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Swiss Centre for International Health

UNITAID

Mid-Term Review

CHAI Second-Line Project

Partner: Clinton Health Access Initiative (CHAI)

FINAL

Swiss Centre for International Health
Swiss Tropical and Public Health Institute

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Abbreviations

ABC	Abacavir
API	Active pharmaceutical ingredient
ART	Anti-retroviral therapy
ARV	Anti-RetroViral
ATV	Atazanavir
ATV /r	Atazanavir / Ritonavir
CHAI	Clinton Health Access Initiative
DAT	Drug Access Team
DFID	UK Department for International Development
FDC	Fixed-dosed Combination
FTC	Emtricitabine
GPRM	Global Price Reporting Mechanism
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome
IDA	International Dispensary Association Foundation
IDPIG	International Drug Price Index Guide
LIC	Low Income Countries
LMIC	Lower Middle Income Countries
LPV/r	Lopinavir / Ritonavir
MDC	Global Fund Market Dynamics and Commodities Ad-hoc Committee
MoH	Ministry of Health
MoU	Memorandum of Understanding
MSA / LTA	Master Supply Agreement / Long Term Agreement
MSH ERC	Management Sciences for Health – Electronic Resource Center
NDRA	National Drug Regulatory Authority
NRTI	Nucleoside Reverse Transcriptase Inhibitor
PEPFAR	The U.S. President's Emergency Plan for AIDS Relief
PFSCM	Partnership for Supply Chain Management
PI	Protease Inhibitor
PQR	Price and Quality Reporting
QA/QC	Quality Assurance / Quality Control
RTV	Ritonavir (as a single compound, otherwise 'r' if in combination)
SCMS	Supply Chain Management System
SDRA/SRA	Stringent (Drug) Regulatory Authority
SWOT	Strengths, Weaknesses, Opportunities, Threats
TDF	Tenofovir Disoproxil Fumarate
UMIC	Upper Middle Income Countries
US FDA	United States Food and Drug Authority
VPP	Voluntary Pooled Procurement
WHO	World Health Organization

Executive Summary

Background

The Second-Line HIV/AIDS project is a partnership between UNITAID and the Clinton Health Access Initiative (CHAI). The main objectives of the project were to scale up access to quality second-line treatments in 27 specified low and middle income countries and first-line Tenofovir-based treatments in three countries, and to facilitate price reductions for these drugs over the project life span. UNITAID financed the purchasing of ARVs, while CHAI organized the tenders, negotiated with suppliers and contracted a procurement agent for order processing, pre-shipment testing and shipment to the respective countries.

CHAI facilitated price reductions for second-line ARVs by fostering competition among suppliers through increasing the number of eligible suppliers, making demand more predictable and assisting manufacturers of the active pharmaceutical ingredients (APIs) and finished pharmaceutical products in order to optimize their pricing and manufacturing processes.

Methodology

This is a summative, external, independent mid-term evaluation, including recommendations based on the findings. The evaluation was undertaken in three phases: [1] first the team assessed project design and achievement against the criteria of *relevance*, *effectiveness*, *efficiency,* and *impact,* using an evaluation matrix with general questions; [2] then, the team reviewed specific features of the project such as procurement efficiency, patients' access to treatment and sustainability/transition; [3] Lastly, the team evaluated the financial and program reporting arrangements.

The period summarized in this review spans from signing of the Agreement in May 2007 to the 4th Annual Report for the year ending 31st December 2010. The review was based on key project documents such as annual Agreements, Interim and Annual Reports and Board Resolutions. Further information or clarifications were also requested by e-mail or phone from UNITAID and CHAI.

Based on their findings, the evaluators drafted recommendations and set priorities according to what were understood to be critical issues in each evaluation area, as well as across all of the areas. Several options for addressing each critical issue were listed and assessed against two main criteria: (a) the available evidence that a recommendation would effectively address critical issues; and (b) the feasibility of implementing the recommendation.

Key Project Information

The project started in March 2007, and UNITAID committed funds for the purchase of drugs from July 2007 through December 2008 (with an initial budget of US$54 Millions for 2007 and US$64.4 million for 2008). In December 2007, the UNITAID Board approved a project extension until the end of 2009 (with a provisional budget of US$64.3 million), and in May 2009 again extended the project to the end of 2011 (with a provisional budget of US$120.41 million). These extensions were intended to support beneficiary countries while they gradually transitioned to other donors. The actual annual budgets and beneficiary countries were as follows:

Year	Budget	Number of countries
2007	US$ 35,900,000	27 countries
2008	US$ 64,330,000[1]	26 countries[2]
2009	US$ 73,402,618[3]	25 countries[4]
2010	US$ 78,525,434[5]	17 countries

The project also relied on complementary funding from CHAI for country-level support activities to ensure the effective ordering, receipt and use of project-supplied drugs. UNITAID's contribution to CHAI support activities at the country level, and to the CHAI Drug Access Team at the corporate level, amounted to 1 % of the ARV budget.

Key Findings

Project Management

- 16 of the 17 activities were implemented as scheduled.
- The objectives, activities and targets in the Project Agreement, Action Plan and M&E Logical Framework (log frame) were not fully aligned.
- Information on country selection did not include any assessment of the risks pertaining to a country's readiness to manage a project focusing on second-line treatment or whether a country's national laboratory and clinical staff had the capacity to effectively diagnose treatment failure and rationally use second-line ARVs.
- CHAI signed MoUs with fewer than 70 % of beneficiary countries in 2009 and 2010, which potentially exposed project drugs to risks of theft and/or diversion.
- CHAI does not appear to have informed UNITAID about the project's possible exposure to drug theft and diversion.
- CHAI's report on compliance with UNITAID's eligibility criteria was incomplete as it did not include information on targeting vulnerable populations in lower middle income countries (LMICs) or on co-financing in upper middle income countries (UMICs).
- There were possible breaches of UNITAID's principle of additionality as fund substitution may have occurred in countries where multiple donors were active, and UNITAID-funded drugs were used to fill the gaps that resulted from delays in partner organizations' supply chains.
- Purchase and delivery of first-line treatment ARVs to Uganda and Zambia (which were recipients of Global Fund grants, and were under performing on those grants), did not appear to be the most efficient use of UNITAID funding.
- The project appears to have suffered from inaccurate forecasting which negatively impacted the predictability of demand (key information required during 'cost plus' negotiations with suppliers). Moreover, CHAI's opportunity to revise a contract's value without re-tendering was not capped and, hence, not deemed fair to all bidders.

[1] US$62,481,000 for ARVs and US$1,848,000 for procurement support
[2] out of which only 24 ordered commodities
[3] including US$14,059,851 from the 2008 budget, carried forward ($70,949,621 for commodities and $2,452,997 for procurement support)
[4] out of which only 24 ordered commodities
[5] including US$9,719,030 2009 budget carried forward ($75,900,000 for commodities and $2,625,434 for procurement support)

- All the drugs procured fit the UNITAID quality assurance policy and passed the pre-shipment quality control testing organized by the procurement agent. However, the evaluators had access only to the list of tests performed in 2008[6] and hence cannot comment on the appropriateness of a test or on actual results of the drugs over the project's life span.
- Pooled procurement was reasonably successful as more than 70 % (69 % to 89 %) of the number of orders and more than 84 % (84 % to 90 %) of the orders by value, were pooled. However, the link between low drug prices and pooled procurement could not be drawn as a result of insufficient information on price negotiations. Pooled procurement was not a means of achieving lower prices, as prices were fixed during the tendering process; rather it was a means of reaching a minimum threshold above which manufacturers agreed to initiate production.
- Delivery lead times exceeded the expected time frame for various reasons that cannot be reasonably attributed to CHAI, but do raise questions about: the efficiency of pooled procurement (which may put pressure on manufacturers' production capacity); and, about the reliability of the information which manufacturers provided in their bids.
- While the project focused on the purchase and delivery of second-line ARVs, and not on building healthcare capacity to use these commodities, countries' capacity for timely product registration, accurate forecasting, efficient in-country distribution, proper inventory management (storage or a logistics management information system – LMIS), and rational use of drugs, were all required for this initiative's success. Capacity development in these areas should have been considered at the time of project design.
- Information was lacking about CHAI's achievements in developing the capacity of national partners and on whether UNITAID's contribution was delivered through a well-integrated channel.
- Discussion on the exit/transition strategy focused on alternative sources of funding for the commodities. Although deemed critical, support activities for the effective ordering, receipt and use of drugs were not considered. Once the transition was completed, there was no assurance either that these support activities would be funded under a Global Fund grant or by other donors.
- Reconciliation of budgets, open commitments and expenditures was not possible. Varying table formats, variation in definitions (inclusion and exclusion of certain parameters) and varying cut-off dates made reconciliation impossible;

Public Health Outcomes

- From 2007 to 2010, up to 71,000 patients were reported as treated with UNITAID-funded second-line ARVs, and 87,000 with UNITAID-funded first-Line TDF-based ARVs. The average achievement rates (number of patients treated against project targets) for 2008-2010 were 89.5 % for second-line ARVs, and 100.6 % for first-line TDF-based ARVs, but there was great discrepancy between countries.
- The reliability of data on the number of patients treated depends on the national health information system, which could suffer from significant weaknesses. Data accuracy, data quality and the assumptions used in analyzing data could not be confirmed by CHAI. Thus, data reliability was a serious limitation to implementing the

[6] 2008 Interim Report

CHAI second-line project. CHAI did not fully investigate discrepancies between the quantity of drugs ordered and the number of patients treated.

- The lack of baseline information on the number of patients already treated by existing programs in each country, as well as national targets, prevented the evaluators from analyzing whether the increase in the number of patients treated under the project was indeed a scale up at the national level

Market Outcomes

- Working at both ends of the market, CHAI has effectively removed obstacles to the delivery of quality ARVs for the treatment of patients in line with WHO recommendations, and CHAI has also negotiated unprecedented price reductions by applying innovative strategies in collaborating with the pharmaceutical industry.
- As a result of registration with stringent regulatory authorities (SRAs) or prequalification with WHO, the number of eligible suppliers increased over the project's life span. Two new formulations were delivered to countries in 2010 (ATV and RTV). However, CHAI's actual contribution to SRA drug registration, WHO prequalification or development of new formulations could not be estimated.
- A comparison of the applicable prices from 2007 to 2010 shows a decrease in all treatment prices. From 2007 to 2008, a secondary supplier increased the price of one ARV (TDF 300mg) by 34 %, but in 2010, the supplier decreased the price by 59 %. Over the whole project lifespan, all ARVs showed a price decrease.
- The project's had a positive impact on prices beyond the beneficiary countries as the countries under the CHAI consortium, as well as the Global Fund and PEPFAR recipients, benefited from the ARV price reduction.
- There is currently no defined mechanism for maintaining project gains. This increases the risk of market segmentation that could potentially push up ARV prices and decrease the availability of ARVs for countries with small orders.

Key Recommendations

Project Management

- UNITAID and CHAI should collaborate on a log frame with consistent and relevant objectives, activities and measurable targets, as well as indicators that adequately reflect all dimensions of the objectives.
- Funding for support activities aimed at helping countries in the effective ordering, receiving and use of drugs should be earmarked as part of the transition plan. This would ensure that countries which were over-relying on CHAI expertise manage their transition smoothly.
- UNITAID should clarify countries' eligibility criteria as well as its own additionality principle, and request CHAI to provide country-specific information on its compliance (e.g. cases where UNITAID ARVs were used to fill short-term gaps because of delays in the supply chains of country partners. If these fillings of emergency gaps occurred frequently, CHAI and UNITAID should have considered creating a revolving fund.
- The evaluators recommend that UNITAID and CHAI review the information reported and ensure that all reconciliations of disbursements, commitments and expenses, and of reported cash balances and bank statements, are carried out.

Public Health Outcomes

- For each beneficiary country, CHAI should provide unified/national forecasting (showing UNITAID's contribution as a percentage of total annual needs), the total number of people under treatment, and an estimate of the number of patients treated with UNITAID-funded ARVs.
- It is recommended that CHAI prepare country briefs summarizing the challenges faced by national HIV programs in reporting and forecasting (including activities to overcome these) and give a reliability rating for the figures reported to UNITAID.
- CHAI should regularly report to UNITAID on synergies between the UNITAID project and the in-country activities of other actors, and show that the UNITAID-funded ARVs meet actual demand and increase peoples' access to treatment.
- UNITAID could consider increasing its contribution to CHAI's activities in order to allow for effective implementation of the above-mentioned recommendations.
- CHAI should develop and implement a risk management plan addressing all risks identified at the country level (including drug theft, storage conditions, and others) and defining mitigating measures. This plan should include measures for enforcing MoU conditions.

Market Outcomes

- UNITAID and CHAI should explore the opportunity to negotiate ceiling prices or tier prices with manufacturers as there was a great difference in the forecast used in tenders, and the actual orders placed. Moreover, increasing a supplier's contract without retendering should be capped at a fixed percentage of the contract value.
- CHAI, UNITAID, The Global Fund, and The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) should determine a mechanism to maintain project achievements, especially in countries with small orders and countries with low supply chain management capacity.

1 Conclusions and Recommendations

	Conclusion	Recommendation	Responsibility
1	Scale up in the number of patients treated is not sufficiently documented. Moreover, there is no link between the volume of drugs ordered and the number of patients reported as treated. CHAI did not share information with UNITAID on the reliability of reported information, challenges faced by countries in forecasting and reporting, and on CHAI's results in supporting national authorities.	For each beneficiary country, CHAI should provide unified/national forecasting (showing UNITAID's contribution as a percentage of total annual needs), the total number of people under treatment, and an estimate of the number of patients treated with UNITAID-funded ARVs. It is recommended that CHAI prepare country briefs summarizing the challenges faced by national HIV programs in reporting and forecasting (including activities to overcome these) and give a reliability rating for the figures reported to UNITAID.	CHAI/ UNITAID
2	Synergies between the activities of the UNITAID/CHAI project and other actors in country to increase access to treatment were not shared with UNITAID. This prevented UNITAID and CHAI from identifying gaps and acting upon them.	CHAI should regularly report to UNITAID on synergies between the UNITAID project and the in-country activities of other actors, and show that the UNITAID-funded ARVs meet actual demand and increase peoples' access to treatment.	CHAI
3	UNITAID's contribution to CHAI in-country activities was very limited.	UNITAID may consider increasing its contribution to CHAI's activities in order to allow for effective implementation of the above-mentioned recommendations.	UNITAID
4	The project had no risk management plan which potentially exposed UNITAID-funded ARVs to risk of theft and waste.	CHAI should develop and implement a risk management plan addressing all risks identified at the country level (including drug theft, storage conditions, etc.) and defining mitigating measures. This plan should include measures of enforcing MoU conditions.	CHAI (and UNITAID for the allocation of additional funding if required)
5	The Agreement, action plan and log frame featured multiple objectives, activities and targets that were not fully aligned.	UNITAID and CHAI should collaborate on a log frame with consistent and relevant objectives, activities and measurable targets, as well as indicators that adequately reflect all dimensions of the objectives.	CHAI/ UNITAID

6	Procurement arrangements did not allow the project to negotiate lower prices if the volume of drugs ordered increased.	UNITAID and CHAI should explore the opportunity to negotiate ceiling prices or tier prices with manufacturers as there was a great difference in the forecast used in tenders, and the actual orders placed. Moreover, increasing a supplier's contract without retendering should be capped at a fixed percentage of the contract value.	CHAI/ UNITAID
7	UNITAID and CHAI discussions on the exit/transition strategy focused primarily on alternative sources of funding for the commodities, and did not touch upon the continuation of support activities.	Funding for support activities aimed at helping countries in effective ordering, receiving and use of medicines, should be earmarked as part of the transition plan. This would ensure that countries which were over relying on CHAI expertise, manage their transition smoothly.	CHAI/ UNITAID
8	There were possible breaches to UNITAID's additionality principle and a lack of information on CHAI's compliance with country eligibility criteria.	UNITAID should clarify countries' eligibility criteria as well as its additionality principle, and request CHAI to provide country-specific information on its compliance (e.g. cases where UNITAID ARVs were used to fill short-term gaps because of delays in the supply chain of country partners. If these emergency gap fillings regularly occurred, CHAI and UNITAID should have considered creating a revolving fund.	CHAI/ UNITAID
9	There is no mechanism currently in place to maintain project achievements in terms of price reduction and sustained demand.	CHAI, UNITAID, The Global Fund, and PEPFAR should determine a mechanism to maintain project achievements, especially in countries with small orders and countries with low supply chain management capacity.	CHAI/ UNITAID
10	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 made reconciliation impossible	The evaluators recommend that UNITAID and CHAI review the information reported and ensure that reconciliation of disbursements, commitments and expenses, and reconciliation of the reported cash balance and bank statements are carried out.	CHAI/ UNITAID

2 Project Description

In 2009, only 5 out of 15 million people who needed anti-retroviral (ARV) treatment were receiving it. Every year about 3 % of patients under treatment develop resistance to first-line ARVs and hence require second-line treatment. However, in 2009, only 2.4 % of people under anti-retroviral therapy (ART) were receiving second-line drugs. Tenofovir Disoproxil Fumarate fixed-dose combinations (TDF FDC) are newer, safer and more effective formulations (less prone to resistance) of first-line drugs but can also be used as second-line drugs. However, these new formulations, as well as second-line ARVs, are more expensive and put a heavy burden on country resources that are already strained by donors' decreasing support for HIV programs.[7] In 2007, WHO estimated that by 2010, in the absence of price reductions, and based on current average switch rates (from first-line to second-line treatment) of 3 % per year, the cost of second-line drugs would consume up to 90 % of a country's annual ARVs budget.

UNITAID, in partnership with CHAI (the Clinton Health Access Initiative) aims at scaling-up access to second-line treatments in low and lower middle income countries (LICs and LMICs), where need for such treatments is increasing, but the price is much higher than first-line ARVs. UNITAID and CHAI are also working on reducing the price of second-line AIDS drugs by fostering competition through encouraging more producers to enter the market. Besides scaling up access to second-line treatment, the project also increased access to Tenofovir (TDF)-based ARVs as first-line treatment in Namibia, Uganda and Zambia. The increase in TDF-based ARV volumes, for both first and second-line treatment, is expected to have a larger impact on price than second-line purchases alone. In summary, the project's six objectives were as follows:

(i) scaling up access in developing countries to second-line ARVs in order to increase the number of patients receiving effective treatment for HIV/AIDS
(ii) influencing market dynamics to lower the prices of critically-needed, quality drugs;
(iii) stimulating an increase in the number of quality assured manufacturers and products;
(iv) decreasing product delivery lead times;
(v) encouraging prequalification of approved manufacturers and products; and
(vi) applying appropriate procurement strategies to develop a healthy market that favours competition and sustainability, while also reducing prices.

The initial Agreement for the procurement and supply of second-line ARVs, covering 27 LICs and LMICs, was signed in May 2007. Although intended to end in 2008, at the end of 2007, UNITAID's Board extended financing to the end of 2010 and in May 2009, the Board agreed to extend the project through 2011 to allow beneficiary countries to transition to other donors' funding. By the end of 2010, 11 out of 27 countries had replaced their UNITAID funding and only 16 continued to receive UNITAID financing. For the years from 2007 to the end of 2011, UNITAID committed a total of US$305,799,000 to the project.[8]

[7] The percentage of countries where antiretroviral treatment programmes were adversely affected by reduced external funding rose from 11 % to 21 % from July 2008 to July 2009, UNAIDS (2009, October) 'Report on the Impact of the Global Financial and Economic Crisis on the AIDS Response'

[8] http://www.unitaid.eu/en/secondline.html

Most of UNITAID's funding is used to purchase drugs (including procurement-related costs). CHAI's contribution (US$17-20 million) supports CHAI's own ongoing activities carried out since 2003. CHAI is working with suppliers to increase quality and lower prices, as well as stimulate demand from the countries concerned. According to CHAI's 2010 Annual Report, UNITAID funding provides significant leverage for CHAI in its negotiations with suppliers because UNITAID represents 77 % of the second-line market and UNITAID can finance additional supplies in countries where access to second-line ARVs is limited.

From 2007 to the beginning of 2010, beneficiary countries reported that the project provided 185,000 patient treatments of second-line ARVs (between 46,000 and 71,000 patients per year), and 176,900 patient treatments of first-line TDF-based ARVs (between 39,000 and 87,000 patients treated per year). The ratio for the target versus patients reported under treatment was 89.5 % for second-line ARVs and 100.6 % for first-line TDF-based ARVs. Up to 2010, 8,814,872 packs of second-line ARVs were delivered, with 64 % of this to Kenya, Uganda and Zambia.

The UNITAID/CHAI model for this project includes a procurement agent who is responsible for submitting purchase orders to suppliers selected by CHAI, and ensuring pre-shipment testing and delivery to beneficiary countries, as well as processing suppliers' payments. The initial procurement agent, Missionpharma, was replaced in April 2009 by the International Dispensary Association Foundation (IDA). CHAI is responsible for floating tenders, selecting suppliers and negotiating prices. CHAI also carries out upstream and downstream activities such as: forecasting needs in collaboration with each beneficiary country; submitting countries' orders; planning for receipt, clearance, storage, and distribution of drugs; and confirming the delivery of drugs in order to trigger payment to suppliers.

CHAI consolidates all countries' orders four times a year (15th of March, June, September, and December). Individual orders are placed as well to meet emergency needs or to solve supply chain problems. On average, target countries' estimated lead-time is 12 weeks and manufacturers' estimated lead time is 6 weeks.

In addition to its procurement functions, CHAI is responsible for providing technical support to countries to ensure the effective ordering, receipt, and use of project drugs.[9] UNITAID support to CHAI for these deliverables represents about 1 % of the project's budget for commodities. According to CHAI, UNITAID covers only 5 % of CHAI support for the regional and country teams that support 25 countries (*CHAI is contributing US$17 to 20 million for the technical assistance and project implementation costs of the Paediatric and Second-Line Projects*).[10] There is no formal agreement on the objectives for CHAI self-funded activities or on their costs.

In fact, CHAI undertakes all activities not related to the purchasing of drugs but does, to some extent, ensure fast payment of suppliers. UNITAID's financing allows countries to scale

[9] *Activities include product quantification, national protocol review and guidance, coordination of the provision of necessary technical assistance, and support to national drug regulatory authorities for timely registration of products* and to *report to UNITAID any case of countries non compliance with their obligation to dispense treatment to patients free of charge* CHAI/UNITAID 2010 Agreement section on project support

[10] CHAI 2009 project plan, page 26

up or start a second-line ARV program, and procure as a group, providing the large, sustainable demand needed to attract suppliers.

Since the project's inception, one of the main challenges has been ensuring transition to other funding sources and helping countries to pool their orders.

Item	Description
Name	Second-line HIV/AIDS Project
Project summary	UNITAID, with the Clinton Health Access Initiative (CHAI), is working to scale-up access to the newer second-line treatments. It is also working to reduce the price of second-line AIDS medicines by encouraging more producers to enter the market. This helps foster the competition that drives prices down. UNITAID is now supplying second-line anti-retrovirals in 25 countries, reaching more than 59,000 people.
Partners	Clinton Health Access Initiative (CHAI)
Number of countries	27 countries at the project's inception
Period	2007-2011
Budget	US$ 356,855,346

3 Findings details

This section summarizes the findings recorded in the evaluation matrix template (annex 1). A summary of key findings is also provided for each evaluation area in a box at the beginning of each section.

The main objectives of the project were to scale up access to quality second-line treatments in 27 specified LMICs, and facilitate a price reduction for these drugs over the project life span. Globally, achievement of the project's objectives is obvious considering: [1] the volume of drugs delivered and the number of patients reported under second-line ARV treatment; and [2] the competitive unit cost at which those drugs were purchased which potentially allowed treatment of more patients. However, in countries where the health systems were not performing well, the impact was difficult to measure, as health and logistics information systems did not consistently provide quality data.

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

- Sixteen out of the 17 activities were implemented as scheduled
- General and specific project objectives in the Agreement are mostly consistent with project plans and are revised annually
- Project plan- and Agreement-specific objectives are the result of a mix of general objectives, actions and targets. Moreover, some project activities are worded as results
- Objectives, although not mentioned in the List of Indicators for achievement of objectives (the M&E log frame), all relate to at least one activity
- Indicators are mostly output and process indicators, and do not fully reflect the achievement of objectives. Hence, some objectives' dimensions are not captured in the indicators, targets or activities (e.g. *scale up access to second-line ARVs* and *develop a healthy market that favours competition and sustainability*)
- The evaluators found overlap among objectives and misalignment of activities and targets
- CHAI project support activities (support to the National Drug Regulatory Authority [NDRA], coordination of technical assistance and support for distribution) are not adequately reflected in the M&E log frame
- Quality data were not consistently available in all beneficiary countries

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 was to increase access to quality second-line ARV treatment (and first-line TDF-FDC) in low and lower middle countries (LICs and LMICs) with large unmet needs. The following activities support the achievement of that goal: fostering competition by increasing the number of eligible suppliers, negotiating price reductions with suppliers, consolidating demand, facilitating new product roll out and supporting countries in quantifying product needs, coordinating technical assistance, and registration of drugs.

Contrary to other UNITAID-funded projects, the Agreement to procure and supply second-line ARVs is signed on an annual basis and thus allows the project to maintain relatively flexible project objectives and implementation activities.

The CHAI/UNITAID Agreement and its related M&E log frame, the CHAI project plan and CHAI project proposal, feature project-wide and specific objectives, activities and expected outputs. Specific objectives are numerical targets e.g. numbers of patients to be treated per year and/or a treatment cost per patient per year.

As a first step, the evaluators reviewed consistency between the Agreement and the Project Plan (also called the Plan of Action), and then between the objectives, activities, outputs, and indicators used in the M&E log frame.

Consistency between Agreement objectives and Project Plan objectives/outcomes

The evaluators noted that the Agreement and Project Plan were mostly consistent. However, the Project Plan objectives include specifics, e.g. targets for the cost of second-line treatment per patient per year, which are not reflected in the Agreement or in the targets included in the M&E log frame. The 2008 Plan of Action, unlike the original 2008 Agreement, made no mention of increasing the number of suppliers (broadening the base of suppliers) and had no target for a price reduction.

Another minor discrepancy between the two 2008 documents is reference to *additional* treatments (60,000 for second-line ARVs and 80,000 for TDF-based ARVs). However, the Plan of Action refers to procurement of commodities for the treatment of 60,000 and 80,000 patients. The word *additional* is assumed to relate to UNITAID's objective to scale up the project and UNITAID's principle of additionality.[11]

The objectives stated in the 2009 and 2010 Agreements are identical but the specific numerical objectives have been revised each year to reflect the number of patients receiving second-line treatments. For 2009 and 2010, the specific objectives of the Agreement are not entirely consistent with the Project Plan as they do not include: [1] the cost of second-line treatment per patient per year, whereas project plans aim at US$500 per WHO-recommended treatment regime per year; [2] any reference to transition, whereas two waivers of transition are planned, [3] patient targets for TDF treatment, whereas the Project Plan states that TDF would be supplied on an *exceptional basis*. In addition, the 2010 Project Plan

[11] Please refer to boxes in annex section 9.

includes a target for Atazanavir (ATV) roll out that does not appear in the 2010 Agreement objectives.

It should also be noted that in 2009 and 2010, Project-plan and Agreement-specific objectives[12] were a mix of general objectives, actions and targets (e.g. number of treatments to be procured, target treatment cost per patient per year). Moreover, some Project Plan activities are worded as results (5.1 and 5.11).

Review of the consistency between Objectives, Activities, Outputs and Indicators

The evaluators reviewed the objectives described in the Agreement against the M&E log frame and noted the following:

The general and specific objectives of the Agreement do not appear on the M&E log frame. Hence the link between objectives, activities and indicators is not straight forward. The same applies to the Project Plan, which does not contain any link between the Agreement objectives and activities.

The M&E log frame links actions to 'Project Plan/Plan of Action' activities. The majority of these indicators are output and process indicators. However, these indicators are relevant to demonstrate achievement of objectives that are closely tied to a numeric indicator (e.g. decrease in price, decrease in lead time, increase in pre-qualified/SRA registered products, and suppliers per product).

Neither activities nor the indicators featured in the M&E log frame or the Project Plan actions address the following three aspects of the objectives:

- Are the activities fully compliant with UNITAID's eligibility criteria[13] (objective 1)?
- Do the activities contribute to scaling up access to treatment: Do orders and deliveries of second-line ARVs actually translate into more patients treated globally and are patients actually receiving treatment (objective 1)?[14]
- Is CHAI's market-shaping approach sustainable: are prices going to remain low and will demand be sustained (objectives 2 and 6)?

Most objectives are very broad and included multiple dimensions (e.g. access, price and quality). Therefore they are supported by more than one activity and hence require more than a single intervention to be fully achieved.

Conversely, some activities support more than one objective because the results of objectives overlap. For example, some overlap was noted between the activities for objectives 2 and 6, as both refer to price reductions. Overlapping activities could be the result of a lack of hierarchy between goals and objectives. Objectives 2 and 6 are believed to be goals and objectives, whilst objectives 3 and 5 contribute to their achievement.

12 Please refer to Box 3, Box 4, Box 5 and Box 6 in annex section 9.

13 In the case of both lower middle income countries and upper middle income countries, the UNITAID contribution should be used to scale up existing programs targeted principally at vulnerable groups with co-financing from beneficiary countries).

14 Information on national programs is lacking to allow some measure of whether the UNITAID contribution actually resulted in a scale up (e.g. number of patients currently under second line treatment, in-country stock, estimate of the country's absorption capacity).

Some targets are not exactly aligned with the indicators in the M&E log frame. For example, indicator 5.2 states that CHAI pays the lowest price whereas the target is achievement of a price reduction (and is not consistent with the 2008, 2009 and 2010 Project plan objective of US$400 and US$500 per patient per year). Similarly, indicator 6 related to the percent of suppliers with which CHAI has signed a Master Supply Agreement / Long Term Agreement (MSA/LTA) whereas the target refers to a deadline (100 % of the contract concluded by Q3).

Of CHAI project support activities, only CHAI's support for quantification and protocol review/guidance, are reflected in the M&E logical framework. Coordination of the provision of necessary technical assistance and, most importantly, support for national drug regulatory authorities for timely registration of drugs, are both missing.

Although CHAI support for in-country distribution appears in both the 2009 and 2010 project plans, with targets[15] agreed upon by both parties, CHAI reported that these activities have not been implemented, although they were partly funded by UNITAID through its contribution to the CHAI Drug Access Team. This 'orphan' action is deemed critical to ensure achievement of objective 1 (increase number of patients receiving treatment), objective 2 (influence the demand side of the market) and objective 6 (increase sustainability of the demand).

However, consistency rates have been high. All objectives could be matched with activities (100 %). Conversely for the M&E log frame, all activities could be matched with an objective to a consistency rate of 100 %. The percent of objectives measured with at least one relevant indicator was 100 %.

In Table 2 in annex (section 10), the evaluators linked the objectives as stated in the UNITAID/CHAI Agreement, Project Plan activities and the M&E log frame's actions, indicators and targets.

For the last reporting period (2010), of the 17 activities scheduled, 16 were implemented on time. CHAI experienced minor delays in the submission of their reports.

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

It was a major obstacle that disbursements, expenses and the bank balance in Annual Reports were reported against the budget year, but often 2 months after the end of the calendar year (e.g. 28th February of the next year).

In addition, the following issues were identified by the evaluators:

- The cut-off dates for reporting on disbursements, expenses or the bank balance were inconsistent over the years (e.g. 31.12 or 31.01).
- Disbursements related to the upcoming budget year were included in the table of sources and uses of funds (e.g. 2008 Annual report).
- CHAI's terminology in the Reports has not been consistent. Specifically, the budgeted disbursement from UNITAID to CHAI was sometimes reported with the procurement support costs and sometimes without them (e.g. Annual Report 2008, pg. 4). Another issue arose as a result of CHAI's definition of "commitments". For CHAI, this meant

[15] Please refer to Box 7 and Box 8 in annex section 9.

including both expenses and committed expenditures, rather than merely committed expenditures.

- Inconsistencies were identified for figures reported in yearly reports; specifically the following two numbers could not be reconciled:

  - in the 2008 Annual Report, CHAI's total commitments for commodities and procurement costs (pg. 4 states for the 31st of December 2008 (adjusted through January 2009) was US$49,330,922 vs. US$49,330,992 on pg. 9).
  - in the 2010 Annual Report, the Expenses for Commodities (pg. 7 states US$37,320,142, but when recalculating the disbursements for the calendar year 2010, with the additional disbursement for January 2011, the total was US$37,324,753).

The evaluators could not complete the reconciliation of financial information because of the limitations above and because the information featured in the Annual Reports was incomplete. The evaluators calculated a theoretical cash balance using the Annual report data and compared this number to CHAI's reported cash balance. The evaluators found that the end of period cash balance (31.12.2010) reported by CHAI was less than the estimated theoretical cash balance. This difference cannot be explained based on the information available.

The budget execution rate (please refer to Table 3 below), calculated on the basis of available information, varied between 100 % in 2008 and 78 % in 2009. Budget absorption was least in 2010 (50 %) and highest in 2009 (63 %).

It should also be noted that the procurement fee featured in the Agreement (e.g. the 2010 Agreement under Section 16.2.2) cannot be traced when comparing the Annual Reports' financial information with the Agreement's requirements. The difference between commitment and actual expenses relates to orders delivered after the end of the reporting period[16] and hence with payment pending.

Table 3. Breakdown of budgets, commitments and disbursements for commodities.

Year	Budget* (Agreement)	Disbursed to CHAI	Committed (Expenses and outstanding expenses)	Budget execution rate	Expenses	Budget Absorption
2007	35,900,000*	Not available	Not available	Not available	Not available	Not available
2008	64,330,000	64,329,000	51,178,992	100 %	35,442,719	55 %
2009	75,989,000	59,343,149	65,883,827	78 %	48,096,312	63 %
2010	78,502,000	66,819,206	72,392,286	85 %	39,945,576	51 %

Source: CHAI Annual reports 2008, 2009 and 2010.

* Budgets from Agreements, including other costs such as CSD, Procurement Agent fees, QA costs, and UNITAID's contribution to CHAI, do not include carry over

[16] "disbursements to suppliers are recorded by CHAI based on the payments made by the procurement agent to suppliers, which are made only after confirmation of delivery of a product is received from the country. In practical terms, this means that given current lead times, disbursements are recorded and payments are made to suppliers an average of four months after an order is placed" (2010 Annual Report, p. 9).

3.1.2 Effectiveness

This section assesses whether project objectives were achieved, and which factors contributed to whether or not objectives were achieved

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

Key findings

- Eligibility criteria for allocating the budget among LICs, LMICs and UMICs were complied with in 2008 and 2009, but not in 2010 because countries started transitioning from UNITAID to other donors. However, CHAI's report on compliance with UNITAID eligibility criteria is incomplete; it does not include information on targeting vulnerable populations in LMICs and co financing requirements for UMICs.
- The target for CHAI signing an agreement with each beneficiary country was not met in 2009 and 2010 (67 % of beneficiary countries signed an MoU). This increased the risk of UNITAID-funded commodities being diverted and of their improper storage and use. It also raises questions about country ownership of the project and its integration into national HIV programs.
- MSAs and LTAs were signed with primary and secondary suppliers but not with the suppliers which provide drugs under access prices.
- Number of registrations per drug in beneficiary countries increased over 2007-2008
- Lead time per supplier generally increased between 2008 and 2010 (for Cipla, Abbott, Matrix, and Aurobindo), and in 2008, 11 out of 21 countries, and 2010, 13 out of 17 countries, experienced lead times greater than 12 weeks.
- Pooled procurement of orders was achieved to a large extent, but not to the target of 100 %.
- Although there were targets, activities to facilitate improvement of in-country distribution systems for ARVs were not implemented, and hence not reported, in 2009 and 2010.

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

Signature of MoU and budget allocation

The number of MoUs and related amendments signed never reached the target of 100 %. It was the highest in 2008 when 24 out of 25 countries signed an MoU for the 2007-2008 period, but in subsequent years only 67 % of countries signed.

UNITAID eligibility criteria

Budget allocation did not comply with UNITAID eligibility criteria in 2007 and in 2010 as the proportion of LMI countries increased at the expense of LI countries. The budget allocation could not be pre-determined by UNITAID's eligibility criteria as over the transition phase, budgets were allocated based on countries' on-going needs and the likelihood of a timely transition to another source of funding.

No information was available on other UNITAID eligibility criteria requirements such as the vulnerability of patients treated, eligible countries' contribution to costs and the pre-existence of second-line ARVs procurement and supply.

UNITAID eligibility criteria:

- 'At least 85 % of UNITAID funds dedicated to purchase commodities should be spent on low income countries (LICs).
- No more than 10 % of UNITAID funds dedicated to purchase commodities should be spent on lower middle income countries (LMICs)
- No more than 5 % of UNITAID funds dedicated to purchase commodities should be spent on upper middle income countries (UMICs) with priority given to those with a high disease prevalence, subject to these countries proving co financing for their project as to 20 % in year 1 rising to 40 % in year 5 (the same arrangement as per the Global Fund).
- In the case of both LMICs and UMICs, UNITAID contributions should be used to scale up existing programmes target principally at vulnerable groups (in accordance with the UNAIDS definition)'

Source: Annex 1 to 2007 Agreement page 24 - 25

Signature of Long-term Agreements or Master Supply Agreements

Every year, CHAI signed **long-term agreements** (sometimes referred to as a "Master Supply Agreement" or an "MSA") with certain primary and secondary suppliers with whom CHAI had negotiated reduced prices on behalf of UNITAID and its beneficiaries. Some of these MSAs were for multiple years and also covered purchases over more than one year (specifically with Abbott, Cipla, GSK, and Hetero). In the 2010 log frame, the target for signing MSAs was set for Q3 2010, but in the Agreement, the indicator is the percentage of suppliers that have signed an MSA or other long-term agreement. Over the period 2007-2010, this percentage never exceeded 50%. Considering that the date on which MSAs were concluded is unknown (as is the number of products falling under the Agreement), and that the indicator did not have a numerical target, the evaluator cannot determine whether this objective was achieved.

In 2007, CHAI signed an MSA with 4 out of 8 primary/secondary/pool suppliers (Matrix, Cipla, Aspen and Aurobindo); in 2008, with 2 out of 7 primary/secondary/pool suppliers (Matrix and Cipla); in 2009, with 3 out of 6 primary/secondary/pool suppliers (Cipla, Matrix and GSK), and in 2010, with 4 out of 8 actual suppliers (Abbott, Cipla, GSK, and Hetero). However, for 2010, the total number of suppliers is not known as CHAI did not report on the pool but merely on the primary and secondary suppliers.

CHAI started that it did not sign MSAs with suppliers providing products under access prices because these are fixed prices. According to the CHAI 2010 Annual Report, '*Gilead/Aspen and Bristol Meyers Squibb all provide products to CHAI under their "Access Prices", which are fixed public prices for procurement in select LMIC. In 2010, all generic and some branded suppliers signed on to the terms and conditions of the supplier selection'.*

Lead time

Please refer to Table 4 in annex section 10.

In 2007, suppliers' production lead time for all products was below or around 12 weeks. The maximum average production lead time was 75.3 days for Aspen and 72 days for ddI (250mg and 400mg entero-coated).

Although the list of countries is incomplete (21 countries listed out of 23 beneficiary countries that ordered drugs in 2007), it appears that 15 out of 21 countries experienced lead times greater than 12 weeks. The main reasons were: i) Ranbaxy (ddI primary supplier) had its certificate of good manufacturing practice compliance suspended, and ii) BMS (ddI secondary supplier) was not prepared to manage this unexpected increase in orders following the change in supplier

In 2008, for two suppliers, Bristol-Myers Squibb (BMS) and Glaxo Smith Kline (GSK), production **lead time** exceeded 12 weeks (89 and 103 days, respectively) and for two ARVs, both produced by BMS (ddI 200mg and 400mg), average lead time was exceeded by 12 weeks (93 and 95 days, respectively).

Although the list of countries is incomplete (21 countries listed out of 25 beneficiary countries that ordered drugs in 2008), it appears that 11 out of 21 countries experienced lead times greater than 12 weeks. The main reasons were: i) a change of suppliers (Matrix encountered quality problems in its production and Ranbaxy could not deliver the orders as planned); ii) CHAI's decision to re-allocate shipments to other countries (presumably to avoid stock outs), iii) administration-related problems (pre-shipment inspection, import declaration, and drug registration); and, iv) the country-requested delivery date.

In 2009, no information was available to the evaluators for review.

In 2010, for two suppliers, Matrix and Aurobindo, production lead time exceeded 12 weeks (89 and 103 days, respectively). For three ARVs, of which only two could be identified (ddI 200mg and 400mg), the average lead time exceeded 12 weeks (98 and 123 days, respectively). Although the list of countries is incomplete (17 countries listed out of 20 beneficiary countries that ordered drugs in 2010), it appears that 13 out of 17 countries experienced lead times greater than 12 weeks. The main reasons for the delays were the production delays of two suppliers, Matrix and Aurobindo. These delays resulted from technical problems and capacity constraints.

Based on the information available for 2007, 2008 and 2010, the evaluators noted that the lead time per supplier generally increased, and for some, it exceeded the 12-week target. The lead time per country exceeded 12 weeks for a majority of countries.

Drug registration

Between 2007 and 2009, the number of registrations per drug in beneficiary countries increased except for drugs which had a change in the primary or secondary supplier. However, information provided in the CHAI Annual Report was not always consistent. Sometimes the date of registration was reported and sometimes it was the registration number; information

on a drug's registration status in a given country differed between the 2007 and 2008 reports; and registration status was not available or not updated. As a result, this information needs to be viewed with some caution.

In the 2009 CHAI Annual Report, the evaluators found no information **on drug registration status.** Thus, CHAI's achievement for this target could not be measured. Nor did the evaluators find information on the number of instances when CHAI had to request a waiver for drug registration.

In 2010, the information provided was mostly incomplete and referred to paediatric formulations.

The evaluators concluded that the target was achieved for the 2007-2008 period, but could not conclude the same for 2009-2010 due to the absence of necessary information.

Pooled procurement orders

In 2007, none of the orders were pooled because the priority was to get the drugs into the country. Between 2008 and 2010, pooled procurement was reasonably successful as more than 70 % (69 % to 89 %) of the number of orders, and more than 84 % (84 % to 90 %) of the orders by value, were pooled.

CHAI explained in its last three Annual Reports that orders were not always pooled because of:

- Emergency orders or supply chain management needs that were off cycle
- Difficulties in securing the attention of and obtaining information from various in-country partners in order to ensure appropriate quantification for the September order cycle. This order cycle occurred at the same time that CHAI and many of its country partners were undertaking their annual budgeting and forecasting process for the following year. This resulted in delaying many orders until October.

The second reason listed above for failing to pool orders is a recurrent problem mentioned in all three Annual Reports which CHAI could not resolve (e.g. by rescheduling the last quarter's ordering cycle).

The evaluators have concluded that this annual target was not met but also acknowledge that 100 % pooled procurement may be overly ambitious as emergency orders are likely to occur in any country.

Actual deliveries vs Budget

Less than 25 % of countries in 2008 and 2009 had commitments matching their budget +/- 15 %. This percentage went up to 40 % in 2010.

	2008	2009	2010*
Number of countries with commitments matching their budget +/- 15%	6	6	8
Number of countries with commitments lower than the budget by more than 15%	17	11	5
Number of countries with commitments higher than the budget by more than 15%	3	8	7
Total	26	25	20

Source: CHAI 2008, 2009 and 2010 Annual Reports

*The difference between the total number of countries in the list of beneficiary countries in Annex 1 to the 2010 Agreement and in the 2010 Annual Report stems from the fact that, CHAI, as of August 2010, expected 19 countries to place an order in 2010 (although the Agreement mentioned only 17 countries) '*as some countries have faced unanticipated delays with Global Fund disbursements and PEPFAR commitments*'[17]: Benin, Botswana, Burundi, Cambodia, Cameroon, Chad, the Democratic Republic of Congo, Haiti, India, Kenya, Mali, Mozambique, Nigeria, Senegal, Togo, Uganda, Zambia, and Zimbabwe. Namibia eventually placed an order which increased the total number of beneficiary countries to 20.
Tanzania had a 2010 budget but did not place any order in 2010. Mali and Namibia did not appear in the list of beneficiary countries in Annex 1 to the 2010 Agreement. It is unclear to the evaluators whether the change in the list of beneficiary countries was discussed and approved by UNITAID.

The target '100% of budgeted products are delivered' is not deemed to have been met.

Facilitating in-country distribution

No activity pertaining to facilitating in-country distribution was ever implemented. The evaluators could not get any clarification on this matter from CHAI or UNITAID.

The table below summarizes project achievements:

[17] CHAI response to UNITAID request for clarification on CHAI 2010 Interim Report

Table 5. Summary of the project's achievements.

Action		Indicators (as mentioned in Agreement)	Target	Achievement	Comments
	Identify beneficiary countries for the project in line with UNITAID's eligibility criteria	Percent of total budget allocated to LICs, LMICs, UMICs	At least 85 % disbursed to LICs; <10 % disbursed to LMICs; < 5 % disbursed to UMICs by Q4 of the previous year	Target is met in 2008 and 2009 but not in 2007 and 2010	In 2010, the decrease in LMICs may be the result of the transition. UNITAID has endorsed the list of beneficiary countries and hence was aware that the 2010 country list did not meet eligibility criteria There is no information in CHAI Annual Reports on whether patients belong to 'vulnerable groups' as defined by UNAIDS
	Sign amendments to MoUs containing updated annexes for ARVs to be supplied	Percent of beneficiary countries with signed amendments and updated annexes with ARVs to be supplied	100 % of beneficiary countries have signed amendments and updated annexes with ARVs to be supplied in each year by Q4 of the previous year	The target was not met in 2009 and 2010 (less than 70 % of participating countries signed an MoU) but was substantially met in 2007-2008 (96 % of participating countries signed an MoU)	The main reasons quoted by CHAI to justify the absence of signed MoUs are political and administrative challenges
	Engage in forecasting with countries for the purposes of estimating purchases of ARVs and the number of people to be treated (to be provided in September of each year)	Forecast of estimated quantity of ARVs, and estimated number of patients to be treated	Forecast of estimated quantity of ARVs and estimated number of patients to be treated to be provided by September	Forecasting and budget were prepared each year but the evaluators lacked information to assess the timelines of CHAI's submission to UNITAID	Quality of the forecasting (for both required budget and patients to be treated per country) is questionable
		Forecast of estimated patients to be treated with ARVs purchased	Annual consolidated targets for patients to be treated with first-line and second-line	Consolidated annual targets were substantially met between 2008 and 2010 (90 % for second-line and 100 % for first-line)	Although consolidated targets were met, the level of achievement of the individual target per country varies significantly
	Identify potential suppliers and prices to be paid for products in each year	Number of suppliers in each product area where possible	At least 3 suppliers available for 4 of the existing products	For the four existing second-line ARVs (ABC, LPV/r, ddI 250mg and 400mg) there were at least three available suppliers from 2007 onwards Target was met	

Action		Indicators (as mentioned in Agreement)	Target	Achievement	Comments
		CHAI pays the lowest price for products in each product category	Price reductions in median price (US$) paid for ARVs procured every year achieved	Comparison of the applicable prices from 2007 to 2010 shows a decrease in all treatment prices.	CHAI paid the lowest prices compared to MSF and WHO GPRM, however countries under the CHAI consortium appear to have benefited from lower ceiling prices
	Enter into contractual arrangement with suppliers for the supply of ARVs based on the outcome of the application selection and price negotiation process for the product	Percent of suppliers that have signed MSAs or other long-term agreements	100 % of the annual Master Supply agreements or other long-term agreements concluded by CHAI and suppliers by Q3, as applicable per product type	CHAI signed an MSA/LTA with primary and secondary suppliers or purchased ARVs under Access prices. CHAI did not sign an LTA/MSA with pool suppliers.	
	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 of each year	2007 lead time per supplier was below or around 12 weeks. Based on the information available for the years 2008 and 2010, the evaluators note that lead time per supplier has generally increased, and for some suppliers, exceeded the 12-week target. Between 2007 and 2010, lead time per country was above 12 weeks for the majority of countries.	Most delays are attributable to suppliers, and result from technical problems. Other causes of extended lead times are CHAI's re-allocation of shipments to other countries (deemed necessary to avoid a stock out) and, in a few cases, caused by delays in getting documentation (registration, pre shipment testing or waiver)
		Number of suppliers that have had products registered or applied for waivers during 2010, including those still supplying product based upon previous waiver(s)	Increased number of registrations per drug in beneficiary countries	This target is deemed achieved for the 2007-2008 period. However achievement of this target could not be measured for 2009 and 2010. Moreover, the evaluators did not have information on the number of cases where CHAI had to request a registration waiver.	More information is required to assess CHAI's actual contribution to the achievement of this target

Action		Indicators (as mentioned in Agreement)	Target	Achievement	Comments
	Work towards improving the market for UNITAID-funded commodities to support UNITAID's mission of lowering prices and broadening the supplier base	Number of pre-qualified ARV formulations available each year	Complete dossiers submitted to WHO Pre-qualification Programme (or SRA) for at least 2 ARV formulations (new formulations or products from new manufacturers) by Q4 of each year	This target was achieved in 2008, 2009 and 2010, with an additional 6, 9 and 10 newly-approved suppliers by SRA	More information is required to assess CHAI's actual contribution to the achievement of this target
	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	80 % (in 2008 MoU) or 100 % (in 2009 and 2010 MoU) of all orders placed through the application of pooled procurement each year unless there is a significant impact on the delivery schedule	This target was not fully achieved but in 2008, 2009 and 2010, more than 74 % of orders were pooled	Procurement pooling does not have an effect on drug prices but rather on lead time. Pooling orders allows CHAI to reach the minimum volume/threshold of product above which suppliers agree to start production
	Placement of purchase orders for and delivery of products	Percent of value of ARV packs ordered and delivered to each country that match the value of ARV packs budgeted	100 % of budgeted products are delivered, allowing for a 15 % deviation per country budget allocation	This target has not been achieved. Less than 25 % of countries in 2008 and 2009 have had their commitments matching their budget +/- 15 %. This percentage went up to 40 % in 2010	Weak forecasting, compounded by imponderable factors and CHAI flexibility (gap filling) in the use of UNITAID-funded second-line ARVs, has negatively impacted the budget per country, although the overall budget has not been affected.
	Facilitate improvements in in-country distribution systems for ARVs	Project support provided where needed to increase the timely delivery of products to ports of entry or a designated central medical store	Relevant processes in place for in-country distribution support by Q4 2010	N/A	Activities not implemented

- **What are the main factors influencing the achievement or non-achievement of the objectives?**

Factors influencing achievement or non-achievement of the objectives pertain to:

- Countries' commitment and ownership of the procurement and supply of second-line ARVs (especially on the objectives pertaining to the timely signature of MoUs, the quality of the forecasting, and the registration of drugs)
- The absorption capacity of country treatment access programmes, management of the supply chain, country's diagnostic and laboratory capacity and management of antiretroviral-therapy failure, are directly linked to achievement of individual country targets that contribute to the objective of scaling up access to treatment
- Availability of robust in-country health and logistics information systems are prerequisite for accurate forecasting and reporting on the number of patients treated and drugs consumed
- The selection of manufacturers that offer fixed access prices to beneficiary countries as a primary or secondary supplier prevents CHAI from negotiating lower prices and thus impacts CHAI's achievement in reducing prices
- A change of primary or secondary supplier impacts the number of registrations per drug in beneficiary countries
- Suppliers' access to API and their priorities in drug production directly impacts the lead time
- CHAI's ability to obtain information from various in-country partners to ensure appropriate quantification for the September order cycle impacts the percentage of orders that are pooled
- Political problems (civil unrest, etc.) negatively impact the timely signature of MoUs

- **Based on the results at mid-term, to what extent are these objectives likely to be achieved?**

Budget allocation as per UNITAID eligibility criteria

Compliance with UNITAID's eligibility criteria is not likely to be achieved by the end of the project. The 2010 budgets were prepared with the aim of facilitating countries' transition through bridge funding from UNITAID to the Global Fund and PEPFAR, and to support countries' access to ATV/r. Hence it was impossible for them to comply with the pre-determined allocation model.

Signature of MoUs with all beneficiary countries

Although CHAI states that it invests great effort in getting the amendments to extend the original MoU signed every year, it is not likely that all countries will have signed an amended MoU before the project ends. CHAI, in its answer to UNITAID's request for clarification on the 2010 interim report, stated that the fact that UNITAID did not authorize CHAI to sign a multi-year MoU, compounded by political and administrative challenges, did not allow for timely signing of annual amendments for extension. Moreover, a valid MoU is not a pre-condition for the procurement of drugs, and hence there is little incentive for countries to sign the amendment on time.

Signature of an LTA/MSA

There appears to be a misunderstanding between CHAI and UNITAID on the requirement for manufacturers to sign an MSA/LTA. CHAI understands that MSAs are to be signed only with primary and secondary suppliers, whereas UNITAID expects MSAs to be signed with all suppliers.

This misunderstanding could result from misalignment of the indicator under the activity (*Percent of suppliers that have signed MSAs or other long-term agreements*) and the related target, which only refers to a timeline (*100 % of the annual master supply agreements or other long-term agreements concluded by CHAI and suppliers by Q3, as applicable per product type).*

In view of the above, if UNITAID's objective is to have CHAI sign an LTA with every supplier, this target is not likely to be achieved by the end of the project. CHAI purchases drugs from the pool of suppliers at tiered prices, and the quantities concerned may not be large enough to entice suppliers to commit to a long-term agreement. Moreover, for suppliers from whom drugs are available at access price, there is no added value to further fix those prices through an LTA/MSA.

Lead time

Lead time is believed to have increased for certain suppliers. The 12-week target is not likely to be achieved, as manufacturers will always encounter unforeseeable technical and production problems. Second-line ARVs do not represent a significant part of manufacturers' product portfolio and hence may not get priority on their production lines. Moreover, scarcity of certain APIs is a problem that manufacturers have no authority to resolve. Lastly, the current tracking system does not allow for removing outliers from the average for the lead time per country, per product or per manufacturer. Hence, it is not possible to know what the actual average lead time would be once orders with country-requested delivery dates that exceed the lead time, as well as orders for which CHAI reallocated shipments to another country, are removed from the database.

Registration

The target relating to the increase in the number of registrations per drug in beneficiary countries is likely to be achieved considering the increase in registrations between 2007 and 2008, which reflects CHAI's and suppliers' commitment to get products registered rather than rely on waivers.

Pooled procurement

The target pertaining to pooled procurement (100 % of all placed orders pooled procured each year) is not likely to be achieved. Some flexibility is needed in any procurement arrangement to allow countries to procure outside the planned schedule. The monetary value of pooled procurement achieved in 2009 and 2010 is likely to be the highest that can reasonably be expected.

Actual deliveries vs Budget

The target '100 % of budgeted products are delivered'[18] has not been achieved and will not likely be achieved, considering CHAI's performance in forecasting countries' needs. Some factors that could have contributed to this underachievement include patients' enrolment/scale up rates, delays in Global Fund disbursement, problems in partners' supply chains, the unavailability of expected government or transition funding or changes in treatment guidelines. CHAI showed flexibility in the use of UNITAID-funded second-line drugs to mitigate the risk of stock outs, but this approach may have had a negative impact on CHAI's performance against project indicators and targets. Although the overall budget has not been exceeded, large variances have been noted between the quantity of each drug budgeted and planned for procurement (as shown in the RfP), and the quantity actually purchased (as reported in the Annual Report).

Support to in-country distribution

As previously stated, activities aiming at the target 'Relevant processes in place for in-country distribution support by Q4 2010' have never been implemented.

[18] Excerpt of 2010 List of achievement on objectives under the project: 100 % of budgeted products are delivered allowing for a 15 % deviation per country budget allocation

3.1.3 Efficiency

This assesses whether the partners are using UNITAID funding in the most efficient manner in order to achieve the objectives of the project. Depending on the project, this covers aspects related to the procurement model, coordination with national authorities, as well as other aspects of implementation arrangements.

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

Key findings

- There is no target or indicator on CHAI's collaboration with national authorities. However, the Annual Reports feature instances of collaboration between CHAI and the authorities in beneficiary countries.
- CHAI's procurement model is well defined and designed to identify and solve procurement-related problems. However, the model had limited influence over suppliers' performance. The efficiency of CHAI's model was affected by the inaccurate forecasting of ARV needs (which impact both drug price and production planning) and by the order pooling system which may have put a strain on suppliers' production capacity
- In case of a significant increase in the volume of orders compared to the RfP (noted as +40 % to 300 % for most ARVs in 2009 and 2010), using ceiling prices instead of fixed prices would have offered CHAI the opportunity to re-negotiate the unit costs. This does not apply to originator drugs that are sold at the fixed access price
- CHAI reported that some countries over relied on CHAI's expertise in forecasting which possibly hindered their transition to other donors with whom they would receive less or no support in forecasting

- **Are the project partners working closely with the relevant national authorities in the project's beneficiary countries? (where applicable to the project)**

Documents available to the evaluators contain limited information on how closely (and with what impact) partners work with relevant national authorities.

CHAI program support activities

CHAI's anticipated collaboration with national authorities is described in the UNITAID/CHAI 2010 Agreement's project support section (please refer to Box 17 in annex section 9). These activities, and CHAI's achievements in the respective areas, were not consistently reported on in CHAI's Annual Reports.

Forecasting

In CHAI's Annual Reports, CHAI states that it contributes to strengthening country forecasting capacity by:
1) providing the latest information on the availability of formulations,
2) sharing best practices to help avoid stock-outs and product expiries,

3) assisting with data scrubbing and analysis. In several countries, CHAI drives quantification meetings, supporting the Ministries of Health in their collaborations with additional partners, such as SCMS.[19]

However in the 2008 Annual Report, several countries appeared to have fully entrusted CHAI to do the forecasting for them (Chad, DR Congo [although slowly handed over to the Ministry of Health], Ghana, Haiti, Mali and Togo). In Cambodia and Cameroon, CHAI reported that forecasting was done using a CHAI tool with approval by MoH, but how national authorities were involved is not clear. Moreover, CHAI repeatedly stated in Annual Reports that countries' over reliance on CHAI forecasting expertise was a threat to transition to another donor.[20]

There is no apparent link between the quality of the forecasting and CHAI's country presence. On the contrary, it appears that countries supported by a regional office (no physical presence in the country) have been forecasting better than the others. It should also be noted that CHAI's presence and work in beneficiary countries is primarily for the implementation of the UNITAID Paediatric Project. CHAI has confirmed that there were no in-country CHAI resources dedicated to monitoring the procurement and supply management of the second-line ARV project and that further collection and analysis of site-level data for forecasting was not currently feasible.

Similarly, the level of partners' presence in a country did not seem to impact the quality of forecasting. However, in the 2009 CHAI Annual Report, CHAI identified the following reasons for inaccurate forecasting: poor data availability and quality; turnover in CHAI's Regional Team for Western Africa, compounded by the unsuccessful submission of a proposal to the Global Fund; uncertainty about other sources of funding for second-line drugs which leads countries to increase their ordering through CHAI; and faster uptake of enrolled patients than anticipated.[21]

CHAI also states in its 2010 Annual Report that '*information flow between the health facilities and the central medical stores that place order requisitions with CHAI does not smoothly function, implying some weaknesses in the forecasting (and potentially in reporting) at the central level. Moreover, as the 2nd line treatments have been newly introduced in the countries and as for many countries, it is difficult to anticipate migration rate. Weak diagnostics capabilities may also compound the difficulty to prepare accurate forecasts.'*

Support to countries in adopting WHO's priority and cost-effective regimen

Reviewing treatment protocols and providing guidance on these is part of CHAI's effort to assist countries in choosing among WHO-recommended treatments and increasing ordering of the most relevant products by analyzing the pros and cons of each combination, based on costs, availability, etc.…[22] This was not fully reported on by CHAI in its annual activity report

[19] 2010 Annual report
[20] CHAI 2009 and 2010 Annual Reports
[21] Forecasting for West African countries continues to pose a challenge for the Project (2009 Annual Report) and there are few CHAI staff in that region (2010 Annual Report)
[22] CHAI Feb 2006 presentation: Engaging ARV marketplace to optimize patients outcome

to UNITAID, although for ATV/r, CHAI states that it *works with beneficiary country governments to encourage the adoption of ATV/r as a preferred or equivalent PI option in their national treatment guidelines.*

Coordination of the provision of necessary technical assistance

Country-specific information on CHAI's achievements in this area is extremely limited. It is clear that the complexity of the coordination role increases with the number of donors and specialized technical agencies present in the country. CHAI states that it works on the harmonization of quantification (*unified forecasting*) in several countries where SCMS is present. CHAI is part of the SCMS-led 'Coordinated Procurement Planning Initiative' which *provides a framework for coordination and supports the development of roles and activities at country level. This initiative strives at producing at country level a Coordinated Procurement Plan, documenting all funding commitments.*[23] However, there is not much information on the other (non-procurement related) areas of collaboration that could positively impact the project.

Information on synergies in the UNITAID-beneficiary countries with other projects implemented by CHAI is also lacking. For instance, on the results yielded by CHAI's approach in forecasting, CHAI wrote to the evaluators that results have varied significantly by country, and are dependent *on the level of country commitment and also on the breadth of complimentary CHAI programs in country.*[24] Another example of the lack of synergies was brought to the attention of the evaluators during the interview with CHAI staff. The evaluators asked about CHAI's response when discrepancy between the number of patients reported by MoH, and the volume of drugs ordered was noted. CHAI's reply was that '*As there are no in-country CHAI resources dedicated to monitoring the 2L Project, further collection and analysis of site-level data is not currently feasible*'. But CHAI staff later stated that '*CHAI has complementary funding to do further tracking'.* It is not clear to the evaluator why synergies could not be sought between the two initiatives in order to improve the national logistics management information system (LMIS).

In CHAI's presentation to the UNITAID executive board, CHAI indicated that two other donors, namely the UK Department for International Development (DFID) and the Bill and Melinda Gates Foundation, were supporting activities complementary to the project that are aimed at:

- Driving product roll out
- Optimizing manufacturing via improving the chemistry of processing & the sourcing of raw materials
- Accelerating uptake of clinical guidelines
- Supporting national forecasting

This last activity requires close collaboration with the national authority, and in addition to UNITAID's project activities relating to quantification, this is expected to have a synergistic effect.

[23] SCMS presentation on the coordinated procurement planning initiative http://www.who.int/hiv/amds/scms_cpp_initiative.pdf.

[24] Excerpt from communications from UNITAID's project coordinator at CHAI.

Support to the national drug regulatory authority

The number of ARVs actually registered is the only indicator that could be linked to CHAI's support to the national drug authority (NDRA). However, this indicator appears to be too narrow to measure the impact of CHAI collaboration and NDRA capacity strengthening.

UNITAID/CHAI project impact on national systems

Although system strengthening was not the focus of the UNITAID/CHAI project, the UNITAID/CHAI procurement model may have negatively impacted beneficiary countries' capacity to carry out procurement. This argument is well described in a WHO article on the global strategies to reduce the price of antiretroviral drugs.[25]

Based on the evidence available to the evaluators, the UNITAID/CHAI project support component did not *develop and increase the technical capability for managing procurement systems.*

This concern was echoed in a second article that followed a study on UNITAID/CHAI's support in Cameroon. The authors noted that the Cameroonian government's high level of dependency on international financial mechanisms represents a major and continuous threat to a sustainable national response to HIV/AIDS. In practice, the provision of second-line drugs has restricted the role of CENAME[26] to simply storing the drugs provided by CHAI. As a result, the agency was not apt to improve its competency as a market analyzer and negotiator with regard to supplying second-line drugs. It must be noted that, in effect, CHAI was unable to fulfil its commitments in this domain. In future, negotiations should address this very important issue.[27]

In the specific case of Cameroon, contrary to what is described in this article, CHAI appears to have carried out significant capacity development activities such as seconding for 6-months, a supply chain and logistics expert from Glaxo SmithKline GSK to implement best practices and standard procedures in stock management. CHAI also conducted a thorough review of previous orders to identify the regional depots that have placed irregular orders and therefore require follow-up.[28]

In conclusion, CHAI appears to work with national authorities but the outcome of this collaboration is not sufficiently documented and described in the report.

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[25] "While mechanisms for improving procurement efficiency are certainly desirable, they should be designed to develop and increase the technical capability for managing these procurement systems in the countries concerned. New procurement arrangements, whereby donors and international organizations act on behalf of countries for selected diseases, may fail to strengthen those countries' health systems,"
Waning B, et al. Global strategies to reduce the price of antiretroviral medicines: evidence from transactional databases. Bull World Health Organ 87, 2009.

[26] Centre for Essential Drugs Procurement and Medical Disposables.

[27] Access to Second-Line Antiretroviral Therapeutic Regimens in Low-Resource Settings: Experiences From Cameroon
http://journals.lww.com/jaids/Fulltext/2011/07011/Access_to_Second_Line_Antiretroviral_Therapeutic.11.aspx#P53

[28] CHAI 2010 Annual Report.

CHAI support to Global Fund Grant recipients

The Global Fund appears to be the most rational and obvious alternative source of funding for UNITAID project beneficiaries. However, efficiency in use of UNITAID funds for the purchase of first-line drugs in countries already receiving Global Fund grants is questionable. Delays in HIV grant implementation have resulted in unspent funds, which could have been used to purchase first-line drugs (through re programming). In Zambia, Global Fund HIV grant implementation has been slow and a grant was terminated due to fraud. In Uganda, the national budget for ARV treatment was used for other purposes, putting patients' life at risk.[29] Supply of UNITAID-funded ARVs is not performance based, hence for Global Fund recipients, UNITAID ARVs are likely to be preferred, especially for Grants that are under performing. This additional 'untied' source of ARVs could potentially undermine Global Fund management of its grantees as UNITAID and the Global Fund do not work under the same principles.

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

The project's procurement model is well defined and achieves its objective of delivering quality ARVs. However, the procurement model does not have much influence over suppliers' performance. For certain manufacturers (Aurobindo, BMS, GSK), product (especially ddI) and country procurement lead times exceeded the 12-week target set in the UNITAID/CHAI annual Agreement.

According to the 2010 lead-time analysis, the main reasons underlying longer procurement lead times were:

- Manufacturers technical problems and capacity constraints (for example scarcity of APIs)
- Countries wanting drugs delivered later
- CHAI re-allocating shipments from one country to another (most likely to guard against the risk of stock outs)
- Delays in obtaining a waiver or import-related documents as a result of last minute changes (in product shelf life, for example) or miscommunication between countries and suppliers (on pre shipment inspection)

Although the exact nature of technical issues and capacity constrains is not known, pooled procurement may be putting pressure on manufacturers, which could result in overstretching their production capacity. This may be an adverse effect of the pooled procurement mechanism. It also raises questions about the accuracy of the information that manufacturers provide about their production capacity when they bid (please refer to Box 18 in annex section 9) and also about CHAI's potential leverage to ensure that suppliers honour their commitments.

[29] http://www.crestedjournal.com/news/3-headlines/294-uganda-health-ministry-diverts-arv-money-

This being said, as stated earlier, pooled procurement, although it does not impact the negotiated price, is a pre-requisite for ordering, especially for small countries as the order size has to be significant enough for a supplier to start production.

Mandatory conditions for manufacturers' participation that are included in the RfP (please refer to Box 18 in annex section 9) give CHAI sufficient flexibility to cancel a purchase order with a supplier and work with another one. Moreover, contracting a primary and a secondary supplier (and keeping a pool of suppliers in case a primary or a secondary supplier defaults) is a good practice to mitigate the risks of late delivery.

For example, in 2010 CHAI experienced delays with both the primary and secondary supplier of ddI and so switched its order to BMS, without needing to retender.

As mentioned earlier, CHAI's negotiations with suppliers during the procurement process can be affected by inaccurate forecasting of country needs. Although the relationship between the volume and the price of ARVs is not known, it is assumed that when an order for an ARV increases between 2 to 4 fold, on average, the unit price should be less. UNITAID and CHAI would have benefited from negotiating ceiling prices instead of fixed prices, because it would have given CHAI the opportunity to request a lower price if the volume of an order increased.

A possible direct consequence of inaccurate forecasting is the strain it puts on manufacturers' production capabilities as they cannot anticipate the volume of quarterly orders. In the case of ddI, CHAI partially cancelled purchase orders with Aurobindo and Matrix because the manufacturers were too slow in producing the drug, however for the same year, it appears that the orders for ddI were close to 90 % above the quantity featured in the RfP.

Inaccurate forecasting negatively impacts the predictability of demand which is crucial during cost plus negotiation and it also impacts CHAI's estimates of need for a co-secondary supplier (for a contract above US$1 million as per the RfP). For example, in 2010, procurement of LPV/r amounted to US$1.15 million, whereas the forecast was for US$0.6 million. CHAI's RfP and procurement standard operating procedures do not appear to have a provision that would cap the possible increase of orders under a contract, but merely stipulate that a contract increase of more than 20 % must be reviewed by CHAI's contract review committee. It is not fair to those who bid and lost to increase the volume of the order, and hence the value of the contract, without giving losing bidders the opportunity to propose a new price based on the higher volume.

Apart from delays in procurement lead times, the evaluators could not identify any problem that was not promptly resolved through using the project's procurement model.

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

In May 2009, Ernst and 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 the evaluators have listed in Table 6 in annex section 10. From the original list, the evaluators kept only the ones deemed relevant to the project. When information on their im-

plementation was available, the evaluators noted that most recommendations were implemented. However, the most critical ones relating to data collection on patients treated, on ARV consumption (No. 10), and on the establishment of MSAs with all suppliers (No. 9), were not implemented.

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

Transition has been discussed and planned since the project's inception. There are two main donors that UNITAID-supported countries could transition to and these are PEPFAR and the Global Fund. Out of the 16 beneficiary countries in 2008, 12 were funded by PEPFAR. CHAI's challenge has been to secure alternative funding for beneficiary countries that were receiving first-line TDF-based ARVs, which have a higher unit cost, but also provide greater benefits for patients and countries in the long run (higher adherence and hence lower resistance and fewer side effects). PEPFAR does not support the use of TDF, so only the Global Fund could take over this support from UNITAID/CHAI.

CHAI has successfully supported countries in preparing their proposals for the Global Fund. On average, proposals supported by CHAI have been more successful in securing Global Fund grants than has been the case with countries not supported by CHAI. According to CHAI's 2008 and 2009 Annual Reports, the success rate of HIV/AIDS proposals to the Global Fund Round 8 (GF Rd8) was 63 % (versus the GF Rd8 overall approval rate of 49 %). CHAI has also coordinated efforts with UNAIDS, WHO, and other partners to ensure that all countries needing support receive technical assistance.

Of the countries receiving technical assistance for Global Fund Round 9 submissions (GF Rd9), the following were successful: Cambodia; India; Mozambique; Nigeria; the Organization of Eastern Caribbean states; Senegal; and Vietnam. This meant that the success rate of HIV/AIDS proposals receiving CHAI technical assistance was 67 % versus the overall GF Rd9 approval rate of 41 %.

CHAI's 2010 Annual Report states that in December 2010, nine countries had successfully transitioned to other funders.

Another reason why the transition to the Global Fund is deemed more secure than transition to PEPFAR funding, is that PEPFAR itself is gradually handing over its financial responsibilities to beneficiary countries (national budget) and the Global Fund. Some organizations such as Medecins sans Frontieres (MSF) have expressed concern that donors are gradually withdrawing from HIV programmes, and putting pressure on the Global Fund, whose resources have not increased to match these new demands. The immediate result of transition to the Global Fund is that countries cannot enrol new patients to the extent initially planned. According to MSF, in the DRC, the handover of treatment costs from PEPFAR to the Global Fund resulted in a five-fold reduction in funding for actual, monthly treatment slots.[30] Limited availability of funding resulted in delayed or incomplete implementation of WHO's recommendations to initiate treatment at CD4 <350/µl instead of CD4 <200/µl, as previously recommended. In Malawi and Kenya, which approved the use of WHO's recommendations,

[30] Donor retreat widens HIV/AIDS treatment gap in Africa, MSF July 2011

National Programmes await financial support to implement them. In Mozambique and Uganda, limited funding resulted in an incomplete implementation of WHO's recommendations as National Programmes initiate treatment at CD4 counts of <250/µl, and target only some beneficiary groups.

Moreover, according to MSF, the Global Fund's request to grantees to do more or as much with less (also known as efficiency gains), result in cuts in the means of providing quality treatment.

3.2 Public Health impact

The main objectives of the project were to scale up access to quality second-line treatments in 27 specified LMICs, and facilitate a price reduction for these drugs over the project life span. These objectives were achieved.

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

Key findings

- Consolidated patient targets were substantially achieved (89.5 % for second-line ART and 100.6 % for first-line TDF-based ART) but large variations occurred between countries with regard to achieving their targets. In addition, there were concerns about the reliability of data
- CHAI can report in a timely manner on the use of UNITAID funding for drugs purchased and on the estimated number of patients treated, but the link between the volume of drugs ordered and the number of patients treated cannot be established
- Discrepancies between the number of patients under treatment and the volume of drugs ordered was not investigated by CHAI
- It was not possible for the evaluators to assess the impact of UNITAID-funded commodities on patients' access to treatment as the team lacked information on the countries' context, and the complementarities and synergies between UNITAID's contribution and the activities undertaken on the ground by CHAI and other partners.

Improving public health by increasing access to quality ARVs

Between 2007 and 2010, UNITAID and CHAI likely increased access to second-line ARTs by delivering treatments, which national authorities and CHAI reported as having been used to treat between 46,000 and 71,000 patients per year in 26 countries, most of which were LICs. During the same period, UNITAID and CHAI delivered WHO-prioritized first-line TDF-based treatment, which national authorities and CHAI reported as having been used to treat between 39,000 and 87,000 patients each year in Namibia, Uganda and Zambia. From 2008 to 2010, the estimated number of patients treated with second-line drugs increased from 46,106 in 2008 to 71,342 in 2010. Conversely, the estimated number of patients treated with first-line TDF-based ARVs decreased by more than half as a result of the transition. Taking into consideration both first- and second-line drugs, the estimated numbers of patients treated in 2008, 2009 and 2010 were respectively, 133,322, 117,324 and 111,192 (see Annex in section 10).

The consolidated volume of ARVs ordered and correlated with CHAI estimates for patients treated substantially achieved the target for the second-line ART (the 3-year average achievement rate was almost 90 %, with a rate above 100 % in 2009) and reached the targets for first-line TDF-based ART (with a rate above 100 % in the first year). However, although global demand for second-line ARVs and estimates about project uptake were relatively-well anticipated ((see Annex in section 10), there were substantial disparities between countries. The anticipated number of people to be treated in each beneficiary country as per the UNITAID/CHAI Agreement, significantly differs from the number of patients reported as treated in CHAI Annual Reports (see section below on *quality of forecasting*).

The figures reported above are to be reviewed with some caution as it appears that quality data on the number of patient treated were not consistently available across the beneficiary countries. Hence CHAI had to estimate the number of people potentially treated based on the volume of ARVs ordered. The lack of quality data may have not only negatively impacted countries' ability to report on the number of patients treated but also on their ability to accurately forecast their needs (please refer to following section).

Moreover, drugs delivered to a country at the central level do not automatically translate into increased access to appropriate treatment for the patients. A variety of factors can hinder access to treatment. These include: [1] weaknesses in the supply chain (poor storage, inadequate inventory management, inefficient distribution, and lack of internal controls that result in theft or diversion); and, [2] weaknesses in the capacity of medical personnel to adequately diagnose, rationally prescribe and appropriately support patients' adherence to treatment. Further research would have to be conducted to evaluate the impact of the intervention on public health.

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

An estimate of the number of patients treated is available annually by country in each Annual Report for both second-line ARVs and first-line TDF-based ARVs. Similarly, CHAI reported on the numbers for each ARV purchased over the project. In annex 2 to the Annual Report, CHAI provides information on the number of packs delivered per year per country (please refer to Table 10 in annex section 10). This information is reported on time in each Annual Report but the consistency and accuracy of the information cannot be easily assessed. The evaluators faced challenges when comparing the volume of ARVs ordered, with number of patients treated, and noted that number of patients treated was not consistently reported, and thus could not reconcile variance in the ARV budget with variance in the number of patients treated.

Lack of correlation between the volume of ARVs ordered and patients treated

In general, the number of patients reported as treated each year was based upon patient data or estimates provided by the country's MoH and/or partners. In cases where patient figures were not provided, or were not in line with actual volumes ordered, patient estimates were calculated based on the number of patients that could be reasonably treated with the volumes ordered. During interviews, CHAI informed the evaluators that CHAI did not undertake any further analysis to understand the reasons why a discrepancy occurred between the quantity of treatments ordered and the number of patients enrolled. The number of countries

to which is applies is unknown but the 2007 Annual Report shows that out of 22 beneficiary countries for which the estimated number of patients treated has been reported, CHAI used orders or forecast data for half (11 countries). Subsequent Annual Reports do not feature the source for the estimated numbers of patients.

CHAI's approach to estimating the number of patients treated based on the quantity of ARVs ordered (rather than received) is not deemed appropriate because orders cannot be directly linked to the number of people treated. Orders include buffers, and drugs are not immediately available to patients because of the four-month procurement lead time. CHAI's approach is likely to result in overestimating the number of patients treated. CHAI's reply to the evaluators' request for clarification on CHAI's method of estimating the number of patients treated (as described in CHAI's Annual Report) appears to support this finding:

'Because of transition efforts, estimated number of patients based on order quantities may not be an accurate to assess the issue in question.

In addition to patient data, considerations must be made to account for buffer stock, expiries, anticipated scale-up, and shortfalls or delays on the part of other supply chains and partner organizations. As countries work towards transitioning to alternative funding sources these factors have resulted in increased variability with respect to the quantities ordered. Adjustments to levels of buffer stock, particularly for drugs where UNITAID has been the major or sole provider, skew consumption calculations reliant on patient estimates. With countries having experienced increased funding disbursement delays – both in number and in length – quantities ordered have seen increased variability as UNITAID is called upon to fill unexpected, short-term gaps in the supply chain'.[31]

This problem appears to have been recurrent but no medium- to long-term solution has been identified over the project's lifespan to remedy this flaw in the reporting system. CHAI staff told evaluators that CHAI actively works in areas that contribute to strengthening systems in countries, but as these activities are not funded by UNITAID, they are not reported on in the context of this project.

The evaluators lack information on how UNITAID's contribution fits into national systems and programmes for HIV/AIDS, and hence whether drugs reach patients and are rationally used. Without country-level information, it is not possible to accurately assess the impact of the UNITAID project. Without such key information, little can be concluded about why there is a lack of correlation between the number of patients reported as treated, and the volume of ARVs ordered. This key information needed includes: forecasting assumptions and information on each country's specifics (partners' activity, challenges in distribution or diagnosis, stock outs, the amount of expired drugs, the number of patients reported at the national level as treated with second-line drugs, and the proportion treated with UNITAID-funded drugs).

Absence of reporting on the number of patients treated

In addition concerns about the quality of reporting, evaluators noted that in a given year (especially 2010), several countries allocated budget and received drugs, but did not report on the number of patients treated. These countries were:

[31] Additional response to evaluators' queries provided by CHAI former second-line project associates in an e-mail dated 26 June 2011

- Cote d' Ivoire: In 2009, had commitments amounting to more than 122 % of its original budget but did not have a target and did not report on the number of patients treated
- Botswana: in 2010, had commitments amounting to more than 133 % of its original budget, and had a target for the number of patients treated, but did not report on it
- Ethiopia, Mali, Namibia: In 2010, all had commitments equivalent to their budget but did not have a target and did not report on the number of patients treated

When the evaluators asked CHAI for clarification about Botswana and Ethiopia, CHAI replied that patient treatment figures were reported for the end of year 2010, by which point Ethiopia and Botswana had completed their transitions to other donors. The 2010 budget year for both countries had five order cycles – Dec 2009, Mar 2010, Jun 2010, Sept 2010, and Dec 2010. Ethiopia placed its last order in Dec 2009. Botswana transitioned in mid-2010. Based on this information, it appears that even though ARVs were procured and delivered to both countries, CHAI exempted them from reporting on the number of patients treated with those ARVs because the countries were transitioning to another donor that year or the following year.

Lack of correlation between the budget for drugs and the number of people treated

There is also no link between the change in budget (increase or decrease) and variance in the number of people reported as treated versus the number of patients planned for treatment. Some countries received drugs as per the budget or sometimes more, but did not meet their targets. These countries are believed to have built some buffer, as scale up in the number of patients treated did not occur. These countries were:

- Botswana: 2009 commitments were equal to the budget, but only 46 % of the target for patients under treatment was met
- Cambodia: 2009 commitments were equal to the budget, but only 57 % of the target for patients under treatment was met. In 2010, commitments amounted to more than 200 % of the budget and 100% of the target for patients under treatment was reported as met
- Cameroon: 2009 and 2010 commitments exceeded the budget by more than 30 % in each year but only 50 % of the target for patients under treatment was met
- Togo: 2009 commitments exceeded the budget by more than 150 % but only 70 % of the target for patients under treatment was met

Other countries have met or sometimes exceeded their target with only a fraction of their budget. If the data on this are reliable, perhaps patients were treated with stock purchased in the previous year. However, if this was the case, it was not reported. These countries were:

- Burundi: in 2009 and 2010, with commitments amounting respectively to 66 % and 86 % of the budget, targets for patients under treatment were met
- Haiti: in 2010, with 91 % of the budget, Haiti exceeded targets by more than 70 %
- India: in 2009 and 2010, with commitments amounting, respectively, to 25 % and 33 % of the budget, targets were met. In 2009, 84 % of the target was met, and in 2010, the number of patients under treatment increased by more than 700 % over the 2009 number

- Mozambique: in 2009, with commitments amounting to 69 % of the budget, targets were exceeded by 51 %
- Nigeria: in 2009, with commitments amounting to 72 % of the budget, targets were exceeded by 46 %
- Tanzania: in 2009, with commitments amounting to 51 % of the budget, targets were exceeded by 173 %, while, the number of patients under treatment rose by more than 300 % over the previous year
- Uganda: in 2009, with commitments amounting to 77 % of the budget, targets were exceeded by 37 %
- Senegal: in 2009 with commitments amounting to 9 % of the budget, 66 % of the target was met

There are some limitations regarding this analysis:

- In some countries, a change in national treatment guidelines that may not have been anticipated at the time of budgeting (and the setting of patient treatment targets), can significantly alter the quantity and the nature of the ARVs procured, and hence expenditures
- The Annual Report describes activities carried out between January and December of a given year and provides a number for patients under treatment as of December. However, as already stated, procurement does not follow the same time frame, hence the ARVs ordered in a given year may be used to treat patients well into the following year.
- Country budgets were calculated based on CHAI's conservative estimate of price reductions. Actual prices for 2010 were lower than those estimates which may have inflated country budget requirements

- **How has the project's procurement model allowed for the scale up of ARTs of better quality and from more generic manufacturers?**

The project has undoubtedly increased the volume of second-line ARVs and TDF-based ARVs purchased and delivered to beneficiary countries. However, lack of information on the baseline (number of patients already treated by existing programmes) in each country, as well as information on the national targets, prevent the evaluators from analyzing whether the increase in the number of patients treated under the project was indeed a scale up at the national level. Access to this information is deemed essential, especially in countries where project targets and reported numbers of patients under treatment have decreased. In 2008, Benin reported 1,108 patients treated using UNITAID-funded commodities, and while the target for 2009 was 1,384, the actual number of patients treated fell to 96. The same situation was noted in Botswana where, in 2008, 3,293 patients were treated using UNITAID-funded commodities, and while the target for 2009 was 4,168, the actual number of patients treated fell to 1,921. This occurred as well in other countries (e.g. Cambodia, Cameroon, Malawi, and Namibia) and is most likely the result of transition to other funders (e.g. to the Global Fund or PEPFAR). This raises some concerns about the reliability but also the relevance of a system that would track the number of patients treated as reported by the donors.

There is also no baseline or any information on the quality of second-line ARVs before the project's inception and hence the evaluators can only confirm the increase of SRA-approved, and WHO pre-qualified, manufacturers from 2007 to 2010 (please refer to section 4.3 on market outcome).

The number of originator manufacturers (i.e. non generic) among primary and secondary suppliers has remained stable: one in 2007, 2008, and 2009 (BMS for ddI) as well as one in 2010 (GSK for LPV/r). However, the poor performance of both primary and secondary suppliers can result in contracting an originator from the pool of suppliers. For instance in 2010, both Aurobindo and Matrix could not deliver ddI, and CHAI reassigned part of the order to BMS (please refer to the 2010 Annual Report).

- **How has the project contributed to the global efforts to increase access to quality treatment in line with Millennium Development Goal 6?**

Millennium Development Goal 6 pertains to reversing the spread of the disease and providing universal access to HIV/AIDS treatment:

- Target 6A. By 2015, has halted and begun to reverse the spread of HIV/AIDS
- Target 6B. Achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it.

By supplying second-line ARVs to countries that had high unmet needs and no resources available to procure those drugs, the UNITAID/CHAI project has contributed to increasing access. However, access to treatment includes dimensions such as affordability, accessibility and availability, factors over which the UNITAID project may have had limited impact. UNITAID-funded drugs were provided free of charge but there was no information available to the evaluators on whether costs associated with treatment occurred in beneficiary countries. Availability of drugs has increased at the central level, but there is limited information across beneficiary countries on whether those drugs were available to patients. As stated above on the lack of correlation between the volume of ARVs ordered and number of patients treated, the availability of drugs depends on the supply chain and health infrastructure, including health staff.

3.3 Market outcomes

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

Key findings

- The number of eligible suppliers increased (+1 in 2008, +6 in 2009 and +2 in 2010)
- Price reductions were achieved between 2007 and 2010 (-31 % in the price of the second-line regimen) which appears to have had a positive impact on CHAI consortium prices and SCMS.

- **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 to treat, diagnose and prevent HIV/AIDS, tuberculosis and malaria?**

Using innovative, global-market based approaches

The UNITAID/CHAI partnership focuses on improving access to the four second-line ARVs recommended by the World Health Organization (WHO) during the Technical Working Group meeting in May 2007 (Nucleoside Reverse Transcriptase Inhibitor: TDF+3TC and ABC+ddI; Protease Inhibitor: LPV/r and ATV), and on TDF and its FDCs for use in first-line treatment, as per WHO August 2006 guidelines for HIV/AIDS treatment.

CHAI was, and still is, UNITAID's partner of choice in pursuing innovative, market-shaping approaches to improving public health in low and lower middle-income countries (LICs and LMICs). Both agencies share the common goals of influencing the health product market, and their collaboration has provided leverage for CHAI that has boosted its successful interventions on both sides of the market. UNITAID's financial contribution of unprecedented magnitude has been used by CHAI to create secure and sustainable additional demand for second-line ARVs and Tenofovir. This, in turn, has positively impacted competition among supplies (increasing the number of eligible suppliers per ARV) as well as innovation (the introduction of two new formulations). The UNITAID/CHAI partnership has also allowed manufacturers to gain a comprehensive view of the second-line ARV market and increase manufacturers' degree of certainty with regard to order volumes and payment.

Since 2003, CHAI has been engaging both on the demand and the supply side of the ARV market, using an innovative, worldwide, approach to the market. CHAI has also been engaging with countries in developing operational plans, forecasting demand, supporting purchasing, and monitoring consumption. In addition, CHAI has been engaging with manufacturers in: reviewing production processes and identifying potential improvements and savings; conducting an in-depth analysis of production costs; and identifying cost drivers as well as estimates of the impact of large orders on production costs.

UNITAID's contribution is believed to have increased the speed and extent to which CHAI achieved its goals. Thanks to UNITAID, CHAI's estimated purchasing power grew to 77 % of second-line ARV demand in the LICs and MICs that can access generic drugs (excluding Argentina, Brazil, China, Mexico, and South Africa).[32] This market power has enabled CHAI to negotiate lower prices for second-line drugs. Since the project's inception in 2007, UNITAID's intervention has yielded savings worth an estimated US$84 million.[33] These savings amount to US$116 million if one adds in the price reductions negotiated for TDF (and its FDC) for the three countries that benefited from UNITAID support for first-line drugs (see Figure 2 in annex section 10).

[32] According to CHAI's 2010 Annual Report, page 26

[33] Direct Cost Savings: Difference between baseline price (= average market price in a LI country at the inception of UNITAID) and the average price paid each year by UNITAID for that product; multiplied by product volume (source: ' Transition update and next steps', CHAI's presentation to the UNITAID Board, November 2010)

CHAI's procurement arrangements that combine tendering, negotiating with suppliers and pooled procurement have also been instrumental in the success of the project. CHAI's *cost plus* innovative approach to negotiation with manufacturers has shown itself to be far more effective than models that merely rely on pooled procurement.

Increasing the number of eligible suppliers of quality ARVs

Since 2007, according to CHAI, the number of quality assured, and either WHO pre-qualified or SRA approved suppliers per ARV, has steadily increased and so has the number of ARVs registered in beneficiary countries (the latter could not be measured over the project lifespan, please refer to section 4.1). Although CHAI's actual influence over these developments cannot be measured directly, the procurement arrangements under the project[34] are believed to have contributed to these achievements.

Broadening the base of suppliers is also the mandate of CHAI's Drugs Access Team ("DAT") whose cost was supported by UNITAID's small contribution to CHAI. DAT works with the industry and has, according to CHAI, contributed to increasing the number of new, qualified manufacturers for both existing and new drugs.
Specifically, DAT has been:

1) Providing technical assistance to suppliers and manufacturers of active pharmaceutical ingredients (APIs);
2) Coordinating contract research projects at independent research laboratories around the world to address the urgent chemistry challenges that are difficult for generic suppliers to resolve on their own;
3) Increasing competition by providing strategic guidance to new, high-quality API manufacturers;
4) Gathering and sharing with manufacturers, market intelligence on demand trends and usage patterns for these target drugs; and
5) Undertaking research to develop new formulations of existing ARVs with lower dosing of drugs.

According to CHAI, over the project's lifespan, the eligible products (SRA approved or WHO prequalified) have increased from 19 in 2007 to 46 in 2010. The evaluators believe that the increase in the number of quality assured manufacturers, and the number of prequalified ARVs, has had a positive impact on the prices of drugs procured under the project.

The evaluators did not have access to information pertaining to the **number of complete dossiers submitted to the WHO Pre Qualification Programme or SRA**, and thus could not measure whether CHAI achieved its target of stimulating an increase in the number of quality-assured manufacturers and products by encouraging prequalification of approved manufacturers and products. It was also not possible to assess CHAI's actual involvement in the process. However, it was possible to measure the outcome of the process by reviewing the number of ARVs newly approved by SRA or prequalified by WHO. Between 2007 and

[34] e.g., CHAI split the award between two suppliers, encouraging multiple suppliers to bid. During the 2009 and 2010 tenders, CHAI used product registration status in beneficiary countries as a bidder selection criterion. If the selected supplier was not registered in beneficiary countries, CHAI sometimes provided technical assistance to help manufacturers to register their product.

2010, 25 drugs were newly approved by an SRA (please refer to tables 11, 12 and 13 in annex section 10).

Decreasing the price of ARVs

A comparison of the applicable prices from 2007 to 2010 shows a decrease in all ARV prices (please refer to Table 14 in annex section 10). From 2007 to 2008, one ARV (TDF 300mg) increased by 34 % for a secondary supplier, but in 2010, it decreased by 59 %. Hence over the project's lifespan, all ARVs registered a price decrease. So, the evaluation team has concluded that this first market target has been achieved. However, there was no precise target negotiated by UNITAID and CHAI on the extent of price decreases for each individual ARV.

Target treatment cost per patient per year is usually stated in the project plan (also known as the action plan) and appears in the May 2008 project amendment on the 2009 - 2010 project extension.[35] A target treatment cost of US$400 per patient per year was eventually increased to US$500.[36] According to the 2008 Annual Report (Table 3.8.1), this target was largely achieved (except for LPV/r) for both primary and secondary suppliers of individual ARVs, but not for the reference TDF–based WHO-recommended regimens (TDF + 3TC + LPV/r or TDF + FTC + LPV/r) or ABC + ddI + LPV/r (please refer to Figure 2 and Table 14 in annex section 10).

According to the CHAI 2007 to 2010 Annual Reports, the decrease in the unit price of second-line ARVs purchased under the project is significant when compared to the WHO Global Price Reporting Mechanism (GPRM) and the MSF '*Untangling the web*' price list. For both 2009 and 2010, CHAI compares its negotiated prices (secured in the last quarter of the previous year) against 2008 prices reported in the GPRM. Although this approach is deemed appropriate for the 2009 price comparison, for the 2010 comparison, it overestimates the price decrease in 2010 as it includes the decrease that occurred in 2009 for most ARVs.

According to WHO GPRM reports (please refer to Tables 16 and 17 in annex section 10), between 2004 and 2007, prices of some ARVs for second-line treatment decreased substantially (especially ABC 300mg -50 % and LPV/r 133mg -75 %) in low and middle income countries. However, median prices of other ARVs for the second-line regimen were very stable over those years. Between 2007 and 2010, prices of second-line drugs decreased dramatically. Considering that with UNITAID funding, CHAI had purchasing power of 77 % of the market for second-line ARV demand in the LICs and MICs that could access generic drugs, one can assume that CHAI's activities under the project had a direct, positive impact.

However, when looking at Management Sciences for Health's International Drug Price Index Guide (MSH IDPIG), the project's positive market impact is harder to demonstrate. For a majority of second-line ARVs, only two procurement agents, SCMS and the International Dispensary Association Foundation (IDA), reported ARV prices. As observed in the GPRM, second-line ARV prices (except Abacavir 300mg) remained stable from 2004 to 2006 and only started decreasing from 2007 onwards. Although the causal relationship between the project and the decrease in prices reported by procurement agents since 2007 cannot be conclusively proven, one can assume that CHAI's advertisement of ARV prices negotiated for the

35 Please refer to Box 9 in annex section 9.
36 Please refer to Box 4, Box 6 and Box 10 in annex section 9.

consortium provided the procurement agents (such as SCMS and IDA) with critical leverage in their negotiations with suppliers.

Limitation of the exercise:

- SCMS is primarily a supplier to UMICs, whereas CHAI procured second-line ARVs for LICs and LMICs.
- Originators' products are sold at access prices which increases the average product price.
- Prices of ddI 250mg and 400mg enteric-coated (EC) delayed-release formula were not available before 2008; hence prices reported in both tables from 2004 to 2008 are for the regular formula (not EC).
- WHO GPRM (countries reporting median prices for the interquartile range) and MSH IDPIG (the procurement agents' average price) are not comparable and are therefore only used to identify some trend in ARV price fluctuations

Impact on prices beyond the project's beneficiary countries

CHAI-negotiated prices under the project potentially had a positive impact on CHAI consortium ARV prices and Supply Chain Management System (SCMS)-prices that were negotiated under PEPFAR funding. The tenders organized by CHAI for the procurement of Second-line ARVs all include a clause that stipulates that the price offered to the UNITAID/CHAI partnership should, *at minimum,* be available to countries participating in the CHAI consortium.[37]

When comparing second-line ARV prices between 2007 and 2010, it should be noted that the prices negotiated by CHAI under the UNITAID project are sometimes higher than the price offered by CHAI to the countries in the CHAI consortium. As confirmed by CHAI management during their phone interview, there were no synergies between the CHAI consortium and the CHAI/UNITAID project. Purchases under the project and under the consortium were not coordinated, and hence the opportunity to lower prices due to economies of scale, was missed. Similarly, although CHAI acts as the negotiating agent for the Global Fund's voluntary pooled procurement (VPP) initiative,[38] in order to negotiate a ceiling price and terms and conditions, the Partnership for Supply Chain Management (PFSCM) is the VPP procurement agent (whose role is to contract suppliers on the basis of negotiations conducted by the negotiating agent, and to process country orders). Its sister organization, SCMS, is PEPFAR's negotiating agent. To date (March 2011), the CHAI consortium, PFSCM, and SCMS have not held joint negotiations with the pharmaceutical industry.

However, the CHAI prices under the UNITAID project were consistently lower than the prices reported by SCMS (according to the MSH ERC drug price index). In 2010/2011, one can see the harmonization of prices across the board for CHAI, UNITAID, the CHAI Consortium, and SCMS (please refer to Table 15 in annex section 10).

[37] Please refer to **Box 11** in annex section 9.

[38] CHAI drug quality policy http://clintonhealthaccess.org/node/122

The reasons for the difference between CHAI consortium ceiling prices in 2008 and 2009 and CHAI-negotiated prices under UNITAID, are as follows:[39]

- The ceiling price is a voluntary arrangement whereby a supplier joins if they agree to maintain the price. The tender is a separate mechanism where selection is based on the bids submitted. Hence, some of the selections under the tender may be for suppliers who are not part of the ceiling price arrangement and vice versa. Thus, suppliers are not bound by the ceiling price arrangement.

- The second difference comes from timing. CHAI consortium ceiling prices were released in April 2008, August 2009, April 2010, and May 2011. However, CHAI-negotiated prices under UNITAID were released during the first quarter of the year (the tender is floated between October and December for annual orders that are placed in March of the following year). SCMS prices are based on the calendar year. Thus, the difference in timeframe can partly explain the difference in unit price that appears between CHAI/UNITAID and the CHAI consortium. If prices change between the dates just listed, there will be a difference in the price.

Overall, savings could be slightly larger than what was reported under this project due to CHAI's impact on the market beyond its procurement for UNITAID.

There were some limitations to this analysis:

- The quality of drugs on the market varies within and between low-resource countries, but in the case of the PEPFAR and UNITAID projects, prices of ARVs of equal quality were compared (WHO pre-qualified or SDRA registered).
- The pack size is missing in descriptions of certain ARVs; hence these comparisons may not be 100 % accurate.
- The individual efforts of SCMS and CHAI to achieve price reductions could have a positive effect that cannot be attributed conclusively to either SCMS or CHAI alone.

The project's positive impact on market prices beyond the beneficiary countries and CHAI consortium members cannot be absolutely demonstrated, but it is highly probable.

[39] Excerpt of communication with UNITAID Project coordinator at CHAI

3.4 Reporting

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

Key findings

- Each Agreement provides well-defined templates for each part of the report, including the forms for the required tables and annexes. This ensures a standardized way of reporting, for the programmatic part as well as for the financial part.
- The report validation process was not well specified in the Agreement and there was no protocol for seeking and receiving clarifications
- It was not possible to know to what extent reports were used for decision making following performance-based funding principles
- The report does not cater for supplying information pertaining to country-specific information that would explain the discrepancy between the country budget and the patients treated
- Some transitioning countries were allocated a budget and received ARVs, but did not report against any target

The annual reporting template includes three main sections: financial, programmatic and procurement, and additional sections look at the key issues. Each of the first three sections reports against key performance indicators defined in the performance framework.

CHAI submitted three types of reports to UNITAID on financial, programmatic and procurement progress. Two reports are mandatory as per the UNITAID/CHAI Agreement:

- The Annual Report (covering the period 1 January to 31 December) includes a preliminary financial statement and estimates of patient numbers. It is to be submitted to UNITAID 90 days after the end of the calendar year
- The Annual Report also includes a statement of all income and expenditures for the project and a detailed financial reconciliation statement, certified by the Chief Financial Officer of CHAI. This is to be submitted to UNITAID on the 1st of May of the following year (120 days after the end of calendar year)

The third report, which is an interim report 'Interim Programmatic Procurement and Financial Report' is only submitted if CHAI requests an early disbursement of the first half of the following year's budget (as in 2008 when early disbursement of the 2009 budget was requested).

CHAI also has an order tracker, which gives details on all orders placed in a given year for all beneficiary countries. A copy is provided in the annex to the Annual Report.

All reports except the 2009 Annual Report (submitted 1 month late) were submitted on time or with minor delays (the 2008 Interim Report was submitted 2 days late) and reports clearly show the quantity of each drug purchased with UNITAID funds and report on the estimated number of patients treated. The evaluators are not aware of other sources of funding channelled through CHAI that could be mistakenly confused with UNITAID's funding.

- **Reports received from implementing partners**

Agreements do not describe the report validation process in detail, and only mention that "*UNITAID is responsible for ongoing review of the financial and programmatic process of the project*". Under section 14.1, it is further stated that "...*where standardized formats are used, a template or illustrative copy will be provided to UNITAID sufficiently in advance of their use to allow UNITAID a reasonable opportunity to provide input.*" Similarly, there is no protocol for seeking and receiving clarifications. For example, after the 2010 Semi Annual Report, UNITAID wrote a letter asking for many clarifications, but this did not include any date or signature.

Each agreement contains clear templates for the content of the report, including a template for the mandatory tables and annexes. The report format and templates are standardized and follow requirements for the project plan. Each Agreement also provides a schedule for reporting and disbursements (annex 6) with a specific reporting date and milestone for each disbursement.

The evaluators noted only minor deviation from the template and concluded that reports provide clear information on project achievements and challenges. With the exception of the financial section, this allowed a reasonably good overview of the project's implementation.

It is not possible to know to what extent reports were used for decision making. Thus, it appears that decisions regarding commitments for countries' drug orders were processed independently of countries' situation, as described in the reports (e.g. some delays in Global Fund Grants or rapid target achievement implied additional support from UNITAID, which means that the reasons for justifying the funding did not follow performance-based funding principles).

- **Financial reporting**

This section reports on the following key information:

1. Total Funds Committed vs. Funds Received
2. Total Funds Committed and Disbursed vs. Budget
3. Funds Committed and Disbursed vs. Budget by Country
4. Breakdown of Funds Committed and Disbursed by Income Level
5. Breakdown of Funds Committed and Disbursed by Drug
6. Interest Earned

According to the UNITAID/CHAI Agreement, the Semi-annual Report should include a full statement of account that details all financial transactions for the project. CHAI should also supply UNITAID with pertinent information from CHAI's order tracker system (which monitors the progress of orders) and provide an account of the project's financial and programmatic progress.

CHAI is to provide an annual financial report and information on all disbursements received and expenditures incurred during the preceding period. Thus, the Annual Report includes a statement of all income and expenditures for the project and a detailed financial reconciliation statement, certified by the Chief Financial Officer of CHAI.

For both Annual and Semi-Annual Reports, the Agreements refer to templates and tables in annexes which ensure that financial reporting is undertaken in a standardized way.

Financial reports also mention interest earned on both the UNITAID operating account and the money market account in which the bank invests the funds. A specific form, "Breakdown of interest earned", is provided in the annexes to the Annual and Semi Annual Reports (annexes 11 and 12).

- **Program reporting**

As stated in the section on relevance, the evaluators noted that the scope of the indicators could have been wider as the dimensions of some objectives were left out and should have been more concerned with 'impact' than with 'process'.

As stated in the section on impact, it would have been useful to have information on the assumptions used in quantifying needs in order to understand the country context regarding: the number of patients treated (vs. the national target) and the funding source; the estimated switch rate from first-line to second-line; attrition rate; information on buffer stock in month of stock; expired drugs; excess stock; and stock out occurrences.

The reports follow the instructions and format provided by the Agreement between UNITAID and CHAI. The structure of the Annual and Semi-annual Report is well-defined in the annexes to the Agreement.

As the Agreements take into account the start of a new second-line ARV project each year when the new Agreement is signed, the reports only include information for the past year. Thus the reports do not provide an overview of the whole project and its progress since project inception. It would be helpful to have information covering the whole project on the key trends concerning health and market outcomes.

The reports do not include sufficient analysis of the results: for example, there is no explanation about the decrease in patient targets or on how to overcome the challenge of poor data quality and reliability which has negatively impacted quantification of needs throughout the project.

3.5 Strengths, Weaknesses, Opportunities, and Threats (SWOT)

Strengths	Weaknesses
• CHAI's experience with the HIV market, CHAI's procurement model, and CHAI's innovative global market approach • Effective impact on market dynamics • Transition to other sources of funding as anticipated since the project's inception • Country adoption and use of the WHO prioritized cost efficient regimen	• Accuracy of forecasting and the reliability of numbers reported for patients treated • Information sharing on country challenges and project synergies with the on-going program (supply chain management, diagnostics…) • The initiative was mostly driven by partners, with little country ownership • Scale up vs substitution and gap filling • Weak product tracking, no monitoring of free dispensing of drugs and no risk mitigation measure to prevent drug theft/diversion • Too much attention on transition and not enough on whether CHAI had enough resources to fulfil its part of the partnership (SCM, rational use of second-line ARVs…) and how to sustain demand
Opportunities	**Threats**
• Global Fund UNITAID roadmap • Global Fund market-shaping strategy	• Market segmentation resulting from the closing of the project threatens product availability (ddI) and project gains in price reductions • Sustainability of demand • Suppliers confidence in countries' ability to pay quickly • Shortages of first-line drugs

- **Strengths**

  - ***CHAI experience, procurement model and innovative global market approach (including the cost plus negotiation)***

CHAI is UNITAID's partner of choice for this project. CHAI has had strong experience and an on-going relationship with suppliers and countries since 2003, and has undertaken key activities that contributed to the project's success.

Working at both ends of the market, CHAI has effectively removed obstacles to the delivery of quality ARVs for the treatment of patients, as per WHO recommendations, and CHAI has also negotiated unprecedented price reductions by applying innovative strategies in collaborating with the pharmaceutical industry.

- ***Market impact***

The project's impact on ARV prices has had a positive effect beyond UNITAID projects, as country members of the CHAI consortium, the Global Fund, and PEPFAR recipients have all benefited from it, as reported in the GPRM and in Management Sciences for Health's International Drug Price Index Guide.

- ***Transition to other sources of funding anticipated since project inception***

Since the project's inception, transition to other sources of funding was at the core of the UNITAID project. CHAI explored options for alternative funding and supported countries in their application for Global Fund grants. Although transition required more time and resources than anticipated (two project extensions for bridge funding), it was close to completion at the end of 2010.

- ***Country adoption and use of the WHO prioritized cost efficient regimen***

The project has contributed to mainstreaming WHO recommendations for priority treatments which has reduced the number of ARV drugs and combinations, and thus contributed to price reductions.

- **Weaknesses**

- ***Accuracy of forecasting***

This is a major project weakness 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 for tracking the number of patients treated and of drugs consumed, which is an ongoing problem in developing countries. Unreliable quantification may potentially have had a negative impact on price negotiations (as eventually more drugs were procured than shown in the original RFP) and on suppliers' performance (as the predictability of order volumes was weak). One of the reasons CHAI gives in the Annual Reports for the lack of accuracy in forecasting was the unsuitable timing of the September order which coincided with in-country partners' engagement in budgeting for the next year. According to CHAI, it was difficult to get partners' attention at that time. This is a recurrent issue that has never been addressed since the project's inception.

- ***CHAI's report to UNITAID***

CHAI reports did not provide UNITAID with an accurate idea of how UNITAID's contribution fitted into a larger, comprehensive program that provides quality care to patients. As a result, and in the absence of reliable data and country-specific information (total number of patients treated irrespective of the donor, quantity of expired drugs, support to rational drug use, actual laboratory capacity, etc.) the evaluators could not state the magnitude of impact on countries' public health.

Information on how UNITAID funding has impacted the market is available, but information on how the project has improved patients' access to treatment and treatment outcomes, as well as on country capacity in forecasting, rational drug use and drugs registration are limited and not entirely reliable. This is potentially the result of insufficient UNITAID funding for CHAI's costs.

- ***Diagnostics***

The project's reliance on clinical diagnostics of first-line treatment failure limited the project's impact on patient health outcomes.

The limited availability of viral load testing to adequately determine first-line treatment failure was discussed in 2010. CHAI stated in the 2010-2011 proposal for the project's extension, and in its 2010 Annual Report, that insufficient availability of appropriate diagnostics means to determine first-line treatment failure, was one of the on-going challenges CHAI was facing.

In 2009, the UNITAID Executive Board asked CHAI to explore work in this area. Proposals were submitted by PASCAL and WHO, but both were rejected in November 2010. A new tender was planned for 2011.

Expansion of in-country laboratory capacity to support rational use of second-line ARVs is a priority also for civil society delegates and board members who issued a statement that:

- stresses the ethical implications of treating patients with the right drugs
- supports innovative approaches that decrease prices such as those seen in the PASCAL proposal
- highlights the risk of extra expense without accurate diagnosis and also the importance of implementing WHO treatment guidelines and ensuring a better quality of life for people living with HIV/AIDS

This approach is supported by medical articles which have concluded that *early identification of first-line antiretroviral treatment failure is critical to prevent morbidity, mortality, and drug resistance. Misclassification of failure may result in premature switching to second-line therapy, which [is] costly and may represent the last available regimen.* [40] [41]

- ***Scale up, additionality vs gap filling, buffer stock and substitution***

The project has contributed to the treatment of up to 71,000 patients with second-line drugs but there is insufficient information on whether these patients were an addition to the patients already under treatment.

CHAI reported that UNITAID-funded commodities were used to prevent or mitigate the risk of stock outs by filling gaps resulting from delays in partner organizations' supply chains. While the intent is laudable, such contribution does not meet the requirement of UNITAID's principle of additionality because it does not increase the number of patients treated but merely prevents treatment interruption. The evaluators do not have information on whether UNITAID

[40] http://cid.oxfordjournals.org/content/49/3/454.full

[41] http://www.aidsmap.com/Second-line-ART-in-South-Africa-shows-good-results/page/1437594/

approved of this practice. In the 2008 plan of action, CHAI appears to support funding substitution which breaches the principle of additionality supported by UNITAID.[42]

Evaluators noted a second breach in UNITAID's principle of additionality as substitution may have occurred in countries where multiple donors are active. The number of countries where substitution may have taken place is not known. This approach is deemed inadequate considering that it opposes UNITAID/CHAI's efforts in preparing for transition to other donors.[43]

The lack of baseline information on the number of patients already treated by existing programs in each country, as well as national targets, prevent the evaluators from analyzing whether the increase in the number of patients treated under the project is indeed a scale up at the national level. Access to this information is deemed essential, especially in countries where project targets and the reported number of patients under treatment have decreased (as described in the section of this report on project-specific questions).

Similarly, in Cote d'Ivoire, UNITAID-funded commodities were used *in case of emergency,* which is understood to be a means of preventing treatment interruption. The number of patients benefiting from this arrangement cannot be counted as additional patients.

CHAI also states that in some countries, UNITAID-funded commodities are used to replenish the stock (buffer stock) as a result of new supply chain management arrangements (for instance in Kenya). There is no assurance that this would result in an increase in the number of patients treated. However, buffers are needed, especially when countries are transitioning. Signature of a grant agreement may be delayed and the lead time for procurement of drugs is long (3 to 4 months after signature). The establishment of bridge funding in the 2010–2011 project extension did mitigate the risk of treatment interruption, but did not necessarily contribute to an increase in the number of patients under treatment.

- ***Risk management***

In countries where the number of patients treated is not aligned with the quantities ordered, CHAI estimated the number of patients being treated, based on the quantity of dugs ordered and did not carry out an analysis to understand the causes behind this discrepancy.

The lack of accurate consumption data, compounded with the absence of a signed MoU with countries, increased the exposure of UNITAID-funded drugs to theft and diversion. The MoU signed by CHAI and countries is the only provision against diversion[44] and CHAI fully relies on national authorities' capacity and commitment to prevent theft or diversion from occurring.

CHAI did not include in its supply chain any monitoring of free dispensing of drugs to patients, although the UNITAID/CHAI Agreement stipulated that CHAI would inform UNITAID promptly of any non-compliance (please refer to Box 20 in annex section 9). In Zimbabwe, reports indicate that patients pay up to one month's salary in order to be enrolled and have access to an ARV. About two thirds of the people who could not pay were denied service and had to buy drugs from the private sector.[45] The extent of the exposure of UNITAID-funded

[42] Please refer to Box 21 in annex section 9.
[43] Please refer to Box 22 in annex section 9
[44] Please refer to Box 19 and Box 20 in annex section 9.
[45] http://www.plusnews.org/report.aspx?Reportid=90680

ARVs to such practices is not known, but the evaluators believe that the mitigation measures in place were insufficient to prevent this.

CHAI estimates, however, that UNITAID exposure to drug theft and diversion was limited as ARVs are widely available and free of charge in all countries where UNITAID operates, and hence ARVs do not carry much resale value. However, in a country where the Global Fund has suspended HIV grants and which benefits from the UNITAID project (Zambia), CHAI does not appear to have informed UNITAID about the possible knock-on effect of the Global Fund decision, or about UNITAID's exposure to similar problems.

- ***Countries' eligibility criteria***

UNITAID and CHAI's criteria for the selection of beneficiary countries included, *inter alia*, countries' official requests for assistance and positive reports in the World Bank and Global Fund assessment of countries' procurement capacity and supply chain management capacity.

However, it is noted that countries' eligibility criteria do not include any indicator pertaining to country readiness following a capacity gap analysis to manage a program with second-line treatment. This should have included an assessment of the capacity of laboratory and clinical staff to effectively diagnose first treatment failure and to rationally use second-line drugs and manage national inventory and distribution systems (including capacity to store, distribute and report on the quantity of drugs consumed and the number of patients treated). The evaluators did not have information on the scope of the World Bank and Global Fund assessment that positively assessed countries' procurement systems, nor any information on how countries were selected.

There is a risk that market impact has been aggressively pursued without enough attention and resources dedicated to strengthening countries' ability to absorb this contribution.

- ***Capacity strengthening and country ownership***

Transition has been at the core of the UNITAID intervention since its inception. Countries' ownership and capacity development have not received much attention, although the intervention has lasted three years longer than initially planned.

- **Opportunities**

There are two main opportunities that are expected to critically contribute to the sustainability of project gains.

- ***The Global Fund market-shaping strategy***

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

In 2009, the limited achievements of these two instruments in terms of value for money, led the Global Fund Board to create the Market Dynamics and Commodities Ad-hoc Committee (MDC) and assign to the MDC, the task of defining *more active, market-shaping, strategic*

interventions that *are required to enable the Global Fund to significantly improve the value for money achieved with health products*.

The Global Fund's Board endorsed the market-shaping strategy in May 2011:

Excerpt from the Report on the Market Dynamics and Commodities Ad-hoc Committee, Twenty-Third Board Meeting Geneva, Switzerland, 11-12 May 2011

The Global Fund market-shaping strategy encompasses four objectives: 1) accelerate introduction of new, superior products; 2) ensure recipients procure the most cost-effective product options; 3) strengthen countries' strategic procurement capacity; and 4) ensure sustained availability and affordability of products with challenging market conditions.[46]

The Global Fund will only intervene in markets not addressed by partner actions and will work closely with partners such as UNITAID to implement market-shaping interventions.

This paves the way for stronger collaboration between the main actors in procurement of ARVs: The Global Fund, CHAI and PFSCM/SCMS (and potentially PEPFAR). CHAI has been facilitating negotiations for ARV procurement on behalf of the Global Fund VPP and PFSCM if the Global Fund procurement agent and its sister organization, SCMS, procured ARVs for a PEPFAR-funded project. The stronger ties between the three actors could radically change the relationship between the pharmaceutical industry and beneficiary countries.

- ***Roadmap for strategic collaboration between UNITAID and the Global Fund***[47]

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 a "roadmap", for future collaboration with UNITAID (GF/B14/DP23). Discussions on the progress for developing the roadmap began in December 2006.

This partnership proposed to expand the UNITAID/CHAI pooled procurement partnership model for new grants and rolling continuation channel grants (grants extended after the five-year term). Countries could voluntarily choose whether they want to procure drugs, and hence receive the funds to procure them, or use the UNITAID/CHAI pooled mechanism and receive the drugs directly. Some technicalities still needed to be discussed between CHAI and the Global Fund in order to define the terms of the collaboration (in particular with regard to performance-based funding requirements).

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

[47] http://www.unitaid.eu/en/governance-mainmenu-4/policies-mainmenu-58.html

- **Threats**

  - ***Market fragmentation***

The sustainability of gains made in price reductions and the level of demand are not likely to be achieved unless UNITAID and CHAI agree upon and offer an effective support mechanism to countries that have transitioned in order to give them sustainable access to low-priced drugs, irrespective of the size of their order.

The LPV/r price may increase because global demand will decrease as a result of the ATV/r phase in. The availability LPV/r could also decrease for countries with low-volume orders which would force them to transition to ATV/r. This was already noted in the 2010 Annual Report with regard to ddI being phased out.

With the exception of Uganda, transition appears to be complete for countries which applied for Global Fund grants, although no report on this was made available to the evaluators.

Global Fund Round 10 grants: Cameroon, Kenya and Zambia
Global Fund Round 9 grants: Mozambique, Nigeria
Global Fund Round 8 grants: Burundi, Chad, DR Congo, Togo, Zimbabwe

However, less than five months away from the completion of the project, there was still no mechanism to ensure that these countries would have access to quality second-line ARVs at competitive prices.

  - ***Sustainability of demand***

Countries that have been over relying on CHAI's assistance for forecasting and supply chain management, and which did not budget any technical assistance in their Global Fund grants, will find themselves in a difficult situation when estimating their needs. This could result in a price increase if global demand decreases.

  - ***Suppliers' confidence in countries' ability to quickly pay***

One of the features of the program was the assurance that CHAI and IDA gave to suppliers that they would be paid upon receipt of their products. Following the end of the project, suppliers will most likely experience delays in the processing of payments in some countries. This, in turn, may negatively impact suppliers' willingness to bid on tenders in those countries.

  - ***Shortages of first-line drugs***

The greater cost of TDF-FDC and shortages of available resources are putting tremendous pressure on countries which may not be able to allocate sufficient resources to second-line drugs.

4 Annex. Approach and Methods

This is a summative, external, independent, mid-term evaluation with a SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis and recommendations based on the evaluation's findings.

The evaluation was conducted by a principal evaluator, supported by a second evaluator who was responsible for preparing the project outline, extracting the data used in the evaluation matrix, and contributing to the other evaluation tasks, including report writing. Both evaluators were supported by a financial expert, a procurement and supply management expert, a project team leader, and a 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.

4.1.1 Common evaluation areas

The following common evaluation areas, which were specified in UNITAID's Request for Proposals (RFP), comply with the evaluation criteria of the Organisation for Economic Co-operation and Development (OECD):

- **Relevance**: consistency of project activities with project plans as well as with UNITAID's objectives and strategy.
- **Effectiveness**: degree to which project objectives were achieved.
- **Efficiency**: relationship between effort invested in carrying out project activities and the results, especially with regard to procurement.
- **Impact**: project impact beyond the achievement of short-term project objectives.

For each of these four evaluation areas, 'questions', 'indicators', 'sources of information' and 'analytical methods' were defined before the evaluation actually started. 'Questions' concerned evaluation areas that could be measured by either quantitative or qualitative 'indicators'. For each indicator, sources of information where identified as well the methods needed to assess each indicator (see Annex 1 Evaluation Tool, common questions). The same questions were administered across all projects to minimize the risk of bias resulting from the use of different evaluators.

4.1.2 Project-specific questions

UNITAID, in the RFP, proposed a series of project-specific questions. These questions were further adapted in discussions between the team of assessors, implementing partners and the UNITAID secretariat. A full list of the project-specific questions can be found in Annex1: Evaluation Tools, project-specific questions.

4.1.3 Quality of reporting

The team of assessors was notified by UNITAID that the program and financial reports submitted to UNITAID could pose challenges because: some were incomplete, and not consistent with the memorandum of understanding between UNITAID and the projects, and they also lacked internal consistency (e.g. between the items formulated as objectives and the activities). Given that evaluation of the project's progress was based mainly on the informa-

tion contained in semi-annual and annual operational and financial reports, reporting problems could affect the quality of the evaluation's findings.

See Annex 1: Evaluation Tools, reporting checklist for the checklist that was prepared to ensure a consistent assessment across all projects and with all evaluators.

4.2 Methods

4.2.1 Sources of information

The sources of information used in conducting this evaluation were the:

- Project proposal and related amendments;
- Agreements, where appropriate, between UNITAID and the project's implementing partners as well as other legal documents;
- Semi-annual or annual project implementation reports submitted to UNITAD on the project's implementation up to December 2010;
- Financial reports;
- Other documents such as follow-up reports by the UNITAID Secretariat, the initial project proposal, and financial audits.

4.2.2 Project outline

A preliminary review of project documents indicated that projects were not all consistent regarding what was considered an 'objective' and what was considered an 'activity', or the links between them. The first step, therefore, was to create a 'project outline' using a common log-frame that identified 'objectives' and the 'activities' linked to them. An 'objective' described what should be achieved at certain times and/or by the end of the project; an 'activity' was an event that should occur at a certain time and place, with specific people. Where possible, activities were linked to objectives, based either on information contained in project reports or on the judgment of the evaluators. Any other information retrieved for the evaluation was also referenced to the project outline. The project outline was adapted to reflect changes in the scope and objectives of the project that took place during implementation. Ideally such changes were reflected in amendments to the project Agreement. Among others, the project outline included the:

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

4.2.3 Data sources and extraction

Information was extracted from the CHAI Interim and Annual Reports that were submitted to UNITAID, as well as from UNITAID's Board reports and resolutions. Reports included the 2008 Interim and Annual Reports and the 2009 and 2010 Annual Reports. 'Outcomes' were extracted from the latest progress report available (March 2011) and from information compiled in the project outline.

Based on the log frame, documents were reviewed to extract relevant data for the evaluation. A set of templates were used to record data, and where necessary, tables were also pasted into additional sheets. Data extraction was based on the indicators

attached to each evaluation question in the four evaluation areas, as well as specific questions.

For market information, the evaluators relied on publicly available information on the drugs and diagnostics marketed for HIV/AIDS. This included the WHO list of pre-qualified suppliers, drugs and diagnostics, the MSH (Management Sciences for Health) International Drug Price Indicator, and ARV ceiling prices for countries that were part of the CHAI consortium.

UNITAID portfolio managers and implementing partners were contacted to clarify issues related to the availability and quality of data.

4.2.4 Analysis

Analysis for each of the four key areas was a composite of analysis of data for each question's indicator, as defined in the evaluation matrix. Quantitative indicators were calculated and qualitative indicators formulated. When information to estimate an indicator was missing, this was made explicit in order to avoid equating missing indicators with poor performance.

The evaluation for each of the four areas was accompanied by an assessment of the quality of the underlying data. Data were considered to be poor quality when they were partial (e.g. describing what happened in one country but not in another), 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 are missing or of poor quality, one can have little confidence that the evaluation correctly reflects the project; conversely, when data quality is good, it is reasonable to trust the evaluation. Thus, throughout this report alongside the findings, the quality of the underlying data is always explicitly described.

Based on the available data, efforts have been made to provide good explanations for successes and failures. Where data were deemed insufficient, no attempt has been made to extrapolate from other projects or to speculate based on anecdotal evidence.

A meeting was held between all evaluators and project leaders to review the findings. This review covered the project outline, the indicators and the data analysis. Where necessary, findings were fine tuned to limit those aspects that could be seen as subjective.

A two-part qualitative rating was provided for each common evaluation area, based on consensus among the evaluators. These were: the rating for the evaluation area itself and an assessment of the quality of the underlying data that indicated how much confidence could be placed in the evaluation area rating. For a guide to the rating scale and an interpretation of the different categories, see Table 1.

Table 1. Rating of evaluation areas and quality of supporting information.

	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
Major concerns	Most of the indicators showed poor performance.	The project needs important adjustments to improve its performance
Quality of supporting information		
Good quality	Data to estimate all indicators were available without obvious inconsistencies	The rating reasonably reflects the true performance of the project
Moderate quality	Some data were 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 were 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

4.2.5 Validation exchanges with key stakeholders

At the start of the evaluation, key questions were shared and discussed with the UNITAID secretariat and the implementation partners. The aim was to establish common understanding of the project status, progress and key issues, and to discuss the open-ended questions to be used in the evaluation. An interview questionnaire was developed specifically for each meeting in order to ensure relevance for the respective stakeholders.

4.2.6 Analysis of project Strengths, Weaknesses, Opportunities and Threats (SWOT)

The SWOT analysis was based on the evaluation matrix and internal factors that favour/hinder implementation of the project (strengths, weaknesses) and external factors (opportunities/threats). Thus, it summarizes the key factors influencing achievement of the project's objectives. However, this was not a fully-fledged SWOT analysis. The items identified in this report's SWOT grid could be analyzed in more depth if a formal SWOT analysis is undertaken.

4.2.7 Evaluation recommendations

This evaluation's recommendations are based on all the findings and consensus among the evaluators involved in all the individual country projects. The recommendations have been prioritized according to what were understood to be the critical issues for each key evaluation area and across all four key areas. Several options for addressing a critical is-

sue were identified and assessed against two main criteria: (a) the evidence that a recommendation would effectively address a critical issue; and (b) the feasibility of implementing a recommendation. In this case, evidence was drawn from research, best practice or anecdotal evidence. Each recommendation was addressed to a specific actor or actors (project implementation entities and/or UNITAID).

4.2.8 Project Specific Recommendations

Outstanding issues were discussed and validated with key stakeholders and a series of questions was developed to guide interviews / phone conversation with the UNITAID and CHAI project managers (see Annex 2).

Following the interviews, requests for missing or needed documents were issued. Further clarifications were obtained regarding reporting to UNITAID, including reporting templates, risk plans, and CHAI’s management issues.

5 Annex. Evaluation Matrix

Evaluation matrix of the common evaluation areas.

Evaluation area and question	Indicators	Sources	Methods
Relevance			
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 objectives with activities / total (%) - Number 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 to measure 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 logframe for the project
1.3 Are all activities implemented as scheduled for the period?	Activity completion rate - Number 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 period / Budget - Verify that expenditures are in line with activities initially planned / implemented - Explain main variances

Evaluation area and question	Indicators	Sources	Methods
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 to treat, diagnose and prevent 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			
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

Evaluation area and question	Indicators	Sources	Methods
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 prequalified 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 likely to be achieved?			
4.1 Likelihood to achieve health outcomes objectives	High / Medium / Low	Progress reports / interviews	No data collection here - This should be answered in the evaluation based on what has been achieved and what is known on the project
4.2 Likelihood to achieve market objectives	High / Medium / Low	Interviews / Market knowledge	No data collection 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 or non-achievement of the objectives?			
5.1. What were the reasons for patient outcome targets not met?	List of factors.	Progress reports / interviews	For the main patient outcome indicator, analyze the chain of events: - were the activities from project plan implemented? - if yes, what were the factors for non achievement of targets - separate 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 activities from project plan implemented? - if yes, what were the factors for non achievement of targets

Evaluation area and question	Indicators	Sources	Methods
5.3. Was there an effective risk management plan in place during the project	Yes / Limited / No	Progress reports / interviews	1- Did the partner make an initial risk assessment 2- Were the issues that happened during implementation foreseen in the risk assessment? 3- Did the partner take mitigation measures to limit the impact of negative events?
Efficiency			
6- Are the project partners working closely with the relevant national authorities?			
6.1 Have MoU been signed with all beneficiary countries?	Number of MoU Signed / Total planned	- Latest progress report - Update by interviews	- Number of MoU signed against Number planned - Analyze the reasons for MoU not signed
7- Is the project's procurement model well defined and designed to identify and solve procurement-related problems as they arise?			
7.1 Is a procurement agent selected and operational for 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 (in the case there are minority of extremes values do not include them but mention into the comment) It is in line with initial plan?
7.4 How many stock-outs of more than 7 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 to reasons - Number of stock-outs with responsibility - Number of stock-out without responsibility

Evaluation area and question	Indicators	Sources	Methods
7.5 Is the procurement model functioning as designed in the project plan?	- Yes - No	- compare procurement model from project plan to reality	If deviations from the project plan are identified, try to obtain information on the reason of the change.
Impact			
8- Can the partner organization attribute UNITAID funding to medicines and diagnostics purchased and patients treated by beneficiary country in a timely manner?			
8.1 Did the project report on treatments/diagnostics procured per country under UNITAID Funding?	No of treatments/diagnostics procured per country	- Latest progress report	
8.2 Did the project report on patients treated/diagnosed per country under UNITAID scheme?	No of patients treated/diagnosed with UNITAID funding per country	- Latest progress report	

Evaluation matrix of the specific questions.

CHAI 2nd line
1-How has the project's procurement model allowed for the scale up of ARVs of better quality and from more generic manufacturers?
1.1. Number of new products/manufacturers either WHO prequalified or registered by a stringent regulatory authority since the start of the program
1.2. Median Price reduction per box and per treatment/year achieved under the program
1.3. Estimated number of people under second-line ARV treatment
1.4. Number and percentage of ARV second-line drugs procured by the program over the past 12 month which are WHO prequalified or registered by a SRA
1.5. Number and percentage of branded products out of second-line ARV drugs procured
2-How has the project contributed to the global efforts to increase access to quality treatment in line with Millennium Development Goal 6?
2.1.Estimated number of people under treatment receiving UNITAID funded 2nd lines ARV and as a percentage of the people in need of treatment since the beginning of UNITAID support
2- Number and percentage of 2nd lines ARV procured using UNITAID grant that are WHO pre-qualified or registered by a SDRA
3- Were the recommendations of a past procurement evaluation implemented?; if not, what further adjustments are needed?
3.1. Were previous recommendations addressed in time, insufficiently or not addressed ?
3.2. Was there an increase of bidders in the last bids compare to first bid?
3.3 What was the median price decrease of key products procured under the program after implementation of previous recommendations?
3.4 What was the average time reduction or lead time for key products procured under the program once past recommendation were implemented?
4- What steps have been taken towards transitioning this project to more sustainable sources of funding?
4.1 What is the list of actions taken?
4.2- What results have been obtained so far?

Table c. Reporting checklist.

Reporting received from implementing partners
1.1 Are project reports (interim report, annual reports) submitted on time?
1.2 Are they many clarifications required by UNITAID following the transmission of reports?
1.3- Is the content of the reports according to 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 identifying readily common budget items (e.g. salaries, travel, major acquisitions, and drugs/diagnostics)?
2.3 Does the financial reporting give a clear picture on activities implemented and expenditures occurred on 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 Are interests received on bank accounts or others incomes 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 statements 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 requirements in terms of content?
3.3 Does the programmatic reporting provide a clear and actionable picture of program implementation?
3.4 Does the programmatic reporting provide a clear picture on procurement activities (order list, etc…)?

6 Annex. Meetings with Stakeholders and List of Persons Interviewed

Stakeholder	Name of person interviewed
CHAI	Amy Meyers Naoko Doi 1st July 2011 14th July 2010 19th July 2010
UNITAID	Kate Strong Gauri Khanna Jane Galvão

7 Annex. List of Documents Reviewed

Document Title	Source	Year
Agreement for the procurement and supply of second-line	UNITAID	2007
EB n°11, HIV7Aids, 2nd line ARV, Nov. 2006	UNITAID	2006
EB n° 6, HIV/Aids 2nd line ATV niche (Dec. 2007)	UNITAID	2007
1st Amendment to agreement for the procurement and supply of second line ARV drugs	UNITAID	2008
EB n°6, extension of 2nd line ARV Project (Nov. 2008)	UNITAID	2008
Amendment project proposal for program 2009 (Nov. 2008)	UNITAID	2008
EB n° 10, extension of CHAI 2nd line ARV Project (May 2009)	UNITAID	2009
EB n° 11, harmonization of CHAI 2nd line ARV Project Budget (May 2009)	UNITAID	2009
Agreement for the procurement and supply of second-line ARV drugs for 2009 (draft 2 June 2009)	UNITAID	2009
Project plan 2009	UNITAID	2009
Annexes to the Agreements for the P & S for 2009	UNITAID	2009
Extension proposal for program 2010-2011 (Feb. 2009)	UNITAID	2009
Agreement for procurement and supply of second-line ARV drugs for 2010	UNITAID	2010
Project Proposal for UNITAID Paediatric HIV/AIDS Program 2008-2010 –	UNITAID	Revised November 26, 2007
Order tracker	UNITAID	2007-2008
Interim report for May to Oct. 2008, November 17, 2008	UNITAID	2008
Annual report for Jan. to Dec. 2009	UNITAID	2009
CHAI responses to project assessment, Oct. 13, 2010	UNITAID	2010
UNITAID assessment of interim report 2010	UNITAID	2010
Annual Report 2010	UNITAID	2010
UNITAID assessment of Interim Report	UNITAID	2010
Answers to clarification to 2010 interim report	UNITAID	2010

8 Annex. CHAI's answer to UNITAID's need of clarification

CHAI's answer to UNITAID's request of clarification (letter of the 13th October 2010)[48]:

> ***"****We appreciate your desire to understand the nature of forecasting difficulties with more detail. The reasons for forecasting difficulties are multiple, specific to all beneficiary countries, and involve multiple nuances of local government, other stakeholders in the country, geography and politics. We are unable to give you a detailed description of specific challenges and possible solutions to forecasting issues in each country because this request would require conducting detailed investigations and providing detailed reports for every country. Such a project would be an enormous undertaking, which would tax CHAI's limited staffing band-width and detract from ongoing transition efforts. Such a process is not considered at this time.*
>
> *In the alternative, in the past we have provided a summary on a country-by-country basis, of our forecasting assistance to date. We are happy to provide that to you again, but we recommend a discussion between CHAI and UNITAID regarding the topic before we engage in this effort."*

[48] Document sent by UNITAID, called „CHAI responses to Project Assessment of UNITAID-CHAI Second-Line HIV/AIDS Project 2010 Semi-Annual Report"

9 Annex. Excepts of project's reference documents

Box 1. UNITAID CHAI 2007 and 2008 agreement on additionallity.

UNITAID CHAI 2007 Agreement

CHAI acknowledges that UNITAID is an initiative capable of providing to Beneficiary Countries additional resources in relation to national and other donors' resources. CHAI further acknowledges that UNITAID does not intend to promote either the displacement of previously committed resources to a national HIV/AIDS response to other public health areas, nor the reduction of resources in the overall National AIDS Programme budget of a Beneficiary country. CHAI thus agrees to work with countries and donors to help assure that UNITAID's resources are effectively additional.

UNITAID CHAI 2008 Agreement

As stated in the 7 December 2007 resolution of the Board, objectives of the Project for 2008 are two-fold: to scale-up the access to Second-Line ARVs to reach an additional 60,000 people in 2008 and to influence the market dynamics to further reduce the price of priority Second Line ARV drug regimens. An additional objective of the 2008 Project is to provide access to First Line regimens of tenofovir to an **additional** 80,000 people.

Box 2. Excerpt of Annex 7 to the 2008 Agreement: Plan of action.

The goal of the Program in 2008 is to broaden supply and decrease prices of second-line ARVs targeting to as low as US$ 400 per a WHO prioritized regimen per year, to scale up second-line treatment in 26 countries and increase the number of suppliers of quality products. The budget forecasts that the commodities purchased correspond to the treatment of an estimated 60.000 people with second line treatments, and an estimated 80.000 people with first line Tenofovir treatments in Zambia, Uganda and Namibia, and ensure continued funding of second-line treatment after the expected extension in 2009 ends.

Box 3. Excerpt of UNITAID CHAI 2009 Agreement.

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

Specific Objectives of the Second Line Project for 2009

The specific objectives of the 2009 Project are:

(i) provide access to Second-Line ARVs in Beneficiary Countries, which will reach an estimated 60,779 patients on Second-Line treatment and 55,834 patients on First-Line Tenofovir in 2009;
(ii) influence the market dynamics to further reduce the price of a priority Second-Line regimen; (iii) scale up Second-Line treatment in 25 countries; and (iv) increase the number of suppliers of quality Second Line ARVs in the marketplace.

Box 4. Excerpt of Appendix A to UNITAID CHAI 2009 Agreement: project plan.

The goal of the Project in 2009 is to 1) continue to broaden supply and decrease prices of second-line ARVs targeting to as low as US$ 500 per a WHO prioritized regimen per year, 2) to continue to scale up second-line treatment in 25 countries 3) prepare the Project to transition to other donors starting in 2010, and 4) increase the number of suppliers of quality second-line ARVs in the marketplace. In addition, the Project is supplying tenofovir for first line regimens on an exceptional basis.

Box 5. Excerpt of UNITAID CHAI 2010 Agreement.

Specific Objectives of the Second Line Project for 2010

The specific objectives of the 2010 Project are:
(i) provide access to Second-Line ARVs in Beneficiary Countries, which will reach an estimated 85,888 patients on Second-Line treatment and 39,900 patients on First-Line Tenofovir in 2010;
(ii) influence the market dynamics to further reduce the price of a priority Second-Line regimen; (iii) scale up Second-Line treatment in 17 countries; and (iv) increase the number of suppliers of quality Second Line ARVs in the marketplace.

Box 6. Excerpt of Appendix A to UNITAID CHAI 2010 Agreement: project plan.

The goal of the Project in 2010 is to 1) continue to broaden supply and decrease prices second-line ARVs targeting to as low as US$ 500 per a WHO prioritized regimen per year, 2) to continue to scale up second-line treatment in remaining participating beneficiary countries 3) make funds available for the targeted purchase of ATV/r in six countries, 4) for those countries not already transitioned, prepare the Project to transition to other donors starting in 2011, and 5) increase the number of suppliers of quality second-line ARVs in the marketplace. In addition, the Project is supplying tenofovir for first line regimens on an exceptional basis.

Box 7. Excerpt of Appendix A to UNITAID CHAI 2009 Agreement: project plan.

In addition to its responsibilities for procurement and delivery of Products, CHAI performs technical assistance for second-line ARVs and Project support for the Paediatric HIV/AIDS programs at the national level under the terms of a Paediatric Project Agreement with UNITAID. This project support is designed for Paediatric Project support, but also supports the Second-Line Project. 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. Portions of the costs associated with the Drug Access Team ("DAT") are covered by UNITAID support of CHAI

Box 8. Excerpt of Appendix A to UNITAID CHAI 2010 Agreement: project plan.

There are many reasons why the supply chains are failing but the most common problems experienced across the UNITAID countries are 1) stock out of commodities and 2) expired stocks.

While these problems occur in most countries, the reasons for these issues vary from lack of information, lack of forecasting tools and methods, poor distribution systems, poor inventory management to lack of skilled supply chain resources. CHAIs focus is traditionally on the supply chain, tackling commodity pricing and availability however as countries struggled with efficient distribution and the prevention of stock-outs once the commodities actually arrived they started to reach out to CHAI looking for assistance in addressing these demand side supply chain problems.

A Supply Chain expert from the private sector was hired to establish a specialist Global Supply Chain Management Team with a specific focus on in-country supply chain strengthening. Her work for the past 12 months has included 20 country visits working with the CHAI country teams and MOH in 4 key areas:
i. Conducting supply chain Assessments to better understand the challenges;
ii. Developing Action Plans and set priorities for in-country teams;
iii. Conducting Local and Global Training to build capacity; and
iv. Support to move existing supply chain initiatives forward.

The majority of the support has been focused on the whole system – either helping countries address their overall strategy/priorities e.g. Liberia and the development of their Supply Chain Technical Working Group with a focus on developing a Supply Chain Strategy, or on advising countries on their approach to decentralization as is the case in India and Dominican Republic.

CHAI would welcome the development of further plans to expand supply chain support across the Project in 2010 or 2011.

Box 9. Except of the first amendment to the agreement on the 2009 2010 project extension (Effective May 2008).

The contemplated objective of the 2009 Project is to support CHAI in its efforts to achieve further price reductions of ARVs (as low as USD$400 per patient annually), to introduce new priority products to the Project and to provide Second-Line ARVs to an additional 90,000 patients.

Box 10. Excerpt of the amendment to the 2009 project extension (dated November 2008).

In the 2008-2009 Second-Line Extension Proposal ("the Extension Proposal"), CHAI provided UNITAID an aggressive estimate of the lowest price of second-line treatment that could be achieved by the end of 2009 – $400 per patient annually. For clarification, this figure was created with the intention of providing UNITAID the most aggressive estimate for the potential reduction in prices, not a concrete goal or projection, based on the following assumptions: (1) The price of TDF+3TC could be reduced to as low as $125 per patient annually by the end of 2009.

(2) A heat-stable ATV/r FDC would be launched in 2008.
(3) The price of the ATV/r FDC could reach as low as $275 per patient annually by the end of 2009, based on growth in volumes from the product's assumed launch in 2008.
…
It is too early to predict the actual price reductions that CHAI will achieve in its negotiations with suppliers at the end of 2009/ beginning of 2010. However, CHAI can provide price projections for the upcoming round of supplier selection at the beginning of 2009. In this round, CHAI predicts that the annual price per patient for TDF+3TC+ATV/r will be lowered to $530 or below based on the following assumptions:
(1) The price of TDF+3TC is expected to fall below $150.

Box 11. Excerpt of UNITAID CHAI Request for Proposal dated October 2010.

Although UNITAID will finance purchases only for the countries specified in Section B of Schedules 1 and 2, respectively, it intends to extend prices agreed to other low and middle income countries as UNITAID may request, including the members of the CHAI Consortium.

Condition of participation of manufacturer

Manufacturer agrees to extend prices to additional countries that are not UNITAID beneficiaries for the second-line and paediatric projects, including, at a minimum, members of the CHAI Consortium

Box 12. Excerpt of CHAI UNITAID 2010 Agreement.

Under the terms and conditions of CHAI's MoU with the government of each Beneficiary Country, CHAI is also responsible for providing support to ensure the effective ordering, receipt and use of the medicines provided through the Project. Activities include product quantification, protocol review and guidance, coordination of the provision of necessary technical assistance and support to national drug regulatory authorities for timely registration of products.

Box 13. Summary of applicable UNITAID Quality Assurance standard for drugs procured in paediatric and second line projects.

All drugs procured under the UNITAID funded paediatric and second line projects are required to be in compliance with national regulatory standards

Box 14. Excerpt of CHAI UNITAID 2010 Agreement.

5.10.1 The Procurement Agent will be responsible for confirming that the Products are registered with the national drug regulatory authority of each Beneficiary Country or granted waivers of registration, if necessary, prior to the delivery of initial orders.
5.10.1.1 The Procurement Agent will communicate with the national drug regulatory authority of each Beneficiary Country to get information about drug registration, if necessary, prior to the delivery of initial orders and will convey this information to CHAI.
5.10.1.2 In case the product is not registered and CHAI confirms use of the supplier, CHAI shall be responsible for obtaining the necessary waiver for importation into the country of destination. CHAI will pass on this waiver to the Procurement Agent immediately upon receipt of the same.

5.10.1.3 The Procurement Agent will monitor the registration status of Products from the contracted suppliers and provide updates to CHAI on a quarterly basis and as otherwise requested.
5.10.2 CHAI will **provide substantial assistance to ensure necessary product registration** with the national drug authority, including requesting a Beneficiary Country's government to expedite the registration of products, or grant a waiver for registration, in line with the terms of the MOU signed between governments of Beneficiary Countries and CHAI as set out in Annex 10.

Box 15. Excerpt of the RFP.

Manufacturers selected by the outcome of the process set forth in this letter will be responsible for the following: manufacture of high-quality products; submission of dossiers for the registration of these products with the national drug regulatory authorities of the beneficiary countries…

Hence, all drugs procured for these projects are required to be in compliance with national regulatory standards

Box 16. Excerpt of Standard Terms and Condition for procurement of drugs under UNITAID.

Manufacturer further warrants that it shall obtain any and all necessary approvals from the appropriate National Drug Regulatory Authority ("NDRA") to distribute and sell all Products under a specific Purchase Order

Box 17. Excerpt of the 2010 MoU.

5.2.2.2 Project Support
Under the terms and conditions of CHAI's MoU with the government of each Beneficiary Country, CHAI is also responsible for providing support to ensure the effective ordering, receipt and use of the medicines provided through the Project. Activities include product quantification, protocol review and guidance, coordination of the provision of necessary technical assistance and support to national drug regulatory authorities for timely registration of products.

Box 18. <u>Excerpt of CHAI RFP for Second line and Paediatric ARV.</u>

For each product to be supplied, assurance of the manufacturer's capacity to supply up to 100 % of the volumes listed in Section A of Schedules 1 and 2, or, alternatively, assurance of the magnitude of capacity available for that product in 2011

Mandatory conditions of participation of manufacturers

If a Manufacturer is selected for a product (i.e., is either the primary or secondary Manufacturer or a member of the Manufacturer pool), in case of failure by the Manufacturer to perform under the terms and conditions of the purchase order, including but not limited to failure to make delivery of all or part of the goods by the agreed delivery date(s), the procurement agent may, after giving the Manufacturer reasonable notice to perform and without prejudice to any other rights or remedies, exercise one or more of the following rights:

• Procure all or part of the goods from another source(s), in which event the agent may hold the Manufacturer responsible for any excess cost occasioned thereby;
• Refuse to accept delivery of all or part of the goods; and/or
• Terminate the purchase order.

Box 19. Excerpt of CHAI UNITAID 2010 Agreement.

It is acknowledged that CHAI includes in its MoUs with Beneficiary Countries a commitment by the Country to provide UNITAID-financed Products free of charge to patients in order to facilitate the scale up of treatments; CHAI agrees to promptly notify UNITAID of any non-compliance in this regard of which it becomes aware

Box 20. Excerpt of CHAI MoU with beneficiary countries.

Commit to safe and secure storage and distribution of formulations comprising the free supply of adult ARV formulations to the intended destination(s) and vigorously attempt to prevent, detect and prosecute any diversion of such

Ensure that the formulations comprising the free supply of Adult ARV formulations are provided to patients free of charge and in accordance with the eligibility criteria

Box 21. Excerpt of 2008 Plan of action.

In cases where funding is currently available from other donors, this process might, for example, allocate the funds of another donor to services or commodities not in the scope of the UNITAID Program, if UNITAID funds are allocated to the full volume of commodities in scope for second-line treatment.

Box 22. Excerpts of 2008 and 2009 Annual report.

<u>2009 Annual Report</u>
In Cote d'Ivoire, a country which usually does not order all of its second-line ARVs through the Project, a shortfall of funding from other in-country partners led to increased commodity needs from the Project in the latter half of the year
<u>2008 interim report</u>
Cote d'Ivoire is the only country which has not re-ordered as they are currently procuring most second-line ARVs through other partners and only using the UNITAID program for emergency and stock out situation

10 Annex. Tables and figures

Table 2. UNITAID/CHAI Agreement objectives, project plan activities and M&E log frame actions, indicators and targets.

	Objectives		Activities (Project plan)		Activities (Annex 5)	Indicators (Annex 5)
1	Scale up the access to Second Line ARVs 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 Second-Line to be supplied in 2010	5.2	Sign Amendments to MoU containing updated annexes of ARVs to be supplied in 2010	Percent of beneficiary countries with signed amendments and updated annexes with ARVs 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 in 2010	Forecast of estimated quantity of ARVs, and estimated number of patients to be treated in 2010
				5.3	Engage in forecasting with countries for the purposes of estimating purchases of ARVs in 2010	Forecast of estimated patients to be treated with ARVs purchased in 2010
		5.12	Placement of Purchase orders for and Delivery of Products	5.12a	Placement of Purchase Orders for and Delivery of Products	Percent of value of ARVs packs ordered and delivered by each countries that match the value of ARVs packs budgeted
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	5.7a	Identify potential suppliers and prices to be paid for products in 2010	Number of suppliers in each product area where possible
				5.7b	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	5.8	Enter into contractual arrangement with suppliers for the supply of ARVs based on the outcome of the application selection and price negotiation process for the product	Per cent of suppliers that have signed MSAs or other 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	5.9b	Determine the suppliers to be used for each purchase order (Monitoring of supplier development and usage)	Number of suppliers that have had products registered or applied for waivers during 2010, including those still supplying product based upon previous waiver(s)
		5.10	Work to improve market for UNITAID-funded commodities to support UNITAIDs mission of lowering prices and broadening supplier base	5.10	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 ARV formulations available each year
4	Decrease product delivery lead times	5.9	*See above*	5.9a	Determine the suppliers to be used for each purchase order (Monitoring of supplier performance)	Decrease lead time from purchase order to delivery in country
		5.14	Provide staff to manage procurement activities of Second-Line Project	5.13	Facilitate improvements in in-country distribution systems for ARVs	Project support provided where needed to increase the timely delivery of products to ports of entry or a designated Central Medical Store

	Objectives		Activities (Project plan)		Activities (Annex 5)	Indicators (Annex 5)
5	Encourage prequalification 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	5.10	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 ARV formulations available each year
6	Apply appropriate procurement strategies to develop a healthy market that favours competition and sustainability, with reductions in prices	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	5.7a	Identify potential suppliers and prices to be paid for products in 2010	Number of suppliers in each product area where possible
				5.7b	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	5.8	Enter into contractual arrangement with suppliers for the supply of ARVs based on the outcome of the application selection and price negotiation process for the product	Per cent of suppliers that have signed MSAs or other long term agreements
		5.11	Submission of Order Requisition by Country Teams to Central Project Managers on a quarterly basis	5.11	Submission of Order Requisitions by Country Teams to Central Project Managers on a quarterly basis	Per cent of orders (per product area) placed through pooled procurement
		5.18	Identify 2011 commodities required and plan procurement processes	5.18	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.
	General Project Implementation activities	5.15	Provision of robust staff support to Second-Line project		n/a	n/a
		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

Table 4. Lead times per supplier per year in days.

Suppliers	2008	2009	2010
Cipla Ltd.	41	N/A	75.15
Abbott Logistics B.V.	55	N/A	78.45
Matrix Laboratories Ltd	58	N/A	101
Aspen Pharmacare International Pty. Ltd.	62	N/A	N/A
Aurobindo Pharma Ltd.	64	N/A	104.78
Bristol-Myers Squibb	89	N/A	N/A
Glaxo Smith Kline Export Ltd	103	N/A	N/A
Hetero			42.83
Emcure			44.5

Source: CHAI Annual Reports

Table 6. E&Y recommendations following assessment of CHAI procurement arrangements under second-line and paediatric projects.

#	E&Y recommendation	Evaluators comments
1	Target price reductions should be defined and agreed upon between CHAI and UNITAD.	CHAI's specific objectives in the 2009 and 2010 project plan include a target price for second-line treatment per patient per year. More detailed targets for price reductions per ARV may not be feasible as they depend on various factors over which CHAI may have little influence.
2	A strategy should be developed to manage the risk of foreign exchange price fluctuation	Each agreement includes a part concerning "risk review, risk mitigation", which primarily concerns the exchange rate. All annual reports mentioned that no exchange rate mitigation was conducted. However, the 2010 UNITAID/CHAI Agreement has a section on the risk mitigation strategy. The evaluators lack information on actual implementation.
3	Targets should be defined in terms of number of suppliers to be induced into the market of different products	The target under the objective 'Stimulate an increase in the number of quality assured manufacturers and products' is 'at least 3 suppliers available for 4 of the existing products'. This target does not fully reflect CHAI's performance in increasing competition by increasing the number of suppliers induced into the market. However, as previously stated, it would be unfair to assess CHAI's performance against a more precise target because there are many factors that determine the induction of new suppliers into the market, and CHAI has limited influence over these.
4	Sole sourcing of products should be avoided and where more than one supplier is available in the market	According to the procurement evaluation report, only one ARV was sole sourced. In that case, there was only one eligible supplier.
5	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 that exceeded 15 % of the budget.
6	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 evaluators could not review the status of this recommendation.
7	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 the E&Y evaluation report) that was being developed and to be implemented in 2009, was not shared with the evaluators.
8	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 the revised version, dated November 2009, both include in an annex, a declaration of conflict of interest for members of the adjudication panel, and a section on conflict of interest.
9	CHAI should enter into MSA with all suppliers sourcing products for UNITAID projects	The PO terms appear to provide a guarantee of drug quality, and CHAI, as stated in CHAI's reply to UNITAID comments on the 2010 interim report, did not plan to sign MSAs with all suppliers. Instead only CHAI only signed with primary and secondary suppliers. Based on the information available to the evaluators, this recommendation has not been implemented.
10	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	This recommendation addresses an important project weakness, but should not result in establishment of a parallel system to the existing national health and information system, despite the latter being weak in some countries. On a quarterly basis, CHAI reviews its forecasting against available consumption data which contributes to mitigating the risk of excess stock/ stock outs. As stated earlier, UNITAID could have been more informed about countries' situation, especially on the availability of quality data on patients and consumption, and on the in-country stocks built with UNITAID funds.
11	CHAI should follow the process of approval of OR as required by the SOP	The evaluators could not review the status of this recommendation.

12	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.
13	Only drugs meeting shelf life requirements should be delivered to recipient 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	According to CHAI's annual report, drugs with a shorter shelf life were delivered to countries upon receipt of approval from MoH (please refer to annex 7 of 2010 annual report). In 2010, this was the case in Mali, Togo, Cameroon, Zimbabwe and Botswana
14	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 the PO. On pooled procurement, the evaluators reckon, based on available evidence, that order pooling was quite successful under the project and that CHAI should enjoy some level of flexibility in order to address emergency situations
15	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 action	The evaluators could not review the status of this recommendation.
16	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.
17	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	The evaluators could not review the status of this recommendation. However, the 2010-2011 project extension request clearly stipulates that *approval for payment of CSD costs is granted on a case-by-case basis following submission of a written request by the specific country office, and authorized by the CHAI/UNITAID Liaison Officer, justifying the proposed use of UNITAID funds.* Moreover the 2010 UNITAID Agreement includes an SOP on payment of CSD costs which states that *legitimate CSD costs are payable with UNITAID funds only if they can be shown to have met the following two criteria:* *• Cannot be paid or waived by the Government, or paid by another donor* *• Represent the best available supplier, achieved through a competitive and transparent process for supplier selection*
18	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
19	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
20	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

Table 7: Estimated number of patients treated with second-line ARVs, by country.

Country	Estimated patients supported		
	2008	2009	2010
Benin	1,108	96	110
Botswana	3,293	1,921	0
Burkina Faso	0	0	0
Burundi	789	1,040	1,536
Cambodia	1,686	1,259	1,404
Cameroon	1,192	788	1,444
Chad	189	298	580
Cote d'Ivoire	0	900	0
DR Congo	180	480	900
Ethiopia	1,457	2,501	0
Ghana	210	0	0
Haiti	222	325	645
India	200	338	2,750
Kenya	7,888	17,141	17,992
Malawi	1,217	430	0
Mali	450	700	0
Mozambique	868	1,940	2,050
Namibia	962	788	0
Nigeria	6,421	13,020	13,020
Rwanda	1,042	730	0
Senegal	561	431	639
Tanzania	729	3,020	0
Togo	1,000	845	1,100
Uganda	6,069	10,282	13,873
Zambia	7,599	7,038	11,952
Zimbabwe	774	1,179	1,347
Total	**46,106**	**67,490**	**71,342**

Source reference: Annual reports 2008, 2009 and 2010

Table 8. Estimated number of patients treated with first-line TDF based therapy, by country.

Country	Estimated patients supported		
	2008	2009	2010
Namibia	4,053	0	0
Uganda	14,000	17,716	19,750
Zambia	69,163	32,118	20,100
Total	**87,216**	**49,834**	**39,850**

Source: CHAI Annual Reports 2008, 2009 and 2010

Table 9. Achievement of health outcome.

Year	Second-line ART			First-line TDF based ART		
	Targets (a)	Patients potentially treated (b)	Achievement rate Ratio (b)/(a)	Targets (c)	Patients potentially treated (d)	Achievement rate (d)/(c)
2008	60,000	46,107	76.85	80,000	87,216	109.02
2009	60,779	67,490	111.04	55,834	49,834	89.25
2010	85,888	71,342	83.06	39,990	39,850	99.65
Average			**89.49**			**100.61**

Source: For the treatment targets, see the 1st Amendment to the Agreement, 2008; and the 2009 and 2010 Agreements
For the number of patients treated, see the Annual Reports for 2008, 2009 and 2010

Table 10. Number of packs delivered per country under the project.

Country	2007	2008	2009	2010	TOTAL
Ghana	0	3,807	0	0	3,807
Benin	0	5,597	3,830	9,600	19,027
Botswana	49,409	120,654	43,986	224,262	438,311
Burundi	10,831	8,195	33,809	49,640	102,475
Cambodia	15,016	28,314	68,789	50,364	162,483
Cameroon	35,898	24,229	43,358	156,730	260,215
Chad	15,471	4,968	8,521	40,770	41,828
Cote d'Ivoire	11,828	0	30,000	0	41,828
DR Congo	3,556	15,414	22,164	70,114	111,248
Ethiopia	18,060	42,900	58,016	17,505	136,481
Haiti	3,000	4,000	19,445	27,285	53,730
India	2,160	27,154	16,900	52,607	98,821
Kenya	34,300	222,921	846,364	392,012	1,495,597
Malawi	17,650	14,040	6,858	0	38,548
Mali	250	26,757	39,400	21,510	87,917
Mozambique	34,490	17,600	42,135	85,189	179,414
Namibia	8,515	57,349	7,915	2,600	76,379
Nigeria	29,382	97,384	269,948	296,319	693,033
Rwanda	6,745	43,925	30,230	0	80,900
Senegal	15,675	16,159	1,300	47,515	80,649
Tanzania	5,730	43,501	87,374	0	136,605
Togo	22,699	3,000	15,307	86,505	127,511
Uganda	216,458	399,921	571,'712	829,523	2,017,614
Zambia	136,315	739,780	664,623	591,108	2,131,826
Zimbabwe	9,230	35,651	39,132	114,612*	198,625
Total	**702,668**	**2,003,220**	**2,971,116**	**3,1165,770**	**8,814,872**

* For Zimbabwe, figures include 48'566 packs pending delivery.

Source: Annex 2, Annual Report 2010.

Table 11. Number of ARVs approved by a SRA between 2007 and 2010.

ARVs	2007	2008	Variance	2009	Variance	2010	Variance
ABC 300mg	4	5	+1	6	+1	8	+2
Atazanavir 300mg				1	+1	3	+2
ddI EC 250mg	2	3	+1	3	0	4	+1
ddI EC 400mg	2	3	+1	3	0	4	+1
LPV/r200/50mg	1	2	+1	4	+2	4	0
Ritonavir hs 100mg						2	+2
TDF 300mg	2	3	+1	5	+2	7	+2
TDF+3TC 300/200mg	N/A	1	+1	2	+1	2	0
TDF+FTC 300/300mg	1	1	0	3	+2	3	0
Total			**+6**		**+9**		**+10**

Source: CHAI Annual Reports

Table 12: Number of ARV newly pre qualified by WHO between 2007 and 2010

ARVs	2007	2008	2009	2010
ABC 300mg		+3		
ATV 300mg				+1
ddI 250mg				
ddI 400mg				
LPV/r 200mg+50mg			+1	
RTV 100mg				+2
TDF 300mg			+3	
TDF+3TC 300mg+300mg				+1
TDF+FTC 300mg+200mg				+1
TOTAL	0	+3	+4	+5

Source: WHO prequalification project website

Table 13. Number of eligible suppliers per ARV (SRA approved or WHO pre-qualified)

ARVs	2007	2008	Annual Progress	2009	Annual Progress	2010	Annual Progress	Progress since project's inception
ABC 300mg	4	5	+1	6	+1	8	+2	+4
Atazanavir 300mg				1		4	+3	+3
ddI EC 250mg	3	3	0	5	+2	5	0	+2
ddI EC 400mg	3	3	0	5	+2	5	0	+2
LPV/r200/50mg	4	4	0	5	+1	5	0	+1
Ritonavir hs 100mg						2	+2	+2
TDF 300mg	2	3	+1	6	+3	8	+2	+6
TDF+3TC 300/200mg	1	2	+1	3	+1	4	+1	+3
TDF+FTC300/300mg	2	4	+2	4	0	5	+1	+3
Total			**+4**		**+10**		**+11**	**+25**

Source: CHAI Annual Reports (table 3.8)

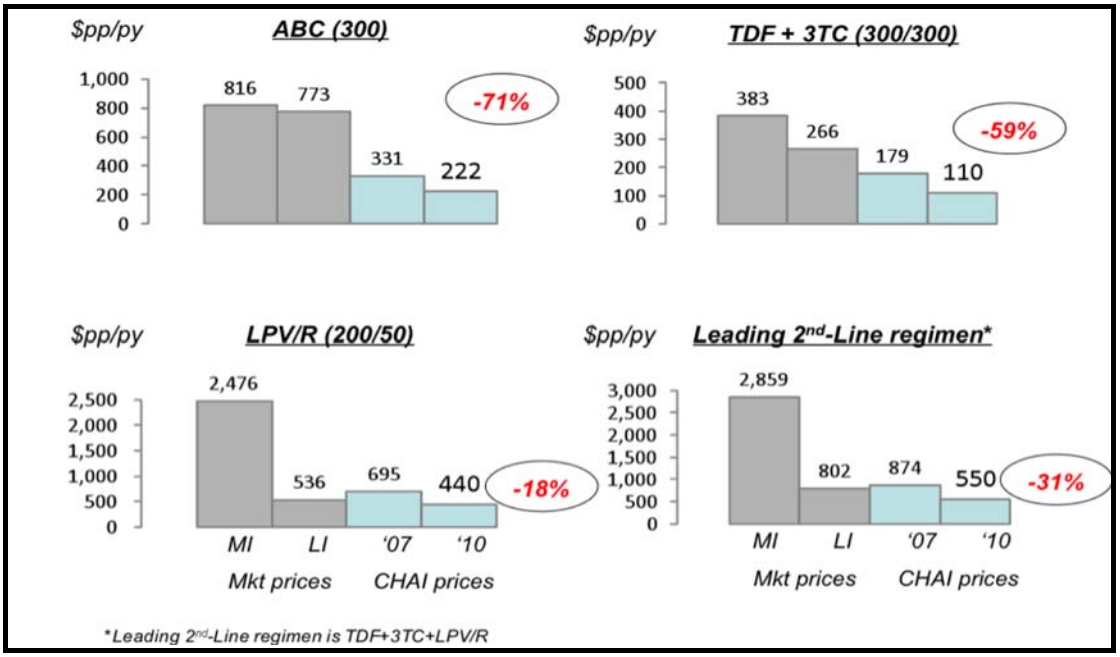
Table 14. Prices negotiated between 2007 to 2010 with primary and secondary suppliers – Final price per pack (US$)

Price reductions achieved between 2007 and 2010

ARVs	Supplier	2007 price	2008 price	2007-08 change (%)	2009 price	2008-09 change (%)	2010 price	2009-10 change (%)	2007-10 change (%)
ABC 300mg									
ABC 300mg	Primary	27.58	25.75	-7	19	-26	15.99	-16	-42
ABC 300mg	Secondary	28.30	23.00	-19	19	-17	16.85	-11	-16
ddI EC 250mg									
ddI EC 250mg	Primary	12.97	14.14	9	13.00	-8	13.00	0	-0.2
ddI EC 250mg	Secondary	18.34	18.34	0	18.34	0	14.14	-23	-23
ddI EC 400mg									
ddI EC 400mg	Primary	20.65	22.20	8	20.00	-10	20.00	0	-3
ddI EC 400mg	Secondary	23.67	23.67	0	23.67	0	21.98	-7	-7
TDF 300mg									
TDF 300mg	Primary	12.42	12.45	0	8.25	-34	6.80	-18	-45
TDF 300mg	Secondary	12.66	17.00	34	17.00	0	7.00	-59	-45
LPV/r200/50mg									
LPV/r200/50mg	Primary	41.10	41.10	0	36.75	-11	36.16	-2	-12
LPV/r200/50mg	Secondary	57.92	47.21	-18	36.75	-22	35.00	-5	-40
TDF+3TC300/300mg									
TDF+3TC300/300mg	Primary	14.92	14.25	-4	10.00	-30	8.81	-12	-41
TDF+3TC300/300mg	Secondary	15.41	/	NA	11.48	NA			
TDF+FTC 300/200mg									
TDF+FTC 300/200mg	Primary	26.25	17.08	-35	11.75	-31	11.48	-2	-56
TDF+FTC 300/200mg	Secondary	18.75	26.25	40	11.72	-55	11.48	-2	-39

Source: Annual reports 2008 and 2010

Figure 2. Comparison of the average market price of Second-Line ARVs per patient per year and CHAI prices.



Source: The UNITAID-CHAI ARV projects: Transition update and next steps, November 10, 2010 Presentation to UNITAID board

Table 15. Comparison of the price for second-line ARVs negotiated with primary and secondary suppliers by CHAI under the UNITAID partnership, the CHAI consortium and SCMS for the PEPFAR-funded project.

Prices in the table below are highlighted when they are lower than the CHAI primary supplier's price.

ARV		2007 price	2008 price	2009 price	2010 price	2011 price
ABC 300mg						
CHAI UNITAID I		27.58	25.75	19	15.99	
CHAI UNITAID II		28.3	23	19	16.85	
CHAI			25	19.5	18.5	17.5
SCMS		28.08	25.96	22.49	16.68	
ddI EC 250mg						
CHAI UNITAID		12.97	14.14	13	13	
CHAI UNITAID II		18.34	18.34	18.34	14.14	
CHAI			12.5	13		
SCMS			13.26	13.65	13.65	
ddI EC 400mg						
CHAI UNITAID		20.65	22.2	20	20	
CHAI UNITAID II		23.67	23.67	23.67	21.98	
CHAI			20	20		
SCMS		24.14	20.4	21	21	
TDF 300mg						
CHAI UNITAID		12.42	12.45	8.25	6.8	
CHAI UNITAID II		12.66	17	17	7	
CHAI			11.25	8.25	7.25	6.5
SCMS		17.34	13.55	8.96	6.9	
LPV/r200/50mg						
CHAI UNITAID		41.1	41.1	36.75	36.16	
CHAI UNITAID II		57.92	47.21	36.75	35	
CHAI			45.83	39.17	36.67	33.3
SCMS		41.92	41.92	37.97	37.8	
TDF+3TC300/300mg						
CHAI UNITAID		14.92	14.25	10	8.81	
CHAI UNITAID II		15.41	/	11.48	0	
CHAI			13.25	10	9.17	8.3
SCMS			14.54		8.82	

Source: CHAI Annual Reports, the CHAI ARVs ceiling price list and the MSH ERC International Drug Price Index

Table 16. GPRM median price cost per patient per year (in US$)

GPRM median price cost per patient per year (in US$)		2004	2005	2006	2007	2008	2009	2010	2004 - 2007	2007 - 2010			GPRM 2007	GPRM 2010	CHAI 2010	
Median transaction price (25th -75th Quartile range)		(US$/ ppy)	(US$/ ppy)	(US$/ ppy)	(US$/ ppy)	(US$/ ppy)	(US$/ ppy)	(US$/ ppy)	vari-ance	vari-ance	De-fined daily dose	Pack size	US$/pac k	US$/pac k	Primary supplier	Secon-dary supplier
ABC 300mg	*LIC*	887	887	578	426	313	280	203	-52 %	-52 %	2	60	35.0	16.7	15.99	16.85
	MIC	887	954	951	410	350	271	206	-54 %	-50 %	2	60	33.7	16.9		
ddI EC 250mg	*LIC*	N/A	N/A	N/A	N/A	223	284	172			1	30		14.1	13	14.14
	MIC	N/A	N/A	N/A	N/A	799	190	159			1	30		13.1		
ddI EC 400mg	*LIC*	253	288	288	288	288	261	246	14 %	-15 %	1	30	23.7	20.2	20	21.98
	MIC	1876	902	988	1811	1267	274	244	-3 %	-87 %	1	30	148.8	20.1		
TDF 300mg	*LIC*	316	301	219	207	166	151	89	-34 %	-57 %	1	30	17.0	7.3	6.8	7
	MIC	279	234	344	225	207	154	91	-19 %	-60 %	1	30	18.5	7.5		
LPV/r200/50mg	*LIC*	N/A	N/A	500	500	500	501	440		-12 %	4	120	41.1	36.2	36.16	35
	MIC	N/A	N/A	1489	1085	1000	1000	575		-47 %	4	120	89.2	47.3		
TDF+3TC300/300mg	*LIC*	N/A	N/A	N/A	N/A	173	140	114			1	30		9.4	8.81	
	MIC	N/A	N/A	N/A	N/A	N/A	N/A	596			1	30		49.0		
TDF+FTC 300/200mg	*LIC*	N/A	362	318	320	319	319	137		-57 %	1	30	26.3	11.3	11.48	11.48
	MIC	N/A	N/A	360	357	475	385	137		-62 %	1	30	29.3	11.3		

Source: WHO GPRM

Table 17. MSH IDPIG annual median pack prices (in US$)

ARVs	2005	2006	2007	2008	2009	2010t	Variance 2007 - 2010
ABC 300mg	86.0	55.6	42.4	40.7	29.4	24.5	-42%
ddI EC 250mg		18.7	23.0	13.3	13.3	13.7	-41%
ddI EC 400mg		24.5	21.0	20.4	21.0	21.0	0.2%
TDF 300mg		17.3	17.3	13.6	9.0	9.2	-47%
LPV/r200/50mg		41.9	41.9	41.9	38.0	48.3	15%
TDF+3TC300/300mg				15.1		11.7	N/A
TDF+FTC 300/200mg		26.8	26.8	26.8	12.3	15.0	-44%

Source: MSH IDPIG