



BILL & MELINDA GATES foundation

Artemisinin Monotherapy Replacement in the Private Sector in Myanmar:
October 2013 – September 2014



Artemisinin Monotherapy Replacement in the Private Sector in Myanmar: End-of-year Summary of Progress



Submitted 5 January 2015

Population Services International (PSI) – Myanmar



Please refer to the <u>Progress Report Guidelines</u> for instructions on completing this form.

I. Summary Information

GRANT INFORMATION (BMGF)

Project Name Containment of Artemisinin Resistance in Eastern Myanmar				
Organization Name	Population Services International			
Grant ID#	1024757	Found Progra	ation m Officer	Thomas Kanyok
Date Grant Awarded	October 2011	Project End Date		March 2016
Grant Amount	\$7,500,000	Project	Duration	54 months
Report Period From	October 2013	То	Septembe	r 2014
Report Due	December 31 st 2014			
Has this projec	Yes, a no-cost extension was approved, and the a tract was amended to extend the duration until 31 March 2016 March 2016			• •
GRANT INFOR	MATION (DFID)			
Project Name	Replacement of Malaria Monotherapy	Drugs in	the Private	Sector
Organization Name	Population Services International			
Component #/ Purchase Order #	202759-101/40049299	Progra	m Officer	Nan Hom Nwet
Date Grant Awarded	October 2011	Project	End Date	March 2016
Grant Amount	\$17,655,000	Project	Duration	54 months
Report Period From	October 2013	То	Septembe	r 2014
Report Due	December 31 st 2014	Vas	a na aaat ay	stancian was approved and the con
Yes, a no-cost extension was apportune tract was amended to extend the of March 2016 Yes, a no-cost extension was apportune tract was amended to extend the of March 2016				

An additional \$1,000,000 has been awarded by Good Ventures.

PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR

Prefix	Mr.		E-mail Addres	ss <u>bwhittle@p</u>	simyanmar.org	
Surname	Whittle		Phone	00 95 1 375	854-8	
First name	Barry		Fax	00 95 1 527	7 668	
Suffix			Web Site	www.psi.org	g/myanmar	
Title	Country	y Representative				
Mailing Address	No. 16 W	est Shwe Gone Dine 4th Stre	et, Bahan Township, Ya	angon		
Report Prepa	ared by	Reid Moorsmith	D	ate Submitted	31/12/2014	
Phone		+95 0979 631 5713				
E-mail		reid@psi.org				

Geographic Location(s) of Worl		
Country and Region/State	Amount	Donor
Myanmar (80% coverage)	\$7,500,000	BMGF
Myanmar (80% coverage)	\$17,655,000	DFID
Myanmar (80% coverage)	\$1,000,000	Good Ventures
Total Grant Amount	\$26,155,000	

Geographic Area(s) to be Served		
Country/Continent	Amount	Donor
Myanmar (80% coverage)	\$7,500,000	BMGF
Myanmar (80% coverage)	\$17,655,000	DFID
Myanmar (80% coverage)	\$1,000,000	Good Ventures
Total Grant Amount	\$26,155,000	

II. Progress and Results

GENERAL PROGRESS

A priority objective in Myanmar's national plan for artemisinin drug resistance containment (MARC) is the rapid replacement of oral artemisinin monotherapy (oAMT) with a quality-assured artemisinin-based combination therapy (QAACT) in the private sector. This report provides an update on this component of the MARC, implemented by Population Services International (PSI), with support from the UK Department for International Development (UKAID), the Bill & Melinda Gates Foundation (BMGF), and Good Ventures.

Progress made on key activities and achievements during this reporting period include:

- Analysis of the results from RDT pilot study was finalized and shared with MOH through a
 formal report as well as through a dissemination workshop attended by partners and stakeholders. All partners discussed the opportunities and challenges associated with deployment of RDT in the informal private sector, and recommendations for a future action plan
 were also discussed. (2 page summary report attached.) A paper on the RDT pilot study has
 been submitted to Malaria Journal.
- A distribution contract with the second largest artemisinin monotherapy distributor, Poly-Gold, was signed in July 2014. This will help increase market penetration and availability of QAACT in the private sector and reduce monopolistic dominance of the first distributor, AA. A new brand of ACT, Artel+, distributed by PolyGold debuted in August.
- 3. A communications campaign to support the RDT scale up, "Get tested First," has been developed and stands ready for roll out (once MoH approval is obtained).
- 4. RDTs procured and in warehouse, ready to start distribution; all RDT-related promotional/IEC materials developed and procured (such as gloves, sharp boxes etc).
- 5. RDT related training manual developed and Training of Trainers was conducted with field supervisors and product promoters.
- 6. 60 Interpersonal Communicators were recruited and deployed in the field. They have worked on increasing demand for quality ACT, reducing demand for monotherapies, and improving treatment completion adherence. They stand ready to engage in demand creation for malaria RDT testing.

The results to date of the AMTR project strongly suggest that a sustained QAACT price subsidy, when combined with supportive interventions, can bring about rapid changes in antimalarial markets within the Mekong. PSI continues to advocate for approval for mRDT distribution through the same private sector channels that have been receptive to QAACTs. Once achieved, this will enable the project to demonstrate that improved case management in the private sector can and should be an important pillar in the developing regional plan for the elimination of Pf by 2030 in the GMS.

CRITICAL MILESTONES

After the primary objective of the project to rapidly replace the oAMT with the QAACT in the private sector market in Myanmar has been achieved, PSI aims to improve fever case management practices among private sector informal medicine providers, through the scale-up and appropriate use of RDTs. This will reduce drug wastage, decrease the risk of resistance to non-artemisinin partner drugs, and improve treatment of non-malaria-related fevers. To be in line with the project's shifting focus towards appropriate case management through RDT testing, the project logframe has been revised; this has included the modification of output and indicator language as well as revision of

targets. Donor approval for these changes has been requested.

The revised improved outputs are:

- Increased opportunity, ability, and motivation of private providers to effectively test for and appropriately treat Pf malaria.
- Increased opportunity, ability, and motivation of the target population in eastern Myanmar to request an RDT before accepting malaria treatment and to know where such tests are offered.
- Increased opportunity, ability, and motivation of private sector providers to conduct a rapid diagnostic test prior to the appropriate prescription and dispensing of nationally approved, quality assured ACT.

Having completed all agreed project activities and met all critical goals (see summary table below), this report primarily focuses on the results/key achievements in Year 3 (from Oct 2013 to Sept 2014). The milestones that were agreed upon when the AMTR project was approved in Sept 2011 will no longer be relevant after Year 3. Thus, PSI is currently in the process of revising/developing milestones/new activities for NCE period (through March 2016). The revised milestone/workplan will be discussed in the Year 3 annual donor review visit in February 2015.

For each objective, describe the critical milestones for the reporting period and whether they were achieved or delayed	If achieved: what source of evidence do you have to support the result? If delayed: what was the cause of the delay?	
Objective 1: Increased opportunity, ability, and metest for and appropriately treat Pf malaria	notivation of private providers to effectively	
Activity 1.1: Baseline Research		
Milestone 1: Baseline Studies complete by end of Q2	Achieved see section following this table for summary results	
Milestone 2: Target price points agreed by end of Q2	Achieved A second distributor, PolyGold, has been engaged and prices set at the same level of subsidy as the initial distributor	
Activity 1.2: Replace Monotherapy Distribution w	rith Branded ACT Distribution	
Milestone 1: Treatment formulations agreed upon, drugs ordered	Achieved	
Milestone 2: Contract with distributor(s) signed and first ACTs sold by end of Q2	Achieved Contract with a second distributor, PolyGold, was signed during this reporting period	
Activity 1.3: Develop a provider-targeted behavior	r change communications campaign	
Milestone 1: Communication plan developed for health providers by end of Q2, including medical detailing support materials	Achieved	
Milestone 2: Communications campaign launched and approximately 130 "product promoters" deployed and active by Q2	Achieved With the exception of some active conflict areas (notably in Kachin State), a total of 148 field staffs for BCC activities were deployed (including newly recruited IPCs)	
Activity 1.4: Undertake advocacy activities to prevent the renewal of FDA regulation of oAMT		
Milestone 1: New registrations and license renewals of oral monotherapies are stopped by FDA once the replacement of oAMT with ACT is underway	Achieved One particular oAMT has been seen in the market with a June 2013 manufacturing date. The product is being imported from Vietnam. It is not being distributed by AA or PolyGold. PSI has made both the DOH and FDA aware, including information regarding the manufacturer and incountry distributor. It is worth noting that institutional support for the FDA is included in the recently completed Global Fund RAI Concept Note for Myanmar.	
Objective 2: Increased opportunity, ability, and motivation of the target population in eastern Myanmar to request an RDT before accepting malaria treatment and to know where such tests are offered		
Activity 2.1: Develop a user-targeted behavior ch	ange communications campaign	
Milestone 1: Communications plan developed for users by end of Q2	Achieved detailed in 2013 progress report	
Milestone 2: Communication materials produced and tested, campaign placed and aired from Q3	Achieved detailed in 2013 progress report	

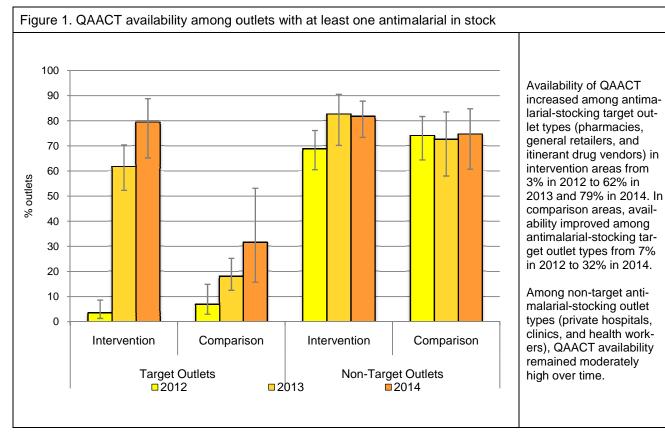
Additional Activities: Product Packaging	
Milestone 1: Packaging of ACT	Achieved samples available upon request
Milestone 2: Packaging insert and overall design	Achieved samples available upon request
Milestone 3: Packaging options designed and market research conducted	Achieved A new brand of QAACT specific to the 2nd distributor PolyGold was developed, and tested for acceptability by the distributor, wholesalers/retailers and end-users.
Additional Activities: Human Resources	
Milestone 1: International Technical Advisor recruitment	Achieved
Milestone 2: Project Manager recruitment	Achieved
Milestone 3: Project staffing restructure and additional recruitment	Achieved Additional research capacity is currently being sourced due to increasing malaria program complexity and workload (costs to be shared across multiple malaria funding streams)
Objective 3: Increased opportunity, ability, and moduct a rapid diagnostic test prior to appropriately proved, quality assured ACT.	
Activity 3.1: Develop plan, and gain no-objection tribution in the private sector (plan to cover BCC structure, protocols for non-Pf treatment, and res	/detailing approach and incentives, pricing
Milestone 1: Pilot RDTs with informal providers in year 1	Achieved Phase 1 pilot successfully conducted. Report submitted.
Milestone 2: Plan agreed to by MoH	<u>Delayed</u> MoH denied approval for RDT scale- up. New leadership at the Ministry has not yet concurred with previous leadership's favorable view of this intervention. Advocacy on ongoing to achieve agreement which is hoped for in early 2015.

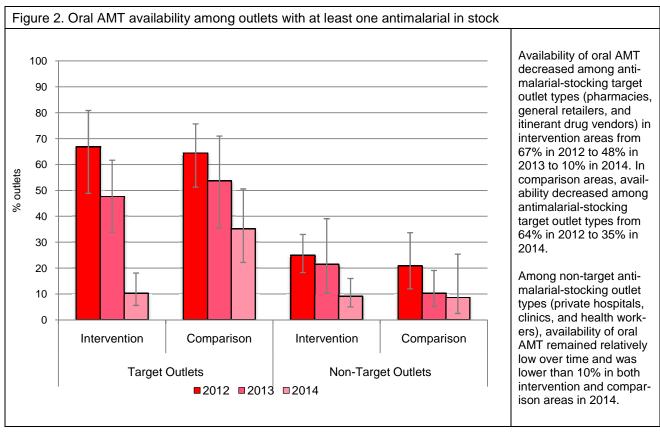
Objective 1: Increased opportunity, ability, and motivation of private providers to effectively test for and appropriately treat Pf malaria.

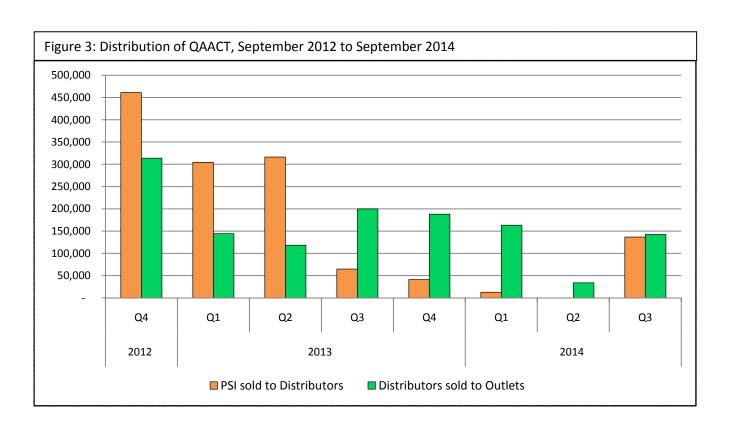
Indicators of success during this project period include:

- 1. PSI has signed a distribution contract with a private pharmaceutical distribution company, PolyGold that has the second largest oAMT market share. A new brand of QAACT specific to PolyGold was developed and distribution beginning in August 2014. PolyGold has a strong market position in northern part of Myanmar, where AA has less coverage.
- 2. As of November 2014, more than 1.3 million QAACTs have been sold to the two licensed distributors and more than 3,000 drug shops located in 247 townships. This total does not include the more than 10,000 informal outlets in rural areas reached by PSI's product promoter team, many of which now also stock QAACTs.
- 3. QAACT availability in intervention area priority outlets (pharmacies, general retailers, and itinerant drug vendors) continued to increase. From 3% at the project outset, 79% of priority

- outlets that stocked any antimalarial stocked QAACTs in 2014. In comparison area outlets, QAACT availability increased more slowly, from 7% to 32%. (see Figure 1)
- 4. Oral Artemisinin Therapy availability continued to decline steeply. From 62% at the outset of the project, oAMT availability in intervention area priority outlets declined to 10% in 2014. It has also declined in comparison area priority outlets, but more slowly, from 64% at project outset to 35% in 2014. (see Figure 2)
- 5. The project continues to meet the price targets for QAACTs. In year 2 90.9% of priority outlets sold Supa Arte 4 for 500 mmk or less, the cost of one typical dose of artemisinin monotherapy. In year 3, 79% of outlets stocking Supa Arte 4 sold it for less than 500 mmk (the benchmark was 70%). The small decrease in the proportion of outlets charging 500 mmk or less for Supa Arte 4 is likely attributable to inflationary pressure on all points of the supply chain beyond the price PSI charges to the distributors.
- 6. Over 10,000 outlets have now been mapped and entered into a GIS database in preparation for real-time, mobile device-derived monitoring of ACT (and RDT) availability across eastern Myanmar using DHIS2 (although future progress on this will, to some extent, be determined by the rate at which telecommunications infrastructure is developed). PSI will introduce mobile data collection, feeding the data directly into DHIS2 in 2-3 pilot townships (where the internet coverage is available and the infrastructure already exits) in quarter 1 of 2015 and will scale up in 2016 aiming to provide malaria caseload data from the private sector integrated into the NMCP database. The system promises to enable critical private sector surveillance for the pre-elimination phase.
- 7. There has been a significant decline in sales/distribution of QAACTs over the past 2 years (2013 and 2014), due mainly to declining malaria prevalence, itself a result of intensive partners' efforts and donor support over the past several years. (see Figure 3) As previously documented, this decline has had major implications on the project in terms of commodity procurement and expired ACT and RDT stocks. It will also have a major impact on commodity projections as well as improved case management using RDTs to avoid drug wastage. Improved case management will be critical to the next phase of the project to minimize resistance pressure and maximize value for money.







Key Milestone Deviation and Course Correction related to Objective 1:

- 1. The target for market share of ACTs vs. oAMTs in priority outlets was 95% vs. 5%. The project improved slightly from year 2 to year 3, (from a ratio of 77:23 to 79:21). Based on the outlet survey and anecdotal information from field visits, PSI has found that the malaria market varies substantially by region. The outlet survey has limitations in its ability to measure differences by region, as it is not powered to do so for reasons of cost, logistics, and other reasons, including political instability and conflict. PSI will conduct an internal review to assess why there has been a high degree of success in some regions and what obstacles remain to bringing other regions that continue to have substantial oAMT sales under the 5% oAMT benchmark.
- 2. The goal for the percentage of target outlet providers who prescribe a "mystery client" with suspected malaria a full course of ACT, including providing instructions for correct use for year 3 was 40%. The project achieved only 10.4% on this goal, according to the mystery client survey. This represents a decline from 29% achieved in the year 2 mystery client survey. There are several potential explanations for the results and the decline: 1) in conditions of rapidly declining malaria prevalence, providers are adjusting by becoming less likely to dispense an antimalarial to a person presenting with fever; 2) antimalarial medicines are becoming slower moving inventory for private sector providers, which makes then less inclined to stock them; and 3) the assumption that a client presenting with malaria-like symptoms has malaria and should be given a QAACT no longer pertains (Sun Quality Health providers had an RDT positive rate of 6% in 2014; this is strong rationale for approval of private sector RDT scale-up).

Objective 2: Increased opportunity, ability, and motivation of the target population in eastern Myanmar to request an RDT before accepting malaria treatment and to know where such tests are offered

In the first phase of the project the primary objective was to rapidly replace oAMT drugs. Toward this end, PSI developed the Padonmar quality seal, an identifier used for all QAACT. All communications campaigns and efforts were centered on this quality seal, aiming to increase the awareness of and demand for QAACTs in the private sector among the target population. However, in response to rapidly declining malaria prevalence, PSI's strategy has evolved to focus on improved case management using malaria RDT testing for all fever cases before dispensing QAACTs. This will not only help improve value for money by increasing the rationalized use of QAACTs, the main cost driver of the project, it will also reduce the likelihood of development of parasite resistance to the partner drug. In this scenario, PSI believes that the original 2 indicators under Output 2 are no longer relevant, and has thus requested to remove and replace them with the RDT-related indicators: knowing that a person with fever should demand/receive an RDT; and knowing where to go for RDT testing. It is important to note that the RDT scale-up plan is dependent on MOH approval, which is still pending, and that PSI will set the targets only after obtaining the approval. Given this delay, the following are summarized indicators of success and key activities carried out during this project period:

- In order to address lower than expected performance to date against the original indicators, PSI has revised its BCC strategy, including deployment of IPC teams using locally relevant dialects (60 additional IPC workers recruited, trained, and deployed in the field), adding four additional ethnic languages to radio spots aired across five stations, and improving TV spots.
- 2. The round two household survey suggests that suspected malaria cases are now more likely to receive QAACT (61%); receive a full course of QAACT (77%); and complete a full course of QAACT (35%). The baseline percentage for all three of these indicators being zero. With only 5 RDT-positive cases in the sample in the year 3 survey, there aren't enough cases to meaningfully report on these indicators. The rapid decline in fever incidence (and therefore sample size) has undermined the power of the analysis for these indicators. Thus, PSI requested to remove these indicators and replace them with the following:
 - a. % target population with fever in the last two weeks who received a diagnostic test for malaria (within 24 hours of the onset of fever).
 - b. % target population with fever in the last two weeks who received a diagnostic test for malaria and who did not receive any antimalarial treatment if the test showed negative.

This will be discussed during the next annual review visit in February 2014.

3. A phase two communications campaign to encourage rapid diagnostic testing before treatment was developed, and is now ready to launch, pending MOH approval. PSI plans to carry out intensive advocacy meetings with MOH with support from the donors for RDT approval, and anticipates receiving approval in quarter 1 of 2015. Despite the delay in approval for RDT scale-up in the private sector, RDT stocking rates across all outlets has increased slightly compared with the previous year among the priority outlets in the intervention area (from 5.2% to 9.6%). This largely mirrors the increase in the comparison area (from 5.6% to 12.1%). The slow growth of RDTs shows readiness to adopt but also a strong need for push-factor support through the supply chain and demand creation to realize comprehensive growth as has been the case with QAACTs over the first two years of AMTR support.

Output 3: Increased opportunity, ability, and motivation of private sector providers to conduct a RDT prior to the appropriate prescription and dispensing of nationally approved, QAACTs

Under this output, PSI is expected to increase the availability and correct use of RDTs in the private sector. This includes ensuring that all patients receive a positive test for malaria before purchasing QAACTs in the private sector. This will help to avoid inappropriate treatment of non-malaria fevers, reduce ACT drug wastage, and reduce the threat of resistance emerging to non-artemisinin partner drugs. There is an end-of-project coverage and correct usage target of 18% (among target outlets).

Achievements and indicators of success for this reporting period include:

- RDT phase one study implemented and the results were widely disseminated through a
 workshop to all partners including MOH. The results suggested that the demand for, and
 appropriate use of, RDTs among informal providers can indeed be increased significantly
 with the appropriate demand drivers deployed.
- 2. The study demonstrated that introduction of RDTs in the informal sector in Myanmar is feasible, and resulted in increased RDT use in the community and improved clinical diagnostic practices. Results also indicate that education and counseling of providers led to the largest increases in RDT use, and greatest likelihood that proper treatment would follow RDT results. Monetary incentives for providers had a nearly equivalent effect on RDT volume, and a positive, but lower, effect on quality. Both interventions were cost-effective, according to WHO standards. (full report attached).
- 3. The benefits and threats associated with RDT deployment in the private sector were discussed by all partners and all partners recommended RDT scale-up as a critical component for resistance containment as well as for malaria elimination. The summary report from the RDT dissemination workshop was submitted to MOH.
- 4. A communications campaign targeting to both providers and end-users was developed. All promotional and IEC materials have been developed, tested, and procured, and are ready to be launched once the RDT scale-up is approved by MOH.
- 5. Initial discussions have begun with the national distributor regarding the pricing and distribution of RDTs, and the distributor has agreed to work with PSI on this.
- A training manual for RDT testing has been developed, and PSI plans to roll out TOT training to all provider BCC team (product promoters) in Quarter 1 of 2015, and training to informal providers in Quarter 2.

UPDATED APPENDIX A: RESULTS AND CRITICAL MILESTONES TABLE

A critical milestones table has not been attached as all milestones have now been achieved. It is suggested that a new milestones table/workplan be negotiated during the next end-of-year annual review visit (February 2015), which takes into account the results of the RDT pilot, budget remaining, no-cost extension discussions, and technical updates related to epidemiology.

An updated logframe is attached with the latest data from the household, outlet and mystery client surveys. Note, the household survey results and methodology will need to be discussed in detail at the next review visit. A general decrease in malaria transmission is driving a related reduction in fever prevalence and antimalarial demand at household level, with implications for survey study design and scope.

OTHER RELEVANT UPDATES

Context and Rationale

The two major shifts in context relevant to the AMTR project that have emerged in year 3 of the project are: 1) the steep slope of declining malaria prevalence; and 2) the central role now played by the elimination by 2030 of Pf in GMS.

The decline in malaria prevalence in the region places much greater emphasis on improved case management, which the project has already made progress on but which is dependent on MoH approval for RDT scale-up to reach its full promise.

The GMS malaria elimination agenda presents an opportunity for full engagement of the private sector in improved case management, delivering data from the private sector to NMCP, and, crucially, real-time monitoring and surveillance in the pre-elimination and elimination phases. PSI's plan to use mobile data collection and DHIS2 to be able to link directly with the public health data system can be a major asset during these phases. PSI is also poised to play an expanded role across the GMS in antimalarial market monitoring through ACTwatch, as well as K13 mapping in partnership with the University of Maryland, Baltimore and the Department of Medical Research, to better understand pattern of drug resistance in Myanmar. Aligned with the next NMCP strategy (2016-2020) and the GMS elimination strategy, PSI, supported by BMGF, is preparing to pilot different intervention models that will better respond to pre-elimination conditions wherein cases will be rarer, harder to reach, and concentrated in high-risk populations.

Challenges, Threats and Opportunities

The central immediate threats to AMTR are: 1) PSI's ability to scale up RDT distribution in the private sector, which is reliant on MOH approval; 2) Supply chain management under conditions of declining malaria prevalence; 3) leadership changes within MoH, and 4) the potential for political unrest surrounding the planned elections in late 2015.

Receiving approval for RDT scale-up will largely determine the value for money of the project, and will also have implications on sustainability. PSI is currently considering a number of options/strategies for sustainability of the project beyond 2016, including requesting an additional twelve month no-cost extension and seeking additional funding under the Pf elimination agenda to further improve case management and surveillance in the private sector. PSI proposes this to be discussed in the February 2015 donor review visit.

As referenced in the Montrose Assessment, commodity and supply chain management have been major challenges for the AMTR project. PSI continues to strive to maintain a balance between the risk of drug expiry and the risk of drug stock out. A detailed description of supply chain issues follows:

One of the primary objectives of the project was the rapid replacement of monotherapy with QAACTs, and to achieve this the project had to ensure no stock outs would be experienced that might allow monotherapies to get a foothold back into any markets where they might have been replaced. This objective has been substantially achieved, with QAACT availability in outlets that stock antimalarials increasing from 3% to 79% in intervention areas.

However, product expiry has been a major challenge in this project to date, for two main reasons. The first is that both QAACT and RDTs have a particularly short shelf life of just 2 years (compared for example, to other products that PSI has historic experience distributing, including oral contraceptives (5 years), condoms (4 years); ORS (3 years); and amoxicillin (2 1/2 years)), narrowing the

window of distribution to approximately 18 months and making accurate forecasting critical. The second challenge has been the difficulty in making these demand forecasts with the accuracy needed. They have been made based on the best available data, which has been incomplete and did not anticipate the rapid changes in epidemiology. These sources included: national data on malaria; complicated assumptions around the past sales of monotherapy; the degree to which informal vendors have historically cut up individual monotherapy blister treatments into multiple treatments for multiple customers; and the rapid sales of QAACT when they were initially introduced to the market. All these assumptions were shared with DFID at the outset of the project, and approved prior to contract signature.

Specifically for QAACTs: Procurement supply chains have been relatively long, with suppliers not willing to enter into longer term contracts given the relatively small volumes PSI has been procuring (volumes are small relative to some large purchases in African countries where malaria prevalence is much higher), and a competitive tender following PSI and donor rules was launched for each of the three QAACT procurements to date.

During the initial burst of interest by the private sector that absorbed 60% of the initial batch ordered within the first nine months of product launch, a second procurement was rapidly entered into. These early orders turned out to be sufficient to fill the supply chain for the coming 24 months (beyond the expiry period of the first batch ordered), indicating a significant over-estimation by the private sector in the face of an unexpected decline in prevalence. PSI had originally surmised that the supply chain filling effect would be relatively low due to the fact that the new product would gradually replace the well-stocked monotherapies in the market, and thus the early sales numbers would relatively closely reflect the longer term regular demand levels, rather than reflect the early burst that it turned out to be.

Specifically for RDTs: In agreement with DFID, PSI began the procurement process for RDTs in anticipation of approval for scale up, with technical support from NMCP and informal indications of support from relevant figures at the MoH. PSI conducted the procurement in parallel with the pilot research to confirm which intervention model would be most successful. This was done to offset the project delays from earlier stages (waiting for overall project approval from the MoH), enabling the project timing to get back on track. Instead, likely due to a change in personnel at the top of MoH in mid-2014, the approval for scaling up RDTs under the AMTR project was denied, despite a comprehensive and well-researched dossier being presented. Efforts for RDT approval are ongoing.

When compounded, these factors led to significant quantities of the two early QAACT procurements and the initial RDT procurement remaining beyond their expiry dates. Subsequent orders from suppliers have been significantly reduced to ensure that they will match factual demand and minimize the risk of both expiry and stock out.

PSI will also develop a "revised theory of change," incorporating the changing epidemiology, public sector scale-up, and other factors, also to be discussed during donor review visit in February 2015.

Conclusion

All critical milestones for this project have now been achieved and results to date suggest that a sustained QAACT price subsidy, when combined with supportive interventions, can bring about rapid changes in antimalarial markets in Myanmar and more broadly across the Greater Mekong Subregion. A major challenge that remains is testing the degree to which the formal and informal private sector can contribute to improved national case management and surveillance through utilization of RDTs and thus play an important role in *P.falciparum* elimination efforts.

III. Plans for the Next Reporting Period

For the next reporting period (October 2014 to March 2016), PSI anticipates implementing the following key activities:

- 1. Internal assessment of variability in oAMT elimination success and targeted adjustment of ongoing efforts for remaining pockets of higher oAMT distribution (output indicator 1.5).
- 2. Internal assessment of drivers and barriers of treatment-seeking and dispensing behavior to: a) improve BCC efforts to increase client demand for diagnostic testing and QAACT use where warranted; and b) to improve provider BCC efforts to improve case management (output indicators 1.6 and 1.7).
- 3. Advocacy meeting and resubmission of case for RDT scale up to MoH, and attainment of RDT scale-up approval.
- 4. Signed contract with distributor and RDT distribution started.
- 5. Training in RDT testing for distributor sales team, and to approximately 5,000 informal private outlets/providers (through PSI's product promoters).
- 6. National roll-out of a communications campaign with the message, "Get Tested First," comprising both a provider and consumer component.
- 7. Routine, monthly data collection feeding into a GIS-linked DHIS2 database, enabling real-time data analysis and associated adjustment of project strategy as necessary.
- 8. Develop and discuss the project sustainability plan beyond 2016 with donors.

IV. Financial Update for the Reporting Period

BUDGET NARRATIVE - Reports previously provided under separate cover.

Sub-grantees and Subcontractors

Report all amounts in U.S. dollars.

Organization Name	Location (city, country)	Total contracted amount	Actual disbursement for this reporting period

Other Sources of Project Support

Report all amounts in U.S. dollars.

Donor	Amount	Received or Potential
Bill & Melinda Gates Foundation	\$7,500,000	Received
DFID	\$17,655,000	Received
Good Ventures	\$1,000,000	Received

Description of in-kind support, if any: This project is jointly funded by the Bill & Melinda Gates Foundation, the United Kingdom's Department for International Development (DFID) and Good Ventures Foundation.

V. Optional Attachments

CLINICAL STUDIES AND REGULATED RESEARCH QUESTIONS

Question	Yes or No
Will the project involve a clinical trial ¹ ?	No
According to the definition provided, what phase(s) will the projectinclude (Phase I, II, III, or IV)?	Phase
Does your project involve research using human subjects ² and/or vertebrate animals?	No
Does your project involve the use of recombinant DNA?	No
Does your project involve the use of biohazards or genetically modified organisms or plants?	No
Will the project involve the use of pathogens/toxins identified as select agents ³ by U.S. law?	No
1 clinical trials	

² human subjects

http://www.selectagents.gov/Select Agents and Toxins List.html ³ select agents

If you answered "yes" to <u>any</u> of the questions above, you must complete the <u>Clinical Studies</u> and <u>Regulated Research Assurances Attachment</u> and submit it along with your progress report.

TECHNOLOGY AND INFORMATION MANAGEMENT QUESTIONS

Please provide a response to the following questions using the definition of terms provided below. If you have submitted an annual report previously and nothing has changed from your previous submission, please indicate "no change".

Question	Yes/No/No Change
Do any Third Parties have Rights to Background Technology ?	No
Do any Third Parties have Rights in Project Technology ⁴ ?	No
Have you filed any copyright registrations for or patent applications claiming any Project Technology?	No

¹**Third Parties**: All individuals, organizations or companies that have not executed a foundation approved collaboration agreement associate with the project.

If you answered "yes" to <u>any</u> of the questions above, you must complete the <u>Technology and Information</u> <u>Management Attachment</u> and submit it along with your progress report.

Privacy Notice

This document is subject to the Gatesfoundation.org Privacy policy and Terms of Use.

tion agreement associate with the project.

Rights: (i) Any interest in patents, patent applications and copyrights (e.g. license, ownership, option, security interest and (ii) the rights to use any technologies, information, data or materials.

Background Technology: All technologies and materials, and all associated Rights, used as part of your project that were created prior to or outside of the project.

⁴Project Technology: All technologies and materials created, conceived or reduced to practice as part of your project and all associated Rights.