

UNITAID

Mid-Term Review

Acceleration of the prevention of Mother to Child
Transmission (PMTCT-1)

Partners: UNICEF, WHO

FINAL

Swiss Centre for International Health
Swiss Tropical and Public Health Institute

Final Draft Report

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Table of Contents

Executive Summary.....	1
1 Project Description	3
2 Approach and methods	6
2.1 Evaluation components	6
2.2 Methods.....	7
2.3 Project specific	10
3 Findings	11
3.1 Relevance.....	11
3.2 Effectiveness	19
3.3 Efficiency	32
3.4 Impact.....	35
3.5 Project Specific Questions	37
3.6 Comments on reporting arrangements.....	39
3.7 Projects Strengths, Weaknesses, opportunities and Threats (SWOT)	45
5 Conclusions and Recommendations.....	47
Annex 1: Evaluation Matrix, Common questions.....	52
Annex 2: Evaluation Matrix, PMTCT specific questions.....	55
Annex 3: Evaluation Matrix, Reporting checklist	56
Annex 4: Meetings with Stakeholders and List of Persons Interviewed.....	57
Annex 5: List of Documents Reviewed.....	62

Abbreviations

3TC	Lamivudine
ANC	Antenatal Care
AR	Annual Report
ART	Antiretroviral Therapy
ARV	Antiretroviral
AZT	Zidovudine
CDC	Communicable Disease Control
CHAI	Clinton Health Access Initiative
CMS	Content Management System
CTX	Cotrimoxazole
DBS	Dry Blood Spot
EB	UNITAID Executive Board
EID	Early Infant Diagnosis
EMA	European Medicines Agency
Eoi	Expression of Interest
ERP	Expert Review Panel
FDA	Food and Drug Administration
GF	Global Fund to fight AIDS, Tuberculosis and Malaria
HAART	Highly Active Antiretroviral Treatment
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome
HIV+PW	HIV infected Pregnant Women
HIV-PW	HIV uninfected Pregnant Women
HMIS	Health Management Information System
IATT	Inter-agency Task Team on HIV prevention among Pregnant Woman, Mothers and their Children
IR	Interim Report
ITB	Invitation to Bid
KPI	Key Performance Indicator
LIC	Low Income Countries
LMIC	Low-Middle Income Countries
LTA	Long Term Agreement
MBP	Mother and Baby Pack
M&E	Monitoring and Evaluation
MoH	Ministry of Health
MTCT	Mother to Child Transmission
MoU	Memorandum of Understanding
NVP	Nevirapine
OECD	Organisation for Economic Co-operation and Development
OIG	Office Inspector General
OPEC	Organization of the Petroleum Exporting Countries
OPR	Official Purchase Request
PCR	Polymerase Chain Reaction
PEPFAR	President's Emergency Plan for AIDS Relief
PMTCT	Prevention of Mother to Child Transmission
PSM	Procurement Supply Chain Management
PO	Purchase Order
QA	Quality Assurance
RFP	Request For Proposal
RUTF	Ready to use Therapeutic Food
SAM	Severe Acute Malnutrition
Swiss TPH	Swiss Tropical and Public Health Institute
SWOT	Strengths, Weaknesses, Opportunities and Threats
TA	Technical Assistance
UNICEF	United Nations Children's Fund
WAP	Weighted Average Price
WHO	World Health Organization
WHO EMP	WHO Essential Medicines Programme

Executive Summary

The mid-term review covers the UNITAID funded Project “Acceleration of Prevention of Mother-to-Child Transmission (PMTCT) and scale-up of Linkages to Paediatric HIV Care and Treatment for 2007-2009”. The project was launched in 2007 and has since then been subject to several amendments. Today, the project consists of four project components: 1st PMTCT Component, Expansion Component, Nutrition Component and Extension Component. The project is coordinated by the United Nations Children's Fund (UNICEF), in collaboration with the World Health Organisation (WHO).

Methodology

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

Project key information

The four project components of the PMTCT project (see Table 1) have separate project outlines, objectives and budgets:

1. 1st PMTCT Component – MoU December 2007
2. Expansion Component – agreed in 1st Amendment to MoU, July 2009
3. Nutrition Component – agreed in 1st Amendment to MoU, July 2009
4. Extension component – agreed in 2nd Amendment to MoU, December 2010

Table 1. PMTCT Initiative: The four Project Components.

	1st PMTCT Component	Expansion Component	Nutrition Component	Extension Component
Project period	2007 to 2009, extended to June 2011	Mid-2009 to mid-2011	Mid-2009 to mid-2011	2011
Recipient countries	Burkina Faso, Ivory Coast, Cameroon, Rwanda, Tanzania, Malawi, Zambia, India	Central African Republic, China, Haiti, Lesotho, Myanmar, Nigeria, Swaziland, Uganda and Zimbabwe	Rwanda, Tanzania, Malawi, Zambia	Ivory Coast, Cameroon, Rwanda, Tanzania, Malawi, Zambia, India
Amount approved (MoU)	20'838'432 USD	46'679'993 USD	4'510'847 USD	26'763'660 USD
Implementing partners	UNICEF and WHO	UNICEF and WHO	UNICEF and WHO	UNICEF and WHO

Key findings

The key findings are relevant for all project components if not indicated otherwise.

- All objectives (9 in total) were measured with at least one indicator in all four project components.
- Budget Execution Rate was 100% and Budget Absorption Rate was 57% for 1st PMTCT, 27% for Expansion Component and 39% for Nutrition Component.
- Major issues are related to the M&E log frame and corresponding project reporting.
- Project management is marked by several limitations.
- No information is available on patients treated or treatments delivered. A proxy of “number of products procured” was used for reporting on health outcome targets.

- Re-allocations of budgeted quantities for procurement resulted in achievements according to proxy reporting that are very different from the targets:
 - 1st PMTCT Component, Years 1 and 2: procured PMTCT-related commodities for maternal interventions 2'186'461 or 102 % of target achievement; for paediatric interventions 2'143'137, 58% target achievement.
 - Expansion Component Years 1 and 2: procured PMTCT-related commodities for maternal interventions 6'947'783, 74 % target achievement; for paediatric interventions only 67'371 or 17% of targeted commodities were procured.
 - Nutrition Component: no data reported on products procured.
- The following achievements are reported for market related outcome indicators:
 - 1st PMTCT and Expansion Components:
 - Price reductions were achieved for Antiretrovirals (ARVs) and RDTs according to the targets.
 - Two new prequalified paediatric ARVs were reported.
 - Lead-time has not been reported at a sufficient level of detail, as defined in the indicator target and therefore assessing the achievement of the indicator has not been possible.
 - Development of the Mother Baby Pack (MBP) encountered several challenges, such as delays, complexity of treatment guidelines and finally a suspension of its further production and distribution. A major concern regarding the MBP is also the differing views of the project partners on the extent of UNITAID funding for the MBP.
 - Nutrition Component:
 - Identification and approval of 2 new Ready to use Therapeutic Food (RUTF) products for procurement.
 - Authorisation of two new local African RUTF manufacturers, however information on signed Long Term Agreements (LTAs) specified for the target of this indicator is missing and therefore the target cannot be reported as achieved.
- Extensive technical assistance in relation to forecasting and supply management, assessment of training needs, M&E, implementation of updated WHO PMTCT guidelines, and country scale-up plans has been provided in all recipient countries delivered by implementing partners: UNICEF and WHO.
- The UNITAID funded PMTCT project was integrated into the national forecasting processes and thorough coordination of funding sources improved the possibility of avoiding funding overlaps, as well as stock-outs of key PMTCT related commodities. However, the evaluation team had no access to national forecasts and information on the proportion of the contribution to PMTCT related procurement.
- No plan is in place for a transition of the project to more sustainable funding sources.
- No measurable impact of the effects on the global market for PMTCT related commodities could be verified.

Key recommendations

The evaluation resulted in 15 recommendations related to the conclusions made by the evaluation team. It is not recommended to approve cost extensions for all three project components, in order to support project completion. Special emphasis should be placed on five of the recommendations:

1. Implementation of a performance based monitoring and disbursement system.
2. Identification of suitable indicators that support reporting on project-specific achievements.
3. Formalise involvement in national forecasting with integrated project-specific forecasting. This would improve the possibility to assess the proportion of UNITAID contributions to overall PMTCT related procurement.
4. Report on interests earned.
5. Clarify the status of the Mother and Baby Pack as a part of the UNITAID funding.

1 Project Description

The UNITAID funded Prevention of Mother to Child Transmission (PMTCT) Initiative, which was evaluated as part of the present mid-term reviews, has four components (see Table 2 below for details).

1. First PMTCT Component
2. Nutrition Component
3. Expansion Component
4. Extension Component

Each component has its own separate project and time plans, budget, beneficiary countries, objectives and disbursement, and reporting plans. 2010 was marked by a funding gap for seven of the UNITAID funded recipient countries pertaining to the 1st PMTCT Project Component, as negotiations were ongoing for an extension of the project. The funding gap was covered by joint efforts of other funding agents such as PEPFAR and the Global Fund. The Initiative has undergone several adjustments (1st and 2nd Amendment) since 2007, as presented in Table 2 below.

Table 2. PMTCT Project Components, Time periods, budget and scope.

MoU	Period covered (signature date)	Amount (USD, Treatment Targets*)	Scope
1st PMTCT Component¹	2007-2009 (extended to June 2011) (10 December 2007)	Total: 20'893'506 USD (EB approved ceiling), 20'838'432 USD (MoU) Total Treatment Targets*: 2'397'700 Treatments	8 countries LIC and LMIC: Burkina Faso, Ivory Coast, Cameroon, Rwanda, Tanzania, Malawi, Zambia, India
Nutrition Component² (1st Amendment)	2009-2011 (31 July 2009)	Total: 4'764'288 USD (EB approved ceiling), 4'510'847 USD (MoU) Total Treatment Targets*: 757'406 Treatments	4 countries of the 1st PMTCT Initiative: Malawi, Rwanda, Tanzania and Zambia
Expansion Component³ (1st Amendment)	2009-2011 (31 July 2009)	Total: 50'009'221 USD (EB approved ceiling); 46'679'993 USD (MoU) Total Treatment Targets*: 9'845'717 Treatments	9 additional countries: Central African Republic, China, Haiti, Lesotho, Myanmar, Nigeria, Swaziland, Uganda and Zimbabwe
2010 UNITAID funding gap			
Extension Component⁴ (2nd Amendment)	Jan – Dec 2011 (22 December 2010)	Total: 28'799'353 USD (EB approved ceiling); 26'763'660 USD (MoU) Total Treatment Targets*: 1'9780'740 Treatments	7 countries of the 1st PMTCT Component, except for Burkina Faso: Ivory Coast, Cameroon, Rwanda, Tanzania, Malawi, Zambia, India

* Total Treatment Targets also includes patients receiving diagnostics linked to PMTCT (RDTs, etc.)

1st PMTCT Component

On 10th December 2007 an initial Memorandum of Understanding (MOU) was signed between UNITAID, the United Nations Children's Fund (UNICEF) and the World Health Organisation (WHO) to launch the project "Prevention of Mother to Child Transmission of HIV Initiative 2007-2009 and scale-

¹ MoU for 1st PMTCT Component 2007-2009 10 December 2007, Annex 1: Project Plan

² 1st Amendment to MoU 31 July 2009, Annex 2: Nutritional Final Project Plan

³ 1st Amendment to MoU 31 July 2009, Annex 3: Expansion Project Plan

⁴ 2nd Amendment to MoU 22 December 2010, Annex 1B: Project Plan for Extension

up of Linkages to Paediatric HIV Care and Treatment”, hereafter referred to as the 1st PMTCT Component. The overall aim of the project is “to contribute to the acceleration of the global scale up of national PMTCT programs with the explicit associated benefits of improved maternal and child health and survival in the context of universal access to HIV prevention, treatment, care and support services”⁵. In the MoU, a budget of 20’838’432 USD was allocated to finance the supply of drugs, diagnostics and related commodities for PMTCT interventions. Eight countries with high Mother to Child Transmission (MTCT) were selected as beneficiary countries (Burkina Faso, Ivory Coast, Cameroon, Rwanda, Tanzania, Malawi, Zambia and India). The UNITAID Executive Board (EB) originally approved a funding ceiling of 20’893’506 USD. A total of 2’397’700 maternal and paediatric treatments, as expressed in the MoU (includes prophylaxis courses and diagnostic reagents and supplies), were planned for delivery, and complied with the WHO PMTCT treatment guidelines. Interventions included:

- Introduction of health provider initiated HIV testing and counselling with the option to opt out in antenatal, childbirth and postpartum care settings.
- Phasing in of more efficacious ARV prophylactic regimens and moving away from single dose Nevirapine.
- Increasing access to Antiretroviral Therapy (ART) for HIV-infected pregnant women in need of treatment for their own health, including timely immunological assessment using CD4 cell counts for decision-making.
- Increase access for HIV-infected pregnant women, mothers and their children to Cotrimoxazole prophylaxis to ward off opportunistic infections.
- Optimizing identification of HIV-infected infants using highly sensitive polymerase chain reaction (PCR) and Dry Blood Spot (DBS) technologies.

The 1st Component has received an extension until June 2011, when a final report will be submitted.

Expansion Component

The Project “Acceleration of Implementation of Comprehensive PMTCT Services in the ‘Era of Access’ of HIV Care and Treatment”, hereafter called the Expansion Component, is the expansion of the 1st PMTCT Component to nine additional countries in order to increase the global response to PMTCT through scaled-up provision of drugs and diagnostic commodities. The MoU was signed on the 31st July 2009 as a 1st Amendment to the original MoU. The project includes the same maternal and paediatric interventions, as listed above for the 1st PMTCT Component. The UNITAID funding for the two-year project period amounts to 46’679’993 USD, to reach a target of 9’845’717 treatments. The EB approved funding ceiling was 50’009’221 USD.

Nutrition Component

The Project “Acceleration of Nutritional Care for Pregnant Women and Lactating Women and Children linked to PMTCT: address Nutritional Problems that Impact Negatively on PMTCT outcomes”, called the Nutrition Component, was also signed on the 31st July 2009 as part of the 1st Amendment to the 1st PMTCT Component. A budget of 4’510’847 USD has been allocated to attain the target of 757’406 treatments within a two-year period in four of the eight original beneficiary countries (Malawi, Rwanda, Tanzania, Zambia) of the 1st PMTCT Component. The approved EB Ceiling amounted to 4’764’288 USD. Existing PMTCT services are used as an entry point to reach both HIV positive and negative women and children for nutritional comprehensive care. The project aims to improve the management of severe malnutrition (SAM) using Ready-to-use therapeutic food (RUTF) as part of common PMTCT and Paediatric HIV care. The most vulnerable population groups (i.e. HIV infected pregnant women (HIV+PW), HHIV uninfected pregnant women (HIV-PW) and HIV infected and uninfected children suffering from SAM), are screened for anaemia using an easy point-of-care diagnostic HemoCue system.

⁵ MoU for PMTCT Component 2007-2009 10 December 2007, Annex 1, Project Outline, p.4

Anthropometric measurements are also taken. Children with SAM receive RUTF treatment. This project will be implemented in close collaboration with country PMTCT and nutritional programs and complements the UNITAID support to CHAI for the purchase of RUTF. CHAI and UNICEF will jointly work on forecasting the requirements for RUTF in order to prevent funding overlaps. An important aim of the Nutrition Component is to implement the HemoCue system for haemoglobin testing and to increase the network of producers for RUTF in developing countries.

Extension Component

A second amendment ('Extension component') of the 1st PMTCT Component was signed on the 22nd December 2010. It is a 12-month extension to seven of the original eight beneficiary countries with the exception of Burkina Faso. The allocated budget amounts to 28'799'353 USD to reach a target of 1'9780'740 maternal and paediatric treatments. The maternal and paediatric interventions are the same as in the 1st PMTCT and Expansion. The development of transitional plans from UNITAID funded sources to other partners/funding agents (e.g. Global Fund and PEPFAR or other alternative sources of funding) are expected until the targeted project end date in December 2011.

Overall, UNITAID funded commodities target health facilities in order to provide more efficacious PMTCT interventions, which are complemented by capacity building and service delivery interventions supported by governments and other entities. Country governments, in cooperation with UNICEF Country Offices, develop treatment plans and drug and diagnostic needs.

Roles and responsibilities

- **UNITAID** is primarily responsible for the timely provision of funding to UNICEF for the purchase of PMTCT (and RUTF and anaemia diagnostics) and related commodities for all beneficiary countries. Additional responsibilities comprise the ongoing review of financial and programmatic project progress and active cooperation with project partners and provision of strategic advice in order to achieve defined project objectives, e.g. contribute to influence market dynamics to improve affordability, accessibility and availability of more efficacious and appropriate PMTCT regimens.
- **UNICEF** coordinates and manages procurement and delivery of high quality PMTCT commodities (including drugs, diagnostics, reagents and related commodities). Key procurement activities comprise the development of a procurement strategy and in-country assessments of procurement and supply management infrastructure and practices, among others. Additional responsibilities include issuing implementation letters to beneficiary countries, the provision of Technical Assistance (TA) to these countries, supporting transition planning (Extension Component), monitoring of project progress and submitting standardised Interim and Annual programmatic and financial reports to UNITAID.
- **WHO's** key responsibility within the UNITAID funded PMTCT projects is to provide Technical Assistance, mainly through its regional and country offices. TA includes: the provision of WHO normative guidance on the diagnostic and therapeutic aspects of PMTCT and SAM in children; the provision of training modules and tools to develop the capacity of health care workers; the promotion of the use of WHO PMTCT guidelines; and the support to beneficiary countries to revise their national PMTCT (and nutritional) policies and M&E guidelines.

2 Approach and methods

This is a summative, external, independent mid-term evaluation including suggested parameters for a SWOT analysis and recommendations based on the findings of the evaluation.

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

2.1 Evaluation components

The assessment had three components: (1) core evaluation common to all UNITAID projects, (2) project-specific questions and (3) supporting data and quality of reporting.

(1) Core evaluation

The common evaluation areas have been provided in the RFP issues by UNITAID, they are compliant with the Organisation for Economic Co-operation and Development (OECD) evaluation criteria⁶ and are defined as follows:

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

For each evaluation area, 'questions', 'relevant quantitative and qualitative indicators', 'sources of information' and 'analytical methods' were defined. For each indicator, sources of information were identified and the analytical methods to estimate each indicator were defined (see Annex 1- Evaluation Matrix). All core evaluation questions common to all UNITAID projects were addressed consistently across all projects to minimise the risk of bias attributable to differences in the approaches used by different evaluators.

(2) Project-specific questions

UNITAID, in the RFP, proposed a series of project-specific questions. These questions were further adapted in discussions between the evaluation team and UNITAID secretariat. The key questions relevant for the PMTCT project focused on:

- Is the mother and baby pack for PMTCT ready to be implemented in all countries? What were the major factors influencing the achievement or non-achievement of this objective?
- Describe WHO's and UNICEF's role in making the Mother and Baby Pack more widely available.
- What steps have been taken towards transitioning this project to more sustainable sources of funding?

A full list of the project-specific questions is presented in Annex 2.

(3) Quality of reporting

UNITAID alerted the evaluation team that programmatic and financial reports of projects sent to UNITAID might pose challenges in terms of their completeness, consistency across projects related to

⁶ OECD DAC Network on development evaluation. Evaluation development co-operation. Summary of key norms and standards. Second edition. OECD 2010.

the memorandum of understanding between UNITAID and the projects, and internal formal consistencies (e.g. between the items formulated as objectives and as activities). Given that the evaluation of the project progress was mainly based on the information contained in semi-annual and annual programmatic and financial reports, reporting problems could affect the findings of the evaluation.

A guiding checklist was prepared to have a consistent assessment of the quality of reporting across evaluators and projects evaluated (Annex 3: Evaluation Matrix, Reporting checklist).

2.2 Methods

1. Sources of information

The sources of information to conduct the evaluation were:

- Memorandum of Understanding between UNITAID and the implementing partner(s) and other legal documents where appropriate;
- project progress reports (semi-annual or annual) submitted to UNITAID from the start of the evaluation of a given project;
- financial reports;
- other documents i.e. initial project proposals, Executive Board Resolutions etc. (see Annex 5)

Reports

With regards to the 1st PMTCT Component, the most recent project report was the 2nd AR covering the period from 1st January 2009 up to 31st December 2009. A report covering the activities of 2010 was not available and a first report on the Extension Component was only expected in July 2011. Therefore, no evaluation could be conducted for this component. For the Nutrition and Expansion Components, all interim and annual programmatic (including financial information) reports were received and accepted by UNITAID.

2. Project outline

A preliminary reading of project documents suggested that not all projects were consistent in terms of what was considered to be an 'objective' and an 'activity', and the links between them. The first step was to create a "project outline" that identified the key project characteristics:

- Project objectives,
- Project targets to measure the achievements of objectives,
- Activities and timelines for each activity,
- Procurement plan and
- Budget and disbursement plan.

Any additional information deemed useful to understanding the project was retrieved for the evaluation and reported in the project outline. For example, any changes in the objectives or in the number of beneficiary countries were mentioned in the project outline. This "project outline" was based on existing literature⁷ addressing the logical framework.

Key definitions applicable to each project were also defined to make the collected information consistent:

- An objective was defined as a statement that describes what should be achieved at certain points in time and/or at the end of the project;
- An activity was defined as a description of the events that should occur in certain times and places, and involve certain people. Where possible, activities were linked to objectives, either based on the information contained in the reports or on the judgment of the evaluators.

⁷ Nacholas S. How to do (or not to do)... A Logical Framework. Health Policy and Planning 1998; 13(2): 189-93.

- Budget Absorption Rate was defined as the comparison between expenditures and the project budget.
- Budget Execution Rate was defined as the comparison between disbursements and the project budget.

3. Data extraction

Based on the project outline, documents included in the evaluation were examined to extract the relevant data for the evaluation. A matrix evaluation addressing the three components of the mid term review was filled in and some additional tables were added to summarize key findings where necessary. The matrix evaluation in Annex 1-3 provides:

- The core evaluation questions by relevance, effectiveness, efficiency and impact.
- The question specific to the PMTCT project.
- The reporting questions common to all UNITAID projects.

For the market information, we relied on publicly available information on drugs and diagnostics markets for HIV/AIDS, TB and Malaria. This specifically included the WHO list of pre-qualified suppliers, drugs and diagnostics and MSH drug price indicators.

For Budget Absorption Rate calculations, financial reports attached to the annual reports were used, as they appeared to provide the most reliable, complete and updated information. Section C.2 of the programmatic report was incomplete in some instances, provided unverifiable figures (e.g. a figure for expenditures made under "Actual for reporting period" according to 1st AR 1st PMTCT Components) or was not available and the respective Budget Absorption Rate could not always be calculated.

For health outcome reported data, a verbally agreed proxy "Total of PMTCT commodities procured" between project partners was reported on for the Project Components 1st PMTCT and Expansion, instead of the indicator "% of target treatments delivered". No information was provided for the "number of patients treated". Although classified as a non-achievement within this mid-term evaluation, the proxy-based information was considered for further analysis (see report section 4.2 Effectiveness for further details) in order to identify a possible link between project status and health outcome, and to provide some general information on project developments. For the Nutrition Component, no data was reported thus far. The MoU baseline figures⁸ for maternal and target interventions were compared with the reported proxy information "number of products procured" in the respective 1st Annual Reports for Year 1 data and 2nd Annual Reports Year 2 data.

UNITAID portfolio managers and implementing partners were contacted to clarify issues related to the availability and quality of data (see Annex 4 for stakeholders interviewed and questions raised).

4. Analysis

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

The evaluation of each area was accompanied by an assessment of the quality of the underlying data. Data was considered of poor quality when it was partial (e.g. describing what happened in one country but not in another), 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).

⁸ Drugs to be procured and indicative treatment plans have been identified and developed by country governments in cooperation with UNICEF Country Offices and are defined in respective Exhibits i.e. for 1st PMTCT, Annex 1, Exhibit 1

When data is missing or of poor quality, not much confidence can be placed on the truthfulness of the evaluation and its ability to reflect the real situation of the project. On the contrary, when quality issues are minimal, the results of the evaluation can be reasonably trusted. The quality of the underlying data is explicitly described alongside the evaluation findings.

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

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

A rating was attached to each common evaluation area. The rating was qualitative and based on consensus within the evaluation teams, which included the evaluators of other projects. The rating consisted of two parts: the actual rating of the evaluation area and an assessment of the quality of the underlying data. This was determined by weighing the confidence of the actual rating. The rating scale and the interpretation of the different categories are presented in Table 3 below.

Table 3. Rating of Evaluation Areas and Quality of Data.

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

5. Clarification meetings with key stakeholders

Key clarification questions were shared and discussed with the UNITAID secretariat and the implementation partners. The aim of this exchange was to establish a common understanding of the project status, progress and key issues and to discuss open questions. An interview questionnaire was specifically developed for each meeting in order to focus on stakeholder relevant questions.

6. Analysis of project Strengths, Weaknesses, Opportunities and Threats

Suggested parameters for a SWOT analysis were used to evaluate possible strengths, weaknesses, opportunities and threats related to the evaluated project. The attempt was to identify potential internal and external factors that were either favourable or unfavourable in achieving the objective. Additionally, it presents a summary of potential key factors that influence the achievement of the project's objectives.

7. Issuing of recommendations

Recommendations were issued by consensus between the team of evaluators involved in all projects, in order to allow for a comprehensive overview of the issues encountered in the different projects and to harmonize the recommendations. Separate recommendations were made for each project, based on the findings of the evaluation. Some recommendations were common to several projects. Recommendations prioritised the identified critical issues in each evaluation area and across all areas. Several options to address the critical issues were listed and assessed against two main criteria: (a) the available evidence that the recommendations would effectively address the critical issue; and (b) the feasibility of implementing the recommendation. Evidence was drawn from research, best practices or colloquial evidence, e.g. evidence based on professional experience. Recommendations were addressed both to UNITAID and to the implementing partners.

2.3 Project specific

Initial clarification meetings were held with UNITAID on the 11th of April 2011 in Geneva. Follow-up clarification meetings with WHO and UNICEF took place on 27th May 2011 in Geneva and Copenhagen. The topics discussed during the meetings were related to the project status and progress, project achievements, reporting standards, log frame issues, reporting requirements and an update on the final status of the Mother and Baby Pack. The MBP is a box containing all antiretroviral drugs and prophylactic Cotrimoxazole needed to reduce HIV transmission from the mother to the child. A list of key stakeholders met and the interview questions are presented in Annex 4.

The mid-term evaluation experienced some delays, mainly due to:

- Incomplete project portfolio/documentation at the beginning of the mid term evaluation.
- Duplicities between what was sent to the evaluators and the UNITAID website, which required additional cross-checks.
- Long time spans to set up meetings and accessing key informants.
- Unclear or outdated information on key project issues (e.g. MBP status and funding).

3 Findings

This section reports the findings of the evaluation, which are based on the evaluation matrix (Annex 1). Each sub-section starts with a summary of key findings for the respective evaluation area.

3.1 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
<input type="checkbox"/> Optimal	<input type="checkbox"/> Optimal
<input type="checkbox"/> Minor concerns	<input checked="" type="checkbox"/> Minor concerns
<input checked="" type="checkbox"/> Major concerns	<input type="checkbox"/> Major concerns

Key findings :

Findings common to all Project Components

- For all project components, all activities were related to at least one of the objectives.
- All objectives were measured with at least one indicator in all four project components.
- The Budget Execution Rate is 100% for all project components.
- Several indicators were not designed to assess project specific achievements:
 1. Population and service based indicators (e.g. Annex 4B of MoU 1st PMTCT Initiative) refer to national data, i.e. for the WHO Access Reports.
 2. The “number of commodities procured” was used as a proxy for the “percentage of treatments delivered”.
- A common M&E log frame was used, facilitating misinterpretations of indicator definitions.
- About 50% (6-7 out of 13) of activities referred to routine managerial functions, rather than activities that achieve specific projects objectives.
- Several important formalized project documents were not available (e.g. signed MoU for 1st PMTCT, extension requests for Nutrition and Expansion Component).
- The Budget Absorption Rate is only 27% for the Expansion Component, 57% for 1st PMTCT Component (without Extension Component Funds) and 39% for the Nutrition Component.

Component Specific Findings

- Expansion Component: a clear definition of the objective could not be found in the project plan (Annex 3).
- 1st PMTCT Component and Expansion Component: according to evaluation team, 7/13 activities have been achieved for 1st PMTCT Component and 6/13 for the Expansion Component, of which all except one activity refer to routine managerial functions. The other activity focuses on achieved price reductions and price containment. The remaining health and market outcome activities have either been partially achieved, not achieved or information was unclear, which jeopardized timely project completion.
- Nutrition Component: according to evaluation team, based on available information, 5/13 activities refer to routine managerial functions, and all have been achieved. The remaining health and market outcome activities have either been partially achieved, not achieved or information was unclear or not applicable, which jeopardized timely project completion.

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

Project plan

Objectives and Activities

In total, nine objectives have been identified for all four project components, of which six objectives refer to the 1st PMTCT Component, and one objective for each of the other three project components (see Table 4). For the Expansion Component, a clear definition of the objective could not be found in the project plan (Annex 3). Instead a set of five guiding principles was listed (for example: Coherence with UNITAID's Country eligibility criteria or Transition Strategy). The evaluators took the following statement as a substitute for the objective of the Expansion Component *"to improve the availability of the programme commodities through improved forecasting, procurement and in-country supply chain management, as well as to prompt the development of more user-friendly products, thereby promoting adherence to treatment"*⁹. All 13 activities of the Expansion Component related to this objective definition.

While the 1st PMTCT, Expansion and Nutrition Component, defined 13 activities and expected outputs, the Extension Component only defined 9 activities, as activities 5.1-5.4 were not reported on. All 13 activities only indirectly related to at least one of the objectives. A clear allocation to a single objective was not possible for all activities, as many described general managerial steps instead of objective and specific activities.

Table 4. Objectives and activities of the PMTCT Initiative.

PMTCT Initiative Components	Objectives	Activities
1st PMTCT	1 Accelerate the scale-up of provider-initiated HIV testing and counselling in antenatal, maternity and postpartum services.	5.1 Beneficiary country selection 5.2 UNICEF Agreements with relevant authority of beneficiary country
	2 Reduce the proportion of infants born with HIV by providing more efficacious ARV regimens, including ART to women and their newborns.	5.3 Development of Program Approach and Key Activities 5.4 Development of Procurement Strategy
	3 Accelerate early access of young HIV-infected infants to paediatric ART treatment through optimized identification strategies, such as Early Infant Diagnosis.	5.5 Identification of commodities for use in PMTCT, including early diagnostics
	4 Reduce morbidity and mortality among HIV-infected pregnant women, mothers and their infants by providing Cotrimoxazole prophylaxis for the prevention of opportunistic infections.	5.6 Engage and negotiate with industry to stimulate an increase the availability of quality assured drugs and diagnostics suitable for PMTCT intervention including to facilitate price reduction.
	5 Increase access to ART for eligible HIV-infected women.	5.7 Agree with recipients on treatment regimen and confirm forecasts.
	6 Achieve continuous supply of suitable, high-quality PMTCT medicines, diagnostics and other commodities at the best possible price, and facilitate price reduction.	5.8 Tendering and Long Term Agreements (LTAs) with suppliers of PMTCT commodities
	Nutrition Component	7 Include nutrition interventions as part of PMTCT and HIV care and treatment interventions to improve maternal and child health outcomes. (Nutrition Component).

⁹ 2nd AR Expansion, p.6, 2nd paragraph

PMTCT Initiative Components		Objectives	Activities
Expansion Component	8	The primary focus is to improve the availability of the program commodities through improved forecasting, procurement and in-country supply chain management, as well as to prompt the development of more user-friendly products, thereby promoting adherence to treatment. (2nd AR Expansion, p.6, 2nd paragraph).	5.10 Placement of Purchase Orders and Delivery 5.11 Technical Assistance (TA), including involvement of in-country partners
Extension Component	9	To contribute to the acceleration of the global scale up of PMTCT programs by influencing market prices and packaging HIV commodities towards lower prices and by improving availability, affordability, forecasting, procurement and supply chain management of drug and diagnostic commodities. (1st Extension Component).	5.12 Monitoring, Evaluation including reporting to UNITAID 5.13 Reporting to UNITAID

Project monitoring

Overall, there are three sources in the project plans that were used to monitor the project achievements and progress of the three project components (1st PMTCT, Nutrition and Expansion):

- 1) The “Harmonised M&E log frame: List of indicators on achievement” in Annex 4A¹⁰: It defines key target indicators for some of the key activities of all three components.
- 2) “Indicators for Current Implementation Status of PMTCT Interventions for the PMTCT Initiative” in Annex 4B.¹¹ It provides a set of 19 population - and service based indicators that require information on health facility, women and children related indicators. Reported information is based on national programme data from the Annual Report Card for PMTCT and Paediatric HIV, and on progress of the implementation of national PMTCT programmes reported by UNICEF and WHO country offices.
- 3) Descriptive sections in section 5 of the respective project plans (Annex 1, Annex 2 and Annex 3) that define milestones and information on the status of key project activities.

In general, all objectives of the project components could be allocated with at least one measurable indicator. However, not all indicators were designed to be measured. As the same M&E log frame (Annex 4A) was used for the 1st PMTCT, Nutrition and Expansion Components, some indicators were common to several components. This caused confusion if defined target indicators should be achieved per project component or achieved for several components together (e.g. "LTAs signed by July 2010 indicating 5% price reduction for at least 2 ARV products" might be valid for all or some of the three components).

Limitations with regards to the population and service based indicator framework (Annex 4B) referred to the nationally generated data. As mainly national data was reported, i.e. for the WHO Access Reports, it was not possible to identify UNITAID funded specific PMTCT treatment interventions and outcomes (see report section 4.6 for further details).

¹⁰ 1st Amendment to 1st PMTCT Component project plan (Annex1), Annex 4A: Harmonised M&E log frame: List of Indicators on Achievement for the 1st PMTCT, Expansion and Nutrition Component.

¹¹ 2nd Amendment to 1st PMTCT Component project plan (Annex 1B), Annex 4B new M&E log frame for the Extension Component.

For the Extension Component, a new M&E log frame has been developed that will be used in future reports. The new M&E log frame contains 16 measurable indicators, which are all related to the one objective (see section 4.6 for further details on the new M&E log frame).

Project Implementation

All 13 activities in the 1st PMTCT Component (source: UNICEF reporting on the achievement ratings of the identified key activities), 12 out of 13 activities for the Expansion Component (one is still ongoing) and 7 out of 13 activities for the Nutrition Component (the other six are ongoing) have been completed. For the Extension Component, no progress reports were available.

According to the evaluators, based on available information (progress reports and corresponding Annexes and Exhibits and other documentation (see Annex 3)), considerably less activity achievements (as presented in the Table 5 below) could be verified for the different project components. Two important reasons were that the report structure had either not been fully aligned with the M&E log frame or that M&E log frame indicators had not always been well reported. These M&E log frame and reporting constraints contributed to the different rating and the unverifiable reported information on activity achievements, as described in further detail in report section 4.6.

The evaluation team verified the reported data by applying a grid of five classification types, (achieved, partially achieved, unclear, not achieved and not applicable), to the 13 activities reported on by the implementing body (see Table 5 and following paragraphs below).

Table 5. Activity Achievement Rating by Evaluation Team.

Component	Activities Achieved	Activities Partially achieved	Activity status unclear	Activities not achieved	Activities not applicable	Total number of Activities
1 st PMTCT	7	3	2	1	na	13
Expansion	6	4	2	1	na	13
Nutrition	5	4	2	1	1	13
Extension	na	na	na	na	na	na

Achieved activities

As presented in Table 5 above, achieved activities for all three components mainly refer to general project management and implementation steps (e.g. beneficiary country selection, development of a procurement strategy and project program approach) and key activities (provision of TA, ongoing tendering and reporting according to schedule (valid for 1st PMTCT only). Seven out of 13 activities (54%) were achieved for 1st PMTCT Component, six out of 13 (46%) for the Expansion Component and five out of 13 activities (38%) for the Nutrition Component.

The activity that represents the market impact indicator price reductions of ARVs and price containments for RDT's has only been achieved for the 1st PMTCT and Expansion Component.

Partially achieved activities

Partially achieved activities, 3/13 activities (23%) for the 1st PMTCT Component and 4/13 (31%) for the Expansion Component and Nutrition Component, mainly refer to unavailable signed framework agreements [e.g. MoUs with beneficiary countries, discrepancies between reported information and requirements, according to M&E log frame indicators, and the MBP suspension (relevant for 1st PMTCT and Expansion Component only)] Information on important health outcome and other market outcome indicators for all three Project Components have either not been available or were unclear.

Activities not achieved

A non-achievement rating was allocated for the indicator “% of target treatments delivered per maternal and paediatric intervention per country M&E log frame” for all three components, since a verbally agreed proxy “number of commodities procured”, for which no formalized agreement exists, had been reported on.

Unclear status of activities

For all three Project Components, reported information on the two indicators referring to delivery lead times and timely forecasting, is unclear.

Activities rated with non applicable

The market impact indicator price reductions of ARVs and price containments for RDT's was rated as not applicable for the Nutrition setting, as the indicator definition in the M&E log frame Annex 4A had not been adapted.

In addition to the above mentioned issues, several documents have not been made available:

- A signed version of the original MoU between UNITAID, UNICEF and WHO for the 1st PMTCT Component.
- All MoUs with beneficiary countries for all components.
- All implementation letters, except for the eight beneficiary countries of the 1st PMTCT Component.
- Formalized documentation on extension requests for the Nutrition and Expansion Component. The evaluation team does not know time frame, funding conditions, and other important information. Only general verbal confirmations from UNICEF and UNITAID have been provided.

Project financing

Based on Financial Report Information, a total budget of 72'029'272 USD was available for all three PMTCT Project Components. Of this total budget, 71'036'775 USD (98%) have been disbursed and 25'470'777 USD (35%) expended. The Budget Execution Rate was 100% for all components, based on programmatic report information on disbursements (section C.1 of respective reports) or almost 100% based on financial report information. An overview of the financial indicators is provided in Table 6.

Table 6. Total Budget, Budget Execution and Budget Absorption Rate*.

Sources	Total Budget USD (MoU)	Total Disbursements USD	Total Expenditure USD	Budget Execution Rate (C/B)	Budget Absorption Rate (C/A)
1st PMTCT Initiative					
Programmatic Report	20'838'432	20'838'432 ¹¹	11'295'257 ¹²	100%	54 %
		-1'071'232 (refund)			
Programmatic Report	19'767'200	19'767'200 ¹²	n/a for 1 st disbursement (section C.2, 1 st AR) 6'277'694 for 2 nd disbursement (section C.2, 2 nd AR)	100%	n/a
Financial Report	20'838'432	20'676'649 ¹²	11'295'257 ¹²	99%	54 %
Financial Report	19'767'200	19'605'417 ¹³	11'295'257 ¹²	99%	57 %
Expansion Component					
Programmatic Report	46'679'993	46'679'993 ¹⁴	23'577'459	100%	51 %
Financial Report	46'679'993	45'916'696 ¹⁵	12'396'600	98%	27%
Nutrition Component					
Programmatic Report	4'510'847	4'510'847 ¹⁶	2'040'831	100%	45 %
Financial Report	4'510'847	4'443'430 ¹⁷	1'778'920	99%	39%
Total					
Financial Report	72'029'272	71'036'775	25'470'777	98%	35%

* Especially the C/A percentage ratings need to be seen with caution as relevant information might have been unavailable to the evaluators e.g. additional clarification/information exchange and updates between UNICEF and UNITAID portfolio managers, calculation basis.

Sources: Programmatic Report (Section C), or Financial Reports

1st PMTCT Component

The full amount of 20'838'432 USD (based on latest budget version¹⁸, see Table 4 above), was disbursed in 3 disbursements for the 1st PMTCT Component from 2007-2009 (programmatic report information section C.1), with a Budget Execution Rate of 100%. The budget absorption rate was 54% (based on latest budget version¹⁵) for the 1st PMTCT Component, based on programmatic and financial report information. The relatively low Budget Absorption Rate led to a refund in 2009 of 1'071'232 USD to UNITAID. If the refund would be considered, the Budget Absorption Rate would be only marginally higher at 57%.

The 1st disbursement was according to schedule, while the 2nd (Jan 2009) and 3rd (July 2009) disbursements were delayed for more than two months due to clarification requests from UNITAID to UNICEF. Some of the disbursement conditions were verified (MoUs for 1st and 2nd Amendment) for

¹² Based on 1st AR and 2nd AR 1st PMTCT Component, programmatic report e.g. section C1 information

¹³ Based on 1st AR and 2nd AR 1st PMTCT Component, financial report (Exhibit 2 (2nd AR) or Annex 2 (1st AR) information

¹⁴ Based on 1st AR and 2nd AR Expansion Component, programmatic report e.g. section C1 information

¹⁵ Based on 2nd AR Expansion Component, financial reports (Exhibit 5 for Year 1 and Year 2)

¹⁶ Based on 1st AR and 2nd AR Nutrition Component, programmatic report e.g. section C1 information

¹⁷ Based on 2nd AR Nutrition Component, financial reports (Exhibit 1 for Year 1 and Year 2)

¹⁸ Based on latest budget version¹⁸, defined in the MoU for the 1st PMTCT Initiative 2007-2009 10 December 2007, Annex 1, Project Outline, p.31

the 1st PMTCT while others were not, because contracts between the suppliers and UNICEF had not been made available.

Financial and programmatic report differences were mainly a result of slight variations of financial data between information from the programmatic and financial reports. This indicates a need for a harmonization or explanation of data discrepancies.

The evaluation team considers the 1st PMTCT Component to end in June 2011, as a final report is expected at that time. The evaluation team has not received any official documentation confirming the extension or an explanation for the delay of the final report. The last available report refers to the reporting period 2009, which is outdated. The final report might draw a better picture for the Budget Absorption Rate, as the issues leading to the low Budget Absorption Rate might have been overcome by in the final report, e.g. delayed procurement processes. However, considering the limited time left and based on the current available expenditure status, project accomplishment is clearly jeopardized, even though all funds were disbursed by July 2009. The funds disbursed for the Extension Component of 26'763'660 USD (based on UNITAID information) have not been included in the analysis, as it represents a separate Project Component for which no reports are available yet.

Expansion Component

As presented in the above table, the full budget of 46'679'993 USD¹⁹ (MoU) for the Expansion Component was disbursed in two payments, the first in 2009 and the second in 2010, with a Budget Execution Rate of 100%. The second disbursement was delayed by several months. Based on the most comprehensive financial report information, the total budget absorption rate was 27%.

The low Budget Absorption Rate is mainly attributable to the seven of the nine beneficiary countries (Uganda, Lesotho, China, CAR, Haiti, Myanmar and Nigeria) that reported zero expenses until the date of report submission. As a result, only 406'704 USD (1.5%) of the 2nd disbursement had been spent by that time. According to information on page 9 of the second AR, this was because not all expenditures for the first half of Year 2 were reported by 31 December.

Financial and programmatic report differences refer to:

- Some expenditure activities are given in table 3.9.1 of 2nd AR indicating the placement of Purchase Orders. In this table, an expenditure figure that contradicts the information provided in the financial report (zero expenditure) was provided for Uganda.
- Even if the programmatic figures are used as a calculation basis, only a 51% rating for the Budget Absorption Rate would be achieved.

Based on the available information, it was unclear why such a discrepancy in reported expenditure figures between the different reports existed. This requires future harmonization of programmatic and financial report information, documentation of the calculation basis, provision of analysis and explanations and provision of cross-references. Considering that the Expansion Component was planned to end in July 2011 and that funds have been disbursed since July 2010, major issues in regards to the current expenditure status exist. According to verbal information from UNITAID and UNICEF, an extension for the Expansion Component might be considered. If an extension should be granted, expenditure status would present a less concerning picture, as additional time would be made available for project progress and related project expenditures. However, the evaluation team has not received any formal documentation indicating the intention, scope and funding conditions for a potential extension.

¹⁹ 2nd AR Expansion Component, programmatic report e.g. section C1 information

Nutrition Component

Table 6 presents a Budget execution rate of 100%. The entire budget of 4'510'847 USD²⁰ (MoU) has been disbursed in two disbursements in 2009 and 2010, with a several month delay for the 2nd disbursement. The total Budget Absorption Rate for the nutrition is calculated based on available information, at around 39 %, with reservations. The 2nd AR Nutrition informed that the 2nd disbursement has not been touched as no orders have been placed for year 2. This explains the low Budget Absorption Rate for the entire project.

Financial and programmatic report differences are as follows:

- The financial reports of the 1st AR provide a different figure for funds received than the programmatic reports.
- For three of the "Statements of Account" of the 2nd AR Nutrition Financial Report Year 1, it is not clear for which countries/purposes these have been made as no country names have been listed.
- If programmatic figures were used as a calculation basis, Budget Absorption Rate would be slightly higher with 45%.

Considering that the Nutrition Component is supposed to come to an end in July 2011, major concerns with regards to project completion should be raised by UNITAID and the implementing agency. If an extension is granted, expenditure status would present a less concerning picture. The evaluation team has however not received any kind of formalized documentation indicating the go-ahead, scope and funding conditions for a potential extension.

In summary:

- Several data inconsistencies exist between the programmatic report section C.2, financial report data and additional financial information (e.g. in Table 3.9.1, Expansion Report) of the report. This requires harmonization of the data and explanations regarding data differences.
 - Based on the available information, it cannot be verified if the expenditures are in line with activities initially planned, as the "financial reports" only provide information on Total funds received, Total expenditures and unexpected balances per country.
 - The reported financial information cannot be linked to any specific activities nor traced in neither the programmatic report or other sources.
 - The relatively low Budget Absorption Rate achievements are also influenced by the fact that not all invoices are submitted to UNITAID, according to defined deadlines, for a given reporting period at the time of report submission.
- 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?**

UNITAID funded project specific contributions to improve access to quality products to treat, diagnose and prevent HIV/AIDS cannot be described based on the information available. No information was reported on the number of patients diagnosed or treated, or on the percentage of treatments delivered (see report section 4.6 Reporting Arrangements for further information).

²⁰ 2nd AR Nutrition Component, programmatic report, section C1

3.2 Effectiveness

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

Rating		Level of confidence	
<input type="checkbox"/>	Optimal	<input type="checkbox"/>	Optimal
<input type="checkbox"/>	Minor concerns	<input type="checkbox"/>	Minor concerns
<input checked="" type="checkbox"/>	Major concerns	<input checked="" type="checkbox"/>	Major concerns
Key findings:			
Findings common to all Project Components			
<ul style="list-style-type: none"> It was not possible to evaluate achievements for lead-time related targets due to incomplete reporting. No specific risk management was in place for the three project components, apart from general individual de-risking activities. A wealth of Technical Assistance measures provided by the implementing bodies has been reported. Non-existent formal approvals for budget re-allocation and corresponding adjustments of treatment targets have led to substantial under- and over-achievements. Average weighted prices are still reported on, despite UNITAID's request to report only on median prices, and the range and inter-quartile range of commodities procured. 			
Component Specific Findings			
<ul style="list-style-type: none"> 1st PMTCT and Expansion Component: the Mother Baby Pack was developed with a two-year delay but is currently suspended. 1st PMTCT and Expansion Component: better-adapted and more user-friendly products have been identified, two new paediatric ARVs have been prequalified, but the target was only partly achieved because the Mother Baby Pack was unavailable. 1st PMTCT and Expansion Component: targets for price reduction of ARVs and price containment of RDTs were achieved (although price increases can be seen for other key products). 1st PMTCT and Expansion Component: no market impact was attributed to the achievement of the project indicator targets. The Mother Baby Pack had the potential to become such an accomplishment, but the future of the product is uncertain. 1st PMTCT proxy "number of commodities procured": maternal interventions have mostly been overachieved, while paediatric interventions have been under-achieved. Expansion Component proxy "number of commodities procured": maternal interventions have been overachieved in Year 1. Under-achievements in paediatric interventions have been reported for Year 1 and Year 2 and in maternal interventions for Year 2. Nutrition Component: no data was available on treatments/diagnostics procured or "% of treatments delivered" per country under UNITAID funding. Nutrition Component: the target to approve new products was only partly achieved and is at major risk of not being achieved within the project period. 			

*Treatment Targets also includes patients receiving diagnostics linked to PMTCT (RDTs, etc.)

3. To what extent were the objectives of the project achieved?

Health Outcome Objectives (based on proxy information)

1st PMTCT Component

The MoU baseline figures²¹ for maternal and paediatric target interventions have been compared with the reported proxy information “number of products procured” in the 1st AR 1st PMTCT for Year 1 and the second AR 1st PMTCT for Year 2. Based on the proxy, maternal interventions were mainly marked by over-achievements as far as data was available, while paediatric interventions were experiencing under-achievements (see Table 7 for overview information and, Table 8 for further details per individual maternal and paediatric key intervention).

Maternal interventions

The Year 1 overall maternal treatment target of 891'612 could not be verified due to missing data on # of Rapid tests procured for Year 1, while the overall Year 2 maternal treatment target of 1'255'652 has been met with 156%, as a result of improved coordination of national forecasting.

In more detail, in Year 1 all maternal key intervention targets have been achieved, except that HIV+PW did not receive more efficacious ARVs for PMTCT. In Year 2, four out of five maternal treatment targets have passed the 100% target line. These include the number of Rapid tests, efficacious ARVs for PMTCT, CD4 test for HIV+PW, and HAART for HIV+PW, which reached a rating between 149%-291%. The only maternal treatment target not reached in Year 2 is the distribution of Cotrimoxazole (CTX) for HIV+mothers.

Paediatric interventions

In comparison, overall paediatric treatment targets remained well below the defined targets. Both, the Year 1 overall paediatric target of 78'217 (only 55% achievements) and the Year 2 overall paediatric target of 172'221 were not met (only 58% achievements), mainly due to a pending procurement for India and the need to improve coordination among partners in regards to procurement and planning processes.

Table 7. 1st PMTCT Component: Overall Baseline and Target Values for Maternal and Paediatric Interventions in Year 1 and Year 2.

Baseline/Target Values	Maternal Treatment Target	Paediatric Treatment Target
Total Year 1 Baseline	891'612	78'217
Total Year 1 Commodities procured	227'714	43'250
% of Total Target met in Year 1	Na	55%
Total Year 2 Baseline	1'255'652	172'221
Total Year 2 Commodities procured	1'958'747	99'887
% of Total Target met in Year 2	156%	58%

In more detail, (see Table 8) all three paediatric key interventions, i.e. CTX for exposed infants at the age of 3 months and 2 years and PCR to test HIV exposed infants, missed both the Year 1 and Year 2 targets. These targets only reached between 24% and 87% of achievements for Year 1 and between 40% and 75% of achievements for Year 2.

²¹ Drugs to be procured and indicative treatment plans have been identified and developed by country governments in cooperation with UNICEF Country Offices and are defined in respective Exhibits i.e. for 1st PMTCT, Annex 1, Exhibit 1

Table 8. 1st PMTCT Component: Treatment vs. Supply Targets per each Key Maternal and Paediatric Intervention.

1 st PMTCT Component: Treatment vs. Supply Targets for Year 1 and Year 2								
	Maternal Interventions					Paediatric Interventions		
	# of Rapid Tests (No of PW tested)	HIV+ PW receive more efficacious ARVs for PMTCT	NB of HIV+ PW receiving CD4 tests	Nb of HIV+PW in need of HAART treatments	CTX treatment for HIV+ mothers	PCR test for HIV-exposed infants	CTX prophylaxis for HIV-exposed infants - 3 months	CTX prophylaxis for HIV-exposed infants - 2 years
Baseline Treatment Targets Year 1	761'021	51'303	45'085	5'972	28'231	33'715	24'850	19'652
PMTCT Commodities procured in Year 1	n/a	43'764	129'200	5'948	48'802	8'064	21'566	13'620
% of the Target met in Year 1	n/a	85%	286%	100%	173%	24%	87%	69%
Baseline Treatment Targets Year 2	940'415	117'181	109'731	17'090	71'235	73'997	46'713	51'511
PMTCT Commodities procured in Year 2	1'403'954	158'865	319'650	25'305	50'973	29'568	35'075	35'244
% of the Target met in Year 2	149%	136%	291%	148%	72%	40%	75%	68%
% of Target met as a Total (Year 1 and Year 2)	n/a	120%	290%	136%	100%	53%	79%	69%

n/a = not available

The observed over- and under-achievements with regards to health outcome indicator proxy “Number of products procured” as visible in the table above, were a direct result of the forecasting exercises. Due to the time gap between the original proposal and forecasting and funding approval, a thorough review of actual needs and coordination of available funding sources for all the different commodities took place at the national level, after MoU signing. In most cases, this exercise was assisted by UNICEF local or regional representatives. As a consequence of this repeated forecasting process, the quantities in the final requests for Cost Estimates presented to UNICEF were very different from those originally budgeted. However, UNICEF accepted these differences and there was no available documentation on any formal requests for re-allocation of funds, neither directed to UNITAID nor to UNICEF. No adjustments of agreed targets were made for this substantial digression from the original project outline, and consequently, no possibility of achieving the original treatment targets existed.

The 2nd Annual Report and the 1st Annual Report for the 1st PMTCT Component demonstrated national progress for several PMTCT indicators. For example, the 2nd Annual Report for the 1st PMTCT Component contained 2007-2008 data published in the WHO/UNICEF/UNAIDS Universal Access Report 2008 and 2009 (see Exhibit 1). National progress for several PMTCT indicators was visible, as seen in the “nb of PW tested for HIV” and in “nb of HIV infected PW who received antiretrovirals to reduce the risk of mother-to-child transmission (UNGASS) (2007 to 2008: 23% increased uptake for Malawi, 39% for Tanzania and 12% for Zambia)”. However, the UNITAID specific contributions could not be identified.

Expansion Component

Maternal interventions

Achievements or overachievements (111%) of overall maternal interventions have only been reported for Year 1 while for Year 2 overall maternal (44%) targets have not been met (see Table 9 for details).

As presented in table 10 below, almost all maternal key interventions reached or overachieved the set targets for Year 1 (e.g. 367% for CD4 tests, 430% for CTX treatment for mothers). A revision of maternal treatment targets has not yet been undertaken, which resulted in these considerable overachievements.

The under-achievements for almost all of Year 2 maternal interventions were because data was only available in three of the beneficiary countries (Uganda, Swaziland and Zimbabwe) at the time of report submission. For the other six countries, data was still being reviewed (see Table 9 for overview information and Table 10 for more details per individual maternal and paediatric key intervention).

Table 9. Expansion Component: Overall Baseline and Target Values Maternal and Paediatric Interventions in Year 1 and Year 2

Baseline/Target Values	Maternal Treatment Target	Paediatric Treatment Target
Total Year 1 Baseline	4'170'556	138'093
Total Year 1 Commodities procured	4'614'656	53'660
% of Total Target met in Year 1	111%	39%
Total Year 2 Baseline	5'265'531	265'975
Total Year 2 Commodities procured	2'333'127	13'711
% of Total Target met in Year 2	44%	5%

Paediatric interventions

For both Year 1 (39%) and Year 2 (5%), overall paediatric targets have not been achieved for the same reasons stated for the maternal interventions.

In Year 1, only one (CTX treatments for infants) of two paediatric interventions reached the defined target. Year 1 paediatric DBS/PCR test of infants born to HIV+ mothers achieved considerably lower procurement levels (12% of indicator achieved), mainly due to Early Infant Diagnosis (EID) programme scale up, continued support from PEPFAR/ Communicable Disease Control (CDC) and CHAI, and coordination to avoid funding overlaps. In general, the same reasons for under- and over reporting existed as for the 1st PMTCT Initiative, but neither an updated benchmark nor a reallocation of funds had been considered.

In summary, careful estimation of the likelihood of achieving maternal interventions was classified as high, but appeared to be low for paediatric interventions. Population and service-based indicators (where available) mainly based on national data indicated some progress for PMTCT Implementation Status indicators in all nine beneficiary countries²².

²² 2nd AR Expansion, Exhibit 1 Indicator Status of PMTCT Interventions in PMTCT II Countries in 2008-2010

Table 10. Expansion Component: Treatment vs. Supply Targets per each Key Maternal and Paediatric Intervention.

	Expansion Component: Treatment vs. Supply Targets for Year 1 and Year 2						
	Maternal Interventions					Paediatric Interventions	
	Projected # of rapid tests	CD4 tests of ART eligibility	More efficacious ARV treatments for PMTCT	No. Of HIV+PW in need of treatments for their own health	CTX treatment for mothers	DBS/PCR test of infants born to HIV+mothers	CTX treatments for infants
Baseline Treatment Targets Year 1	3'900'001	91'913	137'464	18'545	22'633	115'400	22'693
PMTCT Commodities procured in Year 1	3'834'044	337'750	321'277	24'269	97'316	13'536	40'124
% of the Target met in Year 1	98%	367%	234%	131%	430%	12%	177%
Baseline Treatment Targets Year 2	4'907'588	130'098	167'205	29'220	31'420	225'054	40'921
PMTCT Commodities procured in Year 2*	1'953'819	89'000	287'859	2'449	0	11'520	2'191
% of the Target met in Year 2	40%	68%	172%	8%	0%	5%	5%
% of Target met as a Total (Year 1 and Year 2)	66%	192%	200%	56%	180%	7%	67%

Nutrition Component

No data was available on diagnostics or treatments procured or on the percentage of treatments delivered per country (see Table 11 for an overview).

Table 11. Nutrition Component: Overall Baseline and Target Values for Maternal and Paediatric Interventions in Year 1 and Year 2.

Baseline/Target Values	Maternal Treatment Target	Paediatric Treatment Target
Total Year 1 Baseline	243'518	48'000
Total Year 1 Commodities procured	Na	na
% of Total Target met in Year 1	Na	na
Total Year 2 Baseline	395'888	70'000
Total Year 2 Commodities procured	Na	na
% of Total Target met in Year 2	Na	na

In Year 1, some countries had received funding for RUTF from non-UNITAID sources, reducing their requests to UNITAID. In Year 2, the four countries had not yet requested RUTF and/or diagnostic commodities, as some were continuing to utilize supplies previously ordered in Year 1 or stocks supplied by other in-country partners (e.g. PEPFAR, CHAI), which would impact the achievements of treatment targets.

UNICEF promised updated forecasts on treatment targets for the 1st IR, but no updated figures were provided. Hence, Year 1 data was not available. It should however be noted that data has been reported both on price reductions and delivery lead-times (see section on Market Outcome below), indicating that procurement processes have not only been started but also concluded, and products have been delivered within the scope of this project.

The only reported information available on treatment related issues on nutritional relevant activities referred to national data and developments (WHO Access Reports, WHO/UNICEF/UNAID joint reporting tool for the HIV sector's response to HIV/AIDS). These achievements could however not be specifically attributed to the UNITAID funded Nutrition Component:

- Rwanda: out of 13'879 children < 5 years old with SAM, 18'784 (> 100%) were recorded as having received treatment with SAM and RUTF (however no information existed on their HIV status).
- Malawi: In Jan-June 2010 period, 12'013 infants were born to HIV+ PW and given ARVs. In the same period, 26'161 children with SAM were treated with RUTF. In the July-Dec 2010 period, 18'046 SAM cases were treated with RUTF.
- Tanzania: exact figures for RUTF treatments were still being compiled, no national data existed regarding RUTF treatment, the available data was provided by PEPFAR.
- Zambia did not have data on PMTCT coverage indicators for 2010, nor for SAM or RUTF coverage.

None of the 4 countries reported on HemoCue use.

Technical Assistance

The implementing partners were very strong in offering a wealth of technical assistance in all project components. UNICEF country offices have supported the establishment of national coordination mechanisms for PMTCT, which convene regular meetings for all PMTCT stakeholders. Countries have set up their own PMTCT Task Forces or technical working groups, which contribute to regular dialogue between the funding bodies and UNICEF. UNICEF placed a large importance on supporting in-country management, strategic planning and coordination down to the regional and district level through technical and financial assistance. In summary, typical TA focused on:

1. Capacity Building
 - Provision of TA and financial support for the assessment of capacity building needs.
 - Supporting the development of PMTCT and Paediatric HIV guidelines, training modules and staff trainings.
 - Provision of TA to review national PMTCT policies and plans.
 - Implementation of training modules and provision of tools for health workers.
2. In-country Management and Coordination of PMTCT services and Procurement and forecasting process
 - Establishment of coordination mechanisms.
 - Dissemination of normative guidelines through WHO country and regional offices, promotion of PMTCT M&E guidelines and indicators.
 - In several countries (e.g. Rwanda, Zambia), UNICEF supported MoH in annual quantification, forecasting and procurement of PMTCT supplies.
 - Improving PMTCT interventions and linkages to appropriate care and treatment of mothers and babies e.g. in Rwanda and Malawi, support was provided to MoH to revise and update registers to strengthen mother-baby tracking and referral systems, or to support community-based programmes.
 - Quantification of laboratory supplies and development of national policies and protocols based on individual country needs.
3. Monitoring and Evaluation
 - Emphasize continuous M&E by supporting national M&E systems to harmonize national data collection, reporting according to international recommended standards

e.g. through the development of M&E tools, registries, implementation of field monitoring visits to assess storage, stock outs or data audits, as in Zambia.

- Data collection through a harmonized reporting tool- the PMTCT/Paediatric HIV report card, integration of new programmatic indicators (e.g. maternal CTX, more efficacious regimens) to improve data tracking.

Market related outcomes

Targets in terms of market related outcomes were found in the M&E log frame²³ common to all three project components:

- Price containment in actual price compared to baseline price for product in question (all components). Target: price containment of RDTs in reference to price estimates.
- Percentage price reduction in actual price compared to baseline price for product in question (all components). Target: at least 5 % reduction of two ARV products by December 2010.
- Number of better adapted and more user-friendly products submitted for prequalification (1st PMTCT & Expansion components). Target: two additional products pre-qualified at the end of the 1st PMTCT and Expansion Components duration and availability of Mother Baby Pack for country orders.
- Percentage reduction of delivery lead-times of products forecasted (all components). Target: over 90 % of products delivered within 8 to 10 weeks for AIR freights and 14 weeks for SEA shipments per country
- Number of new RUTF products approved (Nutrition component only). Target: six additional RUTF products approved by the end of the PMTCT/RUTF Component duration.
- Number of new authorisations for local procurement (Nutrition Component only). Target: LTAs signed with three new local manufacturers at the end of the RUTF Component duration.

The above market related indicators include only some products for certain components, i.e. RDTs and ARVs for the 1st PMTCT, Expansion and Extension Components, and RUTF for the Nutrition Component. Therefore, other products, such as diagnostic reagents, dispensing devices and Cotrimoxazole, could not be considered when monitoring market impact. Further, according to information from UNICEF, the targets on price reduction and prequalification of new products were the same for the different project components. This means that the targets to achieve were a price reduction of two ARVs in total and two prequalified products in total, for both the 1st PMTCT Component and the Expansion Component. Price indicators referred only to ARVs and RDTs, and therefore no estimates of achievements in terms of prices could be reported for the Nutrition Component.

Table 12. Market Outcomes Achievement Rating.

	1 st PMTCT Component	Expansion Component	Nutrition Component
Price containment	Achieved	Achieved	N/A
Price reduction	Achieved	Achieved	N/A
Better-adapted products	Partly achieved	Partly achieved	N/A
New RUTF products	N/A	N/A	Not achieved
New local RUTF manufacturers	N/A	N/A	Not achieved
Delivery lead time reduction	Unclear	Unclear	Unclear

No data was available for the Extension Component. N/A: not applicable.

²³ 1st Amendment to 1st PMTCT Initiative project plan (Annex1), Annex 4A:Harmonised M&E log frame: List of Indicators on Achievement for the 1st PMTCT, Expansion and Nutrition Component.

As presented in Table 12, the target for better adapted and more user-friendly products had only been partly achieved, since the Mother Baby Pack is currently suspended (for further details see section 4.5 Project specific questions, of this report).

Two new paediatric ARVs relevant for PMTCT had been pre-qualified during the project time, but a link between this achievement and the project activities was not established in the progress reports. Nutrition-specific indicators have only been partly achieved; two new RUTF products have been approved (targets were three by July 2009 and six by the end of this project). New local manufacturers have been approved but there was no evidence of signed LTAs with these suppliers. In relation to the lead-time indicator, not enough data was provided to estimate its achievement.

Table 13. 1st PMTCT: Year 2 reported Procurement Data for PMTCT Commodities.

Products Procured	Quantities Procured* Jan-Dec 09	Budgeted Prices	Average Weighted Prices (Year 1)	Average Weighted Prices (Year 2)	% difference Year 1 vs Year 2	% difference budget vs. Year 2
Test Kits	1,602,470	\$0.97	\$0.99	\$0.83	-16%	-14%
ARVs						
Lamivudine 150mg tabs/PAC-60	9,874	not budgeted	-	\$2.69	N/A	N/A
LPV/r 200mg/50mg heat/st tabs/PAC-120	445	not budgeted	\$41.10	\$39.17	-5%	N/A
Nevirapine 200mg tabs/PAC-60	301,085	\$3.14	\$3.98	\$3.19	-19%	1%
Nevirapine oral sol. 10mg/ml/BOT-240ml	6,486	\$2.20	\$2.20	\$1.90	-14%	-14%
Nevirapine oral susp 10mg/ml/BOT-10ml	94,100	not budgeted	-	\$0.51	N/A	N/A
ZDV + 3TC 300+150mg tabs/PAC-60	183,842	\$11.12	\$9.83	\$9.72	-1%	-13%
ZDV+3TC+NVP 300+150+200mg tabs/PAC-60	88,511	\$13.86	\$14.77	\$11.60	-21%	-17%
Zidovudine 300mg tabs/PAC-60	151,866	\$8.97	\$8.15	\$7.67	-6%	-14%
Zidovudine oral sol. 10mg/ml/BOT-100ml	192,366	\$0.84	\$0.83	\$0.96	15%	14%
Dispensing Device						
Exacta-med oral dispenser 1ml + Tip-cap	135,100	\$0.25	\$0.46	\$0.43	-6%	73%
Co-trimoxazole^a						
Co-trimoxazole oral s. 240mg/5ml/BOT100ml	208,144	not budgeted	\$0.47	\$0.35	-26%	N/A
Co-trimoxazole 100+20mg tabs/PAC-100	175,511	\$0.80	\$0.81	\$0.70	15%	17%
Co-trimoxazole 400+80mg tabs/PAC-100	170,682	\$0.84	\$1.07	\$1.08	-1%	27%
Co-trimoxazole 800+160mg tabs/PAC-100	78,253	not budgeted	\$2.22	\$2.19	-1%	N/A
Bundles						
E1 List for 200 CD4/FACSCount tests	1,011	\$9.92	\$9.33	\$9.92	-4%	-10%
E2 List for 200 CD4/Cyflow tests	750	\$6.22	\$5.72	\$5.58	-3%	-11%
E3 List for 100 DBS collection	163	\$5.77	\$3.68	\$3.53	-4%	-39%
Mini-E3 List for 10 DBS collection	4,220	not budgeted	-	\$5.50	N/A	N/A
E4 List for 288 PCR tests	94	\$23.51	\$21.55	\$13.78	-36%	-41%

*Quantities indicated refer to number of tests for RDTs, number of packs for ARVs/CTX and number of tests for bundles

Source: 2nd AR 1st PMTCT, p. 8. For referral to corresponding tables in all other Progress Update Reports, these are found in the UNITAID Evaluation Matrix.

Results by project component were:

1st PMTCT Component

Price containment & reductions: the targets for price containment and reductions of 5% for at least two ARVs were achieved, and in fact price reductions between -13% and -17% were noted for four different ARVs²⁴. Price containment for RDT's was estimated by comparing budgeted price (0.99 USD) with data from the last AR 2009²⁵ for RDTs (0.83 USD), achieving a 14 % reduction (see also Table 13 above). Additionally in Year 2, as illustrated by Table 13 above, for a total of 9 out of 20²⁶ listed products, price reductions ranged from -10% to - 41%. Prices for five other products have increased to a range of +1% to +73%, and for six other products, information was unavailable. As agreed in the MoU, prices have been reported as weighted average prices and all reported Year 2 price information is shown in Table 13 above. In year 1 the price was reduced for 17 out of 20 key products, ranging from -1% to -36%.

The prequalification of two additional and better adapted products has been reached, thereby complying with the target: Nevirapine 10 mg/ml and Zidovudine 10 mg/ml oral solutions. But the availability

²⁴ Nevirapine, 10 mg/ml, 240 ml oral solution; Zidovudine/Lamivudine 300/150 mg 60 tablets; Zidovudine/Lamivudine/Nevirapine, 300/150/200 mg, 60 tablets; Zidovudine 300 mg, 60 tablets.

²⁵ 2nd AR 1st PMTCT, p. 8

²⁶ RDTs, ARVs, co-trimoxazole, dispensing devices and five different bundles including all necessary reagents and disposables for performance of laboratory CD4 and PCR tests as well as DBS sample collection

of MBP for country orders had to be deferred indefinitely due to a suspension of the MBP in early 2011.

Lead times: Available information was unclear regarding the forecasting activities and reduction of delivery lead times. For both aspects, not enough information was available in order to verify provided information. For example, for forecasting, no information existed for when forecasts were made in order to assess their timely submission. It was unclear if reported deliveries referred to air and/or sea transport. Additionally, reported information for “on time” deliveries did not cater to an assessment of lead-time reductions. Further, the reporting period for lead-time reduction was not defined and as a result, the target was specified per country, a level to which the data was not broken down.

Expansion Component

Price reduction & containment: By considering the weighted average price and comparing the baseline price with Year 2 prices, price containment or reductions were seen in 12 out of 25 products (test kits, ARVs²⁷, Cotrimoxazole, Bundles and dispensing devices). The price of Cotrimoxazole 20/100 mg, 100 disp.tab increased by 63%. For the remaining 8 products, either budgeted or average weighted prices were missing. Price reductions ranged from 0% to -32%.

Prequalification: Progress on the availability of more user friendly products was partially achieved (target: two additional qualified products until the end of the Expansion Component duration and availability of MBP for country orders). According to UNICEF, the target of two new prequalified products was a common target for the 1st PMTCT and Expansion Component, which meant that the two new prequalified paediatric ARVs reported on in the 1st PMTCT 2nd AR also covered the Expansion Component. However, compared to 2009, the paediatric ARVs included in the PMTCT Expansion could be provided from one less pre-qualified source as of August 2010. As mentioned for the 1st PMTCT Component, it was unclear if and when MBP distribution would be taken up again.

Lead times: Available information was not enough to estimate forecasting and delivery lead times as no information was provided on when forecasts had been made and as the reported information “on time” deliveries did not cater for an assessment of lead time reductions.

Nutrition Component

Price reduction & containment: price containment for RDTs and price reductions for ARVs were not reported on in the Nutrition Component reports. Considering weighted average price and comparing baseline prices with Year 1 (Year 2 prices were not available), price reductions could be described for 3 products by June 2010 RUTF (Therapeutic spread, sachet 92g/CAR-150; -7% price reduction) and two Bundles (List E6: 200 Hb tests with HC 301; -6% price reduction and List E7: 200 Hb Tests with HC 201+; -1% price reduction).

New RUTF products approved: The 1st IR Nutrition Report, dated August 2010, reported two new RUTF products approved (Tabatchnik (USA) and Insta (Kenya)) since the project started. The report also mentioned one new LTA for global RUTF supplies (Compact India) although it remained unclear whether this was also a new product approved or not. The 2nd AR only provided limited information on these indicators.

New manufacturers: The 1st IR reported one additional authorised local manufacturer (JB Tanaka Foods, Madagascar) and in the 1st AR, one new African manufacturer for local procurement was reported as authorised (Amwili, Democratic Republic of Congo). However, no information on LTAs reached in accordance with indicator target was provided, making the achievement of this target unclear.

Lead times: Available information was not enough to estimate forecasting and delivery lead times, as no information on when forecasts were made was provided, and since the reported information for “on time” deliveries did not cater for an assessment of lead-time reductions.

²⁷ Nevirapine 200 mg, 60 tablets; Nevirapine 10 mg/ml, 240 ml oral suspension; Zidovudine/Lamivudine 300/150 mg, 60 tablets; Zidovudine/Lamivudine/Nevirapine 300/150/200 mg, 60 tablets and Zidovudine 300 mg, 60 tablets.

As agreed in the MoU²⁸, price containment and reduction were reported using Weighted Average Prices. However, it was also stated that the suitability of this benchmark should be regularly assessed and, if necessary, changed according to appropriateness. Based on available project report information, no such change from WAP to median price had taken place during the execution of the PMTCT project. However, according to available UNITAID internal reports, UNITAID had actively pursued and repeatedly stressed that UNICEF should report on median prices of commodities procured. Furthermore, UNITAID had even provided a list of options to best demonstrate price reductions in comparison with external benchmarks. It remained unclear how the UNITAID requests have been followed-up. In order to verify the results of this project and to compare them with the trends on the global market, comparisons have been made with price development of ARVs using median unit prices from the MSH Drug Price Indicator and development of number of prequalified ARVs, according to the WHO prequalification programme (including approved by other stringent regulatory authorities as FDA and EMEA)²⁹. For price reductions, the project does not coincide with any drastic trend changes and it can be assumed that the PMTCT project is too small to show an attributable impact on prices on the global ARV market. Although UNICEF has succeeded in achieving favourable unit prices below the reported median prices in many of its LTAs. For the number of prequalified sources of ARVs, on the other hand, an increase in prequalified paediatric nevirapine products could be observed in 2009. This progress might be linked to the specific PMTCT project activities, although neither UNICEF nor UNITAID have undertaken any thorough analysis to confirm such a potential market impact achievement.

4. Based on the results at mid-term, to what extent are they likely to be achieved?

Health Outcome objectives

Based on the available information (Annual Reports), which is marked by several limitations as described in previous sections, it was not possible to estimate on the likelihood of achieving health outcome objectives. A careful estimation for the three project components can only be made if the proxy is considered.

1st PMTCT Component

Maternal interventions have already superseded the target achievements for mid 2011. Paediatric interventions are marked by considerable under-achievements, which will most likely remain if the original benchmarks are not revised.

Expansion Component

A careful estimation depends on whether the missing Year 2 order placements for six of the beneficiary countries for maternal and paediatric interventions will be made on time for project completion in June 2011. A timely procurement process could considerably increase the achievement ratings for maternal and paediatric interventions, while delays would maintain the achievement levels at a low level. If the original benchmarks are not revised, paediatric objectives for this Project Component will most likely not be reached according to schedule. Maternal interventions for Year 1 have already met achievements.

Nutrition Component

Countries were still using Year 1 supplies due to additional funding support from other donors. At present, it is not clear how large the "funding needs from UNITAID are due to funding shifts in Year 1", and what the related impact on budget status and on related treatment targets is for the Nutrition Component. Without this information, it is difficult to retrieve a full picture on the project status. The Likelihood of target achievement appears to be low, considering that the project ended in June 2011.

²⁸ MoU for 1st PMTCT Component 2007-2009 10 December 2007, Annex 1: Project Plan, footnote 6, p. 18

²⁹ PMTCT UNITAID Evaluation Matrix, Additional Data worksheet

Market Outcome objectives

1st PMTCT and Expansion Components

Price containment, and in many cases price reduction, will likely be achieved, since the project has assured stable demand for PMTCT related commodities during a period of at least four years. with probable further extensions. UNICEF has also negotiated favourable prices for the LTAs used, compared to market prices (MSH drug price indicator). To a certain extent, this project could also contribute to new providers starting production and submitting applications for prequalification of PMTCT-related products. However, it is unlikely that this project will contribute a sustainable market impact, as it is not the only and probably not the largest funding source for PMTCT interventions. Regarding the Mother-Baby Pack, the original idea was to develop and promote a more suitable product for MTCT prevention. Nevertheless, the future of the MBP and its availability depends on decisions based on working group recommendations regarding the present suspension status of the pack. Therefore, it is unlikely that the target of new products will be fully achieved, even though the first part of two new prequalified ARVs has already been reported as accomplished.

Nutrition Component

With regards to the Nutrition Component, the 2nd AR reports on the tendering for new/ongoing LTAs , for which 27 suppliers have submitted offers indicating possible approvals of additional new products and possible LTAs with new local manufacturers. However, according to results reported thus far, the Nutrition Component achievements on indicators for new products and new authorized manufacturers have not met the set targets and will most likely not be achieved before the end of the project in July 2011. As no true lead-time reduction has been aimed at and reporting so far has not included the details defined in the indicator target, this objective is not likely to be reported as achieved for any of the three project components.

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

Health Outcome objectives

The most visible underperformance was noticed for paediatric interventions for both the 1st PMTCT and the Expansion Component, because the supply requests for PCR diagnostics were adjusted to the actual needs of the national programmes, to which other funding partners also contributed. UNITAID forecasts were developed in collaboration with national health ministries and in-country partners, and were adapted accordingly.

Reporting constraints that contributed to the unavailable data estimates included (valid for 1st PMTCT, Expansion and Nutrition Component):

- Integration in national PMTCT programs made end-user monitoring and reporting for UNITAID commodities not feasible, since the products were included in the overall national pool for PMTCT commodities. Additionally, the M&E framework for the UNITAID Initiative was aligned to the PMTCT and Paediatric HIV CST Report Card, and not all indicators included in the report card could be reported at the country level (e.g. maternal CTX, nb of Antenatal Care (ANC) facilities providing more efficacious regimens).
- Health Management Information System (HMIS) data was only available by the 1st quarter of the subsequent year. Therefore, national PMTCT data for the Report Card, as well as for UNITAID PMTCT reporting was only available by the end of March of the subsequent year. March data could only be included from the next Interim Reports and onward.

1st PMTCT Component

Programmatic process constraints that were potentially responsible for (reporting) lower achievement on the number of products procured could include the following:

- Lengthy decision times to consider the introduction of more efficacious regimens and early infant DNA PCR diagnosis.
- Lack of capacity and/or ownership in some countries (Malawi, Burkina, Cote d'Ivoire) in management of the commodity logistics (custom-clearance, warehousing, distribution);
- Delays in procurement processes in relation to forecasting, procurement and delivery of the supplies. For example, delays due to longer custom clearances in Zambia, lengthy paper work in Tanzania, inadequate procurement management in Burkina Faso, and delays of introducing multi-drug PMTCT regimen in India due to cost-benefit concerns.

Expansion Component

Reasons for the current status of non-achievements in regards to programmatic processes mainly refer to:

- Varying time for finalizing country forecasts and submitting the requests. Five countries had placed HIV medicine and commodity request (i.e. China, Lesotho, Zimbabwe, Uganda Swaziland), and three of them had placed orders. China, Lesotho, CAR, Haiti, Myanmar, and Nigeria continued to review quantification (2nd AR Expansion). Some countries needed more support to change from single-dose NVP to more efficacious regimens, as see in China, Myanmar, Nigeria, Uganda, and Zimbabwe.

Nutrition Component

For the Nutrition Component, no figures were available on the proxy "number of products procured" in any of the available reports. Country specific reasons had been given in the 2nd AR, mainly for programmatic reasons:

- Rwanda: data for first half of 2010 was available, but not for second half for ARVs pregnant women and infants;
- Tanzania: data was still being compiled;
- Zambia: did not have PMTCT coverage indicator data yet.
- For HemoCue, none of the countries were able to provide data yet.
- For year 2, the four countries continued to assess their RUTF and HemoCue needs among in-country partners, ensuring coordination with their respective absorption capacity. They had not yet requested RUTF and/or diagnostic commodities, as some were continuing to utilize supplies from Year 1 or further exhausting stocks of in-country partners (PEPFAR, CHAI).

Market Outcome Objectives

According to the Project Outline³⁰, UNICEF would be in continuous communication with providers. UNICEF was responsible for updating them on the demand situation and demonstrating the available funds and benefits of collaborating with UNICEF and UNITAID. It was expected that the UNITAID funding would create a stable demand for PMTCT-related commodities during the project implementation period and possibly have long-term effects, such as improved availability and decreased prices as a result of the intended scale-up of PMTCT activities in the recipient countries. This would then stimulate and stabilise the market and possibly encourage suppliers to submit pre-qualification applications for products with few or no approved sources, most importantly paediatric ARVs. However, according to the same project outline, the number of beneficiary countries and funding sources needs to be substantially higher than those included in the 1st PMTCT Component to motivate an adequate number of suppliers to participate in WHO prequalification programme and to allow for effective competition. This would lead to market commitments and significantly reduced prices. The substantial changes in quantities requested compared to those originally budgeted, resulting from the thorough forecasting exercise performed, might also have influenced the possibility of preparing manufacturers and encouraging them to produce and apply for prequalification of new products. Later on, the approval of the Expansion Component assured an increased market share for UNICEF, however the pattern of major differ-

³⁰ 1st PMTCT Component, Annex 1 to MoU 2007-2009 "Project Outline"

ences between budget and forecasts was also repeated for this project component, leading to a potentially decreased impact of the PMTCT projects on the market for related commodities. There was no information or discussion on the subject of market impact of this specific project in the progress reports provided by UNICEF, only general statements were expressed. Although activities of engagement and communication with the industry were reported as implemented, the implementing body identified no measurable outcome.

For targets related to **reduction and containment of prices**, UNICEF has performed efficient tendering processes and signed LTA covering commodities not only specific to PMTCT interventions or even HIV. Thus, favourable prices were achieved for ARVs and RDTs, which were generally below comparable market prices (MSH Drug Price Indicator).

The indicator related to **new, better adapted and more user-friendly products** had a target that included new pre-qualifications and availability of the Mother Baby Pack. With regards to prequalification, the stable demand created by this project had been communicated to the industry and this might have incentivised manufacturers to produce and submit applications for prequalification to WHO. The reported achievements were for paediatric ARVs where the project might have had a certain impact, e.g. requesting particular bottle sizes for liquid AZT and NVP. However no efforts have been made by the implementing body to link these new pre-qualifications to the specific PMTCT project activities. With regards to ARVs for adult use, in comparison to the global market for basic 1st line ARVs this specific project was far too small to have any measurable impact on prequalification of ARVs. Factors influencing the availability of the MBP were delays in development, complex and varying treatment guidelines, and ultimately, the suspension of further distribution of the finished product. For more details on the Mother Baby Pack, refer to section 4.5 Project Specific Questions.

For approval of **new RUTF products and authorization of new local manufacturers of RUTF**, according to UNICEF³¹, the volumes procured through UNITAID funding have already lead to the approval of two new RUTF products and two new local manufacturers authorized by UNICEF. The reported 7 % price reduction could however not be verified. Nevertheless, most of these improvements were seen very early in the project's implementation, with a later stagnation of development threatening the achievement of the project targets. Both UNICEF and other actors worked together with manufacturers to improve cost-effectiveness and quality production capacity. During the latest reporting period of the project, a Request of Expression of Interest for potential RUTF suppliers was published in order to establish new LTAs for 2011 and a total of 27 offers were submitted. However, the reasons for non-achievement of targets were unclear, since planned activities such as engagement in and coordination of industry were reported as implemented.

It was not possible to evaluate the achievement of the **lead-time reduction** target because the reporting was not detailed enough to meet the definitions of the indicator target. However, according to discussions with UNICEF, a generally reduced lead-time had not been a true objective of this project, rather it aimed to improve timeliness of deliveries according to agreed delivery dates. To further illustrate this, UNICEF took the initiative to also report "Percentage of on-time deliveries". This is considered a fairer measure, as some deliveries were purposely planned with longer lead-times, e.g. when forecasts had been made for the entire year and deliveries were divided into staggered deliveries in order to meet in-country supply management capacity and obtain longest possible shelf-lives of products procured. It should also be mentioned that the on-time delivery measurement took the delivery date agreed upon between UNICEF and suppliers as a reference, and not necessarily the delivery date originally requested by the recipient countries in their requests for Cost Estimates.

³¹ PMTCT Nutrition Component, 1st Interim Report

Risk Management System

According to available project documentation, a specific risk management system with a list of key risks and a proposal of corresponding risk mitigation measures did not appear to be in place. There were several general de-risking practices applied throughout the projects to mitigate foreign exchange risks in relation to procurement of supplies, which are consistent with standard business practices (original 1st PMTCT MoU), the definition of roles and responsibilities per project partner (UNICEF, UNITAID, WHO), development of programme approach and procurement strategy, UNICEF Competitive Tendering Procedures, Quality Assurance of pharmaceuticals, and customer satisfaction surveys (1st PMTCT Component, 1st AR) etc.

3.3 Efficiency

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

Rating		Level of confidence	
<input type="checkbox"/>	Optimal	<input type="checkbox"/>	Optimal
<input checked="" type="checkbox"/>	Minor concerns	<input checked="" type="checkbox"/>	Minor concerns
<input type="checkbox"/>	Major concerns	<input type="checkbox"/>	Major concerns
Key findings			
Findings common to all Project Components			
<ul style="list-style-type: none"> • UNICEF has been successful in tendering. Unit costs agreed in LTAs were generally lower or in line with the budget and lower than median market prices available for comparison. • Forecasting processes have been prolonged and no monitoring of timely submission of forecasts and Cost Estimates was done. • Average lead-times were between 61 and 91 days for the three components. However, UNICEF rather emphasized timeliness of agreed delivery dates and reports on on-time delivery, as some deliveries were planned with longer lead-times due to long-term planning in forecasts made in several recipient countries. • Procurement was performed by the UNICEF Supply Division in Copenhagen and followed the organisation's procedures and practices, which were further governed by the UN Financial Rules and Regulations. • The majority of acquisitions were accomplished under Long Term Agreements between UNICEF and the suppliers. • Order Status Reports with detailed information on quantities, prices and delivery dates were publicly available online via UNICEF. No summary of this data per country and per commodity type or intervention was made available in the progress report. • According to UNICEF, no stock-outs of UNITAID funded products had occurred. However, this information was not verifiable since such data had not been collected. 			

6. Are the project partners working closely with the relevant national authorities in the projects beneficiary countries?

According to the project plans and progress reports for all PMTCT Components, 17 MoUs (8 original countries plus expansion countries) had been signed and should be available. Each MoU covered a single country regardless of whether a country benefited from several PMTCT Components. However, the MoUs were not made available to the evaluation team for verification. The only signed documents available were the implementation letters for the 1st PMTCT Component. According to UNICEF infor-

mation, the MoUs were only available in country offices and no copies had been provided to UNITAID. UNICEF Supply Division also had its own agreements with all the country governments.

WHO involvement in the UNITAID PMTCT project was limited, despite being outlined in the MoUs and project plans (see report section 2 for further details). Other than what was foreseen in the contractual agreements, WHO did not actively participate in UNITAID project implementation up to the development of the Extension project plan. The main reason given by WHO was that project ownership had been entirely within UNICEF, mainly as a result of all UNITAID's funds being dedicated to procurement and kept at UNICEF level. Programmatic components had, until the Extension Component, not been funded, which led to the limited WHO involvement. WHO's current project responsibilities and project contributions have been outlined in the project description section.

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

UNICEF has been using its own well-established procedures for procurement. The majority of acquisitions have been undertaken under Long Term Agreements that UNICEF signed with a large group of suppliers. The LTAs were usually tendered and issued once yearly, as part of the regular basic operations of UNICEF. When new requirements were identified or when products not covered by the LTAs were to be acquired, additional tenders were launched, resulting in the signatures of additional LTAs or an agreement for a single procurement process. These LTAs were not specific for a given project but rather covered a wide range of products that UNICEF had an interest in procuring. Also, there were usually several contracted manufacturers for the same commodity, in order to assure a constant supply of the most important products acquired in high volumes. For example, of the 18 ARV LTAs reported in the 1st Interim Report of the 1st PMTCT Component, only seven were in fact utilised for the UNITAID PMTCT project³².

The inclusion of basic operations such as tendering and establishment of LTAs, as a project activity to be reported on, masked important health and market outcome activity achievements and non-achievements, and did not add valuable information on project progress. For the procurement of diagnostics, the Project Outlines³³ stated that arrangements under the WHO Bulk Procurement Scheme would be used, and hence no further tendering should be needed. This was not entirely the case. UNICEF had its own LTAs with providers of diagnostic test kits, reagents and consumables, but was collaborating with WHO in tendering and evaluations of offers and benefiting from the technical expertise of the larger organisation. Changes from the original project plan such as the above statement on the use of WHO LTAs, were not officially established as updated document versions, making it difficult to keep track of modifications and assess present arrangements (see further Conclusions and Recommendations section of this report (Recommendation No 1).

The UNICEF procurement principles follow the UN Financial Rules and Regulations, as well as International public procurement principles and practices. For example, all potential suppliers should be eligible to compete for public funds. Nevertheless, in the evaluation of offers UNICEF will primarily award providers that have been prequalified by WHO. If no or only one pre-qualified source is available for a certain product, UNICEF will perform a quality assurance assessment of manufacturers, which includes a mandatory GMP approval, in order to evaluate the suppliers bidding in the tender. In accordance with the procurement principles, the roles and responsibilities within UNICEF are well defined and regulated in order to comply with the interagency guidelines and to avoid conflicts of interest. UNICEF in its role as procurement agent for the current project was responsible for tendering, contracting and coordination of suppliers, as well as for quality assurance, shipment and insurance during transport.

³² In Exhibit 2 of 1st PMTCT Interim Report, "PMTCT 1st IR Questions UNITAID 19.09.2008"

³³ PMTCT Annex 1 to MoU 2007-2009 "Project Outline" and Annex 3 to 1st amendment to MoU "Project Plan for PMTCT Expansion Component"

In the assessment of the procurement model for the PMTCT project, Orders Status Reports publicly available online via UNICEF were used for verification of data. These reports include detailed information on products, quantities, costs, suppliers and dates for Cost Estimates, POs and deliveries for all procurement performed within the reporting period. The following findings have been made:

- The majority of key commodities had been procured at median unit costs under or in line with the budget. This was especially true for RDTs, ARVs and RUTF to which specific price indicators were tied in the M&E log frame. The source for the budgeted costs was prices agreed in the LTAs in effect at the time the budget was established. In comparison with available market price sources (MSH Drug Price Indicator) UNICEF succeeded in signing LTAs at prices lower than the median market prices for ARVs, see table 14 below.

Table 14. ARVs Procured within 1st PMTCT Component Year 2.³⁴

Antiretrovirals Procured	Quantities Procured* Jan-Dec 2009	Budgeted Prices	Average Weighted Prices (Year 2 [†])	% difference budget vs. Year 2 [†]	MSH median price 2009
NVP 200 mg, 60 tabl	301'085	3.14	3.19	2%	4.21
NVP 10 mg/ml, 240 ml	6'486	2.20	1.90	-14%	3.82
AZT 300 mg, 60 tabl	151'866	8.97	7.67	-14%	9.95
AZT 10 mg/ml, 100 ml	192'356	0.84	0.96	14%	1.25
AZT+3TC 300+150 mg, 60 tabl	163'842	11.12	9.72	-13%	10.90
AZT+3TC+NVP 300+150+200 mg, 60 tabl	68'511	13.98	11.60	-17%	11.78

* Quantities indicated refer to number of packs

[†]Year 2 here refers to 2009

- All ARVs procured except one (ZDV+3TC+NVP from Aspen Pharmacare) have been verified as WHO prequalified, and approved or tentatively approved by Food and Drug Administration (FDA) or European Medical Authority (EMA). According to UNICEF, no procurement of non-prequalified ARVs had taken place and hence no independent quality assurance review had been performed. The details found in the Order Status Reports were however not sufficient to assure that the exact product, as defined by manufacturing site and package specifications, was the one prequalified or approved. For several ARVs, the UNICEF warehouse was the reported supplier, and in those cases the prequalification status was consequently not verifiable.
- Forecasting processes have been lengthy and no function for assuring timely submission of forecasts and requests for Cost Estimates was in place. Registration status and Intellectual Property topics were part of the forecasting process, in order to avoid bottlenecks in the subsequent steps of the procurement process. However, no related information was available and it was not possible to assess whether such issues were part of the explanations to the prolonged forecasting processes.
- It should be acknowledged that the differences in national treatment guidelines and policies pose certain constraints/challenges to the pooling of demands and coordination of the procurement processes in this project. The WHO guidelines are open for several alternative protocols within the two main options A and B. According to option A it is possible to omit the single-dose NVP and the AZT+3TC during labour and delivery if the mother has received more than 4 weeks of AZT during pregnancy. Option B suggests five different triple-ARV combinations for pregnant women. Further, the recommendations for infants differ between breastfeeding or non-breastfeeding infants. These are all considerations to be made by the national authorities responsible for development of treatment guidelines. The recipient countries requested commodities after UNICEF in-country resources have assured selected products are in line with national treatment guidelines and demands. Subsequently UNICEF Supply Divi-

³⁴ 2nd AR 1st PMTCT project component, p. 8

sion procured what was requested, in some cases after further technical assistance regarding quantification of needs.

- According to Action 5.9 in the Project Outline³⁵, UNICEF should ensure that required quantities of commodities requested are in line with the targets approved for the project. However, the opposite situation with major differences between targets, original budgeted quantities and actual procurement requests has been accepted without any corresponding adjustments of targets.
- The average lead-time between placement of Purchase Orders and deliveries in countries was 61 days for the 1st PMTCT Component Year 1 & 2 and 91 days for the Expansion Component Year 1 (Year 2 data was only available for three countries with an average lead-time of 138 days). For the Nutrition Component, average lead-time was 61 days for Year 1 (no purchase orders had been reported on for Year 2). The prolonged average lead-time for the Expansion Component was mainly due to the average of 180 days for Uganda and 101 days for China. No further explanation for these two specific cases was provided, but in general, according to UNICEF, some of the longer lead-times were planned as a result of requests for staggered deliveries or submission of requests from countries covering forecasts for one entire year. Nevertheless, it should be noted that UNICEF mainly focused on monitoring on-time delivery and that this was measured according to UNICEF agreements on delivery dates with providers. It did not take into account the original requests for deliveries from the recipient countries, which might have deviated from what was finally agreed.
- According to UNICEF no stock-outs of PMTCT commodities were known. However, the outline of the project did not allow for systematic monitoring of stock levels. The PMTCT commodities procured under the UNITAID funding were entered into the national health systems at delivery in the recipient countries, and there was no possibility to further follow the products in question. UNICEF also stated that no emergency orders were issued as a response to an upcoming or existing stock-out situation. No information was provided on buffer stock considerations and hence it was impossible to evaluate whether this was an important factor for a possible stable supply of commodities.

3.4 Impact

The objective is to assess to what extent it is possible to demonstrate the impact of UNITAID funding in the target countries

Rating	Level of confidence
<input type="checkbox"/> Optimal	<input type="checkbox"/> Optimal
<input type="checkbox"/> Minor concerns	<input type="checkbox"/> Minor concerns
<input checked="" type="checkbox"/> Major concerns	<input checked="" type="checkbox"/> Major concerns
Key findings	
Findings common to all Project Components	
<ul style="list-style-type: none"> • The number of patients treated/ diagnosed was not reported for any of the three Components. • The number of products procured substituted the number or percentage of treatment targets delivered for all three Components. • Furthermore, the population and service based indicators were generated through national data and could not be attributed to the UNITAID funded PMTCT projects. • Procured products were not followed throughout the supply chain to patients. As a result, no information on the effective distribution of treatments procured was available. • Procurement of commodities purchased was not reported per beneficiary country. The data 	

³⁵ PMTCT Annex 1 to MoA 2007-2009 "Project Outline"

could not be verified, as information from the Order Status Reports did not appear to coincide with reported total project summary data in the Annual Reports. Only a summary for key target interventions was provided.

Component Specific Findings

- For the Nutrition Component, no data on procured commodities per beneficiary country was yet available.

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

Patients treated

UNITAID specific contribution to the number of patients treated could not be estimated for the beneficiary country nor as an overall total, based on the reported information. (Please refer to report section 4.6 for further details).

Procurement of medicines and diagnostics

The number of medical and diagnostic products procured and delivered could actually be attributed to UNITAID funding, but for the 1st PMTCT Initiative and the Expansion Components data was only provided on the number of products procured. For the Nutrition Component, no data was available. Procured products were not followed throughout the supply chain to patients, providing no information on whether products had been dispensed. Procurement related achievements and non-achievements based on the indicator “number of products procured” compared to target indicators have already been presented in report section 4.2 Effectiveness Question 3 and corresponding data Tables 7-11.

1st PMTCT Component

A global estimate for all countries on PMTCT commodities procured in Year 2 was only available in the 2nd AR 1st PMTCT per key intervention. The corresponding reference document was the Order Status Report (Exhibit 3 of 2nd AR 1st PMTCT) that listed purchase orders for each individual beneficiary country, but did not provide a summary total per key intervention. The figures per key intervention (as reported in 2nd AR 1st PMTCT Report, section A2) did not add up (e.g. for RDTs: 1'486'539 RDTs had been procured according to programmatic report, findings compared to 1'602'470 RDTs calculated by the evaluation team based on Exhibit 3 Order Status information). Due to these data uncertainties, the information at country level could presently not be verified. A country specific summary of the Order Status Report should be provided as an annex to the report, in order to facilitate data verification.

Expansion Component

For Year 1, only summary information was available on the number of products procured for all countries together. For Year 2, a global estimate on PMTCT commodities procured was only available for three countries (2nd AR 1st PMTCT per key intervention, Order Status Reports). Data for six beneficiary countries was still outstanding. The Order Status Reports were marked by the same limitations as those for the 1st PMTCT Project Component.

Nutrition Component

No data was yet available on treatments/diagnostics procured per country through UNITAID funding, as the four beneficiary countries had not yet requested commodities.

3.5 Project Specific Questions

9. Is the mother and baby pack for PMTCT ready to be implemented in all countries? What were the major factors influencing the achievement or non-achievement of this objective?

The development and implementation of the Mother Baby Pack has been marked by several constraints. The most important constraints refer to considerable delays during MBP development and the temporary suspension. In addition, confusion between UNITAID and UNICEF existed on UNITAID's funding contribution towards MBP development. These issues are further addressed below.

Delays

The Mother Baby Pack suffered major delays in its development; the reasons for this were not reported to a satisfactory extent.

- In the Project Outline of 1st PMTCT Component³⁶ activity 5.6 the Milestone established was Request for Proposals in early 2008 and MBP available by December 2008.
- The actual issuance of the RFP was May 2009, after stakeholders agreed upon the content in February 2009.
- The tender was expected to be finalized in July of 2009, according to Annex 3 of the MoU amendments (Expansion Component). And according to that project outline, the Milestone for the activity was a field-tested MBP by Q4 in 2009 and product made available for ordering in Q1 2010.
- According to Annex 1B of the 2nd MoU amendment (Extension Component), the LTA was established in June 2010. The winning manufacturer was Cipla, which developed the final product: a box containing four inner boxes with commodities specific for each of the four categories: During Pregnancy, Labour & Delivery, After Delivery for Mother and After Delivery for Baby.
- The new Milestone for order availability in the new Project Outline for the Extension Component was Q3 2010.
- The MBP was piloted and tested and finally launched and implemented in four countries: Kenya (29Oct10), Zambia (25Jan2011), Lesotho (28Jan11) and Cameroon (April 2011). Of these four countries, Kenya is not part of the UNITAID PMTCT recipient countries.
- The MBP was also listed in the UNICEF online supply catalogue during a short period in the beginning of 2011.

Suspension

In April 2011, MBP was suspended. According to WHO, the MBP suspension was triggered by investigations (e.g. interviewing mothers) made by the activist group "AIDS-free-world" in Kenya after the MBP launch. They claimed that there was not enough training, not enough commodities etc. and sent a letter to UNICEF about their concerns. Further suggested reasons for the suspension are:

- The MBP only provided drugs for 8 weeks for the infant and did not include information on follow-up for the entire breast feeding period as recommended in the 2010 WHO guidelines.
- Cotrimoxazole was included for all mothers and children regardless of CD4 count as recommended by WHO.
- According to UNICEF, additional reasons for suspension included the readiness of the programmes to supervise and guide the use, as well as weakness of M&E-systems in place

In early May, UNICEF convened a meeting to address the MBP issues with all stakeholders, producing a 6 page report which had not been made available to the evaluators. Working groups were formed to come with recommendations by mid-June. A decision on how to proceed was expected for

³⁶ PMTCT Annex 1 to MoU 2007-2009 "Project Outline"

July. However, there were some reservations, as the guidelines and different treatment options might have been too complex to overcome to still benefit from the concept of a package. It was necessary to thoroughly reassess how the MBP fits into overall support to PMTCT programs at the country level. Meanwhile Zambia decided to unpack the MDPs and use the commodities separately, while Kenya and Cameroon were still waiting for the decision on suspension. No information on the status in Lesotho has been shared.

Deviations in perceptions of MBP funding

The latest available report referred to January 2011³⁷. It described funding sources for the initial phase I of implementation and validation set at 3'414'063 USD in June 2010 (proposal supported by national committee contributions from Austria, Germany, Japan, Netherlands, UK and USA). Further contributions and increased demand for MBP resulted in an overall budget of 5.61 million USD with contributions also from UNITAID, OPEC and CDC, according to the report.

According to WHO, UNITAID does substantially fund MBP, but it was not clear what it was actually funding. On the other hand, according to UNICEF, no UNITAID funds had been used either for the development of the MBP or the procurement of the packs delivered so far. It was however stated that the UNITAID funding had been a very important factor in the accomplishment of the MBP development since it granted a stable funding source for PMTCT related commodities and the project had created a demand for the product.

According to UNITAID, the Mother Baby Pack has been an important part of the PMTCT project from the beginning and the perception was that UNICEF used PMTCT money to develop the MBP. However, it was never clear to UNITAID exactly how much of the money disbursed was directly used for development purposes. It did however represent one of the underlying ideas that made PMTCT attractive to UNITAID, as it represented a new product (and hence an important intervention in the market place). UNITAID anticipated that once the MBP was fully developed, PMTCT funds would be used to finance the purchase of the MBP for UNITAID funded countries.

Due to the delays and suspension of the MBP, it is unlikely that the UNITAID funds will be used for procurement of Mother Baby Packs within the 1st PMTCT Extension. Depending on the decisions made concerning the present suspension and a possible approval for a requested extension of the PMTCT Expansion Component, there is still possibility to procure UNITAID funded MBPs, but this is highly uncertain.

Additional MBP relevant information

The content of the MBP was originally based on WHO 2006 guidelines option A and later, when made available, updated to 2009/2010 guidelines. These included AZT for pregnant women from week 14 but only Nevirapine for 8 week old infants for consumption, making it necessary to refer to other health care facilities for a continuation during the breastfeeding period.

The last progress report did not provide relevant information on the number of women who benefited from the MBP, neither did any of the available and current Order Status Reports present the MBPs procured. 4'500 MBPs were delivered thus far, according to the last MBP update, but how many of those were actually distributed is unknown (Exhibit 4 of 2nd Annual Report of PMTCT2 Expansion Component). Nevertheless, according to UNICEF no MBPs procured and delivered so far were funded by UNITAID.

10. Describe UNICEF's, WHO's and UNICEF's role in making the Mother and Baby Pack more widely available.

There were no clear roles defined for WHO, UNITAID or UNICEF specifically for the Mother Baby Pack. Responsibilities were only defined for the overall project management and implementation level

³⁷ PMTCT Expansion Component 2nd Annual Report Exhibit 4 "Progress Update MBP July to Dec 2010"

for all three key stakeholders. According to WHO, they provided some input to MBP development, although it was not a clear mandate. WHO participated in pilot meetings and training on MBP. UNICEF on the other hand had already started outlining the possible design of the pack before receiving UNITAID funding and had been the responsible party throughout the MBP development.

As described above, the Mother Baby Pack could be ordered for a short period, and if it hadn't been suspended it would have been ready for wider implementation, starting with four additional countries programmed for 2011 in the 1st PMTCT Extension Component. However, as a result of the delay in development and the recent suspension, it has not been possible to implement activities to make it widely available. However, if the MBP is to be made more widely implemented the variety of treatment protocols and how they corresponded to the contents in the pack would be one major limitation. Examples of such national variations include the transition statuses from 2006 to 2009 guidelines, inclusion criteria for Cotrimoxazole prophylaxis and selection of WHO guideline option B for national protocols.

Nevertheless, the objective is to develop and place a new product on the market, which could be offered to all applicable countries in line with national guidelines. However, the complexity of the WHO recommendations and the MBP's aim to cover as many options as possible (e.g. single-dose at delivery, Cotrimoxazole to all mothers and infants), while not including commodities in order to follow 2010 recommendations for breastfeeding could possibly prevent it from becoming widely available on a larger scale. Some of these issues were also part of the reasons for suspending the MBP until further notice.

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

UNITAID was not envisioned to be a long-term founder of national treatment programs, but rather a time-bound initiative aiming to affect market dynamics and enable sustainable delivery of essential commodities. Transition planning in the next 12 month period focused on ability to transfer funds for the commodities being used in treatment, as well as ensuring that the impact of the Initiative on such market dynamics (i.e. demand, availability and price) was sustainable and transferable to other partners/funding agents. Transition planning post-2011 was further envisioned to be phased: (1) transition to alternative external funding by leveraging financial resources from the Global Fund in 2012-2015 and PEPFAR (2) transition to the national government funding.

According to information from UNITAID it was expected that many of the recipient countries would be selected in GFATM Round 10 call for proposals and that this funding would then cover the up-scaled PMTCT interventions started within the present PMTCT project. Nevertheless, no information on success with regards to planned transition activities was provided in any of the reports reviewed. The only countries that were finally recommended for the GF Rd 10 HIV component were Cameroon, Zambia and Burkina Faso. Burkina Faso was the only country that had already shifted to GFATM funding and was excluded in the PMTCT 1 Extension Component. Cameroon and Zambia were included in the PMTCT 1 Extension which ends in 2011 and no further details concerning transition planning has been provided for these countries either.

3.6 Comments on reporting arrangements

Rating	Level of confidence
<input type="checkbox"/> Optimal	<input type="checkbox"/> Optimal
<input type="checkbox"/> Minor concerns	<input checked="" type="checkbox"/> Minor concerns
<input checked="" type="checkbox"/> Major concerns	<input type="checkbox"/> Major concerns

Key findings**Findings common to all Project Components**

- Reports have mostly been submitted on time with only few days' delays in some instances.
- Reporting constraints exist in terms of report content and structure. Reporting is not always aligned with the M&E log frames, some information was missing (e.g. for delivery times and forecasting).
- Reporting limitations were partially a result of the non-user friendly report template design and the generally formulated report standards and requirements.
- Reported information referred to nationally generated data from WHO/UNICEF/UNAIDS joint reporting tool for the HIV sector's response to HIV and WHO Access Reports 2008/2009, which did not allow the identification of UNITAID specific contributions.
- M&E log frame indicators were not always well reported on, as key indicators such as “% of treatment targets delivered” were reported by using a verbally agreed proxy.
- Several data inconsistencies existed between programmatic report section C.2, financial report data and additional financial information in Table 3.9.1 of the report for all project components.
- Financial Reports were marked by several limitations, e.g. cash reconciliation was not supported by financial or bank statements, no information on interest earned.
- No cumulative progress reporting because the Annual Reports only covered the reporting period.
- Reports were submitted on a yearly basis instead of by calendar year.

Component Specific Findings

- Annual Reports for the Expansion and Nutrition Components actually only reported on the six-month period subsequent to the last interim report and could not be regarded as yearly.

As mentioned in previous report sections, KPIs refer to objective and activity achievements for all components that were mainly defined in the corresponding M&E log frame³⁸ (1st Amendment, Annex 1, 4A for 1st PMTCT, Nutrition and Expansion), while population and service based Indicators were defined in Annex 4B of the same document. Although these were agreed upon by all partners with their signature of the MoU, it was questionable whether they were suitable to report on project specific achievements and progress of UNITAID funded projects, because in several instances, they were either not correctly reported on as required in the respective M&E log frame, or mainly referred to national figures. The reasons were as follows:

- 1) The verbally agreed proxy “PMTCT commodities procured in a given year” was used to report on the target indicator “% target treatments delivered per maternal and paediatric intervention per country”, as products integrated into the national system could not be followed throughout the supply chain to patients. No official documentation, such as an agreement on a redefined treatment target indicator, was made available, which would have confirmed such a verbal agreement. Therefore, the evaluation team has attested non-compliance with the defined indicator. It is further unclear how the existing indicator definition should be interpreted, as it could refer to either “% of treatments supplies delivered per maternal and paediatric intervention” or to “number of patients treated per maternal and paediatric intervention”. Considering UNITAID

³⁸ 1st Amendment to 1st PMTCT Component project plan (Annex1), Annex 4A: Harmonised M&E log frame: List of Indicators on Achievement for the 1st PMTCT, Expansion and Nutrition Component. AND

2nd Amendment to 1st PMTCT Component project plan (Annex 1B), Annex 4B new M&E log frame for the Extension Component.

objective and goals, either a stronger monitoring for reporting on indicator compliance or a re-formulation of the definition of this indicator should be considered. Then the important key activities and core competencies of UNITAID funded projects, namely procurement and supply delivery related activities, could be captured.

- 2) A wealth of population and service based indicators have been defined for the UNITAID funded Project Components (Annex 4B), but they were mainly based on national program data generated for the WHO Access Reports and the joint WHO/UNICEF/UNAIDS joint Reporting tool for HIV. These were complemented with additional efforts from UNICEF and WHO to collect further data on project relevant M&E indicators, such as the number of pregnant women initiated on Cotrimoxazole, through a standardized M&E Reporting Framework (developed for the 1st PMTCT and Expansion Project Components). All project partners agreed to use this data to report *“to UNITAID on the annual progress made with regards to program implementation. As agreed on, UNICEF will confirm that the PMTCT interventions to women and infants funded by UNITAID are ADDITIONAL within a country context. The main procurement indicators are: 1) progress towards intervention targets (e.g. the nb of people receiving ARV for PMTCT), 2) price reduction 3) treatment cost 4) nb of appropriate drugs available on the market 5) delivery lead times 6) nb of treatments supplied. The programme indicators are based on international PMTCT M&E guidelines and the WHO framework for monitoring and reporting on health sector’s response towards universal access to HIV/AIDS treatment, prevention, care and support 2007-2010³⁹.”* By completing the report card on the Prevention of Mother-To-Child Transmission of HIV and Paediatric HIV Care and Treatment⁴⁰, data for the WHO Access reports was generated at the country level. The underlying strategy for this approach was to avoid parallel reporting systems and to integrate UNITAID funded commodities into existing national systems. While this was certainly a valid argument, the question arose whether these program indicators were suitable to report on project progress for UNITAID funded Project Components, as no direct interrelationships between specific project achievements could be made. Rather, they provided some important general updates at the country level and acknowledged some unspecific UNITAID contributions to overall national and facility level PMTCT indicators. Considering the complete PMTCT funding landscape for PMTCT interventions and the existence of several funding sources (e.g. GF, PEPFAR, CHAI and government), the reported information did not highlight UNITAID attributed achievements and non-achievements. UNITAID attempted to estimate its contributions to the PMTCT supply chain in the 2nd IR 1st PMTCT for the eight PMTCT countries, which was considerable since 100% of country needs for CD4 reagents and 98% needs for HAART commodities were for eligible PW. Yet, again these figures referred to UNITAID funded procurement and not to treatments provided. In a rapid attempt to extract UNICEF specific data for some of the population-based indicators, the evaluation team was successful. Some UNICEF specific data on key PMTCT indicators, such as “No of HIV+ pregnant women receiving PMTCT treatment/prophylaxis” or “No of HIV-exposed infants receiving HIV PCR test“, were identifiable in publicly accessible documentation⁴¹ for 2008 and 2009. Based on these findings, UNICEF should be able to report on project specific data. Project specific data reporting should be formalized in agreements.
- 3) As UNICEF is not following procured products throughout the supply chain to patients, no information was available whether treatments procured were effectively dispensed.

³⁹ 1st PMTCT, MOU, Annex1, p.28

⁴⁰ 1st Amendment to 1st PMTCT Initiative, Annex 3 Expansion project plan, p. 19: The Report Card includes both policy and program coverage statistics on activities for PMTCT paediatric HIV care and treatment interventions aggregated from all sites (public, private and NGOs).

⁴¹ Country Fact Sheets, Children and Aids. Data source of Fact Sheets: UNAIDS, 2008, 2009

Although the reported proxy for the treatment target indicator did not fully coincide with the agreed on M&E indicator, it did provide some indication of project specific status and progress of the various UNITAID funded PMTCT projects, especially procurement. Findings related to the reported proxy and national data based population and service based indicators were presented in report section 4.2 Effectiveness and 4.4. Impact.

Programmatic Reporting

UNITAID's report requirements were spelled out in the MoUs and respective Project Plans and were almost identical for the three project components. The deadlines for the reports were specified in the disbursement and reporting schedules presented in the project plans. A standardized reporting template was provided. The reporting requirements were formulated rather generally for the Annual, Interim and Final reports, leaving considerable room for interpretation.

Limitations of the reports include:

- For service and population based indicators, data referred to nationally generated data, e.g. from WHO/UNICEF/UNAIDS joint reporting tool for the HIV sector's response to HIV and WHO Access Reports 2008/2009, which did not attribute UNITAID specific achievements.
- Log frame indicators were not always well reported, i.e. reported information on lead times was unclear.
- No cumulative progress report could be found (e.g. for 1st PMTCT Component a summary overview on overall project performance was not provided). Follow-up information was difficult to identify.
- The implementing body could not always verify reported achievements because available information clearly indicated non-achievements, e.g. number of treatments delivered was reported as achieved. However for all indicator targets, the achievement rates for the proxy "number of products procured" were below the 100% target for Year 2.
- The report section "From the MoU" (activities 23-39, 2nd AR 1st PMTCT) did not provide added value. Information was reported by providing a simple "yes" or "ongoing" without adding further details for verification purposes.

The level of communication exchange (e.g. number and type of clarification requests) could not be verified because exchanges between UNITAID and the implementing partners were not documented.

All reports seemed to have passed the UNITAID internal report validation processes and have been approved. Based on information from UNITAID, on several occasions UNITAID has requested UNICEF to clarify M&E programmatic indicators and to improve their project reporting by providing information by calendar year and not grant year, but the response has been limited. In the future, both parties should address reporting and M&E limitations in a more collaborative approach.

Financial reporting

Section C of the programmatic reports and the attached utilization reports in the Exhibits (see reference for the 1st PMTCT Component⁴²) for all PMTCT project components include financial information. Annual Financial and Procurement Report requirements were kept very general. Across all three components, the financial reports referred to Utilization Reports while the procurement reports referred to Order Status Reports, which had been attached to the programmatic report without any additional explanations, calculation basis, reference documents or summary information.

⁴² Based on 1st AR and 2nd AR 1st PMTCT Initiative, programmatic report e.g. section C1 information and the financial reports (Exhibit 2 (2nd AR) or Annex 2 (1st AR))

The limitations of the financial reports were:

- Finance reporting requirements and contractual supporting documentation requested by UNITAID were not fully detailed in the project plan or the MoU of projects. A specific appendix on finance reporting that is in line with activities initially planned and effectively implemented should be developed, according to the approved budget breakdown per cost category, and objectives/outputs (including a summary overview of overall project status). In order to facilitate financial controls and funds tracking and reconciliation, a specific bank account (or sub bank account) could be requested by UNITAID for each project. This finance template should present the figures and should be compared to both current and cumulative budgets associated with respective supporting documentation, e.g. bank statements, bank reconciliations, copies of invoices, etc.
- Budget adjustments and reallocations were not systematically formalized in an addendum to the initial MoU officially approved by both parties. Considering the number of possible financial revisions that could occur through the duration of the projects, this is a source of confusion and limits efficient financial management.
- Projects' implementations did not follow performance based funding principles since disbursements were not related to progress, but rather on the basis of a pre-defined scale described in the MoU.
- Requirements for bank interest generated with funds received from UNITAID were not clearly defined in the MoU. Significant differences existed between projects.
- Several data inconsistencies existed between the programmatic report sections C.2 and the financial reports, which requires harmonization and explanations of data differences, as well as a calculations basis.
- Based on the available information, it was impossible to verify whether expenditures were in line with activities initially planned because the "financial reports" only provided information on Total funds received, Total expenditures and unexpected balances per country.
- The financial information could not be linked to any specific activities or traced in either the programmatic report or other sources.
- No cumulative financial progress reporting was found. Year 1 and Year 2 data was reported separately, but a summary overview on the overall project status was not provided.
- No information was given on common budget items, such as salaries or travel expenses.
- No information was available on interest gained.
- Although not specified as a requirement, Cash reconciliation in section C.3 should be supported by financial statements or bank statements, considering the profile of the reports.
- No reported information on savings made. Reports should provide information on the reallocation of savings.

New M&E log frame

The first report of the Extension Component will report on the new M&E log frame, using the new report template. The evaluation team has conducted a rapid assessment of the new M&E log frame, highlighting strengths and weaknesses:

Strengths:

- Process, Outcome and Output indicators have been formulated.
- Responsibilities have been defined by activity and indicator.
- New verifiable and measurable indicators, specifically for the UNITAID funded Extension project, have been added (e.g. "Number of countries submitting requirements within two months of project commencement").

- Several indicators related to the percentage of target treatments, tests delivered per country, and paediatric interventions have been added. This provides UNITAID with indicators to identify UNITAID specific PMTCT contributions. However, reporting compliance with the exact definition of the indicator needs to be assured. Reporting on a proxy should be avoided.
- The price related indicator is better defined as "percentage of price reduction and/or price containment in actual price compared to baseline price, interquartile range and median price for PMTCT commodities".
- An indicator on transition funding has been added, which facilitates monitoring of sustainable funding.

Limitations:

- The M&E log frame is not entirely consistent with activities and indicators defined in section 5 of the Extension project plan Annex 1B. These two documents need to be harmonised to assure well targeted reporting (e.g. for activity 5.1 the milestone is more precisely defined than the corresponding M&E log frame indicator).
- MBP indicators should only be included in the new M&E log frame if the MBP constitutes a funded component of the Extension Project.
- The new M&E log frame includes Service and population based indicators, which do not identify UNITAID specific achievements.
- So far, no indicator has been defined for Technical Assistance, which represents a key strength of project activities.
- Some indicators do not define how they should be measured (e.g. Nb of stock outs prevented).
- The target for the price indicator should be revised in order to include more PMTCT key products and to better reflect project achievements (not only limited to two ARVs).

New Report Template

A preliminary, rapid assessment of the new report template "PMTCT Reporting Workbook" (received from the UNITAID PMTCT Portfolio Manager) has been conducted, which identified the strengths and weaknesses in Table 15 below.

Table 15. New Report Template: Strengths and Weaknesses.

Strengths	Weaknesses
Instructions to support report template completion have been provided.	Complexity of Excel file.
Caters to project specific reporting on key interventions (e.g. by following up % of differences between targeted supplies and supplies actually procured within the specific reporting period).	No cumulative progress report has been requested.
Reporting on treatment interventions has been defined in more detail by requiring project specific information (e.g. "Estimates of women and children diagnosed and/or treated with supplies procured for the reporting period").	The report does not appear to be harmonized with the new or the old M&E log frame. All key indicators listed in the M&E log frame should be reported on.
The reporting period has been specified as a full year.	Information on interest earned is not requested.
A section for challenges faced per country is available.	The report template does not include the requirement to provide references to certified documents
	No request for financial statements supporting cash reconciliation.

If the identified weaknesses are not addressed, the same reporting and M&E limitations as mentioned for the current PMTCT Project Components will occur again.

The Extension project plan spells out the same general requirements for IR, therefore risking similar reporting problems as seen in the other PMTCT project components.

3.7 Projects Strengths, Weaknesses, opportunities and Threats (SWOT)

Table 16. PMTCT Project: SWOT.

Strengths	Weaknesses
<ul style="list-style-type: none"> • Large quantity of health products procured and delivered in-country in a reasonable time. • Implementing partners have good in-country representation and a good reputation. • Achieved ARV prices have been reduced throughout the project and are generally lower than market prices.* 	<ul style="list-style-type: none"> • Memorandum of understanding insufficiently developed. • Unsatisfactory M&E system in place. • Insufficient evidence on the market impact.
Opportunities	Threats
<ul style="list-style-type: none"> • Improve in country M&E system and establish platform for collaboration between partners working on PMTCT. • Project can help eliminate mother to child HIV transmission.* 	<ul style="list-style-type: none"> • No transition funding. • Possible delays in registering MBP in all the countries.*

*Not relevant for the Nutrition Component

Strengths

- *Large quantity of health products procured and delivered in-country in a reasonable time.* Average lead-time for all types of commodities in large overall quantities was 61 days for the 1st PMTCT and Nutrition Component and 91 days for the Expansion Component. .
- *Implementing partners have good in-country representation and a good reputation.* Implementing partners (UNICEF and WHO) are very active and present at the country level. The UNICEF and WHO country offices provide Technical Assistance, convene planning meetings, support the development of PMTCT guidelines and disseminate normative guidelines, support in-country management, and strategically plan and coordinate down to the regional and district level.
- *Achieved ARV prices have been reduced throughout the project and are generally lower than market prices.*
The procurement model is efficient and the unit prices in Long Term Agreements signed by UNICEF have been reduced throughout the project and are generally below market prices, in comparison to median unit prices from MSH Drug Price Indicator.

Weaknesses

- *Memorandum of understanding insufficiently developed*
Despite the availability of signed MoUs per Project Component, the contractual definitions have not been precise enough, e.g. uncertainties exist with regards to the UNITAID funding contributions towards MBP, performance based funding is not in place.
- *Unsatisfactory M&E system in place*
M&E log frames are marked by several limitations as they are either developed for several

Project Components together or are based on national rather than project specific data generation. Additionally, reporting compliance with defined M&E indicators is not assured.

- *Insufficient evidence on the market impact*
No real efforts have been made to attribute market related project achievements to true market impact. Price reductions compared to budgeted and former prices were observed and new prequalified paediatric ARVs were reported, but a corresponding market analysis needs to be performed in order to prove any links to the present project.

Opportunities

- *Further improve in country M&E system and establish a platform for collaboration between partners working on PMTCT.*
Further increase cooperation efforts to improve the PMTCT M&E system at the project and national level, by defining suitable indicators for reporting, which are harmonized to comply with national level project specific requirements according to international recommended standards.
- *Project can help eliminate mother to child HIV transmission.*
The project could contribute to reduce mother-to child HIV transmission through a scale up and expansion of present PMTCT efforts and the promotion of MBP in countries not covered through the existing grant agreements.

Threats

- *No transition funding*
Initially, UNITAID expected beneficiary countries to be selected for GFATM Round10 grants. Based on the available documentation, no information has yet been provided on the success of planned transition activities. If no transition funding is secured, project sustainability is at risk.
- *Possible delays in registering MBP in all the countries*
Registration of the MBP in more countries is presently hampered due to the complexity of the WHO recommendations and the MBP's aim to cover as many options as possible (e.g. single-dose at delivery, Cotrimoxazole to all mothers and infants), while not including commodities in order to follow 2010 recommendations for breastfeeding.

5 Conclusions and Recommendations

The current mid-term evaluation complied with the OECD evaluation criteria Relevance, Effectiveness, Efficiency and Impact, which also defined the matrix, report structure and presentation of the findings. The findings have been split into health outcome and market outcomes by specifically evaluating compliance of indicator achievements (as reported) with the indicator targets defined in the respective M&E log frames of the project plans for the 1st PMTCT, Nutrition and Expansion Component. Although additional important project achievements might have been reached through the three Components, these were not verified as part of this mid-term evaluation and were only marginally addressed. Based on the available information, a list of 15 main conclusions (see Table 17) was identified, which focused on four key topic areas, as presented below. These are relevant for all project components if not indicated otherwise.

- Project Management & Implementation
- Monitoring & Evaluation
- Market Impact & Procurement
- Reporting

Recommendations and suggestions for responsibilities have also been provided. From this extensive list of recommendations, five recommendations should receive particular attention:

1. Implement a performance based monitoring and disbursement system.
2. Identify suitable indicators that support reporting on project specific achievements.
3. Formalise involvement in national forecasting with integrated project specific forecasting. This would improve possibilities to assess the proportion of UNITAID contributions to overall PMTCT related procurement.
4. Report on interests earned
5. Clarify the status of the Mother Baby Pack as a part of the UNITAID funding.

The overall recommendation of the evaluation team is to **grant a no-cost extension for the three Project Components (1st PMTCT, Nutrition and Expansion)** in order to bring the projects to a satisfactory end. To receive the no-cost extension, a performance based funding system based on reportable indicators should be put in place. This would naturally require more investments at the national level, in order to identify project specific achievements for health and market outcome indicators.

Table 17. PMTCT Project Conclusions and Recommendations.

	Conclusion	Recommendation	Responsibility
Project Management & Implementation			
1	Formal, contractual agreements have not been established or have not been made available for several project modifications, which have apparently been verbally agreed on between UNITAID and UNICEF.	Set up a monitoring system to keep track of all contractual arrangements and changes, by project, component, country and type of arrangement. Important changes need to be formalized.	UNITAID
2	UNITAID Project Management is marked by: 1) A weak archiving system. 2) Not working with log frames as a tool for project management and implementation. As a result, links between activities conducted and the financing/funding of these activities are missing.	1) UNITAID should design a web based Content Management System (CMS) document sharing platform with best archiving practices. 2) Implement additional log frames to identify and continuously monitor links between activity implementation and corresponding funding.	UNITAID

	Conclusion	Recommendation	Responsibility
3	Transition plans for all Project Components are absent.	Include transition planning in contractual agreements, which would require a proactive approach and compliance with defined contractual conditions by partners. This should be time-bound.	UNITAID UNICEF
4	Despite initial agreements signed between UNITAID/WHO/UNICEF, WHO has relatively low project ownership, mainly because WHO has not received funds for programmatic support.	Consider funding programmatic project components to promote a stronger involvement and ownership of implementing partners, e.g. WHO.	UNITAID
5	<p>Financial Management:</p> <ol style="list-style-type: none"> 1) Finance reporting requirements and contractual supporting documentation requested by UNITAID are not fully detailed in the project plan or the MoU of projects. 2) Requirements of bank interest generated with funds received from UNITAID are not clearly defined in the MoU. So far, the project has not reported interests earned. 3) Projects' implementations do not follow performance based funding principles. 4) Budget adjustments and reallocations are not systematically formalized in an addendum to the initial MoU officially approved by both parties. 	<ol style="list-style-type: none"> 1) A specific appendix related to finance reporting in line with activities initially planned and effectively implemented should be developed 2) UNITAID should develop an internal policy on bank interest reporting requirements, and management. This policy would allow close monitoring of bank interest reported as other incomes at the project level, and would also be systematically deducted from disbursement requests or reimbursed to UNITAID. 3) UNITAID should develop and implement a representative and weighted rating system in order to assess project performance and authorize disbursements of funds. This tool could also be used to support cost extension / no cost extension decisions. 4) All budget revisions should be systematically formalized in an addendum to the initial MoU officially approved by all parties. Further, financial reporting should be systematically based on the last version of the budget approved by UNITAID. 	UNITAID
Monitoring and Evaluation			
6	<p>A consolidated M&E log frame (1st Amendment, Annex 4A) for the 1st PMTCT, Nutrition and Expansion Components has been designed, causing:</p> <ul style="list-style-type: none"> • Uncertainties if defined target indicators should be achieved per project component or combined for several components. • Non-compliance reporting on defined indicators. 	Measurable key indicators should be clearly defined, e.g. in one separate M&E log frame per Project Component. Reporting should be harmonised with separate M&E log frames.	UNICEF, WHO, UNITAID

	Conclusion	Recommendation	Responsibility
7	The M&E log frame for population and service based indicators (e.g. Annex 4B, 1 st PMTCT Initiative) is not designed to report on UNITAID's project specific achievements and progress of funded PMTCT interventions, but mostly refers to national data generated for WHO Access Report.	<p>Redefine the M&E log frame for population and service based indicators if UNITAID is interested in project specific results by:</p> <ol style="list-style-type: none"> 1) Ensuring access to national and UNICEF project specific data. 2) Reporting and clearly indicating which indicators are linked to UNITAID funded projects. 3) Reducing existing indicator list by selecting indicators suitable for project specific reporting. 4) Establishing joint agreements on indicator and reporting requirements. 5) Updating indicator definitions in compliance with the most recent WHO guidelines and standards. 	UNITAID, UNICEF, WHO
Market Impact and Procurement			
8	Reported Market Impact achievements, such as price reductions and new prequalified ARVs, cannot be clearly attributed to the project. The target for price reduction does not reflect a true market situation. Average weighted prices, instead of median product prices, are reported. Other positive outcomes such as reduced prices and increased availability of key products other than ARVs and RDTs are not considered in the M&E log frame (Annex 4A).	The price reduction and containment indicators and targets should be changed to reflect the actual market situation for ARVs and other selected key products and reflect actual project achievements. Reporting should be based on median product prices compared with appropriate external benchmarks, as requested by UNITAID. A market analysis should be undertaken.	UNITAID UNICEF
9	National forecasts and contributions from partners including UNITAID/UNICEF are not available. As a result of improved coordination of national forecasting in recipient countries, funds were reallocated to procure very different quantities of commodities than what was originally budgeted. This was done without any formal approval and without adjusting corresponding targets, leading to substantial under- and over-achievements.	Formalise project forecasting processes as part of the national forecasts in order to request reporting on UNITAID share/commitments and from other funding sources. Formal approval and corresponding adjustment of targets should be required when re-allocations of the budget are needed. Strengthening of action 5.9 in the MoU Annexes.	UNITAID UNICEF
10	<p>The project as it is designed now:</p> <ul style="list-style-type: none"> • Does not aim to reduce lead-time but rather to improve on-time delivery. • Does not address transport costs. • Does not follow procured products throughout the supply chain to patients, and therefore does not inform whether treatments procured are effectively dispensed. 	<p>Change project design to:</p> <ul style="list-style-type: none"> • Reflect the actual objective regarding lead-time by changing actions, indicators or targets. • Include an objective to reduce transport costs with maintained or shortened lead times. • Monitor procured products throughout the supply chain to the end user. 	UNITAID, UNICEF

	Conclusion	Recommendation	Responsibility
11	<p>The development and implementation of the Mother Baby Pack has met several challenges due to differing national treatment guidelines.</p> <ul style="list-style-type: none"> It has been developed with delay and is currently suspended. The project partners have diverging views on UNITAID funding of the Mother Baby Pack. 	<p>A new approach is needed regarding the Mother Baby Pack.</p> <ul style="list-style-type: none"> Make the Mother Baby Pack a separate independent project and select suitable recipient countries accordingly. A consensus meeting that includes important stakeholders on the future of the MBP could be convened. Project partners need to determine whether the Mother Baby Pack should be included as a UNITAID funded part of the PMTCT project, and in that case, what activities should be included and to which project components it should be linked. 	UNITAID, UNICEF, WHO
Reporting			
12	<p>Reporting requirements are marked by some limitations:</p> <ol style="list-style-type: none"> MoU and project plans are generally formulated. The report template for the 1st PMTCT, Expansion and Nutrition Project Components does not facilitate well targeted reporting for M&E log frame KPIs and cumulative progress reporting. It also requires information with limited added value. 	<ol style="list-style-type: none"> Provide detailed, clearly formulated and well targeted report requirements in the MoU and project plans. Design and implement a well targeted and suitable report template that facilitates M&E log frame KPI focused reporting, as well as cumulative and project period specific progress reporting that is agreed upon by all parties. 	UNITAID, UNICEF, WHO
13	<p>Programmatic reporting is marked by several limitations:</p> <ol style="list-style-type: none"> Non-compliance of reported information according to indicator definition. For example., no data on % of treatment deliveries, but rather on proxy number of products procured was reported, and missing details for lead-time reduction indicator. Missing added value of provided information. Repetition of contractual obligations (conditions from the original MoU) while information on corresponding achievements is limited. No cumulative progress reporting. Year 1 and Year 2 progress is reported separately in 1st and 2nd ARs without cumulative project progress information. Annual reports for Expansion and Nutrition components only report on six-month periods. Reported achievements can not always be verified because available information indicates non-achievements. Order Status Reports with detailed information on quantities, prices and delivery dates are publicly available online via UNICEF. Reports are submitted on a yearly basis instead of on a calendar basis. 	<ol style="list-style-type: none"> Ensure compliance of reporting on all defined M&E log frame indicators. Report on project information with added value. Report on cumulative project progress including reporting period information. Reports submitted in February should report on UNICEF progress with project specific implementation. Reports submitted in August should report on national progress as well as on UNICEF project specific progress at distribution level. Report on project achievements and non-achievements according to defined target indicators. A summary of this data per country and per commodity type or intervention should be made available in the progress reports. Report submission on a calendar basis as requested by UNITAID. 	UNITAID, UNICEF, WHO

	Conclusion	Recommendation	Responsibility
14	<p>Financial reporting is marked by several limitations:</p> <ol style="list-style-type: none"> 1) Inconsistencies in financial figures between programmatic and financial report information, which can therefore not be fully verified. 2) No reporting on interest earned. 3) No financial statements supporting cash reconciliation. 4) Reference to certified documents missing. 5) No information is given on common budget items such as salaries, travel etc. 6) No reported information on savings made. 	<p>Design and implement a suitable financial report template. Corresponding reporting should be defined as contractual conditions</p> <ol style="list-style-type: none"> 1) Harmonise programmatic and financial report information, document the calculation basis, and provide cross-references, ideally to certified sources. 2) It is recommended that UNITAID has a general policy requiring that interests earned are reported and reinvested in the project. 3) Provide financial statements supporting cash reconciliation 4) Provide and reference certified documents. 5) Provide information on common budget items. 6) Report on reallocation of savings. 	UNITAID, UNICEF, WHO
Expansion Component Specific issues			
15	For the Expansion Component a clear definition for the objective could not be identified in the project plan (Annex 3).	Clearly visible presentation of a well defined objective in the project plan, i.e. in a highlighted text box.	UNICEF, WHO

Annex 1: Evaluation Matrix, Common questions

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 log frame 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
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 pre-qualified product/supplier list, MSH Drug price indicators)	Comment on the achievements in terms of market outcome (price, quality, availability, access)
4- To what extent are they 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
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

Evaluation area and question	Indicators	Sources	Methods
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
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	

Annex 2: Evaluation Matrix, PMTCT specific questions

Question
UNICEF - Acceleration of the prevention of Mother to Child Transmission (PMTCT-1)
1-Is the mother and baby pack for PMTCT ready to be implemented in all countries? What were the major factors influencing the achievement or non-achievement of this objective?
1.1 Is the development of MBP according to initial schedule?
1.2 How many countries have implemented MBP / initial nb of countries planned
1.3 Does the MPB need to be registered in the recipient countries? If yes, in how many countries is it necessary? In how many countries is the MBP already registered? In how many countries did the procedure start?
1.4 Where the MPB is not yet implemented, what are the reasons for the delay?
1.5 In the countries where MPB was not implemented, what was the action taken?
1.6 Since program has started, was there a median price decrease of key products included in the MBP?
1.7 What is the estimated number of mothers who benefited from the MBP or from any other action taken (in the countries where implementation did not yet take place)?
2-Describe UNICEF's, WHO's and UNICEF's role in making the Mother and Baby Pack more widely available
2.1 Have all stakeholders participated as defined in the roles and responsibilities for the project?
2.2 What could have worked better to make the MBP more widely available?
3-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?

Annex 3: Evaluation Matrix, 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 other incomes reported and are they reimbursed to the program / deducted 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 programme implementation?
3.4 Does the programmatic reporting provide a clear picture on procurement activities (order list, etc...)?

Annex 4: Meetings with Stakeholders and List of Persons Interviewed

Stakeholder	Date, Location	Name and title of person interviewed	Role in the PMTCT Initiative
UNITAID	11 April 2011, Geneva	Greg Martin, PMTCT Portfolio manager Gauri Khanna, Monitoring and Evaluation	PMTCT Project funding , ongoing review of programmatic and financial project progress, provision of strategic advice for achievement of project objectives.
WHO	27 May 2011, Geneva	Nathan Shaffer, MD PMTCT Team Leader/ PHS/HIV/WHO	Provision of technical assistance in terms of disseminating normative guidelines, provision of training modules and tools, promotion of the use of PMTCT guidelines, TA to beneficiary countries in reviewing PMTCT policies & plans.
UNICEF Supply Division	27 May 2011, Copenhagen	Francisco Blanco, Chief, Medicines and Nutrition Centre Tine Mortensen, Monitoring and Evaluation Officer Noura Maalaoui, Supply Chain Specialist - Pharmaceuticals Atieno Ojoo, Technical Specialist - Pharmaceuticals	Project Implementing Agency , development of procurement strategy, in-country assessment of procurement and supply management infrastructure, agreeing with beneficiary countries on commodity requirements and confirmation of forecasts, coordination and management of procurement and timely delivery of PMTCT commodities, provision of TA to beneficiary countries, reporting.

Interview Documentation

WHO – Swiss TPH
Interview, 27 May 2011, Geneva
11.00 am – 12.30 pm

Key issues/achievements

- 1) What are the responsibilities of WHO to contribute to/implement to the PMTCT projects funded by UNITAID?
- 2) From a WHO perspective, what are the key achievements/strengths and non-achievements/weaknesses of each project component (1st PMTCT, 1st Extension PMTCT, Nutrition Component, Expansion Component)?
- 3) How has WHO ensured compliance with the new policy recommendations for PMTCT, ART and Infant Feeding adopted in 2009 within the UNITAID funded PMTCT projects? Have these been integrated? What is the status?
- 4) From the WHO perspective – how can the collaboration and interaction between WHO and UNICEF (e.g. close collaboration, frequent interactions, up-dates, guidance on required contributions) and WHO and UNITAID (e.g. guidance on required contributions) be described? What were the strengths and weaknesses?
- 5) What are the transition plans for all three components? E.g. as NC and Expansion Component are coming to an end in July 2011, will they be finalized according to plan or are there attempts to ask UNICEF for extension?

Reporting

- 6) How has WHO contributed to i) Programmatic reporting; ii) Financial reporting, iii) Procurement reporting?
- 7) What is the WHO i) internal and ii) cross-organisational validation process of reports (IR and AR)?
- 8) For which or to which report sections has WHO mainly contributed and how (in writing)?

M & E

- 9) On which key activities and indicators have UNITAID, UNICEF and WHO agreed on to monitor project progress and to report on in the annual programmatic reports?
 - a. Is it a condition to report on all activities and indicators defined in the M&E framework provided in 1st Amendment, Annex 4A and Annex 4B?
 - b. Are there other activities and indicators which are required to be reported on?
- 10) On what grounds have M&E indicators for the PMTCT programmes funded by UNITAID been selected e.g. “% of target treatments delivered per maternal and paediatric intervention per country” and how were they supposed to be monitored and linked directly to the UNITAID funded PMTCT project? This seems to be rather difficult as e.g. for nb of patients treated, national data is used.
 - a. How can these indicators be monitored and directly linked to the UNITAID funded project? Or is it not mandatory that UNICEF and WHO report on indicator achievements that can be directly linked to the UNITAID funded project?
 - b. There is a related key issue regarding UNICEF and WHO reporting on the indicator “no of patients treated/diagnosed” by only providing information on “volume of products procured” and, if treatment information is provided, reference is made to general WHO documentation such as WHO Access Report 2009. Does WHO agree with the reporting on “volume of products procured” as opposed to “no of patients treated/diagnosed”? How is it justified?
- 11) Has WHO been involved in the development of the new PMTCT M&E log frame?
- 12) How is data collected for the WHO Access Reports? Is this data based on national data? How is the UNITAID funded PMTCT program integrated into this data?

Mother and Baby Pack

- 13) What are the key achievements and non-achievements regarding the MBP? What is the current status of the MBP? Based on the last available PMTCT reports, MBP was launched in Kenya (2010), Zambia and Lesotho (2011) and was supposed to be launched in Cameroon in April 2011.
- 14) Does WHO have any comments on the suspension of the MBP and the reasons for this decision?
- 15) Was WHO involved at any stage of the MBP development, e.g. in expert groups?
- 16) Does WHO approve the content of the MBP?

UNITAID, PMTCT Meeting 11 April 2011**General questions**

- 1) How is the implementation/performance of the project partners, UNICEF and WHO/HIV perceived?
- 2) To what extent has UNITAID intervened in the project planning and implementation?
- 3) Was the technical assistance provided from UNICEF and other partners sufficient and appropriate?

Key achievements

- 4) What are the key achievements/strengths and non-achievements/weaknesses of each project component (1st PMTCT, 1st Extension PMTCT, Nutrition Component, Expansion Component)?
- 5) The year 2010 seems to have been marked by several project changes for the 1st PMTCT project such as the EB decision (August 2010) and MoU signing (December 2010) on 1st Extension PMTCT etc. What was the progress of the 1st PMTCT project in 2010, what were the ongoing activities? Will the first interim report for the 1st PMCTC Extension (expected in July 2011) cover both, the 1st PMTCT and 1st PMTCT Extension or is a separate final project report for the 1st PMTCT expected? If the report is identical, how will UNITAID ensure that information on the progress of activities and achievement indicators is separately reported on?
- 6) Does UNITAID have a risk management system in place to oversee project management and fund disbursement?
- 7) What steps have been taken for a transition of this project to a more sustainable source of funding?
- 8) How can the project's contribution to indicators such as price containment/reduction, new WHO pre-qualifications or new commodities suitable for PMTCT be valued (indicators for Procurement very unclear in Exhibit 5A of Annex 1, PMTCT I Project plan)?

Reporting

- 9) Are pre-defined and standardized report templates agreed on by UNITAID, UNICEF and WHO available for i) Programmatic reporting; ii) Financial reporting, iii) Procurement reporting?
 - a. If yes, could we receive a copy of a report template for the programmatic, procurement and financial reports?
 - b. If not, has UNITAID approved the existing reporting format and content (which is similar for all interim and annual reports)?
 - c. Which ones are the financial reports? Do the financial reports coincide with the “Utilization Reports” (2nd AR 1st PMTCT, Exhibit 2)? If yes, how has performance based funding been assured based on these reports (e.g. verification of progress in order to initiate disbursements)?
 - d. Which ones are the procurement reports? Do the procurement reports coincide with the “Order Status Reports” (2nd AR 1st PMTCT, Exhibit 3)?
 - e. Could UNITAID provide us with the log frame/reporting template for the 1st PMTCT Extension year?

- f. What is the internal UNITAID process for validating the progress reports?
- g. How has non-compliance with UNITAID reporting requirements been managed and communicated in order to improve reporting standards?

M & E

- 10) Which key activities and indicators have UNITAID, UNICEF and WHO agreed to monitor project progress and to report on in the annual programmatic reports?
 - a. Is it a condition to report on all activities and indicators defined in the M&E framework provided in 1st Amendment, Annex 4A and Annex 4B?
 - b. Are there other activities and indicators that are required to be reported on?
 - c. There is a key issue regarding "no of patients treated/diagnosed" as UNICEF only provides information on "volume of products procured" and, if treatment information is provided, reference is made to general WHO documentation such as WHO Access Report 2009. It is hence not possible to identify/verify treatment outcomes. How has UNITAID handled this issue as this issue has already occurred in 1st PMTCT Annual Report?

Mother and Baby Pack

- 11) What are the key achievements and non-achievements regarding the MBP? What is the current status of the MBP? Based on the last available PMTCT reports, MBP was launched in Kenya (2010), Zambia and Lesotho (2011) and was supposed to be launched in Cameroon in April 2011.
- 12) How has the MBP been received in the countries?
- 13) Development of the MBP seems delayed in comparison with the PMTCT Project Plan, what are the reasons for this?
- 14) Were UNITAID and/or WHO/HIV involved at any stage of the MBP development, e.g. in expert groups?

Procurement

- 15) Are the product and intervention price lists given in 1st Amendment, Annex 1, Exhibit 2 and 3 for the 1st PMTCT project valid for all other project components (Nutrition, Expansion and 1st PMTCT Extension) or are these different for each project component?
- 16) Have any stock-outs occurred and if so, what were the reasons for this?
- 17) How were possible stock-outs handled and length of them?
- 18) How well have forecasting's coincided with real demands and how frequent have adjustments to forecasts been?
- 19) Have any emergency orders been placed? If so, numbers and reasons?
- 20) Have non-pre-qualified drugs been procured? What measures have in that case been taken to assure the quality of the drugs?

PMTCT – UNITAID Mid-Term Evaluation Meeting UNICEF, 27 May 2011

General

- 1) Please provide an overview of project specific country status implementation for each component (1st PMTCT, Nutrition, Expansion, 1st PMTCT Extension).
- 2) UNICEF planned to provide a transition plan (identifying other possible sources of funding) for the 1st Extension Project (see UNITAID email). Could UNICEF provide us with this transition plan?
- 3) How is UNICEF capitalizing interests earned on the project? If no interests are earned - why not?
- 4) Does UNICEF have a risk management system in place to oversee project management and fund disbursement?
- 5) Long-standing Basic Cooperation Agreements (BCA) have been established with beneficiary countries for all UNICEF activities, apparently these are also valid for the UNITAID PMTCT project. Please provide a signed copy of the MoU established under the BCA for all 17 countries benefiting from the UNITAID funded PMTCT program. If not available, please provide an example MoU.
- 6) The three disbursement conditions for the 1st PMTCT Initiative are formulated as: 1) MoU between UNICEF, WHO and UNITAID, 2) MoUs between UNICEF and countries including provision confirming the acceptance by the beneficiary countries of the use of quality drugs and diagnostics at the lowest possible prices negotiated by UNICEF (Ref. Doc.: EB3 Res4 8March07) and 3) Contract between UNICEF and product suppliers. Please provide a signed copy for the 1st and 3rd disbursement condition.

Key achievements

- 7) What are the key achievements and non-achievements per project component and per country?
- 8) How can reported results on market impact be attributed to this project?

Project outline

- 9) What is the source for prices in budgets?
- 10) What is the difference between the Procurement Fee (= Handling fee?) and Procurement management costs in the budget? Are the Procurement management costs also based on a percentage?

- 11) In the funding conditions for the Expansion Component UNITAID requests clarifications on a number of points – have these been provided and if so, can we obtain copies?
- 12) 1st PMTCT marks a 2010 gap- how did the project progress in this year, which activities were implemented and how where they funded?
- 13) UNICEF highlights in 1st Amendment Request, Annex 1, p. 26 that there are a variety of related ongoing country programmes in all 8 countries. How are programmatic and funding duplications avoided?
- 14) With regards to WHO 2010 recommendations, what is the status of all project components (1st PMTCT, Nutrition, Expansion, 1st PMTCT Extension) and all countries in complying with these updated recommendations? The original 1st PMTCT initiative based on 2006 WHO PMTCT guidelines.
- 15) Evaluation of diagnostic capacities (PCR, CD4) in each country – is there a report of such assessments and how were they performed?

Reporting

- 16) How has the reporting format been working?
- 17) Several reports mention requests differing substantially from forecasted amounts, have re-distribution of budgets taken place in those instances? If so, have the countries or UNICEF led this process and does re-programming have to be approved by UNITAID?
- 18) Please provide the calculation basis for 2nd AR 1st PMTCT, section A2 listed treatment targets and procured commodities and also for the 1 Year data mentioned in 1st AR.
- 19) How does UNICEF gather data on number of patients treated/diagnosed?
- 20) Please provide a copy of the PMTCT and Paediatric HIV CST Report Card as the M&E framework for the UNITAID Initiative is aligned with this card.

Implementation

- 21) What information is available on supply management in countries (e.g. distribution arrangements, cold-chain maintenance, storage conditions, inventory management)?
- 22) Have any stock-outs occurred and if so, what were the reasons for this?
- 23) How were possible stock-outs handled and length of them?
- 24) What information is available on laboratory capacity, transport of samples and delivery of test results?
- 25) Has forecasting been appropriate and what methods have been used? Were calculations assessed by UNICEF?
- 26) What is the present situation for India with regards to policies, protocols implementation etc.?

M&E

- 27) How were the indicators and targets agreed upon, were they primarily suggested by UNITAID or UNICEF?
- 28) For indicator “price reduction”, 2 products with reduced price are set as targets and the indicator is stated to be relevant for all project components – does this mean 2 products per component or 2 in total?
- 29) For indicator “new pre-qualified products”, 2 new prequalified products are set as target and this indicator is valid for PMTCT1 and Expansion components, meaning 2 new per component or 2 in total?
- 30) The indicator “lead time reduction” has a target that mainly aims to increase punctuality, has this been addressed?

Procurement

- 31) Have any emergency orders been placed? If so, numbers and reasons?
- 32) Have non-pre-qualified drugs been procured? In that case, what measures have been taken to assure the quality of the drugs? How was selection of diagnostic products made for inclusion in bundles?
- 33) Are these suitable for all equipment available in the countries?
- 34) What is the coverage, in terms of commodity types, of LTAs reported?
- 35) Proportion of procurement taken place outside LTAs?
- 36) Proportion of procurement taken place without tendering?
- 37) UNITAID has requested an assessment of freight costs and efforts to decrease them, has this been provided and what results were reached?

Mother and Baby Pack

- 38) Please provide an update of the status of the MBP.
- 39) In explanations provide to UNITAID by UNICEF regarding the suspension of the MBP distribution it was listed that: “ A number of observations, some relating to the kit design, others relating to the initial phases of implementation –were brought to our attention lately and led us to review actions in the four participating countries. Based on the review, and in consultation with our counterparts, we determined that certain conditions had to be verified and additional measures taken prior to any further distribution of MBPs. Please provide more detailed information on:
 - i. 1) What observations related to kit design led to UNICEF reviewing the MBP related actions in the 4 participating countries. Please provide examples.
 - ii. 2) What observations with regards to the initial phase of implementation led to the review actions? Please provide examples.
 - iii. 3) Please list some weakness of the MBP as so far only strengths have been given.

- iv. 4) Please provide information on the length of the suspension and when, how and where the MBP distribution will be taken up again?
- 40) Does the MPB need to be registered in the recipient countries? If yes, in how many countries is it necessary? In how many countries is the MBP already registered? In how many countries did the procedure start?
- 41) Where the MPB is not yet implemented, what are the reasons for the delay?
- 42) In the countries where MPB is not implemented, what are the actions taken?
- 43) Since the program started, was there a median price decrease of key products included in the MBP?
- 44) What is the estimated number of mothers who benefited from the MBP or from any other action taken?
- 45) Have all stakeholders participated as defined in the roles and responsibilities for the project?
- 46) What could have worked better to make the MBP more widely available?

Annex 5: List of Documents Reviewed

Document Title	Source	Year
1st PMTCT Initiative		
MoU for PMTCT Initiative 2007-2009	Original MoU, 1st PMTCT Initiative	10 December 2007
MoU for PMTCT Initiative 2007-2009 10 December 2007, Annex 1, Project Outline	Original MoU, 1st PMTCT Initiative	10 December 2007
PMTCT EB3Res4 8March2007	Executive Board Resolution	8 March 2007
MoU 2007-2009, Annex 1, Example Implementation Letters (Burkina Faso, Cameroon, India, Ivory Coast, Malawi, Rwanda, Tanzania, Zambia)	Original MoU, 1st PMTCT Initiative	15 January 2008, 22 January 2008
1st Interim Report 2008 1st Interim Report Final 15July08 Example Implementation Letter Malawi Annex 3 Expert Consultation MBP 29May08 Annex 4 Exhibit 5B 2007 Annex 7 Status May31	1st Interim Report	15 July 2008
PMTCT 1st IR Question UNITAID 19.09.2008	Follow-up UNITAID Questions	19 September 2008
1st Annual Report 2008 1st PMTCT I Annual Report 13Feb09 Annex 1 Exhibit 5B Annex 2 Annual Financial Report Annex 3 Status Annex 4 Customer Satisfaction Form Annex 5 Forecast Year 2 Annex 6 MBP update 19Feb09 Annex 7 Status per country 1st PMTCT I Letter for annual report 13Feb 09	1st Annual Report	13 February 2009
2nd Interim Report 2009 1st PMTCT 2nd Interim Report 24 August 2009	2nd Interim Report	24 August 2009
2nd Annual Report 2009 PMTCT I 2nd Annual Report 2009 15Feb10 Exhibit 1 Indicators PMTCTI and Nutrition Exhibit 2 Financial Report PMTCT I Year I Exhibit 2 Financial Report PMTCT I Year II Exhibit 2 Financial Report UNITAID Consolidated Summary Exhibit 3 UNITAID Order Status Report PMTCT 1 Dec09 Exhibit 4 Mother Baby Pack	2nd Annual Report	15 February 2010

Document Title	Source	Year
1st Amendment to MoU "Nutrition Component"		
1st Amendment to MoU - Annex 2 Nutrition Final Project Plan - Annex 4A UNITAID M&E Indicators Final - Annex 4B Indicators - Annex 5 UNITAID Reporting Disbursement Schedule	1st Amendment MoU	31 July 2009
1st PMTCT EB7Res5, "Nutrition Component", 2 April 2008	Executive Board Resolution	2 April 2008
1st PMTCT Project Proposal	UNICEF and WHO Proposal	February 2007
1st Nutrition Annual Report 2009	Annual Report	15 February 2010
1st Interim Report 2010 - Exhibit 1 and Exhibit 2	1st Nutrition Interim Report	18 August 2010
2nd Nutrition Annual Report 2010 15Feb11 - Exhibit 1	2nd Nutrition Annual Report	15 February 2011
1st Amendment to MoU "Expansion Component"		
1st Amendment to MoU (same document as for "Nutrition Component") - Annex 3 Expansion Project Plan - Annexes 4A, 4B and 5 as for the "Nutrition Component"	1st Amendment MoU	31 July 2009
PMTCT EB8Res2 2July2008 "Expansion Component"	Executive Board Resolution	2 July 2008
1st Annual Report 2009 1st Expansion Annual Report 15Feb09 Quality Assurance System UNICEF Exhibit 1, Exhibit 2 and Exhibit 3	1st Expansion Annual Report	15 August 2010
Approval Letter of Disbursement Decision Expansion Component	UNITAID	12 July 2010
1st Interim Report 2010 15 August 2010 Exhibit 1 and Exhibit 2	1st Expansion Interim Report	15 August 2010
2nd Annual Report 2010 2nd Expansion Annual Report 2010 15Feb11 Exhibit 1,2,3, 4, 5	2nd Expansion Annual Report	15 Feb 2011
2nd Amendment to MoU Extension Component		
2nd Amendment to MoU "Extension of 1st PMTCT Component" - Annex 1B: Project Plan for Extension of the 1st PMTCT Component	2nd Amendment MoU	22 December 2010
PMTCT EB12Res10 9June2010	Executive Board Resolution	9 June 2010
PMTCT EB12Res1 17August2010	Executive Board Resolution	17 August 2010