Myanmar Artemisinin Monotherapy Replacement Malaria Project (AMTR) Independent Evaluation

Case Study 2 – June 2014

The Role of Pharmaceutical Distributors and Private Health Care Providers in Containing Artemisinin Resistance in Myanmar

Initial Findings from the AMTR Project

UKaid
from the British people

Myanmar Artemisinin Monotherapy Replacement Malaria Project (AMTR) Independent Evaluation

Is implemented by

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Table of Contents

ABSTRACT

Population Services International (PSI) is implementing the Artemisinin Monotherapy Replacement (AMTR) project funded by UKAid/the Department for International Development (DFID), the Bill and Melinda Gates Foundation (BMGF), and supported by Good Ventures. The project supports the Myanmar Artemisinin Containment Framework (MARC) developed by the Ministry of Health (MoH) in collaboration with the World Health Organization (WHO) and other development partners with the objective to contain the spread of Artemisinin-resistant *(Plasmodium Falciparum*) *P. falciparum* malaria. This case study was undertaken by a team led by Montrose which has been contracted for an independent evaluation of the AMTR project under the Global Evaluation Framework Agreement (GEFA). The case study takes a closer look at the interventions undertaken by PSI for engaging the private sector in the distribution of Artemisinin Combination Therapy (ACT) and Rapid Diagnostic Test (RDT) Kits, for the containment of Artemisinin resistance in Myanmar.

Given the heavy malaria burden in Myanmar at the time of project start (estimated 5 million fever cases in PSI targeted areas and 78% of all malaria cases reported to be infections with *P. falciparum*), weak public health systems and strategic geographic location, resistance to Artemisinin in Myanmar has the potential to threaten global malaria prevention efforts. Thus, it was essential that one of the key factors of resistance pressure - self-diagnosis and partial treatment of suspected malaria cases with oral Artemisinin Monotherapies (oAMTs) - was addressed as quickly as possible. At the time the AMTR project was conceived, the private sector led the supply of oAMTs (>70%). PSI thus designed interventions that could quickly replace the oAMTs on the market. A ban on registration and import of oAMTs was put in place by MoH in 2011 and was subsequently followed up with large scale distribution of subsidised Quality Assured ACTs (QA ACTs) through AA Medical Products (which enjoyed the largest market share of oAMTs). This intervention was complemented with several others related to: the establishment and promotion of a quality seal called Padonmar; over-branding of the QA ACTs distributed by AA Medical Products as Supa Arte; behavioural change communication (BCC); and a pilot of incentive models for deployment of Rapid Diagnostic Test Kits (RDTs) through pharmacies and informal providers. Of key significance, is the 80% subsidy provided through the project on the cost price of the imported QA ACTs, intended to bring down the price of QA ACTs to the level of partial doses of oAMTs.

The interventions undertaken by PSI facilitated quick results - as was demonstrated by the fact that approximately 1.2 million doses of ACTs were distributed by AA within 9 months (between 2012 and 2013) since project inception, and the market share for oAMTs declined from 51% to 36% nationwide. Critical to this success was the fact that PSI played the key role in commodity procurement, packaging, over-branding and market promotion, which enabled

faster implementation and greater control over the interventions. The distribution capacity of AA Medical Products was also instrumental in ensuring fast displacement of oAMTs from the market. Coordination with the MoH and other development partners contributing to the MARC strategy was also a key influencing factor, specifically on introducing the ban on registration and import of oAMTs. With the reduction in malaria cases in Myanmar, an expected increase in the use of RDTs and treatment of only diagnosed cases of *P. falciparum*, theoretically, the market for ACTs is expected to gradually decline to a stage where the demand for ACTs through private channels does not provide a great enough incentive for the private sector to continue its distribution.

The case study does reveal however, that the private sector is still a dominant force in the nationwide anti-malarial market, and may continue to remain so over the next several years. Of particular significance is the fact that there is reportedly fresh supply of oAMTs in the market, and concern amongst the leading pharmaceutical companies that the market could be flooded with counterfeit drugs once the project support and the subsidy on QA ACTs is withdrawn. In addition, the scope of the ban on registration and import is not currently clear to the private sector, and the engagement of the Department of Food and Drug Administration (DFDA) under the Ministry of Health (MoH) on communication and implementation of the ban appears to be limited. Furthermore, even though the RDT pilot has yielded positive results with respect to the deployment of RDTs through informal providers, the project was, at the time this case study was written, still awaiting approval from MoH to scale up the intervention. The RDT scale up is critical to the project's Theory of Change (ToC) and it is therefore essential that the project be able to support concurrent distribution of ACTs and RDTs through the private sector. Facilitating increased rates of accurate diagnosis and appropriate treatment can slow down the resistance and allow time for the partners under the Myanmar Artemisinin Resistance Containment (MARC) framework to strengthen the national efforts for resistance containment.

From this case study, it can be concluded that the private sector is critical for rapid delivery of ACTs and RDTs for the containment of resistance, but its role is time limited and expected to decline over the long term. By assuming the lead role on commodity procurement, packaging, over-branding, distribution and market promotion, PSI was able to fast track the deployment of QA ACTs in the market. With the gradual decline of malaria incidence and demand for commodities in private channels, in the longer term, the private sector is expected to concentrate more on the institutional market for QA ACTs and RDTs. Thus the fact that the project plays a lead role on some of the market functions, does not affect the long term sustainability of the containment of resistance. The success of the containment will depend on an effective transition from a private market to a public market for diagnosis and treatment of malaria in Myanmar. The AMTR project in this context plays a partial role since the capacity of the public sector for diagnosis and treatment of malaria is being

developed by other partners under the MARC framework. Nevertheless, the project would be a key determinant of success to the overall MARC framework and it is thus essential that it continues interventions for the scale up of the deployment of RDTs, and the subsidy and market promotion support for distribution of QA ACTs. Concurrently, it would be essential to work towards a transition strategy (from a private market to a public market) that has to be agreed upon by the partners under the MARC framework. Of particular importance within this, will be identifying responsibilities for sustaining the role of the project in ensuring that the ban on registration and importation of oAMTs is fully functional, and that the Padonmar quality seal is being used for all QA ACTs distributed in the market; and for ensuring that the public sector has the capacity to regulate the distribution of counterfeits. The 18 month no cost extension to the AMTR project which has now been approved by DFID, may prove critical in achieving these milestones.

ABBREVIATIONS AND ACRONYMS

AA	AA Medical Products
ACT	Artemisinin Combination Therapy
AMT	Artemisinin Monotherapy
AMTR	Artemisinin Monotherapy Replacement
ATL	Above-the-line
BCC	Behavioural Change Communication
BMGF	Bill & Melinda Gates Foundation
BTL	Below-the-line
CSR	Corporate Social Responsibility
DFDA	Department of Food and Drug Administration
DFID	Department for International Development
DoH	Department of Health
FDA	Food and Drug Administration
FGD	Focus Group Discussion
GEFA	Global Evaluation Framework Agreement
GMP	Good Manufacturing Practice
GPARC	Global Plan for Artemisinin Resistance Containment
GRS	General Retail Stores
IDV	Itinerant Drug Vendor
IEC	Information, Education and Communication
INGOs	International Non-Governmental Organisation
IPC	Inter-personal Communicator
IPP	Inter Personal Promoter
IRS	Indoor Residual Spraying
KAP	Knowledge, Attitudes, Beliefs
LLIN	Long-Lasting Insecticidal Nets
LLP	Limited Liability Partnership
M&E	Monitoring & Evaluation
MARC	Myanmar Artemisinin Resistance Containment
MoH	Ministry of Health
MPMEEA	Myanmar Pharmaceuticals and Medical Equipment Entrepreneur's Association
NGO	Non-Governmental Organization
NMCC	National Malaria Communication Campaign
oAMT	Oral Artemisinin Monotherapy
OECD	Organization for Economic Co-operation and Development
P.falciparum	Plasmodium falciparum
PSI	Population Services International
QA ACT	Quality Assured ACT
RBM	Roll Back Malaria
RDT	Rapid Diagnostic Test
RMP	Risk Management Plan
SPH	Sun Primary Health
SQH	Sun Quality Health

TES	Therapeutic Effectiveness Study
ToC	Theory of Change
UCSF	University of California, San Francisco
VBDC	Vector Borne Disease Control
VHW	Village Health Worker
VFM	Value for Money
WHO	World Health Organization
WHOPES	WHO Pesticide Evaluation Scheme

1. INTRODUCTION

The Myanmar Artemisinin Resistance Containment (MARC) framework, developed in collaboration with the World Health Organisation (WHO) and in line with the Global Plan of Artemisinin Resistance Containment (GPARC), was endorsed in April 2011 and outlines immediate containment actions to be put in place to contain Artemisinin resistance in Myanmar[1]. To date, resistance of *Plasmodium falciparum (P.falciparum)* has been confirmed in three states along the Thai-Myanmar border (Figure 1); containing this resistance is of upmost importance to prevent the further spread of resistance within Myanmar, as well as regionally and globally.

The goals of MARC are:

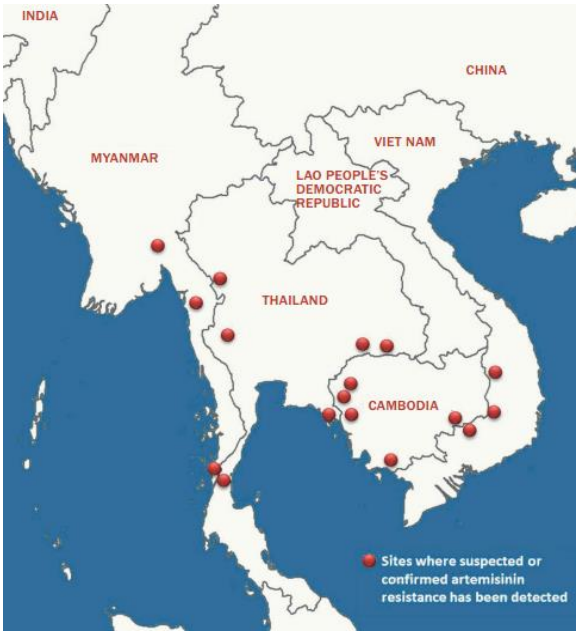
(i) To prevent, or at a minimum, significantly delay the spread of Artemisinin resistant parasites within the country and along its border ;

(ii) To reduce transmission, morbidity and mortality of *P.falciparum* malaria, with priority to areas threatened by resistance.[2]

Key activities include improving case management through community and private sector involvement, by providing subsidised Quality-Assured Artemisinin Combination Therapy (QA-ACT) and diagnosis, as well as banning oral artemisinin-based monotherapies.

The non-governmental organisation (NGO), Population Services International (PSI) has received funding from the UK Department for International Development (DFID), the Bill and Melinda Gates Foundation (BMGF) and Good Ventures, for the Artemisinin Monotherapy Replacement Malaria Project (AMTR). PSI has worked closely with private sector suppliers and providers

Figure 1. Sites where suspected or confirmed artemisinin resistance has been detected as of 2012 (ERAR framework 2013-2015)



[1] Myanmar Artemisinin Resistance Containment Plan, 2011

[2] Myanmar Artemisinin Resistance Containment Plan, 2011

throughout Myanmar to rapidly replace artemisinin monotherapy with highly subsidised QA-ACTs[3].

An independent research team was tasked with evaluating the DFID / BMGF/ Good Ventures-funded AMTR Project in Myanmar, and in addition to this role, produce a series of working papers and case studies on areas of the project that provide valuable learning for project implementation, the internal stakeholders, and indeed the wider malaria community. This case study is one in a series of papers, looking at the specific target area of malaria transmission reduction through use of the drug primaquine (PQ).

[3] Outlet Survey: Baseline Study The Republic of the Union of Myanmar 2012 Survey Report

2. BACKGROUND

In May 2013, DFID contracted an independent evaluation of the project *'Replacement of malaria monotherapy drugs in the private sector to support the containment of drug resistant malaria in eastern Burma'* shortened to the 'Artemisinin Monotherapy Replacement' Project (AMTR). The project started in March 2012 and was originally to end in December 2014, but has now been given an 18 month no cost extension. The independent evaluation team led by Montrose conducted an inception review of the project in two phases, respectively in June and July 2013. Building on the findings from these two field visits, and further discussions with members of the evaluation steering committee, the independent evaluation team identified several thematic issues for case studies and working papers which are intended to highlight and present specific aspects of the evaluation to broader audiences, and complement the monitoring and evaluation work of PSI. Since the private sector is a key element (in addition to a range of public sector interventions) to comprehensively tackle the issue of artemisinin resistance in Myanmar, it was felt that a case study on the role of the private sector in containing resistance to artemisinin in Myanmar can provide answers to several key questions including:

- *Why is the private sector critical to the containment of artemisinin resistance in Myanmar?*
- *How are private sector stakeholders being engaged in the programme and what support is being provided? What has been the response so far?*
- *How does the project define sustainability and what roles are expected to be played by the private sector and other stakeholders in Myanmar for sustaining project interventions for the containment of resistance?*
- *Are the interventions undertaken by the AMTR project sufficient in achieving sustainable containment of the resistance to artemisinin? If not, what more could be done?*
- *What are the lessons learnt with respect to engagement of the private sector, especially in conditions where it might be essential for the project to perform some of the critical roles of supply chain development, market promotion and quality assurance? To what degree, is the private sector required to undertake these roles beyond the programme period?*

To gather information that could be used to answer these questions, a field visit was undertaken by an independent evaluation team in February 2014. This case study summarizes the key findings and conclusions.

2.1. Methodology

Data and secondary literature shared by PSI were extensively reviewed in addition to relevant documents collected through online research. The author conducted several interviews with key members of the PSI team including the Senior Malaria Technical Adviser for the Asia Pacific of PSI.

In depth interviews were conducted with the executive committee members of the Myanmar Pharmaceutical and Medical Equipment Entrepreneurs' Association (MPMEEA), senior management of the private sector partners of the project (AA Medical Products and Polygold), senior staff of NGOs and projects working on malaria control in Myanmar, representatives of the Vector Borne Disease Control (VBDC) programme of the Myanmar Ministry of Health, and the Department of Food and Drug Administration (DFDA). Further interviews were conducted with wholesalers and retailers in the markets in Mandalay to assess the current status of the anti-malarial market. The author also interviewed pharmaceutical companies and medical equipment distributors who are not directly involved with the project but are being impacted by project interventions. This includes Mega Pharmaceuticals, one of the leading manufacturers, importers and distributors of pharmaceutical products in Myanmar. Field findings were triangulated with findings from the secondary literature review to derive the key conclusions presented in this case study. The list of respondents is attached at Annex 1. The secondary literature reviewed in connection with this study is presented in the bibliography.

2.2. Scope

The AMTR project is still being implemented and therefore the conclusions in this case study are valid for the interim period at the time of writing. Some of the conclusions from this case study will be further reviewed and presented by the evaluation team under the case study topic 'replacement of artemisinin monotherapy with ACT in the private sector in Myanmar – what works and what makes it work' which will present the key findings of the independent evaluation at the end of the project. The current study provides some key insights on the potential long term role of the private sector.

2.3. Structure

The key findings are presented in section 2. For clearer analysis and presentation, the findings follow the order in which the case study questions are presented in the background of this section. Section 3 summarises the key conclusions derived from the study.

3. KEY FINDINGS

3.1. Rationale for intervening in the private sector

Myanmar is on the frontline of the *P. falciparum* resistance to artemisinin reported in the Greater Mekong Sub Region. Pockets of resistance were discovered in Myanmar in recent years and include south-eastern Tanintharyi Region near the Thai-Myanmar border, neighbouring Kayin State and the highlands of eastern Shan State[4]. Myanmar has the highest malaria burden of the four countries (Myanmar, Thailand, Cambodia and Vietnam) that are affected by the emergence of the resistance. Over 40 million people, or an estimated 69% of the Myanmar population, reside in malaria endemic areas and 24 million live in high transmission areas[5]. Around 70% of the confirmed cases of malaria in Myanmar are reportedly caused by *P. falciparum* (WHO, 2012). The country has an extensive migrant population working in mining and plantation areas along porous borders shared with Thailand, India, and Bangladesh. Myanmar is thus recognised as a potential 'Gateway' for the spread of *P. falciparum* resistance to artemisinin. If the resistance were to reach Africa, which has the world's largest burden of malaria, the global progress in malaria control will be severely affected and the lives of millions of children will be threatened. It is in this context that the Myanmar Artemisinin Resistance Containment (MARC) framework was established in 2011 in line with the Global Plan for Artemisinin Resistance Containment (GPARC) by the Myanmar Ministry of Health and key development partners in Malaria control. The AMTR project implemented by PSI aims to contribute to the overall MARC framework primarily through engagement with the private sector.

The AMTR project focuses on private sector supply chains to ensure rapid and nationwide supply and use of Artemisinin Combination Therapies (ACTs) and Rapid Diagnostic Test (RDT) kits in commercial medicine outlets; meanwhile, the public sector is being engaged to ensure a regulatory environment that can support the roll out and market regulation, in addition to directly implementing relevant interventions in the public health system (especially in the resistance focus areas Tiers 1 and 2). Critical to success is the degree to which the supply and use of oral Artemisinin Monotherapy Treatment (oAMT) can be contained. In 2011, prior to the inception of the AMTR project, the anti-malarial market in Myanmar was estimated to be an average of 100,000 strips of 12 tablets per month, or approximately 1.3 million per annum (PSI, BMGF, DFID MARC Proposal, 2011). The majority of this supply was reported to be oAMT and was supplied and administered by the private sector.

[4] http://www.irinnews.org/report/99852/curbing-myanmar-s-spread-of-drug-resistant-malaria

[5] 2012; WHO Global Malaria Programme: The status of drug resistant malaria along the Thailand Myanmar border

The rationale for the engagement of the private sector in containing resistance to artemisinin in Myanmar during the inception phase of the AMTR project was based on the following contemporary findings:

- There were approximately 5 million fever cases in the population of the PSI target area equivalent to a two-week fever prevalence of 1.8% amongst the general population;
- Of these fever cases, 44% tested positive for *P. falciparum* malaria and 78% of all malaria cases were infections with *P. falciparum;*
- The majority of all cases (>70%) were treated in the private sector;
- Of malaria treatments from the private sector, the majority of treatments given were artemisinin monotherapy and most patients only take a partial dose;
- This low dose artemisinin monotherapy is limited in its effects on malaria transmission and represents a tremendous drug pressure on the malaria parasites enhancing the likelihood of selecting resistant strains;
- Reversing this situation by replacing oral artemisinin monotherapy in the private sector with full treatment courses of Quality Assured (QA) ACTs in combination with increased use of diagnostic tests through the PSI project then significantly contributes to the resistance containment efforts.

From these accounts it is clear that the degree to which the resistance of *P. falciparum* to artemisinin could be contained in Myanmar depended on:

(i) Replacement of oAMT in the private sector with QA ACTs supplied at a price that matches the price of the partial courses of treatment taken by the suspected malaria patients;
(ii) Change in awareness, knowledge and practice of the health care providers and consumers on the treatment of malaria; and
(iii) Use of QA ACTs only on cases verified as *P. falciparum* malaria through adequate parasitological diagnosis.

If implemented successfully, the partnership with the private sector could slow down the resistance and therefore buy global stakeholders the time required to contain the resistance and save millions of lives before new drugs are made available.

3.2. Private sector's engagement in the AMTR project

The interventions undertaken by PSI under the AMTR project aim to replace oAMTs with ACTs in the market, change consumers' awareness and behaviour towards diagnosis and treatment of malaria, and introduce diagnostic testing in commercial outlets. The project's scope is national since its primary purpose is to replace oAMTs with QA ACTs in the market, and the supply of commodities cannot be controlled within a specific territory. However, under the project, PSI places specific emphasis on behavioural change communication (BCC) activities and

product detailing in 93 townships in Tier 1, Tier 2, and parts of Tier 3 areas in Myanmar that are critical to the containment of artemisinin resistance. Also, the distribution system is managed in a way that ensures that regions that are highly vulnerable to resistance are served first. It is pertinent to note that Tier 1 areas represent areas with evidence of artemisinin resistance; Tier 2, areas which are directly threatened by resistance; and Tier 3, the rest of the country.

Replacing oAMTs with QA ACTs in the market: To replace oAMTs with QA ACTs in the market, PSI intervened on two fronts:

(i) *Lobbying for a ban on registration and importation of oAMTs:* Supported by PSI, a ban on importation and registration of oral artesunate was put in place by the DFDA in December 2011 and for oral artemether in August 2012; and

(ii) Working in partnership with the leading oAMT supplier in the market to replace its stock of oAMT with subsidized QA ACTs: In mid-2012, PSI partnered with AA Medical Products, a private sector pharmaceutical product importer/distributor which reportedly had the largest share in the anti-malarial market (70% of total anti-malarials sold in the market) at the time the project was designed, and supported it to distribute subsidized QA ACTs over-branded as Supa Arte, in the market. At the time this study was conducted, plans were finalized to support another distributor, Polygold, to introduce a new brand called Artel +.

PSI plays an important and strategic role in procurement, importation, branding, and marketing of the QA ACTs. The commodities are procured directly by PSI from IPCA Laboratories in India and are a WHO pre-qualified formulation of Artemether-Lumefantrine. The imported ACTs are repackaged and rebranded in Myanmar, in PSI's own warehouse. The repackaging is done with the aim of deterring health care providers from cutting the blister packets and using ineffective single doses. The Supa Arte brand was created to be similar to AA's existing oAMT brand and to distinguish the commodities supplied through AA Medical Products in the market from the commodities supplied by PSI through the Sun Primary Health (SPH) and Sun Quality Health (SQH) Channels. The brand Supa Arte carries the Padonmar quality seal which was created by PSI under the National Malaria Communication Campaign (NMCC) funded by Global Fund Round 9. The Padonmar seal is currently owned by DFDA and it is the nationally approved seal intended to identify quality malarial products. Theo Supa Arte ACTs are highly subsidized (to the value of 80%) so that patients are motivated to purchase these instead of AMTs. The subsidy is provided to the extent that the price of a complete dose of Supa Arte could be brought down to the same market price as a single dose of available AMTs.

Furthermore, PSI recruited and trained 77 product promoters who operate in 64 Townships, selecting different types of health care providers and retailers within

the market, (who are the first point of contact for drugs for malaria patients) and educating them about QA ACTs. They are also tasked with deepening the penetration of the AA supply chain, which is predominantly urban, by extending to more rural locations which are closer to the smaller rural-based retailers, than urban–based pharmacies. The retailers include drug shops, general stores, and Itinerant Drug Vendors (IDV). AA, the private sector distributor for Supa Arte, collects the products from the PSI warehouse and distributes to selected drug shops used as distribution supply points. PSI's product promoters establish the link between the supply point, and the health care providers and drug sellers, participating in the AMTR project further down the supply chain.

From the reports made available by PSI, it appears that the two-pronged strategy of banning the registration and import of oAMTs, and increasing supply of subsidized QA ACTs through the leading supplier of anti-malarials in the market, produced the intended result. The ban had an immediate impact on the market share of oAMTs supplied by AA, since it reportedly dropped from around 70% to around 2% by early 2012. However, as of November 2013, AA procured around 1.2 million courses of ACTs from PSI and was able to regain its market share (PSI, AMTR End of Year Report, 2013). Other developments in the market as reported by PSI include:

- Increase in availability of QA ACTs across private sector outlets (27% to 63%) after only nine months of supply (the time between the first sales of AA in September 2012 and the second outlet survey in June/July 2013);
- Significant increase (from 4.5% to 50.4%) in availability among priority outlet categories (pharmacies, itinerant drug vendors and general retail stores);
- Reduced availability of oAMTs nationwide (down to 36% from 51%);
- Increase in market share (from 3% to 73%) of QA ACTs relative to oAMTs among the priority outlet categories; and
- Sales of QA ACTs 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%) in 94% of target outlets.

Change in consumer awareness and behaviour on diagnosis and treatment: PSI approached consumer awareness and behaviour from several directions;

(i) Building on the Padonmar quality seal created under the MARC framework;
(ii) Training providers on use of ACTs and RDTs[6], the relevance of the quality seal, the ban of AMT, the importance of not splitting drug blisters; and
(iii) A mass media behavioural change and communication (BCC) campaign to educate consumers on the same.

Furthermore, the ACTs were over-branded (Supa Arte) and the packaging changed to deter providers, as well as consumers,

[6] To date, the scope of the RDT intervention is limited to the pilot area of 6 Townships in Shan and Mon States.

from cutting the blisters and using single instead of complete doses. The private sector partner of the project, AA Medical Products, does not have any direct role and investment in the interventions other than the fact that the packaging of the Supa Arte brand was created to closely match the oAMT that was supplied by AA Medical Products prior to the introduction of the brand. The ownership of the Padonmar quality seal is now transferred to MoH and the stickers are availed from the DFDA, under MoH by any private or public sector supplier of QA ACTs in Myanmar. PSI has also made available a frequently asked questions (FAQs) document and general guidelines for the use of the Padonmar seal by interested parties and the guide has been disseminated through the DoH, DFDA, WHO, and INGOs in Myanmar.

As reported by PSI, 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% as of September 2013. The result has been reported as less than satisfactory and is attributed to overall decline in fever incidence which might have affected sensitivity towards communication on malaria. In addition, PSI feels that better targeting of BCC interventions could have facilitated reach to populations in remote and rural ethnic groups which might have been beyond the reach of the current campaign. PSI also associated these challenges with the less than satisfactory achievement on increasing the 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%).

The key achievement of the project with regards to behavioural change, as reported by PSI, has been on the percentage of suspected malaria cases that are now more likely to receive QA ACTs (61%), receive a full course of QA ACTs (77%), and complete a full course of QA ACTs (35%). The baseline of these three indicators was reported as zero. PSI is currently planning a phase 2 communication campaign that will focus on encouraging rapid diagnostic testing prior to treatment. However, the roll out of the campaign was subject to the planned scale up phase of RDTs which was due to begin in January 2014, but as at June 2014, has still not commenced.

Introducing diagnostic testing in commercial outlets: PSI implemented the RDT intervention in six Townships as a pilot and the results were being scrutinized at the time this study was conducted. The RDTs imported by PSI are distributed to selected supply points (usually pharmacies or drug shops) in the Townships. The IDVs and drug stores that are participating in the RDT pilot are introduced to the supply points by the PSI product promoters and Inter-Personal-Communicators (IPC), who visit the supply points to collect the RDTs. Currently there are around 11 IPCs working in the field to promote use of RDTs amongst consumers and refer them to the outlets supplying RDTs. The intention is for the IPCs to be disengaged after the pilot and replaced with mass media behaviour change communication when the program is scaled up. In addition to the IPCs there are around 24 product promoters who support product marketing i.e. educate and train retailers on how to stock and utilise the RDTs with customers.

PSI tested three different incentive models separately in the pilot townships, during the pilot stage. All three models build on the core incentive - resupply to the providers at 100 Kyat/RDT ($0.12), upon receipt of a bag of used RDTs. This core incentive is called Arm 1. In Arm 2, PSI tested an additional financial incentive to Arm 1 in the form of either a free/ promotional RDT for every five RDTs purchased at resupply, or a free course of adult malaria treatment. This financial incentive of Arm 2 is replaced in the third model, Arm 3, with provision for twice-monthly intensive support visits (spending more time with the providers during each visit) to all target outlets (incorporating one on one discussion, resupply with printed IEC materials, role-playing with the provider on how to convince new patients to use RDTs, and practice using RDT on a patient or volunteer).

A study on the effectiveness of the different arms of the incentive models was conducted by the University of California, San Francisco (UCSF) in early 2014. At the time of the field visit, conducted in relation to this case study in February 2014, the key findings were available and shared by PSI with the evaluation team. From the presentation of the findings it was gathered that both Arm 2 and Arm 3 produced good results with Arm 3 being comparatively better with respect to improving behaviour of the providers and ratio of use of RDTs to ACT (2:1). However, Arm 3 was reported to be expensive because of the extensive visits that needed to be undertaken by the Product Promoters employed by PSI. At the time the study was conducted, PSI commissioned research on cost effectiveness of the models and intended to take the results to the MoH to obtain the go ahead in favour of a combined approach of Arm 2 and Arm 3. The scale up phase, yet to be initiated, was aimed at rolling out RDTs to 40,000 outlets that were being served by AA Medical Products for QA ACTs.

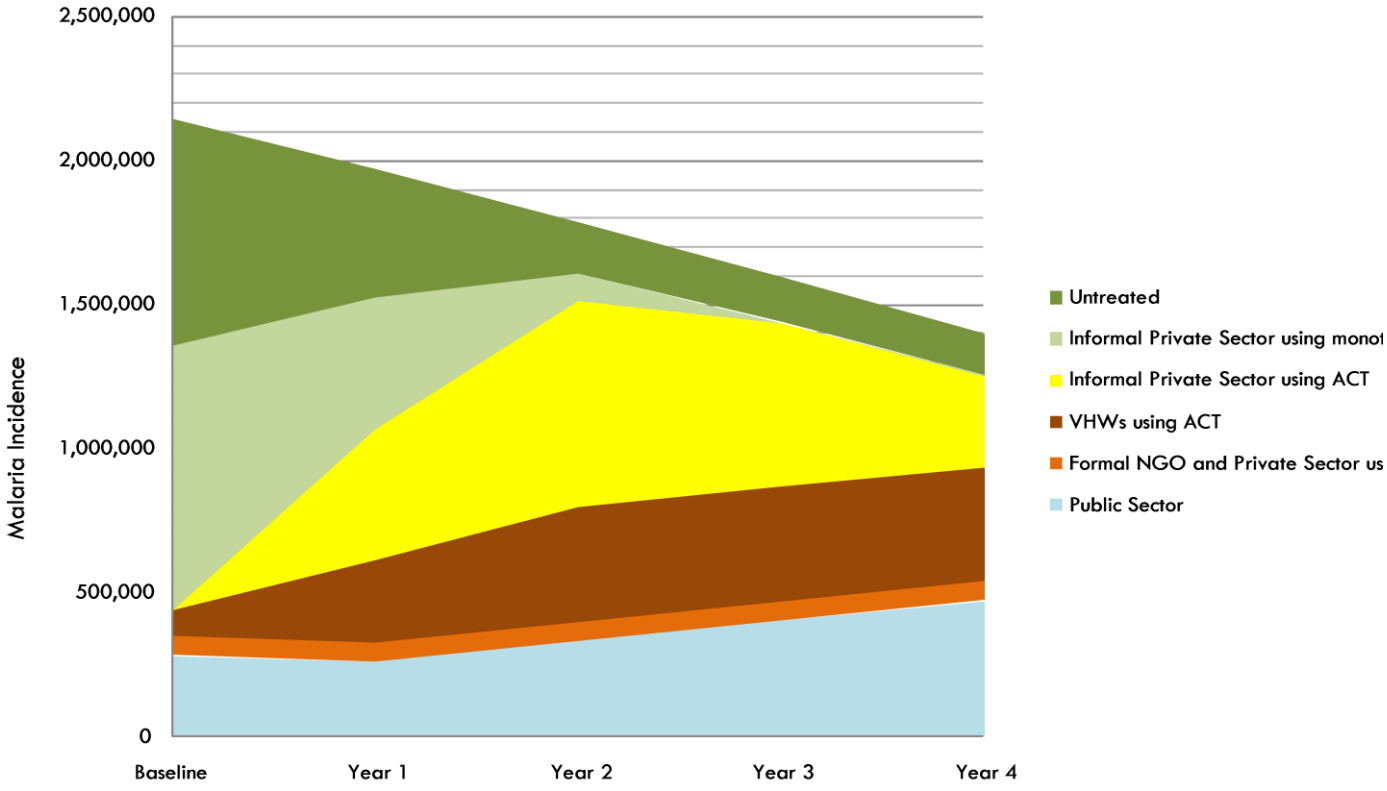
3.3. Sustainability of the containment of resistance to artemisinin

The containment of resistance to artemisinin in Myanmar is subject to use of complete courses of ACTs for cases diagnosed with *P. falciparum*. It is thus critical that the overall supply of ACTs - public and private sectors - is sustained at a level that matches the total number of diagnosed *P. falciparum* malaria cases in Myanmar. With the increase in appropriate use of ACTs and RDTs, it is expected that the total number of *P. falciparum* malaria cases will gradually decline to a stage where the private sector will not have enough economies of scale to sustain nationwide distribution through commercial channels. At that point, the public sector and the NGOs in Myanmar would become the key drivers to sustain the containment of the resistance. Under the MARC framework, several other donor funded programmes are working with the government agencies to increase the overall capacity for diagnosis and treatment of malaria in Myanmar through training and provision of volunteer community health workers (VHWs) and basic health staff. The interventions implemented by PSI can thus be taken as a mechanism to delay the spread of the resistance to allow the time required for

the transition from a predominantly private sector driven health system to a health system primarily governed and served by the government and NGOs. This is demonstrated in the time limited intervention model developed by PSI (Figure 2).

It should be noted that the model reflects the use of ACTs in treatment of *P. falciparum* malaria rather than the supply of ACTs in the private channels. As can be seen in the model, PSI assumes that in four years from inception of the project's interventions, there will be a gradual decline in the number of untreated cases of malaria and the use of monotherapy and ACTs by the informal private sector (IDVs, General Retail Stores etc). On the other hand, there will be a gradual increase in treatment of malaria by public sector, VHWs, the formal private channels (for instance the hospitals and clinics) and the NGOs. With the gradual decline in use of ACTs in informal channels, it is expected that the private sector importers and distributors will observe a gradual decline in sales of ACTs which will lead them to reduce import and distribution in private channels and focus more on institutional channels (private hospitals, NGOs, public sector etc.).

Figure 2: Modelling a time limited intervention for containment of artemisinin resistance in Myanmar Source: PSI



The time limited model thus articulates that the sustainability of the containment of resistance to artemisinin is not necessarily dependent on the private sector's capacity to sustain commercial distribution of ACTs beyond the AMTR project. However, it is not clear at what point, or how long it will take, for the market to reach the stage where the role of the private sector in containing resistance to artemisinin will become less important. Our evaluation suggests that the market has not reached that stage yet. This is further reviewed in the following section.

3.4. Efficacy of the interventions undertaken by PSI

The interventions undertaken by PSI have facilitated increased access and use of affordable QA ACTs through private sector outlets. This might have slowed down the spread of resistance, but sustainability of the containment is dependent on certain other critical success factors. Building on the findings in this review, we conclude that the sustainability of the containment of the resistance to artemisinin in Myanmar will depend on:

(i) The degree to which re-supply of oAMTs can be prevented after project support, especially the subsidy on QA ACTs, is withdrawn;
(ii) The degree to which the private sector is willing to maintain supply of ACTs while increasing the supply of RDTs; and
(iii) The degree to which the public sector has the capacity to make diagnosis and treatment accessible, available and affordable to vulnerable populations (including gametocidal treatment with primaquine).

PSI lobbied the DFDA for the enforcement of the ban on registration and importation of oAMTs in Myanmar. According to PSI, its interventions have elevated the capacity of the DFDA with respect to coordination and regulation. PSI also organized a national event with the DFDA to disseminate notification of the ban on registration and import of oAMTs in Myanmar. The Padonmar seal has been transferred by PSI to the MoH and DFDA is authorized to approve the seal for any agency or private sector distributor supplying QA ACTs in Myanmar. A frequently asked question (FAQ) document along with a guideline on the use of the Padonmar seal was developed in English and Burmese and is now available from the DFDA. Despite these efforts, several challenges were identified during the case study field visit, on enforcement of the regulation on registration and ban on import of oAMTs, and the use of the Padonmar seal.

Discussion with the DFDA and the executive members of Myanmar Pharmaceuticals and Medical Equipment Entrepreneurs' Association (MPMEEA) revealed that the ban is on renewal of licensing for registration and importation. As per the regulation of DFDA, registration is valid for five years and import licenses are valid for three years. It is therefore possible that a company that received renewal of importation for oral artemether in 2012 prior to the ban, has a license that is valid until 2015. PSI reported widespread availability of artesunate marketed by a distributor called Liberty. The brand was found largely available with the wholesalers and retailers in the markets in

Mandalay, where it is being retailed for the price of 1300 Kyat/strip. Interestingly, these outlets were selling higher volume of artesunate (about 500 strips/month) in comparison to Supa Arte (about 300 strips/month) even though Supa Arte was being retailed for around 250 Kyat/strip. Further investigation revealed that the Supa Arte was expiring in April 2014 and AA Medical Products supplied the available stock for free. Discussion with PSI revealed that the order was placed in early 2011 for procurement of 1.2 million doses of ACTs at a time. Subsequently the supply to AA got delayed due to a delay in signing a formal agreement between PSI and MoH, and the stocks thus reached expiry before the market had time to consume the entire volume supplied. In addition, the ordering of a large volume of stock at one time and subsequent declining transmission rate have also led to slow consumption of the ACTs supplied to AA.

It thus appears that the expiring stock of Supa Arte, along with the confusion on the ban on oAMTs, created a gap in the market that was being capitalized by Liberty. It was not possible to verify whether the artesunate marketed by Liberty had a valid registration and import licence, since the DFDA was not able to provide a list of companies with valid registration and import licences. The DFDA was also unable to provide any documentation on the policy related to the ban. Executives of MPMEEA reported that the ban was communicated verbally and they never received any documented copy of the policy. MPMEEA also reported that despite the ban, the MoH continued to procure monotherapy for public hospitals. The military of Myanmar has a Good Manufacturing Practice (GMP) certified pharmaceutical plant. Even though it is now producing ACT formulation and reported that it has stopped the manufacture of oAMTs, the artesunate produced by the military was found available within sampled pharmacies and was being retailed for 3800 Kyat/bottle of 100 tablets.

There is also confusion amongst public and private sector stakeholders on the use and ownership of the Padonmar seal and the Supa Arte brand. Mega Pharmaceuticals, which is one of the five leading pharmaceutical companies in Myanmar, was not aware of the fact that the seal is available for any distributor that has an approved QA ACT. DFDA was also not actively communicating that the seal is available. On the other hand, AA Medical Products, the key supplier of the QA ACTs in the market, reported that they were not clear whether they owned the brand Supa Arte and whether it could be marketed beyond the AMTR project and without project support. There is also confusion about the prospect for ACTs if the project support and subsidy are withdrawn. AA does not have a commercial incentive to continue the supply of ACTs and stated that they had approached this intervention from a CSR perspective, helping them to gain credibility but not leading to them making losses on the sales of the commodities. If the project support is withdrawn, they are concerned that they might start to lose money on the distribution of the commodity. There is thus an apprehension that discontinuation of the programme will lead to a reduction in the supply of QA ACTs through private channels. Considering this in combination

with the known treatment seeking behaviour of consumers, alongside porous borders, an illegal drug trade and regulatory barriers on renewal and registration, a concern is that counterfeit anti-malarials and oAMTs in general, may take over the market when the project ends.

Also of concern is the fact that the RDT roll out is yet to take place, even though the pilot has yielded satisfactory results with respect to positive skills and behaviour shown by front line providers including IDVs. It is essential that RDTs are gradually scaled up to match the gradual decline of ACTs in the market due to a reduction in fever cases and confirmed numbers of malaria cases. Such quantification is difficult, unless and until, the whole population of Myanmar is exposed to diagnosis and treatment under a controlled environment. The other option is to rely on the private sector, which would depend on its sales data for placing future orders. Moving forward, PSI intends to reduce the order size for ACTs, procure in smaller lots, and rely on sales forecast data of AA and Polygold. Again these steps require time, and the 18 month project extension is thus essential in enabling adequate time for the market to adjust to the demand for RDTs and ACTs in the private sector.

It is important for PSI to be aware of the large volume of RDTs being rolled out by the public sector and INGOs in Myanmar, since this affects the volume that can be deployed through the private sector. In our discussion with the major RDT importers and distributors in Myanmar, it was reported that the demand for RDTs was increasing because of public procurement, and the public health market as opposed to the private market is expected to be the major driver for RDTs. There is concern about front line providers' capacity to conduct RDTs and the distributors' capacity to supply the commodity in rural areas without a significant investment in product promotion and training of retailers.

AA Medical Products reported that they are not interested in distributing the RDTs through their own channels since it would be cost prohibitive (because of the requirement to train large number of health workers in the private sector on the front line). In such a context, it is clear that the AMTR project and PSI will have a substantial role in RDT deployment to ensure that the front line providers are trained, have access to QA RDTs that can provide accurate results, and that RDTs are affordable through appropriate subsidisation. PSI was yet to decide on the price subsidy, the model to engage the private sector in the distribution of the commodities, and on scaled up training for the informal providers, as it was still waiting for policy agreement and approval of the scale up strategy from the MoH.

3.5. Lessons Learnt and Key Conclusions

This review of PSI interventions on engaging the private sector in containing the resistance to artemisinin in Myanmar reveals that:

The private sector has a limited long term role in front line distribution of ACTs and RDTs in Myanmar: From the case study, we can conclude that the role of the private sector in containment of resistance to artemisinin is limited in the long term since the market is expected to shrink to the level where commercial and large scale distribution might not be feasible. In our interview with AA Medical Products, it was clear that the company approached the intervention from a CSR point of view. The company did not have a commercial incentive to take a lead role on commodity procurement, over-branding and market promotion for two reasons:

(i) The share of anti-malarials in the overall portfolio of the company was too low (even though it had the largest share of the national anti-malarial market; and
(ii) With increasing public expenditure on malaria control and reduced fever incidence, the market for anti-malarials is forecasted to decline further, particularly once RDTs are introduced and only diagnosed cases are treated (it is suspected that most of the current QA ACTs are not actually treating *P. falciparum* infections). The private sector will however have a continued role in commodity import and institutional sales, since much of the commodities are expected to be distributed through the government, NGOs and development partners who would procure from local or international suppliers in the private sector.

The project and implementing organisation were able to improve and speed up delivery by leading from the front: The AMTR project was designed to rapidly drive out oAMTs from the market with an increased supply of subsidised QA ACTs. Evidence to date suggests that there has been an increase in supply of QA ACTS and that even though oAMTs are yet to be driven from the market completely, their supply has been reduced. The project was largely able to achieve this through PSI's assumption of the lead role on commodity procurement, import, over-branding, market promotion and price subsidy. The progress achieved would have slowed down if PSI had relied solely on the private sector to perform these activities, since the private sector did not have the long term incentive to do so. It was thus a good strategic decision to limit the role of the private sector to distribution only. It is pertinent to note that PSI specialises in commodity procurement, quality assurance and BCC for commodities, including anti-malarials and diagnostics, and also has a long term presence in Myanmar and therefore institutional knowledge about the market. The project was thus able to successfully build on these capacities of PSI. If these internal capacities had not been present, the project would have had to outsource from the private sector, potentially increasing the cost of interventions and slowing down progress.

The private sector is critical to establishing the foundation for containment: Though the AMTR project and PSI led from the front, the private sector was critical to the successes achieved so far, as it was through the distribution capacity of AA Medical Products, and the ban on import and registration of oAMTs in the private sector, that a large volume of ACTs could be deployed in the market. The project in this case, essentially takes a systemic lens on assessing the market, and recognizes the current and long term role of the private sector. If the subsidized ACTs and RDTs were distributed through public channels or directly by PSI, in conditions where the market was dictated by the private sector, the subsidised ACTs and RDTs could have quickly flooded the market and incentivised unregulated use of the commodities. This would have intensified the risk of resistance.

Multi stakeholder intervention is essential for the containment of resistance to artemisinin: Whilst the focus of the AMTR project is on rapid and large scale distribution of ACTs and RDTs through the private sector in Myanmar, this case study suggests that it is essential to engage wider stakeholders (for instance relevant government agencies, other projects and NGOs working under the MARC framework) in the interventions. Table 1 illustrates how the private sector, the project and wider stakeholders have so far participated in the containment of the resistance to artemisinin under the AMTR project and what roles are envisaged for them after the project support is withdrawn.

It is essential to work on a transition strategy in order to ensure a sustainable outcome for the containment efforts: The AMTR project was designed to dry out the market for oAMTs as quickly as possible and allow time for strengthening of the public sector (which is being undertaken under the overall MARC framework). Whilst the 2011 MARC survey suggests that the public sector is the major source of anti-malarials in Tier 1 areas (67% vs. 31% seeking care in the private sector), the private sector continues to be a major force in the national market for anti-malarials in Myanmar. If the subsidy that is being provided under the AMTR project is withdrawn, it is likely that AA Medical Products will reduce the supply to the degree to which its share is limited to urban markets and health care facilities.

This is evident from the fact that larger pharmaceuticals in Myanmar, like Mega, continue to maintain a small share in the market by targeting both urban pockets, and public and private health care facilities. Polygold, the other distributor that is expected to receive the subsidy and market promotion support from PSI, was yet to introduce its product into the market when this study was conducted (anticipated start date in July 2014). Polygold reported that they were already shifting their investment to other commodities since the market for anti-malarials has been shrinking. Both the private sector and public sector stakeholders appeared confused about the scope of the ban on registration and import of oAMTs in Myanmar. This has led to the import of fresh stocks of oAMTs that are being distributed and retailed in the market. There is thus a high risk that the

share of oAMTs and also counterfeit anti-malarials will increase again once the AMTR project ends.

PSI has now received approval from DFID for a no cost extension of 18 months. This case study suggests that the no cost extension would have a positive impact on the containment of the resistance to artemisinin in Myanmar. Moving forward, PSI will have to put a greater emphasis on collaboration with public sector stakeholders (MOH, VBDC, FDA) and other INGOs working under the MARC framework, to increase awareness about the ban on registration and import of oAMTs, regulation of the market, and use of the Padonmar quality seal for QA ACTs. The scope of partnerships with the private sector could also be expanded to include MPMEEA which can play an important role on supporting the DFDA to regulate the distribution of oAMTs, and also create awareness amongst its members around the ban on registration and importation of oAMTs, the MARC framework and its impact on the private sector. This would enable the private sector to have greater clarity about the direction in which the market is moving and also help PSI to facilitate the market in making the transition from a predominantly private sector driven market to a public sector led market as illustrated in PSI's model for *time limited intervention for the containment of artemisinin resistance*.

The no cost extension is also relevant for the transition as it allows adequate time for the scale up the RDT intervention, which is critical to the containment strategy. During the review, it was found that the private sector was not clear about its role in the distribution of RDTs and emphasized that PSI has to take the lead role on the distribution, provider training and market detailing. The no cost extension could help PSI demonstrate to the private sector its role in distribution of RDTs along with ACTs. This will facilitate deployment of RDTs to the scale in which it can drive down the sales of ACTs and therefore, allow the market to reach a point where the public sector assumes the lead for the diagnosis and treatment of malaria in Myanmar.

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5. ANNEX I

Table 1: *An illustration of how the private sector, the project, and wider stakeholders have so far participated in the containment of the resistance to artemisinin under the AMTR project*

Stakeholder	Before the project	During the project	Post Project
PSI/ AMTR	NA	- Lead role in commodity procurement, packaging, over branding, BCC/ market promotion - Lobbying for ban on oAMTs - Capacity building of FDA to regulate the market - Transfer of the ownership of the Padonmar quality seal to MoH - Dialogue and coordination with other programmes/development partners working under the MARC framework - Monitoring and evaluation, reporting and communication of results - Contribution to the development/ update of the MARC strategy	- Subject to approval and design of new project
Private sector Pharmaceutical Companies (directly participating in the interventions)	- Procurement/ import - Packaging, branding, distribution, product detailing - Supply to both institutional and consumer market	- Distribution - Coordination with the project to report progress - Engagement with the project on policy discussion and dialogue about future roles	- Procurement, import (limited scale) - Packaging, branding, distribution, product detailing (limited scale) - Supply limited to institutional market with presence in small pockets (urban) in the consumer market
MoH/ FDA	- Market regulation, registration of drugs, issuance of import licence	- Ban on import and registration of oAMTs - Surveillance of the resistance - Coordination with PSI and development partners on monitoring progress,	- Surveillance of the resistance - Supporting public health facilities for diagnosis and

	- Lead in developing the MARC strategy - Coordination with development partners on implementation of the MARC strategy	communication and update of MARC strategy - Building capacity of public facilities for diagnosis and treatment of malaria	treatment of malaria - Continued collaboration and engagement with development partners on implementation of the MARC strategy
Donors and development partners (beyond the AMTR project)	- Support to MoH on development of the MARC framework - Funding of projects - Design and implementation of projects	- Coordination for monitoring and reporting progress - Support to update MARC strategy - Support for surveillance - Building capacity of public facilities and informal providers for diagnosis and treatment of malaria - Commodity procurement and distribution within the designated territory - Use of the Padonmar seal on QA ACTs	- Coordination for monitoring and reporting progress - Support to update MARC strategy - Support for surveillance - Building capacity of public facilities and informal providers for diagnosis and treatment of malaria - Commodity procurement and distribution within the designated territory - Use of the Padonmar seal on QA ACTs

6. ANNEX II

6.1. List of Respondents

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