

End of Project Evaluation UNITAID-Supported PMTCT Projects



Final Report

Date: 28 September 2012

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ABBREVIATIONS

ART Antiretroviral therapy
ARV Antiretroviral drug

CCP Coordinating Procurement Committee

CHAI Clinton Health Access Initiative

DBS Dried blood spot

EID Early infant diagnosis

EMA European Medicines Agency
FDA Food and Drug Administration

IATT Inter-Agency Task Team
LIC Low-Income Country

LMIC Low-Middle Income Country

LTA Long-Term Agreement MBP Mother Baby Pack

MER More Efficacious Regimen
MOA Memorandum of Agreement

MOH Ministry of Health

MOU Memorandum of Understanding

MTR Mid Term Review

NAC National AIDS Council or Commission

PCR Polymerase Chain Reaction

PMTCT Prevention of Mother-To-Child Transmission
PSM Procurement Supply chain Management

RDT Rapid Diagnostic Test

RUTF Ready to Use Therapeutic Food

SAM Severe Acute Malnutrition

SCMS Supply Chain Management System

sd NVP Single dose NeViraPine
WHO World Health Organisation

ACKNOWLEDGEMENTS

The evaluation team and Euro Health Group would like to thank UNITAID and UNICEF staff for their contributions to this evaluation. Thanks are also due to all those who took the time to respond to the country stakeholder survey.

1 INTRODUCTION

1.1 Background

UNITAID is a global health initiative, which was established to increase the availability and supply of high quality medicines, diagnostics and related commodities for the treatment of HIV/AIDS, malaria and tuberculosis, primarily among populations in low-income and lower-middle income countries. By providing predictable, sustainable and additional funding, UNITAID aims to influence the market for drugs, diagnostics and commodities, through promoting market innovation and addressing market failure, in order to reduce prices and accelerate availability. UNITAID's goal is to use innovative, global market-based approaches to improve public health. It has four specific objectives, which are to:

- Increase access to efficacious safe products of assured quality;
- Support adaptation of products targeting specific populations;
- Ensure affordable and sustainably priced products; and
- Assure availability in sufficient quantities and timely delivery to patients.

UNITAID funds implementing partners¹ to procure medicines, diagnostics and related commodities on the basis of project proposals approved by the UNITAID Board. UNITAID is supported by public funding and is hosted by the World Health Organisation (WHO).

1.2 PMTCT Projects

UNITAID funded three PMTCT projects, implemented between 2007 and 2011 by UNICEF and WHO, providing total funding of US\$98,792,932 for support to 17 countries (see Table 1). These were among the earliest projects supported by UNITAID, which has subsequently enhanced its systems and processes, and as such were described by UNITAID staff as 'legacy projects'.

Table 1: Summary of PMTCT projects

Project	Beneficiary countries	Budget ²
PMTCT 1: Acceleration of PMTCT and scale up linkages to paediatric care and treatment (mid-2007-mid-2009) ³	Burkina Faso, Cameroon, Côte D'Ivoire, India, Malawi, Rwanda, Tanzania, Zambia	US\$20,838,432
PMTCT 1 extension (January-December 2011) ⁴	Same countries as above, except Burkina Faso	US\$26,763,660
PMTCT 2 : Expansion of PMTCT 1 to 9 additional countries (mid-2009-mid-2011)	Central African Republic, China, Haiti, Lesotho, Myanmar, Nigeria, Swaziland, Uganda, Zimbabwe	US\$46,679,993 ⁵
PMTCT 3: Nutritional care linked to PMTCT in 4 of the PMTCT 1 countries (mid-2009-mid-2011)	Malawi, Rwanda, Tanzania, Zambia	US\$4,510,847 ⁶

¹ UNITAID does not provide direct funding to countries

² Figures based on respective project MOA. In some cases figures differ from amounts in Board resolutions

³ UNITAID Board authorised commitment of up to US\$20,893,506 for 2 years in March 2007 (\$6,335,925 in 2007 and \$14,557,581 in 2008); date of first disbursement 1 May 2007

⁴ MOA amendment December 2010, for addition year of support

Board Resolution July 2008 committing up to \$50,009,221 over 2 years for 9 additional countries

⁶ Board Resolution July 2008 committing up to \$4,764,228 for 2008-2010

1.3 End of Projects Evaluation

The terms of reference for the evaluation (see Annex 1) specified assessment of PMTCT project achievements, relevance, effectiveness and public health and market impact, as well as lessons learned. The key objectives of the evaluation were to:

- Assess the progress of each project under review in achieving the objectives set out in the original project plan and MOU with UNITAID;
- Track changes in the projects due to lessons learnt and problems encountered during project implementation;
- Measure the short, medium and longer-term impact of the projects in terms of how the projects have changed the market for products of public health importance; and
- Assess the extent to which UNICEF reported to UNITAID on the projects' impact on public health.

The evaluation methodology included review of project documents and reports (see Annex 2), interviews with UNITAID staff in Geneva, UNICEF staff in Copenhagen and New York and with other key global stakeholders and an online survey of country stakeholders including UN, government, donor agency and civil society representatives (see Annexes 3 and 4)⁷. Findings and lessons learned are based on these sources of information.

The evaluation had a number of limitations including incomplete or missing information, limited country-level inputs, and potential bias. Although all three projects ended in 2011, final project narrative and financial reports from UNICEF had yet to be submitted at the time of the evaluation; other relevant reports and documents were unavailable, as was some key data. The evaluation did not include country visits; UNICEF project reports do not include country perspectives on procurement or technical support. The evaluation drew largely on UNICEF reporting. In addition, survey respondents were either UNICEF staff or were identified by UNICEF, and overall findings were skewed by differences between countries in the number of respondents.

The mid-term review of the projects in mid-2011 includes the most up-to-date project information. UNICEF has not submitted any reports since the review was conducted. UNITAID and the evaluation team agreed there would be limited value in restating information in the mid-term review and that the focus of this evaluation should be forward looking. This report, therefore, concentrates on key findings (see Section 2) and lessons learned and recommendations (see Section 3) to enhance the success of future projects.

2 KEY FINDINGS

2.1 Progress and Impact

Project progress

The PMTCT projects had a complex set of objectives, expected results, targets and indicators, which also changed over time, making it difficult to comment on progress. When UNICEF submitted the original proposal to UNITAID, PMTCT service coverage was low and many countries lacked the resources to expand coverage and to finance the shift from the less effective single dose Nevirapine (sd NVP) regimen to the more efficacious

⁷ The survey had a 60% response rate (42/69). 55% of responses were received from UN agencies, 31% from government representatives and 7% each from donor agencies and civil society organisations. Responses were received from 14 of the 17 countries that received support through the PMTCT projects; no responses were received from Burkina Faso, Central African Republic and Swaziland (Burkina Faso was included in PMTCT 1 but opted out of the extension)

regimen (MER) for PMTCT recommended by WHO. The principal aim of the first PMTCT project (PMTCT 1) was, therefore, to support countries to expand coverage and to shift to the MER. The second PMTCT project (PMTCT 2) expanded PMTCT 1 support to nine additional countries. The third PMTCT project (PMTCT 3) provided additional support to four of the PMTCT 1 countries to improve HIV-related nutritional care.

In UNICEF's view, the main objectives were scaling up of service delivery and making available PMTCT products and new regimens; in addition, there were objectives for reducing prices and increasing procurement efficiencies. Their perception is that, although the projects started with a common understanding of objectives, UNITAID's objectives shifted over time, while UNICEF stayed close to the original objectives.

The overall purpose and objectives of the PMTCT projects, based on the Memoranda of Agreement, is set out in Table 2. For all three projects there was an expectation that support for procurement of drugs, diagnostics and commodities would contribute to an expansion in service delivery coverage and that this in turn would contribute to improving maternal and child health outcomes. For example, the PMTCT 1 extension proposal states that: "By the end of 2009, the seven recipient countries (excluding Burkina Faso) collectively have reached 177,669 (56% of an estimated 317,000) HIV-infected pregnant women with ARV prophylaxis. The Extension Component will further contribute to PMTCT service expansion in these countries to achieve 65% coverage by the end of 2011. At 65% coverage rate and with the increased shift to combination regimens, these countries will likely be able to reduce the annual new paediatric infections due to MTCT to 43,794 infections, thus averting an additional estimated 51,758 annual new paediatric infections"8. There was also an expectation that the projects would contribute to integrated testing and treatment of women and children.

National progress reports, based on population- and service-based indicators (see Table 3), which UNICEF drew on for reporting, show improvements in PMTCT programme coverage. Two of the 12 countries that are reported to have reached the 80% coverage target for HIVpositive pregnant women receiving effective regimens, Lesotho and Swaziland, were supported by the PMTCT projects⁹.

However, it is not possible to identify the specific contribution made to these improvements by UNITAID support, or the impact of these improvements on maternal and child health outcomes. This is partly due to lack of data disaggregated by funder and partly to the fact that improvements in service delivery are dependent on a range of factors, not just the PMTCT project support provided by UNITAID.

For the same reasons, it is also difficult to comment on progress towards the expected results from the UNITAID-supported PMTCT projects (see Table 4), which are linked to the indicators in Table 3. Although commodities to support provision of services and interventions for this number of women and infants may have been procured, there is no data available to determine whether these commodities were distributed or used after delivery to countries.

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⁸ India only recently changed its guidelines to recommend MER. 33 countries reported women were still receiving sdNVP in 2010. Epidemic update and health sector progress towards Universal Access: Progress report 2011.
⁹ Epidemic update and health sector progress towards Universal Access: Progress report 2011.

Table 2: Purpose and objectives of the PMTCT projects

Purpose and objectives

PMTCT 1 - Support to more efficacious ARV combination regimens to optimise programme impact in reducing new infections and improving overall maternal and child survival¹⁰. The overall objective of this Initiative is to contribute to the acceleration of the global scale up of national PMTCT programmes 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 services¹¹.

Specific objectives 12 were to:

- (1) Accelerate the scale-up of provider-initiated HIV testing and counselling in antenatal, maternal and postpartum services
- (2) Reduce the proportion of infants born with HIV through the provision of more efficacious ARV regimens, including ART, to women and their new-borns
- (3) Accelerate early access of young HIV-infected infants to paediatric ART treatment through optimised identification strategies, such as Early Infant Diagnosis
- (4) Reduce morbidity and mortality among HIV-infected pregnant women, mothers and their infants through the provision of cotrimoxazole prophylaxis for the prevention of opportunistic infections (5) Increase access to ART for eligible HIV-infected women
- (6) Achieve continuous supply of suitable, high-quality PMTCT medicines, diagnostics and other commodities at the best possible price and facilitate price reduction

PMTCT 2 - Same as for PMTCT 1

PMTCT 3 - Additional specific objective:

(7) Include nutrition interventions as part of PMTCT and HIV care and treatment interventions to improve maternal and child health outcomes

Table 3: Population and service delivery indicators

Health facilities

- Number of facilities nationally providing ANC services
- Number of facilities providing ANC that also provide HIV testing and ARVs for PMTCT
- Number of facilities providing ANC which also provide a MER for PMTCT interventions
- Number of facilities that provide virological testing services (e.g. PCR) for infant diagnosis on site or through DBS
- · Number of districts with CD4 testing services available
- Number of facilities implementing nutrition interventions linked to PMTCT

Women

- Number of pregnant women tested for HIV
- Number of HIV-infected pregnant women who received ARVs to reduce the risk of MTCT: sdNVP; MER
- Number of HIV-infected pregnant women attending PMTCT services assessed for ART eligibility
- Number of HIV-infected pregnant women eligible for ART receiving ART for their own health
- Number of HIV-infected pregnant women started on cotrimoxazole prophylaxis
- Number of SAM HIV-infected pregnant women treated with RUTF
- Number of pregnant women screened for anaemia using HemoCue

Children

- Number of infants born to HIV-infected women given an ARV for PMTCT
- Number of infants born to HIV-infected women receiving a virological test for HIV diagnosis within 2 months of birth
- Number of infants born to HIV-infected women tested for HIV (antibody or virological test) by 12 months
- Total number of infants born to HIV-infected women started on cotrimoxazole prophylaxis
- Number of HIV-exposed children (and their siblings) treated with RUTF
- Number of HIV-exposed children screened for anaemia using HemoCue

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¹⁰ Board Resolution 4

¹¹ MOA

¹² These were outcomes in the logframe

Table 4: Expected results

PMTCT 1

- 1,174,000 pregnant women counselled and tested for HIV
- ARVs for PMTCT to 342,043 HIV-positive pregnant women; out of which 184,189 HIV-positive pregnant women will be tested for CD4 and receive the new WHO recommended regimen for PMTCT
- ARVs for their own health for 36,838 HIV-positive women
- Cotrimoxazole prophylaxis for 147,351 HIV-positive mothers
- Cotrimoxazole prophylaxis of up to 2 years supplies to 128,932 HIV-exposed infants
- Access to early diagnosis at 6 weeks through PCR testing for 51,573 HIV-exposed infants

PMTCT 1 extension

- 1,353,792 HIV diagnostic tests for pregnant women
- 152,970 CD4 assessments for HIV-infected pregnant women
- MER PMTCT ARV regimens for 151,813 pregnant women and their infants
- Cotrimoxazole prophylaxis for 88,632 pregnant women
- ART for 70,547 pregnant women in need of treatment for their own health until one year after delivery
- Testing 90,534 infants born to HIV-positive mothers at 4-6 weeks to confirm HIV diagnosis Cotrimoxazole prophylaxis for 142,999 children born to HIV-positive women

PMTCT 2

- 8,807,589 HIV diagnostic tests for pregnant women
- 222,011 CD4 assessments for HIV-infected pregnant women
- MER PMTCT ARV regimens for 316,847 pregnant women and their infants
- Cotrimoxazole prophylaxis for 54,052 pregnant women
- ART for 47,767 pregnant women in need of treatment for their own health until one year after delivery
- Testing 340,454 infants born to HIV-positive mothers at 4-6 weeks to confirm HIV diagnosis
- Cotrimoxazole prophylaxis for 63,615 children born to HIV-positive women

PMTCT 3

- 634,226 haemoglobin tests for pregnant women and 98,800 tests for HIV-exposed children
- 5,180 treatments with RUTF for SAM HIV-infected pregnant women and 19,200 treatments with RUTF for SAM HIV-exposed children

Respondents to the end-of-projects evaluation online survey highlighted a range of ways in which UNTAID support had helped to strengthen national PMTCT programmes. These included:

- Accelerated scale-up of provider-initiated HIV testing and counselling and PMTCT interventions in MCH services (68.3% of respondents);
- Accelerated transition to more efficacious regimens (80.5% of respondents);
- Increased number of women and infants enrolled in PMTCT programme (90.2% of respondents);
- Increased access to early infant diagnosis (90.2% of respondents);
- Measurable decline in the proportion of infants born with HIV (41.5% of respondents);
- Increased access to cotrimoxazole prophylaxis for HIV-positive mothers and HIVexposed infants (80.5% of respondents);
- Increased access to nutrition-related diagnosis, care and treatment of HIV-positive pregnant women and their children (this response was only an option for survey recipients in PMTCT 3 countries i.e. Malawi, Rwanda, Tanzania and Zambia) (29.3% of respondents);
- Improved commodity forecasting and procurement planning (78% of respondents);
- More consistent supply of PMTCT drugs, diagnostics and other commodities (e.g. reduced lead times, no stock outs) (85.4% of respondents); and
- Improved quality of PMTCT drugs, diagnostics and other commodities (70.7% of respondents).

Progress towards procurement targets was mixed. The mid-term review reports that for PMTCT 1, 156% of targeted procurement for maternal interventions were achieved in year 2 and 55% and 58% of targeted procurement for paediatric interventions were achieved in years one and two respectively. For PMTCT 2, the figures were 111% and 44% for maternal interventions in years one and two respectively, and 39% and 5% for paediatric interventions in years one and two respectively. Based on progress towards procurement targets, the review concluded that the maternal health objectives were likely to be achieved but the paediatric health objectives were not. It is unclear how the mid-term review came to this conclusion, as UNICEF procurement data spread sheets (see below and Annex 5) and project reports do not include this analysis.

In some cases, quantities procured were revised, to reflect more accurate forecasting, improved coordination of procurement planning, changes in treatment regimens, and additional support provided by other donors. However, targets were not revised and changes were not submitted to UNITAID for approval.

UNICEF reports for PMTCT 3 state, "In the first five months, two of the four countries have finalised their country forecasts and submitted their initial requests for ready-to-use therapeutic food (RUTF) and diagnostic commodities – Malawi and Tanzania. The first shipments of these requested commodities are due to arrive in the second half of Year 1".

However, the mid-term review notes that in second year of PMTCT 3, the four countries were still assessing their needs for RUTF and HemoCue and that no requests were submitted to UNICEF because countries were either using existing supplies or had received supplies from other partners. Reports show that none of the four countries reported on HemoCue use. With respect to RUTF, Zambia had no figures for severe acute malnutrition (SAM) or RUTF for 2010; Tanzania was still compiling data and PEPFAR figures were used in the absence of national data; Malawi reported that 44,207 children with SAM were treated with RUTF in 2010; Rwanda reported 18,784 children with SAM receiving treatment, including with RUTF, but no information was provided on their HIV status.

UNICEF reports do not provide sufficient information to assess progress towards procurement targets on a country basis. UNICEF reported on overall progress towards procurement targets, but project reports do not provide a breakdown of the quantities of drugs and commodities procured for each country or progress towards specific country procurement targets.

Detailed procurement information is available on the UNICEF website, but not in a format that allows for a straightforward analysis of procurement by country or procurements that have been funded by UNITAID. Spread sheets with tracking data on drugs and commodities purchased for the various PMTCT projects are available on the UNICEF website. These spread sheets, which were created and maintained by UNICEF Copenhagen, provide very detailed information on procurements, and indicate that considerable quantities of a wide range of items were procured. However, although the spread sheets are structured around procurements by country, the data is not categorised or correlated with project targets or indicators. Consequently, it is not clear how items procured relate to targets or how UNICEF used this data to track progress.

Public health impact

UNITAID support for procurement of PMTCT commodities has been vital. Over 70% of respondents to the end-of-projects evaluation online survey stated that there were shortages

http://www.unicef.org/supply/index 42657.html The spread sheets are available to download from the highlighted box titled 'UNITAID order status report'. Printed versions of the spread sheets are also included in Annex 5 of this report.

of PMTCT supplies prior to UNITAID support. In addition, 52.4% of respondents stated that UNITAID support for PMTCT had been very important and 21.4% that it had been important. UNITAID funding for commodity procurement was rated as important or very important by 77% of government and 73% of UN respondents.

The online survey also asked respondents to identify the three main funders for national PMTCT programmes. The largest contributors were identified as PEPFAR, the Global Fund or UNICEF. The second largest contributors were identified as the Global Fund, UNITAID, PEPFAR or UNICEF. UNITAID funding is likely to have contributed to UNICEF's high ranking.

UNICEF did not track the projects' overall impact on public health nor did it track UNITAID's contribution to improvements in public health. Tracking focused on procurement and on national PMTCT programme data. Consequently, it is difficult to attribute public health impact to UNITAID funding or to comment on the extent to which the projects contributed to UNITAID's goal of using innovative, global market-based approaches to improve public health.

However, UNITAID did contribute to increased availability and supply of high quality medicines, diagnostics and related commodities. This enabled beneficiary countries to expand the coverage of PMTCT programmes and to increase the number of women and infants benefiting from these interventions (see example of HIV testing in Table 5). Again, however, it is not possible identify UNITAID's specific contribution to these improvements.

Table 5: Change in HIV testing in pregnant women in UNITAID-supported countries included in 22 global priority countries for eliminating MTCT

Country	Estimated % pregnant women tested for HIV 2005	Estimated % pregnant women tested for HIV 2010
Cameroon	17%	41%
Côte D'Ivoire	6%	59%
India	2%	23%
Lesotho	9%	57%
Malawi	10%	66%
Nigeria	1%	14%
Swaziland	39%	83%
Tanzania	14%	86%
Uganda	18%	63%
Zambia	14%	94%
Zimbabwe	29%	90%

Source: Epidemic update and health sector progress towards Universal Access Progress Report 2011

It is not possible to identify the proportion of overall funding for PMTCT commodities in beneficiary countries that is attributable to UNITAID. UNICEF has not systematically tracked or reported on the proportion of total commodities procured with UNITAID funds for beneficiary countries. UNICEF states that UNITAID provided 100% of commodities in Central African Republic and Myanmar, but data to verify this claim is not available. According to UNICEF, tracking the UNITAID contribution was difficult, either because countries do not track drugs for PMTCT and HIV treatment by donor or the UNITAID contribution to the national pool of drugs and commodities was relatively small.

The extent to which public health benefits will be sustained after the end of UNITAID funding is difficult to ascertain. For example, UNICEF states in its proposals for PMTCT 1 and 2 that "Specific arrangements will be established to ensure that pregnant women started on ART will be integrated into national care and treatment centres before UNITAID support for ART ends", but no information is provided in reports to confirm that these arrangements have been made. And, as the discussion on transition planning below highlights, future

funding for PMTCT programme commodities is not secure in a number of project beneficiary countries.

Market impact

The projects also had market-related indicators. Although some targets were met, the project's impact on the market for PMTCT drugs and commodities was limited. Both PMTCT 1 and PMTCT 2 were expected to impact the market in a number of ways including: achieving price reductions, mainly through increased market size^{14;} increasing demand; increasing availability of more appropriate commodities and accelerating WHO prequalification of new formulations and commodities; reducing lead times; and ensuring supply security.

Given the maturity of the market, and already low prices, there has been limited scope to achieve price reductions for PMTCT drugs and commodities. Under PMTCT 1 and PMTCT 2, price reductions were achieved for ARVs and RDTs, but there were parallel price increases for other products^{15.} The mid-term review concluded that while UNICEF had secured favourable unit pricing, no impact on global market prices could be attributed to the projects. The projects do, however, appear to have had a more significant impact on the market for paediatric ARVs. For example, the fact that UNITAID procured 97%-100% of paediatric fixed-dose combination ARVs purchased with donor funds in 2008 and 2009 clearly contributed to the price reductions for paediatric ARVs.

UNICEF focused on the use of annual tenders to encourage market competition and a wider choice of product formulations. UNICEF reports that UNITAID funding increased the number of suppliers in the market and increased competition, contributing to the availability of additional formulations. No data is available in project reports to determine impact on reducing lead times or ensuring supply security.

PMTCT 3 aimed to stimulate the market to produce new nutrition-related products. The decision to develop new RUTF food products again raises questions about entering a market where there is little likelihood of having an impact. In this case, the rapid growth in the number of products and manufacturers as well as the number of players pursuing opportunities in this market should have been a disincentive. Not surprisingly, the target of approval of new products was only partly achieved and the mid-term review notes that the number of participating countries was insufficient to have a significant market impact.

PMTCT 3 also aimed to introduce and encourage use of HemoCue for diagnosis of anaemia. However, because the procurement involved relatively small quantities, there was no market impact. UNICEF also reports "No new tenders for anaemia diagnostics devices were issued in 2010. LTAs for the supply of HemoCue analysers are in place and valid until the end of 2011. Continuous efforts have been made to identify alternative sources of affordable and quality anaemia diagnostics devices. De facto, there are alternative suppliers of analysers to HemoCue. However, most, if not all, exclusively tap markets in industrialised countries and have virtually no commercial and technical representation in developing countries. In addition, none of them can offer both Hb/GLU analysers, the combination of which offers efficiencies in term of training of health workers, procurement and logistics of consumables, and procurement cost effectiveness. It is considered that at present HemoCue is the product that best addresses the needs of programmes in developing countries".

¹⁴ The PMTCT 1 proposal stated that 'UNICEF, through long term agreements and volume discounts will ensure the procurement of lowest possible prices for ARVs and other commodities associated with PMTCT-Plus scale up. Increases in volume of commodities purchased as a result of UNITAID support, combined with UNITAID support for other HIV-related initiatives can be expected to lead to further price reductions beyond those already seen during the last couple of years'.
¹⁵ UNICEF has reported on weighted average price, rather than on median price as requested by UNITAID.

In response to the end-of-projects evaluation survey, 62% of respondents stated that the projects had had some impact on the market, and specifically on the following:

- Price (48% of respondents);
- Quality (80% of respondents);
- Availability (100% of respondents); and
- Local manufacturing (4% of respondents).

Table 6 summarises the findings from the mid-term review related to market-related indicators and targets for the PMTCT projects.

Table 6: Progress against market-related indicators and targets

_	Indicators and targets	Comment	
PMTCT 1 and PMTCT 2	Price reduction: 14% reduction in price of RDTs be end of year 1 and 10-41% reduction in price of other products by end of year 2; >5% reduction in price of two ARVs	Price reductions of 13-17% for ARVs achieved; evidence of price reduction or containment in 12 of 25 products; price of cotrimixazole increased	
	Prequalification of new products: Two additional products pre-qualified by end of projects	Two new paediatric ARVs pre- qualified	
	Reduction in lead times: >90% of products delivered within 8-10 weeks for air freight and 14 weeks for sea freight	Insufficient information to assess this	
	Availability of MBP for country orders	MBP not taken forward under the auspices of the UNITAID-funded projects	
PMTCT 3	Number of new RUTF products approved: six new products; authorisation of two new African manufacturers; LTAs signed with three new local manufacturers by end of project	Two new RUTF products approved; one LTA and two new local manufacturers	

Source: MTR, September 2011

Overall expectations about market impact were revised downwards. The original proposals for the PMTCT projects included expectations that they would have a significant market impact. Both UNITAID and UNICEF now take the view that these expectations were not realistic, given the general maturity of the market for PMTCT products and problems encountered with the Mother Baby Pack, discussed below.

A number of problems were encountered with the introduction of the Mother Baby Pack, a product that was seen by UNITAID as having the greatest potential to impact the market. According to UNITAID, the proposed Mother Baby Pack (MBP), a UNICEF initiative to develop a 'new product' bringing together all the drugs and commodities required for the full package of PMTCT interventions for HIV-positive women and their infants, was a key factor in the initial decision to fund the PMTCT projects. However, because of various problems, UNITAID funds were ultimately not used for development or procurement of the MBP.

An initial pilot in Kenya (not a UNITAID PMTCT beneficiary country) was to be followed by further pilots in Cameroon, Lesotho¹⁶ and Zambia. However, UNICEF suspended work on

¹⁶ Lesotho had already developed a version of the concept of the MBP prior to this and the aim of the pilot was to learn lessons in a context where the idea was more fully developed.

the MBP and no further pilots were conducted after a review was conducted in response to concerns raised by AIDS Free World about the product. These concerns included the lack of clear instructions, insufficient training, lack of programme capacity to supervise and monitor use of the MBP, contents that were not in line with WHO recommendations – specifically, insufficient paediatric drugs and inclusion of cotrimoxazole in all packs regardless of CD4 count – and potential leakage of drugs into the market.

The complexity of developing a range of MBPs with different combinations of contents to reflect differences in treatment protocols between countries was also a challenge for manufacturers. In addition, revisions to the 2006 WHO PMTCT guidelines would have required significant changes to the contents of the MBP. Overall, the procurement and operational implications of the MBP were poorly thought through and potential problems were not well anticipated.

A stakeholder meeting was held but no report was available. Project reports include little information about the status of the MBP; 4,500 packs were reported to have been delivered but no information is available about how many of these were distributed and used or about any problems encountered. At the time of the mid-term review, Cameroon and Kenya were awaiting a decision about the suspension of the MBP, and Zambia had decided to use the contents of the MBP separately. A version of the MBP is reported to be being taken forward in Lesotho; as noted earlier, Lesotho had been working on its own version of an MBP prior to the start of the PMTCT projects. UNICEF reports that it is continuing to explore the concept of bundling a minimum integrated package of products in the context of maternal and neonatal health.

There is little evidence of market analysis or informed engagement with industry or other significant players in the market. UNICEF project reports include little information about engagement with industry or other significant players in the market (e.g. Clinton Foundation, Global Fund and PEPFAR) or outcomes from such engagement, or about market analysis. For example, the proposal for PMTCT 3 states that "A specific supplier meeting will be held in Copenhagen in October 2009 to brief industry on requirements for nutrition products in the context of UNICEF-supported programmes, including those supported by UNITAID" but this was not reported on.

Both UNICEF and UNITAID participate in the Coordinated Procurement Planning (CPP) initiative, which is part of the larger PEPFAR-funded Supply Chain Management System (SCMS) project. This initiative is designed to facilitate and improve coordination of national-level ARV procurement plans, including by key country stakeholders and major donors and providers of drugs. Despite being active members of the CPP, there is no information in UNICEF or UNITAID project documents about the role of this initiative in the PMTCT projects. It is important to note that UNITAID has recently provided financial support to the secretariat of the CPP, which signals a strong and positive commitment to on-going engagement with and the success of the initiative.

2.2 Implementation Issues

Planning and selection of countries

It is unclear why some countries were included as recipients of UNITAID-funded support. Beneficiary countries were selected by UNICEF, based on UNITAID criteria, and endorsed by the UNITAID board. Criteria included a high burden of mother-to-child transmission, joint IATT (Inter-Agency Task Team) assessment mission recommendations, national commitment to scale up PMTCT programmes, availability of other financial resources, and partner organisations' capacity to provide technical assistance. Some but not

all beneficiary countries are consistent with the global priority countries for eliminating MTCT. These 22 global priority countries do not include the Central African Republic, China, Haiti, Myanmar or Rwanda, which were included in the UNITAID-funded PMTCT projects. It is also debatable whether China or India required donor funding for procurement of drugs and other commodities.

Procurement and delivery of drugs and commodities

Weak country systems and delays in submitting requests were the main challenge for procurement. UNICEF based its procurement plans on quantification and forecasting provided by national authorities. However, delays in generating this data led to corresponding delays in submitting procurement requests. These problems reflect structural weaknesses in national supply chains, including inadequate management capacity, as well as a lack of strong country ownership of the overall process. The PMTCT projects did not include budget allocations for strengthening these national systems, which may have contributed to limited engagement by national authorities. UNITAID does not provide funding for capacity building activities, expecting that project partners such as UNICEF will fund them from other sources. UNICEF believes that this has had an adverse impact on implementation. However, UNITAID does make this position quite clear and, if there were systems challenges, UNICEF should have taken steps to address them¹⁷.

Differences in national policies and treatment guidelines were also a challenge. As a result, UNICEF was required to tailor procurement activities to different country needs, which prevented it from implementing pooled procurement. Not only did this create additional work for UNICEF, it also reduced their ability to influence the market and leverage price reductions. While it is unlikely that all recipient country governments would readily agree to common policies and treatment guidelines, the negative impact on external procurement of disparate policies and guidelines is an issue.

Upfront funding from UNITAID enabled UNICEF to achieve short lead times and ensure delivery in line with country requests. In general, UNICEF worked with countries to deliver shipments when they were requested. For example, some countries wanted deliveries at very short notice, others requested a phased delivery schedule, and others wanted products held by UNICEF until a specific date because of limited storage capacity. As is the case with almost all procurement, bureaucratic problems and customs clearance delayed delivery of some shipments. UNICEF tracked and reported on shipments to UNITAID, including reasons for delayed or late deliveries and measures taken to address the problem.

UNICEF took steps to secure the best possible prices for products. UNICEF used efficient tendering processes and long-term agreements (LTAs) to secure favourable prices for products; prices that were generally below comparable market prices. UNICEF reports that prices have remained relatively stable with price reductions for some products and price increases for others. Overall price reductions have been achieved mainly though bulk packaging for diagnostics. It is important to note that UNICEF follows applicable UN rules and regulations and therefore awards contracts to pre-qualified providers; this has an effect on pricing because it limits the number of suppliers.

UNICEF took steps to reduce freight and distribution costs. UNICEF took a number of steps to reduce freight and distribution costs, including: 1) shipping products direct from

¹⁷ The following paragraph is taken from the Financial Arrangements in the agreement between UNITAID and UNICEF for PMTCT 2: "It is estimated that an additional 20% of commodity cost is required for effective implementation and capacity building activities in supply chain at local and national level. These include, but are not limited to, activities related to the distribution, storage and clinical administration of diagnostics and drugs. As a result, the identification of needs and support of in-country implementation, together with the ability of the recipient to access technical assistance and funding for the operating costs of scale up, will be crucial to the success of this Project".

manufacturers; 2) use of sea freight versus air freight; 3) use of global freight contracts which are monitored against market rates; and 4) use of tenders with freight forwarders.

There were specific problems with the procurement of liquid formulations of nevirapine (oral NVP). Problems were due to: 1) the production capacity of a limited number of manufacturers; 2) increased demand in 2011 as a result of PEPFAR scale up; and 3) new guidance on the regimen, which recommended giving oral NVP for a longer time. While it is important to learn from the experience with oral NVP, there were no similar procurement problems with other PMTCT drugs, diagnostics or commodities.

Coordination and partnerships

There appears to have been limited engagement with partners at a strategic level to ensure effective coordination of UNITAID-funded PMTCT projects with other PMTCT implementers and their projects. The IATT on PMTCT and Paediatric AIDS is an important body for coordination and collaboration among international stakeholders. These stakeholders include UN partners (e.g. UNICEF, WHO, UNFPA and World Bank), the US Office of the Global AIDS Coordinator (OGAC), the Clinton Foundation, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) and others. UNICEF presented initial plans for the UNITAID-funded projects to the IATT; however, there is no evidence that UNICEF subsequently coordinated or collaborated directly with key stakeholders at global level, other than WHO¹⁸.

Country level coordination through national PMTCT working groups was effective. UNICEF worked closely with national partners, in particular ministries of health, and, depending on the country, with key funding and technical partners including the Global Fund, USAID, US CDC and EGPAF. In some countries, UNICEF was instrumental in establishing PMTCT working groups where these did not exist and in providing support for the effective functioning of these groups.

UNITAID-funded procurement for PMTCT is reported to have been integrated with national quantification and forecasting processes. The mid-term review, however, highlighted the issue of over-supply in some countries, suggesting the need for more accurate forecasting and better coordination. Lack of country perspectives in UNICEF progress reports make it difficult to judge the views of government and other national stakeholders about the effectiveness of coordination between UNICEF and these partners. However, anecdotal evidence suggests that coordination between partners involved in forecasting and procurement at country level has improved.

The online survey asked respondents to rate the effectiveness of UNICEF coordination of UNITAID-funded activities with other stakeholders. In general, a majority of respondents rated coordination of PMTCT commodity quantification, forecasting and procurement and coordination of PMTCT programme planning and implementation as effective or very effective. Respondents rated coordination of PMTCT programme monitoring and evaluation as less effective.

UNICEF kept national authorities informed on the UNITAID-funded PMTCT projects.Almost all respondents to the online survey stated that government partners (e.g. the Ministry of Health, the National AIDS Commission and supply chain partners) were well informed or very well informed about the projects. Other implementing partners and other agencies and organisations, such as the Global Fund, were perceived by respondents to be less well

¹⁸ As part of its on-going engagement with the international community, UNICEF does maintain working relationships with other key stakeholders. For example, as part of this evaluation, the Global Fund reported that it works very closely with UNICEF on PMTCT and paediatric HIV care and treatment programmes. However, the Global Fund could not identify particular examples of coordination on UNICEF initiatives funded by UNITAID.

informed about the projects. The extent to which partners were informed reflects their participation in national PMTCT coordination mechanisms. If an organisation does not have a country presence or is not a regular participant in the national coordination mechanism, it was less likely to know what was going on and there were no additional mechanisms to keep them informed.

Key country stakeholders are aware that PMTCT commodities were procured with UNITAID funds. UNITAID has raised concerns about the level of awareness of its support for commodities in beneficiary countries. UNICEF did, however, hold initial meetings with national stakeholders about the PMTCT projects and continued to keep them informed through national PMTCT coordination mechanisms.

Respondents to the online survey were asked to rate stakeholder awareness of UNITAID funding for PMTCT commodities. The majority believe that most government and supply chain partners were aware of UNITAID funding, but that implementing partners and donor agencies were less likely to know about it. Health workers and beneficiaries were considered the least likely to be aware of UNITAID support. This reflects the fact that commodities are not branded or identified by funder and, hence, only those stakeholders involved in project planning and coordination would be likely to know that supplies were procured with UNITAID funding. Although UNITAID wanted branding, UNICEF does not brand supplies. UNICEF reports that boxes of supplies have UNITAID labelling but individual packages do not.

Technical support

UNICEF and WHO provided technical support to countries for PMTCT programming. Technical support is central to the mandates of both UNICEF and WHO and the PMTCT project proposals identified areas where technical support would be provided. However, UNITAID does not provide funding to cover the costs of technical support. This approach created problems for UNICEF because it meant funding these activities through other budget lines. Historically, UNICEF has had more internal control over the use of funds provided by external donors, which enables them to determine the allocation of funds for activities such as technical support as well as institutional overhead costs.

Project reports and responses from the online survey cited examples of technical support provided. These included: technical guidance; training modules and tools; support to develop and revise national PMTCT policies; guidance and support for national and district operational planning; strengthening the capacity of services and of M&E systems to collect PMTCT data; and assessment of commodity procurement and supply chain management systems. In some countries, for example, Myanmar, Rwanda and Zambia, specific support was provided for quantification and forecasting for PMTCT supplies. No assessment of the effectiveness or the outcomes of technical support has been conducted.

UNICEF worked with national authorities on transition planning; however, procurement of future PMTCT supplies is not fully funded and it is unclear where the funds will come from. According to UNICEF, transition planning was part of the projects from the outset. This planning was based on the assumption that, at the end of the UNITAID projects, procurement would be funded by other donors – primarily the Global Fund and PEPFAR – and by national governments in recipient countries. A key expectation was that these countries would secure funding under Global Fund Rounds 10 and 11 for PMTCT scale up.

Overall, UNICEF reports provided very limited information on transition planning. In interviews, UNICEF staff reported that countries were informed well in advance about the end of funding from UNITAID for PMTCT supplies and that UNICEF provided assistance to countries to ensure that PMTCT was included in Round 10 and 11 proposals to the Global

Fund. The cancellation of Round 11 – as well as scale up of plans linked to the push for elimination of MTCT – has left some countries with a significant funding gap and it is not clear how this will be addressed. UNICEF reports that it has been assisting these countries to determine funding requirements – a gap analysis was included in a proposal to UNITAID for an extension to PMTCT 2 but this proposal was not approved – and to mobilise resources, including advocating for additional support for PMTCT from other donors such as PEPFAR. However, substantive discussions have not been held with PEPFAR at a strategic level about on-going funding and no commitment to additional funding for procurement of commodities has been secured.

While 76% of survey respondents confirmed that UNICEF had worked with partners on transition planning, only 43% stated that procurement of commodities for the national PMTCT programme is fully funded. Many commented on the funding gap (see Annex 4).

Expenditure against budget

The budget absorption rate was low. Based on information available at the time of the mid-term review, the budget absorption rate was 57% for PMTCT 1, 27% for PMTCT 2 and 39% for PMTCT 3. The review report highlighted the potential negative impact of this underspending on the achievement of project objectives. No updated information on the budget absorption rate is available, as final financial reports have not yet been submitted, so it is not possible to comment on whether the budget absorption rate has improved since the mid-term review. The low absorption rate reflects delays in the submission of country requests, but it also raises questions about the accuracy of the projected country requirements. The mid-term review identified a pattern of major differences between budgeted and actual forecasts – i.e. between what was proposed and what countries actually requested – suggesting the need for more accurate proposals and budgets, which should contribute to higher absorption rates.

2.3 Project management

Roles and responsibilities

With some exceptions, UNITAID, UNICEF and WHO have broadly fulfilled the roles and responsibilities set out in the Memorandum of Agreement (MOA) for each project. Table 7 includes a summary assessment based on available information.

Table 7: Role and responsibilities of UNITAID, UNICEF and WHO

	Roles and responsibilities	Comment
PMTCT 1		
UNITAID	Timely provision of funding to UNICEF to enable the purchase of PMTCT-related commodities for the 8 beneficiary countries	Funds have mostly been disbursed on a timely basis. Delays in disbursements have been due to UNITAID requests for clarification from UNICEF (e.g. with the second and third disbursements for PMTCT 1) and low absorption rates (e.g. with the second disbursements for PMTCT 2 and PMTCT 3). Disbursements were not initially linked to progress; UNITAID has since introduced a system where disbursements are linked to performance.
	On-going review of financial and programmatic project progress	UNITAID has reviewed reports on project progress and provided feedback to UNICEF. Systems have been introduced to

	Roles and responsibilities	Comment
	•	improve the review process but have not been used consistently. New reporting formats were introduced during the project timeframes (see Reporting and M&E in this Section).
	Working jointly with UNICEF, WHO and other partners to consider available actions to achieve all project objectives	No evidence of working jointly to consider actions.
	Provision of strategic advice, where appropriate, for achievement of the project's objectives, most notably on how to leverage market dynamics to avail more efficacious and appropriate PMTCT regimens at reduced prices	No evidence of provision of strategic advice to achieve project objectives, including on how to leverage market dynamics.
UNICEF	Development of a procurement strategy	Procurement plans were developed; see Procurement in Section 2.2.
	In-country assessments of procurement and supply management infrastructure and practices as necessary	No reports of formal assessments of country procurement and supply management, but this was identified as an area of technical support provided by UNICEF.
	Agreeing with recipients on PMTCT- related drugs, including prophylactic regimens, ARVs and cotrimoxazole to be used and confirmation of forecasts	This has been challenging due to changes in guidance and regimens and time taken by countries to provide forecasts; see Procurement in Section 2.2.
	Support to national programmes for revision of national PMTCT operational plans within the context of UNITAID support.	Support was provided to develop or revise operational plans.
	Issuance of implementation letters to health authorities of beneficiary countries	Implementation letters issued for PMTCT 1. Other project activities carried out under auspices of pre-existing MOU between UNICEF and national authorities.
	Coordination and management of procurement and timely delivery of high-quality PMTCT commodities to beneficiary countries including ensuring appropriate quality assurance arrangements and maintaining buffer stocks where applicable	Procurement coordinated and managed in partnership with national authorities and coordination mechanisms. Delivery mostly timely. No documented evidence of action taken to ensure quality assurance or buffer stocks
	Engagement and negotiation with industry to stimulate an increase in the availability of more appropriate PMTCT commodities of assured quality, accelerate submission of prequalification applications and facilitate the stimulation of lower prices	Negotiation to secure competitive prices did occur but limited scope to impact the market; see Market impact in Section 2.1.
	Provision of technical assistance to beneficiary countries in PMTCT programming, including M&E	Technical assistance was provided for PMTCT programming; support for M&E was limited.

	Roles and responsibilities	Comment
	Submission of Interim Progress Reports and Annual Procurement and Financial Reports to UNITAID	For PMTCT 1, no interim progress reports were available; an annual report was only available for Year Two. Annual reports were not in line with the UNITAID annual cycle. Final reports not yet submitted for all three projects.
WHO	Dissemination of WHO normative guidance for use of ARVs for PMTCT, and diagnosis and clinical management of HIV in children, pregnant women and mothers through WHO country and regional offices	Implemented as part of WHO routine activities rather than project-specific.
	Making available training modules and tools for health care workers on the use of ARVs and other medicines for PMTCT and management of HIV in children, pregnant women and mothers	Implemented as part of WHO routine activities rather than project-specific.
	Promoting the use of PMTCT M&E guidelines and use of indicators proposed in the WHO framework for monitoring and reporting on the health sector's response towards universal access to HIV/AIDS treatment, prevention, care and support	Implemented as part of WHO routine activities rather than project-specific.
	Provision of technical assistance to beneficiary countries in the review and revision of their national PMTCT policies and plans and in PMTCT implementation, including M&E	Implemented as part of WHO routine activities rather than project-specific.
PMTCT 2		
UNICEF	In addition to the above for PMTCT 1: Make additional human resources available at its Supply Division and in the nine UNICEF country offices to support supply planning and management of commodities, including those needed for CD4 testing and for early infant diagnosis. Specifically to:	UNICEF has not reported on additional human resources made available.
	Document current status, strengths and weaknesses in PSM of recipient countries	No documented evidence of PSM in recipient countries.
	Provide technical assistance in supply planning and management of commodities needed to operationalize the PMTCT Expansion Component	Technical assistance provided for PMTCT programming overall.
	Assist UNICEF country offices, governments and other partners with preparation for UNITAID implementation and to participate in country missions, specifically focusing on access to cotrimoxazole prophylaxis, supply planning and management of ARVs for mothers and rapid diagnostic tests assessed and approved by WHO	Difficult to assess as not specifically documented in UNICEF reports.

	Roles and responsibilities	Comment
	Develop and/or review existing guidance on supply management for PMTCT, and update to support the PMTCT Expansion Component	Not possible to assess as not documented in UNICEF project reports.
	Monitor progress towards established indicators and provide UNITAID with reports on a semi-annual basis	For PMTCT 2, no interim progress reports were available; an annual report was only available for Year One.
WHO	In addition to the above for PMTCT 1:	
	Adaptation of PMTCT and paediatric care guidelines at the country level	Implemented as part of WHO routine activities rather than project-specific
	Provision of technical support in developing tools to guide programme implementation. WHO Technical Officers in country offices working on HIV and MCH will work with UNICEF Programme Officers in coordinating programme inputs drawing on in-country and regional capacity	Implemented as part of WHO routine activities rather than project-specific. Difficult to assess the extent to which WHO Technical Officers have contributed to project implementation or drawn on regional capacity as this is not documented in UNICEF project reports.
DMTCT 2	Provision of technical support to develop capacity of health care workers for PMTCT and management of HIV in children, pregnant women and mothers, including M&E	Implemented as part of WHO routine activities rather than project-specific. Difficult to assess the extent of technical support for capacity development as this is not documented in UNICEF project reports.
UNICEF	Assessment of RUTF and HemoCue needs for scale-up of anaemia testing and treatment and nutritional interventions linked to PMTCT	Progress was slow. In the second year of the project, the four countries were still assessing needs; this suggests limited impact of UNICEF support for the assessment.
	Coordination and management of procurement and timely delivery of RUTF and diagnostic supplies to beneficiary countries in response to identified need, including ensuring appropriate quality assurance arrangements	As of the MTR, countries had not submitted requests for procurement.
	Monitoring and documentation of strengths and weaknesses in programme implementation, and application of lessons for improvement of national programmes via policy revision	As of the MTR, no data available on nutrition-related commodities and no documentation of programme implementation.
	Provision and coordination of technical assistance in the review and revision of national nutrition policies and plans linked with PMTCT implementation	No evidence in UNICEF reports of technical assistance provided to review and revise national nutrition policies and plans.
	Provision and coordination of technical assistance for scale up of national programmes for providing nutrition care and treatment linked to PMTCT	No evidence in UNICEF reports of technical assistance provided for scale up of national programmes.
	Engagement and negotiation with industry	Some progress; see Market impact in

	Roles and responsibilities	Comment
	to stimulate an increase in the availability of appropriate RUTF and diagnostic commodities of assured quality and facilitate the stimulation of lower prices	Section 2.1.
	Provision of timely and complete reports on project progress	Interim report and annual reports for years one and two submitted
WHO	Dissemination of WHO normative guidance for diagnosis and clinical management of SAM in children, through WHO country and regional offices	Implemented as part of WHO routine activities rather than project-specific.
	Making available training modules and tools for health care workers on the management of nutritional problems in those with HIV	Not possible to assess as not documented in UNICEF project reports.
	Provision of technical assistance to assist beneficiary countries in the review and revision of their national nutrition policies and plans linked with PMTCT implementation	Not possible to assess as not documented in UNICEF project reports.
	Development of specifications for RUTF	Not possible to assess as not documented in UNICEF project reports.

UNITAID's funding approach has provided UNICEF with considerable flexibility but has also created challenges. UNITAID funding does not cover operational costs, only the costs of procurement and the costs associated with procurement¹⁹. However, UNITAID has significant expectations for project management and reporting that have staff implications for implementing partners. The lack of funding for operational costs, and for M&E, was a challenge for UNICEF; essentially, they had to use funds from other sources to manage the UNITAID projects. This appears to have resulted in management of the UNITAID projects being under-resourced within UNICEF, particularly in the area of M&E.

UNITAID has evolved during the time that the PMTCT projects were being implemented. When PMTCT 1 was initiated, UNITAID was a very new organisation. As UNITAID has become more established, it has better defined its objectives, its approaches and its systems. This evolution created challenges for UNICEF, which has had to deal with changing objectives, new M&E frameworks and reporting templates, and additional requests for project information. UNICEF has tried to be flexible in responding to changes and additional requests but has on occasions been unwilling to modify positions set out in the original project MOAs. This has caused some tension between the two organisations, although meetings between key staff from both organisations did improve the relationship.

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¹⁹ UNICEF has charged a procurement fee, stating that. "The handling fees that are established are the minimum amount UNICEF reasonably concludes is required to meet all related transaction costs and to support the supply of quality assured goods and services. These costs include staff salaries, technical services (e.g., inspection, quality assurance, additional services at Supply Division, Country Offices etc.). In order to meet the specific needs of this Project component, including monitoring and reporting requirements, additional resources are needed, which are included as procurement management costs. The handling fees appear beneath each line item of the Cost Estimate. A detailed breakdown of expenses for the related transaction costs and to support the supply of quality assured goods and services will be provided to UNITAID as part of the Annual Programmatic and Financial Reports". However, the MOA for PMTCT 1 states "The aforesaid funds may not be used to cover operating costs nor to pay for administrative expenses (unless such expenses are the subject of an express provision in the Project Budget) nor the payment of customs charges, taxes, tolls or other duties, local charges (such as demurrage charges, local storage charges, national fees for legalisation of documents and the like) (collectively "Duties and Local Costs")".

UNITAID systems for the management of project documentation and the review of and feedback on project reporting were weak. For the purposes of this review, UNITAID did not have a complete set of all relevant documentation and reports, suggesting the need for a more effective system for management of project documents and records. During the course of the PMTCT projects, new systems and processes were introduced to improve review of and feedback on project reports, but these have not been used consistently. In addition, UNITAID has on occasion approved reports and then subsequently suggested that UNICEF has not met requirements.

The respective roles and responsibilities of UNICEF offices in New York, Copenhagen and in countries could have been better defined. In some cases, roles and responsibilities were clear; in others, they were not. For example, there is no question that UNICEF Copenhagen was directly responsible for procurement. However, staff in Copenhagen assumed certain activities were being implemented by New York (e.g. global coordination and monitoring of project implementation) and by country offices (e.g. national level coordination and capacity development). Ultimately, it is not clear where in UNICEF the ultimate responsibility rested for ensuring delivery of project objectives or effective coordination across the organisation. One outcome of this was the failure to use procurement and order-tracking data to measure and report on progress against project targets and objectives.

UNICEF did not meet all of the conditions set out by the UNITAID Board. For example, PMTCT 2 funding was dependent upon UNICEF meeting a number of conditions. Some of these, for example, providing greater clarity about the status of the MBP and developing a detailed procurement supply chain management plan and a comprehensive M&E plan, were not met. However, UNITAID took no follow up action.

WHO played a limited role in project implementation. WHO has fulfilled its expected role in providing normative guidance and technical support in beneficiary countries, although this support would most likely have been available to countries regardless of their involvement with the UNITAID-funded projects. UNICEF reports include limited information about the contribution of WHO and the UNITAID Board requested clarification of the role of WHO in July 2008. However, it is worth noting that no funding was provided to WHO through the PMTCT projects to support additional activities, although a budget was originally submitted.

Inadequate attention was paid to risk assessment and risk management. Although UNICEF does employ some risk mitigation measures, for example, quality assurance of commodities, neither UNITAID nor UNICEF had a comprehensive system for risk assessment or risk management system in place for the projects. Given that market innovation, which carries an inherent risk of failure, is central to UNITAID's approach and was intended to be integral to the three PMTCT projects, this was a significant weakness. If a comprehensive approach to risk assessment and risk management had been in place, the problems that arose with the MBP could have been foreseen and addressed proactively.

Reporting and M&E

The quality of UNICEF project reports was poor. The mid-term review noted that project reports lack detailed information and analysis – in some cases, data was incomplete or of poor quality – and that reports do not link activities to objectives. The evaluation team concurs with these findings. Reports do not provide an overall assessment of progress and achievements, analysis of challenges and lessons learned, or explanations for over- or under-achievement of targets or deviations from the budget. Not all indicators are reported on and there is little or no information about issues such as public health or market outcomes. Inconsistencies between reports make it difficult to assess trends and compare

issues such as unit costs. Reports provide data for the reporting timeframe but no cumulative data so it is difficult to assess overall project progress towards targets.

UNITAID introduced a new reporting template during the course of the PMTCT projects. Although an improvement, it still did not require cumulative project reporting. As noted earlier, reports do not provide a breakdown of progress towards targets on a country-by-country basis, so it is not possible to assess what has been procured or quantities procured for each country and how this measures up against planned procurement. It is possible that the lack of UNITAID funding for operational expenses contributed to weak reporting. Regardless of the reason, UNICEF should have produced significantly better reports for UNITAID and, given the size of the investment, UNITAID should have been much more forceful in demanding accountability for the funds.

UNICEF has found it difficult to respond to **UNITAID** requests to improve or change **project reporting.** Examples include UNITAID requests to UNICEF to report on the basis of a calendar year rather than a project year and to report project-specific data as well as to link expenditure on procurement to services provided in recipient countries. Despite UNITAID requests, UNICEF also continued to report on weighted average price, rather than on median price²⁰, and on the percentage of on time deliveries rather than reduced lead times.

Monitoring and reporting have been undermined by the lack of an agreed M&E framework and core set of indicators. Milestones, targets and expected results were initially defined in project plans. However, there was no M&E framework or clearly defined indicators at the start of the first PMTCT project. For the extension of PMTCT 1, an M&E logical framework with 16 indicators was developed. This framework was further revised for PMTCT 2, with the addition of new indicators, including ones related to the specific contribution of UNITAID. UNITAID has subsequently developed a framework for all projects to measure and report on progress.

In addition to the milestones and targets in the initial project plans, there were two other sets of indicators²¹, related to 1) achievement of objectives and 2) PMTCT implementation status. The latter included 19 population and service delivery indicators, based on national programme data reported through UNICEF's PMTCT report card (see Table 3). While the use of indicators from the report card was intended to avoid creating parallel M&E and reporting systems in countries, these indicators do not provide project-specific data or allow analysis of UNITAID's contribution. UNICEF continued to report on these indicators despite UNITAID concerns that they were not project specific.

The situation was further complicated by the existence of some indicators common to all three PMTCT projects and others that were project specific. It was not clear whether common indicators were to be achieved by individual projects or by the contributions of all three projects. And from a practical perspective, a number of indicators were not well defined and not all of them were measurable.

UNITAID has had on-going concerns about the quality, completeness and timeliness of UNICEF financial reporting. Problems first arose when the initial UNITAID template for financial reporting was changed. The initial template was very basic and only required information on funds received and spent by the implementing partner. UNITAID subsequently established a finance unit and, recognising that the template was inadequate, requested more detailed financial reports. The expanded financial reporting requirements were not included in the original project MOAs, and there was resistance from UNICEF to providing more detailed information and to responding to requests for clarification from UNITAID.

²¹ Set out in Annex 4A and 4B of the MOA

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²⁰ UNICEF reported on price is consistent with the MOA, although the MOA provided scope to change this

The financial reports submitted by UNICEF did not provide cumulative financial reporting or a summary of overall project financial status. More specifically, cash reconciliations were not supported by financial statements; annual financial reports did not include updated budgets; and budget adjustments and reallocations were not formally agreed by UNITAID. In addition, expenditures were not clearly linked to activities and UNITAID had problems verifying expenditure and reconciling financial reports. The mid-term review also highlighted discrepancies between expenditures reported in progress and financial reports and difficulties in linking expenditure to activities. There have been recent improvements; for example, budget and financial reporting templates are now consistent, and UNITAID has a financial reporting template that has been agreed with UNICEF and that will be used for the final financial reports for the PMTCT projects.

UNITAID concerns about independent audit and disclosure of interest earned were not resolved. UNICEF follows UN in-house audit procedures and, consequently, is unwilling to allow an independent audit of project finances. UNITAID can access internal audit reports on the UNICEF website but cannot download or print these reports. UNICEF has also been unwilling to disclose the interest earned on project funds held. Although UNITAID now includes financial reporting requirements in project MOAs and contracts, it unclear that this will be sufficient to ensure that UN implementing partners comply with its requirements regarding independent audit and the disclosure of interest earned.

The mid-term review was done late and was not followed up. The mid-term review of all three projects was conducted in 2011, with the report submitted in September 2011, after the project timeframes were completed. This was too late to make changes to the projects to address the weaknesses identified. In addition, the MTR report was not shared with UNICEF. Not surprisingly, systematic implementation of the recommendations has been limited. Table 8 provides a summary of the recommendations and action taken.

Table 8: Summary of MTR recommendations and follow up action

Recommendation	Comment
Formalise adjustments to targets and budgets	Too late for the PMTCT projects. Needs to be considered for future projects.
Implement a performance-based monitoring and disbursement system (UNITAID)	UNITAID has introduced performance-based disbursement of funds.
Identify suitable indicators for reporting on project-specific achievements (UNITAID)	Too late for the PMTCT projects. Needs to be considered for future projects and as part of UNITAID efforts to develop a standard M&E framework and core indicators that are measurable and useful.
Formalise involvement in national forecasting with integrated project-specific forecasting (to improve possibility of assessing UNITAID contribution to overall PMTCT procurement) and monitor procurement supplies through the supply chain (UNICEF)	Too late for the PMTCT projects. UNITAID needs to consider what attribution should be measured, and what it is feasible to measure, in future projects.
Clarify policy on interest earned (UNITAID) and report on interest earned (UNICEF)	UNITAID needs to decide if this will be a mandatory requirement of all partners in future and, if so, what the implications are for implementing partnerships with UN agencies. Not done by UNICEF for the PMTCT projects.
Clarify status of MBP as part of UNITAID funding (UNICEF)	Insufficient detail in financial reports to assess expenditure on MBP. UNICEF reports that no UNITAID funds were used for MBP development or procurement and distribution. No evidence of documented lessons learned from the MBP experience.

Recommendation	Comment
Agree a no-cost extension with UNICEF to allow completion of project activities (UNITAID)	UNICEF has submitted a request for a no-cost extension to complete activities in China. UNITAID has not made a decision on this request.
Strengthen the UNITAID archiving system and formalise and establish a system to keep track of contractual amendments (UNITAID)	No evidence of any steps taken.
Consider funding for WHO programmatic activities (UNITAID)	Too late for the PMTCT projects. Raises a wider question for UNITAID about funding operational costs of implementing partners or, at a minimum, funding the costs of project management, M&E and reporting.
Include transition plans in contractual agreements (UNITAID)	Too late for PMTCT projects. Needs to be considered for future projects.
Introduce logical frameworks, define indicators to be reported on, reduce indicator list and update indicator definitions (UNITAID)	UNITAID is working to address this recommendation.
Include clear progress and financial reporting requirements in MOA and project plans, develop reporting guidance and a reporting templates to ensure performance-based and cumulative progress and financial reporting, and ensure compliance with reporting requirements (UNITAID)	Reporting templates have been revised and reporting requirements now included in project MOAs and contracts.

3 LESSONS LEARNED AND RECOMMENDATIONS

The PMTCT projects, specifically PMTCT 1, were one of the first initiatives supported by UNITAID. They were funded at a time when the organisation's systems were still being developed and there was pressure from various stakeholders to begin disbursing funds, and this contributed to some of the problems encountered. UNITAID has learned from experience with these projects and has applied much of that learning to the on-going evolution of its systems and approaches. The evaluation team has identified a number of lessons learned and recommendations for UNITAID to consider as the organisation continues to refine its operations.

Project proposals and plans

Lessons learned. Proposals and plans for the PMTCT projects were inadequate. For example, they lacked important practical information and sufficient detail about implementation; they did not define clearly enough the roles and responsibilities of key partners and stakeholders; they lacked clear objectives; they were ambiguous about budget and accountability issues; and they did not include clearly set out feasible and relevant approaches to M&E. This created management and oversight problems for both UNITAID and UNICEF.

Recommendations. UNITAID should require potential implementing partners to submit robust project proposals that provide comprehensive information about objectives, strategies, stakeholder roles and responsibilities, core activities, budgets, timelines, financial reporting, risk assessment and mitigation measures, and an M&E framework and plan. Proposals should also clearly demonstrate how a project is aligned with UNITAID's objectives and approach. Requests for Proposals issued by UNITAID should provide clear guidance on the issues that must be addressed in a proposal.

Selection of projects and recipient countries

Lessons learned. Had the PMTCT project proposals been subjected to a thorough review by independent experts against a set of clear criteria, funding may not have been recommended. Rigorous assessment by experts in public health and programme implementation would also have identified or anticipated some of the problems encountered with the Mother Baby Pack. A Proposal Review Committee has been established since the PMTCT projects were approved, which makes recommendations to the UNITAID Board. As noted above, the prospects for significant and sustainable market and public health impacts were limited; the latter could have been anticipated if a thorough assessment of the state of the market had been conducted.

UNITAID focuses on support to lower income and lower-middle income countries; additionally, one of the criteria for selection of recipient countries was a high burden of mother-to-child transmission of HIV. On this basis, China would not seem to be a priority for support. Although India is a priority for global elimination of paediatric HIV, it is debatable whether India required funding for procurement of PMTCT commodities.

Recommendations. UNITAID should continue to strengthen its process for review and selection of projects to receive funding. This should be structured around a set of criteria to ensure that a proposed project is aligned with UNITAID core objectives and approaches. The review process should be rigorous and transparent with qualified, independent experts playing a primary role. In addition, any UNITAID representatives, including staff or board members, involved in the selection process should have access to adequate technical information, to enhance their ability to contribute to the process. The process and the participants should be free of any actual or perceived conflicts of interest.

Legal agreements

Lessons learned. The weaknesses of the proposals and plans were reflected in the project MOA, which did not set out expectations in sufficient clarity and detail. These legal agreements between UNITAID and UNICEF did not adequately address key project management and implementation issues, including specific issues that were important to UNITAID such as the use of independent, external auditors²² and a policy on interest earned on funds. UNICEF subsequently used the MOA to resist changes, for example, in project and financial reporting requirements. UNITAID has since modified its approach to legal agreements. For example, it now renews MOA and contracts annually and is also engaged in on-going efforts to link financial disbursements to partner performance.

Recommendations. As a funding organisation, UNITAID should – in principle and practice – ensure that all legal agreements (i.e. MOA, MOU and contracts) with implementing partners fully and adequately address all of the issues considered relevant by UNITAID, including reporting and M&E requirements, as well as providing the flexibility to address problems or issues that could not have been envisaged. Assuming agreements are clear and comprehensive, UNITAID should minimise the extent to which it changes requirements during project implementation; annual review of agreements should allow for mutually agreed revisions to be made as necessary as well as providing an opportunity to formalise and approve changes in targets and budgets.

²² The agreement between UNITAID and UNICEF for PMTCT 1 made no mention of audit arrangements for the project. The agreement for PMTCT 2 stated that the audit arrangements for the project were "UNICEF standard procedures", which essentially eliminated UNITAID's ability to conduct an independent, external audit. Similarly, the audit arrangement outlined in the agreement for PMTCT 3 was as follows: "The books and records of UNICEF and its operations are subject exclusively to the internal and external auditing arrangements as set forth in the financial regulations and rules of UNICEF and other relevant documents." Again, ensuring that UNITAID had no ability to conduct an independent, external audit.

Partnerships and capacity development

Lessons learned. The partnership between UNITAID and UNICEF was undermined by lack of clarity and agreement about project objectives, inconsistent direction and feedback from UNITAID, poor reporting by UNICEF, and lack of formal and informal arrangements to enable staff of the respective organisations to meet and discuss project issues. The more significant underlying problem was the lack of a well-defined partnership strategy within UNITAID to provide the framework for the relationship with partner organisations, including UNITAID's expectations with respect to issues such as engagement with industry and market impact.

It may be that UN agencies are not best placed to influence markets, as this is not central to their mandates and most have limited understanding and experience of market dynamics and of working with the private sector. In addition, UNITAID's choice of implementing partners also influences the choice of national partners. UN agencies such as UNICEF and WHO have a mandate to work with government ministries and, in the case of procurement and logistics, tend to work with central medical stores or equivalents. These national partners often have limited experience and capacity related to working with the private sector and influencing markets.

A significant challenge for procurement was the delay in country submission of requests, due to the time taken for quantification and forecasting. There is no evidence to suggest that implementing partner agreements with beneficiary countries included a commitment to timely quantification, forecasting or submission of requests, or that UNICEF systematically monitored country submission of forecasts or cost estimates. Although supply chain issues are not UNITAID-specific, they do have an impact on UNITAID-funded programmes such as the PMTCT projects. Differences in national policies and treatment guidelines were also a challenge for procurement.

Engagement with global partners was limited. This represents a missed opportunity and may have resulted in duplication of effort, given the role that many of these organisations play in PMTCT and paediatric AIDS. For example, EGPAF has programmes in 11 of the 17 countries where UNICEF worked with UNITAID funding, but there is no information about collaboration with this organisation. UNICEF acknowledges that it should have been more proactive and engaged in strategic efforts to coordinate and collaborate. Consultation with other key stakeholders, including major donors and implementing organisations, could have helped to ensure that the projects maximised their potential to leverage markets and enhance existing PMTCT efforts. UNICEF has worked with national authorities and PEPFAR on transition planning; however, procurement of future PMTCT supplies is not fully funded.

Recommendations. UNITAID should develop a partnership strategy for both internal and external use. Internally, UNITAID should have a clear vision of what it wants and expects from an effective and responsive implementing partner. Externally, UNITAID needs to ensure that existing and potential partners understand its vision of partnership. The strategy should be supplemented by straightforward guidelines on issues that are essential to a productive partnership, including clear, unambiguous project proposals and partnership agreements; agreed objectives, indicators and plans for M&E; systems and processes to ensure efficient and accurate reporting; open and on-going dialogue about project progress; and mutually agreed mechanisms for review of progress, revision of project plans and resolving disagreements.

UNITAID and implementing partners should, in future, ensure that agreements with beneficiary countries set out clearly the expectations and responsibilities of national authorities, and monitor the extent to which countries meet these commitments. Greater attention also needs to be paid to transition planning, to ensure the sustainability of funding, and of impact, once UNITAID support to recipient countries ends.

UNITAID should consider a collaborative effort with other key stakeholders, including WHO and large funding partners such as Global Fund and PEPFAR, to raise awareness among national governments of the benefits of common policies and guidelines. UNITAID should also consider collaborating with national and international stakeholders to strengthen country capacity to generate timely quantification and forecasting data. UNITAID should require that funding recipients work closely with other stakeholders at the global level to maximise market impact. Coordination and collaboration should be tracked as part of a project's standard M&E framework.

Risk assessment and risk management

Lessons learned. The experience with the Mother Baby Pack highlights the need for UNITAID to have a comprehensive system of risk assessment and risk management in place. Given the importance attached by UNITAID and UNICEF to the Mother Baby Pack, it would have been useful to assess the risk associated with the product before agreeing to provide funds for its development and procurement. The problems encountered should have been anticipated earlier in the process.

Recommendations. Market innovation is inherently risky and UNITAID should have systems in place to effectively assess and manage risk. Unlike many systems for risk assessment and risk management, which are designed primarily to mitigate risk and the negative exposure from it, UNITAID needs a system that looks at risk versus reward in the context of innovation. An organisation such as UNITAID may be willing to fund a high-risk project if the potential reward is also high. Without a strong system in place to initially assess and then manage these opportunities, UNITAID will be vulnerable to criticism. However, with a strong system in place, UNITAID will have more freedom and flexibility to pursue potential 'game-changing' opportunities.

UNITAID also needs to determine its institutional tolerance for risk. For example, UNITAID and its implementing partners may want to reconsider requirements related to prequalification in order to take advantage of potential opportunities to influence markets through use of local manufacturing capacity in developing countries.

Market impact

Lessons learned. The impact of the PMTCT projects on the market was more limited than originally envisaged and expectations were revised. A better understanding of the market for PMTCT products would have ensured that expectations were more realistic. Initial objectives for market impact were limited to price reductions. However, UNITAID's efforts to improve understanding of markets and market impact have since evolved, including through landscape analyses of markets for drugs and diagnostics for HIV, tuberculosis and malaria. UNITAID now seeks other ways of positively impacting markets, for example, improving availability, access, procurement and supply chain lead times as well as the price and quality of drugs and commodities. Although UNICEF has reported that it has achieved lower prices for supplies procured, UNITAID was more interested in impact on the overall market.

Recommendations. For potential implementing partners UNITAID needs to be more explicit about its 'model' and market objectives and to ensure that partners fully understand these. For example, it would be helpful if market information generated were to be linked to specific Requests for Proposal. This would enable UNITAID to demonstrate how its innovative financing model can be linked with innovative spending models.

Information available from UNITAID provides a useful perspective on markets and market impact, but would be more useful if emerging opportunities were linked to the organisation's

objectives and to proven or preferred approaches. Some approaches, for example, the 'X-Prize' incentive model, do not require an implementing partner, which has been the main strategy used by UNITAID to date.

UNITAID should also be more explicit about the 'other commodities' that it is willing to fund, particularly if there is an interest in market impact. For example, in both PMTCT 1 and PMTCT 2, UNICEF procurement records show multiple orders for biohazard bags, gloves, compresses, bandages, etc. It is highly unlikely that UNITAID had – or could have had – any impact on the market for these commodities. In addition, tracking attribution for these types of products is difficult as there is no way to ensure that their use is restricted to PMTCT services. Providing funds for the purchase of these types of commodities seems at odds with the strategic objectives of UNITAID.

Private sector engagement

Lessons learned. UNITAID aims to use its funds to address market failure and to achieve market impact. It does not engage directly with the private sector but expects implementing partners to influence and engage with industry, with UNITAID providing advice. However, during project implementation, UNITAID did not provide this type of guidance to UNICEF.

Recommendations. UNITAID needs to be more explicit about expectations of implementing partners and clearer about its own role in influencing markets and working with private sector partners. This has implications for the skills and experience required of implementing partners, of UNITAID staff and of those UNITAID engages to review project proposals. UNITAID is conducting a series of landscape analyses, but could also benefit from commissioning market analysis from external organisations that specialise in this field.

In addition, UNITAID may want to engage directly with the private sector, either on its own or through collaborative opportunities such as CPP and SCMS. UNITAID's significant financial resources give it the potential to establish relationships with key actors in the market and to influence market dynamics, particularly if it coordinates and collaborates with other key funders (e.g. Global Fund and PEPFAR).

Management and finance

Lessons learned. UNITAID management of the PMTCT projects had a number of weaknesses, including management of project documents and record keeping – the midterm review highlighted the need to strengthen systems for archiving and keeping track of contractual amendments. They also include providing consistent feedback on project reporting and ensuring that the implementing partner fulfilled its roles and responsibilities and met UNITAID Board conditions. Lack of understanding by UNICEF about the extent to which UNITAID covers operating costs and administration costs was an issue. Significant problems were experienced with financial reporting; however, meetings between UNITAID and UNICEF staff helped to resolve these problems

Recommendations. UNITAID has taken steps to strengthen project management but needs to ensure that it has effective systems in place to manage project documentation, provide consistent feedback, monitor performance and ensure that partners meet their obligations, as well as clearly agreed steps to address poor performance. Higher priority should be given to efficiency and value for money in projects. UNITAID should consider establishing benchmarks and regular review of issues such as unit costs and the costs of delivering projects as part of project selection and monitoring; guidance on this is reported to be in development for submission to the UNITAID Board.

UNITAID also needs to provide clear guidance about what it expects to see in project budgets and about what costs it will and will not cover. Consideration should be given to providing adequate funding to cover the cost of meeting UNITAID project management, M&E and reporting requirements, as is done by other funders such as the Global Fund and PEPFAR. All UNITAID agreements with implementing partners need to be explicit about financial reporting requirements. It would be useful for UNITAID financial staff to meet their counterparts in implementing partner organisations at the outset, to ensure that there is a common understanding of these requirements.

M&E

Lessons learned. Since M&E is often a challenge for new organisations, UNITAID relied on UNICEF's experience and existing approaches for the PMTCT projects, while it was building its own internal capacity. However, project M&E was not given high priority by UNICEF. In addition, project objectives were unclear, and there were too many indicators. Many of the indicators were not particularly useful for tracking project performance, or measuring project achievement. For example, none of the service delivery indicators (see Table 3) can be directly linked to UNITAID funding.

In addition, data requested by UNITAID changed over time. For example, after the projects had commenced, the UNITAID Board requested information on impact at country level including data on service delivery and beneficiaries as result of UNITAID support for procurement, but M&E systems were not in place to collect or analyse this information.

Recommendations. All projects should have a clear logical framework and indicators, and use standard reporting formats to report against these, so that it is feasible to assess progress and trends over time. UNITAID should consider identifying a limited set of core indicators that apply across all procurement projects^{23.} As far as possible, these indicators should be drawn from those already used by countries, other organisations and projects. The majority of these indicators are likely to be process measures to ensure that UNITAID knows what quantities of commodities have been procured and where these have been distributed. Other core indicators would be outcome indicators designed to track issues such as access and affordability. At a project level, it will be difficult to track both public health and market impact, given their complexity and the relatively short timeframes of most projects. UNITAID could therefore consider the monitoring and evaluating of impact as a separate issue, using tools such as longitudinal or specifically commissioned studies.

UNITAID should also consider whether it wants to extend its M&E activities beyond engagement with implementing partners. For example, there currently is no formal relationship between UNITAID and beneficiary countries and, as a result, no mechanism to obtain country-level data or perspectives directly. Similarly, there is no system for UNITAID to conduct independent monitoring and evaluation to verify reports submitted by implementing partners. UNITAID could consider collaboration with other partners in recipient countries to strengthen its M&E activities and obtain better data on its projects and their contributions, including through existing country and sector reviews.

Attribution

Lessons learned. When commodities are procured through multiple channels or by different donors, they are often pooled at the country level. This makes tracking and attribution to a specific donor a significant challenge. Tracking is further complicated by the fact that it relies on implementing partner and national systems and on the quality and completeness of

²³ If UNITAID embarks on other types of projects (e.g. generating and publishing market forecasts) it will need to develop other types of indicators. Core indicators need to include or correspond with KPIs currently being developed by UNITAID.

country data. Despite these challenges, evidence of its support for drugs, diagnostics and other commodities is a priority for UNITAID. However, attribution was not explicitly included in UNICEF PMTCT project proposals or legal agreements, and UNITAID did not have a clear strategy for ensuring that products procured were attributed to UNITAID funding.

Recommendations. Since UNITAID does not currently engage directly with country stakeholders, expectations that implementing partners will ensure that these stakeholders are aware of UNITAID support need to be made explicit in project plans and agreements. UNITAID should have clear objectives and guidelines in place related to product attribution including, for example, its position on which target audiences need to know, and how products should be labelled. If UNITAID wants greater awareness of its contributions at the level of health workers and beneficiaries, it needs to have a clear communications strategy and an agreement with the implementing partner on executing this, including the financial implications and any issues with co-branding with the partner and/or the manufacturer.

To ensure that tracking does not constitute an additional, and unfunded, burden for implementing partners and countries, UNITAID could consider collaborating with organisations with specific expertise in logistics and tracking commodity procurement and distribution, for example, the USAID Deliver Project, Crown Agents, and Supply Chain management System (SCMS) among others. UNITAID could also reconsider its position with respect to support for strengthening national systems that are responsible for quantification, forecasting and other aspects of procurement supply chain management.

ANNEXES

ANNEX 1: TERMS OF REFERENCE

UNITAID End of Project Evaluation: PMTCT 1, 2 and 3

Objectives

The objectives of the consultancy are to:

- Assess the progress of each project under review in achieving the objectives set out in the original project plan and MOU with UNITAID
- Track changes in the project due to lessons learnt and problems encountered during project implementation
- Measure the short, medium and longer term impact of the project in terms of how the project has changed the market for products of public health importance
- Assess the extent to which UNICEF reported to UNITAID on the project's impact on public health

Tasks and responsibilities

The project evaluation will be coordinated by the Monitoring and Evaluation team of the WHO/UNITAID Secretariat. EHG will undertake project reviews using official documents, evaluation checklists, questionnaires and other associated tools to be discussed and developed with WHO/UNITAID M&E Officers.

EHG will evaluate the PMTCT projects funded by UNITAID, which have reached the end of their project life cycle and are considered to have been completed. The evaluation should consider project achievements and lessons learnt as a result of the implementation of the WHO/UNITAID funded projects. The resulting evaluation report will be widely disseminated and available to all WHO/UNITAID stakeholders, including the general public, via the WHO/UNITAD website www.unitaid.eu.

The evaluation should be based on the completed projects' contractual agreements and project plans. These will include any specific objectives that were initially set by WHO/UNITAID and its implementing partner as well as an assessment of the project's achievements and impact. Project impact should be evaluated from two perspectives:

- Market impact (intentional and unintentional) for the products provided under the project agreements
- Public health impact for the beneficiaries of the medicines, diagnostics and related products provided through the projects

Evaluation questions should cover the areas of product selection, forecasting, procurement and response time in addition to the project relevance, effectiveness, efficiency and impact questions listed below.

Relevance:

- Identify the activities and outputs of the project and demonstrate that they are consistent with the objectives and expected outcomes as described in the project plan.
- Indicate if and demonstrate how the project has contributed to WHO/UNITAID's overall
 goal of contributing to the scale up of and access to treatment for HIV/AIDS, malaria and
 TB for the most disadvantaged populations in low and middle income countries using
 innovative global market based approaches.

Effectiveness:

 Were the objectives of the project achieved? If yes, were they achieved within he timeframe specified within the initial project plan? • What were the main factors influencing the achievement or non-achievement of the objectives? Were problems in placing or delivering orders dealt with in a timely manner?

Efficiency:

- How well did the project partners work closely with the relevant national authorities in project beneficiary countries? Is it possible to demonstrate a close connection between implementing partners and national authorities?
- Demonstrate that the project's procurement model was well defined and designed to identify and solve procurement-related problems as appropriate. Were bottlenecks experienced in the procurement of products for this project? If so, how were these dealt with and what could be done to improve the risk management of similar projects in future?

Impact:

 Demonstrate that the partner organization has delivered the required volume of WHO/UNITAID-funded medicines, diagnostics or preventive products in beneficiary countries in a timely manner.

EHG will need to meet with:

- WHO/UNITAID staff to develop and refine evaluation questions and methodology
- All relevant stakeholders to ensure a balanced and fair perspective of the end of project achievements

EHG will need to:

- Review project documentation including project specific monitoring indicators and financial reports
- Review the current reporting templates for project activity and financial reporting and suggest improvements to routine project reports and modify, if necessary, the frequency and timing of reporting
- Provide an overall evaluation of the management of each project including strengths, weakness, opportunities and threats

EHG will need to consider the following sources of information for the evaluation:

- Legal agreements between WHO/UNITAID and its implementing partners for each project
- Progress reports and follow-up performed by WHO/UNITAID portfolio managers with regards to semi-annual and annual reports from implementing partners
- End of project reports from implementing partners
- Market intelligence gathered by WHO/UNITAID and from external sources
- Beneficiary country PMTCT reports and information
- Financial reports from implementing partners

The Secretariat will provide project plans, legal agreements, project reports, including financial reports, from implementing partners as well as any other information deemed necessary to perform a thorough evaluation. The scope of the project evaluations should not extent beyond the scope of the relevant programmatic review provisions contained in the applicable agreements that WHO/UNITAID has with its implementing partners.

ANNEX 2: DOCUMENTS REVIEWED

Project documents

PMTCT 1

Project proposal. February 2007

Board Resolution. 8-9 March 2007

Memorandum of Agreement 2007-2009

Project plan 2007-2009 (Annex 1 to MOA)

Second annual report (January-December 2009). 15 February 2010

1-year extension of PMTCT 1

Proposal for extension. July 2010

Board Resolution. 17 August 2010

Second amendment to the Memorandum of Agreement. 22 December 2010

Project plan (Annex 1B)

Interim report (January-June 2011) (Excel file) and UNITAID feedback

PMTCT 2 (Expansion component)

Board Resolution. 2-3 July 2008

First amendment to the Memorandum of Agreement. 31 July 2009

Project plan (Annex 3)

Letter to MOH Zambia. 5 January 2011

First annual report (July-December 2009). 15 February 2010

Financial report Years 1 and 2 (as of 31 December 2010). 15 February 2011

PMTCT 3 (Nutrition component)

Board Resolution. 2-3 April 2008

Project plan (Annex 2)

First annual report (July-December 2009). 15 February 2010

First interim report (January-June 2010). 18 August 2010.

Second annual report (July-December 2010). 15 February 2011, UNITAID feedback and UNICEF response

Financial report Years 1 and 2 (as of 31 December 2010). 15 February 2011

Final statement of account Year 1. 2 March 2012

UNITAID procurement assessment of project reports: PMTCT 2 and 3 (January-December 2010)

UNITAID indicators (Annex 4A)

UNITAID indicators (Annex 4B)

Reporting and disbursement schedule (Annex 5)

Swiss Tropical and Public Health Institute. Mid-term review. 2 September 2011.

UNITAID

Strategy 2010-2012: Improving global markets to address HIV/AIDS, tuberculosis and malaria

Generic logframe template

Key performance indicators

HIV, Tuberculosis and Malaria Medicines Landscape (January 2012)

HIV/AIDS Diagnostic Technology Landscape, 2nd Edition (2012)

HIV/AIDS Diagnostic Landscape (July 2011)

Policy Brief: ACT Demand Forecast, 2012-2013 (April 2012)

Demand Forecast for Artemisinin-based Combination Therapies (ACTs) in 2012-2013 (Q1-2012 Report)

<u>Other</u>

Global HIV/AIDS response. Epidemic update and health sector progress towards Universal Access: Progress report 2011

ANNEX 3: PEOPLE CONSULTED

The following individuals were consulted during the evaluation:

UNITAID

Irina Avchyan, Finance Administrator
Raquel Child, Director Market Dynamics and Operations
Paloma Cuchi, HIV Portfolio Manager
Louise Kleberg, Technical Officer
Greg Martin, Technical Advisor
Kate Strong, M&E Officer
Lorenzo Witherspoon, Technical Advisor
Jane Galvao, Paediatric HIV Officer

UNICEF Copenhagen

Francisco Blanco Gitanjali Sakhuja Noura Maalaoui

UNICEF New York

Chewe Luo, Senior Advisor HIV and AIDS

Global Fund

Ade Fakoya, Senior Advisor HIV and AIDS Annette Reinisch, Monitoring Specialist

OGAC/PEPFAR

Thurma Goldman, PMTCT Technical Advisor William Coggin, Senior Technical Officer

ESTHER

Aurélie Bonfils, Pharmacist Procurement and Supply Advisor, ESTHERAID Project Manager and UNITAID focal point.

ANNEX 4: COUNTRY STAKEHOLDER ONLINE SURVEY AND SUMMARY OF RESPONSES

- 1. What type of organisation do you represent?
 - UN (54.8%)
 - Government (31%)
 - Civil Society (7.1%)
 - Donor (7.1%)

2. What country do you represent?

	UN	Government	Civil Society	Donor	Total
Burkina Faso					0
Cameroon	3	4			7
CAR					0
China	3	3			6
Côte D'Ivoire	3		3		6
Haiti	1				1
India	1				1
Lesotho	1				1
Malawi	2				2
Myanmar	1	1			2
Nigeria	1				1
Rwanda	1	1			2
Swaziland					0
Tanzania	1	2		1	4
Uganda	1	1		2	4
Zambia	2				2
Zimbabwe	2	1			3
Total	23	13	3	3	42

- 3. Which agencies and organisations are the main stakeholders for PMTCT in the country? Please select all that apply:
 - MOH (95.2%)
 - NAC (64.3%)
 - Other national government ministries, agencies and/or departments (38.1%)
 - UN agencies (81%)
 - Multilateral and bilateral donors (e.g. Global Fund, UNITAID, USAID) (78.6%)
 - Implementing partners (e.g. CHAI, EGPAF) (76.2%)
 - International NGOs (57.1%)
 - Local NGOs (59.5%)
- 4. Which agencies and organisations are the three main funders for the national PMTCT programme? Please list in order, starting with the largest source of funds:
 - PEPFAR (14)
 Global Fund (11)
 UNICEF (8)
 National Government (2)
 Ministry of Health (2)
 Ministry of Finance (1)
 Clinton Foundation (1)

EGPAF (1)

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USAID (1)
    CDC (1)
2. Global Fund (15)
    UNITAID (9)
    UNICEF (5)
    PEPFAR (4)
    WHO (2)
    Children's Investment Fund Foundation (1)
    Ministry of Health (1)
    US Government (1)
    United Nations (1)
    EGPAF (1)
    USAID (1)
3. UNICEF (9)
    United Nations (6)
    Clinton Health Access Initiative (3)
    World Bank (3)
    Global Fund (3)
    National Government (2)
    UNITAID (2)
    PEPFAR (2)
    UNFPA (2)
    CDC (2)
    WHO (1)
    Canadian International Development Agency (1)
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5. How important has UNITAID funding for commodity procurement been for the national PMTCT programme? Please rate on a scale of 1 to 5 (where 1 is not important at all and 5 is very important)

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1 - (2.4%)
2 - (7.1%)
3 - (16.7%)
4 - (21.4%)
5 - (52.4%)
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6. Was there a shortage of PMTCT commodities in the country before UNITAID provided support through UNICEF?

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Yes (71.4%)
No (28.6%)
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7. Did UNICEF keep stakeholders in the country's PMTCT programme informed about UNITAID support and project progress?

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Yes (97.6%)
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• No (2.4%)

If No, please go directly to question 9.

- 8. If Yes, how well informed did different stakeholders feel about the project? Please rate each group of stakeholders on a scale of 1 to 5 (where 1 is not informed at all and 5 is very well informed):
 - Government partners (e.g. MOH, NAC)
 - 1 (0%)
 - 2 (0%)
 - 3 (5%)
 - 4 (27.5%)
 - 5 (67.5%)
 - Implementing partners
 - 1 (0%)
 - 2 (10%)
 - 3 (17.5%)
 - 4 (32.5%)
 - 5 (40%)
 - Supply chain partners
 - 1 (0%)
 - 2 (0%)
 - 3 (10.3%)
 - 4 (23.1%)
 - 5 (66.7%)
 - Other agencies and organisations working on PMTCT (e.g. Global Fund, bilateral donors, international and domestic NGOs)
 - 1 (0%)
 - 2 (2.6%)
 - 3 (28.9%)
 - 4 (36.8%)
 - 5 (31.6%)
- 9. How effective was UNICEF coordination of UNITAID-supported activities with other PMTCT stakeholders? Please rate each area on a scale of 1 to 5 (where 1 is not effective at all and 5 is very effective):
 - PMTCT commodity quantification, forecasting and procurement
 - 1 (2.4%)
 - 2 (2.4%)
 - 3 (14.3%)
 - 4 (35.7%)
 - 5 (45.2%)
 - PMTCT programme planning and implementation
 - 1 (2.4%)
 - 2 (2.4%)
 - 3 (12.2%)
 - 4 (46.3%)
 - 5 (36.6%)
 - PMTCT programme M&E
 - 1 (2.4%)
 - 2 (12.2%)
 - 3 (29.3%)
 - 4 (36.6%)
 - 5 (19.5%)

10. Are country stakeholders involved in PMTCT aware that commodities were procured with funds from UNITAID? Please select from the options below:

Government partners (e.g. MOH, NAC)

None (0%)

Some (31.7%)

All (68.3%)

Implementing partners

None (0%)

Some (57.1%)

All (42.9%)

• Supply chain partners

None (0%)

Some (28.2%)

All (71.8%)

 Other agencies and organisations working on PMTCT (e.g. Global Fund, bilateral donors, international and domestic NGOs)

None (0%)

Some (48.8%)

All (51.2%)

Health workers

None (19.5%)

Some (65.9%)

All (14.6%)

Beneficiaries

None (47.5%)

Some (50%)

All (2.5%)

11. Has UNICEF provided technical support for PMTCT commodity procurement and supply chain management and service delivery?

- Yes (95.2%)
- No (4.8%)

If No, please go directly to question 13.

12. If Yes, please select all that apply from the options below:

- Technical guidance (100% of respondents)
- Training and capacity building for service delivery (77.5% of respondents)
- Assessment of commodity procurement and supply chain management systems (67.5% of respondents)
- Development of PMTCT operational plans (92.5% of respondents)
- PMTCT M&E (85% of respondents)
- Other (please explain)
 - "Participation à l'élaboration du Plan national de PTME, Plan national d'élimination de la transmission du VIH de la mère à l'enfant, Plans opérationnels de PTME pour chaque district sanitaire"
 - "Developpememnt des plans des approvisionnements operationels nationaux et regionaux"
 - "Running funds"
 - "UNICEF provides upstream support to MOH in terms of TA, printing of stationery and policy guidelines, supporting of coordination meetings and as

- well financial support for support supervision and M&E of the PMTCT program at sub national levels. It also provides both TA, and direct funding to 23 districts to support scale up of the PMTCT services"
- "Technical support for operational research for OVC, couple counselling etc.
 has been provided by UNICEF in coordination with other UN agencies. Capacity
 building on PSM still needs to be strengthened especially for service delivery
 areas."
- "Not much training support has come from UNICEF directly although some has come through partners that they support to implement through funds from donors such as CIDA"
- "PMCT commodities forecasting Gap analysis of PMCT funding with technical support of UNITAID (Noura and team) and use the findings to advocate other donor for PMCT e.g. reprogramming of Phase II GF Rd 9"
- "Compiling reports of the support and progress of the PMTCT implementation"

13. Has WHO provided technical support for PMTCT commodity procurement and supply chain management and service delivery?

- Yes (64.3%)
- No (35.7%)

If No, please go directly to question 15.

14. If Yes, please select all that apply from the options below:

- Technical guidance (96.3% of respondents)
- Training and capacity building for service delivery (25.9% of respondents)
- Assessment of commodity procurement and supply chain management systems (40.7% of respondents)
- Development of PMTCT operational plans (66.7% of respondents)
- PMTCT M&E (51.9% of respondents)
- Other (please explain)
 - "Participation à l'élaboration du Plan national de PTME, Plan national d'élimination de la transmission du VIH de la mère à l'enfant"
 - "Just like UNICEF, WHO provides upstream support to MOH in terms of TA, development and adoption of the WHO policy guidelines into the local context, printing of selected stationery and policy guidelines and meetings and as well financial support for training of trainers among others."
 - "WHO is planning to adopt the three interlinked patient monitoring system (ART, MCH/RH and harm reduction) in close collaboration with NAP and all implementing partners."
 - "1: WHO has been well recognised by partners for PMTCT and by partners for ART. In China, AIDS response has been decentralized down to village/township level. That is why the integration of PMTCT into the general public health but not only limited to Maternal and Child Health is very important. And the service models are different from province to province or from site to site. e.g., PMTCT has been integrated into ART in some of the big city, like Shanghai. This showed that WHO is the organisation plays the important role for the above selected technical support. 2: In addition, WHO has support the operations research on bottlenecks of PMTCT, congenital syphilis criteria and M&E system improvement, and demonstration project of integrated PMTCT implementation models for HIV, HBV and Syphilis."
 - "WHO is a member of the PMTCT Partnership Forum and their officers are members of the various technical sub-committees"

 "Part of PMCT M&E and PMCT guideline revision in line with global guideline 2010."

15. Did UNITAID-funded commodities strengthen the national PMTCT programme?

- Yes (97.6%)
- No (2.4%)

If No, please go directly to question 17.

16. If Yes, please select all of the ways that the PMTCT programme was strengthened:

- Accelerated scale-up of provider-initiated HIV testing and counselling and PMTCT interventions in MCH services (68.3% of respondents)
- Accelerated transition to more efficacious regimens (80.5% of respondents)
- Increased number of women and infants enrolled in PMTCT programme (90.2% of respondents)
- Increased access to early infant diagnosis (90.2% of respondents)
- Measurable decline in the proportion of infants born with HIV (41.5% of respondents)
- Increased access to cotrimoxazole prophylaxis for HIV-positive mothers and HIVexposed infants (80.5% of respondents)
- Increased access to nutrition-related diagnosis, care and treatment of HIV-positive pregnant women and their children (This response is only an option for survey recipients in Malawi, Rwanda, Tanzania and Zambia) (29.3% of respondents)
- Improved commodity forecasting and procurement planning (78% of respondents)
- More consistent supply of PMTCT drugs, diagnostics and other commodities (e.g. reduced lead times, no stock outs) (85.4% of respondents)
- Improved quality of PMTCT drugs, diagnostics and other commodities (70.7% of respondents)
- Other (please explain)
 - "Gratuité des intrants améliore l'accès des couches les plus défavorisées et renforce la notion d'équité."
 - "Commodities procured were used for piloting more efficacious regimen which were later rolled out in the whole country"

17. Has UNITAID funding through UNICEF had any impact on the market in the country for PMTCT diagnostics, drugs and other commodities?

- Yes (61.9%)
- No (38.1%)

If No, please go directly to question 19.

18. If Yes, please select all that apply:

- Price (48% of respondents)
- Quality (80% of respondents)
- Availability (100% of respondents)
- Local manufacture (4% of respondents)
- Other (please explain)

- "Pour réussir la mise à échelle de son Programme PTME, le pays a résolument opté pour la production locale de médicaments ARVs. Une réflexion est en cours et des études de faisabilité devraient être rapidement initiées."
- "Les médicaments et autres intrants stratégiques sont gratuits"
- "La transparence dans la gestion des intrants acquis avec les fonds UNITAID, et le partage de l'information sur les couts à l'acquisition avec le Gouvernement a amélioré le pouvoir de négotiation des prix des structures nationales à l'achat."
- "I do not have sufficient response for this question. The HIV program is fully donor funded, hard to measure in country market impact as it is all free access to all patients."
- "I don't have details on this question but all PMTCT diagnostics, drugs and others commodities used in Rwanda come from outside of the country"
- "Government self-funded procurement system to be set up after the UNITAIDsupported project"

19. Did UNICEF work with partners to plan for transition to other funding (e.g. national government and other donor funding) when UNITAID support for commodity procurement ends?

- Yes (76.2%)
- No (23.8%)

20. Is procurement of commodities for the national PMTCT programme currently fully funded?

- Yes (42.9%)
- No (57.1%)

If No, please explain:

- "Le pays vient de terminer son Plan national pour l'élimination de la transmission du VIH de la mère à l'enfant. Le Plan de financement qui a été élaboré indique un Gap financier assez important. Le pays s'apprête à lancer une large concertation pour la mobilisation des ressources visant à combler le Gap identifié. Dans le même temps, le pays a été jugé éligible aux Fonds de l'Initiative PPTE. Une partie de ces ressources pourrait servir au financement du Gap financier identifié."
- "Quelque aspects ont été financé par: Le budget de l'état: les test de dépistage des femmes enceintes"
- "car pour le moment, c'est le CDC/USAID/PEPFAR qui sont pratiquement les seuls grands bailleurs environ 90% des achats"
- "le plan stratégique et le plan eTME couvrent 5 ans et le finanecment de ces plans n'est pas encore acquis."
- "Le finacment est fonction du plan de passage à echelle de la PTME et maintenant du plan d'élimination de la TME avec l'anayse des goulots d'étranglement. Les besoins sont importants après l'analyse des bottlnecks et les microplannifications des districts et regions."
- "Négotiations en cours pour débloquer les ressources financières du 10 round du Fonds Mondial. -Enveloppe financière allouée pour l'achats des ARV et produits connexes est très et ne pourra pas permettre de couvrir le 1/5 des besoins du pays. Actuellement le pays utilise en PTME la dotation UNITAID recue entre octobre 2011 et fin juillet 2012. - La mise en oeuvre du plan d 'élimination de la PTME vers l'horizon 2015 requiert une mobilisation accrues des ressources."
- "Uganda is planning to transition to OptionB+. This requires significant resources for ARV commodities. The current funding gap is \$25m."

- "Still huge gap to fill. GFATM and PEPFAR contribution are still below the country needs as it concerns commodities procurement."
- "Côte d'Ivoire intends to roll out PMTCT option B in October 2012 and the country still has some budget constraint."
- "There are still gaps in the funding following change of regimen as proposed by WHO and also change in the testing algorithm"
- "There are no enough funds on EID, ARV for HIV-exposed infants in China PMTCT programme. There are also on fund on related Custom service, transportation and distribution of PMTCT recourses from Beijing to each PMTCT site."
- "Not yet because the country is requesting other partners to support this"
- "Government and partners have revised SSF and also done reprogramming of GF activities to secure PMTCT and ART drugs in country. However, current programme will secure up to March 2014."
- "Fully funded by Global Fund up until April 2014, thereafter there is no known funding for commodities."
- "There is currently no direct funding of the PMTCT commodities, except for the buffer stocks that are provided by PEPFAR. The bulk of the PMTCT commodities have often come in as donations from UNITAID. The MOH for sustainability of the PMTCT program as the Major donor (UNITAID) support ends has decided to transition to option B + to partly leverage the funding on ARVs provided by GOU. The First line ARV for adult treatment has been harmonized with the option B + regimen to simplify programming, forecasting and procurement."
- "The gap with phasing out of UNITAID from June to December 2012 is covered by UNICEF. From 2013 onwards, all required commodities will be covered by GF round 9 phase II (2013-2015)."
- "There are some gaps beyond 2012 for ARVs especially ART for treatment eligible HIV positive pregnant women. Gaps also for EID bundles and PCR reagents as well as POC CD4 reagents. Gaps also for management of malnutrition in P&L women and in HIV exposed and HIV infected children"
- "The budget for PMTCT is huge and with suggestion of moving on to option B+ there is need for more money to procure ARVs"
- "ART for mothers is part of the national ART program and this has huge funding gaps in 2012"
- "Discussion was done on the transition. However this involves funds. Secondly the supplies could be available but are also used for the general HIV program resulting into recurrent shortage especially the HIV test kits"
- "Other major funder was Global Fund and so far commitment from GF is based on option A. Now that the country has new PMTCT targets and plans to move from Option A to B/B+ there will be a huge gap in supplies especially ARVs which might not be covered by PEPFAR and GF"

ANNEX 5: UNICEF PROCUREMENT SPREADSHEETS