project start (due to prolonged MOU negotiations), which deferred delivery schedules for Cambodia, Ethiopia, Madagascar and South Sudan. ▪ Delayed signing of Implementation Letters between GF and Principal Recipients

[12] Cambodia, Indonesia, Ghana, and North Sudan.
[13] Madagascar PSI, Madagascar CRESAN, North Sudan, Zambia MoH, Zambia CHAZ, Ethiopia and Mozambique.

	(notably Ethiopia and South Sudan) ▪ Negotiations relating to change in participating grant (Cambodia, Madagascar, South Sudan and Zambia), as these grants reached their closure date before absorbing their UNITAID funded ACT treatments ▪ GF process of grant consolidation
Challenges and actions taken	**Measuring progress:** Measurement of progress against targets is constrained by the fact that the results reported by the Global Fund (in terms of people treated) represent combined results and are not necessarily attributable to UNITAID. **Grant Performance:** The procurement of ACTs is only one of the multiple service delivery areas of Global Fund grants participating in this project. Therefore, a participating grant that has not done well in the area of "people treated with ACTs" but has performed well in other service delivery areas may be rated as well performing under the GF rating system.
Next Steps	• The Global Fund has indicated its intention to submit a formal request for no-cost extension to 2013 in order to allow 3 grants (Madagascar PSI, South Sudan and Zambia MOH) to use their treatment targets. • An external mid-term review is expected to be completed by the end of July 2011 and recommendations will inform how UNITAID proceeds with this project.
Implications for sustainability	This is time-limited support from UNITAID to The Global Fund and UNICEF.

PROJECT TITLE: Affordable Medicines for Malaria (AMFm)

Key Partner(s): The Global Fund
Project Duration: November 2009 - April 2012
Updates for the Period Ending: December 2010

Updates : A project update (as of May 2011) including information submitted to the AHC is provided as a separate document.	
Goals and Objectives	**Goals:** To reduce malaria-related mortality and delay resistance to effective antimalarial treatments by reducing the price of ACTs, the only effective treatment remaining for malaria, in the private, retail sector in 8 countries [14]. **Objectives :** • Increase affordability of ACTs by co-paying for a substantial portion of the price of ACTs • Increase availability of ACTs for all malaria affected populations through the public, NGO and private sectors in Beneficiary Countries • Increase the market share of ACTs to displace the artemisinin oral mono-therapies
Finance	• Board ceiling: US$130,000,000 • MoU amount (as of December 2010): US$130,000,000 • 2010 Disbursement: US$65,000,000 • Cumulative Disbursement (as of December 2010): US$130,000,000 • Last Project Year Budget : No annual budget is attributed • Performance by the Partner against budget: US$29.49 reported as spent in 2010 against the pooled fund provided by UNITAID, DFID and Gates Foundation. • Performance by the Partner against budget: Not applicable
Achievements	• Ghana and Kenya were the first two countries to receive deliveries of co-paid ACTs in August 2010. • Delivery of ACTs started in August 2010. As of December 2010, orders for 29.4 million ACTs were approved. 4.54 million (15.5%) of these orders have now been delivered to Ghana, Kenya, Madagascar and Tanzania.
Project Progress	• Delivery of AMFm ACTs started nine months after signing of the AMFm agreement between UNITAID and The Global Fund. The delay was mainly due to the lengthy AMFm host grant amendments. • AMFm co-paid ACTs have are now arriving in all countries except Cambodia, Uganda and Tanzania (Zanzibar). • Baseline outlet surveys and contextual information collection for the AMFm Independent Evaluation (IE) have been completed in all participating countries. • TGF is collaborating with Interpol to monitor counterfeiting and diversion of AMFm co-paid ACTs. The first assessment completed in August 2010 in Tanzania, Uganda and Kenya reported no issues. • Eleven operational research projects coordinated by CHAI are currently ongoing in seven AMFm countries and one non-AMFm country.

[14] Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania, Uganda

Challenges and actions taken	**Cambodia:** The drug of choice for Cambodia, Dihydroartemisinin Piperaquine is not yet WHO prequalified or Expert Review Panel (ERP) approved. As a result, Cambodia will not receive the drug through the AMFm. **Rational use of ACTs:** The increase in the availability of ACTs in the AMFm countries is not supported by a corresponding increase in rapid diagnostic tests. The UNITAID Secretariat has been raising concerns about improving the rational use of ACTs through improved diagnosis of malaria with rapid tests in the AMFm Ad Hoc Committee (AHC) meetings. **Demand Forecasting:** The Boston Consulting Group (BCG) led a consortium to produce an ACT demand forecast for AMFm that estimates that 141 million treatments will be needed for 2011 and 160 million for 2012. This is 54% and 59% of the forecasted global ACT demand for the 2011 and 2012, respectively. In-country data collection on ACT consumption is being planned with BCG to address a limitation in the forecasts which are based on models and not yet supported by consumption data from countries.
Next Steps for the project	The UNITAID Secretariat is currently working with The Global Fund to: • Ensure continuation of delivery of AMFm co-paid ACTs to eligible first-line buyers in Phase I countries, • Refine ACT demand forecast estimates for AMFm countries to inform disbursement decisions, • Follow status of implementation of the independent evaluation on availability, affordability and market share of ACTs as well as use of ACTs by the poor/vulnerable groups. • Monitor status of ACT utilization in-countries.
Implications for sustainability	The decision on whether to scale-up, modify, suspend or terminate the AMFm will be made by The Global Fund Board based on findings of the Independent Evaluation (IE) and recommendations of AMFm Ad Hoc Committee (AHC). The UNITAID commitment is limited to Phase I of the AMFm. The issues of concern to UNITAID during this phase will be: a) the availability of adequate funding for ACTs for the period of implementation of Phase I, and, b) To ensure availability of funding for ACTs to support responsible exit in case of termination of the AMFm. The cost implications for either or both these scenarios will need to be presented and decided by the UNITAID Board at EB 14.

PROJECT TITLE: Accelerating Scale-up of Long Lasting Insecticide Treated Nets

Key Partner(s): UNICEF
Project Duration: February 2009 - December 2010
Updates For The Period Ending: December 2010

Updates	
Goals and Objectives	**Goals:** To increase access to insecticide-treated mosquito nets for the prevention of malaria in eight countries in Sub-Saharan Africa. To reduce global market price of quality Long Lasting Insecticidal Nets ("LLINs") through injection of secured funding and support to market stabilization. **Objectives:** • Support eight African countries[15] to achieve Roll Back Malaria Partnership ("RBM") targets of 80% Insecticide Treated Net ("ITN") use by 2010. • Secure the additional financing to procure and distribute 20 million WHOPES recommended nets to support LLIN needs identified by the national plans in 8 high burden malaria countries[1]. • Introduce stability to the global LLIN market through increased investment and appropriate procurement strategies, leading to increased competition and lower prices.
Finance	• Board ceiling: US$109,250,000 • MoU amount (as of December 2010): US$109,246,140 • 2010 Disbursement: US$ 0 • Cumulative Disbursement (as of December 2010): US$109,246,140 • Last Project Year Budget: No budget for 2010 • Performance by the Partner against budget (cumulative): US$100,794,000 • Performance by the Partner against budget (cumulative) (%): 92%
Achievements	• 20 million WHO Pesticide Evaluation Scheme (WHOPES) recommended LLINs have been delivered to eight countries. • Price reductions of between 2.5% (small LLINs) and 17.3% (conical LLINs) were achieved respectively since 2007 and 2010. • The target lead-time for delivery of 12 weeks was achieved for 80% of the purchase orders. • During the implementation period, three new LLIN products obtained WHOPES recommendations bringing the total number to eight as of December 2010.
Project Progress	• Implementation of this project was completed in December 2010 as scheduled. • A remaining batch of 420,000 LLINs was distributed in the Central African Republic in January 2011. • There are no pending implementation issues.

[15] Angola, Congo-Brazzaville, Central African Republic, DRC, Guinea, Nigeria, Sudan, and Zimbabwe

Challenges and actions taken	**Storage of LLINs:** Availability of storage facilities was a challenge during the implementation of this project. To ensure optimal storage, LLIN delivery points suitable to warehouse locations were selected. **Distribution to households:** Distribution of LLINs to households in some countries was delayed due to lack of operational funds.
Next Steps for the project	• An external end of project evaluation is being done in 2011 and will make recommendations to inform the implementation of similar projects in the future.
Implications for sustainability	The UNITAID funding for this project was a one time support. However, evidence suggests that the useful life of LLINs ranges from 3 to 5 years. ITNs distributed in 2008 and 2010 will soon need to be replaced. Maintaining effective LLINs in high burden malaria countries will require continued funding from other sources.

PROJECT TITLE: First Line Anti-TB Drugs Initiative

Key Partner(s): The Stop TB Partnership Global Drug Facility
Project Duration: September 2007 - December 2011
Updates For The Period Ending: December 2010

Updates	
Goals and Objectives	**Goals :** To support first-line TB control and to positively impact TB drug market dynamics so as to increase the affordability and availability of high quality first-line anti-TB drugs. **Objectives:** • Establish Transitional Grants**:** minimize the risk of stock-outs and therefore drug resistance among countries that will face a gap in drug supply between the end of a GDF grant and the beginning of a planned future source of funding for first-line anti-TB drugs; • Establish Strategic Rotating Stockpile(s)(SRS)**:** reduce lead times and overall treatment costs for drug deliveries by reducing the ratio of expensive freight/emergency orders to non-expensive freight/urgent orders A no-cost extension signed by all parties in December 2009 will come to an end in December 2011. The key objectives for the no cost extension of this Project is as follows: • To facilitate the delivery of consignments under the Transitional Grants for two of the 19 countries and; • 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).
Finance	• Board ceiling: US$27,646,256 • MoU Amount (as of December 2010): US$27,645,947 • 2010 Disbursement: US$0 • Cumulative disbursement (as of December 2010): US$27,645,947 • Last Project Year Budget: No budget for 2010 • Performance by the partner against budget: Not applicable • Performance by the partner against budget for 2010 (%) : Not applicable
Achievements	• 785,080 first-line TB treatments were ordered, supplied and delivered to all 19 countries to avoid stock-outs and ensure sufficient in-country stocks until anti-TB drugs paid for from alternative funding sources were provided. • In 2010, the number of countries accessing the SRS has steadily decreased from a reported 54 countries accessing the Stockpile in 2008 to a reported 29 countries in 2010. • During 2010 four priority first-line TB drugs were prequalified bringing the total number of pre-qualified drugs to thirteen out of the 16 UNITAID priority products identified for pre-qualification. • 15 product prices decreased or remained within 10% of the baseline price • One product price increased between 11-20%
Project Progress	• All funds related to this project have been disbursed (as of February 2008). • The no-cost extension signed in 2009 has been implemented.

Challenges and actions taken	**Price:** One product Streptomycin (1g) increased in price significantly. This is due in part to the fact that the Streptomycin previously supplied through GDF was no longer eligible and an alternate source was used. **Stock-outs:** Three country representatives (Nepal, Uganda and Zambia) reported the risk of stock-out of first-line drugs. A request for clarification and mitigation of risk for the reported countries was sent by UNITAID. In December 2010 the GDF responded stating the key factors contributing to delays for the reported was as follows: o Late disbursement of GFATM funds o Delayed periods for the signing of Grants and Technical Agreements o Availability of quality assured Streptomycin While no actual stock-outs were reported, UNITAID is working with GDF to better understand the risks of stock-outs in these countries and to identify practical steps that can be taken to mitigate those risks in the future. **Streptomycin shortage:** At the World Union Conference on Lung Health, WHO/STB reported a global shortage of Streptomycin. The breakdown in the supply was mainly based on the GDF's quality criteria which resulted in the main supplier of the API being unable to meet the demand. UNITAID has requested further information from the GDF on the steps taken to avoid such supply disruptions in the future. Currently there are 4 suppliers of S 1 with SRA status.
Next Steps for project	• This project will end in Dec 2011. A final report will be due in Q1 of 2012 • GDF has requested that unspent 1st Line funds be reallocated to the SRS. An Amendment to the MoU to that effect is pending and will be contingent on changes to the current reporting framework being used by GDF for this project. • A mid-term review of this project is ongoing. The results of this review will be presented to the Board in Nov. The results of this review will inform ongoing TB projects with GDF.
Implications for sustainability	This project is coming to an end in December 2011.

PROJECT TITLE: MDR-TB DIAGNOSTICS

Key Partner(s) : WHO's Global Laboratory Initiative, Foundation for Innovative New Diagnostics, The Stop TB Partnership's Global Drug Facility
Project Duration : January 2009 - December 2013
Updates for the Period Ending: December 2010

Updates	
Goals and Objectives	**Goals:** • To narrow the diagnostic gap in MDR-TB control by expanding and accelerating access to new and rapid diagnostic technologies within appropriate laboratory services at country level, accompanied by the necessary know-how for technology transfer, and ensuring these new technologies are properly integrated within TB control programmes to address one of the key obstacles to the scale-up of MDR-TB care. • To identify an estimated 119,000[16] patients with MDR-TB in priority settings in 27 countries, thereby achieving a significant impact on the global gap in scaling up access to diagnosis of MDR-TB. **Objectives:** • To expand and accelerate access to modern TB diagnostic technologies; • To leverage price reductions for diagnostic tools, instruments, reagents, and supplies and stimulate a greater number of suppliers of modern TB diagnostics; and • To 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
Finance[17]	• Board Ceiling : US$89,663,434 • MoU Amount (as of December 2010) : US$89,611,950 • 2010 Disbursement : US$18,228,934 • Cumulative disbursements (as of December 2010) : US$38,216,465 • Last Project Year Budget 2010 : US$25,365,855 • Performance by the Partner against budget : US$7,437,391 • Performance by the Partner against budget (%) : 29%
Achievements	• 4,166 patients have been diagnosed in 6[18] countries. Where MDR-TB patients have been detected, most are already on treatment. • 10 out of 24 targeted countries[19] have received diagnostic equipment and supplies. • Price reductions of 5%[20] generated for BBL MGIT tubes for use in Bactec MGIT 960 (7ml).
Project Progress	• Delays have occurred in infrastructure upgrade, policy and implementation. One of the key phases is the ''Laboratory preparedness'' and this has proven to be a complex and labor intensive phase of project implementation. • Two countries that had committed to be part of the EXPANDx-TB project have not been able to sustain their commitments and have withdrawn from the Project. • The project has completed its second year of implementation and most countries have

[16] Adjusted target as of December 2010. Original estimated target 129,000 was based on WHO data available in 2008
[17] Includes 2006-2007 PSC on all projects and 2008-2010 PSC on GDF (3%)
[18] Uzbekistan, Uganda, Myanmar, Lesotho, India, Ethiopia
[19] Lesotho, Ethiopia, Cote d'Ivoire, Myanmar, Uzbekistan, India, Georgia, Kyrgyzstan, Haiti, Djibouti
[20] 2009:US$205 and 2010 US$195 per pack

	completed their laboratory needs assessments, mapping of partner efforts at country level and the introduction of new diagnostics.
Challenges and actions taken	**Access to second-line TB drugs:** A key challenge is to mitigate the risk of diagnostics outpacing MDR-TB control efforts. There is a need to supply treatments to match the number of people diagnosed with MDR-TB through improved technology. UNITAID continues to collaborate with the GLI, GLC, GDF and FIND to ensure that treatments are available for UNITAID supported EXPANDx-TB countries. **In country capacity and implementation:** As different countries have different laboratory capacities, they have been divided into three categories to allow for start up of the project based on their respective capacities.
Next Steps for project	• The EXPANDx-TB Partners have submitted a rationale requesting a re-allocation of the EXPANDx-TB funds for the introduction of this technology. It is proposed for six of the EXPANDx-TB countries. UNITAID is currently reviewing the request for re-allocation of the budget to facilitate the procurement of 23 instruments (Xpert MTB/RIF) these countries. • The partners have proposed the inclusion of two new countries to substitute for the two[21] that had to withdraw from the project. The rationale for inclusion of the new countries is being reviewed by UNITAID for approval.
Implications for sustainability	Partners need to identify a transition strategy either to government or to another funding agency.

[21] Democratic Republic of Congo and Zambia

PROJECT TITLE: MDR-TB Scale-Up Initiative

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 Duration: July 2007 - December 2012** **Updates for the Period Ending: December 2010**

Updates	
Goals and Objectives	**Goals** : To finance an increase in the number of patients accessing and receiving quality second-line drugs and positively impact market dynamics through improvement in price, quality and delivery lead times. **Objectives** : • Scale-up the number of patients accessing and receiving second-line anti-TB treatment; • Decrease drug delivery lead times and prevent stock-outs; • Increase the number of quality manufacturers and products; and • Ensure cost-containment per treatment by 31 December 2011 and subject to a sufficient number of quality assured sources being available • Achieve price reductions of 5-25% for key second-line anti-TB drugs by 31 December 2012
Finance[22]	• Board ceiling : US$55,667,380 • MoU Amount (as of December 2010) : US$55,667,380 • 2010 Disbursement : US$12,305,410 • Cumulative disbursements (as of December 2010) : US$34,517,671 • Budget 2010 : No yearly budget • Performance by the partner against budget : US$23,885,893[23] • Performance by the partner against budget (%): 46%
Achievements	• 918 patient treatments were delivered in 2010. The cumulative total of patient treatments delivered for the project is 3973[24]. • Four additional new suppliers (the Chao Centre, Olainfarm[25], Lupin and Meiji) were supplying quality assured medicines in 2010. As of December 2010 GDF sources 21 products from 15 suppliers. • One (Moxifloxacin 400 mg) second-line anti-TB medicine was prequalified in 2010. This brings the number of second-line drugs pre-qualified under the project to five.
Project Progress	• The GDF product portfolio has increased focused mainly on Injectables[26] and Oral tablets[27]. • The Project is on track to achieve its target of at least two manufacturers available for most products by 2011. At the end of 2010 nine of the thirteen products are available from multiple sources • UNITAID has initiated a joint collaboration between the Green Light Committee, the Global Fund and the EXPANDx-TB Project. The main objective of the collaboration is to review the status of the countries supported by the UNITAID MDR-TB Scale-Up Initiative, including providing updates on supply and deliveries of medicines, laboratory and diagnostics developments and other

[22] Includes 2006-2007 PSC on all projects and 2008-2010 PSC on GDF (3%)
[23] Total cumulative disbursements at the end of 2010
[24] See ''Methodology for reporting on patient treatments delivered''
[25] Prequalified in March 2011 to supply p-Amino salicylic acid (powder for oral solution 4g)

	programmatic or strategic issues.
Challenges and actions taken	**Prequalification of second-line medicines:** There are only five second-line medicines which have been pre-qualified. This is due mainly to the limited market for these products and the consequent lack of industry interest in investing in prequalification. UNITAID, GDF and WHO Prequlaification programme are working together to stimulate supplier interest in these important medicines for TB control. **Treatment of extensively drug-resistant TB (XDR-TB):** UNITAID is working with the Green Light Committee to prevent the development of acquired resistance to MDR-TB drugs, especially in relation to XDR-TB, by ensuring that the second-line drugs are used properly. UNITAID has included these group 5 medicines in its indicative list of drugs in this Project and in its list of priority medicines for the WHO prequalification programme.
Next Steps for project	• The Project is on track to achieving its target of at least two manufacturers available for most products by 2011. • A total of 6,525 patient treatments is targeted for delivery in 2011[28].
Implications for sustainability	Through the UNITAID initiated joint collaboration (Global Fund, GLC, EXPANDx-TB), as of the end of December 2010 17 of the 18 countries have secured financing for the continuation of the programmes. The main source of funding is from the Global Fund.

[26] Kanamycin (1gr)
[27] PAS sodium powder, Levofloxacin (250mg and 500mg), and Moxifloxacin (400mg)
[28] GLC projections for 2011 of planned treatments is approximately 22,000

PROJECT TITLE: MDR-TB Acceleration of Access Initiative: Strategic Rotating Stockpile (SRS)

Key Partner(s): The Stop TB Partnership's Global Drug Facility **Project Duration: November 2008 - December 2011** **Updates for the Period Ending: December 2010**	
Updates	
Goals and Objectives	**Goals:** To provide improved, accelerated services for a major portion of newly enrolled patients under GLC approved country projects/programmes. The SRS will be able to service 5,800 patient treatments. **Objectives** : • Accelerate scale-up of the number of patients accessing and receiving second line anti-TB treatment through a decrease in drug delivery lead times • Increase the number of quality manufacturers and products • Achieve price reductions for key second-line anti-TB drugs by 2011
Finance[29]	• Board Ceiling : US$11,801,740 • MoU Amount (as of December 2010): US$11,801,740 • 2010 Disbursement : US$0 • Cumulative disbursements (as of December 2010) : US$9,872,962 • Last Project Year Budget : No budget for 2010 • Performance by the partner against budget[3] : US$6,902,66730 • Performance by the partner against budget(%):72%[31]
Achievements	• Medicines are available to cover 6 months of treatment for 5,800 patients to meet urgent needs for treatment • 54 countries accessed the SRS in 2010 compared with 39 countries in 2009 • For 2010 the average rate of use of the SRS was 72% • Average lead time remained constant in 2010 • No Stock outs were reported for countries benefiting from UNITAID and GDF supported MDR-TB Scale up project
Project Progress	• The provision of 5,800 patient treatments to the SRS to improve and accelerate the treatment of patients enrolled under GLC approved programmes as well as GF MDR-TB grantees has averted the risk of stock-outs. • The SRS continues to be used to respond to urgent orders and at the end of 2010 it was operating at 100% of its capacity for all target anti-TB medicines.
Challenges and actions taken	**Trends in medicine use:** The original composition of the SRS has changed as a result of assessment of trends in stock turnover and patterns of country use. The revised composition[32] is

[29] Includes 2006-2007 PSC on all projects and 2008-2010 PSC on GDF (3%)
[30] Total usage as at the end of 2010
[31] Cumulative reporting against disbursed funds not MoU budget
[32] Among others also includes Amikacin and PAS Sodium powder for Oral solution following GLC recommendations

	designed to maintain 156 days[33] worth of treatment for each medicine in the SRS. The impact of this revised composition will become apparent in 2011. **Availability of Active Pharmaceutical ingredients:** Limited availability of Active Pharmaceutical Ingredients (APIs) is one of the key challenges in the provision of quality TB medicines. UNITAID will conduct an analysis of the key drivers of high prices and why manufacturers are not pre-qualifying products. UNITAID is actively engaged with manufacturers to understand the drivers of market dynamics to address this challenge.
Next Steps for project	• UNITAID will continue to foster partnerships and alliances facilitating coordination with Partners (Global Fund, USAID, World Bank) on funding and strategies for MDR-TB medicines. • Innovative, new drugs are soon to be on the market and are expected as early as 2012. New drugs and regimens for drug-susceptible and drug-resistant TB will revolutionize treatment (shorter treatment regimens) of patients. On going currently is a series of Phase II and Phase III trials of shortened treatment of drug-sensitive TB including repurposed drugs (fluoroquinolones) or new dosages of new drugs (rifamycins, rifapentine). • UNITAID will conduct a mapping of the landscape for MDR-TB medicines by Q4 2011 • Pending the finalization of UNITAID mid-term review of the SRS, a one year no cost extension (until December 2012) has been approved by the UNITAID Secretariat.
Implications for sustainability	The findings of the mid-term review will facilitate further decisions to be taken by UNITAID on its current investment in the SRS.

[33] 6 months of 26 days of treatment.

PROJECT TITLE: Paediatric TB Project

Key Partner(s): Stop TB Partnership Global Drug Facility
Project Duration: January 2007 - December 2011
Updates For The Period Ending: December 2010

Updates	
Goals and Objectives	**Goals:** To provide appropriate-strength paediatric drugs for children under 15 years of age and ensure development of new child-friendly formulations for infants under 5 years of age **Objectives:** The supply of approximately 750,000 paediatric treatments to 58 countries.
Finance	• Board ceiling: $37,690,781 • MoU Amount (as of December 2010): $11,627,061 • 2010 Disbursement: $1,713,920 • Cumulative disbursements (as of December 2010): $11,626,950 • GDF spending on commodities in 2010: $1,911,164[34] • Performance by the partner against budget (cumulative) : $8,103,620 • Performance by the partner against budget (cumulative)(%): 71% Note: The EB approved ceiling include last EB approval of $23,465,000
Achievements	• 380,744 paediatric patient treatments delivered[35] and 534,615 paediatric prophylactic delivered. • Price reductions of 30% for four key paediatric products has been achieved through negotiations in comparison to 2008 prices for the same products • Average manufacturing lead times have been further reduced from 105 days (in 2008) to 87 days per order in 2010 • One Paediatric TB drug (Izoniazid) has been pre- qualified by the WHO PQ Programme in 2010, bringing the cumulative total pre-qualified products to 11 since project's start.
Project Progress	• The UNITAID Board (EB12 Resolution 12) approved additional funding support (US$2,207,486) for this Project for the period 2010-2011 to cover the implementation of new WHO recommendations for paediatric treatment. This money has not been disbursed because GDF had an existing unspent amount of US$ 3 million. UNITAID and GDF are working on a proposal for a more comprehensive project plan to address the change in WHO recommendations for paediatric TB treatment. • Two high burden beneficiary countries (Philippines and Indonesia) are not using their UNITAID grant allocations. Funding will be released from these two countries and will instead be used to cover the increased costs for 7 countries that have or are expected to switch to the new WHO recommendations for paediatric TB treatment. • UNITAID and GDF are working together to simplify and improve the monitoring of and reporting on GDF projects.
Challenges and actions	**New paediatric treatment recommendations:** In December 2010, WHO published the "Rapid Advice" guidelines which recommend higher doses for paediatric treatments. Existing formulations and FDCs

[34] Annual estimate calculated by UNITAID based on Annual Reports received from GDF which report by Grant Year.
[35] From 2007 to 2010

taken	do not accommodate these recommendations. UNITAID and GDF are discussing a new project plan which takes these changes into account. **GDF restructuring:** GDF is undergoing internal restructuring and are changing their role in global health landscape. This will affect their procurement activities, improve project management and reporting of project outcomes.
Next Steps for project	• A review of the Paediatric TB project is planned. The results of this review will inform UNITAID's engagement with GDF in the future. • UNITAID and GDF are discussing a new project plan which will address the changes to paediatric treatment of TB.
Implications for sustainability	For countries who have finished their grants and have not been able to secure funding from other sources for needed paediatric drugs, GDF has provided an Emergency Grant or 2nd term grants (Cambodia, Djibouti and Somalia) through alternate donor funding.

PROJECT TITLE: UNITAID Project Support for Quality Assurance of Diagnostics

Key Partner(s): WHO Diagnostics and Laboratory Technology
Project Duration: March 2009 - February 2013
Updates for the Period Ending: December 2010

<table>
<tr><td colspan="2">Updates</td></tr>
<tr><td>Goals and Objectives</td><td>Goals: To increase access to appropriate diagnostic technologies of assured quality for the diagnosis, monitoring and treatment of HIV/AIDS and malaria.

Objectives:
• Prequalification of UNITAID priority diagnostics to support HIV/AIDS and malaria treatment,
• Facilitate access to appropriate diagnostics of ensured quality at reduced costs,
• Build and/or strengthen regulatory capacity for diagnostics in five beneficiary countries including countries currently manufacturing diagnostics for HIV/AIDS and/or malaria, and
• Build and/or strengthen capacity for post-market surveillance of UNITAID priority diagnostics in five beneficiary countries.</td></tr>
<tr><td>Finance</td><td>• Board ceiling: US$ 7,500,000
• MoU amount (as of December 2010): US$ 7,500,000
• 2010 Disbursement: US$ 0
• Cumulative Disbursement (as of December 2010): US$1,130,000
• Last Project Year Budget : US$ 2,200,000
• Performance by the Partner against budget : US$913,681
• Performance by the Partner against budget (%): 15%</td></tr>
<tr><td>Achievements</td><td>• 14 product dossier are being assessed,
• One malaria Rapid Diagnostic Test (RDT) prequalified in 2010</td></tr>
<tr><td>Project Progress</td><td>• The project was started in March 2009 with a primary objective of prequalifying 50 diagnostic products for HIV/AIDS and malaria.
• Fourteen product dossiers are currently under review. However, the progress towards the target is slow.

<table>
<tr><th colspan="6">Summary of product applications received and dossier under assessment</th></tr>
<tr><th>Test</th><th>Project Target (2009-2013)</th><th>Applications Accepted</th><th>Dossier Received</th><th>Products under review</th><th>Products Prequalified</th></tr>
<tr><td>HIV rapid test</td><td>21</td><td>24</td><td>9</td><td>7</td><td>0</td></tr>
<tr><td>Malaria rapid test</td><td>21</td><td>12</td><td>7</td><td>7</td><td>1</td></tr>
<tr><td>CD4 tests</td><td>4</td><td>6</td><td>2</td><td>0</td><td>0</td></tr>
<tr><td>HIV viral load</td><td>4</td><td>5</td><td>1</td><td>0</td><td>0</td></tr>
<tr><td>Total</td><td>50</td><td>47</td><td>19</td><td>14</td><td>1</td></tr>
</table>

• Capacity building support to National Regulatory Authorities (NRAs) in pilot countries is in progress. The pilot countries include: Burkina Faso, China, Cote d'Ivoire, Tanzania and South Africa.
• Three of the pilot countries have completed preparation of their country</td></tr>
</table>

	action plan (Burkina Faso, China and Tanzania). • Partner institutions for post marketing surveillance of diagnostics at country level have been identified,
Challenges and actions taken	**Timeframe for prequalification:** The prequalification process has started slowly. The WHO prequalification programme is now fully staffed but there are still delays in processing dossiers for some products. UNITAID and WHO are working towards streamlining the process. **Manufacturers' concerns:** manufacturers have little clarity on the benefits of prequalification their products. UNITAID and WHO are working together to improve visibility of the Prequalification Programme and its important role as part of UNITAID's quality assurance policy. **Adequate staff for prequalification:** Staff turn-over and shortage has been reported as one of the major problems hindering progress. WHO/DLT is working towards having the programme fully staffed in 2011.
Next Steps for the project	▪ To monitor timely implementation of the project, WHO/DLT has been requested to prepare a project log-frame and timeline for deliverables, ▪ Based on the approved project logical framework, necessary adjustments on the activity plan and budget may be considered. ▪ WHO/DLT is charging a dossier assessment fee of US$12,000 per application. The service fee is expected to strengthen financial resources of the program and to minimize dependence on external support.
Implications for sustainability	The demand for quality assured diagnostics for HIV/AIDS and malaria will increase with the increasing access to health services. The range of diagnostic products that are being developed and their performance and appropriateness to guide treatment decision requires stringent assessment.

PROJECT TITLE: UNITAID Project Support for Quality Assurance of Medicines

Key Partner(s): WHO/Medicines Prequalification Programme
Project Duration: December 2006 - December 2012
Updates for the Period Ending: December 2010

Updates	
Goals and Objectives	**Goals:** To improve the quality of medicines supplied through UNITAID and other international procurement agencies. **Objectives**: • Facilitate availability of good quality UNITAID priority medicines • Increase the number of prequalified products in UNITAID priority areas • Increase capacity in production of quality of priority medicines, facilitate the development of national regulatory processes and promote capacity building for quality control of medicines in recipient countries, • Further the development and updating of global norms and quality standards needed for the production and regulation of medicines with assured quality, • Accelerate and expand testing of the quality of medicines to ensure quality for the end-user, and • Improve awareness of the prequalification of medicines through communications and advocacy activities.
Finance	• Board ceiling: US$53,110,000 • MoU amount (as of December 2010): US$53,110,000 • 2010 Disbursement: US$0 • Cumulative Disbursement (as of December 2010): US$16,950,000 • Last Project Year Budget: US$10,000,0000 • Performance by the Partner against budget: US$6,627,100 • Performance by the Partner against budget (%): 66%
Achievements	• Fifteen of the 36 products prequalified in 2010 are UNITAID priority medicines, • The prequalified medicines include 10 anti-retrovirals to treat HIV/AIDS, 4 anti-TB medicines and 1 anti-malarial. • Six quality control laboratories were prequalified, • Training was provided for 200 regulatory agency personnel from low and middle income countries, 200 Quality Control Laboratory personnel and over 800 participants from the manufacturing sector, • 58 manufacturing site inspections were completed; • Support was provided to manufacturers of anti-tuberculosis medicines in China to improve the quality of their dossiers, • The median number of days from submission of dossiers to prequalification of products was reduced in 2010 from 736 days to 663 days
Project Progress	• Since the start of the project in 2007, a total of 45 UNITAID priority medicines for HIV/AIDS, Tuberculosis and malaria have been prequalified. • A total of 118 product dossier have been accepted for assessment since the start of the project. • Assessment of dossiers for 8 active pharmaceutical ingredients (API) for HIV, tuberculosis and malaria is being done,

	• Re-qualification[36] of 54 products prequalified in 2005 has been started.
Challenges and actions taken	**Time from submission of dossier to prequalification:** The prequalification process remains time consuming. The WHO prequalification programme is now fully staffed but there are still delays in processing dossiers for some products. Part of the problem lies with the knowledge and attitudes of manufacturers about the benefits of prequalification. UNITAID and WHO are working together to improve visibility of the Prequalification Programme and its important role as part of UNITAID's quality assurance policy. **Predictability of funding for the Prequalification Programme:** Prequalification is a continuous process that involves prequalification of new products and re-qualification of prequalified products. This type of programme needs pre financial resources to maintain its services. UNITAID and WHO are exploring the possibility of using a fee for service arrangement with manufacturers to provide a more sustainable revenue base for this important area in the future.
Next Steps for the project	• Mid-term review (MTR) of the project has been completed. UNITAID is working with WHO to follow up on some of the MTR recommendations.
Implications for sustainability	The demand for quality assured medicines for HIV/AIDS, tuberculosis and malaria will increase with the increasing access to diagnostic and treatment services, especially in low income countries. This will increase demand for quality assured active pharmaceutical ingredients (API) and finished pharmaceutical products from generic manufacturers. The prequalification programme is important to ensuring that these products are of the highest quality.

[36] Product re-qualification is carried five years after the date of first prequalification.

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

Key Partner(s): The Global Fund
Project Duration: December 2007 - June 2010
Updates for the Period Ending: December 2010

Updates	
Goals and Objectives	**Goals**: To scale up access to treatment and to positively impact market dynamics to increase the affordability of drugs for the treatment of HIV/AIDS, MDR-TB and malaria **Objectives**: • Increase the number of patients accessing and receiving treatment for HIV/AIDS, MDR-TB and malaria through Global Fund grants in Round 6, Phase 1 • Support price reductions of high quality drugs for HIV/AIDS, MDR-TB and malaria in national treatment programs through efforts to facilitate the use of a reference price mechanism and pooled procurement
Finance	• UNITAID Board Approved ceiling: US$52,500,000 • MOU agreed amount: US$38,691,956 • Disbursement in 2010: US$0 • Cumulative disbursements (as of December 2010) : US$38,691,956 • Last Project Year Budget: No specific budget attributable to UNITAID • Performance by the Partner against budget : no specific information available • Performance by the partner against budget (%): no specific information available
Achievements	For 2010, the project : • Added an additional 1,182 children, totaling 31, 197 children on treatment with ARVS at the end of 2010 • Added an additional 587,872 ACT treatments, totaling 2,650,652 at the end of 2010 Cumulatively, the project • Achieved 8461 treatments for second line ARV treatments in adults • Achieved 3,961 treatments for MDR TB
Project Progress	• The project officially closed in June 2010 but The Global Fund has submitted a formal request to use the project's unexpended funds and an agreement is pending.
Challenges and actions taken	**Reporting :** Due to the limitations of the Global Fund's procurement reporting system, an extension has been requested during which time the Global Fund plans to reconcile information on funds spent and procurement achieved for The Project.
Next Steps	• Reconciliation of expenditure and procurement. • An end-of-project review is scheduled in 2011.
Implications for sustainability	This is a time-limited and grant-specific project support by UNITAID to Global Fund.