Type of Review: Annual Review

Project Title: Replacement of Malaria Artemisinin Monotherapy drugs in the private sector to support the containment of drug resistant malaria in eastern Burma

Date started: 01 Oct 2011, Date review undertaken: 17- 21 Feb 2014

Introduction and Context

What support is the UK providing?

The UK is providing £11.3 million for a three year project (September 2011-2014) which is being implemented by the international non-governmental organisation Population Services International (PSI) to replace malaria drugs containing only artemisinin (oral artemisinin monotherapies or AMTs) with those containing artemisinin with other effective drugs (artemisinin combination therapies or ACTs) in private markets in Burma. The "Artemisinin Monotherapy Replacement Project" is co-funded by the Bill and Melinda Gates Foundation (Gates Foundation) and Good Ventures. DFID is providing £10.7 million to PSI for project implementation and up £600,000 for independent evaluation and monitoring.

What are the expected results?

The expected impact of the project is to prevent (or at minimum significantly delay) the spread of artemisinin resistant *plasmodium falciparum* malaria parasites within Burma and beyond its borders.

The specific outcome is for sub-standard anti-malarials in the private sector (particularly artesunate monotherapy) to be replaced with government approved and quality assured ACT, and sub-optimal dosing reduced among the target population in eastern Burma.

The outputs delivered by this project include:

- The increased opportunity, ability and motivation of private sector providers to effectively prescribe and dispense nationally approved, quality assured ACTs.
- Increased opportunity, ability and motivation of the target population in Burma to promptly and effectively treat suspected malaria with a nationally approved and quality assured ACTs
- Increased opportunity, ability and motivation of private sector providers to conduct a rapid diagnostic test (RDT) prior to the appropriate prescription and dispensing of nationally approved quality ACTs.

The project logframe[i], attached as annex 1, provides further details of the expected results in Burma.

The expected global benefits are substantial. Mathematical modelling of the impact of resistance if were allowed to spread globally suggests that malaria deaths could increase by 25% globally and economic productivity losses could be over US 4 billion annually.[ii] The Business Case[iii] for the project stated that estimated halting the spread of resistance by four years will avert almost 7.5 million Disability Adjusted Life Years (DALYs) globally.[iv]

What is the context in which UK support is provided?

Context of artemisinin resistant malaria. Artemisinin is a highly effective cure for *Plasmodium Falciparum* malaria. Artemisinin based drugs have helped reduce the global burden of malaria[v], however, this is now threatened by the emergence of malaria parasites that are resistant to artemisinin.

Artemisinin resistant malaria has emerged on the eastern borders of Burma. The country is critical to global efforts to contain resistance, yet the overlap of transmission risk and geopolitical sensitivity makes it a challenging operational context. The malaria burden is far higher than in any other country in South East Asia; there is extensive migration in high transmission areas increasing the spread of resistance; there has been 60 years of civil conflict along some border areas; there has been inadequate investment in malaria control and historically high usage of artemisinin monotherapy.

History of the spread of resistance to previous malaria drugs suggests that spread from Burma to India is a pathway to Africa. Containing malaria drug resistance is time critical. Every year of delaying the spread of resistance westwards may save many thousands of lives and buy time to develop and deploy new antimalarial compounds.

Response to containing artemisinin resistance in Burma. Burma has developed the Myanmar Artemisinin Resistance Containment Framework in 2011, which is in line with the World Health Organisation's Global Plan for Artemisinin Resistance Containment.

Replacement of artemisinin monotherapies with artemisinin combination therapies is a key part of these strategies, and experts agree that this will have one of the biggest and quickest impacts on preventing the development and spread of artemisinin resistance.

The use of artemisinin monotherapies, partial courses and sub-standard drugs produces significant selection pressure on the artemisinin such that artemisinin resistant malaria parasites are selected for and are then able to spread. These practices are known to exist in Burma, in particular as people cannot afford the more expensive complete course of drugs.[vi]

ACTs are more effective than AMTs as the combination of the two drugs protects both components and reduces the risk that resistance will emerge. According to WHO: "A 3-day course of a recommended ACT generally results in rapid clearance of parasites and resolution of symptoms. In addition, the artemisinin component of the combination reduces gametocyte carriage, thus reducing malaria transmission." [vii]

Thus increasing access to timely, quality assured ACTs will improve patient outcomes, limit transmission and reduce the number of people with malaria. This in turn significantly limits the spread of artemisinin resistant parasites.

The role of the private sector in Burma. An estimated 70% of people seek malaria treatment in the private sector, which is largely due to the historical underfunding of the public sector, and difficulties of service delivery in remote, border and conflict affected areas. These remote border areas are the very places which experience high malaria burden and are at the heart of emerging drug resistance.

The private sector outlets consist of private doctors, private health workers, pharmacies, general retail shops, informal providers (also known as itinerant drug vendors). The last three categories are largely unregulated and considered the priority outlets in the project.[viii]

The project design to rapidly replace AMTs with ACTs in the private sector. The donors, DFID, Gates Foundation and Good Ventures, are providing funds to PSI for a subsidy for quality assured ACTs and to manage the project to replace AMTs with ACTs using private sector channels. PSI sells subsidised quality assured ACTs (co-formulated artemether lumefantrine),

branded as Supa-Arte, to a major private drug distributor in Burma, AA Medical Products Ltd, that at the time of project conception accounted for approximately 70% of the market share for anti-malarials. The subsidised ACTs pass down the supply chain, reaching private sector outlets throughout Burma, and effectively squeezes AMTs out of the market due to price competition. PSI is seeking to work with a second distributor, PolyGold, to broaden the distribution channels using the same ACT (co-formulated artemether lumefantrine), but branded as Artel Plus.

The switch of AMTs to ACTs and the correct use of diagnostic testing, are supported by product and behaviour change promotion, which is vital for changing market preferences. This includes the use of product promoters to work with private outlets and national communication campaigns to encourage the public to demand quality ACTs from drug sellers. While the project's coverage is national there is particular emphasis in townships in eastern Burma with indicated or potential high artemisinin resistance.

Since the start of the project the Ministry of Health's Food and Drug Administration has banned the new importation of two artemisinin monotherapies (artesunate and artemether).[ix] This supports the uptake of ACTs. However, AMTs can still be purchased in Burma while existing stocks are used up. The Ministry of Health have produced a national quality seal, known as the Padonmar seal, for all quality assured ACTs, including Supa-Arte, to assist service users identify and demand for quality assured drugs.

Complementary funding to the response of artemisinin resistance. Long-term strengthening of the public sector is also vital for containing artemisinin resistant malaria. This project is complementary to the other funding that DFID, and other donors (such as Australia and the EU) have provided to the Three Diseases Fund for HIV, TB and Malaria (2007 – 2012) and its successor, the Three Millennium Development Goal Fund (2013-2016) to scale up free malaria diagnosis and treatment with an emphasis in the public sector and through NGOs.[xxi]

DFID also provides core funding to the Global Fund for AIDS, TB and Malaria (the Global Fund) which has provided funding for malaria control in Burma, and for the regional response to artemisinin resistant malaria.

Further details of the context and theory of change can be found in the project's Business Case[xii].

Section A: Detailed Output Scoring

Output 1: Increased opportunity, ability and motivation of private sector providers to effectively prescribe and dispense nationally approved, quality assured ACT (QAACT)
Output 1 score and performance description: B (Outputs moderately did not meet expectation)

Progress against expected results:

OUTPUT 1	Output Indicator 1.1		Baseline[10]/Milestone (Y1)	Milestone 1[11] (Y2)
Increased opportunity, ability and motivation of private sector providers to effectively prescribe and dispense nationally approved, quality assured ACT.	% target outlets with nationally approved and quality assured first-line ACT in stock at time of survey [9]	**Planned or baseline**	Priority outlets = 4.47% All outlets = 26.4%	Priority outlets target = 50%; All outlets target = 70%
		Achieved		Priority outlets = 50.4 % All outlets = 62.6%
		Source		
		Source: Baseline Outlet Survey - 2012 Target: Annual Outlet Surveys at 2013 and 2014.		
	Output Indicator 1.2		**Baseline/Milestone (Y1)**	**Milestone 1 (Y2)**
	% target outlets with no reported stock-out of nationally approved and quality assured first-line ACT lasting more than 1 week within the past 3 months (denominator = those outlets that normally stock ACT)	**Planned or baseline**	Priority outlets = 99 % All outlets = 98.16%	Priority outlets target = 100% All outlets target = 100%
		Achieved		Priority outlets = 90.6 % All outlets = 94%
		Source		
		Source: Baseline Outlet Survey - 2012 Target: Annual Outlet Surveys at 2013 and 2014.		
	Output Indicator 1.3		**Baseline[13]/Milestone (Y1)**	**Milestone 1 (Y2)**
	% target outlets selling nationally approved, quality assured ACT at a price less than or equal to the cost of a typical dose of the most common artemisinin monotherapy at baseline [12]	**Planned or baseline**	n/a	Priority outlets target = 70%
		Achieved		Priority outlets = 94 %
		Source		
		Source: Baseline Outlet Survey - 2012 Target: Annual Outlet Surveys at 2013 and 2014.		
	Output Indicator 1.4		**Baseline/Milestone (Y1)**	**Milestone 1 (Y2)**
	% target outlet providers that correctly state the recommended first line ACT treatment for uncomplicated malaria	**Planned or baseline**	Priority outlets = 5.5% All outlets = 19.3%	Priority outlets target = 25% All outlets target = 50%
		Achieved		Priority outlets = 10.1 % All outlets = 25.4%
		Source		
		Source: Baseline Outlet Survey - 2012 Target: Annual Outlet Surveys at 2013 and 2014.		
	Output Indicator 1.5		**Baseline/Milestone (Y1)**	**Milestone 1 (Y2)**
	Relative ratio of volume of ACT to Oral Artemisinin Monotherapy (sold in the past 7 days) 1) quality assured (QA) ACTs; 2) oral artemisinin monotherapies	**Planned or baseline**	For Priority Outlets ACT = 3% Oral Artemisinin Monotherapy = 97% For all outlets ACT (38%) Oral monotherapy (62%)	For Priority Outlets ACT target = 50% Oral Artemisinin Monotherapy target = 50% For all outlets ACT target = 70% Oral monotherapy target = 30%
		Achieved		For Priority Outlets ACT = 73% Oral Artemisinin Monotherapy = 27% For all outlets ACT = 79% Oral monotherapy = 21%
		Source		
		Source: Baseline Outlet Survey - 2012 Target: Annual Outlet Surveys at 2013 and 2014.		
	Output Indicator 1.6		**Milestone (Y1)**	**Milestone 1 (Y2)**
	% target outlet providers who	**Planned or**	NA±	Target = 35%

	prescribe a "mystery client" with suspected malaria a full course of ACT, including providing instructions for correct use.	**baseline**		
		Achieved		29%
		Source		
		Baseline: Baseline mystery client survey 2013. Milestones and Target: Annual mystery client surveys to be cross referenced with household and outlet surveys.		

Summary of Progress

Summary:

Output 1 is scored as B. 4 of the 10 milestones have been met. The remaining 6 milestones have not been met, although 3 of these show 80 to 90% achievement. The milestones met show a rapid and significant change in market share of ACTs to AMTs of 73%: 27% as compared to the baseline of 3%: 97% (output indicator 1.5), and good availability of ACTs at affordable prices in the priority outlets (output indicator 1.3). The milestones not being met reveal that providers lack knowledge in the correct treatment of ACTs (output indicator 1.4) and are not prescribing ACTs sufficiently (output indicator 1.6). The data for the milestones was collected in June and July 2013, and during the review team visit in February 2014 there was some anecdotal evidence for progress against all indicators since that time.

Detail:

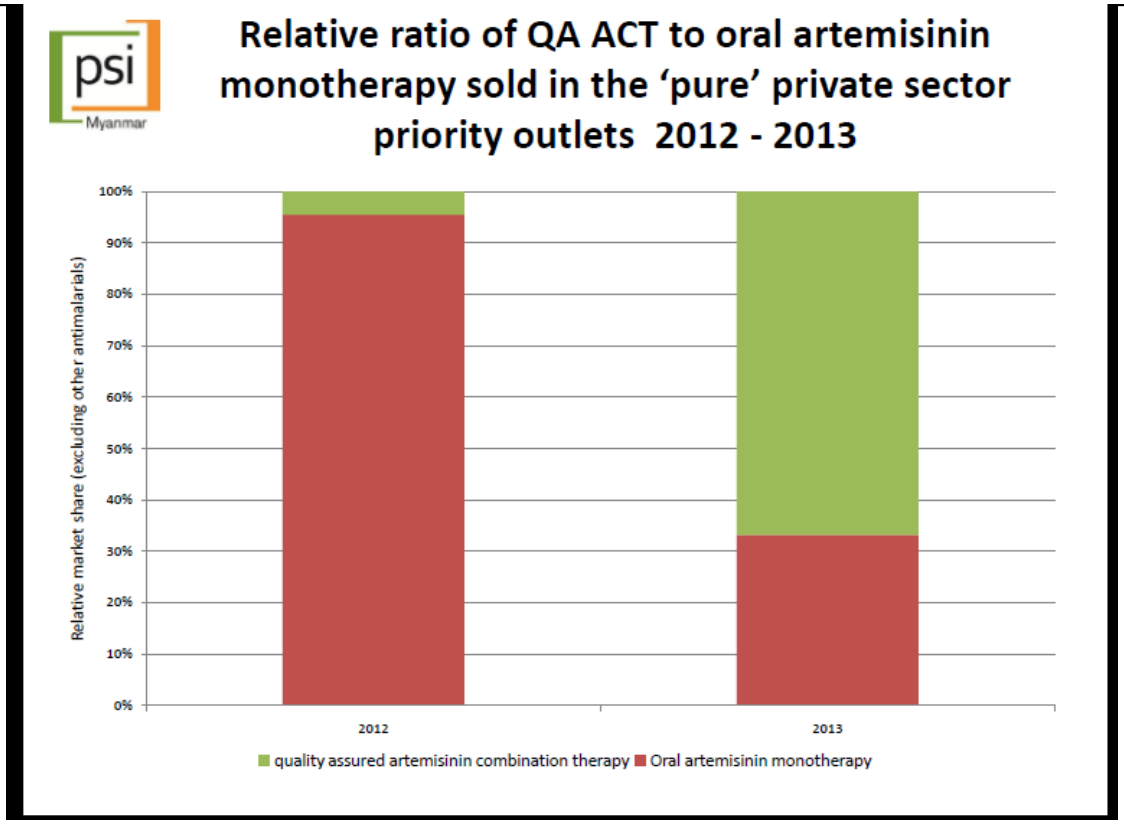
There are five types of private sector outlets, as set out in the context section, of which three - pharmacies/ drug sellers, itinerant drug vendors and general retailers – are considered the priority outlets for the project. Data collected for the outlet survey took place between June and July 2013.

Significant progress has been made on the availability of ACTs, in particular in the priority outlets. The "% target outlets with nationally approved and quality assured first-line ACT in stock at time of survey" (indicator 1.1) in priority outlets was 50.4% (target = 50%) and 62.6% for all outlets (target = 70%).

The Review Team visited 20 private sector outlets, the majority of which were 'priority' outlets. AMT was found in only one of the outlets visited, with the outlet also being well stocked with Supa-Arte1-4. AMT may still available in many places, particularly conflict areas and other difficult-to-reach outlets. However, it is extremely encouraging to note that the demand for AMT (volumes sold during the week before the survey) continues to decline. The outlet survey showed a decrease of oral AMTs from 32.9% to 12.10% in 2012 to 2013.

The market share for quality assured ACT has substantially increased from 3% to 73% (target = 50%) with AMT falling from 97% to 27% (target = 50%). among the priority outlets. These outlets previously accounted for the majority of national AMT sales), informing indicator 1.5, "relative ratio of volume of ACT to Oral Artemisinin Monotherapy (sold in the past 7 days)". For all outlets, the ACT market share is 79% (target = 70%) and oral AMT was 21% (target= 30%). This exceeds expectations and is likely to be even higher given the progress in the last 6 months since the data was collected.

Figure 1. Graph illustrating the relative ratio of ACTs to AMTs in the priority or 'pure' private outlets.



The Outlet Survey found that the "percentage target outlet providers that correctly state the recommended first line ACT treatment for uncomplicated malaria" (indicator 1.4) had not met expectations. Progress had been made on this indicator, however only 10% of priority outlets (target = 25%) and 25% of all outlets (target = 50%). These figures may have increased since the outlet survey, and anecdotal evidence from the Review indicates that this may be the case. Overall, there are concerns over the lack of knowledge on the correct treatment of ACTs by the outlet providers.

Indicator 1.6, "% of target providers who prescribe a "mystery client" with suspected malaria a full course of ACT, including providing instructions for correct use" is slightly lower than expected (29% compared to a target of 35%). Again, progress may have been made since the survey and evidence from the Annual Review visit supports this. All providers that were asked correctly stated that the recommended treatment for uncomplicated malaria was ACT, specifically Supa-arte. All providers said they recommended Supa-Arte due to the price, and more importantly, the effectiveness of the drug. Providers that were asked correctly stated the importance of completing the full course. However, there remain concerns that providers are not prescribing ACTs correctly.

For indicator 1.2, "% target outlets with no reported stock-out of nationally approved and quality assured first-line ACT lasting more than 1 week within the past 3 months," the Review team found strong progress towards this target. 19 of the 20 outlets were well stocked with Supa-Arte1-4. The Outlet Survey 2013 found 91% of priority outlets (target = 100%) and 94% of all outlets (target = 100%) reporting no-stock outs. There are some concerns regarding stock outs of ACTs, however, it should be noted that the number of outlets stocking ACTs at Milestone 1 (Year 2) are far greater than at the Baseline/ Milestone (Year 1), reflecting an increase in the new number of outlets selling ACTs since the start of the project.

As of December 2013, nearly 1.3 million courses of quality-assured ACT, Supa-arte, have been purchased from PSI by AA Medical Products Ltd. The subsidy was seen to be passed down to the patient in the areas visited during the review visit. Indicator 1.3, "% target outlets selling nationally approved, quality assured ACT at a price less than or equal to the cost of a typical dose of the most common artemisinin monotherapy at baseline," 94% of target outlets (target = 70%) are selling quality assured ACT at a price less than or equal to the cost of a typical dose of the most common artemisinin monotherapy at baseline (exceeding the year two target by 24%). The Review team consistently found

prices of Supa-Arte to be 300 – 500 Kyats per packet (24 tablets for the adult dose). Supa Arte retail price continue to match incomplete AMT dose price, which ranged was from 250 -500 per tablet.

Challenges:
The Review team found the expiry date on Supa-Arte products was April 2014 (with some at March 2014). A well-managed and monitored switch of drugs with short expiry dates to those with longer expiry dates, within all outlets, in particular those at the end of the supply chain will be critical over the coming months to reduce the possibility of stock-outs. Initial explanations for unused stocks of drugs are that the malaria burden has decreased faster than expected, and hence the reduced need for the drugs. In addition, forecasting for drug volumes at the start of the project was highly challenging due to the severe paucity of data within Burma.

Recommendations:

- Providers' knowledge and use of ACTs. PSI to intensify strategies on improving the knowledge of service providers on the use of ACTs and on prescribing the drugs correctly to service users. Action: PSI by May 2014.

- Expiry date of drugs.
  a) PSI to stop providing drugs with expiry dates of March and April 2014 to AA. Action: PSI with immediate effect (done.)
  b) The risks of expired drugs to artemisinin resistance and case management should be added to the risk matrix. Action: PSI by April 2014.
  c) PSI to provide the value of the expired drugs and a background note on the reasons for having unused drugs. Action: PSI by May 2014
  d) PSI to draft standard operating procedures (or equivalent) on managing drug expiry dates, within all outlets, in particular those at the end of the supply chain. PSI to consider the options having expiry dates written in Myanmar language on tertiary packaging and ensure more explanation to distributors on expiry dates and stock management throughout the supply chain. Action: PSI by May 2014

Impact Weighting (%): 40%

Revised since last Annual Review? Yes
The impact weighting was changed from 25% to 40% after the last Annual Review, which was agreed between DFID, PSI and other partners to better reflect the percentage for the contribution each is likely to make towards the achievement of the overall outcome.

Risk: High

Revised since last Annual Review? No

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

Output 2 score and performance description: C (Outputs substantially did not meet expectation)

Progress against expected results:

OUTPUT 2	Output Indicator 2.1		Baseline/Milestone (Y1)	Milestone 1 (Y2)
Increased opportunity, ability and motivation of the target population in eastern Myanmar to promptly and effectively treat suspected malaria with a nationally approved and quality assured ACT. [15]	% target population (disaggregated by age and gender) who associate the Padonmar quality seal as an identifier for the most effective malaria treatment	**Planned or baseline**	0.8%	Target = 50%
		Achieved		14.6%
		Source		
		Source: Baseline Household Survey - 2012, HH in 2013. Target: **LQAS in 2014**.		
	Output Indicator 2.2		**Baseline/Milestone (Y1)**	**Milestone 1 (Y2)**
	% target population (disaggregated by age and gender) who can identify a local outlet where a nationally approved and quality assured first-line ACT can be purchased	**Planned or baseline**	1.2%	Target = 50%
		Achieved		2.4%
		Source		
		Source: Baseline Household Survey - 2012, HH in 2013. Target: **LQAS in 2014**.		

Summary of Progress

Summary:
Output 1 is scored as C. This reflects that the two milestones have not been reached. During the visit, a lot of mass promotional material was very visible and the service providers met stated that service users requested Supa Arte. The change in market share at outlets is significant; however, this may be due to price primarily. Overall, there is not enough evidence to suggest that service users are fully aware of the Padonmar quality seal as an identifier for the most effective malaria treatment or that they are aware of the outlets which sell quality ACTs.

Details:
Output 1.1, "% target population (disaggregated by age and gender) who associate the Padonmar quality seal as an identifier for the most effective malaria treatment," has not met expectations. 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, but well below the target (50%).

During the Review, private outlets mentioned the 'Padonmar' (lotus) quality seal. Beneficiaries met during the mid-term review in May 2013 (quest number 4379895) recognised Supa-Arte and the Padonmar seal, which they had heard of through mass media channels, such as the radio and posters. The packaging in Burmese language as effective, and many reported the correct use of Supa-Arte, including completing a full course. However, many stated they still used AMTs and other ACTs. See section 1.3.

The majority of outlets also noted the reasons for recommending Supa Arte were price and effectiveness. All reported the correct use of Supa Arte, including completing the full course. There was no evidence of blister cutting of Supa Arte. Supa Arte promotions were very evident at all points of sale and by the side of many roads.

Output 2.2, "% target population (disaggregated by age and gender) who can identify a local outlet where a nationally approved and quality assured first-line ACT can be purchased," has not met expectations. This has increased by from 1.2% at baseline to 2.4%, well below the target of 50%.

This lower than anticipated result may be the result of several factors. Existing channels of mass communication, such as radios and posters, may not be totally effective, and more inter-personal communication may be required. Tertiary packaging in Burmese language appears to be effective (as most packaging is in English, Chinese or other non-Burmese languages), however, communications in

other ethnic languages may be needed to improve recognition of the Padonmar seal amongst more remote and ethnic groups. In addition, as overall incidence of fevers has decreased, so has treatment seeking behaviour and therefore awareness and sensitivity to the communications and the Padonmar seal.

Challenges:
Improved knowledge of case management by the target population, such as managing all types of fevers, increasing demand for being diagnosed when having fevers, and the completing full coursers of drugs, is an important output from the project, as well as recognising the Padonmar quality seal. Improving the behaviour of the target population may require wider strategies and activities. Thus output 2 could be revised to incorporate indicators that measure the knowledge and practice on using appropriate quality drugs. It is important the target population understand that quality assured ACTs, are affective and worth taking, even when drugs are more expensive, in order to prepare for a time when the subsidy may be reduced or removed.

The review team also noted that the methods to monitor this output may not adequately assess its progress. For example, there is a time lag between treatment seeking behaviour and being interviewed during the household survey, thus leading to memory recall bias. Other data collection methods, such as exit interviews, could be considered.

Recommendations:

- PSI to revise their behaviour change and communication strategies, which should incorporate interpersonal communication. There should be increased emphasis on improving service users' understanding of case management of malaria and other fevers. PSI to revise the indicators accordingly in time for the no cost extension.
- PSI to consider further languages, including ethnic languages and Thai, within their communication strategies. This should take place by June 2014.
- PSI to revise the methods of collection (such as exit interviews) to assess the progress of output 2, by September 2014, in time for the proposed no-cost extension period.

Impact Weighting (%): 30%

Revised since last Annual Review? Yes
The impact weighting was changed from 70% to 30% after the first Annual Review and has been agreed by DFID, PSI and other partners, to better reflect the percentage for the contribution each is likely to make towards the achievement of the overall outcome.

Risk: High

Revised since last Annual Review? No

Output 3: Increased opportunity, ability and motivation of private sector providers to conduct a rapid diagnostic test (RDT) prior to the appropriate prescription and dispensing of nationally approved, quality assured ACT.

Output 3 score and performance description: B (Outputs moderately did not meet expectation)

Progress against expected results:

OUTPUT 3	Output Indicator 3.1		Baseline/Milestone (Y1)	Milestone 1 (Y2)
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.	% target outlets with RDTs in stock at time of survey	**Planned or baseline**	Priority outlets = 3.5% All outlets = 17.7%	Priority outlets target = 5%; All outlets target = 40%
		Achieved		Priority outlets = 5.4% All outlets = 28%
		Source		
		Source: Baseline Outlet Survey - 2012 Target: Annual Outlet Surveys at 2013 and 2014.		
	Output Indicator 3.2		**NA (Y1)**	**Baseline/Milestone 1 (Y2)**
	% 'priority' outlet providers that correctly describe and demonstrate the 5 key steps in the process of conducting and interpreting a rapid diagnostic test for malaria (denominator = providers that have been trained in the use of RDTs within the last 6 months and have RDTs in stock at the time of the survey)	**Planned or baseline**	NA	43.9% (RDT pilot townships)
		Achieved		
		Source		
		Mystery Client Surveys		

Summary of Progress

Summary:

Output 3 is scored as B. The milestone for output indicator 3.1 has been partially met. Output 3.2 did not have a baseline. Data collected to inform progress was taken from a sample of 100 townships in June and July 2013. The RDT pilot started in May 2013 and in only 6 townships, thus its impact is unlikely to feature in the results collected in the national outlet survey at that time. The review team visit to the pilot areas showed good anecdotal evidence that diagnostic testing in these areas was taking place, that RDTs were in stock and that they were being used correctly.

Detail:

Indicator 3.1, "% of target outlets with RDTs in stock at time of survey" has met expectations in the priority outlets (5.4% against a target of 5%). The target was not met in all outlets (28% against a target of 40%). The data collected is not significantly influenced by the RDT pilot due to its timing and limited geographic area. The result for all outlets, which includes the more formal providers of GPs and village health workers, is disappointing low. This shows that within Burma there is little progress in the use of RDTs, without concerted interventions such as this PSI project. More progress might have been expected in the more formal providers, as they have access to information on appropriate service delivery standards, such as from the Ministry of Health.

During the annual review visit to the RDT pilot areas, all outlets were found to have RDTs in stock. An unplanned stop at a general store also provided evidence that RDTs are being conducted (as demonstrated by the provider).

There is evidence of good progress on indicator 3.2, "% of priority providers that correctly describe and demonstrate the 5 key steps in conducting and interpreting RDTs." About 44% of priority providers in the RDT pilot townships were found to be able to correctly describe and demonstrate the use of RDTs. This data was collected in October 2013, after the pilot had taken place. The result is considered promising by PSI considering the context. There has been little history on the use of diagnostics, and many of the informal providers of the priority outlets have little formal healthcare training.

The RDT Pilot

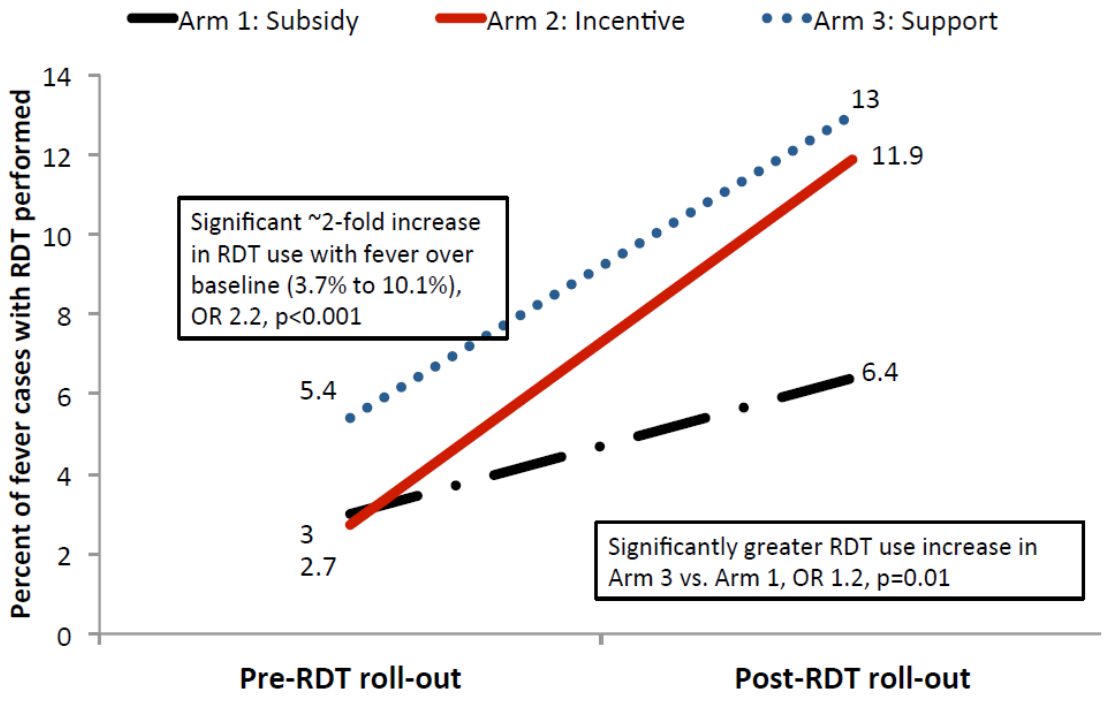
PSI and the University of California San Francisco (UCSF) undertook a pilot between May to October 2013 to assess three different incentive mechanisms to drive demand for diagnostic testing, and appropriate case management, among informal private providers. The pilot showed that it is feasible for informal providers to use RDTs, and the study has led to increased uptake of RDTs in the pilot

areas, as set out in Figure 2 below.

Arm 3 (education and counselling) led to the largest increases in RDT use, and greatest likelihood that proper treatment would follow RDT results. Arm 2 (incentives) 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.

Arm 1 (subsidy alone) led to lower uptake rates.

Figure 2. Graph showing RDT use pre- and post- roll-out from the household survey.



Challenges:
The RDT was delayed due to the overall delay in the start of the project and specific delays in having permission granted from the Ministry of Health to undertake the pilot. Therefore progress is limited at this stage of the project. However, the pilot itself has shown a quicker and more thorough uptake, in particular by informal providers, than had been expected, showing good potential for the full roll out.

Recommendations:

- There needs to be continued management and monitoring of the roll-out of RDTs by PSI, to ensure quality of testing, and ascertain whether this results in appropriate case management.

Impact Weighting (%): 30%

Revised since last Annual Review? Yes
The impact weighting was changed from 5% to 30% after the first Annual Review which was agreed by DFID, PSI and partners to better reflect the percentage for the contribution each is likely to make towards the achievement of the overall outcome.

Risk: High

Revised since last Annual Review? No

Section B: Results and Value for Money

1. Progress and results

1.1 Has the logframe been updated since last review? Yes

A DFID specific indicator has been added: “Estimated number of P.f malaria cases (disaggregated by age and gender) treated nationwide with quality assured ACT through DFID funding of this project.”

Output 2 from the logframe will be revised following this Annual Review, as detailed in section A.

1.2 Overall Output Score and Description: B (Outputs moderately did not meet expectation)

Output Number	Output Description	Impact Weight (%)	Output Performance	Risk
Output 1	Increased opportunity, ability and motivation of private sector providers to effectively prescribe and dispense nationally approved, quality assured ACT (QAACT)	40%	B	High
Output 2	Increased opportunity, ability and motivation of the target population in eastern Burma to promptly and effectively treat suspected malaria with a nationally approved and quality assured ACT	30%	C	High
Output 3	Increased opportunity, ability and motivation of private sector providers to conduct a rapid diagnostic test (RDT) prior to the appropriate prescription and dispensing of nationally approved, quality assured ACT.	30%	B	High

1.3 Direct feedback from beneficiaries

During this Annual Review period, there was no direct feedback from beneficiaries. However, during the mid-term review in May 2013, the review team did meet beneficiaries and their views were captured in the review aid memoire (quest number 4379895) and have informed this Annual Review. Beneficiaries met during the mid-term review were able to name a range of anti-malarials, including Supa-Arte and the Padonmar seal, which they had heard of through mass media channels, such as the radio and posters. The packaging in Burmese language as effective. Beneficiaries reported the correct use of Supa-Arte, including completing a full course, however, they did mention partial courses for AMTs and other ACTs. Some beneficiaries stated that Supa-Arte had unpleasant side effects, and preferred taking fewer tablets of AMTs. Others showed ‘brand loyalty’ or familiarity in their preferences for AMTs and other non-quality assured ACTs.

Beneficiary feedback is also captured in the household surveys, which establishes the knowledge and behaviour of service users, and this feeds in the review process informing its outcome.

The review team for this Annual Reviews received feedback directly from twenty service providers, who are key informants assess project progress. It is recommended that all subsequent reviews ensure that there is direct feedback from beneficiaries during review visits, including in more remote areas further down the supply chain.

1.4 Summary of overall progress

Certain key critical milestones are exceeding expectations, such as the change in market share of quality assured ACTs to AMTs, and the good availability of ACTs at prices less than AMTs in the priority outlets (output Indicators 1.5 and 1.3 respectively). Other milestones relating to the private providers dispensing ACTs have not been met to date, according to the data surveys from 6 months ago, although anecdotal evidence from the review visits shows improved progress. The product promoters were seen to be very active during the visits on this Annual Review and during the mid-term review, and are likely contributing to the good availability of Supa-Arte in the outlets. More work needs to be done on improving the knowledge of the providers to ensure the correct use and prescription of quality assured ACTs.

Milestones relating to service users preferences to treat suspected malaria cases with quality assured ACTs have not been met. More work on improving knowledge and practice by service users on effective case management is needed, and measuring this more effectively will take place for the remainder of the project.

While the RDT pilot was delayed, the results from the pilot show good take up of RDTs, in particular for the informal providers, as shown in Figure 2, section A, progress against output 3 for details. Continued management and monitoring of the roll-out of RDTs, and whether this results in appropriate case management, will be critical to the achievement of the outcomes in the remaining period of the project.

Overall, the results to date suggest that a sustained price subsidy for quality assured ACTs, when combined with supportive interventions, can bring about changes in antimalarial markets in Burma, and hence contribute to containing artemisinin resistant malaria. The main drivers of change and their contribution to the project to date include:

- The price subsidy. This is passing down to the service users, and is a key driver in the rapid and significant change in the anti-malarial market in Burma.

- The strong private sector supply chains. These enable the subsidised ACTs to be distributed widely throughout the country and down to remote areas. However, there needs to be improved knowledge of the correct use of ACTs by the private providers.

- Product and behaviour change promotion. These have contributed to good uptake of drugs by the providers and service users. However, greater understanding of case management and the appropriate use of ACTs by the target population is required to ensure that the drugs are used effectively.

- Policy regulation by the government of Burma. The Food and Drug Agency have banned the import of the main oral AMTs, artesunate and artemether, in December 2011 and August 2012 respectively. However, there are now concerns that another AMT (distributed by Liberty), may still being imported due to a possible change in regulations (see key challenges, section 1.5 below.)

1.5 Key challenges

- Sustainability of the project and use of subsidy. The theory of change, as set out in the Business Case[xiii], contained assumptions which would lead to the longer sustainability of the intervention. These assumptions and their status are set out below:

    - *Public sector scale-up of free services.* The project aimed for a rapid switch between AMT and

ACTs in the private sector, to provide an immediate contribution to containing artemisinin malaria and give time for the public sector public to increase its free malaria services. While the public sector has scaled up for the containment response, this has not been sufficient, and is unlikely to be so in the near future. Private provision of anti-malarials remains an important source for service users. A reduction or removal of the subsidy would mean that the cost of ACT will increase significantly, and be out of reach for most consumers. The market share of ACTs pre-intervention showed that there is no market demand for ACTs at unsubsidised prices. This is likely to lead to consumers purchasing individual pills, switch to other treatments, including AMTs, or purchase fake or poor quality drugs – all of which are drivers for artemisinin resistance.

- *Decrease in malaria burden.* There has been a decline in malaria burden due to a range of effective interventions. WHO's World Malaria Report shows a decrease in malaria deaths from over 80,000 in 2000 to around 500 in 2013 in Burma.[xiv] PSI's SUN channel network show a decrease in positivity rates from 2007 to 2013, with a particular decrease in 2012 and 2013. They also show a 50% reduction in malaria cases between 2011 and 2013.[xv] The decline in malaria burden is unequal within the country and relates to the intensity of malaria control interventions. Burma is still classified as a "malaria control" country, rather than a "malaria elimination" country, and rates of malaria could increase should control efforts weaken.

- *AMTs being squeezed out of the market.* There has been significant progress in removing AMTs from the market, but they have not been totally removed. There are concerns that an oral AMT, distributed by Liberty and imported from Vietnam (manufactured by Mediplantex as recently as June 2013), may still being imported due to a possible change in regulations (see next bullet point.)

The target population are unlikely in the foreseeable future to buy ACTs at un-subsidised prices, even if they appreciate its effectiveness, and therefore the project is not sustainable without a subsidy. The aim of the project was to be a rapid switch of AMTs to ACTs, while the public sector scaled up to provide free services. Under the current circumstances, for the project goal of containing artemisinin resistant malaria to be realised, there needs to be a global decrease in the price of ACTs (through new technologies, which is outside of this project) or there is a long-term commitment to a continued subsidy by the international community.

It is recommended that the subsidy remains for the proposed no-cost extension period. However, PSI should undertake analysis of the market dynamics to ascertain whether, and when, it is feasible that the level of subsidy could be reduced DFID has already advocated the merits of the project to other funders, and the Global Fund Regional Artemisinin Initiative has pledged funding to PSI for this project.

- AMTs within private markets. The imports of two AMTs, artesunate and artemether, were banned in Burma in December 2011 and August 2012 respectively by the Food and Drug Agency (FDA). Stocks of these residual AMTs are still being sold, as there is not a ban on sales of AMTs. Most concerning however is that another AMT distributed by Liberty, appears not to have had its importation banned by the agency, and is being seen within markets. This means that at least one AMTs is still entering the top of the private sector supply chain.[xvi]

  There have been some initial dialogue with the FDA on these areas of concern, however, it is recommended that further dialogue takes place by DFID-Burma, and others, within Burma, regionally and globally. DFID-Burma should also raise issues of concern through the Global Fund, who have pledged to provide resources for capacity building to the FDA under the Regional Artemisinin Initiative. DFID-Vietnam should raise issues of concern with relevant authorities in Vietnam, and DFID HQ and should raise issues through WHO, the Asia Pacific Leaders Malaria Alliance (APLMA), the Asia Development Bank and others as appropriate.

  The health systems strengthening component of the multi-donor 3MDG Fund (to which DFID is a

major contributor) should also analyse the FDA and look into improving its effectiveness of the organisation.

- Delays in registering Artel Plus. PSI has been working to finalise a contract with PolyGold, a second distributor, to distribute additional quality assured ACTs, branded as Artel Plus. However, there have been extended delays and blockages in registering this brand by the Food and Drugs Agency. It is recommended that DFID-Burma also raises this issue with the FDA and via the Global Fund. PSI should continue to maintain and further develop constructive relationships with the Ministry of Health, including the FDA.

- Knowledge and correct use of ACTs. The change in the anti-malarial market has been rapid and impressive. However, there needs to be intensified strategies to improve the knowledge of effective case management of malaria and other fevers, and ensure the correct use of ACTs by providers and service users.

- Conflict affected areas. There is some anecdotal evidence that Supa-Arte reaches conflict affected areas which have a high burden of drug resistance. However, PSI is unable to undertake surveys and project management in many of the conflict affected areas, due to lack of access or lack of permission from the government of Burma. It is recommended that PSI consider how it improves the project impact in conflict affected and border areas. This may include training organisations that have access to those areas to undertake surveys, and pursing the growing interest in having regionally consistent cross-border ACTwatch outlet surveys in priority containment areas.[xvii]

1.6 Annual Outcome Assessment

There has been good progress in some areas from the last Annual Review to this second Annual Review, which has been demonstrated following the completion of the second set of surveys. Set out below are the summary of the progress against outcomes.

OUTCOME	**Outcome Indicator 1**		**Baseline/Milestone (Y1)**	**Milestone 1 (Y2)**
Sub-standard anti-malarials in the private sector (particularly artesunate monotherapy), replaced with government approved and quality assured [5] ACT, and sub-optimal dosing reduced among the target population in eastern Myanmar.	% target population (disaggregated by age and gender) with suspected malaria in the last two weeks who **received** a nationally approved, quality-assured artemisinin-based combination therapy (ACT) within 24 hours of the onset of fever	**Planned or baseline**	0%	50%
		Achieved		61%
		Source		
		Baseline Household Surveys - 2012 & 2013 Target: Exit Interviews in 2014.		
	Outcome Indicator 2		**Baseline/Milestone (Y1)**	**Milestone 1 (Y2)**
	% target population (disaggregated by age and gender) with suspected malaria in the last two weeks who **received a full course** of a nationally approved, quality-assured ACT within 24 hours of the onset of fever (denominator = those that received a QAACT)	**Planned or baseline**	0%	50%
		Achieved		77%
		Source		
		Baseline Household Surveys - 2012 & 2013 Target: Exit Interviews in 2014.		
	Outcome Indicator 3		**Baseline/Milestone (Y1)**	**Milestone 1 (Y2)**
	% target population (disaggregated by age and gender) with suspected malaria in the last two weeks who **completed a full course** of a nationally approved, quality-assured ACT within 24 hours of the onset of fever (denominator = those that received a full course of QAACT)	**Planned or baseline**	0%	40%
		Achieved		35.2%
		Source		
		Baseline Household Survey - 2012 Target: Exit Interviews and Patient Follow-up surveys in 2014.7		
	Outcome Indicator 4		**Baseline/Milestone (Y1)**	**Milestone 1 (Y2)**
	Estimated number of P.f malaria cases (disaggregated by age and		N/A	Sept '12 - Oct '13 = 790,232 (DFID

	gender) treated nationwide with QAACT through DFID funding of this project.			ONLY)
		Source		
		Calculated as follows: Number of QAACT courses distributed by AA (80% funded by DFID, minus BMGF funded 20%); national average P.f RDT +ve rate over time (disaggregated by age and gender).		

Outcomes indicators 1 and 2 have exceeded their targets. 61% of the target population can been seen to be using ACTs, as compared to 0% in the household baseline survey, showing remarkable changes in the malarial market. 77% of the target population receive a full course of ACTs, indicating that service providers are largely providing full course of ACTs to service users.

Outcome indicator 3 has not met its target. More information is needed on the reasons for this and responsive action taken. This is likely to include improving interpersonal communication at all levels of the supply chain. While the product promoters and promotional material appear to be effective in getting Supa-Arte into outlets and being used by service users, they need to enhance behaviour change communication more effectively, in particular in providing information on the importance of completing a full course of ACTs. Exit interviews can also be considered to assist with memory re-call for data collection.

Outcome indicator 4 is a new indicator, and shows an estimate of the number of *Plasmodium Falciparum* malaria cases treated through the project. Data from this indicator will feed into DFID-Burma's corporate monitoring malaria treatment indicator.

2. Costs and timescale

2.1 Is the project on-track against financial forecasts: Yes

There has been improved financial management, in particular improved forecasting, and disbursements have been as scheduled. The project has had its budget revised, and is on track for the revised budget (but not the original proposal budget). There will be an underspend at the end of the project, and a no cost extension is recommended, as set out below.

2.2 Key cost drivers

Set out below are the costs of the projects based on up to date expenditure reports.

Supplies	**79%**
Total Personnel	**13%**
Total Travel	**1%**
Total Consultants	**1%**
Total Equipment	**1%**
Indirect Costs	**7%**

The key costs drivers are commodity supplies (ACTs, RDTs and promotional material) and personnel.

2.3 Is the project on-track against original timescale: No

The project was delayed at the start by 5 months as PSI did not have a Memorandum of Understanding (MOU) with the government at the beginning of the project. This meant delays in purchasing of ACTs and in obtaining permission for surveys. The RDT was further delayed as permission from the Ministry of health took longer than expected. However, the project has 'caught up' to meet many of its targets. The project is under spent due to some extent of the delayed start, but also due to the lower than expected requirement of ACTs (which is one of the main cost drivers). The amount of ACTs required for the project was based on market data on AMT consumption, and also the knowledge that packs of AMTs were often sold in partial doses, known

as blister cutting. A key assumption used to estimate ACT need at the start was the prevalence of blister cutting, and the decreased requirement for anti-malarials may be due to reduced blister cutting of ACTs relative to AMT as had originally thought. In addition, improved treatment adherence of ACTs may result in fewer disease relapses and subsequent repeat visits to providers (which is anecdotally supported in interviews with providers).

It is recommended that the project be granted a no-cost extension from October 2014 to March 2016. The project goals are not considered sustainable at this stage, and the overall impact of containing artemisinin resistance malaria will benefit from a continuation of the project using un-spent funds.

3. Evidence and Evaluation

3.1 Assess any changes in evidence and implications for the project

The status of artemisinin resistant malaria is defined by WHO, and this has informed the design of this project. WHO defines resistant areas according to tiers or zones. Tier 1 areas are those for which there is credible evidence of artemisinin resistance. Tier 2 areas are those with significant inflows of mobile and migrant populations from Tier 1 areas or who share borders with Tier 1 areas. While the project reach is nationwide, PSI has concentrated its product promotion and medical detailing efforts on Tier 1 and Tier 2 townships in eastern Burma where there are indicated or potential areas of artemisinin resistance.

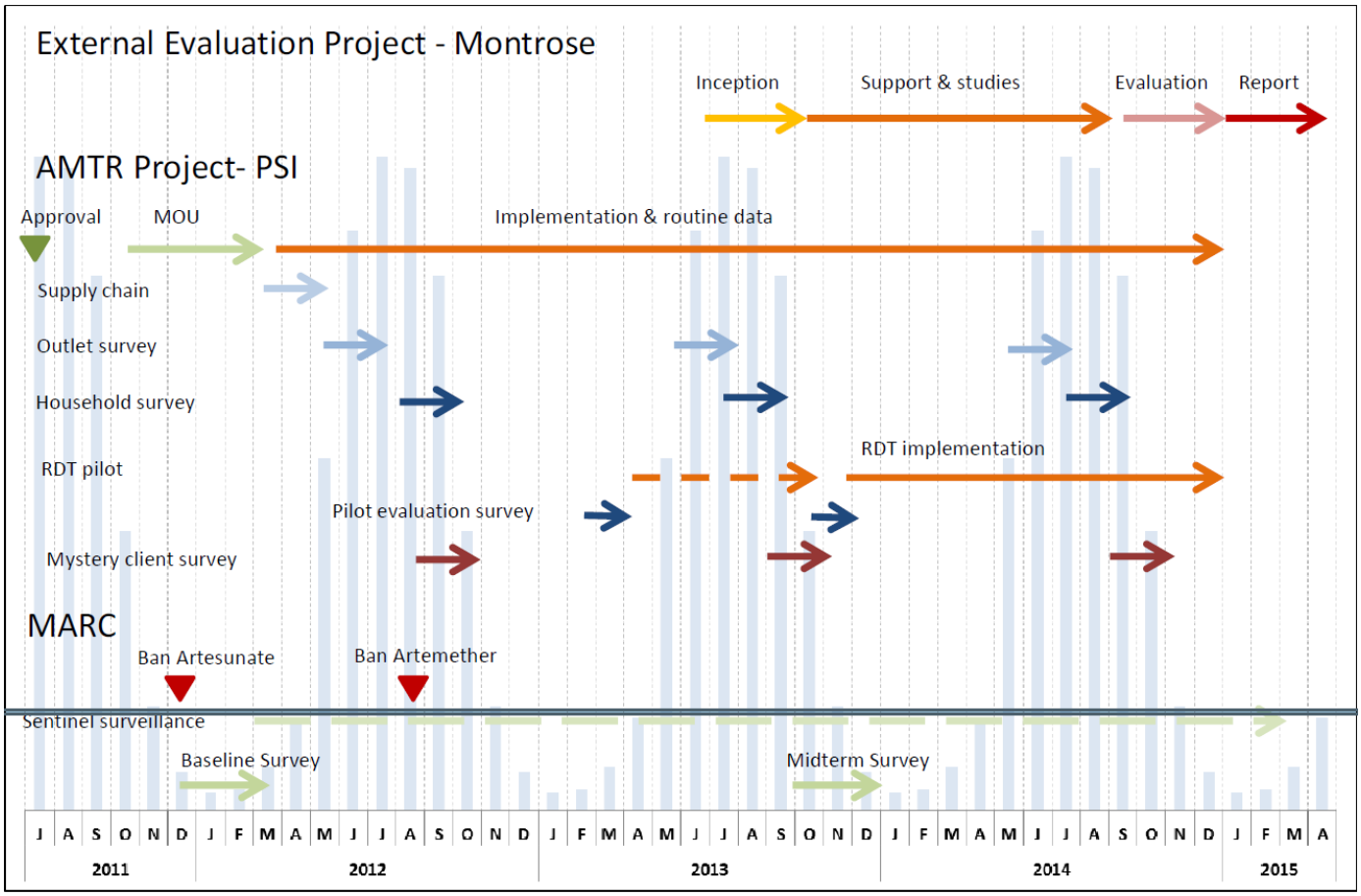
In January 2014, WHO issued an update on the status of resistance in Burma.[xviii] It did not recommend the revision of tier stratification, and also stated that artemisinin resistance has not reached western Burma. However, during a recent Global Fund workshop on resistance, WHO, the Ministry of Health and other key partners agreed to intensify their efforts into Tier 2 areas such as townships in Kayah State and Bago Division. As this PSI project already concentrates its efforts on these areas, there is no additional change required from the project at this stage. PSI continues to keep updated on the status of resistance in Burma, and will respond when and where necessary.

Following the last Annual Review, PSI has disaggregated results from the outlet survey by tiers to demonstrate results in the key areas for containing artemisinin resistance. PSI also responds to data evidence from its surveys, and modifies project activities and methods accordingly.

3.2 Where an evaluation is planned what progress has been made?

A contract was awarded to Montrose International in May 2013 for an independent evaluation of the project, which will be finalised in March 2015. The diagram below shows the timing of the evaluation together with PSI key activities and data collection surveys. (The blue, vertical bars represent average monthly rainfall.)

The evaluation is in the implementation phase, and an inception report and evaluation framework have approved by the evaluation steering committee (made up of representatives from DFID, the Gates Foundation and an independent expert) in September 2013. As part of the review, Montrose will produce cases studies and working papers, and the concept notes for these have been developed.



In addition to the evaluation, the project had a mid-term review, (quest number 4379895), which included a competition assessment (quest number 4379894) completed by a competition specialist from the UK Office of Fair Trading in May 2013. The competition assessment found that there is no competition risk at this stage or the near future, and the consumer is protected due to price controls within the contract between PSI and AA. However, the assessment noted that a subsidy to AA for a prolonged period in time could give AA market power that could allow AA to foreclose competitors and/or allow AA to build up the dominant brand in the market.

PSI is actively working with PolyGold to develop and distribute a second subsidised ACT, branded as Artel Plus, in Burma. This has the primary focus to improve market penetration, increase the rate of AMT displacement, and improve clarity of the use of the quality seal within the private sector. It also serves to mitigate against any future competition risks.

The EU Council Decision on sanctions against Burma was in place at the start of the project, and therefore it was not possible to provide the subsidy at the import level, but rather work with individual distributors. With the changing context in Burma, it may be possible to provide the subsidy at the import level, which would mean subsidised ACTs could pass through the supply chains of all distributors in Burma.

4. Risk

4.1 Output Risk Rating: Low/Medium/High

The project is recognised as high risk given the difficult and rapidly changing political and epidemiological environment.

4.2 Assessment of the risk level

The risk level for this project remains 'high'. This reflects the difficult and rapidly changing political and epidemiological operating environment. In addition to external factors to be managed, PSI will also include on the register internal implementation and management risks.

Key risks to achievement of outputs and the mitigating actions will be discussed at the monthly meetings between PSI and DFID including: the imminent replacement of Supa-Arte with expiry date of April 2014 across the supply-chain; the current and future policy of the Food and Drug Agency towards the imports of AMT; the lack of knowledge of case management and correct use of ACTs by providers and service users, and the roll-out of RDTs through the informal private sector following a successful pilot.

4.3 Risk of funds not being used as intended

There is low risk that funds will not be used as intended. Project finances are managed by PSI which has a good track record of project financial management. PSI has reported on funds from a number of donors and demonstrated that these have been used as intended. PSI has robust internal policies and procedures in place for reporting and managing fraud that have been tested in practice. A clean audit report was submitted after the first year of the project.

4.4 Climate and Environment Risk

There is low risk of climate and environmental damage from this intervention. The use of product promoters and monitoring staff does impact on the environment due to travel. However, this is mitigated by good case management, which ensures that patients are treated with the correct drugs in a timely manner, thus avoiding travel for referrals for severe untreated cases.

Following the RDT pilot and the roll-out across project areas, there is a risk of used tests being discharged into the environment. PSI are confident that appropriate disposal mechanisms will be in place and these will continue to be monitored as the roll-out of RDTs in the private sector continues.

Changes in climate and the environment impact on the epidemiology of malaria. Containing artemisinin resistant malaria will mean that the drug will be effective in areas that may experience in an increase in malaria burden. Thus the project can be seen to minimise such negative impacts of climate or environmental change.

5. Value for Money

5.1 Performance on VfM measures

The Business Case[xix] assessed the value for money (VFM) of this project.

Economy: The main cost driver is the purchase of ACT and RDTs. The procurement of the quality assured ACT (Artemether Lumefantrine (AL) was carried out through a competitive tender. PSI and DFID agreed a price fixed for 2 years, allowing for significant flexibility in purchasing the required amount of AL. The purchase of ACTs is still under this contract and remains good value for money.

Efficiency: The project is progressing well. The market share of ACTs is increasing and stock-outs of ACTs are limited.

Effectiveness: The key conclusion of the Business Case is that there is a very strong VFM case for

preventing the spread of artemisinin resistance, remains valid. This project is an important part of fighting the spread of resistance in Burma and project outcomes will have impacts globally.

Equity: Malaria predominantly affects rural people living in poverty, including migrant workers. Hence the project is assisting poor people in Burma with quality treatment for malaria and preventing the spread of malaria to poor people globally who would be vulnerable to malaria.

The independent evaluation team have worked with PSI on an action plan for VFM improvement. The action plan is being finalised and will be implemented, monitored and reported on by PSI to partners for the remainder of the project and the no-cost extension period.

5.2 Commercial Improvement and Value for Money

It is recommended that PSI either re-negotiate a similar contract with the same supplier, or re-tender the contract and use one or a range of suppliers which offer similar value for money, when the current contract for drug procurement expires.

5.3 Role of project partners

- Donors. The donors provide the funding for the subsidy, which has been recognised by the review team and other assessments as a key driver for the achievement of the result of the project. During the next phase of the project, PSI will analyse whether a lower level of subsidy can still realise the project's goals, hence improving VFM even further.

  It is recommended that the donors work more closely together, such as having quarterly meetings to increase co-ordination and provide greater support to PSI.

- PSI. PSI manages the product and behaviour change promotion, which are key drivers for changes in market preferences. PSI needs to revise and intensify its promotion and communication strategies to ensure that service providers and users improve their knowledge on the correct use of ACTs in order to improve the overall project results and VFM.

  PSI will manage the roll of diagnostic testing following the RDT pilot. The review team met retailers who sold significantly less ACTs during the pilot in the RDT pilot areas, indicating that providers did not provide ACTs following a negative malaria result. Thee correct use of RDTs leading to improved case management could potentially result in costs savings as less ACTs need to be purchased (and fewer ACTs will be wasted on non-malarial cases) while still achieving good project results.

  PSI's procurement practices are important for realising VFM. Its large operation benefits from economies of scale, and it follows stringent procedures and controls, following international procurement guidelines.[xx] It has maintained an uninterrupted supply of ACTs for the project.

- AA Medical Products Ltd. The ACTs are distributed via the existing supply chains of AA. There are minimal extra costs for distribution of the ACTs to the project, and the supply chains are extremely extensive and effective, which assist the project's achievements significantly. AA state that its participation in the project is to contribute to the global public good of contain artemisinin resistant malaria, and have agreed to a fixed price clause in their contract for Supa-Arte, limiting any profit that they would make on selling the drug.[xxi] Supa-Arte accounts for less than 5% of AA's pharmaceutical portfolio, and it does cover its costs when distributing Supa-Arte. Working with a second supplier is likely to improve market penetration and also improve VFM further.

- Ministry of Health. The Ministry of Health set the policy environment and operating regulations, which provide the framework for the project. The banning of the two main AMTs have contributed to good VFM and assisted the project's goals. There are concerns that the Food and Drug Agency may be allowing another AMT brand to continue to be imported, and are delaying the registration of the second subsided ACT, branded as Artel Plus, with PolyGold, which will impact on the project, both in terms of VFM and project results. Communication, dialogue and relationship management are important to

ensure that these issues are resolved effectively.

5.4 Does the project still represent Value for Money : Yes

Yes. A paper prepared for the October 2012 Malaria Summit in Australia reiterated the importance of the issue of artemisinin resistance spread and estimated that if unchecked, global malaria mortality could rise by 25% with an economic cost of $4billion annually.[xxii] The project is intended to contribute significantly to containing that spread, despite the delays that have occurred at the beginning of the project

5.5 If not, what action will you take?

The Independent Evaluation will produce an action plan for VFM improvement.

6. Conditionality

6.1 Update on specific conditions

Not applicable

7. Conclusions and actions

The project is producing a significant and rapid change in market share of ACTs to AMTs. There is good availability of ACTs and the subsidy is being passed down to the consumers. In addition, the RDT pilot showed positive results and good potential for the use of RDTs in the private sector. However, there are concerns regarding the knowledge of service providers and users on effective case management and on the correct use of ACTs, which could undermine the benefits of having affordable and available ACTs within the private sector.

There are a number of recommendations following the Annual Review, which have been agreed by DFID, Gates Foundation and Good Ventures. These are set out below.

1. **No-cost extension. It is recommended that DFID-Burma agrees to a no-cost extension to continue the project for a further 18 months until March 2016. The project goal is not considered sustainable at this stage, and using unspent funds will contribute to the expected impact of containing artemisinin resistance malaria. Action: DFID to grant PSI a no-cost extension after approval of the Annual Review.**

2. **Subsidy of the ACTs. During the proposed no-cost extension period, the level of subsidy is to remain at its current level. However, it is recommended that PSI undertake further market analysis to improve understanding of the factors that will influence this decision. This analysis will help to ascertain whether, and when, it is feasible that the level of subsidy could be reduced while not compromising the project goals. Action: PSI from October 2014.**

3. **Theory of change. PSI to revise the theory of change and its timelines for the remainder of the project and the no-cost extension period. Action: PSI by September 2014.**

4. **Improved knowledge and correct use of ACTs. PSI to revise and intensify its communication strategies in order to improve the knowledge of service providers and users on the correct use of ACTs. PSI to also consider further languages, including ethnic languages and Thai, for promotional materials. Action: PSI by May 2014.**

5. **Revisions to the logframe. PSI to recommend to DFID revised indicators to assess the**

progress of output 2. Action: PSI by September 2014.

6. **Expiry date of drugs.**
   e) **PSI to stop providing drugs with expiry dates of March and April 2014 to AA. Action: PSI with immediate effect (done.)**
   f) **The risks of expired drugs to artemisinin resistance and case management should be added to the risk matrix. Action: PSI by April 2014.**
   g) **PSI to provide the value of the expired drugs and a background note on the reasons for having excess drugs. Action: PSI by May 2014**
   h) **PSI to draft standard operating procedures (or equivalent) on managing drug expiry dates, within all outlets, in particular those at the end of the supply chain. PSI to consider having expiry dates written in Myanmar language and ensure more explanation to distributors on expiry dates and stock management throughout the supply chain. Action: PSI by May 2014**

7. **Food and Drug Agency. DFID-Burma to raise the issues of concern with the Food and Drug Agency in Burma, and via the Global Fund. DFID HQ and to explore international opportunities to address the issues through WHO, the Asia Pacific Leaders Malaria Alliance (APLMA), Asia Development Bank and others as appropriate. DFID-Vietnam to raise issues of concern with relevant authorities in Vietnam. Action: DFID on-going.**

8. **RDT Roll-out. PSI to monitor the roll-out of RDTs to ensure quality of testing, and ascertain whether this results in appropriate case management. Action: PSI on-going**

9. **New distributor. PSI to continue to working with PolyGold to distribute a second subsidised ACT brand in Burma, in order to improve market penetration, increase the rate of AMT removal and improve clarity of over the use of the quality seal. Action: PSI on-going.**

10. **Value for money (VFM).**
    a) **PSI and DFID-Burma to finalise the VFM action plan, which will be implemented, monitored and reported on by PSI to partners for the remainder of the project and the no-cost extension period. Action: PSI and DFID by end of May 2014**
    b) **PSI to demonstrate value for money during their negotiations for the next phase of drug procurement. Action: PSI by end of August 2014.**

11. **Conflict affected and border areas. PSI to consider how it improves its impact in conflict affected and border areas, for example through training organisations that have access to those areas to undertake surveys, and implementing a regionally consistent ACTwatch in bordering countries. Action: PSI by July 2014.**

12. **Donor co-ordination. The donors to increase co-ordination, such as quarterly meetings. Further donors to join the PSI-DFID monthly meetings when feasible. Action: DFID-Burma, Gates Foundation and Good Ventures on-going.**

13. **Relationship management.**
    a) **The donors will jointly write a letter to AA thanking for them for their contribution to the project and to the containment of artemisinin resistant malaria. Action: DFID-Burma by May 2014.**
    b) **PSI to continue building relations with all components of the Ministry of Health, including the Food and Drug Agency and others. Action: PSI on-going.**

14. **External communications. PSI to communicate the project more rigorously including updating their website, and acknowledging donor support. Action: PSI by May 2014.**

15. **Next annual review. PSI to facilitate opportunities for the review team to meet with beneficiaries (patients and consumers) to assess their views, and also to visit more remote areas and outlets further down the supply chain. Action: PSI by January 2015.**

The first annual review (quest number 3776759) had a number of recommendations, which have

been completed or are on-going. A summary of the recommendations and their follow up actions is documented (quest number 4396230).

8. Review Process

The review process took place between 17 and 21 February 2014 conducted by a DFID Health Adviser, Economic Adviser and Programme Manager. The draft was peer reviewed with Senor Health Adviser and the Results and Evaluation Adviser and consulted with PSI, the Gates Foundation and Good Ventures.

The review process consisted of:

- **Documents review (see below)**
- **PSI presentations to DFID**
- **A meeting with AA Medical Products Ltd**
- **A 3 day field visit to Tier One MARC area (Mon State) with PSI, the Gates Foundation, Good Ventures and Ministry of Health National Malaria Control Programme (NMCP) Liaison Officer including visits to and discussions with: the AA office in Mawlamyaing, drug wholesalers, retailers and pharmacies in urban and rural areas of Kyike Hto and Mawlamyaing townships, a private doctor, itinerant drug vendors.**
- **A concluding meeting between PSI and Donors for the findings from the review and discussion of recommendations**

List of Documents in the Review Process are:

- **DFID First Annual Review (Quest no 3776759)**
- **DFID mid-year AMTR programme review Aide Memoire (Quest no 4379895)**
- **Follow up actions from DFID First Annual Review (Quest no 4396230)**
- **RDT pilot : Final RDT Pilot SOW and Design Protocol agreed with UCSF Myanmar 11 Aug 2012, Final RDT Pilot SOW and Design Protocol agreed with UCSF Myanmar 11 Aug 2012, PSI and UCSF RDT Phase One Pilot Results Summary and RDT Pilot Phase 1 PSI and UCSF Final Report (Quest no 4380407)**
- **Risk Matrix as of February 2014 (Quest no 4380268)**
- **Value for Money : (Quest no 4380252)**
- **Malaria National Audit report (3 July 2013) (Quest no 4380241)**
- **PSI AMTR annual review briefing presentation 17 February 2014 (Quest no 4380200)**
- **PSI AMTR summary of mid-year progress report (Quest no 4380132)**
- **PSI AMTR Annual progress report**
- **Summary of progress against output indicators (Quest no 4380121)**
- **Independent evaluation inception report and evaluation framework August 2013 (Quest no 4379904)**
- **Independent evaluation 1st progress report December 2013 (Quest no 4379903)**
- **Competition assessment : Competition Assessment Framework and Competition in the market for anti-malaria treatments in Burma (Quest no 4379894)**
- **PSI Project Proposal (Quest no 3252513)**

List of Acronyms

AA	AA Medical Products Ltd
ACT	Artemisinin-Based Combination Therapy
AL	Artemether/Lumefantrine
AMT	Artemisinin Monotherapy
APLMA	Asia Pacific Leaders Malaria Alliance
AsDB	Asia Development Bank
FDA	Food and Drug Administration
HH	Household
IPCA	IPCA laboratories company

LQAS	Lot Quality Assurance Sampling
MoU	Memorandum of Understanding
NCE	No-cost extension
NMCP	National Malaria Control Programme
P.f	Plasmodium Falciparum
PSI	Population Services International
QAACT	Quality Assured Artemisinin-Based Combination Therapy
RDTs	Rapid Diagnostic Tests
VFM	Value for money
WHO	World Health Organisation

[i] All project documents can be found on: http://devtracker.dfid.gov.uk/projects/GB-1-202759/documents/

[ii] White LJ; Lubell Y; Meek S; White NJ; Day NPJ; Nosten FH; Ashley E; Socheat D; Nguon C; Dondorp AM; Malaria in the Asia-Pacific: Modelling the current and potential impact of artemisinin resistance and its containment. Issue Paper Number 4 Malaria 2012. http://malaria2012conference.com/materials.php

[iii] All project documents can be found on: http://devtracker.dfid.gov.uk/projects/GB-1-202759/documents/

[iv] One DALY represents one lost year of "healthy" life. The sum of these DALYs across the population, or burden of disease, can be thought of a measurement of the gap between current health status and an ideal health situation where the entire population lives to an advanced age, free of disease and disability. (WHO definition)

[v] Artemisinin has reduced malaria by more than half in 43 countries over the past 10 years, saving an estimated 730,000 lives in Africa

[vi] It is estimated that more than 80% of all malaria cases were treated with AMT, before the bans of artesunate and Artemether. A study has estimated that 20-40% of artemisinin containing tablets bought in Burma are counterfeit. (Newton P et al. Fake Artesunate in Southeast Asia. The Lancet. Vol 357, June 16, 2001.)

[vii] Strategic Framework for Artemisinin Resistance Containment in Myanmar (MARC) 2011- 2015 April 2011

[viii] The reason these are the priority outlets is that historically they had very low availability of ACTs due to cost, and therefore experienced subsequent lack of consumer demand for ACTs, and as these outlets then carried the majority of oral AMT across Myanmar.

[ix] The main oral AMTs, artesunate and artemether, were banned in Burma in December 2011 and August 2012 respectively

[x] Information on the 3MDG Fund can be found on: http://3mdg.org/index.php/about-3mdg

[xi] PSI is also a partner of the 3MDG Fund for its SUN Health Franchise network of private General Practioners and Village Health Workers

[xii] All project documents can be found on: http://devtracker.dfid.gov.uk/projects/GB-1-202759/documents/

[xiii] All project documents can be found on: http://devtracker.dfid.gov.uk/projects/GB-1-202759/documents/

[xiv] World malaria report 2013 can be found on: http://www.who.int/malaria/publications/country-profiles/profile_mmr_en.pdf?ua=1

[xv] Data from PSI SUN network, 2007 to 2013.

[xvi] . The main issue is that there seems to be lack of clarity over immediate import bans versus stopping renewals of existing licences, which may remain valid for some time

[xvii] This currently being discussed with BMGF, AsDB/APLMA,and WHO.

[xviii] Status report on artemisinin resistance. Global malaria programme. WHO. January 2014.

[xix] All project documents can be found on: http://devtracker.dfid.gov.uk/projects/GB-1-202759/documents/

[xx] PSI Project Proposal (quest number 3252513) outlines the experience of PSI's Procurement and Logistics Department. PSI has procured more products worldwide than any other private entity engaged in social marketing. In 2010, PSI procured more than 10 million courses of ACT worldwide.

[xxi] The price subsidy is passing down to service users, showing that AA is not making large profits from the

project.
xxii
White LJ; Lubell Y; Meek S; White NJ; Day NPJ; Nosten FH; Ashley E; Socheat D; Nguon C; Dondorp AM; Malaria in the Asia-Pacific: Modelling the current and potential impact of artemisinin resistance and its containment. Issue Paper Number 4 Malaria 2012. http://malaria2012conference.com/materials.php