

Management Sciences for Health
Rational Pharmaceutical Management Plus Program
(RPM Plus)

Support to Malaria Control in Tanzania
US President's Malaria Initiative

Revised Work Plan FY 2006

August 2006

Background

Every year, malaria causes 300 to 500 million cases of acute illness resulting in more than a million deaths worldwide of which 80% at least, occur in Sub Saharan Africa. Malaria is a deadly disease that can kill within hours following few days of incubation. Most affected populations are children under five, pregnant women and people living with HIV/AIDS. The economic burden of the disease is quite significant with GDP reduction estimated at 1.3% per person per year in high transmission areas. This is an intolerable human and social tragedy knowing that malaria is curable and preventable disease.

The burden of malaria has been intensified by the appearance of Chloroquine and Sulfadoxine Pyrimethamine-resistant *Plasmodium falciparum* forcing countries to change their first line therapies for malaria. To address this challenge, the World Health Organization (WHO) recommended that all countries, revising their first-line treatment policies for malaria, should opt for a combination treatment preferably an Artemisinin-based Combination Therapy (ACT)¹.

Tanzania is one of the high malaria burden countries in sub-Saharan Africa that has been selected by the United States Government to benefit from the recently launched President's Malaria Initiative (PMI) which seeks to “*dramatically reduce malaria as a major killer of children in sub-Saharan Africa*”². The overall five-year \$1.2 billion initiative intends to rapidly scale up malaria prevention and treatment interventions such as promotion of insecticide –treated nets (ITNs), indoor residual spraying (IRS), prompt and effective case management of malaria and intermittent preventive treatment. The goal is to reduce malaria-related mortality by 50% after three years of full implementation in targeted countries. It is expected that this malaria mortality reduction will be achieved if each selected country can reach 85% coverage of the most vulnerable groups with proven and effective interventions.

In 2005 the US Government conducted a rapid assessment in Tanzania and in March 2006 asked the Rational Pharmaceutical Management Plus (RPM Plus) Program to provide technical support for the implementation of the President's Malaria Initiative in Tanzania. In the context of the national policies, the RPM Plus/President's Malaria Initiative program activities will support the NMCP's ACT policy implementation through private sector distribution of subsidized ACT through the Accredited Drug Dispensing Outlet (ADDO) program, technical support to the Medical Stores Department (MSD) and support to TFDA to undertake adverse drug reaction (ADR) monitoring of ACTs.

RPM Plus is currently providing technical support to Tanzania for the implementation of Artemisinin-based Combination Therapy policies through USAID's Regional Economic Development Services Office (REDSO) for Eastern, Central and Southern Africa (ECSA) but also support the distribution of essential medicines, including antimalarials pharmaceutical through the private sector under the Accredited Drug Dispensing Outlets (ADDOS).

Under PMI funding from USAID Tanzania, RPM Plus will provide support to prompt and effective malaria case management and intermittent preventive treatment in pregnancy, both in the private and public sectors. Using the comprehensive approach proposed in the *Implementation Guide “Changing Malaria Treatment Policy to Artemisinin-Based Combinations”* prepared by RPM Plus in collaboration with the RBM partnership and the Global Fund, this support will contribute to the PMI expected results in the context of the National malaria policies in Tanzania while achieving RPM Plus technical objectives.

¹ WHO (2004). Position of WHO's Roll Back Malaria Department on malaria treatment policy

² <http://www.whitehouse.gov/news/releases/2005/06/print/20050630-8.html>

RPM Plus Technical Objectives and Rationale

The RPM Plus Malaria overall strategic objective “*Strengthened health systems for the appropriate management of malaria*” supports the USAID/Bureau for Global Health (BGH) SO5 “*Increased use of effective interventions to reduce the threat of infectious diseases of major public health importance*”, SO3 “*Increased use of key child health and nutrition interventions*” as well as SO2 “*Increased use of key maternal health and nutrition interventions*”. Activities under each technical objective emphasize both treatments of children less than five years and the management and control of malaria in pregnancy (MIP).

Objective 1: Improve the supply and quality of antimalarials and related supplies

RPM Plus plays a strong role in advocacy for appropriate policies and practices that contribute to the reduction of morbidity and mortality due to malaria. Policies need to be supported by the availability of recommended treatments and mechanisms to access them. A key issue is the procurement and distribution of quality antimalarials in quantities sufficient to meet anticipated demand, both in the public and private sector.

Objective 2: Improve the management and use of antimalarials

Due to increase in parasite resistance against the existing monotherapies, Tanzania NMCP adopted change of policy from SP as first line drug for uncomplicated malaria to ACTs with aim of improving efficacy and delaying development of resistance. In order to have successful implementation of the new policy, appropriate management and use of the recommended antimalarials is essential. This will ensure continuous availability and will curb malaria morbidity and mortality while reducing the development of resistance. Planned Activities

1. Technical Activity Coordination and Monitoring

This activity includes technical activity coordination, workplan development, budget monitoring, progress monitoring, reporting, meetings, and communications with partners and collaborators.

Implementation of the listed workplan activities will be through the MSH/RPM Plus office in Tanzania. RPM Plus is hiring a Senior Program Associate in Tanzania who will work closely and coordinate with the President’s Malaria Initiative team, NMCP, TFDA, and other partners at the national level, and stakeholders at the district level including councils, district medical officers, ward and village executive officers in Ruvuma and Morogoro regions. RPM Plus will coordinate activities with Ifakara Health Research and Development Center (IHRDC). The RPM Plus Tanzania team will be supported by the regional technical malaria team based in Nairobi, and the RPM Plus malaria team based in Arlington, Virginia.

2. Private sector distribution of subsidized ACT through the Accredited Drug Dispensing Outlet (ADDO) program³

Accredited Drug Dispensing Outlets (ADDOs) constitute a network of upgraded Duka la Dawa Baridi (DLDBs) to provide non-prescription and a limited list of approved prescription essential medicines in licensed retail outlets in Tanzania. It is estimated that there are more than 4,600 DLDBs across all districts (mostly in the rural); over 50% more than all public health facilities. Based upon the successful

³ Additional details contained in a concept paper prepared by RPM Plus and submitted to USAID/PMI team- “Distribution of Subsidized ACTs Through Accredited Drug Dispensing Outlets”

pilot implementation of ADDO in Ruvuma where there are about 210 ADDOs are in place, the Ministry of Health and Social Welfare (MOHSW), through the TFDA with support from RPM Plus and MEDA, is expanding the ADDO model into other regions.

There are 210 ADDOs in five districts of Ruvuma region and in Morogoro region there are 67 ADDOs in Ulanga and 140 in Kilombero, with additional ADDOs established in Morogoro region by July 2007. In addition to replicating the basic ADDO system, the program will further develop ADDOs to support other public health interventions such HIV/AIDS, child health and ACT-based malaria treatment.

It is planned that under current USAID Tanzania funding for PMI activities, \$ 300,000 worth of ACT treatment (Artemether-Lumefantrine) will be procured from Novartis for ADDOs. RPM Plus will support the implementation of this strategy through the following sub-activities:

Sub-activities planned:

- 2.1. Quantification of ACT consumption and morbidity data in Ruvuma and Morogoro regions to be used in quantification of ACTs for ADDOs. Share the estimated quantities with PMI team and Private whole seller for procurement purpose.
- 2.2. Assist MOHSW/NMCP, donors and other stakeholders to develop a model/mechanism for determining pricing for ACTs as a basis for pricing policy decisions within the private sector.
- 2.3. Develop distribution plan and map out all distributors for ACTs for ADDO. Conduct meetings with selected ACTs distributors for Ruvuma and Morogoro region to discuss the, distribution, storage, record keeping, pricing and incentives.
- 2.4. Develop and implement commodity tracking for ACTs consumption within the overall ADDO monitoring system. In particular, monitoring for leakage and discouraging the sale of subsidized products intended for rural ADDOs at urban pharmacies or through other illegal channels.
- 2.4. Strengthen the ADDOs' capacities to implement the new malaria policy related to artemether-lumefantrine storage, inventory control, and reporting [trainings and orientation of owners, dispensers and inspectors on the new ACT policy].
- 2.5. Strengthen the ADDO supportive supervision and monitoring system to track artemether-lumefantrine distribution, quality, distributor's performance and rational use in collaboration with NMCP, TFDA, and district authorities.
- 2.6. Implement NMCP communication strategy to promote the access of Artemether-lumefantrine through ADDOs in Ruvuma and Morogoro regions.

3. Provide technical assistance in support of ACT policy implementation to the Medical Stores Department (MSD).

Ensuring an uninterrupted supply of ACTs is crucial to the success of the new malaria treatment policy. The purchase of ACT from Novartis through WHO as well as other antimalarials for public sector has been mandated to MSD by NMCP. MSD will be responsible for customs clearance, storage and distribution of ACTs up to district level.

The initial quantification of first order of ALU was done based on morbidity and average health facilities attendance. The follow up orders will base on consumption figures after two cycles of pushing without feedback from facilities. To have enough data on actual consumption of ACTs, there must be a mechanism that will facilitate the process of getting feedback information from facilities which will enable MSD together with NMCP to quantify the right amount of ACTs needed and distribute accordingly. RPM Plus in conjunction with the NMCP will support MSD by providing technical assistance to enable the efficient quantification and tracking of ACTs.

Sub-activities include:

- 3.1. Review of MSD core operation functions and previous interventions done by other agencies to strengthen MSD capacity to ensure uninterrupted supply of ACTs to public health facilities. Based on the identified gaps, develop specific strategies for technical support.
- 3.2. Develop supportive supervision system and conduct supervision to the facilities that will help MSD to get accurate feedback information from facilities on the ACTs consumptions in the first two cycles of distribution.
- 3.3. Assess MSD database/DMIS capacity in capturing all information regarding ACTs consumption and distribution. Work with MSD to analyze consumption patterns from the collected information and share the information with NMCP and PSU for better quantification.

4. Support to TFDA to undertake adverse drug reaction (ADR) monitoring and also to establish systems to detect unintentional exposure to Artemether-Lumefantrine during pregnancy.

The Tanzania Food and Drug Authority (TFDA) has established drug information unit that has responsibility of monitoring Adverse Drug Reaction (ADR) in the country. The existing ADR monitoring system mainly relies on a passive reporting approach whereby the prepaid ADR forms are distributed to Health Facilities (HF) in the country and the Health Workers (HW) are required to note and record and send to TFDA any suspected ADR. The ADR forms can also be filled online or downloaded from TFDA website.

Apart from drug information center located at TFDA headquarter; there are four other zonal drug information centers which are located in referral hospitals in Muhimbili (Dar es Salaam), Bugando (Mwanza), KCMC (Moshi) and Mbeya Referral hospital (Mbeya). The Authority has facilitated the training of Zonal Drug Information Officers who among other things are expected to encourage reporting and coordinating ADR activities in their respective zones.

With regard to ACT policy, there is limited experience with the use of ACTs in wide scale and hence the safety profile of ACTs is not yet known. The drug is not recommended to be used in the first trimester of pregnant women and to children below 5kg.

Therefore, TFDA pharmacovigilance system will be used to monitor the safety profile of the drug. However; the big challenge with the existing ADR monitoring system is that only a few reports are being received from the zonal centers and health facilities. In order to revitalize the ADR monitoring system, RPM Plus will work with TFDA on the following:

- 4.1. Conduct two days consultative PV meeting to share experiences and lessons learned from ADR monitoring of antimalarials in pregnant women in Ghana and Mozambique. Identify gaps in ADR

monitoring system of ACTs in Tanzania.

- 4.2. Develop and discuss PV implementation plan with NMCP, TFDA and CDC/IHRDC.
- 4.3. Develop strategies to improve surveillance methods and ADR reporting structure at the district level where ADR reports are expected to be generated.
- 4.4. Develop guidelines and SOPs for distribution and collection of ADR reporting forms. Provide training at district level to raise ADR awareness as drug safety issue. Use of SOPs for distribution and collection ADR reporting system.
- 4.5. Monitoring and evaluation of pilots districts PV-intervention.

**Rational Pharmaceutical Plus Program Support to Malaria Control in Tanzania under the US President's Malaria Initiative
Performance Monitoring Matrix.**

Activities	Products	Outputs	Outcomes	Primary HPSS	Secondary HPSS	BGH SO	PAW
1. Technical activity coordination and monitoring	Work plans, budget, reports, communications with staff and partners	Activities planned, budgeted and reported	Effective program implementation, follow up and adjustments based on agreed decisions with partners	IR 1	1.1,1.3	5 5.2, 5.4	C.3
2. Support Private sector subsidized ACT delivery through the Accredited Drug Dispensing Outlet (ADDO) program	<ul style="list-style-type: none"> • ACT quantification report • ADDOs ACT distribution plan • ADDOs monitoring and supportive supervision plan and reports • Training materials and reports for new ACT policy • ACT pricing policy for the private sector report 	<ul style="list-style-type: none"> • Estimated ACT needs will be known to distributors and the program • ACT distributors for ADDO mapped out • RPM Plus, NMCP, TFDA and district authority will provide supportive supervision to ADDOs and monitor their activities • ADDOs owners, dispensers and inspectors will be trained and oriented on the new ACT policy • ACT pricing guidelines will be disseminated to the private sector 	<ul style="list-style-type: none"> • Improved availability, quality and utilization of ACTs because of quantification, following the distribution plan and adhering to the pricing policy. • Improved ACT availability, quality and utilization as because ADDOs activities will be monitored and supervised. • Improved ACT availability and quality because trained ADDOs will apply their skills in the storage, inventory control and monitoring of ACT 	IR 3	3.3,3.1	5 5.4 5.2	C.3

Activities	Products	Outputs	Outcomes	Primary HPSS	Secondary HPSS	BGH SO	PAW
Provide technical assistance in support of ACT policy implementation to the Medical Stores Department (MSD).	<ul style="list-style-type: none"> • Technical report • Supportive supervision plan and reports 	<ul style="list-style-type: none"> • Technical assistance delivered • Supportive supervision system will be used to conduct supervisions 	<ul style="list-style-type: none"> • Improved MSD performance in terms of quantification, ordering, procurement, storage and distribution of ACT 	IR 3	3.3	5 5.4	C.3
Support to TFDA to undertake adverse drug reaction (ADR) monitoring and also to establish systems to detect unintentional exposure to Artemether-Lumefantrine during pregnancy.	<ul style="list-style-type: none"> • Pharmacovigilance(PV) workshop proceedings • PV implementation plan • Revised ADR plan 	<ul style="list-style-type: none"> • PV system integrating ACT ADR s 	<ul style="list-style-type: none"> • The safety profile of ACT will be known as a result of improved ADR reporting system 	IR 2	2.3	5, 5.4	C.3

**Rational Pharmaceutical Plus Program Support to Malaria Control in Tanzania under the US President's Malaria Initiative
Program Activity Matrix.**

Act. #	Activity	Partners and Collaborators	Staff	Travel (Per Diem Days)	Significant Expenses	Total Cost
1	Technical activity coordination and monitoring		D. Keene M. Diara M. Gabra E. Rutta			\$ 50,000
2	Support Private sector subsidized ACT delivery through the Accredited Drug Dispensing Outlet (ADDO) program	TFDA/ NMCP AED/T-MARK Private Pharmaceutical Wholesalers.	R. Mbwasi E. Rutta W. Mlaki.			\$ 190,000
3.	Provide technical assistance in support of ACT policy implementation to the Medical Stores Department (MSD).	MSD/NMCP/PSU TFDA	T. Gladys W. Mlaki M. Salama			\$ 140,000
4.	Support to TFDA to undertake adverse drug reaction (ADR) monitoring and also to establish systems to detect unintentional exposure to Artemether-Lumefantrine during pregnancy.	TFDA CDC/IHRDC NMCP	W. Mlaki D. Tran P. Risha E. Rutta			60,000
Grand Total Cost						\$440,000