DFID Department for International Development

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Containment of Artemisinin Resistance in Eastern Myanmar

Report 4

March 2013 – September 2013

psi

Healthy lives. Measurable results.

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

Submitted 31st December 2013

Population Services International (PSI) – Myanmar

Please refer to the Progress Report Guidelines 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 **Foundation Program Officer** Thomas Kanyok

Date Grant Awarded October 2011 **Project End Date** October 2014

Grant Amount $7,500,000 **Project Duration** 36 months

Report Period From *March 2013* **To** *September 2013*

Report Due *December 31st 2013*

Has this project been granted a no-cost extension? *No (but a NCE has been informally requested)*

GRANT INFORMATION (DFID)

Project Name Replacement of Malaria Monotherapy Drugs in the Private Sector

Organization Name Population Services International

Component #/ Purchase Order # 202759-101/40049299 **Program Officer** NanHom Nwet

Date Grant Awarded October 2011 **Project End Date** October 2014

Grant Amount $17,655,000 **Project Duration** 36 months

Report Period From *March 2013* **To** *September 2013*

Report Due *December 31st 2013*

Has this project been granted a no-cost extension? *No (but a NCE has been informally requested)*

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

PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR

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Geographic Location(s) of Work		
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.

Despite initial start-up delays, significant progress has now been made, confirmed in this reporting period by the second of three nationally representative outlet surveys. Moreover, the observed changes in the relative availability and market share of QAACT versus oAMT is most noticeable among pharmacies, general retail stores and itinerant drug providers; the outlets deemed most critical to the project's success.

In addition to these encouraging findings, the phase one pilot for Rapid Diagnostic Test (RDT) scale up has been implemented and data collected from six townships during this period. When the analysis is finalized, the results will feed into discussions with the Ministry of Health in Q1 of 2014 and determine the strategy for nationwide scale up. This globally relevant data will be presented in the September 2013 – March 2014 report, prior to publication.

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 within the Mekong. In fact, as a result of these data, there is interest among the donor community to geographically expand these surveys to better compare antimalarial markets across the Asia-Pacific region (in both public and private sectors). This would help determine whether or not similar price subsidy interventions are needed elsewhere to mitigate the threat posed by oAMT.

Critical Milestones

The primary aim of the project is to rapidly deliver significant quantities of subsidized QAACTs at national scale, displacing the once prevalent oAMT. With this achieved, the secondary aim is to improve fever case management practices among informal private sector medicine providers, through the scale up, and appropriate use of, RDTs (once drivers to improve demand are identified). The secondary aim should reduce drug wastage, minimize the risk of resistance emerging to non-artemisinin partner drugs, and improve treatment of non-malaria related fevers.

Specific outputs:

- Increased opportunity, ability and motivation of private sector providers to effectively prescribe and dispense nationally approved QAACTs.
- Increased opportunity, ability and motivation of the target population in eastern Myanmar to promptly and effectively treat suspected malaria with a nationally approved QAACT.

Due to the fact that all agreed activities and critical milestones have now been achieved (see summary table below), this report primarilyy focuses on results following 12 months of ACT supply to the initial distributor (AA Medical Products Ltd).

For each objective, describe the critical milestones for the reporting period and whether they were achieved or delayed	If achieved: What source of evidence[2] do you have to support the result? If delayed: What was the cause of delay?
Objective 1: Increased opportunity, ability, and motivation of private sector providers to effectively prescribe and dispense nationally approved, quality assured ACT	
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**, as detailed in the last report. Note, a second distributor (Polygold) is now being engaged and will enjoy the same level of subsidy from PSI.
Activity 1.2: Replace Monotherapy Distribution with Branded ACT Distribution	
Milestone 1: Treatment formulations agreed, drugs ordered	**Achieved**.
Milestone 2: Contract with distributor(s) signed and first ACTs sold by end of Q2	**Achieved**.Contract for the inclusion of a second distributor (PolyGold) to be signed in the next reporting period.
Activity 1.3: Develop a provider-targeted behavior change communications campaign	
Milestone 1: Communication plan developed for health providers by end of Q2, including medical detailing support materials	**Achieved** (described in detail in first report, along with example materials).
Milestone 2: Communications campaign launched and approximately 130 'product promoters' deployed and active in Q3	**Achieved**. With the exception of some areas still affected by conflict, e.g Kachin State, 75 product promoters deployed. IEC campaign launched as reported previously.
Activity 1.4: Undertake advocacy activities to prevent the renewal of FDA registration of oAMT	
Milestone 1: New registrations and license renewals of oral monotherapies are stopped by FDA once the replacement of oAMT with ACT is under way	**Achieved.** However, 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 in-country distributor. It is worth noting that institutional support for the FDA has been successfully included in the recent Global Fund RAI Concept Note for Myanmar.
Objective 2: Increased opportunity, ability, and motivation of the target population in eastern Myanmarto promptly and effectively treat suspected malaria with a nationally approved and quality assured ACT.	
Activity 2.1: Develop a user-targeted behavior change communications campaign	
Milestone 1: Communication plan developed for users by end of Q2	**Achieved.** Detailed in first report.
Milestone 2: Communication materials produced and tested, campaign placed and aired from Q3	**Achieved.** Detailed in first report (including examples of materials).
Additional Activities: Product Packaging	
Milestone 1: Packaging of ACT	**Achieved.**
Milestone 2: Packaging insert and design	**Achieved.** Also, new packaging developed, tested and produced for second distributor's QAACT
Milestone 3: Packaging options and research	**Achieved.**
Additional Activities: Human resources	
Milestone 1: International Technical Advisor recruitment	**Achieved.**
Milestone 2: Project Manager recruitment	**Achieved.**
Milestone 3: Project staffing structure and	**Achieved.** Although, additional research capacity

additional recruitment	is now being sourced due to increasing malaria program complexity and workload (costs to be shared across different funding streams for malaria).
Objective 3: Increased opportunity, ability, and motivation of private sector providers to conduct a rapiddiagnostic test prior to appropriately prescribing and dispensing nationally approved, quality assuredACT.	
Activity 3.1: Develop plan, and gain no-objection from policy makers (plan to cover BCC/detailing approach and incentives, pricing structure, protocols for non-Pf treatment, response to negative tests etc.)	
Milestone 1: Pilot of RDTs with informal providers under way in year 1	**Achieved.** Phase 1 pilot conducted. Data currently being analyzed (conclusions to be reported in next period).
Milestone 2: Plan agreed with MoH	**Achieved.** Phase two scale-up-related policy decisions to be made in Q1 of 2014

Output 1:Increased opportunity, ability and motivation of private sector providers to effectively prescribe and dispense nationally approved, QAACTs.

Indicators of success during this project period include:

1. Nearly 1.2 million courses of ACT (1,187,993) have been purchased from PSI by AA Medical Products Ltd (as of November 2013). This indicates that the observed reduction in AA's market share following the ban on Artesunate oAMT importation in early 2012 was temporary (as hoped).

2. Round two outlet data confirms that the availability of QAACTs increased exponentially across private sector outlets (27% to 63%) after only nine months of supply (the time between the first sales to AA in September 2012 and the second outlet survey in June/July 2013). The increase in availability is most significant among priority outlet categories (pharmacies, itinerant drug vendors and general retail stores), from 4.5% to 50.4%.

3. Outlet data suggests the Food & Drug Administration's (FDA) ban on oAMT importation (initially Artesunate and later Artemether) is having some effect, with reduced availability of oAMT observed nationwide (51% down to 36%).

4. Although oAMT is still available in many places, it is extremely encouraging to note that the demand for oAMT (volumes sold during the week before the survey) has dropped sharply. Relative to oAMT, the market share for QAACT has increased from 3% to 73% among the priority outlet types (those shown previously to account for the majority of national oAMT sales).

5. Regarding price, 94% of target outlets are selling QAACT at a price less than or equal to the cost of a typical dose of the most common artemisinin monotherapy at baseline (exceeding our year two target by 24%).

6. Over 10,000 outlets are now 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).

Output 2: Increased opportunity, ability and motivation of the target population in eastern Myanmar to promptly and effectively treat suspected malaria with a nationally approved and QAACTs

Under this output PSI is expected to increase the awareness of and demand for QAACTs in the private sector among the target population. Indicators of success during this project period include:

1. Padonmar (lotus) QAACT quality seal deployed at scale by the main distributors of QAACT (in both public and private sectors). Related to this deployment, a frequently asked questions (FAQs) document and general guidance for the use of the Padonmar seal by interested parties was disseminated through the DoH, FDA, WHO and INGOs.

2. Mass media and interpersonal communications campaigns continue to create demand for QAACTs through the recognition of the Padonmar seal. Although not as significant a change as we had hoped, the percentage of the target population who associate the Padonmar quality seal as an identifier for the most effective malaria treatment has increased from less than 1% to nearly 15% during this period. This lower than anticipated result may be the result of two factors: 1. As overall incidence of fevers has decreased, so has treatment seeking behavior and therefore awareness/sensitivity to the communications and the Pandomar seal; 2. Existing channels for communication may not be effectively reaching more remote and rural ethnic groups. Better geo targeting of BCC interventions to reach these populations may be needed. These are potentially also the reason for a less than anticipated increase in percentage of people who can identify a local outlet where a nationally approved and quality assured first-line ACT can be purchased (increase from 1.2% at baseline to 2.4%).

3. 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. Although, rapid declines in fever incidence (and therefore sample size) now undermine the power of the analysis to a large extent. This will be discussed during the next annual review field visit in February 2014.

4. A phase two communications campaign to encourage rapid diagnostic testing before treatment is now being prepared for execution (assuming RDT phase two scale-up moves ahead in 2014). Meanwhile, RDT stocking rates across all outlets has improved (from 18% to 28%).

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). Distribution started in May 2013.

Achievements and indicators of success for this reporting period include:

1. RDT phase one study implemented following approval by both PSI's Ethical Review Board and the MoH (DoH).

2. RDTs deployed across six townships, with a significant number being successfully retrieved for analysis and quality assurance.

3. *Preliminary* analysis of the data suggests that demand for, and appropriate use of, RDTs among informal providers can indeed be increased significantly with the appropriate demand drivers deployed (to be reported on in early 2014).

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 2014), 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

In 2014, PSI anticipates further positive changes in the antimalarial market and these will be quantitatively measured during a third round of outlet and household surveys before the end of the year. During this period, critical questions will need to be addressed related to the scale up of appropriate case management (as opposed to QAACT). RDT positivity rates will undoubtedly continue to decline. Against this shifting epidemiological landscape, it will be imperative that the private sector is supported in adopting diagnostic tools to ameliorate the threat of drug wastage, inappropriate fever management and, critically in the context of containment, drug resistance emerging to partner drugs used in combination with artemisinin.

During the next reporting period PSI will disseminate the results of the RDT (Phase I) scale up effort that is designed to identify the most cost-effective way to drive national scale demand for RDTs among private providers. Based on this evidence, the MOH will then determine how PSI implements Phase II of the scale up effort. The combination of decreasing RDT positivity rates and the implementation of an RDT scale up operation will determine the relative ratio of QAACT versus RDTs required in the next few years. Procurements will need to remain relatively small and frequent to mitigate the risk of stock-outs or drug expiration. As far as possible, the distribution of RDTs will mirror that of QAACT to date, utilizing the same distribution networks and supply hubs (as opposed to creating costly and unsustainable NGO driven supply systems with limited reach).

Challenges, Threats and Opportunities

The most pressing threat is sustainability of funding beyond September 2014 (unless a no cost extension is granted through 2015). Although additional resources are now being made available in the Mekong for resistance containment through mechanisms like the Global Fund for AIDS, Tuberculosis and Malaria (GFATM), it is clear that sufficient funding will not be made available to subsidize private sector ACTs/RDTs in Myanmar beyond the current contract period

through this mechanism (GFATM regional support for this initiative is currently limited to six months in 2016).

Considering ongoing conflict in certain areas and widespread internal and cross-border migration for work, even if the public sector is able to make significant strides in the medium term, the private sector will likely remain a vital part of the national health system for the foreseeable future (particularly in the context of malaria elimination). In this regard, the results of the RDT pilot are critical. If the research demonstrates that appropriate case management within the private sector can be achieved with certain levels of resources and effort, then the government and donor community will need to decide whether or not to make the investment. In short, fever treatment (and associated reporting/surveillance) in the private sector will increasingly represent both a threat and an opportunity depending on how well it is resourced and managed.

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 within the Mekong. What now remains to be seen is whether or not the informal private sector can contribute to national appropriate case management targets through utililization of RDTs and assist with targeted *P.falciparum* elimination efforts.

III. Plans for the Next Reporting Period

For the next reporting period (September 2013 to March 2014), PSI anticipates implementing the following key activities:

1. Finalization of the RDT pilot research in six townships in eastern Myanmar.
2. Analysis and write-up of the RDT pilot research.
3. Presentation of the RDT pilot results to the Ministry of Health to inform policy dialogue and define strategies for going to scale nationally in 2014.
4. National roll out of a communication campaign with the message, "Get Tested First", with both a provider and consumer component (assuming RDT scale up moves ahead).
5. Routine, monthly data collection feeding into a GIS-linked DHIS2 database, enabling real-time data analysis and associated adjustment of project strategy as necessary.
6. Signing of a contract with a second distributor (Poly Gold) and commencement of sales.
7. Continued collaboration with the Independent Evaluation team, including a Value for Money Assessment.
8. Preparation and submission of a manuscript to a peer-reviewed journal summarising the project results.

IV. Financial Update for the Reporting Period

BUDGET NARRATIVE - See attached reports.

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]? According to the definition provided, what phase(s) will the projectinclude (Phase I, II, III, or IV)?	No 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
[3] select agents

If you answered "yes" to any of the questions above, you must complete the Clinical Studies and Regulated Research Assurances Attachment 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[1]have Rights[2] to Background Technology[3]?	**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.
[2] **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.
[3] **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.
[4] **Project Technology**: All technologies and materials created, conceived or reduced to practice as part of your project and all associated Rights.

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

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