

Annex 4: Updated Risk Matrix for AMTR Project

Net risk at output or outcome level	Triggers	Mitigation actions	Residual probability (H/ M/ L)	Residual impact (H/ M/ L)	Direction of travel (Increasing/ Decreasing/ Static)	Within appetite (Y/N)	Management action (Tolerate/ Treat / Terminate/ Transfer)	Owner
The risk statement	What will make it to happen/materialise?	What the programme does to mitigate the risk?	Probability of the risk to happen after mitigating action High/Low/ Medium	Impact of the risk if happened after the project has done mitigating action) High/Low/ Medium	Increasing/ Decreasing/ Static	Yes/No	Tolerate (accept) (Or transfer e.g. using insurance Or terminate the programme Or treat – do something about it)	Who is responsible to manage it
Risks related to external conditions								
Negative environmental conditions	The risks & challenges associated with debilitating infrastructure, communications and weather patterns within Myanmar	Ensure continued attention to flexible project management, guided by local decision making on the ground Increased financial resources and improved communication	Low	Low	Decreasing	Yes	Tolerate	PMD
Exchange rate fluctuation	The cost in proposal is in USD and DFID grant is in GBP. The programme was budgeted in dollars. Over the past few weeks, there was a significant exchange rate fluctuation which may have impact in the burn rate.	PSI will monitor the exchange rate impact on the programme intervention and take necessary actions. The dollar:kyat exchange rate does not affect offshore costs, in particular the costs of drugs and commodities, but will have an impact on operations costs in country.	Medium	Medium	Static	Yes	Tolerate	Finance

Government re-structuring and decentralization of authority to lower levels	In the new government structure, there is a central government and 14 local governments at States and Regions. This is affecting the approval process as local governments begin to take more decision making power and coordination between central and local government weakens.	<ol style="list-style-type: none"> 1) PSI Myanmar field operation team will ensure careful advance planning for getting approvals for all activities from different levels of governments. 2) Transparent advocacy at all levels to ensure access for program activities 3) To maintain adequate staff levels to maintain effective monitoring, and monitoring plans are considered and crafted far in advance. 	Low	Low	Static	Yes	Treat	Operations, Senior Management, and PMD
Restrictive operating environment	<ol style="list-style-type: none"> 1) Frequent changes in the protocol/policy and importation and registration into the country 2) Lengthy approval processes for drug import clearances and permission for local programming 	<ol style="list-style-type: none"> 1) Ensuring careful advance planning for procurement process and for importation 2) Transparent advocacy at all levels to ensure that the permission are obtained in time 	Medium	Low	Decreasing	Yes	Treat	PMD and Senior Management
Commodity registration and endorsement by FDA	Resource/capacity limitation and bureaucracy within FDA	Build rapport and advocacy with FDA; Advance planning to prevent the delay in registration/ documentation	Low	Low	Decreasing	Yes	Treat	Supply Chain Department
Importation duty for Drugs	The government has recently communicated to PSI that those organizations importing drugs for sale need to pay importation duty. There is no government mechanism for this as all PSI's imports are consigned to the MoH.	PSI will advocate for this decision to be changed by explaining the concept on social marketing. Wording relating to this within the MoU will be generic and meet the needs of the government, PSI and donors.	Low	Low	Decreasing	Yes	Treat	Country Director

Sale Tax for AMTR drugs	According to Government's law (policy?) that private companies/organizations need to pay sales tax for all goods that are sold.	AA raised their concern on this as government may ask to pay sales tax for AMTR drugs, and thus requested to include this in the mark-up of ACT price. PSI agree and support with this request/decision.	Low	Low	Decreasing	Yes	Treat	PMD
Products not reach to targeted (border group)	Security problems; poor transport infrastructure	Communication campaign through mass media with ethnic language Partnership with partners working in border and conflict affected areas	Medium	Low	Static	No, where security conditions deteriorate	Treat for communications; Tolerate for security	Marketing
Continued import/sales of oral AMT in the market	Limitation of resources within FDA and NMCP to control the compliance among private pharmaceutical companies and wholesalers/retailers	<ul style="list-style-type: none"> Advocacy meeting with FDA to carry out vendor education program with support from RAI Participate in the meeting organized by ERAR to form a drug monitoring task force Improved Provider BCC 	Low	High	Decreasing	Yes	Treat	Operations
Theory of Change Model not updated	Goal of AMTR project is contributing to containment of artemisinin resistance within Myanmar. The project was designed based on the assumptions that there would be sufficient funding for public sector and NGO scale up; that malaria incidence would decrease; and the role of the informal private sector would be reduced over time. Thus, any shortfall in MARC & GFATM funding will impact on the goal and the longer-term theory change if not updated.	PSI has secured funding from GF-RAI for 2016, and is expected RAI to continue funding from RAI beyond 2016.	Medium	Medium	Decreasing	Yes	Treat	PMD

Uncertainty of RDT scale up	Current MOHs policy on RDT testing among (informal) private providers is not clear. Thus, MOH may not allow the RDT scale-up in the private sector. This has huge implication on PSI to be able to implement as planned, and to meet the logframe targets (RDT related indicators/targets). Moreover, this will have negative impact on the cost effectiveness of the project. Since PSI has procured RDTs and associated promo materials, assuming that RDT scale-up will be approved; there are also risk of RDT expiry, and budgetary implications.	MOH approved RDT scale under the condition that RDT will be distributed into private sector free. The efficiency of RDT distribution in this model will not be comparable to the distribution through the distributors' private sector supply chain. Therefore, PSI has carry out a careful assessment on the current resources and additional HR needed, territory management plan and the potential outlets for RDT, the anticipated challenges and how to overcome this etc to ensure successful scale up. PSI will start the field work after the advocacy visits and obtaining approval from all States and Divisional health and administrative authorities.	Medium	High	Static	Yes	Treat	PMD and Senior Management
Sustainability of the project and funding gap	Current level of subsidy is high, and AMTR may be seen as a less cost-effective project especially as the malaria burden is declining (in the malaria pre-elimination stage). On the other hand, the expansion of the public sector is taking longer than expected for many reasons. Monotherapy drugs may remain in the market longer than expected due to weak regulation and the long	<ol style="list-style-type: none"> 1) PSI is advocating for obtaining the RDT scale-up approval to avoid ACT wastage and to improve value for money. 2) Closely monitor the level of public sector scale-up, and will consider the options to reduce the level of ACT/RDT subsidy under AMTR project, and will revised theory of change to have an improved projection model for AMTR. 3) Will advocate MOH to apply different policy within MARC Tier 1 vs outside Tier 1 areas (informal providers residing in 	High	Medium	Static	Yes	Treat	PMD and Strategic Information

	border with China, where bulk of monotherapy manufacturers are located. In such situation, although the quantity of ACT/commodities required may be lower than anticipated in the project design phase, the project (and the commodity subsidy) may be required for a longer period which may lead to the funding gap.	<p>Tier 1 area could be forbidden from providing malaria diagnosis and treatment as there is enough public sector providers/village health volunteers, but those outside Tier 1 would continue to be allowed to test and treat);</p> <p>4) Will consider reducing (the intensity of) supportive interventions including BCC activities, overbranding etc in order to reduce the operational costs; Will look for other sources of funding to fill the gap</p>							
Independent emergence of resistance parasite in multiple places of GMS including India Myanmar border	This has resulted in revision of tier stratifications, GMS strategy shifted from containment to elimination of P.f from GMS by 2030.	<p>PSI plan to expand AMTR project outside current project area especially in western border of Myanmar.</p> <p>Surveillance and follow up to every positive case will become critical in the pre-elimination and elimination phase. With the goal of real time monitoring the positive cases in the private sector and integration of data into NMCP, PSI will develop tools to pilot, revise and adapt into DHIS2 system in the coming years.</p>	Low	Low	Decreasing	Yes	Treat		PMD/MIS/ CSD
Risks related to internal conditions									
Commodity Management (Risk of expiring drugs vs Stock out)	Scarcity of data in the project design phase led to incorrect or inaccurate assumptions. Rapid epidemiological changes (declining prevalence). Scale-up by public sector and NGOs.	<p>1) Close monitoring & tracking the epidemiology, ACT demand/distribution in the private sector and the rate of public sector scale-up</p> <p>2) Careful commodity projection and splitting procurement into smaller quantities of multiple shipments</p>	Low	Low	Decreasing	Yes	Treat		PMD & Supply Chain Team

		3) Identified alternative options such as sole-source procurement, having an IQC contract to reduce the procurement lead time							
Budget forecasting (linked to commodity supply)	Unstable or hard to predict commodity projections due to changes in epidemiology and potential blockage of RDT scale-up	Close monitoring and tracking epidemiological trends and routine ACT distribution data; careful procurement planning; tracking the burn rate and informing donors in advance	Low	Low	Decreasing	Yes	Treat		PMD & Finance Director
Drug leakage to military through distributors	Purchasing request for ACTs from military	1) Explicit ToR in the mutual agreement with distributors 2) Close monitoring of distributors' sales through monthly reports and random market visits	Low	Low	Decreasing	Yes	Treat		AMTR Manager
Bulk selling of AMTR drugs to other INGO/NGOs	There is a risk of bulk selling of AMTR drugs to other INGOs and NGOs where some may already receive funding either from DFID or BMGF	Close monitoring the routine distribution report from distributors to check if there is any abnormally high bulk sales from any outlet/area and inform donor and take necessary action	Low	Low	Decreasing	Yes	Treat		AMTR Manager
Competition risk	The monotherapy supply-chain is centralised and vertically controlled by one large pharmaceutical commercial actor. PSI Myanmar hopes and expects that it will succeed in maintaining, and even expanding, the company's dominant position under the proposed intervention. In the short term, this is certainly to be wished for. In the longer term, the risk of this dominance is that price competition fails and	1) PSI reserves the right to offer subsidised product to other distributors. 2) PSI controls the selling prices to different levels of the supply chain as part of distributor contract. 3) Competition assessment was carried out by an external consultant from Office of Fair Trading. 4) As part of the project monitoring, PSI will undertake a competition assessment of the ACT market with the support of	Low	Low	Decreasing	Yes	Terminate		AMTR Manager

	the company's market position allows them (and other market players) to increase margins to the detriment of patients.	<p>the DFID economist to inform a further response to this risk.</p> <p>5) With support from MOH, PSI developed an umbrella quality seal/logo that all partners including private pharmaceutical distributors can access and use for their quality assured ACTs to prevent the risk of one brand/company dominating the market. Consumer targeted national malaria campaign was also launched through a number of media channels to create the demand around quality seal.</p> <p>6) In August 2014, PSI has signed the contract with an additional private distributor which has the strong market profile in the anti-malaria market to prevent market dominance.</p>						
Research results acceptance for policy dialogue	Leadership changes within MOH; Non-involvement of the MOH from the beginning of the study	Intensive advocacy and involvement of MOH since the design phase of the research study; obtaining the ethical approval from local ERB.	Low	Low	Decreasing	Yes	Treat	PMD
Breach of EU rules on aid to Burma.	The risk is that subsidised drugs are provided to a company on the EU sanctions list, or sold wholesale to armed groups including the Burmese military.	The same background checks carried out on the companies will be applied to any other company being considered for distributing subsidised ACTs. PSI will put in place safeguards against the bulk selling of subsidised ACT, especially to armed groups (including the Burmese military).	Low	Low	Decreasing	Yes	Terminate	AMTR Manager
Adopting the quality (Padonma)	With leadership and support of NMCP, PSI	PSI will monitor and assess the acceptability of the quality seal by	Low	Low	Decreasing	Yes	Treat	PMD

<p>seal for QA-ACT by all partners and its sustainability</p>	<p>developed the Padonma quality seal for QA-ACT. National malaria communication campaign was also developed targeting to both end-users and providers to create the demand for quality seal (recommended quality assured ACT for malaria treatment). The purpose is that all partners can access the quality seal to adopt for their QA-ACT to prevent the market dominance by one brand or one company. However, adoption of this quality seal by all partners and its sustainability over time especially when PSI cannot support the logistics is very challenging.</p>	<p>all partners and how it will affect the success/implementation of the project; and will take necessary actions with advice from donors.</p>						
<p>Fraud/mis-use of Promo materials by distributors</p>	<p>While working with the 2 distributors (AA and PolyGold), to create demand and to push sales of the products, a number of trade marketing promotion, demand creation and brand awareness creation activities needs to be carried (such as 10 plus 1 FOC, cash discount and paid merchandising etc). There is possibility that cash discount, FOC and</p>	<p>PSI Myanmar establishes a good reporting system for the distributors that the distributors need to report detail level of activities and promo/cash discount used. Moreover, a dedicated team was formed to closely monitor all field activities of the distributors and to check the consistency and validity of reports. Whenever there is suspect of fraud or mis-use, the team will inform to donors and will take necessary actions.</p>	<p>Low</p>	<p>Low</p>	<p>Decreasing</p>	<p>Yes</p>	<p>Treat</p>	<p>AMTR Mager</p>



promo materials are
inappropriately used by
the sales teams of the
distributors.

