Swiss TPH
Swiss Tropical and Public Health Institute
Schweizerisches Tropen- und Public Health-Institut
Institut Tropical et de Santé Publique Suisse

Swiss Centre for International Health

UNITAID

Mid-Term Review

UNITAID -CHAI Paediatric HIV/AIDS Project

Swiss Centre for International Health
Swiss Tropical and Public Health Institute

Evaluation team:
CARASSO, Barbara Kashi
KIEFER, Sabine
CLARY, Bruno
GUINOT, Dominique
BOSCH-CAPBLANCH, Xavier

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Contacts

Swiss TPH
Swiss Tropical and Public Health Institute
Schweizerisches Tropen- und Public Health-Institut
Institut Tropical et de Santé Publique Suisse

Swiss Centre for International Health
Swiss Tropical and Public Health Institute
Socinstrasse 57
P.O.Box
4002 Basel
Switzerland
Internet: www.swisstph.ch

Xavier Bosch-Capblanch
Deputy Head of Systems Performance and Monitoring Unit
Swiss Centre for International Health
Tel.: +41 61 284 83 19
Fax: +41 61 284 81 03
E-mail: x.bosch@unibas.ch

Dominique Guinot
Project Leader, Systems Performance and Monitoring Unit
Swiss Centre for International Health
Tel.: +41 61 284 81 91
Fax: +41 61 284 81 03
E-mail: dominique.guinot@unibas.ch

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Abbreviations

3TC	Lamivudine
ABC	Abacavir
API	Active Pharmaceutical Ingredients
ART	Anti-Retroviral Therapy
ARV	Anti-Retro Viral
AZT	Retrovir or Zidovudine
CD4	cluster of differentiation 4
CEO	Chief Executive Officer
CHAI	Clinton Health Access Initiative
CHAI DAT	CHAI Drug Access Team
CSD	Clearing, Storage and Distribution
DDI	Didanosin
DFID	UK Department for International Development
DNA PCR	Deoxyribonucleic acid polymerase chain reaction
EFV	Efavirenz
EID	Early Infant Diagnosis
FDA	(United States) Food and Drug Authority
FDC	Fixed-Dose Combinations
GPRM	Global Price Reporting Mechanism
HIV	Human Immunodeficiency Virus
IATT	Interagency Task Team Paediatric subgroup on retention
IDA Foundation	International Dispensary Association Foundation
LIC	Low Income Country
LMIC	Low and/or Middle Income Countries
LPV/r	Lopinavir/Ritonavir
LTA	Long-Term Agreements
LTFU	Loss to Follow up
M&E	Monitoring & Evaluation
MoH	Ministry of Health
MoU	Memorandum of Understanding
MSA	Master Supply Agreements
MSH ERC	Management Sciences for Health - Electronic Resource Centre
NVP	Nevirapine
OECD	Organisation for Economic Cooperation and Development
OI	Opportunistic Infection
PA	Procurement Agent
PEPFAR	The U.S. President's Emergency Plan for AIDS Relief
PMTCT	Prevention of Mother to Child Transmission
PNG	Papua New Guinea
PPPY	Price-per-Person per Year
RfP	Request for Proposals
RNA	Ribonucleic acid
RUTF	Ready-to-Use-Therapeutic Food
SCMS	Supply Chain Management System
SWOT	Strengths, Weaknesses, Opportunities, Threats
TA	Technical Assistance
UMIC	Upper-Middle Income Countries
VPP	Voluntary Pooled Procurement
WHO	World Health Organization
WHO CRC	WHO Contract Review Committee

Executive Summary

Project key information

The mid- term review covers the UNITAID funded Project “UNITAID-CHAI Paediatric HIV/AIDS Project” for 2006 until 2010. The project was launched in 2006 and has been extended for the period 2008-2010 and once more until 2012. The project is implemented by the Clinton Health Access Initiative. The main objective of the project was to scale up access to paediatric ARV treatment in 40 eligible countries and to influence market dynamics.

Methodology

This external, independent mid-term review has been performed according to Organisation for Economic Co-operation and Development (OECD) evaluation criteria of Relevance, Effectiveness, Efficiency and Impact and in addition, project-specific issues and reporting arrangements have been assessed. A SWOT analysis has been performed as well as issuance of recommendations which are included in this report. The evaluation of achievements was linked to project specific Monitoring and Evaluation (M&E) log frame indicators for health- and market outcome.

Key findings

Project management

- ✓ MoU have not been signed in a timely manner and not by all countries, whilst this is of utmost importance to mitigate risk and improve accountability of beneficiary country governments;
- ✓ There were unexplained differences in actual paid median prices and agreed prices with primary supplier for ARVs. Comparisons for three paediatric FDCs revealed that the medians of actual prices were above agreed prices.
- ✓ Prices paid for DNA PCR, CD4 tests and RNA Viral Load tests were reported to be significantly lower than market prices, whilst median price comparisons for HIV rapid tests revealed that some were lower and others higher than GPRM summary prices.
- ✓ It remains difficult to match paediatric ARV treatments procured with patients treated by country, or to tally expenditure on ARVs with reported patient numbers
- ✓ Reporting formats, tables and figures vary between years and no specified formats are provided;
- ✓ Reconciliation of budget, open commitments and expenditures was not possible. Varying table formats, varying differences of definitions (inclusion and exclusion of certain parameters) and varying cut-off dates make the reconciliation not possible;
- ✓ Reported performance and expenditure is not verified in a systematic manner and disbursements from UNITAID are not based on performance.

Public health impact

- ✓ The UNITAID CHAI Project has delivered good results in providing paediatric ARV treatment to a large number of children, and has been a driver in the uptake of paediatric FDCs in beneficiary countries
- ✓ By the end of 2010, the UNITAID CHAI project provided paediatric ARV treatment to more than 320,000 children in 40 beneficiary countries, compared to 68,000 who received treatment at the start of the Project.
- ✓ Questions remain about the reliability of data on consumption of ARVs and children alive and on treatment

Market outcomes

- ✓ During the duration of the project, the supplier-base of paediatric ARVs, and especially fixed-dose combinations, has expanded considerably. The UNITAID CHAI project is thought to have contributed to this expansion;
- ✓ Prices obtained for the Project for selected paediatric ARVs through primary and secondary suppliers have seen a steady decrease between 2008 and 2010. These prices were in all but one case lower than those reported in the CHAI Consortium Ceiling Price List and in MSH-ERC for SCMS;
- ✓ Prices of key paediatric treatment regimens have seen a rapid drop between 2004 and 2007, whereas this downward trend showed a less dramatic decline since 2007. The main factors driving this decrease in price are the introduction of FDCs (replacing expensive syrups) and generic competition;
- ✓ The Project is thought to have considerably impacted on the paediatric ARV market through securing a large amount of funding for a market which was largely non-existing before the start of the Project; through its expansion of market volume of especially FDCs; through its pooling of orders with one procurement agent between partners and countries; through its innovative procurement strategy of driving down prices of paediatric ARVs, which has subsequently influenced market prices; and through its work on the demand-side uptake of paediatric FDCs;

Key Recommendations

Project management

- ✓ Define clear templates for reporting, a comprehensive and consistent log-frame (including financial monitoring), and ensure consistency in reporting.
- ✓ Conduct an external audit to identify expenditures, open commitments, disbursements, interest payments and other financial information. In addition, improve transparency on how budgets are derived, and closely monitor budget adjustments.
- ✓ Develop and implement a comprehensive risk management plan addressing all risks identified at country level, and define mitigating measures, which also include enforcement measures of MoU conditions.
- ✓ Develop a binding schedule and introduce incentives for signature of MoU with countries. CSD costs should be borne by beneficiary countries, and included in the MoU.

Public health impact

- ✓ Provide unified/national forecasting for each beneficiary country, showing UNITAID’s contribution as a percentage of total annual needs, total number of people under treatment and estimated number of patients treated with UNITAID funded ARV.
- ✓ Include overview of how ARV budget, treatments procured and children on treatment correspond over the years.
- ✓ Increase the understanding of data issues by providing country briefs summarising challenges faced in reporting and give an indication on the reliability of figures reported.
- ✓ Use lessons learnt from the Project to advocate with partners & address high rates of LTFU across beneficiary countries, and actively pursue innovative measures to achieve high retention rates.
- ✓ Make separate funding available to support in-country capacity building on paediatric ARV forecasting and quality data collection & management.
- ✓ Actively pursue negotiations with the Global Fund and other partners to ensure funding sources and in-country activities are handed over.
- ✓ Assess and plan the need for an emergency fund in case not all countries manage to transition to alternative funding sources by end 2012.

Market outcomes

- ✓ Include prices agreed and actual prices paid in the reports, including explanation on calculations. Include median prices for OI, RUTF and diagnostics as well as the original planned unit cost.
- ✓ Clarify basic principles of procurement model: targets for lead-time and pooled procurement, percentage of products via the procurement agent, role of procurement agent, purchase from primary vs. secondary suppliers, procurement from local suppliers/distributors.

1 Conclusions and Recommendations

The goal of the Project in terms of number of children treated with ARVs has largely been achieved. During the period 2007-2010, the CHAI UNITAID Project reached 87% of its annual (adjusted) targets to provide paediatric ARV treatment to children in beneficiary countries. More than 320,000 children are estimated to be alive and on treatment by the end of 2010, compared to 68,000 at the beginning of the Project.

In addition, the CHAI UNITAID Project is likely to have had a considerable impact on the paediatric ARV market. New paediatric formulations – notably FDCs – have been introduced, the market volume has expanded rapidly, pooling of orders between partners and countries ensures that manufacturers can meet batch size requirements, the price of paediatric ARVs has further decreased, and demand-side activities have facilitated uptake of products.

CHAI’s strategy of combining supply-side (global level) and demand-side (in-country) activities has greatly contributed to the success of the paediatric HIV/AIDS treatment program.

A list of recommendations is summarized in the table below. As reported by the UNITAID Secretariat, some of these recommendations are already being addressed, importantly financial management and project reporting.

Conclusion	Recommendation	Responsibility
Project management		
Reporting on **programmatic management** and achievements has been inconsistent	Define clear templates for reporting, including definitions, and UNITAID internal processes for formal reports validation and approval. Develop a comprehensive and consistent log-frame that incorporates financial monitoring on the level of activities. Ensure that Project achievements are consistently reported over the duration of the Project.	UNITAID, CHAI
Reporting on **financial management** has been unsatisfactory	An external audit is strongly recommended to identify expenditures, open commitments, disbursements, interest payments, etc. Some general rules should be introduced: • Performance-based funding (disbursements only after orders are placed) • Monitoring of country specific budget approval • Adherence to provided definitions and financial reporting templates • Finance must be reported cumulatively so that open orders can be traced in the following year(s) Transparency on how budgets are derived should be improved and budget adjustments should be monitored closely. A UNITAID internal policy on bank interest reporting requirement and management should be developed.	UNITAID, CHAI

Conclusion	Recommendation	Responsibility
Budget expenditure on ARVs, **treatment** procured and **children** on treatment could not be matched	Include overview of how ARV budget, treatments procured and children on treatment correspond. (e.g. report budget, expenditure and treatment target over the same period of time). Address this with cumulative (financial) reporting and approximate reporting of patients treated with drugs procured from the different budget years. Increase the understanding of data difficulties by providing country briefs summarizing challenges faced in reporting and forecasting (including activities to overcome them).. Give an indication on the reliability of figures reported.	CHAI
Ownership of the paediatric program by national counterparts is unclear, as reflected by low rates of signed MoU and CSD cost borne by UNITAID	Develop a binding schedule and introduce incentives for signature of MoU with countries. CSD costs should be borne by beneficiary countries, and included in the MoU.	UNITAID, CHAI
The project had **no risk management plan** which potentially exposed UNITAID funded ARVs to risks of theft and waste.	Develop and implement a comprehensive risk management plan addressing all risks identified at country level, and define mitigating measured. This plan should also include enforcement measures of MoU conditions.	UNITAID, CHAI
Adherence to UNITAID **eligibility criteria** remains unclear.	Compare adherence to orders placed rather than expenditures. A formal clarification is needed to what extend eligibility criteria should be respected on a yearly basis.	UNITAID, CHAI
Public health impact		
Forecasting has proven to be a major weakness of the Project, especially in light of lack of reliable data	Provide unified/national forecasting for each beneficiary country, showing UNITAID’s contribution as a percentage of total annual needs, total number of people under treatment and estimated number of patients treated with UNITAID funded ARV. Make separate funding available to support in-country capacity building on paediatric ARV forecasting and quality data collection & management.	UNITAID, CHAI
Loss to follow up (LTFU) of children initiated on treatment undermines the public health impact of the Project	Use lessons learnt from the Project to advocate with partners and address high rates of LTFU across beneficiary countries, and actively pursue innovative measures to achieve high retention rates.	CHAI, partners, UNITAID
Transitioning of funding and in-country PSM activities is not secured for all beneficiary countries	Actively pursue negotiations with the Global Fund and other partners to ensure funding sources and in-country activities are handed over. Include counterparts (e.g. government officials, key implementing partners, donors) of beneficiary country in these negotiations. Also the need for an emergency fund should be assessed and planned for, in case not all countries manage to transition to alternative funding sources by end 2012.	UNITAID, partners, CHAI

Conclusion	Recommendation	Responsibility
Market outcomes		
Prices agreed with suppliers and reported median prices paid deviated. Information was not obtainable in systematic manner.	Include prices agreed and actual prices paid in the report, including explanation on calculations. Include median prices for OI, RUTF and diagnostics as well as the original planned unit cost.	CHAI
Deviations from the procurement model and targeted lead times have been identified.	Clarify definitions on lead-time and pooled procurement, and set clear targets. Clearly outline percentage of products purchased via the PA versus direct procurement from manufacturers/ local distributors. Specify and monitor the role of the PA versus CHAI. Introduce volume-based reporting on the product purchases from primary versus secondary suppliers (60:40 rule) and procurement agent versus local/emergency (85:15). Any variance for the second should be officially approved by UNITAID. Clarify UNITAID’s policy on procurement from local suppliers/distributors. Purchases from local suppliers should not exceed agreed prices with primary suppliers, unless truly reflecting emergency orders. If prices are above agreed primary supplier prices UNITAID should consider if procurement is acceptable or if a third party should be held accountable for price difference (e.g. government, CHAI)	CHAI, UNITAID

2 Project Description

The World Health Organization (WHO) estimates that at the end of 2009 2.5 million children were living with the Human Immunodeficiency Virus *(*HIV*).* Of those children 2.3 million lived in sub-Saharan Africa. Most of these children acquire HIV from their HIV-infected mothers during pregnancy, birth or breastfeeding. While interventions can reduce the risk of mother-to-child HIV transmission to 2% these interventions are not widely available and an estimated 1,000 children were newly infected with HIV in 2009 each day[1].

The 2009 progress report “Towards universal access: scaling up priority HIV/AIDS interventions in the health sector”[2], states that in 2008 only 38% of children in need of Antiretroviral Treatment (ART) received it. Limitations to the scaling up identified by WHO remain, including “limited screening for HIV, a lack of affordable, simple diagnostic testing technologies for children less than 18 months of age, a lack of human resources with the capacity to provide the care that is required, insufficient advocacy and understanding that ART is efficacious in children, limited experience with simplified, standardized treatment guidelines, and limited availability of affordable and practical paediatric ARV formulations. Consequently, far too few children have been started on ART in resource-limited settings.”[3]

Even where simplified and affordable paediatric antiretroviral (ARV) formulations are available, forecasting of need is hampered by poor quality of data and complexity of ARV dosing (according to weight & age band). The recently introduced paediatric fixed-dose combinations (FDCs) have greatly facilitated the treatment of children. However, due to the small and fragmented market, new paediatric formulations are not a priority for pharmaceutical companies.

UNITAID, in partnership with CHAI (Clinton Health Access Initiative) is working to scale up the access to paediatric ARVs and related key products in developing countries. UNITAID and CHAI are also working to reduce the price of paediatric HIV/AIDS medicines by encouraging more producers to enter the market, so that it helps to foster the competition and thus drives prices down. The project pursues the six following key goals and objectives:

I. to scale up the access to Paediatric ARVs and related key commodities to increase the number of patients receiving treatment for HIV/AIDS in developing countries;
II. influence market dynamics to achieve price reductions to increase the affordability of critical quality products;
III. stimulate an increase in the number of quality assured manufacturers and products;
IV. decrease product delivery lead times;
V. encourage prequalification of approved manufacturers and products; and
VI. apply appropriate procurement strategies to develop a healthy market that favours competition and sustainability, with reductions in price.

[1] http://www.who.int/hiv/topics/paediatric/en/index.html
[2] World Health Organization, UNITAID, UNICEF (2009): Towards universal access: scaling up priority HIV/AIDS interventions in the health sector: progress report 2009. Geneva.
[3] World Health Organization (2010): Antiretroviral Therapy for HIV Infection in Infants and Children: Towards Universal Access - Recommendations for a Public Health Approach. Geneva. p. 1

These objectives have been further enriched with specific objectives for each year as Agreements have been signed on an annual basis. This allowed both UNITAID and CHAI to revise the objectives and other arrangements and hence keep a relative flexibility in the implementation of the project.

The initial "Agreement for the Procurement and Supply of Paediatric ARV drugs" and the "Project Agreement for Paediatric HIV/AIDS Program" were signed in January 2007 and concerned 40 low and/or middle income countries (LMIC)[4]. The project was originally designed for the period 2006/2007 but at the end of 2007, UNITAID's Board agreed to extend the project through 2008 until 2010. In June 2010, the Board agreed to extend the project further till 2012 to allow the beneficiary countries to transition funding to other donors and to ensure the continuity of treatment of existing patients. In 2010, two of the countries, namely Rwanda and Burkina Faso had transitioned fully. For 2011 13[5] countries will no longer participate in the UNITAID/CHAI Paediatric program. The project will end in 2012, unless a new extension is signed. Currently it is expected that 11 countries might not have alternative funding secured after 2012 and therefore have not (fully) transitioned to other donors. The UNITAID budget for the Paediatric Project 2006-2012 is approx. US$ 380 million.

UNITAID funding is in its vast majority allocated to the purchasing of medicines (including procurement related costs), whereas CHAI's activities carried out at beneficiaries countries on uptake of these medicines are mostly funded by other donors (e.g. DFID Access to Medicines, Elisabeth Glaser Foundation). CHAI is working with suppliers to increase the quality and to lower priced offer and with countries to increase the demand. UNITAID funding provides significant leverage to CHAI in its negotiation with suppliers as its represents around 70% of the paediatric ARV market[6]. Since the project inception, one of the main challenges of the project has been to ensure the transition to other funding sources and to help countries take advantages of high-volume and consolidation of orders that currently exist under the project.

On behalf of UNITAID, CHAI takes the responsibility for the effective implementation of the projects, including the process to select suppliers, establish pricing and where relevant allocate drug volumes across selected suppliers, manage or serve as the procurement agent and ensure timely and effective delivery of products and disburse funds for payment of procurement and supply for the following commodities: Paediatric ARVs, Diagnostics, Opportunistic Infection (OI) Drugs and Ready-to-Use-Therapeutic Food (RUTF) used in paediatric HIV/AIDS care. Since September 2009 the International Dispensary Association Foundation (IDA Foundation) supports CHAI in the procurement and supply of paediatric ARVs and OI drugs and other associated activities[7]. The responsibility of sourcing and the procurement and supply of diagnostics and RUTF remains with CHAI.[8] Furthermore CHAI provides project support and technical assistance to the governments of the beneficiary countries to address critical bottlenecks to paediatric ARV scale up, including both direct

[4] This includes the "Organization of Eastern Caribbean States (OECS)" which contains 6 separate territories.
[5] These are: Cambodia, China, Dominican Republic, Jamaica, Liberia, OECS (6 countries) and Papua New Guinea (2010 Annual Report Section 3.1 and 4.1).
[6] The Global Fund Twenty-Third Board Meeting GF/B23/9 revision 1 board decision, Geneva, Switzerland, 11-12 May 2011.
[7] These include: the "receipt and processing of order requisitions, placement of purchase orders, quality assurance and quality control, freight forwarding, delivery and payment of suppliers" (2010 Agreement, Section 1.1.3)
[8] 2009 Agreement, p. 4; 2010 Agreement, p. 5

program support (e.g. forecasting) and the provision of CHAI staff to execute and manage the provision of such assistance.

UNITAID provides CHAI with the necessary funds for the purchase and delivery of the products[9] and a related procurement management costs and procurement fee. In 2010 this fee was 3% of the total commodity costs. Of this a maximum of 2% could in special circumstances be used for Clearing, Storage and Distribution (CSD) with the remainder to be used for CHAI's operational support. For 2010 there has been no additional information on the required co-funding by CHAI for operational support[10].

Over the years the number of beneficiary countries varied. In 2008 38 countries benefited (excluding South Africa and Thailand from the original list of 40 beneficiary countries), in 2009 39 countries participated (including Togo[11]) and in 2010 Haiti[12] was included, adding up to the original number of 40 countries.

Table 1. Project Summary.

Item	Description
Name	Paediatric HIV/AIDS Procurement Project
Project summary	UNITAID, with the Clinton Health Access Initiative (CHAI), is working to scale-up access to paediatric ARV treatments. It is also working to reduce the price of paediatric AIDS medicines by encouraging more producers to enter the market. This helps foster the competition that drives prices down. UNITAID has reached out with the supply of paediatric antiretrovirals over the years to more than 300,000 children in 40 countries.
Partners	Clinton Health Access Initiative (CHAI)
Number of countries	40 countries at the project inception
Period	2006-2012
Budget	approx. US$ 380 mill.

Source: UNITAID: http://www.unitaid.eu/en/paedriatics.html (Access: 10.October 2011); Interviews with UNITAID

Table 2. Number of countries included in program over the years[13].

	Number of countries	Comments
2007	40	For a complete list of countries see Annex 4
2008	38	Excluding Thailand and South Africa
2009	39	including Togo
2010	40	including Haiti

Source: 2007, 2008, 2009, 2010 Annual Reports

[9] including reasonable shipping costs, insurance, quality assurance and quality control
[10] In 2007 US$ 400.000 were given for project support supported by CHAI who budgeted US$ 15 million to be raised independently (2007 Project Agreement; p. 12). The 2010 Agreement outlines that for 2008, CHAI contributed up to US$ 20 million to fund the operating costs of the Paediatric HIV/AIDS Program (2010 Agreement, Appendix, Section 5.15).
[11] 2010 Agreement; p. 3.
[12] 2010 Agreement; p. 3.
[13] For an overview of eligible countries please refer to Annex. Supporting Tables.

3 Findings details

3.1 Project management

3.1.1 Relevance

The objective of this section is to assess whether activities implemented by the project are consistent with the initial project plan and in line with UNITAID objectives and strategy.

Rating		Level of confidence	
☐	Optimal	☐	Optimal
☒	Minor concerns	☒	Minor concerns
☐	Major concerns	☐	Major concerns

Key findings

- ✓ There were major inconsistencies between the Project Plan and the M&E Framework
- ✓ There was no logical link between objectives, indicators and targets;
- ✓ Some indicators are difficult to measure, and those for Technical Support are not well-developed

- **Are the activities and expected outputs of the project consistent with the objectives and expected outcomes as described in the project plan?**

The goal of the project is to address the gap between paediatric and adult access to ARVs as a first step towards universal access for children[14]. Activities are divided into procurement activities and programmatic support, the first being the main focus of the program.

Over the years the objectives evolved. In 2007 the three principal objectives concerned the expansion of treatment to 100,000 children, to stimulate a more competitive market place in the medium-long term and contributing to price reductions. The 2008 objectives build on these but expand them further by decreasing delivery lead times and increasing the number of quality manufacturers and products. Since 2009 the Agreements foot on six general goals and objectives[15] which are enriched with project specific objectives each year including annual treatment targets. Further do the Project Plans 2009 and 2010[16] outline four major procurement objectives which are in line with the objectives outlined in the Agreement. Further the Project Plan – Section 5 – describes actions, milestones and their current status. Similarly actions, indicators, calculation of indicators, baselines, targets, milestones and measurement frequencies are outlined in the M&E section[17].

[14] 2010 Agreement, Appendix 1; Section 2.
[15] These goals and objectives are common also to the ARV 2nd line Project.
[16] Project Plans were only available from 2009 onwards. For 2008 there has been a Project Plan Template but with no binding status (see email UNITAID, 3rd November 2011).
[17] 2010 Agreement, Annex 5

Table 3. Overview of Source for Objectives, Activities, Indicators.

Source of Document	Description
2010 Agreement (main document)	Goals and Objectives, including project specific objectives (e.g. annual treatment targets)
2010 Agreement; Project Plan (Appendix 1); Section 2	Objectives
2010 Agreement; Project Plan (Appendix 1); Section 5	Action, Milestone, Status
2010 Agreement; M&E (Annex 5)	Project Plan Section, Action, Indicators, Baseline, Target, Milestone, Measurement frequency

M&E Framework and Project Plan

The evaluators reviewed the consistency of activities from both – Project Plan Section 5 and the M&E Section - with the objectives from the Agreement 2010 and then matched indicators with the objectives.

Reviewing the activities against the objectives (see Annex. Supporting Tables Table 21) the evaluators note the following:

- The objectives do not appear in the Project Plan, Section 5 nor in the M&E section. Hence the link between objectives of the main Agreement document and the activities is not straightforward. Some activities support more than one objective. For instance, some overlap is noted between activities of the objectives 2 "Influence market dynamics to achieve price reductions to increase the affordability of critical quality products" and 6 "Influence market dynamics to achieve price reductions to increase the affordability of critical quality products" as both are referring to price reductions. Overlapping activities could be the result of a lack of hierarchy between goals and objectives. Objective 2 and 6 are believed to be goals and objectives whilst objectives 3 "Stimulate an increase in the number of quality assured manufacturers and products" and 5 "Encourage prequalification of approved manufacturers and products" contribute to their achievement.
- The way activities are phrased between the Project Plan and the M&E section varies slightly, neither is the numbering of activities aligned (e.g. Placement of Purchase Orders for and Delivery of Products is numbered 5.12 in the Project Plan and 5.9 in the M&E section).
- The total numbers of activities between the Project Plan and the M&E section varies (19 actions vs. 11 activities[18]) and therefore some actions do not match activities from the M&E section and in its consequence cannot be associated with indicators[19]
- Project support activities are outlined in the Project Plan, Section 5 (e.g. Provide staff to manage procurement activities of Paediatric Project) but are condensed in the M&E section to technical support.

The consistency rate to measure an objective with at least one activity has been high: all objectives could be matched with activities (100%). The consistency rates varied for matching activities with objectives, depending on the source of information from either the Project Plan (Section 5) or the M&E section. For the Project Plan (Section 5) four actions out of 19 could

[18] The numbering of activities lacks the number 5.10 and therefore reduces the total activities from 12 to 11.
[19] Indicators are only described in the M&E section.

not be matched with objectives (consistency rate: 79%). For the M&E section, only one out of the 11 activities could not be matched translating to a consistency rate of 91%.

All objectives were measured with at least one indicator. The majority of indicators are output indicators and are relevant to demonstrate the achievement of objectives that are closely tied to a quantitative indicator (e.g. price reductions). Targets are also quantified so that their achievement status can be easily measured.

However, the evaluators note the following:

- Some targets are not exactly aligned with indicators in the M&E section. For instance indicator 5.4b states that CHAI pays the lowest price whereas the objective is to achieve a price reduction;
- Indicators for (technical) support are not well developed although crucial for the sustainability of project success[20];
- Some indicators are difficult to measure as they do not immediately translate to the activity (e.g. 5.9b number of children on treatment as a result of drugs delivered)

Moreover neither of the activities nor objectives addresses two major aspects:

- Do the activities contribute to scale up access to treatment, that is: do orders and deliveries of paediatric ARV actually translate in patients being treated (objective 1)?
- Is the CHAI market shaping approach successful in establishing sustainable low prices with sustained demand (objectives 2 and 6)?

Table 21 (Annex. Supporting Tables) links the objectives of the Agreement with the Project Plan actions and the actions and indicators from the M&E Section.

[20] “In addition to its responsibilities for procurement and delivery of products, CHAI performs technical assistance and project support for the Paediatric HIV/AIDS programs at the national level under the terms of a Paediatric Project Agreement with UNITAID. Working in collaboration with governments, CHAI provides technical assistance to ensure the timely delivery of products and monitors the effective distribution of products in- country. In addition, CHAI implements training and mentoring, works to build and improve diagnostic transport networks, seconds employees and renovates facilities. Although UNITAID does not fund related operational costs, the support of in-country implementation and the provision and/or sourcing of technical assistance is crucial to the success of this Project. CHAI contributes significant resources toward the realization of these objectives, independent of UNITAID funding. Portions of the costs associated with the Drug Access Team (“DAT”) are covered by UNITAID support of CHAI” (2010 Agreement, Appendix, Section 5.15).

3.1.2 Effectiveness

The objective of this section is to assess whether objectives of the project have been achieved, and what are the factors for achievement or non-achievement of those objectives.

Rating		**Level of confidence**	
☐	Optimal	☐	Optimal
☒	Minor concerns	☒	Minor concerns
☐	Major concerns	☐	Major concerns

Key findings

- ✓ In terms of the 2010 targets of the Project: four were achieved, one was partially achieved, six were not achieved; and for three targets information was not sufficient.
- ✓ In 2010, funding to UMIC exceeded its ceiling, while disbursements to LIC fell short of the commitment;
- ✓ Only 25 countries signed MoU in 2010, and less than half did this in the first part of the year;
- ✓ A total of 5 new FDCs were pre-qualified: 4 new AZT-FDC suppliers and 3 new RUTF suppliers; in addition, two new formulations (dispersible) were pre-qualified in 2010
- ✓ Price reductions for paediatric ARVs from primary and secondary suppliers were achieved;
- ✓ The average target lead-time of 12 weeks was exceeded for most products, suppliers and countries;
- ✓ The definition of 'pooled procurement' is unclear; however, 95% of ARVs were purchased through the Procurement Agent (IDA-F)
- ✓ Only three of the 35 beneficiary countries deviated less than 10% from their anticipated budget of the year;
- ✓ A total of 70,744 children were initiated on treatment during 2010; the number of children that continued treatment from 2009 was less than envisaged.

- **To what extent were the objectives of the project achieved?**

Implementation of project actions

Table 22 shows the actions and indicators and measures the progress of the project in 2010 against set targets (2010 Agreement, Annex 5).

Of the 11 actions and 14 targets identified, four targets were fully implemented, one was partially and six not implemented. For three targets information was not sufficient.

<u>UNITAID eligibility criteria (5.1)</u>

The UNITAID eligibility criteria stipulate that at least 85% of UNITAID funds should be spent on low-income countries (LIC), no more than 10% on low-middle income (LMI) and no more than 5% on upper-middle income countries (UMI) (2010 Agreement, section 3.2.1). In accor-

dance with these criteria, 40 beneficiary countries have been identified for this project, based on income levels determined at the time of the inception of the project in November 2006.

By the end of 2010, 84.4% of expenditures[21] had been made to low-income countries, while 11.8% went to low-middle income and 3.8% to upper-middle income countries (see Table 4). When both expenditures and open commitments are taken into account, 77.9% of funds were allocated to low-income countries, 17.6% to low-middle income and 4.5% to upper-middle income countries. Taking this into account the 2010 allocations are no longer in line with UNITAIDs overall funding criteria.[22] In this respect it must be noted that for 2010 the budget allocations agreed between UNITAID and CHAI already demonstrate marked deviations from the UNITAID eligibility criteria[23].

Table 4. Allocated budget, open commitments and expenditure to suppliers according to the UNITAID eligibility criteria (2010).

Beneficiary Income Level	Budget*	% of Total	Open commitment + expenditure**	*% of Total*	Expenditure	% of Total
Low Income	$50,279,737	69.5%	$46,893,570	*77.9%*	$23,455,298	84.4%
Lower Middle Income	17,259,247	23.8%	10,628,210	*17.6%*	3,290,422	11.8%
Upper Middle Income	4,854,032	6.7%	2,699,114	*4.5%*	1,059,831	3.8%

* Source: Agreement 2010 Annex 1; ** Source: Annual Report 2010

CHAI's actual expenditures to suppliers have been quite close to UNITAIDs funding criteria (see Table 23 and Table 24). Expenditures for LIC stayed over all years above 80% whilst though across all years below 85%. LMI have in been over the targeted 10%. The targeted budget allocation ratios also varied over the years with the most significant deviation noted for 2010.

Signature of amendments to MoU (5.2)

According to the Agreement, all beneficiary countries should have signed amendments and updated annexes with paediatric products. In 2010, 25 countries (71% of beneficiary countries[24]) signed a Memorandum of Understanding (MoU), and only 12 (34%) of all countries signed it in the first half of the year..

Forecasting and estimated number of patients treated (5.3)

For 2010, a forecast of estimated quantity of drugs and purchases of ARVs, diagnostics, OI drugs, and RUTF and number of patients to be treated in 2010 should be provided to UNITAID by September 2009.

[21] Due to inconsistencies in wording between different reports, this report will use the terminology of disbursements to CHAI as payments made from UNITAID to CHAI; expenditure as a payment from CHAI to a third party supplier; and committed as open commitments (an outstanding placed order by CHAI with a third party which has not yet been paid as payment only takes place once products have arrived in country).

[22] Reasons given for deviations are differences between countries in the pace of implementation, required timing of orders based on existing stocks, delivery lead times and rolling vs. aggregate procurement, price of commodities in this country based on supplier selection and also budget allocated on assumption about patients at the beginning of the year.

[23] It is therefore unclear from the Agreements whether UNITAID eligibility criteria are to be considered on a yearly or cumulative basis. In the Ernst & Young report it was also indicated that further clarifications are needed of whether UNITAID funding principles are to be adhered within each program or overall (see: Ernst & Young (2009), p. 27).

[24] The total of MoUs that need to be signed is 35 countries, as OECS only needs to sign one MoU.

Forecasted quantities of products are included as 'indicative orders' in the invitation letter to suppliers (Request for Proposals, RfP) for the selection of suppliers of paediatric ARVs for the 2010 procurement (Annex 7 Agreement 2010). In addition, the MoU with countries have as Annex the annual and quarterly forecasts of products to be procured for the respective country. However, both these documents are published after September 2009, so strictly speaking this target is not met. Interviews with UNITAID revealed that continuous discussions take place between CHAI and UNITAID to discuss treatment targets and corresponding treatments to be procured, including regular revisions during the calendar year. For a more detailed outline please see section 3.2.

New suppliers and ARV prices (5.4 a+b)

The 2010 targets and achievements to increase the supplier-base of paediatric ARVs, OI drugs and RUTF to the project are summarised in Table 12.

Table 5. New suppliers for paediatric ARVs, OI drugs and RUTF in 2010.

	2010 target*	2010 achievement **	Comments
Paediatric ARVs	2 new FDC products/ suppliers	5 new FDC products/ suppliers	**Cipla: LPV/r (80mg/20ml), LPV/r (100/25mg)** **Strides: LPV/r (200/50mg)** **MacLeods: d4t/3TC/NVP (30/150/200mg), d4T/3TC (30/150mg)** **Varichem: d4t/3TC/NVP (30/150/200 mg)** **Hetero: d4T/3TC (30/150mg)**
	1 new AZT-FDC supplier	4 new AZT-FDC suppliers	**Microlabs: AZT/3TC (300/150mg)** **Varichem: AZT/3TC (300/150mg)** **Cipla: AZT/3TC (60/30mg)** **Ranbaxy: AZT/3TC (60/30 disp)**
OI drugs	1 new supplier	N/A	**Multi-source**
RUTF	1 new qualified supplier	(Procurement from 3 new local suppliers	**Diva (Nigeria, Zambia), Vitaset (Haiti), Compact (India)**

* Agreement 2010, Annex 5 M&E

** 2010 Annual Report, Annex 6, section 5.3

In 2010, the number of approved suppliers for paediatric FDCs has exceeded the target. In addition, the dispersible formulation of AZT/3TC (60/30mg), which had no approved supplier before, has been included in the list in 2010. For more details on the supplier-base for paediatric ARVs over the years, please see 3.3.

An increase in OI suppliers is stated in 2010 Annual Report as target. However, OI drugs are already multi-sourced products, and as such, increasing the number of suppliers will have little, if any, impact on the price or market. Therefore, this declared target of the project should be reconsidered for inclusion in future agreements.

In 2010, the UNITAID CHAI project procured RUTF from three new suppliers: Compact for India, Vitaset for Haiti, and Diva for Nigeria and Zambia. This is in addition to the four manufacturers – Nutriset and Nutriset franchisees in Ethiopia and Malawi – that were already in the suppliers-pool in 2009. This is a significant expansion from the initiation of the Project, when CHAI only purchased from Nutriset. More than half of the UNITAID RUTF budget was spent on the procurement of the patented product Nutriset from France.

Price reductions in median price (US$) paid for selected ARVs procured in 2010
As shown in Section 3.3, Table 14 the UNITAID CHAI project has achieved reductions in median prices for selected paediatric ARVs as negotiated with primary and secondary suppliers.[25] In addition, the actual median price paid for three products for which information was available also showed a steady decline over the past three years.

Even though the target was not quantified, the large drop in median price for most paediatric ARVs suggest a good performance in this area.

Signature of Long-Term Agreements or Master Supply Agreements (5.5)
As reported by CHAI in the 2010 Annual Report, CHAI executed long-term agreements (LTAs, or Master Supply Agreements/MSAs) with certain primary and secondary suppliers in 2009. Some of these MSAs were for multiple years and also covered 2010 purchases. Two originator companies (Merck & BMS) provided products to CHAI under their public "Access Prices." In 2006 and 2007, CHAI also entered into long-term pricing agreements with diagnostic suppliers to the project. An MSA with Nutriset has only been executed mid 2011.

Even though information on the status of the signed MSAs and LTAs was not available to the evaluators, from the Annual Report can be concluded that MSAs were not signed with all suppliers to the UNITAID project. It is also not clear if the 2006/2007 LTAs with diagnostic suppliers were still valid in 2010.

Lead-time & registration of products (5.6a)
Average lead-time for 2010 was 12 weeks for each supplier in each product area (2010 Agreement, M&E Section Annex 5). Lead-time, measured between lead-time between purchase order to delivery in country, should be decreased. In the 2010 Annual report, Annex 4 CHAI reports more detailed lead times per product, for selected suppliers and per country, both for paediatric ARVs as well as OI drugs. For paediatric ARVs it is shown that approximately 12 products exceeded their average production lead-time by more than 12 weeks. Four suppliers, namely Matrix, Aurobindo, Merck and Hetero exceeded the average production lead time whilst standard lead time was agreed for 70 days. Average lead times for these companies varied between 87 days and 115 days. Moreover CHAI reported delivery lead times per country. For approximately 29 countries average lead-time exceeded 12 weeks.

Increased number of registrations per drug in beneficiary countries (5.6b)
As outlined in 5.4a the number of suppliers for different products has overall increased. However on the basis of information available in 2010[26] the evaluators cannot judge in which countries, when and with which status (e.g. waiver or registration) products had been introduced. Also, more in-depth information would be required to assess CHAI's actual contribution to the achievement of increased registrations per drug in beneficiary countries.

Pre-qualified paediatric ARV formulations (5.7)
In 2010, three new pre-qualified paediatric ARV formulations came on the market. Two of these (ABC 60mg and AZT/3TC 60/30mg) already existed before but were launched as dispersible tablets, and nevirapine (NVP 50mg dispersible) was newly introduced.

[25] Paediatric ARV product selection based on formulations included in the RfP/invitation letter to suppliers, which outlines products for which there are more than one supplier, and/or large market volume (e.g. triple FDCs)
[26] The 2010 Annual Report, Annex 5 does include a registration status list. However information on paediatric ARVs are not included.

Pooled procurement (5.8)

Pooled procurement is defined as *"purchasing done by one procurement office on behalf of a group of facilities, health systems or countries. Group members agree to purchase certain drugs exclusively through the group*".[27] If this definition is applied, then one could argue that the majority of orders for ARVs and OI drugs were pooled through one procurement agent (PA, in this case IDA Foundation). In de 2010 Semi-Annual Report, CHAI states that in the first half of the year, 564 of the 662 order requisitions (85%) for ARVs were placed in the pooled procurement process, i.e. placed with the PA, accounting for 75% of value. At the end of 2010, CHAI reports that 95% of ARV orders and 85% of OI drug orders have been pooled.

Budget allocation per country (5.9a)

CHAI reports that as of February 28, 2011 the financial commitment in eight countries exceeded 115% of the amount budgeted and in seven countries it fell below 50% of the budget. CHAI also gave specific reasons for those deviations. For overspending these were: high number of first-line syrups procured, country regulations that influenced supplier choice (e.g. pooled originator), forecast challenges, delays of transition progress, under-spending of anticipated budget in 2009 or rapid scale up of HIV diagnostic capacity. For under-spending the reasons included: lead time of 2009 ordered products, transitioning to other funding sources and forecast challenges in West-Africa. Project expenditures in different countries also depended on the possibilities to sign up new patients to be treated.

However, regarding the defined target of "100% of budgeted products are delivered allowing for a 10% deviation per country budget allocation"[28] only three countries of the 35 beneficiary countries managed to do so (see Annex. Supporting Tables, Table 25). The countries that were between this range were Benin, Papua New Guinea (PNG) and Senegal. Even when allowing for a 15% deviation only four countries had actually products delivered and accordingly used their anticipated budget to this date. An explanation for this is the relatively high amount of orders that were placed at the end of the year and not yet delivered by the 28th of February 2011.

It should be noted that to assess deviations from original budget allocation the more appropriate measure would be against outstanding commitments and expenditure as this reflects the total allocation of the 2010 budget. Including outstanding orders five countries performed within 10% of the original budget allocation (Cameroon, Ethiopia, Haiti, Mozambique and Vietnam). Setting the limit to over- or under-spending allowing for a 15% deviation in orders of the allocated budget there were 27 beneficiary countries that did not meet this target in 2010.

The reasons outlined by CHAI for the cases with spending more than 115% or less than 50% of their anticipated budget will most likely also be relevant for the other countries who did not manage to stay within their anticipated budget range of 10%. However the extent of deviations from the original budget plan when looking at country level are much wider. Whilst particular high order numbers in late 2010 with associated lead times might be the reason why budgets have furthermore not been paid to suppliers by February 2011 the deviations for open commitments and expenditures, when taken together are deemed critical as the budget

[27] Management Sciences for Health (MSH), Managing Drug Supply, 2nd Edition
[28] The M&E Section comment states that requested deviations above 15% only after mutual consultation.

allocation is based on forecasts. The deviations could indicate that forecasts are not of such quality to anticipate these developments and take them into account[29].

According to the 2010 Agreement, any proposed change or reallocation in 2010 over 15% of any annual budget expenditure (designated as commodities A, B, C, D) or any new expenditure other than for per country expenditures is required to have prior written approval from the UNITAID Secretariat (2010 Agreement, Section 16.8.1). Since 2007, budget absorption of 85% or above for commodity areas has also only occasionally been reached and therefore UNITAID should have been informed and approved such deviations (see Table 26). The interviews with UNITAID revealed that such written approval had not been sought although UNITAID was well aware with the issue and the reasons associated with such deviations.

Number of children on treatment (5.9b)

The target states that 70,070 additional children should receive ARV treatment in 2010, with an additional 260,752 that continue treatment from 2009 onwards. As reported by CHAI and shown in Section 3.2, Table 11, a total of 70,744 children were placed on treatment, whereas an estimated 250,794 children were on treatment at the beginning of 2010. This means that this target has been substantially achieved. As further elaborated on in section 3.2, the reliability of these data is questionable so should be considered as best estimates of the actual situation in beneficiary countries.

Technical assistance (5.11)

The target is to provide 40 (all) beneficiary countries with technical assistance (TA) for the paediatric project in 2010. The Appendix to the 2010 Project Agreement outlines plans for TA on specifically forecasting and quantification to be provided to all (but one, Ghana) beneficiary countries. CHAI also includes descriptive experiences on their activities and TA in beneficiary in their Annual and Semi-annual Reports. Although this target could not be independently verified as specific outcome measures have not been defined nor did the Agreement specify exactly what kind of TA was to be given, there is no reason to believe why CHAI would not have been providing TA to all 40 countries.

Development of 2011 project plan (5.12)

The format of the 2011 Agreement has slightly changed. Agreements were signed on the 6th and 20th of June 2011 respectively and include the required information of a project plan. The evaluators cannot judge how much requested timelines were respected as this information is not accessible.

Project Financing

The budget execution rate is calculated comparing disbursement vs. budget and gives an indication how much of the original funds were actually available for the project. The budget absorption rate, calculating the % of the budget that has been spent (expenditures) indicates how much of the budget was actually used for procurement within the budget year. Overall the budget execution rate (disbursement from UNITAID to CHAI) varied over the years between 100% in 2007 and 88% in 2010. The budget absorption rate (paid by CHAI to third

[29] The major obstacle to get better estimates was related to the data quality of forecasts (see also section 3.3).

parties) varied between 55% in 2010 and 74% in 2007[30]. For further details on financial analysis and reporting please refer to section 3.4.

- **Main factors influencing the achievements of the objectives**

Factors that have challenged the achievements of objectives related to the UNITAID CHAI Project include insufficient in-depth understanding by CHAI of factors driving uptake of paediatric ARV treatment, which can translate into unrealistic country targets set at the start of the year and result in wide variations in uptake of treatment across beneficiary countries. Hypothetically, pressure to reach patient numbers and force a very rapid scale-up of treatment may have compromised quality of care provided. There was, however, no indication that this might have been the case.

CHAI's strategy of sourcing RUTF from mainly one supplier, as opposed to pursuing locally available options, have not contributed to an increase in supplier-base for therapeutic food supplements.

The evaluators learnt that staff turnover within CHAI – and to a lesser extent within UNITAID – has been very high during the duration of the project, which undermines institutional memory and continuity of projects and can undermine the Project achievements.

External factors that have challenged the achievement of the UNITAID CHAI Project include:

- the lack of available data in country to accurately report on numbers of patients treated and drugs consumed
- weak health systems and limited capacity in some countries to rapidly scale-up paediatric ARV treatment
- political instability and civil unrest,
- lack of accountability and commitment with national counterparts, as reflected in late/no signing of MoU (and possibly hesitance to cover CSD, see below), can undermine the success of the Project.

Unfortunately, no comprehensive risk assessment was done at the start or during the Project to help mitigate the impact of potential negative events.

[30] The budget absorption rate for the disbursements in 2010 was calculated until the 28th February 2011 in order to align the calculation with the previous years. If it had been done for the budget year, the budget absorption rate would have a reduction of 40%.

3.1.3 Efficiency

The objective is to assess if the partners are using UNITAID funding in the most efficient manner in order to achieve the objectives of the project. This covers aspects around the procurement model, the coordination with national authorities, as well as other aspects of implementation arrangements depending on the project.

Rating		**Level of confidence**	
☐	Optimal	☐	Optimal
☐	Minor concerns	☒	Minor concerns
☒	Major concerns	☐	Major concerns

Key findings

- ✓ MoU have not been signed in a timely manner and not by all countries, whilst this is of utmost importance to mitigate risk and improve accountability of beneficiary country governments;
- ✓ There were unexplained differences in actual paid median prices and agreed prices with primary supplier for ARVs. Comparisons, which were limited to three paediatric FDCs, revealed that the medians of actual prices were above agreed prices.
- ✓ Median prices for OI drugs were in line with market reference prices
- ✓ Prices paid for DNA PCR, CD4 tests and RNA Viral Load tests were reported to be significantly lower than market prices, whilst median price comparisons for HIV rapid tests revealed that some were lower and others higher than GPRM summary prices.
- ✓ Prices paid for RUTF by the CHAI UNITAID program were comparable to UNICEF reference prices. Main supplier for RUTF was Nutriset.
- ✓ Lead-time is reported inconsistently, but data and interviews with CHAI and UNITAID indicate that lead time is more than the targeted 12 weeks (4-6 months or above).
- ✓ The evaluators lack of information on stock-outs or overstocking.
- ✓ The procurement model is well defined in the Appendix of the Agreements. In practice though various deviations have been identified. The procurement model is not followed strictly.

- **Are the project partners working closely with the relevant national authorities in the projects beneficiary countries?**

Under Evaluation Matrix, the collaboration between the project partners and national authorities is measured as the number of Memorandum of Understanding (MoU) signed between the project and beneficiary countries.

CHAI reports that 28 of 35 countries (80%) signed MoU for 2010 accounting for 91% of the orders placed in 2010. However, three countries, namely Mozambique, Tanzania and Uganda only signed the MoU retrospectively and therefore should not be taken into account. So after adjusting 71% of participating countries signed a MoU in 2010. Of the signed MoU only 12 (48%) have been signed in the first half of the year. The lack of signed MoU means, that in 2010 expenditures for a total of US$ 635,845 have not been covered by a MoU. This amount would significantly increase when including purchase orders for countries with no

signed MoU on date of purchase. However in several countries political and administrative challenges prevented MoU from being signed. Also countries that transitioned in 2010 did not need to sign a MoU as they were covered by the 2009 MoU.

In 2009, CHAI reported that of the 34 MoU that should be signed 33 actually were (97%). Only Burkina Faso was not covered by a MoU. Nine countries were covered by their MoU signed in the previous years. However, only 26 countries (76%) signed an updated Annex covering the specific products and forecasts of 2009. According to CHAI, all countries participating in the program signed MoU in 2007 and 2008 without giving more details on whether these were newly signed agreement or (for 2008) were covered by previous year’s MoU.

The delays in signing MoU or even the retrospective signature is deemed critical and has been addressed by UNITAID in various conversations with CHAI. MoU do not help to determine demand but create accountability and responsibility from the partnering MoH in country. The in-country commitment to the paediatric program is of utmost importance to reduce risks of diversion, increase national ownership over the program and transfer the accountability of medicines and commodities to national governments. Ownership and in-country commitments play also an important role in taking responsibility for CSD charges, which are now at least partially paid by the Project. MoU outline that countries agree to the payment of CSD cost once the drugs have arrived in the harbour.

Currently there are no direct repercussions for beneficiary countries if MoU are not signed, as this would increase the risk of treatment interruptions. However, this also implies that – as drugs and commodities continue to be supplied – the incentive to timely sign is low. CHAI has been working on improving rate of signed MoU with beneficiary countries, which should receive high priority with the Project.

The Agreements further state that CHAI takes responsibility for working with governments to develop forecasts and place order requisitions, as well as provide project support. CHAI coordinates paediatric HIV/AIDS programs at the national level and provides technical assistance to governments to scale up paediatric treatment programs in country, including ensuring delivery of products and monitoring prices and distribution (2010 Agreement, Appendix 1, Section 4.2).

These activities and CHAI achievements are not consistently reported in CHAI annual reports. CHAI worked heavily on extending its support on the ground to build capacity for transitioning. UNITAIDs operational contributions were used to include activities on forecasting, tendering, procurement, management of volume allocations, importation, supply-chain management, contracting, reporting, supplier relationship management, financial management, and general operational oversight. CHAI also provides extensive technical and material support to beneficiary governments to improve their underlying health systems. Some examples of this support include providing technical assistance for sample transportation network design, advising on national treatment guidelines, and improving linkages between PMTCT and paediatric treatment centres (2010 Annual Report, Section 5.2.6). This is partly done through CHAI’s in-country staff who oversees the work of in-country analysts and manage relationships with local ministries of health and other in-country partners as well as the UNITAID project management team members that interfaces with in-country staff in order to centrally manage forecasting, procurement and supply chain issues.

- **Is the project's procurement model well defined and designed to identify and solve procurement-related problems as they arise?**

Selection of procurement agent

Since September 2009, following a consultation with WHO Contract Review Committee (WHO CRC), the procurement strategy was revised and certain responsibilities (e.g. placing orders for ARVs and OI drugs with suppliers, tracking shipments, monitoring lead times and confirming deliveries) have been handed over to an external procurement agent. After an initiated international competitive bidding process in July 2008, IDA Foundation has been selected. Whilst the responsibilities are outlined in detail in the Agreements, the actual implementation of the collaboration between CHAI and IDA Foundation remains unclear, as reporting on IDA Foundation activities is scarce. For instance in 2010 IDA Foundation supported the tendering process for OI Drugs whilst according to the Agreement (Section 1.1.3) this is the responsibility of CHAI.

Median price in line with budget

The evaluators ascertained if median prices paid per product in 2010 was in line with the budget for paediatric ARVs. Median prices paid for OI drugs, HIV tests and RUTF could not be compared to the original planned unit cost in the budget for which no information was available.[31] Hence, these prices are compared to available information on market prices.

Paediatric ARVs

The actual median prices paid were only available for three paediatric FDCs, and the indicative price agreed with the primary supplier was taken as a proxy for the price in line with the budget. As shown in Table 13 the median price paid for ABC+3TC (60+30mg) in 2010 was US$ 176 per child per year, whereas the agreed price with the primary supplier was US$ 156 (+13%). Similarly, the prices paid for AZT+3TC (60+30mg) and the triple AZT-containing FDC were also higher, respectively 16% and 8%. As explained by CHAI in email correspondence, difference between medians in agreed prices and actual paid prices may stem from conversions from packs to price-per-person per year (PPPY). For instance, both the tender and the M&E report assume 4 pills per day, but PPPY assumes a 360-day year, while the latter assumes a 365-day year resulting in a minor difference. However, this still leaves part of the price difference unexplained.

Price of drugs for Opportunistic Infections (OIs)

The UNITAID budget for OI drugs is spent primarily on the purchase of cotrimoxazole, mainly because this drug remains the leading antibiotic used in countries for the treatment of HIV-related opportunistic infections in children. In 2010, prices obtained through the Project were in line with market reference prices (MSH ERC).[32]

[31] However, median prices paid for these products through the UNITAID CHAI project were compared with market prices, see Table 6, Table 7

[32] The Project purchased most its cotrimoxazole (480 mg) in 100 tablet pack sizes, whereas the MSH ERC reference price is stated for purchases of 1,000 tabs. Hence, the price per tab came out a little higher ($0.013 vs. $0.011). The price per pill for few orders that were placed for 1,000 tabs pack size came to $0.009). Prices for cotrimoxazole 240mg/5ml were $0.42/100ml bottle for both UNITAID and CHAI, although UNITAID placed most orders for the 60ml pack size. Smaller pack size has advantages when the medicines have to be distributed to a large number of facilities. Also, if small quantities of syrup are needed, lower-volume bottles face less issues with expiry after opening.

Prices of diagnostics

CHAI has conducted price negotiations with several manufacturers of diagnostics products. As reported in the 2010 Annual Report, prices paid for DNA PCR, CD4 tests and RNA Viral Load tests are significantly lower than market prices. Price negotiations were initiated by CHAI, from which the UNITAID project benefited. However, the purchasing power CHAI had through the UNITAID project has likely contributed to the favourable prices obtained for this class of HIV diagnostics. Indeed, CHAI reports in its 2009 Annual Report that CHAI is the single largest purchaser of DNA PCR globally and supports the use of CD4 and Viral Load platforms in use in beneficiary countries.

The median price paid for HIV rapid tests under the CHAI UNITAID project in 2010 was for some tests lower than GPRM summary price, while for others the Project paid more (see Table 6).[33] In its 2010 Annual Report, CHAI stated that the average price paid for HIV tests was above market price. Reasons given were the fact that some HIV rapid tests had to be procured from suppliers with whom no prior relationship was established (due to different national algorithms in beneficiary countries) or through an emergency order from local distributors.

Overall, there seems to be scope for further negotiations with suppliers of HIV rapid tests to ensure prices paid through the project are in line with market prices.

Table 6. Comparison of median transaction price per unit for HIV rapid test between CHAI UNITAID (2010) prices and GPRM (Q1 2010) reference prices.

	2010	Q1 2010
Product	**CHAI UNITAID**	**GPRM**
Determine HIV ½	$0.65	$0.72
DoubleCheck Gold HIV ½	$0.64	$0.83
OraQuick HIV ½	$4.00	$3.50*
SD Bioline HIV 1/2 3.0	$0.86	$0.80
Stat-Pak HIV ½	$0.80 - $1.45**	$1.13
UniGold HIV	$1.63	$1.82

Source: CHAI UNITAID Annual Report 2010, Annex 3: Order Tracker; GPRM Summary Report May 2010

* GPRM 2009 median transaction price

** Stat-Pak HIV 1/2 (20 tests) cost $1.45/unit, while Stat-Pal HIV 1/2 Dipstick (30 tests) cost $0.80/unit.

Price of RUTF

Table 7 shows the average price of RUTF obtained by UNITAID CHAI project compared to UNICEF weighted average prices paid in 2010 for selected suppliers. Some notes should be made. The price of RUTF is subject to fluctuations throughout the year due to the fact that the ingredients are comprised of agricultural products. In 2010, CHAI placed only one order with Compact India, and this price is compared to the average UNICEF price paid for the year. Overall, prices paid for RUTF by the CHAI UNITAID program are slightly above prices paid by UNICEF, with the exception of Compact India. More than half of the UNITAID RUTF budget was spent on the procurement of Nutriset from France.

[33] It should be noted here that the price for Oraquick HIV 1/2 included in the GPRM summary report is only available for 2009. In addition, the median price for Stat-Pak HIV 1/2 as included in the Order Tracker depends on the pack size (20 or 30 unit, dipstick-version), while it is unclear what the GPRM price is based on.

Table 7. Comparison of average price (EUR) of one carton of RUTF (based on 13.8kg) for selected suppliers between CHAI UNITAID and UNICEF in 2010.

	CHAI UNITAID	UNICEF
Compact India	€ 36.90	€ 37.06
Diva Nutritional	€ 40.65	€ 40.08
Nutriset	€ 37.95	€ 36.53
Vitaset	$49.68	$49.13

Source: CHAI UNITAID Annual Report 2010, Annex 1; UNICEF Supply Division Oct 4, 2011 http://www.unicef.org/supply/files/RUTF_Pricing_Data_final.pdf

Average lead time

Table 8 outlines the identified lead times from the Annual Reports 2008-2010 and the Semi-Annual Reports 2009 and 2010.

Table 8. Lead times 2008-2010.

Supplier	2008*	Jun 2009*	2009	Jun 2010	2010
Abbott Laboratories	85	101	99	62***	55***
Abbott Laboratories Puerto Rico, Inc.	65	n/a	n/a	n/a	n/a
Abbott Logistics B.V.	79	n/a	n/a	n/a	n/a
Alkem Labatories Ltd.	57	63	n/a	n/a	n/a
Aurobindo Pharma Ltd.	42	68	83	110	96
Belta Pharma SPA	60	82	n/a	n/a	n/a
BMS (France)	n/a	n/a	n/a	n/a	n/a
Boehringer Ingelheim	n/a	n/a	101	90	n/a
Brystol-Myers-Squibb	60	103	109	123	n/a
Cipla Ltd.	91	99	101	77	72
F. Hoffman-LaRoche Ltd.		43	n/a	n/a	n/a
Glaxo-SmithKline Export Ltd.	119	157**	157**	210**	n/a
Hetero Drugs Ltd.	35	48	61	78	115
International Healthcare Distributors	60	n/a	n/a	n/a	n/a
Macleods	n/a	n/a	n/a	66	n/a
Matrix Laboratories Ltd.	73	98	111	150	87
Merck Sharp & Dohme Asia Ltd.	37	n/a	n/a	n/a	111
Merck Sharp & Dohme B.V.	69	73	128***	120***	n/a
Ranbaxy Laboratories Limited	98	212	196	n/a	n/a
Strides Arcolab Ltd.	142	96	78	64	67
	Average manufacturing lead time; calendar days between purchase	*Average lead time (Number of days between the date of purchase*	*Average ARV manufacturing lead time*	*Cumulative weighted average lead time (number of days between pur-*	*Production lead time (Average number of days between placement*

Supplier	2008*	Jun 2009*	2009	Jun 2010	2010
	order date and invoice date (calculated per order line)	*order and the date of invoice)*		*chase order and the date of invoice)*	*of PO and Confirmed ETD)*

Source: 2008, 2009, 2010 Annual Reports; 2009, 2010 Semi-Annual Reports
* ARV & OI Drugs
** name of supplier has slightly changed
*** name of supplier has been changed so that lead time per supplier is ambivalent

The current lead times are beyond the targeted twelve weeks of the Agreements for a substantial part of the suppliers. Of the reasons given for those delays in 2010 the most common was delay in production, as suppliers may wait to have sufficient orders in to start with the production of a batch. Other reasons mentioned were delay in order, capacity constraints, delay of National Drug Regulatory Authorities approval, delay of request for waiver, decreased demand with consequences for economic viable production size and other administrative delays.

However, information on lead-time is not consistent across the reports. Whilst in the Agreement it is fixed with 12 weeks between order placement and delivery date the Semi-Annual and Annual Reports are inconsistent in their measurement. Inconsistencies identified are weighted average vs. average, production lead-time vs. manufacturing lead-time vs. delivery lead time, variances in presentation of suppliers and inclusion of OI drugs. Hence the comparison between different years is limited. In interviews CHAI reported lead-times usually between four to six months, whilst UNITAID stated that a lead-time of 6 months or above is more rule than exception. Lead times are also given for OI drugs, but no information was given for diagnostics or RUTF

A deviation was noted between the lead-time as defined in the Agreements and the reported production lead-time in the 2010 Annual Report, CHAI explained that from their point of view production lead-time is more relevant than delivery lead time, as delivery only takes a comparatively small amount of time. From a countries and consumer perspective delivery lead times is though the more important indicator.

Particularly when reported lead times are only listing production rather than delivery in country, lead times are beyond the agreed target. This is deemed critical as high lead-times are causing delays in delivery, making forecasting and on time deliveries questionable. In addition, these do not allow for establishing a concrete and traceable link between the number of children treated and drugs procured. From a countries perspective, delivery lead-time is the target that should be minimized as only delivery guarantees possible consumption.

Stock-outs

The Annual Reports do not provide information on stock-outs or expiry of products. During the interview with CHAI, the evaluators were told that problems with under- or oversupply of medicines or other commodities did not occur in beneficiary countries. However, as mentioned in section 3.3, there is some evidence that overstock of medicines may have occurred in beneficiary countries. In addition, adequate stock levels at the central warehouse do not ensure continuous availability of medicines lower down the supply chain. Given the lack of consumption data to base forecasts and distribution schedules on, the paucity of information at implementa-

tion level, the lack of consumption data, and the short shelf life of some products (e.g. laboratory reagents), it seems likely that at least some products have been out of stock or expired in some countries. However, the evaluators did not have information to confirm or refute this statement.

Procurement model vs. project plan (Appendix 2010 Agreement)

The evaluators also determined if the procurement model is functioning as designed in the project plan, which are outlined in the Appendix of the 2010 UNITAID CHAI Agreement.

The supplier selection process begins with the request for proposal, which includes indicative order volumes of paediatric ARVs. Suppliers can submit either a traditional price proposal, or engage in the ‘cost-plus’ price negotiations with CHAI. After further negotiations conducted by the CHAI Drug Access Team, a composite score is calculated (based on a price received, registration status and suppliers’ performance) on which primary, secondary and pool suppliers are selected. The supplier selection process of CHAI for procurement of products is approved by CHAI CRC and CEO.

The requisition for the procurement of products is received from beneficiary countries based on forecasts prepared by the country teams in consultation with local partners. In principle countries submit their order requisitions four times per year (March, June, September and December; 2010 Agreement, Appendix 1) which are subsequently consolidated by CHAI. The procurement agent, IDA Foundation, is responsible for placing orders for ARVs and OI drugs with suppliers, (along the 60:40 divide between primary and secondary suppliers), tracking shipments, monitoring lead-times and confirming deliveries. Procurement of diagnostics and RUTF is done by CHAI directly from the manufacturers. As confirmed by CHAI, some manufacturers will only start production of paediatric ARVs once sufficient orders are placed to meet minimum batch-size. After shipment to the final port of destination, the local beneficiary country government takes over responsibility, including incurring cost for clearing, storage and distribution.

CHAI’s procurement agent IDA Foundation conducts quality assurance and control by way of laboratory retests, pre-shipment inspections, and dossier evaluations. In 2010, no quality issue was identified for the products procured, demonstrating satisfactory quality of the products delivered to beneficiary countries. In the same year, CHAI conducted an audit in an ARV-manufacturing facility, which also passed.

According to the CHAI UNITAID Agreement, orders are expected be pooled on a quarterly basis through a pooled procurement model. However, in reality this model proved to be challenging. CHAI explained that one of the complicating factors was the complex requirements of having to ship to each country separately and meet each countries specific import and clearing requirements. In addition, the lack of streamlined product selection further hampers pooling of orders to meet minimum required batch size with manufacturers. Countries are asked to prepare, aggregate and submit their orders around specified times during the year (end of March, mid June, end of Sept, early Dec), but in most cases, the ordering procedure consists of several steps to obtain additional information on the nature of the order, products etc. Even pooling within countries (as opposed to between countries on a regional level) can pose a challenge, as often large number of implementing partners will have separate and district receiving requirements. The procurement is currently conducted around certain time periods, as opposed to pooled, as also confirmed with CHAI during the telephone interview.

Indeed, the Order Tracker (Annex 3, Annual Report 2010) shows that purchase orders are placed with suppliers throughout the year.
Pooled procurement can be defined as *"purchasing done by one procurement office on behalf of a group of facilities, health systems or countries. Group members agree to purchase certain drugs exclusively through the group*".[34] If this definition is applied, then one could argue that the majority of orders for ARVs and OI drugs were pooled through one procurement agent. In de 2010 Semi-Annual Report, CHAI states that in the first half of the year, 564 of the 662 order requisitions (85%) for ARVs were placed in the pooled procurement process, i.e. placed with the PA, accounting for 75% of value. This suggests also that the remainder (15%, and 25% of value) has been directly procured from manufacturers (without the PA as in-between) or from local distributors (e.g. Phillips Pharmaceuticals in Kenya). Purchases that were not placed through the PA were explained as being emergency orders or due to supply chain management issues. At the end of 2010, CHAI reports that 95% of ARV orders and 85% of OI drug orders have been pooled.
In its Semi-Annual Report (September 2010), CHAI states that it aims to pool 75% of orders. It is unclear if this points to order requisitions or value percentages, and if this applies to ARVs or for all products. This number also implies procurement of a maximum of 25% not by means of procurement agent, directly from manufacturers or local distributors. Especially for ARVs, this seems like an unacceptably high percentage as this type of procurement is usually not subject to competitive bidding processes and standard SOPs, and likely to be more expensive (as also demonstrated in order requisition vs. value).

In principle, the procurement model (as visualized in the 2010 Agreement Appendix) is well defined and designed to identify and solve procurement-related problems. CHAI was reluctant to arrange an interview with the procurement agent (IDA Foundation) or suppliers, and based on the information available it was not possible to verify if the processes described above actually took place as planned.

However, some discrepancies between the theoretical procurement model as outlined in the Agreements/ Project Plan and the way products are procured in practice were identified:

1. The Semi-Annual Report (Sept 2010) states that CHAI purchased 85% of ARV orders (with 75% of value) through the procurement agent in the first half of the year. This suggests that the remaining 15% (of 25% value) was purchased directly from the manufacturer or from a local distributor. Indeed, as already highlighted in the Evaluation Report (2006-2008), procurement from a local distributor in Kenya, Phillips Pharmaceuticals, continues to take place at the request of the Kenyan government, without a competitive bidding process, and without explicit approval from UNITAID. The Order Tracker showed that paediatric ARVs were purchased from Philips Pharmaceuticals for a total of US$ 5.3 million in 2010 (vs. US$ 4 million between November 2006- April 2008[35]).

   When comparing 2010 prices paid to Phillips Pharmaceutical in Kenya to agreed prices with primary suppliers' prices, seven products were more expensive, none was lower and six had equal prices. In total this adds up to approximately $970,000 additional cost in

[34] Management Sciences for Health (MSH), Managing Drug Supply, 2nd Edition
[35] Ernst & Young (2009): Evaluation of the Procurement Process for the UNITAD Paediatric and Second-Line ARV Niches.

2010 for drug procurement in Kenya[36]. For previous years this comparison cannot be done accordingly as various information is missing. However, in 2009 some of Phillips prices were above agreed primary prices and a few were below.

Table 9. Drug prices of Philips Pharmaceutical exceeding reference price of primary supplier (2010).

	Pack size	Philips prices - median by volume*	Agreed prices with primary suppliers*	Quantities supplied	Cost (Philips prices – median by volume)	Cost based on agreed prices with primary suppliers
ABC (20mg/ml)	240 ml	$13.70	$7.50	58'280	$798'436	$437'100
EFV (200mg)	90s	$32.40	$9.58	24'370	$789'588	$233'465
EFV (50mg)	30s	$3.42	$2.23	22'382	$76'546	$49'912
LPV/r (80+20mg/ml)	300 ml	$36.16	$36.00	5'500	$198'880	$198'000
NVP (50mg/5ml)	240 ml	$1.95	$1.75	101'996	$198'892	$178'493
DDI (25 mg)	60s	$7.00	$5.97	4'000	$28'000	$23'880
DDI (50 mg)	60s	$9.50	$7.15	2'000	$19'000	$14'300
Total					$2'109'343	$1'135'149
Difference						$974'193

Source: 2010 Annual Report, 2010 Annual Report (Table 5.1.1b)

* Assumption: ex works prices

2. The pooling of orders as described above does not take place. Indeed, CHAI explained that consolidation of orders between countries proved very challenging as various reiterations with countries needed to take place before the order could be finalized for submission to the procurement agent Rather, the term 'pooling' reflects the fact that purchase orders, which are made throughout the year, are placed with just one procurement agent.
3. UNITAID indicated that there was little information on the interaction between CHAI and IDA Foundation, and processes sometimes did not seem to follow SOPs.
4. According to the 2010 Annual Report a total of US$ 1,675,748 was paid by the UNITAID project for CSD, vs. US$ 1,291,188 by beneficiary countries. The 2010 Agreement states that all costs relating to clearing, storage and distribution (CSD) should be born by the beneficiary countries. It continues by saying that UNITAID support shall not normally be used for such purposes, but funds may be committed to enable the receipt and clearance of products under special circumstances. In particular, certain costs will be funded by WHO/UNITAID for extraordinary costs of clearance, handling, storage and transport up to the relevant limit agreed between UNITAID and CHAI. The amount specified above seems significantly more than 'special circumstances' and well above the ceiling stated as permitted in the 2010 Annual Report of US$ 1,487,860.

- **How have country-level demand forecasts for paediatric ARVs and diagnostic tests been improved?**

CHAI uses a combined top-down and bottom-up approach to estimate the quantity of drugs and commodities to be ordered for the year to come. In the fall, a top-down estimate based on projected expansion of the paediatric ARV program is carried out, and this is translated in

[36] This comparison was done with two aspects that must be considered: 1) calculations from year to pack is difficult for syrups and such calculation were necessary for converting agreed primary supplier prices, 2) Phillips price in order tracker is assumed to be ex works price.

an estimated order for products. Subsequently, countries are contacted with a product selection list were they can indicate their orders per product. CHAI consults with governments and implementing partners of beneficiary countries to jointly determine number of patients per treatment regimens and engage in forecasting for the purpose of estimating purchases of products to be supplied. For this exercise, forecasting tools from either CHAI or SCMS are used. This information is then verified by CHAI with the estimated forecast, and adjustments are made based on nationally available data. Consumption data is often not available in country, so forecasting is to a large extent based on morbidity data and assumptions. A particular challenge with paediatric treatment programs is that information on age/weight bands of children is missing, the pace of uptake of new children in the programs is dependent on a myriad of external factors, and the new WHO recommendations (2010) on who should receive treatment and new preferred treatments do further complicate accurate projections both of patients as well as drugs to be procured. To improve its quality and accuracy CHAI is cooperating with each country to revise projections on an ongoing basis.

The revised patient targets and corresponding drugs to be purchased are at the beginning of each calendar year used to compile the Request for Proposal (RfP) that includes indicative orders for suppliers. In reality, CHAI shared that quantities included in the RfP are more conservative than those based on the consolidated country forecasts, in order to manage expectations of suppliers. Actual orders are placed with suppliers and adjusted throughout the year based on updated information from countries on rate of implementation, pace of scale-up, and treatment uptake among other factors.

Table 10 outlines the indicative orders for 2009 and 2010 for paediatric ARVs (as included in the RfP), which are compared to the actual amount of paediatric ARVs procured. In 2009, the estimated quantity to be purchased for ABC (20mg/ml) and 3TC/AZT/NVP (30/60/50) was considerably lower than the actually procured amount. In 2010, more EFV (200mg) was procured than originally forecasted, while the required quantity of especially AZT (100mg) was over-forecasted. It is unclear to what extent forecasting methods have improved over the years, i.e. the required amount of the AZT-containing triple FDC was underestimated in two consecutive years.

Even though the forecasted quantity of drugs for OI, diagnostic tests and RUTF to be purchased during 2009 and 2010 is known, the evaluators have no information on the actual procured quantities, and could not determine if these were correctly estimated.

Table 10. Indicative orders vs. actual procured selected paediatric ARVs – 2009 & 2010.

Product	pack size	Indicative orders – 2009*	Actual procured – 2009**	% actual// indicative	Indicative orders – 2010***	Actual procured – 2010****	Differ-ence
ABC (300mg)	60s	23,780	16,294	**69%**	15,800	19,247	**122%**
LPV/r (200/50mg)	120s	21,763	23,636	**109%**	35,600	25,849	**73%**
EFV (200mg)	90s	102,832	160,260	**156%**	65,300	266,297	**408%**
ABC (20mg/ml)	240ml	45,527	134,348	**295%**	65,700	116,108	**177%**
AZT (100mg)	100s	256,936	258,517	**101%**	154,200	22,147	**14%**
NVP (50mg/5ml)	240ml	525,000	296,233	**56%**	229,300	404,087	**176%**
3TC (50mg/5ml)	240ml	697,666	476,005	**68%**	299,500	316,393	**106%**
3TC (60mg) + d4T (12mg) + NVP (100mg)	60s	470,605	648,742	**138%**	465,600	609,098	**131%**
3TC (30mg) + AZT (60mg) + NVP (50mg)	60s	300,000	658,436	**219%**	665,700	1,174,585	**176%**
3TC (30mg) + d4T (6mg) + NVP (50mg)	60s	419,154	798,426	**190%**	887,700	572,246	**64%**

* Source: CHAI UNITAID Agreement 2009, Annex 7 – invitation letter to suppliers (RfP)

** Source: 2009 Progress Report, Annex 10 – procurement

***Source: invitation letter to suppliers (Oct 20, 2009) as cited in the Report and recommendations by CHAI of the secondary suppliers selection for UNITAID-financed paediatric and second-line ARV treatment programs, Feb 15 2010

**** Source: 2010 Progress Report table 2.4d

CHAI reported that the observed discrepancies between indicative and actual orders for certain products have thus far not posed any problems with suppliers. Production of drugs is only initiated when actual orders are received by the supplier (thus preventing the risk of wastage at the side of suppliers), and suppliers have been able to meet demand in terms of capacity, even if actual orders vastly exceed the amount indicated in the RfP. There is also indication that CHAI exercises flexibility and in certain cases deviates from the 60:40 divide of total quantity procured between primary and secondary suppliers, if one or the other is not able to meet demand. Also, a relatively large amount of emergency orders seem to take place, to ensure demand at country level is met. CHAI is in regular contact with suppliers to exchange information on market dynamics and projected future trends and developments to maintain good relationships.

However, order volumes as indicated in the RfP do not provide the primary or secondary supplier with a guaranteed quantity to be procured, which is only defined upon issuance of purchase orders. Variance between forecasted and actual orders may therefore result in shortages of specific formulations on the global market place, or alternatively overstock at suppliers (for which CHAI assumes no responsibility), who consequently may be less willing to engage in future agreements with CHAI or invest in new technologies. As interviews with manufacturers could not be conducted, the extent to which this potentially causes difficulties for suppliers could not be verified.

In addition, pricing arrangements are agreed between CHAI and the suppliers for the calendar year, hence there is no possibility to negotiate more favourable prices if the actual quantity procured greatly exceeds the quantity as indicated in the RfP.

From the beneficiary country perspective, it is unclear to what extent challenges of accurate forecasting have resulted in stock-outs of paediatric formulations or wastage of products. Anecdotal evidence revealed that CHAI has approached partner organizations in country when an overstock of paediatric medicines is looming. In addition, adequate stock levels at the central warehouse do not ensure continuous availability of medicines lower down the chain, as preventing stock–outs or wastage at facility level also necessitates a properly functioning distribution and reporting system.

CHAI's operating costs related to the UNITAID project includes a commodity-related component focused on, amongst others, supporting beneficiary countries with developing and improving in-country forecasting tools, conducting joint national forecasting exercises and training partners on forecasting methods. In 2010, this amounted to a total of US$ 3.2 million. In addition, CHAI receives funding from other sources (e.g. DFID Access to Medicines grant) to facilitate national forecasting exercises and build supply chain management capacity amongst partners in-country. In the same year, other donors have contributed US$ 13 million to CHAI's programmatic work in UNITAID-funded countries[37].

It is unclear whether insufficient funding of CHAI's in-country activities is the main bottleneck to improving accurate forecasting (and subsequent consolidation) of needs amongst partners and governments in beneficiary countries, and if additional funding is needed for these activities. Whilst some countries had difficulties in proper forecasting, this was not necessarily better in countries with CHAI presence. A reason for this missing link could be that CHAI provides additional support in countries where challenges are known to be high (e.g. Ivory Coast, Nigeria). If this were the case, forecasting could be worse in those countries without CHAI presence. However, based on the information that was available to the evaluators this remains speculative. Proper forecasting of need for UNITAID-procured products is crucial to support stability on the paediatric ARV market place, as well as prevent stock-outs and wastage at beneficiary countries.

- **What actions are being taken through the project to address the challenge of loss to follow up of paediatric patients?**

In 2007, CHAI conducted an exercise to gain a better understanding of how, when and why children drop out of treatment. This showed that children are lost to follow up throughout the cascade: newborns in PMTCT programs not being tested for HIV, children tested but not receiving test results, children confirmed HIV positive but not initiated on treatment, and children initiated but dropping out of treatment.

Over the project period, CHAI has made considerable efforts to minimize the loss to follow up (LTFU) of children initiated on treatment. Activities include providing support to the beneficiary countries Ministries of Health to improve linkages between PMTCT-programs and the paediatric treatment programmes to support testing of babies born to HIV-positive mothers; introduction and rapid scale-up of early infant diagnosis (EID) to confirm HIV status and set up a comprehensive retention package; introduce SMS-printers and Point-of-Care CD4 equipment to

[37] See Annual Report 2010, Executive Summary

reduce turn-around time of test results; set up outreach programs through community health workers to trace defaulters; set up a system of expert clients to support children on treatment; introduce clinical mentoring of health workers to improve quality of care provided; conduct national surveys of HIV patients retention and survival to improve data for evidence-based decision making. The Annual Reports (2007-2010) describe specific examples of activities conducted in beneficiary countries.

In addition, CHAI works at a global level as part of the UNICEF Interagency Task Team Paediatric subgroup on retention (“IATT”) to share key lessons learned from in-country experiences and draft an advocacy toolkit.

Apart from providing paediatric ARVs, the UNITAID Project has greatly contributed to these activities through supporting the expansion of comprehensive PMTCT services, providing diagnostics and laboratory equipment to scale up early diagnosis and quality monitoring of patients, and funding RUTF and drugs for OI to enhance quality of care and provide additional incentives for patients to remain in care or treatment.

There are no consistent programmatic data that outline achievements in retention of children on treatment for all beneficiary countries. In 2008, CHAI calculated the difference between “children ever initiated on treatment” and “children alive & on treatment” based on data availability of 16 beneficiary countries, and found a default rate across these countries of 20% (weighted average). In its 2009 Annual Report, CHAI aimed to estimate LTFU in five countries for which relevant data were available. Across these five countries – Ethiopia, Malawi, PNG, Tanzania and Zimbabwe – the six month LTFU has been reduced by about 7% over the course of 2009, from around 25% to 18%. Around one in five children default on treatment (either through treatment interruption, progressing to adult treatment, or death). It is not clear whether the LTFU is properly recorded in the national information management systems, and thus if children that are lost are included in the estimated number of children on treatment (for whom medicines are ordered as well).

- **Were the recommendations of the past UNITAID/CHAI procurement evaluation implemented? If not, what further adjustments are needed?**

In May 2009, Ernst & Young carried out an assessment of the procurement process under both the Paediatric and Second-line ARV projects. The report included a list of recommendations that were reviewed by the evaluators against their implementation status. However, implementation of many of the recommendations could not be investigated as annual reports lacked the necessary information. Some critical recommendations (e.g. procurement under competitive tendering) had not been executed. Please refer to Annex. Supporting Tables, Table 28

- **What steps have been taken toward transitioning of this project to more sustainable sources of funding?**

The UNITAID/CHAI Paediatric HIV/AIDS Treatment Project received core funding from November 2006 to the end of 2010, and is currently operating under the 2011-2012 Project Extension. This extension provides Bridge Funding (US$ 84 million for 2011 and US$ 67 million

for 2012) to ensure continuity of funding for beneficiary countries that have not yet secured funding from alternative sources to continue its paediatric treatment program.[38]

CHAI's Paediatric Transition Operational Plan (August 2010) outlines a two-tiered strategy that focuses on securing alternative sources of commodity funding, and transitioning procurement and supply chain management activities to national government and local partners. Over the past years, CHAI has worked with beneficiary country governments to prepare for this transition.

At the end of 2010 a few beneficiary countries had fully transitioned to alternative sources of funding, while some others are expected to transition in 2011or 2012, and 11 have not yet secured alternative funding sources[39].

With respect to the first point, funding for paediatric ARVs, OI drugs and diagnostic products is expected to be covered by the Global Fund – PEPFAR is a less likely to take over this responsibility – while the provision of RUTF may be taken over by UNICEF and Children's Investment Fund Foundation (CIFF). CHAI has supported beneficiary countries with writing of Global Fund proposals in Round 8, 9 and 10. These proposals have achieved a high success rate, but not all were approved.

However, future funding for HIV/AIDS has become increasingly challenging. There is an estimated US$ 10 billion annual shortfall in financing for AIDS in the context of global economic constraints and competing demands[40]. The Global Fund Round 11, to which some countries were expected to transition to, has been postponed indefinitely.

Activities related to procurement & supply chain management are expected to be transitioned to national governments and in some case partners in country (e.g. SCMS). These activities include optimal product selection, forecasting, tendering procedures, consolidating orders between implementing partners, and placing and tracking of orders.

The challenges in handing over these activities are many. Most importantly, in-country capacity on product selection and forecasting is still very low, despite continuous efforts to build local capacity of government officials and partners. Also, the paediatric ARV market can be characterized as 'high-risk' due to its still limited market size and growth potential and high product fragmentation. This makes the consolidation of orders between implementing partners in country (or even between countries) and coordinated ordering on a regular basis crucial to ensure orders meet minimum batch size and can (or are still interested in) deliver.

The Global Fund, together with UNITAID and CHAI, set up a working group to address the issues around transition. A high-level meeting has been organized with PEPFAR, and the Working Group is meeting with representatives from beneficiary countries in January 2012 to address key bottlenecks. In addition, the Global Fund plans to set up a Procurement Consor-

[38] Source: Paediatric Transition Operational Plan, Aug 2010

[39] As of the end of 2010, more than a third of the countries in the Paediatric Project have transitioned (37%), with just over 60% of countries continuing in the project through Bridge Funding in 2011. The countries which transitioned out of the UNITAID program at the end of 2010 are Cambodia, China, Dominican Republic, Guyana, Jamaica, Liberia, Namibia, OECS, PNG and Rwanda.

[40] Treatment 2.0: catalyzing the next phase of scale-up. Comment by Himschall G & Schwartlander B: The Lancet Vol 378, July 16 2011

tium to support the consolidation of orders and limit the number of product variations through procurement of 'high-risk' products through a limited number of procurement channels (agents, including the voluntary pooled procurement (VPP)). It is also expected to support principal recipients of the Global Fund and other countries to ensure that they come up with reliable forecasts and place timely orders for a streamlined selection of products. However, the Consortium will not have presence on the ground (in-country), which is indispensable to influence decision-making processes, support implementation of more cost-effective optimal ARVs, bring implementing partners together, and build local capacity.

CHAI's in-country activities to support implementation of care and treatment of children with HIV/AIDS are for a large part funded by other donors. Even though some donors may shift their attention from HIV/AIDS to other areas in health, it is essential that funding for these demand-side activities continues so that children that have been started on paediatric ARVs continue to receive quality care treatment, those that have been identified HIV-positive can access ARVs when eligible, and finally those that need it will have access in the future.

3.2 Public health impact

Rating		**Level of confidence**	
☒	Optimal	☐	Optimal
☐	Minor concerns	☐	Minor concerns
☐	Major concerns	☒	Major concerns

Key findings

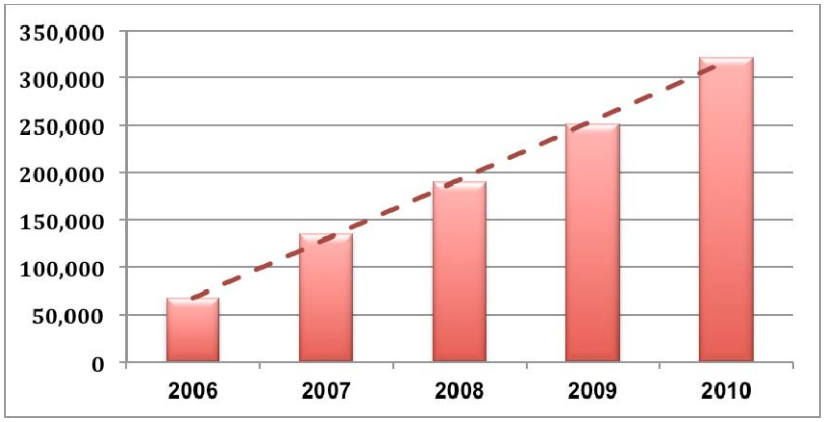
- ✓ The UNITAID CHAI Project has delivered impressive results in providing paediatric ARV treatment to a large number of children, and has been a driver in the uptake of paediatric FDCs in beneficiary countries
- ✓ It remains difficult to match treatment procured with patients treated by country, especially with respect to paediatric ARVs, or tally expenditure on ARVs with reported patient numbers
- ✓ Questions remain about the reliability of data on consumption of ARVs and children alive and on treatment
- ✓ It is of utmost important that current achievements will be maintained and continue to be scaled up in the future

- **To what extent were the objectives of the project achieved in terms of health outcome?**

As shown in Figure 1, the number of children receiving ARV treatment has rapidly increased over the past four years, from around 68,000 in 2006 to more than 320,000 at the end of 2010. Indeed, at the beginning of the project, only an estimated 13% of children who were in need of ARVs actually had access to this life-saving treatment. Following the new WHO recommendations, which expand the estimate of children in need of treatment by 75%, the CHAI UNITAID project now provides paediatric ARVs to 1 in 3 of all eligible children[41].

[41] The previous estimate was that around 523,000 children are in need in treatment. According to updated guidelines that recommend starting children on treatment earlier, the estimate has been increased to around 915,000. The UNITAID CHAI program treats one in three of these children. Current coverage would be 55% relative to the 2009 need estimates that were used before 2010.

Figure 1. Number of children on ARV treatment in the UNITAID/CHAI project 2007-2010.



One of the goals of the Project is to provide additional resources, and not replace or displace funding from other donors or beneficiary country governments. It is highly unlikely that the current increase in scale-up of paediatric ARV treatment would have been achieved with funding from other sources. This strongly suggests that UNITAID's resources have effectively been additional and have resulted in a significant increase in the number of patients under treatment.

Table 11 shows the total number of children on treatment during the reporting period, the annual targets of the CHAI UNITAID program, as well as the adjusted targets and percent (of the adjusted target) achieved in reality.

Table 11. Children on ARV treatment 2007-2010, included adjusted patient numbers, adjusted targets set by project and percentage of target achieved.

	Jan-07	Dec-07	Jan-08	Dec-08	Jan-09	Dec-09	Jan-10	Dec-10
Total on treatment	67,956	135,416	134,677	195,818	189,604	255,970	250,794	321,568
Adjustment on total on Tx			*1%*		*3%*		*2%*	
Target (adjusted)	100,000		74,711		65,025		66,509	
Actual achieved	67,460		61,141		66,125		70,744	
% of target achieved	*67%*		*82%*		*102%*		*106%*	

Source: 2007, 2008, 2009, 2010 Annual Reports

Minor differences between the reported number in December of the previous year and January of the next year can be attributed to the availability of more accurate data on uptake of drugs or patients alive and on treatment. Targets set for the project at the beginning of the calendar year are adjusted during the year to better reflect the actual uptake of treatment in beneficiary countries[42]. However, the budget, which is based on treatments purchased, is not amended accordingly.

[42] According to Section 16.9.1 of the 2010 Agreement treatment targets that are revised up or down by more than 15% should be forwarded to UNITAID. In 2010 it was only Togo were the revised patient number exceeded 15% of the original target. Ideally this deviation analysis should also be done for the target of total patients to be treated and revised target of patients to be treated (including patients that have been put on treatment the previous years). This more advanced comparison would be helpful also to see if the effect of loss to follow up can be mitigated. However this data is unavailable to the evaluators.

During the first year, the overall number of new children on treatment fell well short of the set target. In this year, wide differences between countries were observed, with some surpassing their target (e.g. Ethiopia, Kenya, Zambia and Zimbabwe) and others (e.g. Uganda) just treating half the children planned. CHAI reported that countries where CHAI has a broad program of its own in place in partnership with the government or was previously supporting paediatric treatment, performance was closer to the original target. However, the evaluators could not detect a clear pattern in CHAI presence in country and achievements of targets (see also section 3.3 on forecasting). Reasons for failure to reach targets included the unrealistic expectations set by national programs and CHAI, which overestimated the impact of proposed demand-side activities on actual uptake of treatment. In the following years, the set target was much more in line with the actual uptake of ARV treatment. The main issues in 2008 were attributed to the slower-than-expected scale-up rate in Kenya and Zimbabwe due to political unrest. Other factors mentioned in 2009 and 2010 were the flat lining of PEPFAR-funding that impeded rapid scale-up especially in Uganda, and challenges around decentralization of services in Mozambique.

Over the years, CHAI seemed to have gained a better understanding of drivers of uptake, and was able to set more realistic overall targets. However, a wide variation between countries remained. For instance, in 2010 only 28% of the target was reached in DR Congo (249 instead of the planned 900 children on treatment) whereas in Haiti more than seven times the estimated amount of children were treated with ARVs (4,646 vs. 671 children, see also Annex. Supporting Tables, Table 27).

Data quality from beneficiary countries is often poor. CHAI based its estimated number of children on treatment on national information (if CHAI is the only partner responsible for providing ARV treatment) or on estimated numbers of patients treated with ARVs provided by the UNITAID CHAI Project. Often, children defaulting on treatment migration to adult treatment regimens and deaths were not reported. Especially in West Africa, reported numbers of children on treatment might not truly reflect the actual situation on the ground[43]. It is also unclear how country data incorporated the high rate of loss to follow up, which was an estimated 20% in countries with data on 'children initiated on treatment' and 'children alive and still on treatment'. Similarly, the quantity of ARV treatments purchased in 2010 was only 28% of the ARV-budget.[44] Ideally drugs procured and the budget used should approximately mirror the number of children treated in a given calendar year. However the reported number of children treated within the calendar year in the project did not mirror in the year's annual budget that was absorbed showing that children in 2010 are partially treated with drugs procured from the 2009-budget. It may also be the case that some patients reported as treated by the project may in effect receive medicines from other sources, or that numbers reported do not accurately reflect the actual number of children alive and on treatment in the beneficiary countries. Hence, the numbers here presented should be interpreted as 'best estimates' of the success of the UNITAID CHAI project.

[43] UNITAID addresses these issues in West Africa with ESTHERAID: a pilot project which is not directly related to the CHAI project but focuses on ensuring that patients are prescribed the medicines and tests that implementing partners are delivering to countries.

[44] In 2010, only 28% of the budget projected to be used for the procurement of ARVs was paid to suppliers, which means that the drugs have at that stage been delivered in the beneficiary country.

Lastly, even though information is available on ‘children on treatment, information on actual health outcome – which would include dimensions measuring quality of care and longer-term mortality and morbidity figures – is not available.

- **To what extent are the objectives likely to be achieved?**

Health outcomes were mainly determined through scaling up access to paediatric ARVs for children. As over the Project period, access to treatment for children rapidly expanded. However, uncertainties remain about the quality of data on children actually alive and on treatment. In addition, no information was available on the impact of ARV treatment on child morbidity and mortality, which would be the ultimate health impact indicators.

- **Can the partner organization attribute UNITAID funding to medicines and diagnostics purchased and patients treated by beneficiary country in a timely manner?**

At the start of the project (2006), a mere 68,000 children had access to paediatric ARVs, while at the end of 2010 an estimated 321,000 children in 40 beneficiary countries were treated with UNITAID-funded medicines. Indeed, UNITAID has an estimated 70% share of the paediatric ARV market, and supplies more than 95% of the global market volume of paediatric FDCs. The UNITAID CHAI project has also taken a proactive role in facilitating the uptake of quality FDCs, rationalizing formulations and optimizing treatment regimens at country-level). In addition, it helped to identify children in need of treatment through the provision of diagnostic and monitoring equipment, and provided additional therapeutic food and drugs to treat opportunistic infections for children infected with HIV. CHAI made efforts to reduce dropout throughout the continuum of care by clinical monitoring, introduction of Point-of-Care CD4 and SMS-printers, devising clinical support tools, and supporting decentralization of services. By providing the necessary medicines and equipment, UNITAID has played a crucial role in making these impressive achievements in the global scale up of paediatric treatment a reality.

The 2010 Annual Report outlines the total quantity of paediatric ARV medicines procured for each country as well as the equipment distributed to a selection of 15 countries. It is not possible to tally annual reported ARV expenditure with numbers of children treated, as these are often treated with medicines procured from previous’ year budget. It is also difficult, especially in the case of paediatric formulations, to match the number of packs with amount of patients treated. Consumption data are mostly not available, and forecasts are made based on projected uptake and reported children on treatment. Also, the quality of data on children on treatment remains questionable, especially in light of weak health information systems and the potential high loss to follow up (see sections 3.1.3).

The phasing out of UNITAID funding to other less secure sources and transfer of responsibilities of procurement & supply chain management to partners will pose significant challenges in the near future (see section 3.1.3). It is of utmost importance that the achieved successes of the UNITAID CHAI Project can be maintained and continued in the years to come.

3.3 Market impact

Rating		Level of confidence	
☒	Optimal	☐	Optimal
☐	Minor concerns	☒	Minor concerns
☐	Major concerns	☐	Major concerns

Key findings

- ✓ During the duration of the project, the supplier-base of paediatric ARVs, and especially fixed-dose combinations, has expanded considerably. The UNITAID CHAI project is thought to have contributed to this expansion;
- ✓ Supplier-base of RUTF has also seen an expansion during the past four years, but this increase cannot be solely attributed to the Project;
- ✓ Prices obtained for the Project for selected paediatric ARVs through primary and secondary suppliers have seen a steady decrease between 2008 and 2010. These prices were in all but one cases lower than those reported in the CHAI Consortium Ceiling Price List and in MSH-ERC for SCMS;
- ✓ Prices of key paediatric treatment regimens have seen a rapid drop between 2004 and 2007 whereas this downward trend showed a less dramatic decline since 2007. The main factors driving this decrease in price are the introduction of FDCs (replacing expensive syrups) and generic competition;
- ✓ The Project has had an considerably impact on the paediatric ARV market through securing a large amount of funding for a market which was largely non-existing before the start of the Project; through its expansion of market volume of especially FDCs; through its pooling of orders with one procurement agent between partners and countries; through its innovative procurement strategy of driving down prices of paediatric ARVs, which has subsequently influenced market prices; and through its work on the demand-side uptake of paediatric FDCs;
- ✓ The Project has a small market share of RUTF and had no or very limited impact on the RUTF market. It is unclear to what extent it has used the possibility – possibly linked to the UNITAID PMTCT Program – of making advance market commitment to invest in and stimulate local manufacturing capacity of RUTF, thereby influencing the market.

- **To what extent were the objectives of the project achieved in terms of market impact?**

New quality-assured manufacturers and products

During the duration of the project, the number of quality assured manufacturers and paediatric ARVs have steadily increased (see Table 12). The impact of the CHAI UNITAID project on increasing the number of quality suppliers and products could not be independently verified. The Global Fund's Market Dynamics and Commodities Ad-Hoc Committee (Twenty-third Board Meeting, May 2011) estimates that UNITAID accounts for around 70% of global paediatric ARV demand. It is therefore somehow likely that the funding from UNITAID available for paediatric ARV procurement has incentivised manufacturers to invest in new products for treatment of children with HIV. UNITAID also provides funding to the WHO Prequali-

fication Programme, which further facilitates an increase in number of pre-qualified supplier for paediatric products.

In addition, the CHAI Drug Access Team (DAT), which also receives some financial support from UNITAID, works with industry to increase the number of new qualified manufacturers of existing and new drugs. Specifically, the CHAI DAT has provided technical assistance to suppliers and manufacturers of Active Pharmaceutical Ingredients (APIs), coordinated contract research projects at independent research laboratories to address urgent chemistry challenges, and provided strategic guidance to new high-quality API manufacturers to increase competition on the market place.

Table 12. Number of new eligible suppliers/products for selected paediatric ARVs (2007-2010).

Product	2007	Jan 08	Jan 09	Dec 09	Dec 10	*2007-2010*
Selected paediatric ARVs						
3TC (30mg)+ABC (60mg)	-	1	2	2	2	*+ 2*
3TC (30mg)+AZT (60mg)	-	-	1	2	3	*+ 3*
3TC (30mg)+AZT (60mg)+NVP (50mg)	-	1	1	1	1	*+ 1*
3TC (30mg)+d4T (6mg)+NVP (50mg)	1	1	1	1	1	-
3TC (50mg/5ml)	3	3	3	3	3	-
3TC (60mg)+d4T (12mg)+NVP (100mg)	1	1	1	1	1	-
AZT (50mg/5ml)	4	3	3	4	4	-
EFV (200mg)	2	3	4	6	7	*+ 5*
EFV (50mg)	2	2	2	3	4	*+ 2*
LPV/r (100/25mg)	-	1	1[45]	3	4	*+ 4*
NVP (50mg/5ml)	1	2	2	3	3	*+ 2*

Source: 2007, 2008, 2009, 2010 Annual Reports; GPRM database

In its 2010 Annual Report, CHAI stated that more products were registered in beneficiary countries. However, this statement could not be verified. The Project's procurement strategy is set up as to encourage suppliers to register their products in beneficiary countries, as the composite score based on which primary and secondary suppliers are selected includes a rating on registration status in those countries. In some instances, CHAI also offered support to the manufacturer to get their product registered, especially in the case of FDCs.

Over the past years, the supplier-base for RUTF to the Project has also increased. In 2007, all RUTF was purchased from Nutriset, whereas in 2010 this product was purchased from an additional three Nutriset franchisees in Malawi and Ethiopia, and from three additional manufacturers in Haiti, Nigeria/Zambia and India[46]. Nutriset produced RUTF under patent as 'Plumpy'nut', and has a vast market share (>80%) globally. Funding from the UNITAID CHAI

[45] Data comes from GPRM database
[46] Nutriset has agreed voluntary licenses with Hilina (Ethiopia), Project Peanut Butter (Malawi) and Valid (Malawi). The new manufacturers comprise Compact (India), Vitaset (Haiti) and Diva (Nigeria/Zambia).

project has mostly been used to procure this patented product from Nutriset, or from one of their franchisees locally. Local procurement of quality RUTF is preferable as it reduces expensive shipping cost, and also helps to build local manufacturing capacity. However, current production capacity in African countries is still very limited.

In 2010, the UNITAID CHAI Paediatric Program procured less than 5% of the global RUTF stock[47], which makes it difficult to have a significant market impact in this commodity area. One way the Project might have an impact on the market, even with a relatively small budget, is to use its capacity to make advance commitments to stimulate investment in local production of RUTF. It is unclear to what extent the Project has made use of this possibility.

Price trends of paediatric ARVs

Within the CHAI UNITAID Project, the procurement strategy of primary and secondary suppliers and offering the 'cost-plus' option resulted in a decrease in virtually all paediatric ARV treatment prices of selected ARVs between 2008 and 2010 (see Table 13 and Table 14).[48],[49] As noted in the Ernst & Young report (2009), it may happen that prices of suppliers which quote on a cost-plus basis turn out to be higher than anticipated. Therefore, prices indicated in Table 13 should be regarded as indicative and may in some instances actually be higher than the ones originally agreed on. For some products, only one eligible supplier submitted a bid and was selected as primary supplier. In 2010 this was the case for EFV 30mg/ml, DDI 100mg buffered, EFV 100mg, EFV 200mg scored, d4T/3TC/NVP (6/30/50mg and 12/60/100mg), d4T/3TC (6/30mg and 12//60mg), AZT/3TC (60/30mg) and AZT/3TC/NVP (60/30/50mg).

Table 14 shows the trend in actual median prices paid for three formulations for which information was available. An explanation for the difference between agreed versus actual price paid is provided in section 3.1.2. In addition, prices offered by primary and secondary suppliers are not always applicable to all countries due to patent issues (in LMIC or UMIC countries), lack of registration of products, specific national treatment guidelines or aberrant national treatment guidelines.

Even though no specific target was defined, this objective achieved a good level of performance.

[47] The Paediatric Program purchased roughly 1,500 – 2,000 tons (corresponding to approx. US$ 6m) of RUTF in 2010, compared to production by Nutriset (which has the vast market share) of 52,000 tons [personal communication].

[48] Product selection is based on highest volume products in 2010 plus LPV/r (100/25) (Annual report table 2.4d)

[49] Agreed prices with primary and secondary suppliers for the first 3 products included in the table were available for 2008, but these were calculated in a different way so cannot be compared to those of the subsequent years

Table 13. Prices in US$ agreed with primary and secondary suppliers (UNITAID CHAI I and II) per child (10kg) per year in low-income countries.

		Agreed prices with suppliers			
Product	**Supplier**	**2008**	**2009**	**2010**	***2008-10 % change***
3TC (30mg) + ABC (60mg)	UNITAID CHAI I	N/A	$174.7	$156.0	*-11%**
	UNITAID CHAI II	N/A	$180.0	$172.8	*-4%**
AZT (60mg) + 3TC (30mg)	UNITAID CHAI I	N/A	$79.2	$71.8	*-9%**
	UNITAID CHAI II	N/A	$86.4	$78.0	*-10%**
3TC (30mg) + AZT (60mg) + NVP (50mg)	UNITAID CHAI I	N/A	$103.9	$102.0	*-2%**
	UNITAID CHAI II				
3TC (30mg) + d4T (6mg) + NVP (50mg)	UNITAID CHAI I	$59.8	$57.6	$55.2	*-8%*
	UNITAID CHAI II				
3TC (50mg/5ml)	UNITAID CHAI I	$26.5	$25.5	$24.8	*-7%*
	UNITAID CHAI II	$35.3	$25.5	$24.8	*-30%*
3TC (60mg) + d4T (12mg) + NVP (100mg)	UNITAID CHAI I	$54.5	$51.6	$51.6	*-5%*
	UNITAID CHAI II				
AZT (50mg/ml)	UNITAID CHAI I	$64.3	$57.0	$55.5	*-14%*
	UNITAID CHAI II	$72.0	$57.0	$56.7	*-21%*
EFV (200mg)	UNITAID CHAI I	$63.9	$44.0	$38.3	*-40%*
	UNITAID CHAI II	$58.0	$129.6	$38.3	*-34%*
EFV (50mg)	UNITAID CHAI I	$29.2	$26.9	$26.8	*-8%*
	UNITAID CHAI II	$43.2	$43.2	$43.2	*0%*
LPV/r (100/25mg)	UNITAID CHAI I	$249.9	$249.9	$108.5	*-57%*
	UNITAID CHAI II	$389.3	$276.0	$108.5	*-72%*
NVP (50mg/5ml)	UNITAID CHAI I	$58.1	$54.0	$52.5	*-10%*
	UNITAID CHAI II	$375.0	$375.0	$52.5	*-86%*

Source: 2010 Annual Report (Table 5.1.1b)

* No information was available for 2008, hence the percent change is given for the 2009-2010 period

Table 14. Actual median prices[50] paid 2008-2010 by the Project.

	Actual median price paid		
Product	**2008**	**2009**	**2010**
3TC (30mg) + ABC (60mg)	$197.0	$186.0	$176.0
AZT (60mg) + 3TC (30mg)	$87.0	$86.0	$83.0
3TC (30mg) + AZT (60mg) + NVP (50mg)	$111.0	$111.0	$110.0

Source: 2010 Annual Report Annex 1.

When comparing CHAI UNITAID Project prices with CHAI Consortium prices and those obtained through PEPFAR's Supply Chain Management System (SCMS), the Project's prices obtained through the primary supplier (through which the majority or products should be purchased: CHAI UNITAID I) were more competitive for all but one product, namely 3TC + d4T + NVP (30mg +6mg + 50mg) (see Table 15).[51]

It should be taken into account that the CHAI Consortium ceiling prices are voluntary arrangements whereby a supplier can choose to withdraw from bidding when an actual tender is launched. In contrast, prices stated for CHAI UNITAID I & II are actual bids in response to the Request for Proposal launched. There is also a difference in timing. CHAI Consortium reference ceiling prices were released in April 2008, August 2009, April 2010, whereas CHAI negotiated prices under UNITAID during the first quarter of the year and SCMS prices were based on the calendar year. The difference in timeframe can partly explain the difference in unit price.

One can note a harmonization of prices across the board, and the CHAI UNITAID negotiations and efforts by the CHAI Consortium and other partners are likely to have had a mutually reinforcing effect.

[50] Actual median price paid was only available for three of the selected products.

[51] CHAI Consortium ceiling price states a 2010-price of US$ 55 for the triple FDC (d4T+3TC+NVP 6+30+50mg), whereas the agreed price with the primary supplier under the CHAI UNITAID project is slightly higher at US$ 55.20.

Table 15. Comparison of price of paediatric ARVs negotiated by CHAI under UNITAID partnership with primary and secondary suppliers (I & II), CHAI Consortium and SCMS for PEPFAR-funded projects – price per child (10kg) per year.

Product	Source	2007	2008	2009	2010
3TC (30mg) + ABC (60mg)	UNITAID CHAI I			$174.7	$156.0
	UNITAID CHAI II			$180.0	$172.8
	CHAI	$182.5	$182.5	$180.0	$168.0
	SCMS			$182.5	$191.7
3TC (30mg) + AZT (60mg)	UNITAID CHAI I			$79.2	$71.8
	UNITAID CHAI II			$86.4	$78.0
	CHAI		$79.2	$80.0	$80.0
	SCMS				$78.0
3TC (30mg) + AZT (60mg) + NVP (50mg)	UNITAID CHAI I			$103.9	$102.0
	UNITAID CHAI II				
	CHAI		$132.0	$108.0	$102.0
	SCMS				$163.4
3TC (30mg) + d4T (6mg) + NVP (50mg)	UNITAID CHAI I		$59.8	$57.6	$55.2
	UNITAID CHAI II				
	CHAI	$59.8	$59.8	$60.0	$55.0
	SCMS			$62.6	$62.6
3TC (50mg/5ml)	UNITAID CHAI I		$26.5	$25.5	$24.8
	UNITAID CHAI II		$35.3	$25.5	$27.8
	CHAI		$26.8	$27.0	$25.0
	SCMS	$29.4	$29.4	$30.3	$29.4
3TC (60mg) + d4T (12mg) + NVP (100mg)	UNITAID CHAI I		$54.5	$51.6	$51.6
	UNITAID CHAI II				
	CHAI		$54.5	$54.0	$52.0
	SCMS	$55.6	$55.6	$57.2	$57.2
AZT (50mg/5ml)	UNITAID CHAI I		$64.3	$57.0	$55.5
	UNITAID CHAI II		$72.0	$57.0	$62.7
	CHAI		$64.2	$64.0	$57.0
	SCMS	$65.7	$64.2	$63.6	$63.6
EFV (200mg)	UNITAID CHAI I		$63.9	$44.0	$38.3
	UNITAID CHAI II		$58.0	$129.6	$38.3
	CHAI		$58.0	$48.0	$43.0
	SCMS	$65.3	$62.3	$50.9	$50.9
EFV (50mg)	UNITAID CHAI I		$29.2	$26.9	$26.8
	UNITAID CHAI II		$43.2	$43.2	$43.2
	CHAI		$29.2	$27.0	$27.0
	SCMS	$27.4	$27.4	$28.2	$28.2
LPV/r (100/25mg)	UNITAID CHAI I		$249.9	$249.9	$108.5
	UNITAID CHAI II		$389.3	$276.0	$108.5
	CHAI		$389.5	$280.0	$220.0
	SCMS		$125.9	$113.9	$113.9
NVP (50mg/5ml)	UNITAID CHAI I		$58.1	$54.0	$52.5
	UNITAID CHAI II		$375.0	$375.0	$58.5
	CHAI		$58.3	$55.0	$53.0
	SCMS	$58.9	$58.9	$58.3	$61.6[52]

Source: 2010 Annual Report Table 5.1.1b; CHAI Consortium Price Lists; MSH ERC Price Indicator

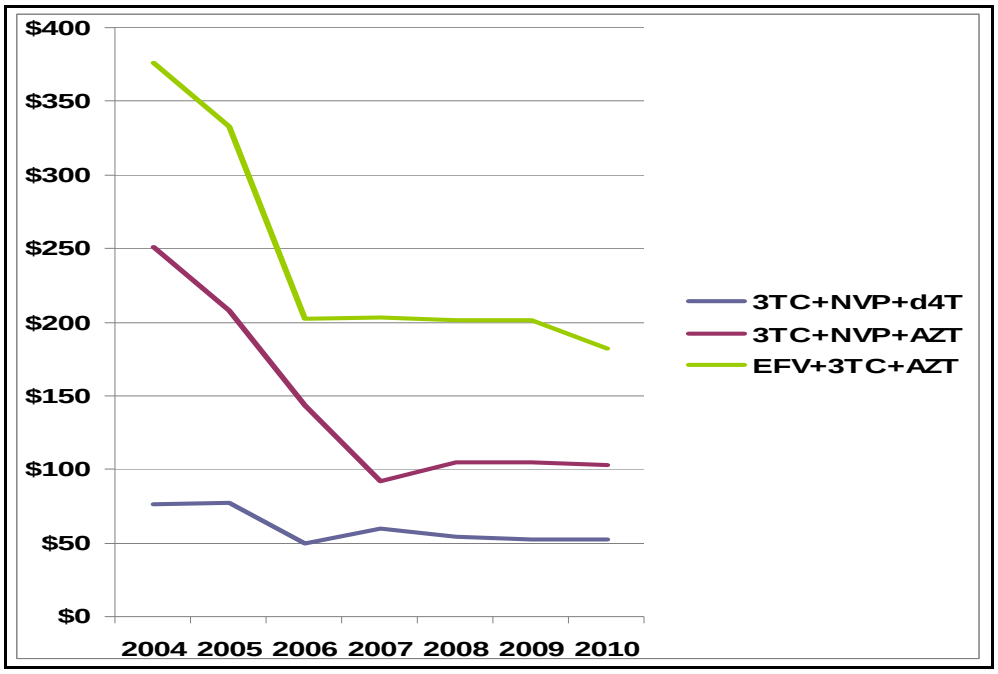
The GPRM provides an overview of prices of ARVs that are purchased and supplied by various procuring agencies for different countries. According to this source, globally the cost of the most commonly used paediatric ARV regimens in low-income countries has seen a rapid

[52] includes syringe
[52] Waning et al; The global paediatric an

decline in the period between 2004 and 2007 (see Figure 2), while this downward trend continued in a less dramatic manner from 2008 to 2010[53]. One of the main drivers of this observed price decrease is the introduction of low-dose FDCs in solid form for very young children (body weight under 10 kg), which were first introduced in 2006. These children were in the past only able to use liquid formulations or sub-optimal solid formulations from mostly innovator companies, making the treatment of children costly and complicated. Over the past years, a number of new generic paediatric FDCs have been pre-qualified by the WHO or a stringent regulatory authorities, and countries are increasingly included these formulations in treatment guidelines and practice. The other main driver is the increase in competition in the paediatric ARV market by generic suppliers. Indeed, the supplier-base of key formulations has greatly expanded over the past years.

As the majority of paediatric ARVs are purchased by UNITAID[54], and more than 95% of paediatric FDCs[55] - GPRM prices are expected to be in line with those obtained by the CHAI UNITAID Project.

Figure 2. Price trend for the most commonly used paediatric ARV treatment regimen for children (10kg) in low-income countries (2004-2010).



Source: GPRM Summary Report 2004-2008, GPRM Summary Report Dec 2010

The impact of the UNITAID CHAI Project on the paediatric ARV market can be ascertained in several ways. Firstly, the large amount of secure funding for the purchase of paediatric ARVs has created a viable market and provided incentives to manufacturers to invest in paediatric ARVs. Over the past years, a number of new products – notably, paediatric FDCs – have been pre-qualified making treatment of children with HIV more feasible.

[53] Source: GPRM Summary Report Dec 2010

[55] Waning et al; The global paediatric an[55] Source: GPRM Summary Report Dec 2010
tiretroviral market, analyses of product availability and utilization reveal challenges for development of paediatric formulations and HIV/AIDS treatment in children, BMC Paediatrics 2010, 10:74

Secondly, the CHAI UNITAID Project has considerably expanded market volume and currently represents approximately 70% of the paediatric ARV market and 97-100% of market volume of paediatric FDCs[56]. Thirdly, under the UNITAID-project, CHAI has engaged in innovative procurement strategies, including pooling procurement via one procurement agent between partners and between beneficiary countries. Before its entrance, few countries were able to match the minimum batch size required for production of paediatric ARVs. In addition, the selection of primary and secondary suppliers and the so-called 'cost-plus' option, where manufacturers are supported with optimizing production processes and lowering production cost, has paved the way for further price decreases.[57] Lastly, the demand-side component of the UNITAID CHAI Project has supported uptake of paediatric treatment – most notably, FDCs – in beneficiary countries.

- **To what extent are the objectives likely to be achieved?**

The UNITAID CHAI project contributed to a substantial increase in the supplier base, new registrations of paediatric formulas as well as a substantial decrease in prices of paediatric ARVs. The objectives of "influencing market dynamics" as well as "increasing the supplier base" were achieved.

- **What positive changes have been made to number of manufacturers, quality products and better prices for opportunistic infection medicines and ready to use therapeutic foods (RUTF)?**

As reported by CHAI and confirmed by UNITAID, increasing the number of manufacturers for OI drugs and RUTF is not a specific objective of the CHAI UNITAID Program. For comparative pricing information on OI drugs and RUTF, see Table 6 and Table 7.

[57] Prior to the UNITAID partnership, CHAI launched a project in April 2005 designed to reach more than 10,000 additional children each year. The firm commitment to purchase and deliver larger volumes of ARVs allowed CHAI to reduce the price of paediatric treatment by more than 50 percent to less than $200, and triggered catalytic action in countries to mobilize the necessary technical assistance to ensure sufficient capacity to deliver the medicines to patients. Other partners, like the MSF 'Campaign for Access to Essential Medicines', also contributed to raising awareness of the need for affordable easy-to-use paediatric treatment. In September 2006, UNITAID was formed to provide catalytic funding to niche areas including paediatric ARV treatment.

3.4 Reporting

Rating		Level of confidence	
☐	Optimal	☒	Optimal
☐	Minor concerns	☐	Minor concerns
☒	Major concerns	☐	Major concerns

Key findings

- ✓ Submission dates for Semi-Annual and Annual Reports deviated from targeted submission dates;
- ✓ There is no consolidation process to detect inconsistencies between different sections of the report;
- ✓ Reporting formats, tables and figures vary between years as no specified formats are provided;
- ✓ Reports follow to large extent the template structure provided in the agreement;
- ✓ Reconciliation of budget, open commitments and expenditures was not possible. Varying table formats, varying differences of definitions (inclusion and exclusion of certain parameters) and varying cut-off dates make the reconciliation not possible;
- ✓ Reported performance and expenditure is not verified and disbursements from UNITAID are not based on performance;
- ✓ Most indicators are defined as outcome indicators and only very few are designed as process measurement;
- ✓ Crucial chapters are rather brief in their description and analysis. Substantial information is provided in the Annexes but does not include further explanations.

The reporting requirements are defined in “14 Reporting by CHAI for UNITAID” and Annex 6 of the 2010 Agreement. The main requirements outlined are: Documentation, Semi-Annual Reports, Annual Programmatic, Procurement and Financial Report, Timing, Contents, Final Project and Financial Report, Documentary Requirements for disbursements, Disclosure to Beneficiary countries, Operational Audit, Conferences and Other Updates and Information.

3.4.1 Reporting received from implementing partner

According to the schedule of the Agreements (Annex 6) since 2008, submissions for Annual Reports have not been on time (see Table 16). Submission dates varied between three working days for the 2008 Annual Report, 18 working days for 2009 Annual Report and seven working days for the 2010 Annual Report[58]. Similar observations have been made regarding Semi-Annual Reports.

[58] This delay is estimated for the first draft of the 2010 Annual Report. Moreover another version dated after the 24th May 2011 was made available due to an error in median prices. UNITAID requested another updated 2010 Annual Report in November as numbering of tables has been inconsistent.

Table 16. Submission Dates of Semi-Annual and Annual Reports.

Reporting Year	Submission Due Date	Submission Date
Annual Reports		
2007	15.04.2008	15.04.2009
2008	15.04.2009	20.04.2009
2009	30.04.2010	26.05.2010
2010	30.04.2011	10.05.2011 (updated 24.05.2011)
Semi-Annual Reports		
2009	03.08.2009	21.09.2009
2010	05.08.2010	13.09.2010

Source: 2008, 2009, 2010 Agreements; 2007, 2008, 2009, 2010 Annual Reports; 2009, 2010 Semi-Annual Reports

After receiving the reports, the Agreements do neither detail how the UNITAID internal report validation should be carried forward nor how clarifications are exchanged between UNITAID and CHAI. The Agreements do mention though that UNITAID is responsible for the "ongoing review of the financial and programmatic process of the project"[59]. This aspect was therefore brought forward in the interviews with UNITAID and the following information was obtained: After UNITAID receives Annual or Semi-Annual Reports from CHAI the reports are internally disseminated to various departments (e.g. M&E, Finance, Procurement). Each department reviews the specific sections covering their expertise. Feedback is then assembled by the project officer. Depending on the nature of comments (e.g. just a minor clarification or a major concern) the feedback will be more formal (e.g. letter) or more informal (e.g. phone conversation) with CHAI. CHAI responds accordingly. After clarification and on the basis that no further concerns are raised the final report is accepted.

The evaluators also assessed the compliance of the 2010 Semi-Annual and Annual Report according to the templates provided in Annex 11 and 12 of the 2010 Agreement (see Annex. Supporting Tables, Table 29) and note the following:

- The Agreement contains a template on the content of the semi-annual and annual report, including annexes. Overall, the Annual Reports follow the template as many headings provided by the template were found with minor phrasing differences in the Annual Report
- The Agreement does not include any specific and standardized reporting template that outlines tables and information concretely. The Annual Reports therefore vary drastically in terms of reporting formats, cut-off dates and definitions, making longitudinal comparisons almost impossible.
- Various chapters of the 2010 template were missing in the Annual Report, e.g. "Section 5: Key Issues Looking Forward"
- The quality and specifics provided in chapters of the Annual Report differ over the years. Analysis of discrepancies between targets and implementation, e.g. "5.2.2. Lead time of Product Delivery" (2010 Annual Report) are often very brief and do not enable the reader to fully understand the circumstances and reasons.

[59] 2010 Agreement, Appendix 1, Section 4.1

- The details on the financial reporting are – for reasons outlined in Chapter 3.1 and below - unsatisfactory and a reconciliation based on the information provided in the Annual Reports is not possible.

The evaluators like to emphasize that changing reporting and table formats or choosing different reporting (cut-off) dates have made it very difficult to compare main targets and activities over the years. However, reporting consistency is of utmost importance to demonstrate sustained achievements and/or also point towards aspects that need improvement. On the basis of the available Semi-Annual and Annual Reports and supporting documents, it was not possible to trace the projects achievements to date without any concerns.

To some extent the reports provide a basis of decision-making. However, their relevance regarding predictions on future developments and requirements are limited. Moreover various discrepancies along this mid-term review have been discovered. In order to use the reports for decision-making, clarifications on these issues are required and need to be incorporated in future reports. In principle, lessons learnt from different country-experiences can be used to help guide future planning, and form the basis of future Agreements between UNITAID and CHAI. Seen the context-specific nature of these examples, the rationale for guiding the future agenda should include experiences gained through the Project as well as evidence from best practices globally.

3.4.2 Financial reporting

In the financial analysis the evaluators tried to reconcile the breakdown of budget with disbursements from UNITAID to CHAI and payments/committed expenditures of CHAI to its suppliers, procurement agent and procurement support department.

The major obstacle was that disbursements, expenses and bank balance in the Annual Reports have not been reported against the budget year but rather often with an extended period of two months (e.g. 28th February of the following year)[60]. These extended periods include also some commitments and disbursements (e.g. from January to February of the following year) versus 2010 budget without including funds received from UNITAID during this period (e.g. January – February) corresponding to the next year's budget. Moreover the allocation of outstanding funds is in this detail not reported in the following Annual Report of the next year - a fact that is deemed critical in evaluating the overall adherence with Agreements

The following general points were identified by the evaluators:

- Reporting periods are inconsistent between different tables and across years
- Reporting format is changing over the four years period
- The bank reconciliation is not possible given that bank balances end of 2007, 2008, 2009 and 2010 were not provided
- Annual Reports only present the annual budget of the procurement. No breakdown (e.g. according to the given separation as required from the Agreements, Section 16.2) of the use of the annual budget for procurement support is provided. Moreover it is not always clear if this amount is included in commitments reported by CHAI. As CHAI also receives funds from other donors to fund operational activities, detailed in-

[60] The cut-off dates of the extended period also have been inconsistent over the years (e.g. 31.03. or 28.02.) making it difficult to compare the reported numbers over the years.

formation on activities funded by UNITAID is needed to ensure that no double-funding of activities occurs.

- CSD fee is shared with 2nd line project, which make it difficult to separate, and reasons why this is paid in some instance, as usually countries should do so, are not provided.
- Reports have been inconsistent regarding terminology. Specifically the budgeted disbursement from UNITAID to CHAI was sometimes reported including the procurement support and sometimes without (e.g. e.g. Annual Report 2009; Financial Overview vs. Section 1.1).
- The financial reporting does include supplementary financial statements and bank statements, but these do not include sufficient information.
- Relatively high open commitments remain after the calendar year, pointing towards high number of purchases during the last quarter of the year.

As a consequence of all the issues raised above and given the information from the Annual Reports, reconciliation of the expenditure was not possible. The evaluators calculated a theoretical cash balance on the basis of the Annual Reports and compared this to the reported cash balance of CHAI. The cash balance end of period reported by CHAI is lower than the theoretical cash balance as calculated by the evaluators. This difference cannot be verified based on the information available. The evaluators therefore recommend UNITAID and CHAI to review the information provided and to ensure that reconciliation of disbursements, open commitments and expenses and a reconciliation of the reported cash balance and the bank statements are made.

The financial reporting format of the Annual Reports does allow identifying readily common budget items e.g. commodities. At the country level, detailed information on different commodities is available. However, laboratory equipment, freight and procurement fee cannot be differentiated on this level. Moreover other readily common budget items, e.g. personnel costs, are not further differentiated and can therefore not be identified[61].

The difficulties for reconciliation are in the inconsistencies used in reporting format and reporting periods. Moreover, various discrepancies between narratives of the text and tables, as well as between tables, have been identified. Overall CHAI managed to stay within the given budgets. However, budget adjustments and reallocations during the budget year are not systematically formalized in an addendum to the initial Agreement, officially approved by both parties. Considering the number of possible financial revisions that can occur through the duration of the projects, this is a source of confusion and a limitation to the creation of efficient financial management. Disbursements from UNITAID to CHAI are made according to a pre-defined schedule as detailed in Annex 6 of the Agreement. The disbursements are triggered by the fulfilment of certain reporting conditions rather than real performance progress. Therefore the project does not follow performance-based funding principles.

[61] The 2010 Annual Report details in Section 5.2.6 more about the procurement support given rough guidance on personal involved with the Paediatric HIV/AIDS project. However due to funding of other donors it is unclear how much of those support activities have been funded by UNITAID.

Requirements in terms of bank interest generated with funds received from UNITAID are described in the Agreements (Section 16.1)[62]. There it is stated that interests are “carried forward and held in reserve for exchange rate mitigation purposes”[63]. Information on interests earned as well as the bank balance is detailed in the Annual Reports. However, based on the information provided in the documents reviewed, it cannot be investigated how these are reimbursed to the program or deducted from disbursement requests. Due to the confusions around financial reporting, it is not possible to have a clear picture on the activities implemented and expenditures that occurred due to those activities.

These difficulties regarding reconciliation have also been acknowledged by UNITAID. Since 2011 changes have been stipulated in the Agreements particularly regarding financial reporting.

3.4.3 Programmatic reporting

As stated in Section 3.1 Project management, Relevance, the evaluators note that the scope of the indicators could have been wider as some dimensions are not covered completely.

Most indicators are defined as outcome indicators and only very few are designed as process measurement (e.g. decrease lead time from purchase order to delivery in country). In addition, some key indicators seem to be missing, for instance uptake of fixed-dose combinations in beneficiary countries. As the overall goal of the project is also stated to influence market dynamics, the Project’s impact on the market is a major focus that is better measured in outcome/impact rather than process. It would have been useful to have information on quantification assumptions to track the overall programmatic achievements in the different country contexts: number of patients treated (vs. national target) and funding source, information on buffer stock in month of stock, expired drugs, excess stock and occurrence of stock-outs. This information is lacking in the Annual Reports and therefore the validation of reported data has its limits.

Due to Annual Agreements between UNITAID and CHAI, the reports also refer solely to the last budget year and only have limited information on cumulative achievements and the progress since project inception. To better understand ore the impact of the program on health and market outcomes it would have been helpful to include an outline of key trends available.

As outlined above, some chapters are rather brief in their description and analysis. However, substantial information is provided in the Annexes that need to be re-processed by the reader and does not include further explanations. UNITAID requirements regarding the programmatic and procurement reporting are not further specified and must therefore – under given circumstances - be considered satisfactory.

[62] However the Agreements always state in Section 16.1 that interests from 2007 will be carried forward regardless which budget year.
[63] UNITAID/CHAI (2010): Agreement fort he Procurement and Supply pf Paediatric ARV Drugs, Diagnostics and related Commodities and for Paediatric Project Support, p. 42

3.5 Strengths, Weaknesses, Opportunities and Threats

Strengths	Weaknesses
• Scaling up ARV treatment for children • Purchasing power and related market impact • CHAI experience, procurement model and innovative global market approach • Consolidation of demand and stream-line product selection, incl. introduction of FDCs • Linkage between supply-side and de-mand-side (in-country) activities	• Reporting format/finances • Poor national forecasting • Loss to follow-up • Risk management • Capacity strengthening and ownership
Opportunities	**Threats**
• Global Fund market shaping strategy and Procurement Consortium • Roadmap for the strategic collaboration between UNITAID and the Global Fund • Focus on in-country capacity building	• Transition to other sources of funding, including the Global Fund • Market fragmentation • Forecasting complexity • Suppliers confidence in liquidity

- **Strengths**

1) Scaling up ARV treatment for children

A major strength and achievement of this project is that over 320,000 HIV positive children have access to treatment, compared to a mere 68,000 five years ago. As UNITAID has a 70% share of the global paediatric ARVs market, it is evident that most of these children would otherwise not have been able to access appropriate treatment.

2) Purchasing power and related market impact

The purchasing power associated with stable funding and a predictive need and supply of paediatric ARVs had a major impact on the market. Over the Project period, the supplier-base has increased and prices have continued to decline. A major factor described by CHAI to encourage suppliers to enter, pre-qualify and also tender was the money held out in prospective by a reliable funding source. The selection criteria for primary and secondary suppliers also fostered the registration of new products in different countries.

3) CHAI experience, procurement model and innovative global market approach

CHAI has longstanding experience and continuous relationship with suppliers and countries. Under the Project, CHAI has negotiated unprecedented price reductions applying innovative procurement strategies (incl. cost-plus negotiations) of collaboration with the pharmaceutical industry.

4) Consolidation of demand and streamlining product selection

To overcome the obstacles that characterize the paediatric ARV market – which is small and fragmented – the Project has worked on consolidation of orders between partners and countries to reach minimum batch size required for production. At the same time, it worked

on streamlining product selection, which has reduced the number of paediatric ARV formulations on the market. One specific achievement here is the focus on the introduction and uptake of FDCs, which has greatly simplified treatment of children infected with HIV, and reduced cost.

5) Linkage between supply-side and demand-side (in-country) activities

CHAI works at the global level to optimize product design, enhance competition, reduce production costs and risks, and negotiate pricing. Country-level activities include creation, consolidation, and communication of demand, and setting up systems to support uptake of products. Both side of the spectrum are needed to capture the full market impact, and have greatly contributed to the success of the paediatric HIV/AIDS treatment program.

- **Weaknesses**

1) Reporting format/finances

CHAI reports did not provide sufficient and consistent information to trace the use of UNITAID funds over the years, to readily compare prices paid or to identify procurement and delivery. As a result, reconciliation of budget was not possible, and comparisons of main targets and activities over the years proved very difficult. In addition, matching ARV expenditure with treatments procured and patients treated during the calendar year could not be done. Although information on how UNITAID funding has impacted the market is available, information on how the project has improved patients’ access and treatment outcome and in country capacity in forecasting, use and registration are limited and not entirely reliable.

2) Forecasting

Forecasting is a major weakness of the project for which CHAI has not been able to find a solution. The challenge of preparing an accurate forecast was compounded by the absence of reliable systems to track the number of patients treated and drugs consumed, which is a recurrent issue in developing countries. Unreliable quantification may have potentially had a negative effort on the price negotiation (as eventually different quantities of drugs were procured than shown in the original RFP) and on suppliers’ performance (as predictability of orders’ volume was weak). In addition, poor quantification of need also implies that no further negotiations with suppliers on previously agreed prices are possible if the quantity of drugs procured turns out to be much higher than anticipated.

3) Loss to follow up

There are no consistent program data that outline achievements in retention of children on treatment for all beneficiary countries. Data from selected countries indicate that the rate children default on treatment may be as high as 20%. CHAI has over the years devoted considerable attention to reducing the gap between “children ever initiated on treatment’ and ‘children alive and on treatment’. However, the data on actual number of defaulters remain scarce. From a patient, a public health and a financial perspective, reducing loss to follow up should be a key priority.

4) Risk management

The lack of accurate consumption data compounded with the absence of signed MoU with countries increase UNITAID funded drugs liability to theft and diversion. The MoU signed by CHAI and countries is the only provision against diversion and CHAI fully relies on the national authorities’ capacity and commitment to prevent diversion from occurring. In addi-

tion, a comprehensive risk management strategy has not been devised during the evaluation period.

5) Capacity strengthening and ownership

Transition has been at the core of UNITAID intervention since its inception. The Project has devoted relatively little attention to ensuring proper implementation of medicines and supplies, ensuring rational use of drugs, and building capacity of counterparts in beneficiary countries. From the reports, it is unclear to what extent these activities have been covered by funding from other sources.

- **Opportunities**

1) Global fund market shaping strategy

Realizing its unique purchasing power and opportunity to impact market dynamics while assisting countries with weak procurement capacity in procuring quality commodities, the Global Fund created the Voluntary Pooled Procurement (VPP) and Price and Quality Reporting (PQR).

In 2009, the limited achievements of the two instruments in terms of value for money lead the Global Fund board to create Market Dynamics and Commodities Ad-hoc Committee (MDC) and assigned the MDC the task to define more active —market-shaping- strategic interventions, required to enable the Global Fund to significantly improve the value for money achieved with health products.

In May 2011, the Global Fund board endorsed the Global Fund market shaping strategy[64]. This document specifically outlines strategies to be deployed with respect to ‘high-risk products’, specifically paediatric ARVs. These include ensuring a sustained supply of paediatric ARVs through the Procurement Consortium; collaborating with partners to support country paediatric procurement practices and supply management; and reducing fragmentation through streamlined product selection. A specific note was made on close collaboration with UNITAID to implement market-shaping interventions.

If this Strategy becomes a reality, it will pave the way for a stronger collaboration between the main actors in procurement of ARV: The Global Fund, CHAI and PFSCM/SCMS. CHAI has been facilitating negotiation for ARV procurement on behalf of the Global Fund VPP and PFSCM if Global Fund procurement agent and its sister organization SCMS procured ARV for PEPFAR funded project. The stronger ties between the three actors could potentially radically change the relationship between the pharmaceutical industry and beneficiary countries.

2) Roadmap for the strategic collaboration between UNITAID and the Global Fund

At the 14th Board Meeting the Global Fund board requested the Policy and Strategy Committee to work with the Secretariat and the Finance and Audit Committee to develop a strategic framework, also known as “roadmap”, for future collaboration with UNITAID (GF/B14/DP23). Discussions on the progress for developing the roadmap began in December 2006.

[64] Report of the market dynamics and commodities ad-hoc committee, Twenty-Third Board Meeting Geneva, Switzerland, 11-12 May 2011

This partnership proposed to expand UNITAID CHAI pooled procurement partnership model for future and rolling continuation channels grants. Countries would voluntarily choose whether they want to procure drugs and hence receive the funds or use the UNITAID CHAI pooled mechanism and directly receive the drugs. There are some technicalities that still need to be discussed between CHAI and the Global Fund to define the terms of the collaboration in particular with regards to performance based funding requirements.

3) Focus on in-country capacity building

Even though efforts on building capacity of partners in country have been ongoing, there is still much scope – and much need – for improvement. The focus areas could include the rational selection of cost-effective formulations (esp. when new paediatric guidelines are published), forecasting and quantification with validated tools, procurement and tendering mechanisms, access to competitive pricing information, and the rational use of drugs. Another important area to focus on would be data management to improve reliability of national database, including indicators to measure loss to follow up.

- **Threats**

1) Transition to other sources of funding

Since project’s inception, transition was at the core of the UNITAID/CHAI paediatric ARV project. CHAI explored countries options for alternative funding and supported countries in their application to Global Fund grants. However transition requires more time and resources than anticipated. At the current stage UNITAID assumes that by end 2012, 11 countries will not have transferred to alternative funding sources. The current global financial crisis directly affects funding for HIV, and recent development within the Global Fund to indefinitely postpone Round 11 are not encouraging.

2) Market fragmentation

Sustainability of the gains in terms of price reduction and level of demand is not likely to be achieved unless UNITAID and CHAI agree upon and offer to countries that have transitioned a mechanism that will effectively support them and grant them sustainable access to low price irrespective of the size of their order. Currently there is no readily available alternative mechanism proposed to ensure effective price negations, e.g. through a pooled forecasting mechanism.

3) Forecasting complexity

Countries have been heavily relying on CHAI assistance for forecasting and supply chain management. Forecasting paediatric ARV demand and consumption is particularly complex. Where countries were unable to build sufficient capacity on forecasting in the past, they are likely to run into major difficulties in the future. Countries which did not budget any technical assistance in the Global Fund grants will find themselves in a difficult situation to appropriately estimate their needs and indicative orders. It is also unclear to what extent the Procurement Consortium can provide this kind of in-country assistance.

4) Suppliers confidence in liquidity

One of the features of the program was the assurance that CHAI and IDA Foundation were giving to suppliers that they would be paid on time upon receipt of the products. Following the end of the project, suppliers will most likely experience delays in payment processing

by some countries, which may negatively impact on their willingness to bid for supplying products to those countries.

4 Annex. Approach and Methods

This is a comprehensive external independent mid-term evaluation with an analysis of strengths, weaknesses, opportunities and threats (SWOT), including recommendations based on the findings of the evaluation.

The evaluation was conducted by a lead evaluator supported by a support evaluator responsible for preparing the project outline, compiling the data in the evaluation matrix and contributing to the other tasks in the evaluation process. The evaluators were supported by a financial expert, a procurement and supply management expert, the project leader and the project manager.

4.1 Evaluation components

The evaluation had three components: (1) four common evaluation areas, (2) project-specific questions and (3) an assessment of the quality of reporting

(1) Common evaluation areas

The common evaluation areas have been provided in the RFP. They are compliant with the Organisation for Economic Cooperation and Development (OECD) evaluation criteria[65] and are defined as follows:

- Relevance: consistency between the activities of the project with the project plan and with UNITAID’s objectives and strategy.
- Effectiveness: degree of achievement of the objectives of the project.
- Efficiency: relation between the efforts invested in carrying out the activities of the project and the results of the projects, mainly in procurement.
- Impact: effects of the project beyond the achievement of the short term objectives of the project.

For each evaluation area, ‘questions’, ’indicators’, ‘sources of information’ and ‘analytical methods’ had been defined beforehand. ‘Questions’ were designed to unfold evaluation areas into items that could be described by quantitative or qualitative ‘indicators’. For each indicator, sources of information were identified and the analytical methods to estimate each indicator were defined (see Table 18 for the common questions). All common questions were addressed consistently across all projects to minimise the risk of bias attributable to differences in the approaches by different evaluators.

(2) Project-specific questions

UNITAID, in the RFP, proposed a series of project-specific questions. These questions were further adapted in discussions between the evaluators team, implementing partners and UNITAID secretariat. A full list of the project-specific questions is found in the Annex Table 19.

[65] OECD DAC Network on development evaluation. Evaluation development cooperation. Summary of key norms and standards. Second edition. OECD 2010.

(3) Quality of reporting

The evaluation team was alerted by UNITAID to the fact that programmatic and financial reports of projects sent to UNITAID might pose challenges in terms of their completeness, consistency across projects and with the Agreements between UNITAID and the projects, and internal formal consistency (e.g., between the items formulated as objectives and as activities). Given that the evaluation of the project progress was mainly based on the information contained in semi-annual and annual programmatic and financial reports, reporting problems could affect the findings of the evaluation.

A guiding checklist was prepared to have a consistent assessment of the quality of reporting across evaluators and projects evaluated (

Table 20).

4.2 Methods

1. **Sources of information**

   The main sources of information to conduct the evaluation were:

- Project Proposal and related amendments
- Agreements between UNITAID and CHAI 2007, 2008, 2009, 2010 and related Letters of Agreements
- Annual Reports 2007, 2008, 2009, 2010
- Semi-Annual Reports 2009, 201066
- Other supplementary documents, e.g. financial audit
- Interviews (face-to-face and telephone) with UNITAID and CHAI

The evaluation took documentation into account that was submitted by UNITAID to the evaluators until the 18.11.2011. A full list of documents included in this review is provided in Annex. List of Documents Reviewed.

2. **Project outline**

   A preliminary reading of project documents suggested that not all projects were consistent in terms of what was considered to be an ‘objective’ and an ‘activity’, and in the links between them. The first step, therefore, consisted of creating a ‘project outline’ using a common log-frame[67] to identify the objectives and the activities linked to them. An objective was defined as a statement which described what should be achieved at certain points in time and/or at the end of the project; an activity was defined as a description of the events that should occur in certain times and places, and involving certain people. Where possible, activities were linked to objectives, either based on the information contained in the reports or on the judgment of the evaluators. Any other information retrieved for the evaluation was references to the project outline. The project outline was adapted to reflect changes in the scope and objec-

[66] Semi-Annual Reports were only available since 2009. Before Quarterly Reports have been submitted to UNITAID. Those were made available to the evaluators but have not been the major focus of this mid-term review.

[67] Nacholas S. How to do (or not to do)… A Logical Framework. Health Policy and Planning 1998; 13(2): 189-93.

tives of the projects that took place in the course of implementation, ideally reflected in amendments to the Agreements.

The project outline included, among others:

- objectives and targets
- action plan (including dates and milestones)
- procurement plan
- budget and disbursement plan

3. Data extraction

Based on the log-frame, documents included in the evaluation were scrutinised to extract the relevant data for the evaluation. A set of templates were used to record the data and where necessary, tables were also copied into additional sheets. Data extraction followed the indicators attached to each evaluation question in the four evaluation areas and specific questions.

Comparative pricing information for paediatric ARVs and drugs for Opportunistic Infections (OIs) was obtained from the Management Sciences for Health (MSH) drug price indicator for prices paid by the Supply Chain Management System (SCMS), as well as the CHAI Consortium ARV Ceiling Price List (April 2008, August 2009, April 2010) for paediatric ARVs. The Global Price Reporting Mechanism (GPRM) was used to compare prices obtained for HIV rapid tests, and also to establish trends in prices of paediatric treatment regimens. Lastly, information from the UNICEF Supply Division served to provide comparative data on ready-to-use therapeutic food.

The UNITAID paediatric HIV/AIDS project portfolio manager, other UNITAID staff (Monitoring & Evaluation (M&E), financial, Procurement Officer) and representatives of the implementing partner CHAI, have been contacted to discuss the project and clarify issues related to the availability, reporting and quality of data.

4. Analysis

The evaluation in each area was a composite of the evaluation of each question based on the indicators, as defined in the evaluation matrix. In the analysis, quantitative indicators were calculated and qualitative indicators formulated. When information to estimate an indicator was missing, this was made explicit to avoid confounding missing indicators with poor performance.

The evaluation of each area was accompanied by an assessment of the quality of the underlying data. Data was considered of poor quality when it was partial (e.g., describing what happened in one country but not in another one), when sources were not indicated, or when there were obvious inconsistencies not attributable to project performance (e.g., different figures for the same event in different reports).

When data is missing or of poor quality in a given evaluation area not much confidence can be placed on the truthfulness of the evaluation in reflecting the real situation of the project. On the contrary, when quality issues are minimal, the results of the evaluation can be reasonably trusted. The quality of the underlying data is explicitly described alongside the evaluation findings.

Efforts have been made to provide explanations to the findings, based on the available data - reasons for success and failure. Where it has been deemed that data was insufficient to provide reliable explanations, no attempt was made to extrapolate from other projects or to speculate based on anecdotal evidence.

A meeting was held between all evaluators and the project leaders to review the findings of the evaluations. The review process included the project outline, the indicators and the data analysis. Where necessary, findings were fine tuned to reflect the status of the project limiting those aspects that could be seen as subjective.

A rating was attached to each common evaluation area. The rating was qualitative and based on a consensus within the evaluators team, which included the evaluators of other projects. The rating had two parts - the proper rating of the evaluation area and an assessment of the quality of the underlying data to weight the confidence that can be put in the rating itself. For a guide to the rating scale and an interpretation of the different categories see Table 17.

Table 17. Rating of evaluation areas and quality of data.

	Definition	Interpretation
Rating scale		
Good Performance	All indicators showed acceptable or positive results, according to the targets set.	The project works as expected.
Some Concerns	Most of the indicators showed acceptable or positive results, but there were isolated cases where indicators suggested poor performance.	The project needs minor adjustments to improve its performance or a further evaluation focusing on certain areas may be needed.
Serious Concerns	Most of the indicators showed poor performance.	The project needs important adjustments to improve its performance.
Quality of data		
Good quality	Data to estimate all indicators was available without obvious inconsistencies.	The rating reasonably reflects the true performance of the project.
Moderate quality	Some data was missing or inconsistent, but most of the indicators could be estimated.	It is possible that additional data might change the rating of the project.
Poor quality	Most of the data was missing or inconsistent and only one or two indicators could be estimated.	There is major uncertainty about the extent to which the rating reflects the true performance of the project.

5. **Validation exchanges with key stakeholders**
   Important question were shared and discussed with the UNITAID secretariat and CHAI. The aim of this exchange was to establish a common understanding of the project status, progress and key issues and to clarify open questions. A guiding list of questions was specifically developed for each meeting in order to focus on stakeholder relevant questions

6. **Analysis of project Strengths, Weaknesses, Opportunities and Threats**
   The analysis of project SWOT was performed based on the analysis done along the evaluation matrix, differentiating internal factors that favour/hinder the implementation

of the project (strengths/weaknesses) and external factors (opportunities/threats). It is a **summary** of the key factors influencing the achievement of the project’s objectives. Rather than being a formal fully-fledged SWOT analysis, the items identified in the frame of this mid-term evaluation are considered in a formal SWOT analysis of the project, in case such an analysis is undertaken.

7. **Issuing of recommendations**
   Recommendations were issued by consensus of the team of evaluators involved in all projects, based on the findings of the evaluation. Recommendations prioritised what was understood as being the critical issues in each evaluation area and across all areas. Several options to address the critical issues were listed and assessed against two main criteria: (a) the available evidence that the recommendations would effectively address the critical issue identified; and (b) the feasibility of implementing the recommendation. Evidence was drawn from research, best practices or colloquial evidence. Recommendations were addressed to specific actors: projects implementation entities or UNITAID.

4.3 Project specific

The process of drafting this mid-term review of the Paediatric HIV/AIDS project closely followed the general outline presented above. Background documents (LoA, Agreements, Progress Reports) were obtained and reviewed, and a project outline was elaborated. The evaluation matrix was then completed. Conversations were arranged with representatives of all project partners, namely UNITAID, and CHAI, (see Annex. Meetings with Stakeholders and List of Persons Interviewed) to clarify specific questions from the evaluator side, gain a deeper understanding of the project and discuss the perceptions of the partners of the project and its progress. These interviews were held in person during a visit to Geneva on the 17th November 2011, by phone or e-mail.

The evaluators appreciate the commitment of the implementing body, suppliers and procurement agents to provide information, respond to questions and make time available for meetings and interviews.

5 Annex. Evaluation matrix

Table 18. Evaluation matrix of common evaluation areas.

Relevance			
Evaluation area and questions	**Indicators**	**Sources**	**Methods**
1- Are the activities and expected outputs of the project consistent with the objectives and expected outcomes as described in the project plan?			
1.1 Are the activities from the project plan consistent with the objectives?	Consistency Rates: Number of objectives with activities/total (%) Number of activities related to objectives/total (%)	In the project outline, match the activities with the objectives	Match activities planned to reach each objective Also indicate if some of the activities are not linked to any of the objectives, and question their relevance
1.2 Do indicators, as defined in the project plan, allow measuring progress on each of the objectives?	% of objectives measured at least with one relevant indicator	In the project outline, match the objectives with indicators	Comment on the development of a log-frame for the project
1.3 Are all activities implemented as scheduled for the period?	Activity completion rate: Number of activities implemented/total	Planned activities from project plan Implemented activities from the last available progress report	Follow up on the completion of activities and milestones as described in the project plan. Give reasons for delays.

1.4. Are disbursements according to current budget forecasts and expenditures on the progress report?	Budget execution rate % (Disbursements vs. Budget) Budget absorption rate % (Expenditures vs. Budget)	Budget from project plan Disbursements and Expenditures from financial reports	Calculate total expenditures/disbursements for the budget period Verify that expenditures are in line with activities initially planned/implemented Explain relevant deviations
2- Is it possible to show how the project has contributed to UNITAID’s overall goal of using innovative, global market-based approaches to improve public health by increasing access to quality products for treatment, diagnosis and prevention of HIV/AIDS, tuberculosis and malaria?			
2.1 Has the project already demonstrated the contribution of UNITAID to increased access to quality products to treat/diagnose HIV, TB, and Malaria?	Yes / No	Progress reports: estimated number of patients treated or diagnosed per country	
2.2 Are the numbers reported by the implementing partner reliable?	Yes / Mostly / No	Description of methods to estimate patients treated (if available) Interview UNITAID/partner	How did the partner estimate the number of estimated patients treated (or diagnosed)? Are the methods reliable? Does the partner have programmatic support in countries ensuring that treatments procured are effectively dispensed? Can the numbers be cross-checked with number of treatments procured?
Effectiveness			
Evaluation area and questions	**Indicators**	**Sources**	**Methods**
3- To what extent were the objectives of the project achieved?			
3.1 Were the targets of the project achieved in terms of health outcome (estimated number of patients treated or diagnosed)?	% achievement rates on patient outcome indicators	Project outline: targets in terms of health outcomes Results from the most recent progress report	Comment on the achievements in terms of patient outcome(number patients treated/diagnosed) against the targets Comment on reliability of information

3.2 Were the targets of the project achieved in terms of market outcome?	Include quantitative result/% achievement rate (or qualitative if % not applicable)	Project outline: targets in terms of market outcome Results from the most recent progress report Verify with market information (WHO pre-qualified product/supplier list, MSH drug price indicators)	Comment on the achievements in terms of market outcome (price, quality, availability, access)
4- To what extent are they the objectives likely to be achieved?			
4.1 What is the likelihood of achieving health outcomes objectives?	High / Medium / Low	Progress reports / interviews	No data collection should be included here. This should be answered in the evaluation based on what has been achieved and what is known on the project
4.2 What is the likelihood of achieving market objectives?	High / Medium / Low	Interviews / market knowledge	No data collection should be included here: This should be answered in the evaluation based on what has been achieved and what is known on the market for the drug or diagnosis
5- What are the main factors influencing the achievement of or failure to achieve the objectives?			
5.1. What were the reasons for patient outcome targets not being met?	List of factors	Progress reports / interviews	For the main patient outcome indicator, analyze the chain of events: - Were the project plan activities implemented? - If yes, what were the factors causing targets not to be achieved? - Differentiate between internal factors (related to partner's organization and project implementation) and external factors (country context, market, complementary funding)
5.2. What were the reasons for market impact targets not met?	List of factors	Progress reports / interviews	Were the project plan activities implemented? If yes, what were the factors causing targets not to be achieved?
5.3. Was there an effective risk management plan in place during the project	Yes / Limited / No	Progress reports / interviews	Did the partner make an initial risk assessment? Were the issues that arose during implementation foreseen in the risk assessment? Did the partner take mitigation measures to limit the impact of negative events?

Efficiency			
Evaluation area and questions	**Indicators**	**Sources**	**Methods**
6- Are the project partners working closely with the relevant national authorities?			
6.1 Has the MoU been signed by all beneficiary countries?	Number of MoU signed/total planned	Latest progress report Update by interviews	Number of MoU signed compared to number planned Analyze reasons for MoU not being signed
7- Is the project’s procurement model well defined and designed to identify and solve procurement related problems as they arise?			
7.1 Has a procurement agent been selected and is he/she operational in the project?	Yes (name) In progress Process not started	Progress update Latest procurement review	
7.2 Is the product median price procured in line with the budget?	Median unit cost/planned unit cost (%) for key selected products	Procurement orders Targets and budget from initial project plan	Select a few items driving the overall procurement budget Comment on the reliability of information
7.3 What is the average lead time between purchase order and reception of health products in country?	Average lead time for all operational countries	Project plan Progress reports Copy of order sent by the country, reception certificate	Target time: effective time (in months) Number of months delay/lead compared to project plan Calculate average lead time for all the countries (if there is a minority of extreme values do not include them in the calculation, but mention then in the comment) Is it in line with initial plan?
7.4 How many stock-outs of more than seven days were observed since the beginning of the project?	Number of stock-outs	Progress reports if information is reported Otherwise ask the implementing partner	Identify likely reasons for stock-outs / attribute stock-outs responsibility: Number of stock-outs with responsibility Number of stock-out without responsibility
7.5 Is the procurement model functioning as designed in the project plan?	Yes / No	Compare procurement model to project plan to reality	If deviations from the project plan are identified, try to obtain information on the reason of the change.

Impact			
Evaluation area and questions	**Indicators**	**Sources**	**Methods**
8- Can the partner organization attribute UNITAID funding to medicines and diagnostics purchased, and patients treated by beneficiary countries in a timely manner?			
8.1 Did the project report on treatments/diagnostics procured per country in UNITAID Funding?	No information on treatments/diagnostics procured per country	Latest progress report	
8.2 Did the project report on patients treated/diagnosed per country in the UNITAID scheme?	No information on patients treated/diagnosed with UNITAID funding per country	Latest progress report	

Table 19. Project specific questions.

1. Show how country-level demand forecasts for paediatric ARVs and diagnostic tests have been improved
1.1 What is the tool (CHAI specific or other) and methodology used for forecasting (Morbidity based, consumption based or both)
1.2 How many stock out of paediatric ARV and Diagnostic tests lasting for more than 1 week were recorded in the beneficiary countries per year?
1.3 Is there any difference in the quantity and nature of Paediatric ARV and Diagnostic test procured by the beneficiary countries?
1.4 How many products have more than 18 months of stock?
1.4What is the proportion of products likely to expire before consumed (based on the average monthly consumption and patient enrolment target)
1.5 Quantity/Value (and % as the total amount procured) of drugs that have expired over the past 12 months
1.6 Actual consumption vs. Forecast
2. What actions are being taken through the project to address the challenge of loss to follow up of paediatric patients?
2.1 List of actions taken through the project to address the challenge of loss to follow up for paediatric patient / comment on their relevancy
2.2 What were the improvements in paediatric patient loss to follow up following implementation of actions?
3- What positive changes have been made to number of manufacturers, quality products and better prices for opportunistic infection medicines and ready to use therapeutic foods (RuTF)?
3.1 Number of new products/manufacturers either WHO prequalified or registered by a stringent regulatory authority since the start of the program
3.2 Median Price reduction per box and per treatment/year achieved under the program
3.3 Number of procured products registered by a Stringent Drug Regulatory Authority as per the ICH definition
3.4 Number and percentage of procured products over 12 months that are manufactured in a GMP certified site as per WHO standards
3.5 Median price reduction of 10 selected OI (10 items representing highest value) compared to international market price using MSH ERC price index and comparison with previous year prices
3.6 Number of bidders per tender for OI
3.7 Number of bidders per tender for therapeutic food
3.2 Median Price reduction per RTuF unit and per treatment achieved under the program
3.7 Improvements in Quality
4- Were the recommendations of the past UNITAID/CHAI procurement evaluation implemented?; if not, what further adjustments are needed? Done in 2008, review will be made available. Procurement agent IDA foundation. Another procurement review ongoing
4.1 Were previous recommendations addressed in time, insufficiently or not addressed ?
4.2 What was the median price decrease of key products procured under the program after implementation of previous recommendations?
4.3 What was the average time reduction or lead time for key products procured under the program once past recommendations were implemented?

5. What steps have been taken towards effective transitioning of this project to more sustainable sources of funding?
5.1 What is the list of actions taken?
5.2 What results have been obtained so far?

Table 20. Reporting checklist.

Reporting received from implementing partners
1.1 Are project reports (interim report, annual reports) submitted on time?
1.2 Are there many clarifications required by UNITAID following the transmission of reports?
1.3 Does the content of the reports meet the requirements in the project plan?
1.4 Is the content of the report useful for decision making?
1.5 What is the internal UNITAID process for validating a progress report? How could it be improved?
Financial reporting
2.1 Are the reporting requirements clear in the project plan and MoU?
2.2 Does the financial reporting format allow easy identification of common budget items, e.g., salaries, travel, major acquisitions, and drugs/diagnostics?
2.3 Does the financial reporting give a clear picture of activities implemented and expenditures of the period compared to budget and work plan?
2.4 Does the project implementation follow performance based funding principles? Are the disbursements based on progress made?
2.5 Is interest received on bank accounts or others income reported, and are they reimbursed to the program/deduced on disbursement requests?
2.6 Does the financial reporting include a cash reconciliation supported by financial and bank statements?
Programmatic reporting
3.1 Are indicators defined both at the process level and outcome/impact level?
3.2 Does the programmatic/procurement reporting follow UNITAID content requirements?
3.3 Does the programmatic reporting provide a clear and actionable picture of programme implementation?
3.4 Does the programmatic reporting provide a clear picture of procurement activities (order list, etc.)?

6 Annex. Meetings with Stakeholders and List of Persons Interviewed

Organisation	Name	Role	Date
UNITAID	Raquel Child	Director Market Dynamics and Operations	17th November 2011
	Kathleen Louise Strong	Head Monitoring & Evaluation	
	Dr. Gauri Khanna	Technical Officer (Monitoring & Evaluation)	
	Brigitte Laude	Financial Director	
	Greg Martin	Technical Officer (Transition Team)	
	Lorenzo Llewellyn Witherspoon	Procurement Advisor	23. November 2011
CHAI	Amy Meyers	Manager UNITAID Projects	15th November 2011
	Meredith Moore	Country Support Manager, Drug Access	“
	Cyril Khamsi	Paediatrics Project Manager	“

7 Annex. List of Documents Reviewed

Document Title	Source	Year	Submitted/ Signed
Agreements			
Project Agreement for Paediatric HIV/AIDS Program	UNITAID	2006-2007	19./25.01.2007
Agreement for the Procurement and Supply of Paediatric ARV Drugs	UNITAID	2006-2007	19./25.01.2007
First Amendment to the Procurement and Supply of Paediatric ARV Drugs	UNITAID	2007	31.08.2007/ 28.09.2007
Extension Amendments to Project and Procurement Agreements for UNITAID Paediatric HIV/AIDS Program 2008-2010	UNITAID	31.12.2007-29.02.2008	21.12.2007 (signed 04.01.2008)
Extension Amendments to Project and Procurement Agreements for UNITAID Paediatric HIV/AIDS Program 2008-2010 and to Second-Line ARV Drugs Program 2008-2009	UNITAID	n/a-15.04.2008	14.03.2008[68]
First Amendment to Project Agreement for the Paediatric HIV/AIDS Program for 2008	UNITAID	2008	15.04.2008
Agreement for the Procurement and Supply of Paediatric ARV Drugs, Diagnostics and Related Commodities for 2008	UNITAID	2008	15.04.2008
Extension to Project and Procurement Agreements for UNITAID Paediatric HIV/AIDS Project 2008-2010	UNITAID	31.12.2008-27.02.2009	23.12.2008
Extension Amendments to Project and Procurement Agreements for UNITAID Paediatric HIV/AIDS Program 2008-2010 and to Second-Line ARV Drugs Program 2009	UNITAID	27.02.2009-31.03.2009	03.03.2009
Extension Amendments to Project and Procurement Agreements for UNITAID Paediatric HIV/AIDS Program 2008-2010 and to Second-Line ARV Drugs Program 2009	UNITAID	n/a-09.06.2009	29.05.2009

[68] Extension of Amendment not signed by CHAI.

Document Title	Source	Year	Submitted/ Signed
Agreement for the Procurement and Supply of Paediatric ARV Drugs, Diagnostics and Related Commodities and for Paediatric Project Support for 2009	UNITAID	2009	08.06.2009
Agreement for the Procurement and Supply of Paediatric ARV Drugs, Diagnostics and Related Commodities and for Paediatric Project Support for 2010	UNITAID	2010	10./11.02.2010
Annual and Semi-Annual Reports			
Annual Report 01.11.2006 – 31.12.2007	UNITAID	2007	15.04.2008
Annual Report 01.01.2008 – 31.12.2008	UNITAID	2008	30.04.2009
Annual Report 01.01.2009 – 31.12.2009	UNITAID	2009	26.05.2010
Annual Report 01.01.2010 – 31.12.2010	UNITAID	2010	10.05.2011; updated 24.05.2011[69]
Semi-Annual Report 01.01.2009-30.06.2009	UNITAID	2009	21.09.2009
Semi-Annual Report 01.01.2010-30.06.2010	UNITAID	2010	13.09.2010
Resolutions			
Resolution N°8	UNITAID	29.-30.11.2006	
Resolution n°5	UNITAID	08.-09.03.2007	
Resolution EB6 / 10	UNITAID	06.-07.12.2007	
Resolution n°7	UNITAID	24.-25.11.2008	
Resolution n°7	UNITAID	14.-15.12.2009	
Resolution n°11	UNITAID	08.-09.06.2010	
Resolution n°13	UNITAID	10.-11.11.2010	
Other			
CHAI (2010): Paediatric Transition Operational Plan.	CHAI	31.08.2010	

[69] Document has been revised once more due to an error in the original report regarding median prices (Report dated: 7th June 2011). Another version has been requested in November 2011 by UNITAID due to some formal errors (e.g. table numbering).

Document Title	Source	Year	Submitted/ Signed
Ernst&Young (2009) Evaluation of the Procurement for the UNITAID Paediatric and Second Line HIV/AIDS Niches	UNITAID	06.05.2009	
Memorandum of Understanding (2010) for Burkina Faso, Swaziland and Vietnam	UNITAID	2010	
Letter to Suppliers	CHAI		

8 Annex. Supporting Tables

Table 21. Objectives and activities of the paediatric HIV/AIDS procurement project.

Objectives		Action (Project Plan, Section 5)		Action (M&E, Annex 5)		Indicators (M&E, Annex 5)
1	To scale up the access to Paediatric ARVs and Second-Line ARVs and related key commodities to increase the number of patients receiving treatment for HIV/AIDS in developing countries	5.1	Identify List of Beneficiary Countries for the Project	5.1	Identify beneficiary countries for the project in line with UNITAIDs eligibility criteria	Percent of total budget allocated to LIC, LMIC, UMIC
		5.2	Sign Amendments to MoU with Countries which contain updated Annexes of Paediatric Products to be supplied in 2010	5.2	Sign Amendments to MoU containing updated annexes of paediatric products to be supplied in 2010	Percent of beneficiary countries with signed amendments and updated annexes with paediatric products to be supplied in 2010
		5.3	Engage in forecasting for countries for the purposes of estimating purchases in 2010	5.3	Engage in forecasting with countries for the purposes of estimating purchases of ARVs, diagnostics, OI drugs and RUTF in 2010	Forecast of estimated quantity of drugs and purchases of ARVs, diagnostics, OI drugs, and RUTF and number of patients to be treated in 2010
		5.12	Placement of Purchase orders for and Delivery of Products	5.9a	Placement of Purchase Orders for and Delivery of Products	Percent of value of ARV packs ordered and delivered by each countries that match the value of ARV packs budgeted
				5.9b	Placement of Purchase Orders for and Delivery of Products	Number of children on treatment as a result of products delivered
2	Influence market dynamics to achieve price reductions to increase the affordability of critical quality products	5.4	Identification of which commodities (both broad product areas and specific products) are to be procured for the project in 2010		n/a	n/a
		5.7	Determine potential suppliers and prices to be paid for products in 2010	5.4a	Identify potential suppliers and prices to be paid for products in 2010	Number of suppliers in each product area where possible
				5.4b	Identify potential suppliers and prices to be paid for products in 2010	CHAI pays lowest price for products in each product category
		5.8	Enter into contractual arrangement with suppliers for the supply of commodities based on the outcome of the application selection and price negotiation process for the product	5.5	Enter into contractual arrangement with suppliers for the supply of commodities based on the outcome of the application selection and price negotiation process for the product	Number of suppliers that have signed MSAs or long term agreements
3	Stimulate an increase in the number of quality assured manufacturers and products	5.9	Determine the suppliers to be used for each purchase order	5.6b	Determine the suppliers to be used for each purchase order (Monitoring of supplier performance	Number of suppliers that have had products registered or applied for waivers during 2010
		5.10	Work to improve the market for UNITAID-funded commodities to support UNITAIDs mission of lowering prices and broadening supplier base	5.7	Work towards improving the market for UNITAID funded commodities to support UNITAIDs mission of lowering prices and broadening the supplier base	Number of pre-qualified paediatric ARV formulations and OI medicines available each year

Objectives		Action (Project Plan, Section 5)		Action (M&E, Annex 5)		Indicators (M&E, Annex 5)
4	Decrease product delivery lead times	5.6	Transition of Certain Procurement Actions from CHAI to an External Procurement Agent		n/a	n/a
		5.9	Determine the suppliers to be used for each purchase order	5.6a	Determine the suppliers to be used for each purchase order (Monitoring of supplier performance	Decrease lead time from purchase order to delivery in country
		5.13	Development of suggestions to support in-country distribution systems		n/a	n/a
		5.14	Provide staff to manage procurement activities of Paediatric Project		n/a	n/a
5	Encourage pre-qualification of approved manufacturers and products	5.10	Work to improve market for UNITAID-funded commodities to support UNITAIDs mission of lowering prices and broadening supplier base	5.7	Work towards improving the market for UNITAID funded commodities to support UNITAIDs mission of lowering prices and broadening the supplier base	Number of pre-qualified paediatric ARV formulations and OI medicines available each year
6	Influence market dynamics to achieve price reductions to increase the affordability of critical quality products	5.5	Development of an Effective Procurement Strategy, including (ii) use of a product specific approach to establish the most competitive prices available and (ii) revise the scope of CHAI's procurement responsibilities for the Project		n/a	n/a
		5.7	Determine potential suppliers and prices to be paid for products in 2010	5.4a	Identify potential suppliers and prices to be paid for products in 2010	Number of suppliers in each product area where possible
				5.4b	Identify potential suppliers and prices to be paid for products in 2010	CHAI pays lowest price for products in each product category
		5.8	Enter into contractual arrangement with suppliers for the supply of commodities based on the outcome of the application selection and price negotiation process for the product	5.5	Enter into contractual arrangement with suppliers for the supply of commodities based on the outcome of the application selection and price negotiation process for the product	Number of suppliers that have signed MSAs or long term agreements
		5.11	Submission of Order Requisition by Country Teams to Central Project Managers on a quarterly basis	5.8	Submission of order requisitions by country teams to central project managers on a quarterly basis	Percent of orders (per product area) placed through pooled procurement
		5.18	Identify 2011 commodities required and plan procurement processes	5.12	Identify 2011 commodities required and plan procurement process	CHAI to develop a project proposal and budget for 2011 in collaboration with UNITAID and subject to UNITAID Board approval.

	Objectives		Action (Project Plan, Section 5)		Action (M&E, Annex 5)	Indicators (M&E, Annex 5)
7	Reaching an additional 70,000 children in 2010	5.12	Placement of Purchase Orders for and Delivery of Products	5.9b	Placement of Purchase Orders for and Delivery of Products	Number of children on treatment as a result of products delivered
	General Project Implementation activities	5.15	Provision of robust staff support to Paediatric project	5.11	Provide staff to support paediatric project	Number of countries receiving technical assistance and project support to the project
		5.16	Establishment of Performance Indicators for the Project		n/a	n/a
		5.17	Timely submission and review of Semi-annual Reports and Annual Reports		n/a	n/a
		5.19	Manage transition of funding from UNITAID to other long-term donors		n/a	n/a

Source: 2010 Paediatric Project Support and Procurement Agreement; p. 5, Appendix 1 Section 5 and Annex 5

Table 22. Actions implemented (2010 progress report).

	Action (M&E, Annex 5)	Indicators	Target (M&E, Annex 5)	Progress	Implementation-Status 2010	Source
5.1	Identify beneficiary countries for the project in line with UNITAIDs eligibility criteria	Percent of total budget allocated to LIC, LMIC, UMIC	At least 85% disbursed to LIC; <=10% disbursed to LMIC; <=5% disbursed to UMIC by Q4 2010	By Q4 2010: 84.4% of expenditures[70] had been made to LIC, 11.8% to LMIC; 3.8% to UMIC	Not implemented	2010 Agreement p. 10 and Annex 5; 2010 Annual Report; Table 2.3, 2.4a; Section 2.4
5.2	Sign Amendments to MoU containing updated annexes of paediatric products to be supplied in 2010	Percent of beneficiary countries with signed amendments and updated annexes with paediatric products to be supplied in 2010	100% of beneficiary countries have signed amendments and updated annexes with paediatric products to be supplied in 2010	25 countries (71% of all countries[71]) signed MoU. Only 12 (34%) of all countries signed it in the first half of the year	Not implemented	2010 Agreement Annex 5; 2010 Annual Report Section 3 and Table 4a

[70] Expenditures for commodities only, excluding lab equipment, advance orders, procurement agent fee and QA/QC costs.
[71] The total number of countries is 35 as OECS includes six countries.

	Action (M&E, Annex 5)	Indicators	Target (M&E, Annex 5)	Progress	Implementation-Status 2010	Source
5.3	Engage in forecasting with countries for the purposes of estimating purchases of ARVs, diagnostics, OI drugs and RUTF in 2010	Forecast of estimated quantity of drugs and purchases of ARVs, diagnostics, OI drugs, and RUTF and number of patients to be treated in 2010	Forecast of estimated quantity of drugs and purchases of ARVs, diagnostics, OI drugs, and RUTF and number of patients to be treated in 2010 to be provided by September 2009	Forecast on patient numbers and drugs to be purchased has not been provided to UNITAID by September 2009. The required information is included in the MoU with beneficiary countries and in RfP to suppliers, and is discussed with UNITAID more informally at a regular basis.	Not implemented	As confirmed with UNITAID, and official document dated Sept 2009 outlining required forecast was not available.
5.4a	Identify potential suppliers and prices to be paid for products in 2010	Number of suppliers in each product area where possible	Number of Paediatric FDC product/suppliers increases by 2 in 2010. Number of AZT FDC suppliers increases by 1 in 2010. Number of qualified RUTF suppliers increases by 1 in 2010. Number of new OI suppliers to the program increases by 1 in 2010	5 new FDC products pre-qualified; 4 new AZT-FDC FDC suppliers; The UNITAID CHAI project sourced RUTF from 3 new suppliers in 2010; it was not a goal of the project to source from new suppliers for OI drugs	Implemented	Agreement 2010, Annex 5 M&E; 2010 Annual Report, Annex 6, section 5.3; WHO Prequalification Programme; UNICEF Supply Annual Report 2010
5.4b	Identify potential suppliers and prices to be paid for products in 2010	CHAI pays lowest price for products in each product category	Price reductions in median price (US$) paid for selected ARVs procured in 2010 achieved	Price reductions achieved in median prices for selected paediatric ARVs as negotiated with primary and secondary suppliers. However, the target was not quantified.	Implemented	2010 Annual Report Table 5.1.1b
5.5	Enter into contractual arrangement with suppliers for the supply of commodities based on the outcome of the application selection and price negotiation process for the product	Number of suppliers that have signed MSAs or long term agreements	100% of the 2010 Master Supply agreements concluded by CHAI and Suppliers by Q3 2010 (as applicable per product type)	Evaluators were not able to verify, but based on 2010 Annual Report it is unlikely that 100% of MSAs/LTAs were signed by Q3 2010	Not implemented	2010 Annual Report

	Action (M&E, Annex 5)	Indicators	Target (M&E, Annex 5)	Progress	Implementation-Status 2010	Source
5.6a	Determine the suppliers to be used for each purchase order (Monitoring of supplier performance)	Decrease lead time from purchase order to delivery in country	Average lead time no greater than 12 weeks for each supplier in each product area by Q4 2010	For paediatric ARVs, approximately 12 products exceeded their average production lead-time by more than 12 weeks. Four suppliers, namely Matrix, Aurobindo, Merck and Hetero exceeded the average production lead-time of 12 weeks. For approximately 29 countries average delivery lead-time exceeded 12 weeks.	Not implemented	2010 Annual Report, Annex 4 and Order Tracker
5.6b	Determine the suppliers to be used for each purchase order (Monitoring of supplier performance	Number of suppliers that have had products registered or applied for waivers during 2010	Increased number of registrations per drug in beneficiary countries	Based on the available information, the evaluators could not determine if target was achieved	n/a	2010 Annual Report, Annex 5
5.7	Work towards improving the market for UNITAID funded commodities to support UNITAIDs mission of lowering prices and broadening the supplier base	Number of pre-qualified paediatric ARV formulations and OI medicines available each year	At least 2 new pre-qualified ARV formulations by Q4 2010	The dispersible formulations ABC 60mg, AZT/3TC 60/30mg and NVP 50mg were pre-qualified in 2010	Implemented	2010 Annual Report Annex 6
5.8	Submission of order requisitions by country teams to central project managers on a quarterly basis	Percent of orders (per product area) placed through pooled procurement	100% of all orders places through the application of pooled procurement by Q4 2010 unless there is a significant impact on the delivery schedule	CHAI states that 95% of ARVs and 85% of OI drugs were pooled, but definition of ‘pooled procurement’ needs to be clarified	n/a	2010 Annual Report; 2010 Semi-Annual Report (Sept)
5.9a	Placement of Purchase Orders for and Delivery of products	Percent of value of ARV packs ordered and delivered by each countries that match the value of ARV packs budgeted	100% of budgeted products are delivered allowing for a 10% deviation per country budget allocation	Only three countries of the 35 beneficiary countries deviated less than 10% from their expenditure. Even when allowing for a 15% deviation only four countries had actually products delivered and accordingly used their anticipated budget to this date.	Not implemented	2010 Agreement, 2010 Annual Report, Table 2.4b

	Action (M&E, Annex 5)	Indicators	Target (M&E, Annex 5)	Progress	Implementation-Status 2010	Source
5.9b	Placement of Purchase Orders for and Delivery of products	Number of children on treatment as a result of products delivered	70,070 additional children on treatment in 2010 plus 260,752 continued from 2009.	70,744 children were placed on treatment, whereas an estimated 250,794 continued treatment from 2009	Partially implemented	2010 Annual Report
5.11	Provide staff to support paediatric project	Number of countries receiving technical assistance and project support to the project	40 countries provided with technical assistance in 2010 for paediatric project	The evaluators did not have information to verify if this target was met; detailed project descriptions in Annual Reports	n/a	Annual Reports 2007-2010
5.12	Identify 2011 commodities required and plan procurement process	CHAI to develop a project proposal and budget for 2011 in collaboration with UNITAID and subject to UNITAID Board approval.	Project plan developed for 2011 by November 2010 to include a) preliminary estimated quantities of products and number of patients to be treated in each beneficiary country, b) preliminary budget, c) modified supplier selection criteria, d) plan for the issuance of EOI or tender to select ARV and OI suppliers, e) procurement strategy for diagnostics and RUTF.	Information required is included in the 2011 Agreement. The evaluators do not have information on the timely submission.	Implemented	2011 Agreement

Source: 2010 Agreement; 2010 Progress Report

Table 23. Expenditure to suppliers according to the UNITAID eligibility criteria per year[72].

Beneficiary Income Level	2007	2008	2009	2010
LIC	83.1%	80.2%	81.2%	84.4%
LMI	14.6%	12.4%	14.4%	11.8%
UMI	2.3%	7.4%	4.4%	3.8%

Source: 2007, 2008, 2009, 2010 Annual Reports

Table 24. Allocated Budget according to the UNITAID eligibility criteria per year.

Beneficiary Income Level	2007	2008	2009	2010
LIC	85.7%	86.7%	83%	69.5%
LMI	10.4%	9.7%	12.7%	23.8%
UMI	3.9%	3.6%	4.3%	6.7%

Source: 2007, 2008 Annual Report, 2009, 2010 Agreement

Table 25. Budget absorption rates and commitments as of the allocated budget per country for 2010.

	2010 Budget	Disbursement to Suppliers (31 Dec 2010)	Budget Absorption (31 Dec 2010	Disbursement to Suppliers (28 Feb 2011)	Budget Absorption (28 Feb 2011)	Commitments (28 Feb 2011)	Commitments (28 Feb 2011)
Angola	$1'018'307	$24'647	2%	$62'335	6%	$604'687	59%
Benin	$420'105	$291'600	69%	$421'246	100%	$516'671	123%
Botswana	$2'189'583	$819'170	37%	$1'048'514	48%	$1'710'476	78%
Burkina Faso	$576'295	$175'221	30%	$206'878	36%	$272'534	47%
Burundi	$289'520	$119'954	41%	$205'406	71%	$247'576	86%
Cambodia	$750'182	$155'948	21%	$179'290	24%	$498'941	67%
Cameroon	$1'189'272	$522'961	44%	$750'321	63%	$1'092'110	92%
China	$715'975	$0	0%	$239'023	33%	$840'007	117%
Cote d'Ivoire	$382'714	$98'880	26%	$157'432	41%	$471'484	123%
D R Congo	$1'313'991	$324'932	25%	$975'855	74%	$1'018'956	78%
Dominican Republic	$446'068	$41'987	9%	$45'051	10%	$89'616	20%
Ethiopia	$3'144'612	$1'505'821	48%	$1'742'689	55%	$2'867'591	91%
Guyana	$79'624	$11'098	14%	$13'498	17%	$24'615	31%
Haiti	$1'019'935	$328'722	32%	$332'634	33%	$925'755	91%
India	$3'678'403	$479'693	13%	$483'765	13%	$2'528'568	69%

[72] Note: No indication of cut-off dates for expenditures to suppliers.

	2010 Budget	Disburse-ment to Sup-pliers (31 Dec 2010)	Budget Ab-sorption (31 Dec 2010	Disburse-ment to Sup-pliers (28 Feb 2011)	Budget Ab-sorption (28 Feb 2011)	Commit-ments (28 Feb 2011)	Commit-ments (28 Feb 2011)
Jamaica	$119'332	$10'045	8%	$13'809	12%	$38'544	32%
Kenya	$8'927'109	$2'831'076	32%	$4'650'945	52%	$7'135'512	80%
Lesotho	$1'505'570	$733'832	49%	$969'941	64%	$1'087'787	72%
Liberia		$57'348	n/a	$57'348	n/a	$77'771	n/a
Malawi	$4'788'987	$3'186'803	67%	$3'836'813	80%	$5'397'788	113%
Mali	$649'176	$239'706	37%	$419'079	65%	$530'131	82%
Mozambique	$5'103'137	$2'532'873	50%	$3'616'485	71%	$4'626'599	91%
Namibia	$2'040'297	$170'521	8%	$313'174	15%	$829'292	41%
Nigeria	$6'484'906	$902'393	14%	$1'562'582	24%	$2'738'265	42%
OECS	$58'752	$18'108	31%	$21'223	36%	$31'186	53%
PNG	$155'355	$86'178	55%	$143'896	93%	$206'540	133%
Rwanda	$1'975'473	$647'357	33%	$718'242	36%	$776'920	39%
Senegal	$264'192	$192'080	73%	$275'895	104%	$409'199	155%
Swaziland	$2'049'121	$430'740	21%	$749'733	37%	$1'034'147	50%
Tanzania	$4'493'962	$1'830'354	41%	$2'577'410	57%	$3'308'574	74%
Togo	$212'896	$211'913	100%	$249'440	117%	$392'677	184%
Uganda	$6'231'648	$3'721'780	60%	$5'493'185	88%	$8'516'018	137%
Vietnam	$703'901	$249'364	35%	$296'927	42%	$639'404	91%
Zambia	$4'791'901	$1'892'045	39%	$2'345'497	49%	$3'513'051	73%
Zimbabwe	$4'622'715	$2'960'402	64%	$3'394'082	73%	$5'221'903	113%
TOTAL	**$72'393'016**	**$27'805'551**	**38%**	**$38'569'641**	**53%**	**$60'220'895**	**83%**

Source: 2010 Agreement, 2010 Annual Report, Table 2.4b

	Deviation less or equal 10% of allocated budget
	Deviation less or equal 15% of allocated budget

Table 26. Budget absorption rate, expenditure and outstanding commitments of budget per commodity area.

	Budget	Committed	Disbursed to Supplier	Expenditure and out-standing commit-ments/ budget	Budget absorption rate	Date
ARV (Commodity A)						
2007	$18'700'952	$20'286'107	$14'779'080	108%	79%	n/a
2008	$24'874'647	$26'893'407	$17'042'202	108%	69%	31 Dec
2009	$33'128'563	$28'633'562	$16'375'557	86%	49%	n/a
2010	$39'966'516	$31'268'554	$11'502'899	78%	29%	31 Dec
OI-Drugs (Commodity B)						
2007	$4'241'689	$1'843'346	$718'048	43%	17%	n/a
2008	$3'686'282	$3'179'460	$1'113'412	86%	30%	31 Dec
2009	$3'828'632	$3'695'270	$2'246'703	97%	59%	n/a
2010	$3'744'205	$2'455'502	$460'972	66%	12%	31 Dec
Diagnostics (Commodity C)						
2007	$7'757'241	$8'932'127	$7'290'207	115%	94%	n/a
2008	$20'258'504	$9'905'444	$8'151'152	49%	40%	31 Dec
2009	$15'757'555	$18'045'322	$15'272'733	115%	97%	n/a
2010	$20'053'776	$23'586'727	$12'087'363	118%	60%	31 Dec
RUTF (Commodity D)						
2007	$4'778'169	$4'394'123	$3'448'370	92%	72%	n/a
2008	$7'204'570	$6'519'937	$5'278'950	90%	73%	31 Dec
2009	$8'103'893	$8'623'896	$7'818'933	106%	96%	n/a
2010	$10'628'519	$9'456'161	$4'526'510	89%	43%	31 Dec

Source: 2007, 2008, 2009, 2010 Annual Reports

	Deviation less or equal 10% of allocated budget
	Deviation less or equal 15% of allocated budget

Table 27. Treatment targets, revised treatment targets, treated patients and achievement rates per country (2010).

	Country	Patient targets Jan 2010	Revised patient target 2010	Deviations from original target	New children on Tx end 2010	Patients treated as of original Jan 2010 target	Patients treated as of revised target
1	Angola	200	200	100%	n/a	n/a	n/a
2	Benin	325	325	100%	381	117%	117%
3	Botswana	700	700	100%	1,377	197%	197%
4	Burkina Faso	275	275	100%	45	16%	16%
5	Burundi	500	500	100%	374	75%	75%
6	Cambodia	498	498	100%	496	100%	100%
7	Cameroon	800	800	100%	880	110%	110%
8	China	150	150	100%	95	63%	63%
9	Cote d'Ivoire	50	50	100%	450	900%	900%
10	D R Congo	900	900	100%	249	28%	28%
11	Dominican Republic	95	95	100%	77	81%	81%
12	Ethiopia	2,500	2,500	100%	3,999	160%	160%
13	Guyana	24	24	100%	n/a	n/a	n/a
14	Haiti	670	671	100%	4,646	693%	692%
15	India	5,404	4,800	89%	715	13%	15%
16	Jamaica	50	50	100%	36	72%	72%
17	Kenya	8,000	7,200	90%	8,734	109%	121%
18	Lesotho	765	800	105%	633	83%	79%
19	Liberia	102	102	100%	74	73%	73%
20	Malawi	6,300	6,300	100%	6,186	98%	98%
21	Mali	400	400	100%	242	61%	61%
22	Mozambique	5,317	5,317	100%	3,890	73%	73%
23	Namibia	1,090	1,090	100%	509	47%	47%
24	Nigeria	8,500	8,500	100%	8,349	98%	98%
25	OECS	-	-	-	3		
26	PNG	125	125	100%	173	138%	138%
27	Rwanda	1,000	1,000	100%	968	97%	97%
28	Senegal	115	115	100%	196	170%	170%
29	Swaziland	1,000	1,000	100%	1,503	150%	150%
30	Tanzania	6,200	6,200	100%	7,546	122%	122%

	Country	Patient targets Jan 2010	Revised patient target 2010	Deviations from original target	New children on Tx end 2010	Patients treated as of original Jan 2010 target	Patients treated as of revised target
31	Togo	500	400	80%	336	67%	84%
32	Uganda	5,129	5,129	100%	3,270	64%	64%
33	Vietnam	664	664	100%	662	100%	100%
34	Zambia	4,300	4,300	100%	4,751	110%	110%
35	Zimbabwe	6,000	6,000	100%	8,929	149%	149%
	TOTAL	**68,648**	**67,180**	**98%**	**70,774**	**103%**	**105%**

Source: 2010 Agreement, Annex 1, 2010 Annual Report, Table 4.2.1

	Revised treatment target per country differs by more than 15% to original target

.

Table 28. Ernst & Young recommendations following assessment of CHAI procurement arrangement under paediatric and second-line projects.

#	Ernst &Young recommendations	Evaluators comments
1	Target price reduction should be defined and agreed upon between CHAI and UNITAD.	A decrease in price for paediatric ARVs is specified as objective, but does not include a concrete price reduction target.
2	Development of strategies to increase the supplier base for cotrimoxazole, other OI drugs and RUTF products	The number of suppliers for RUTF was increased since the Ernst & Young review. The increase in the supplier base for OI Drugs and RUTF is also mentioned as a target in the 2010 Agreement, Annex 5 (M&E Section). However, personal interviews with UNITAID revealed that the increase of the supplier base for OI drugs was not a target of this project as it is a multi-source product.
3	Self-assessment of prices of diagnostic products, comparing CHAI’s list against retail prices existing in the market on a periodic basis	Section 3.3.2 of the 2010 Annual Report states that the projects pays significantly lower prices for diagnostics purchased compared to market price (except for rapid test). The evaluators could not review what benchmarks CHAI uses for this market comparison.
4	A strategy should be developed to manage the risk of foreign exchange price fluctuation	Each agreement includes a part covering "Risk Review, Risk Mitigation", essentially concerning the exchange rate risk mitigation. Also it is acknowledged that interest rates are taken forward and held in reserve for exchange rate mitigation purposes. However none of the Annual Reports Annual Reports include information on the mitigation of foreign exchange risk as provided in the Agreements 2009 and 2010. The evaluators therefore lack information on its actual implementation.
5	Targets should be defined in terms of number of suppliers to be introduced into the market of different products	In the 2010 Agreement, Annex 5, M&E Section it is specified that the supplier base should be increased according to different products (e.g. FDCs).
6	Allocation ratio amongst primary and secondary and pool suppliers should be formalized and monitored	The allocation ratio is formalised (60/40). However evaluators were unable to verify the monitoring status, and there is some indication that allocation ratio is not strictly adhered to.
7	Sole sourcing of products should be avoided where more than one supplier is available in the market	In principle, sole sourcing is only done where one supplier is available. However, CHAI also sourced directly from manufacturers for emergency purchases. Some of these manufacturers were established primary or secondary suppliers, whereby procurement was done against the agreed price. However, procurement from local distributors (e.g. Phillips Pharm in Kenya) also took place.
8	Independent quality control should be expanded to include ARVs supplied by other generic suppliers, RUTF and diagnostic products	CHAI’s procurement agent IDA Foundation conducts quality assurance and control in three manners: laboratory retests, pre-shipment inspections and dossier evaluations. The frequency of testing will depend on the regulatory status of the product. For generic suppliers in 2010, 20% of batches were tested for products that have been WHO-prequalified or FDA-approved. 100% of batches were tested for all other products (2010 Annual Report, Section 3.5)
9	Strengthen controls over procurement of products which should be restricted to those approved by UNITAID. Products procured outside the agreements should be placed after UNITAID approval.	In September 2008 Ranbaxy has been banned from US FDA approval. CHAI stopped procurement from Ranbaxy, unless no alternative source would be available. There are 3 products were Ranbaxy is the only supply source (ddI 25mg, ddI 50mg, AZT/3TC 60/30disp.,) and Ranbaxy is the only possible secondary supplier for d4T 30mg. Approval from UNITAID was obtained before purchase. No other information was available.

#	Ernst &Young recommendations	Evaluators comments
10	Conduct strategic review for further funding RUFT products based on requirements of recipient countries	The evaluators could not review the status of this recommendation.
11	CHAI should obtain UNITAID’s approval for reallocation of funds exceeding 15 %. Also, rounding off deviations to nearest digit should at least should be discussed and clarified with UNITAID	The evaluators did not have access to the documentation that would show that CHAI sought and obtained approval for reallocation of funds exceeding 15 % of the budget. Interviews confirmed that over the last year no formal approval was sought.
12	Clarification on income eligibility criteria regarding disbursements	The evaluators could not review the status of this recommendation.
13	Procurement should always be the result of a competitive and transparent process and suppliers must always be pre-selected by CHAI and approved by UNITAID	The 2010 Supplier Selection Report outlines the process of the selection procedure in detail. However, paediatric ARVs have also been purchased without competitive tender, either directly from the local distributor (e.g. Phillips Pharm in Kenya) or through emergency purchases. To the evaluator’s understanding, no prior approval from UNITAID was obtained.
14	CHAI should document a supplier relationship management strategy specifying benchmark/KPIs or measuring and evaluating CHAI’s relationship with suppliers	The evaluators could not review the status of this recommendation as the strategy (mentioned in Ernst &Young evaluation report) that was to be developed and to be implemented in 2009 was not shared with the evaluators
15	Members of CHAI CRC, the CHAI CEO, CHAI PRO team and all Country Procurement Analysts should sign a conflict of interest statement and confidentiality agreement.	CHAI Principles and Procedures for Competitive Tenders Conducted for UNITAID dated March 2007 and revised version dated November 2009 both include in annex a declaration of conflict of interest for members of the adjudication panel and a section on conflict of interest
16	CHAI should enter into MSA with all suppliers sourcing products for UNITAID projects	The evaluators could not review the status of this recommendation.
17	A mechanism for collating information relating to actual consumption of products should be developed in consultation with the MoH of respective recipient countries. Deviations should be analyzed on a periodic basis to identify their root cause so that stock out/excess stock situations can be avoided. Also the stock out & excess situations should be reported to UNITAID on a timely manner	CHAI reviews its forecasting against available consumption data on quarterly basis and adjustments are made accordingly. This contributes to mitigating the risk of excess stock and stock outs. However, reports don’t mention detailed data on stock ruptures or expiry of drugs in beneficiary countries, and this information was not available at UNITAID. Therefore, the evaluators could not review the status of this recommendation in detail.
18	CHAI should follow the process of approval of OR as required by the SOP	The evaluators could not review the status of this recommendation.
19	POs and other supporting documents archived in form of soft copies should be regularly backed up on a server to avoid the risk of loss of data	The evaluators could not review the status of this recommendation.
20	CHAI should keep using systems in order to maintain tracker for diagnostics and RUTF products and to facilitate real time review and approval of OR and POs	Systems have been set-up since the Ernst & Young review. An Order Tracker including diagnostics and RUTF is available since the 2008 Annual Report.
21	Only drugs meeting shelf life requirements should be delivered to recipi-	According to the 2010 Annual Report, all product deliveries made based on orders placed by CHAI

#	Ernst &Young recommendations	Evaluators comments
	ent countries. Alternatively, CHAI SOP should be amended to include that in emergency situation, drugs with lower shelf life can be delivered subject to approval by the MoH of recipient countries	were delivered within the required shelf life of the beneficiary country or consent to the deviation was received prior to shipment. (2010 Annual Report, Section 5.2.3).
22	The general terms and conditions of POs should be amended to include the clauses highlighted above	The Standard Purchase Order for Paediatric and Second-line ARVs are included in 2010 Agreement, Annex 14.
23	Attempt should be made to avoid last minute changes to the terms of PO. Also pooled ordering system should be used to avoid instances of placement of orders in small quantities	The evaluators could not review the status of this recommendation on the changes to the terms of PO. On pooled procurement, please refer to Section □□
24	CHAI should develop a mechanism of analyzing and comparing the freight charges at least on a quarterly basis. The analysis should be focused on identifying situation of invariably high delivery charges, determining their root cause and taking corrective actions	The evaluators could not review the status of this recommendation.
25	The freight charges should be reimbursed only in production of original freight cost invoices by suppliers and the same should be validated for accuracy by the Finance team of CHAI	The evaluators could not review the status of this recommendation.
26	C&F charges and DDU charges should be the responsibility of MoH of respective recipient country. In case the recipient countries are unable to cover these costs, the charges should be paid by CHAI after obtaining approval from UNITAID	In 2010, a total of USD1,675,748 was paid by the UNITAID project for Customs, Storage & Distribution (CSD) CSD, vs. USD1,291,188 by beneficiary countries. This amount seems significantly more than the ‘special circumstances’ as outlined in the Agreement.
27	Lead-time of delivery of diagnostics and RUTF should also be calculated.	Delivery lead-time for Diagnostics and RUTF are not reported in the Annual Report.
28	Confirmation of delivery of products from MoH should be improved either by obtaining proof of delivery from suppliers or C&F agent of MoH	The evaluators could not review the status of this recommendation.
29	A batch should be dispatched after obtaining quality approval from SGS as required by UNITAID	The evaluators could not review the status of this recommendation
30	CHAI should review the testing log book of SGS on a periodic basis to verify that required number of batches were actually tested for appropriate quality. Also the sample size for quality testing should be made consistent in line with SGS framework; alternatively UNITAID’s approval should be obtained for deviation between actual sample size and sample size per SGS framework	The evaluators could not review the status of this recommendation

#	Ernst &Young recommendations	Evaluators comments
31	CHAI should record the batch numbers in the order tracker and reconcile it against the SGS tracker at least on a quarterly basis to verify all batches dispatched by suppliers were communicated to BV/SGS	The evaluators could not review the status of this recommendation
32	Payments should be processed by CHAI finance team after an independent verification of original invoice against PO and POD as required by the Payment SOP.	Systems have been set-up since the Ernst & Young review. If an independent verification of the original invoice against PO and POD has been introduced cannot be verified by the evaluators.
33	Recommendations to avoid duplicate payments	Systems have been set-up since the Ernst & Young review. If the recommendations to avoid duplicate payments have been introduced cannot be verified by the evaluators.
34	Define threshold value beyond which payments should be approved by at least two personnel	Systems have been set-up since the Ernst & Young review. If a threshold value beyond which payments should be approved by at least two personnel have been introduced cannot be verified by the evaluators.
35	CHAI should prepare an ageing analysis of payments outstanding to suppliers on a periodic basis and an analysis of long outstanding cases should be analysed for corrective action.	Systems have been set-up since the Ernst & Young review. UNITAID informed us that various adjustments particularly regarding outstanding payments to suppliers against the budget have been introduced since the 2011 Agreement. Though the evaluators could not review the status of this recommendation.
36	Formal risk assessment exercise should be carried out for identifying strategic and operational risks to CHAI which may affect the achievement if objectives of the programs. An internal audit review should be carried out to review the overall operational efficiency of the program	UNITAID informed the evaluators that a formal risk assessment exercise is planned for 2012.
37	CHAI should document code of conduct policy and require all staff members to comply with it. A transparency policy in line with UNITAID guidelines should be documented.	The evaluators could not review the status of this recommendation.

Source: Ernst&Young (2009) Evaluation of the Procurement for the UNITAID Paediatric and Second Line HIV/AIDS Niches.

Table 29. Reporting compliance according to template.

Reporting Template (2010 Agreement, Annex 12)	2010 Annual Report
Part 1: Financial Overview	
Certification by Chief Financial Officer	Certification by Chief Financial Officer
Part 2: Narrative Updated Report on Progress	
Certification by Executive Vice President, Access Programs	Annual Report to UNITAID (signed by Executive Vice President, Access Programs)
Section 1: Financial Progress	Section 2: Financial Progress
1.1. Total Fund Committed reconciled against Funds Received	n/a[73]
1.2. Total Funds Committed and Disbursed against Forecast	n/a
1.3. Breakdown of Funds Committed and Disbursed by Product Area	2.2. Funds Committed and Disbursed by Product Area
1.4. Breakdown of Fund Committed and Disbursed by Country Level Income	2.2. Funds Committed and Disbursed by Country Level Income
1.5. Breakdown of Fund Committed and Disbursed by Country	2.2. Funds Committed and Disbursed by Country
Section 2: Programmatic and Procurement Progress	Section 3: Programmatic Progress; Section 5: Procurement Process
2.1. Status of Amendments to CHAI's MoU with Countries	3.1. Status of Memoranda of Understanding ("MoU") with Countries
2.2. Number of Children on Treatment by Country Against Treatment Targets	4.2.1. Children Alive and on Treatment
2.3. Use of FDCs	3.2. Fixed Dose Combinations (FDCs)
2.4. Price References and Actual Prices Paid	3.3. Price References and Actual Prices Paid
2.4.1. ARV Prices Paid	3.3.1. ARV Prices Paid
2.4.2. Diagnostics Prices Paid	3.3.2. Diagnostics Prices Paid
2.4.3. Ready-to-Use Therapeutic Food Prices Paid	3.3.3 Ready to Use Therapeutic Food Prices Paid
2.4.4. Co-trimoxazole and Other OI Medicines Prices Paid	3.3.4. OI Drug Prices Paid
2.5. Update on Status of Procurement Procedures and Supply Agreements	3.4. Status of Master Agreements
2.6. Update on any Issues Related to Quality Assurance and Control	3.5. Quality Assurance and Control (3.5.1. Laboratory Re-testing, 3.5.2. Pre-Shipment Inspection, 3.5.3. Friability Tests, 3.5.4. Quality Audit)

[73] Where "n/a" stated it does not mean that information in completely lacking in the report. It just outlines that no such chapter exists.

Reporting Template (2010 Agreement, Annex 12)	2010 Annual Report
2.7. Shipping Costs Paid	3.6. Shipping Costs
2.8. CSD Costs Paid per Expense and per Country	3.7. Clearing, Storage and Distribution (“CSD”) Costs by Country
Section 3: Procurement Process, New Suppliers and Products	Section 5: Procurement Process
3.1 Procurement Process and Outcome	5.2. Procurement Process and Outcome
3.1.1. Status of Procurement as at the end of the period covered by the Report	n/a
3.1.2. Average Product shelf-life before distribution	5.2.3. Percentage of Products meeting Shelf Life
3.1.3. Average length of time (ex-factory) from purchase order date to proof of delivery to the country	5.2.2. Lead time of Procurement Delivery
3.1.4. Percentage of orders placed using pooled procurement process	5.2.4. Pooled Orders
3.2. Suppliers of Products	5.2.5. Suppliers of Products
3.2.1. Number of eligible new suppliers for Products (by product type)	5.3.1. Number of products and eligible suppliers by Product
3.2.2. Number of new quality assured paediatric ARV formulations available	n/a
3.2.3. Number of quality assured non-ARV Products available	5.3.2. Number of new quality assured non-ARV products available
Section 4: Activities under Paediatric Project Agreement	Section 4: Programmatic Performance and Number of Children on Treatment
4.1. Country Specific Perspectives on Implementation	4.2. Performance 2010 (including sub-chapters)
Section 5: Key Issues Looking Forward	n/a
5.1. Overall Perspective on Positioning to Achieve Program Objectives	n/a
5.2. Priorities for Next Semi-Annual period	n/a
5.3 Key Challenges and Necessary Responses	n/a
Section 6: Progress in Project Implementation Against Targets	Section 6: Progress in Project Implementation under Milestones
6.1. Description of progress in Project Implementation as specified in the Targets set out in Annex 5, both cumulatively and for the period covered by the Report, and explanation of variances between the actual and planned Project implementation	
Part III: Annexes	
Annex 1: Summary Financial Report	Table 2.1

Reporting Template (2010 Agreement, Annex 12)	2010 Annual Report
Annex 2: Detailed Financial Report	-
Annex 3. Analysis of Period Paid	Table 2.1
Annex 4: Order Tracker for all Products	Annex 3: 2010 Order Tracker Report – As of February 28, 2010
Annex 5: Bank Statements for Reporting Period	Annex 7: February 2011 Bank Statement

Source: 2010 Agreement, Annex 12; 2010 Annual Report