

## **Trip to Tanzania to Organize and Participate in the Regional Drug Quality Consultative Workshop, November 3-16, 2006: Trip Report**

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## **About RPM Plus**

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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## **Acronyms**

ACT	Artemisinin-based Combination Therapies
ADR	Adverse Drug Reaction
AFRO	Regional Office for Africa [World Health Organization]
CDC	US Centers for Disease Control and Prevention
DRA	Drug Regulatory Agencies
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
MAC	Malaria Action Coalition
MSH	Management Sciences for Health
NMCP	National Malaria Control Program
RBM	Roll Back Malaria
RPM Plus	Rational Pharmaceutical Management Plus
SP	Sulfadoxine-Pyrimethamine
TB	Tuberculosis
USAID	United States Agency for International Development
WHO	World Health Organization

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## **Background**

Management Sciences for Health's (MSH) Rational Pharmaceutical Management Plus (RPM Plus) Program has received funds from USAID to develop strategies to implement malaria policies and to provide technical assistance in pharmaceutical management issues for malaria. RPM Plus is a key technical partner in the USAID Malaria Action Coalition (MAC), a partnership among four technical partners: The World Health Organization (WHO), working primarily through its Africa Regional Office (AFRO), the US Centers for Disease Control (CDC), the ACCESS Program of JHPIEGO and RPM Plus. RPM Plus also is working to support the President's Malaria Initiative (PMI) in Tanzania, Uganda, southern Sudan, and Angola. This request is to support the participation of RPM Plus in the following activities:

Among the key issues of malaria is the quality of its medicines. Poor quality medicines pose a significant public health problem present a significant barrier to providing proper health care services, often leading to decreased treatment effectiveness, increased morbidity and even mortality, as well as the development of antimicrobial resistance.

To address this issue, RPM Plus (malaria and with partial support from AMR) and USP DQI, in partnership with the National Malaria Control Program and Tanzania Foods and Drug Authority (TFDA), Ministry of Health of the Republic of Tanzania and the World Health Organization (WHO), have organized a regional consultative workshop on quality of antimalarials. The idea of holding this workshop was conceived – and subsequently planned – from extensive discussion with USAID and other MAC partners.

The workshop is intended to be a regional forum to share and exchange ideas on quality assurance (QA) of antimalarials in the context of pharmaceutical management, monitoring the quality of antimalarials as well as general quality assurance (QA) implementation obstacles. The workshop will also provide guidance on technical and other issues related to laboratory quality testing. Workshop participants will include representatives from Ghana, Senegal, Nigeria, Guinea, Mali, Southern Sudan, Zambia, Ethiopia, Madagascar, Zanzibar, Uganda, Kenya and Tanzania. These participants are from the national malaria control programs or drug regulatory authorities in their respective countries.

The key objectives of the workshop are to:

- Share experiences and lessons learned from country QA implementation
- Identify common challenges in QA systems, both technical and managerial
- Identify key elements of a regional approach toward strengthening QA systems

## **Purpose of Trip**

Rima Shretta, RPM Plus Senior Program Associate, Dat Tran, RPM Plus Senior Program Associate, Robert Azairwe, RPM Plus Senior Program Associate and Edmund Rutta, RPM Plus Senior Program Associate traveled to Tanzania to conduct the Regional Consultative workshop on the quality of antimalarials.

## **Scope of Work**

### **Scope of work for Rima Shretta, Dat Tran, Robert Azairwe and Edmund Rutta:**

- Provide technical assistance to the regional workshop participants on quality assurance of antimalarials  
Make presentations and facilitate the regional workshop
- Rima Shretta and Dat Tran are co-organizers of the workshop and will also be involved with administrative arrangements for the workshop
- Provide an arrival briefing and/or departure debriefing to USAID
- Dat Tran will also be involved with following up with TFDA on progress of pharmacovigilance and other related QA activities in Tanzania
- Participate in RPM Plus regional malaria team meeting and the EARN meeting
- Brief/debrief USAID/Tanzania staff as requested

## **Activities**

### **1. Provide an arrival/departure briefing to USAID**

An arrival briefing was not required however; Rima Shretta provided a brief telephone debriefing to Mr. Charles Llewellyn on the Regional Consultative Workshop on the Quality of Antimalarials. It was agreed that a trip report would follow as soon as possible.

### **2. Regional Consultative Workshop on the Quality of Antimalarials**

Thirty-one participants from twelve countries (Ghana, Senegal, Nigeria, Guinea, Mali, Southern Sudan, Zambia, Ethiopia, Madagascar, Uganda, Kenya and Tanzania) attended the Regional Consultative Workshop on the Quality of Antimalarials which took place at the Seacliff Hotel in Dar es Salaam from November 14-16<sup>th</sup>, 2006. Participants were from the national malaria control programs or drug regulatory authorities in their respective countries.

The key objectives of the workshop were to:

- Share experiences and lessons learned from country QA implementation
- Identify common challenges in QA systems, both technical and managerial
- Identify key elements of a regional approach toward strengthening QA systems

#### **Day One**

The workshop began with a welcome and introduction to the workshop by Rima Shretta-RPM Plus/MSH together with an outline of the objectives of the workshop. This was followed by an introduction of the facilitators and participants. Dr Alex Mwita-National Malaria Program Manager/Tanzania addressed the participants and welcomed them to Tanzania. He stated the importance and timeliness of the workshop as countries were moving towards the new artemisinin based combination therapies (ACTs) as first line treatments for malaria. He said that the availability of sub-standard and counterfeit medicines would likely increase due to the high cost of the new ACTs. Mr Charles Llewellyn then said a few words on behalf of the United States Agency for International Development Mission to Tanzania. This was followed by the official opening of the meeting by Dr Raphael Kalinga, the Acting Director of Preventive Services, Ministry of Health/Tanzania.

#### **I. Current malaria trends in Africa**

*Presentation: Malaria treatment: ACTs and related policy issues*

*Presenter: Clive Ondari, WHO/EDM on behalf of Dr Issa Sanou, WHO/AFRO*

Dr Clive Ondari presented Dr Issa Sanou's presentation on the current malaria trends in Africa as Dr Sanou was unable to travel to Tanzania due to an AFRO meeting. The presentation included an update of the treatment of malaria, implementation of drug policies in countries, some challenges, and outlined the way forward.

In 2001, WHO recommended that countries change their treatment policies and adopt artemisinin-based combination therapy (ACT) in response to the increasing resistance. To date, almost all the

countries of the region have adopted ACT policies. The new guidelines recommend that countries change their policies at treatment failure rates of >10% as assessed through monitoring of therapeutic efficacy at 28 days. Countries should use their first line drug at community and home level. If ACTs are adopted as first line they should be used at community level and this implementation needs to be documented by countries. WHO recommends an alternative ACT or quinine + tetracycline or doxycycline or clindamycin for second-line treatment. The presentation also covered some elements of ACT policy and implementation, the global ACT demand and production capacity. WHO has also placed a ban on monotherapies. Some challenges and issues of concern include funding sustainability, procurement and supply chain management, the strategic positioning of new ACTs, improving malaria diagnosis at community level, the use of ACTs at community level with the need to engage and sustain communities in malaria control and the involvement of the private sector to deliver ACTs. He discussed some points on the following way forward which included capacity building.

*Presentation: Quality of antimalarials: pre-qualification and related issues*

*Presenter: Clive Ondari, WHO/EDM*

Dr Ondari discussed that as ACTs were relatively new there was limited information available in public domain. Reference standards not readily available for most ACTs and there are no monographs. There are difficulties of proving “interchangeability” and regulators have limited experience with this group of drugs. Therefore, WHO established a process of pre-qualification of manufacturers of artemisinin-based combination antimalarial drug products. This involves four phases; a preparatory phase which includes drafting of specifications and guidelines and a publication of expression of interest (EOI); a documentation review phase which involves receiving of EOI and screening, assessing, and reviewing dossiers; a plant inspection (GMP compliance) phase and a reporting phase. WHO has published 4 calls for EOI since 2002. 55 applications received and there have been approximately 10 inspections a year. 5 products have been pre-qualified (only 1 ACT). Priority is given to paediatric preparations.

### *Discussion*

The discussion following the presentations touched on various topics related to current trends in malaria in the region, as well as pre-qualification of ACT products. The key points of discussion included:

- Many countries expressed a crucial need for drug management of ACTs, including its quantification and procurement. Many participants mentioned that this is especially complex and challenging, as ACTs have a shorter shelf life compared to other medicines.
- Many countries also expressed a need for more guidance from WHO to pre-qualify more manufacturers. To this point, others countered that WHO can only provide technical assistance for GMP inspection, national DRAs must play a role in making sure that local manufacturers comply with GMP standards.
- Countries also shared their experiences and concerns related to malaria treatment. Several countries expressed interest in home-based treatments. Uganda gave the example of using home-based therapy (chloroquine-SP), which led to a 60% decrease in hospitalization. Other countries (e.g. Mali) questioned whether switching to ACTs

makes sense when i) ACTs are expensive; ii) access to ACTs is difficult; and iii) when chloroquine is still shown to be effective.

## **II. Quality Assurance Systems**

*Presentation: Quality Assurance: The backbone of pharmaceutical management*

*Presenter: Dat Tran, RPM Plus/MSH*

The presentation covered common medicine quality concerns, contributing factors, the regulation of medicines, key QA Partners, the difference between quality assurance and quality control. Some information in testing references and pharmacopeial standards was identified as well as testing methods and laboratory management. There is no set mechanism for designing a QA system. The presentation emphasized some simple low-cost measures to improve a QA system which includes simplifying the registration process, placing a focus on essential medicines, better document reviews for registration, inspection simplifying pharmacovigilance. There was an emphasis on the fact that good QA requires coordination of many pieces.

*Presentation: Development of the national drug policy: Assuring the quality of medicines: case study & lessons learned*

*Presenter: Andrew Nyandigisi, DOMC/Kenya*

The Pharmacy and poisons Board (PPB) and the DOMC have set up a post-marketing surveillance team. They have planned for collaborative studies with National Quality Control Lab (NQCL) to carry out quarterly surveys on the quality of AMs in the market. In addition, the PPB will ensure that all the antimalarials (AMs) in the market are registered. A baseline survey will be carried out in collaboration with WHO to determine the quality status of antimalarials in the country. They have also designed a procedure for product recall awaiting gazette. The Kenya Medical Supplies Agency (KEMSA) has contracted NQCL to do routine QC on the drugs in their warehouses awaiting distribution. NQCL is also in the process of attaining WHO prequalification.

*Presentation: Streamlining Registration*

*Presenter: Anthonia Nakamya, Head, National Drug Quality Control Laboratory, National Drug Authority (NDA)*

The presentation focused on the drug regulation in Uganda, quality assurance measures at NDA, drug registration activities, developments and achievements in drug registration, the new antimalarial drug policy and its implications, implementation of the new policy and the way forward. In Uganda, there is a mandatory analysis of each batch of medicines that are imported. In 1996, the NDA embarked on a drug registration exercise to ensure that all pharmaceutical products intended for use in Uganda meet their intended purpose. This involves an evaluation of drug registration applications (dossiers) and consideration by the Committee on National Formulary (CNF). Recommendations are then sent to the NDA Commission. In addition, the human resource capacity has been recently increased and staff have received training in speciality areas (i.e. traditional medicines, vaccines). Better roles and responsibilities have been assigned to specific areas to ensure continuity and effective management. Systems have also been developed to allow channelled flow of documents, information and communication.

*Moderated Discussion: DRA/NMCP coordination: quality, safety, efficacy of antimalarials*

Much of the discussion revolved around a central theme: maintaining good quality ACTs (and other antimalarials) is complex and requires good quality assurance systems. There are many stages where product quality can be affected. For testing purposes, the national DRA must have both the mandate and capacity to design a suitable testing system to fit the country's environment. Testing and monitoring systems must be in place during both pre- and post-marketing phases. This is important because even good quality medicines can have adverse reactions. Some participants remarked that quality-related efforts must include public communication and education of patients. For example, because of its moisture-sensitive nature, ACTs must be handled properly by patients to prevent product degradation.

Most countries acknowledged a gap in and expressed the need for better coordination between NMCP and DRA. Although in most countries DRA and NMCP are both part of MOH, these two bodies often do not have formal mechanisms for collaboration. In some countries, collaboration is restricted to activities related to pharmacovigilance. As the result of poor coordination, antimalarials (including ACTs) are sometimes introduced to malaria treatment programs before registration and quality status are approved by DRA. However, in a few countries, NMCP and DRA do hold regular meetings to discuss regulatory related issues of antimalarial products, including their registration status, quality, and quality monitoring systems.

## **Day Two**

### ***III. Laboratory Quality Testing***

*Presentation: Tiered testing system – role of central QC laboratory*

*Presenter: Abdelkrim Smine, USP/DQI*

The presentation covered basic testing, the reason for using the basic tests, and lessons learned. A framework on a tiered testing system was presented. Criteria for the selection of sentinel sites and human resource issues such as training were discussed. Procedures on sampling and the handling and testing of samples. The example of the use of basic tests using GPHF Minilab was given with the measures taken by the countries to respond to the results. A major finding was that there was weak law and regulatory enforcement at country level.

*Presentation: Testing at peripheral sites*

*Presenter: Prof. Yérim Diop, PNLP/Senegal*

The presentation outlined the recently developed system of quality assurance of antimalarials in Senegal which was funded by USAID. Equipment was purchased and financial and technical assistance was obtained for training on testing. As a result the studies carried out on the quality of antimalarials were presented by the LNCM at the second SEAM conference in 2003. Assistance on using confirmatory tests for dubious samples testing at the sentinel sites was also obtained. Minilabs were used for testing at these sentinel sites. TLC is also used. In addition, a logistics system has also been implemented as well as a tracking system for registered medicines. Some of the results of the quality testing found that for chloroquine, 85.6% had problems with the amount of active ingredient, about 43% of medicines had more active ingredient and 43% had less. Similar results were obtained with SP, amodiaquine, quinine and artemisinin.

*Presentation: Inspection network*

*Presenter: Agnes S. Kejo, Tanzania Food and Drugs Administration*

This presentation covered inspection and surveillance, the role of inspection in a quality assurance program, the underlying reasons for success and challenges. A network of establishments associated with drug supply and the distribution chain are used for carrying out inspection in Tanzania to ensure the quality of drugs entering or circulating in the Tanzanian market including, ports of entry (POEs), pharmacies and medical stores, accredited drug dispensing outlets (both established and new ones before they are licensed), wholesalers (both established and new ones before they are licensed) and manufacturing facilities overseas ( established) and local (both established and new ones before they are licensed). The activities carried out to facilitate this intervention are; training of inspectors, actual inspection, physical examination, sampling & testing of suspicious samples, reporting and corrective action. Drug inspectors at POE use Standard Operating Procedures (SOPs) and a Personal Digital Assistance (PDA) inspection data logging system to determine quickly if the product has market authorization and a valid import permit, have paid the 2% import levy, if the product has an accompanying certificate (s) of analysis relating to the specific batches of the consignment. They also perform physical examination of the drugs including proper labels and packaging material. Antimalarials (artesunate, Quinine, SPs), ARVs and antibiotics are further subjected to screening using Mini lab kits.

*Presentation: Reports of counterfeit and substandard antimalarials: Examples from Africa, Asia and Latin America*

*Presenter: Abdelkrim Smine, USP/DQI*

The findings of results from assessments of counterfeit and substandard antimalarials from 7 countries in Africa were presented. The study found that both dissolution and content were a problem. In Southeast, at least 5 new counterfeit versions of artesunate have been found in since the beginning of 2006. Approximately 53% of artesunate bought in shops in mainland Southeast Asia in 2004 was estimated to be counterfeit. Fake antimalarials, especially artesunate manufactured in China, that have been circulating in Asia are now showing up in Africa. There are now at least 12 types of fake artesunate with either too little active ingredient or none at all. A USP DQI study on antimalarial drugs in Mekong region in 2003 found that 27% of 451 samples tested were counterfeit.

Some findings on the quality of medicines in Guyana were also presented. There was a discussion on the impact of poor quality medicines and causes of proliferation of poor quality.

*Discussion*

The discussion focused on the implementation of testing and inspection networks to ensure good quality antimalarials. All countries agreed that the use of Minilab (portable testing kits), especially at key ports of entry (POEs), would be cost-effective and offers a good solution for countries without a comprehensive system in place (e.g. some countries currently do not have a national quality control laboratory in place). Minilabs are effective screening tools to detect substandard

and counterfeit products and are also easy to learn. In some cases in Cambodia, illiterate people were successfully trained to use the Minilab.

Participants shared their respective experiences on how Minilab at POEs can be an effective part of the inspection network. In Tanzania, the testing failure rate fell from 15% to about 3% as the result of implementing an inspection network. Overall, the participants expressed concerns over the still very high testing failure rate of antimalarials. It is particularly worrisome, some pointed out, that the failure rate is already quite high for simple antimalarials. This situation could be worse in the future for more complicated formulations. To stem this tide, participants agreed that national DRAs and NQLCs must do a thorough self-assessment to optimize the regulatory structure, especially its ability to take corrective actions, i.e. recall of poor quality products. More critically, there must be strong regional collaboration, i.e. a regional network to share and exchange drug quality information and data, if the problems of counterfeit products are to be solved.

#### **IV. Common quality-related challenges**

*Presentation: Technical challenges: testing methods, reference standards, etc.*

*Presenter: Abdelkrim Smine, USP/DQI*

The presentation discussed that the quality of most of ACTs available in African countries especially in the private sector, are not fully assured. Most African manufacturers do not comply with WHO GMP. In terms of procurement, there are challenges in QC of antimalarial due to a lack of monographs; there are challenges in registration and regulation and in coordination. USP is in the process of updating monographs of SP, chloroquine, amodiaquine and primaquine and developing new monographs for artesunate, artemether, lumefantrine and the combination of artemether and lumefantrine. USP will also develop reference standards for antimalarials. WHO is also in the process of updating some artemisinin derivatives monographs.

*Moderated discussion: Technical challenges*

The participants raised some issues related to the use of monographs from different pharmacopeias. USP DQI remarked that each country should make its own decision about which pharmacopeia is appropriate. The key point is to clearly define and follow the accepted pharmacopeial standards. Furthermore, countries can play a greater role being involved in the development of monographs for antimalarial products. For example, the process used by USP to develop monographs is transparent and allows for technical input.

The discussion also touched on the need for countries to pool technical resources to do collaborative studies (e.g. efficacy studies). Many participants remarked that WHO and donors (including NGOs) can be very helpful in facilitating regional collaboration to overcome many technical challenges. Also, participants agree that, while politically difficult, more efforts must be made to appeal to policy decision makers about the need for proper laboratory and technical resources for appropriate testing and analysis.

*Presentation: Managerial challenges: Monitoring & Evaluation*

*Presenter: Rima Shretta, RPM Plus/MSH*

The presentation outlined that monitoring and evaluation covers two basic issues which are monitoring performance and accountability. Definition, key questions, monitoring by phase; pre-marketing which includes manufacturing, prequalification and registration. Post-marketing includes product testing (surveillance), procurement, storage/distribution, rational use, pharmacovigilance, and monitoring of adverse drug reactions (ADRs). A summary of reporting mechanisms followed and the importance of supervisory visits as a system for monitoring followed. The processes were discussed using the example of procurement. This was followed by examples of problem reporting systems and methods of evaluation. The presentation then went on to discuss evaluation and an example of monitoring of ADRs followed. It was stressed that response is key. The types of response were outlined. Some managerial challenges were discussed, which include human resources, operational system, political and financial issues. A good QA system emphasizes on coordination. This was followed by an outlined some interventions to minimize the flow of poor quality medicines.

A Moderated Discussion on the next steps including what to do with the drug quality data findings (rapid alert systems, enforcement etc) followed.

Most participants agreed that drug quality data and findings need to be disseminated appropriately in order to effect regulatory changes. However, they also agreed that this is a complex issue due to the sensitive nature of the data – they can have broad legal and financial interests for many involved parties. Some participants recommended that instead of individual laboratory personnel, a QA committee within national DRAs should make decisions about what and how data should be disseminated.

The discussion also focused on the need to balance regulatory oversight and market competition (to lower prices). A serious problem facing many countries is excessive number of registered generic products for the same medicine. This situation creates a huge challenge to national DRAs to control the quality of the products and negatively affects its ability to take regulatory actions, i.e. making recalls. Many countries said that applying clear defined criteria is the key to limiting the number of registered products. For example, national DRAs can strictly follow and approve only products that are consistent with national STGs (e.g. not approving mono-therapies if a country has adopted combination therapies as STGs for malaria).

### ***Day Three***

#### **V. Regional Approach to improving QA**

*Moderated Discussion: Regional Approach to improving QA*

- Leveraging technical resources
- Leveraging operational resources

The participants were then divided into four working groups to discuss the key elements in designing QA system focusing on both regional/country level approaches. The groups focused their discussion on the following QA priority areas: selection; procurement; registration; QC; post-marketing surveillance; and pharmacovigilance (ADRs).

#### ***Presentation of QA plans***

A presentation of the working group discussions including the QA plans developed as follows:

### Group 1

For selection, group 1 proposed the following activities to improve the selection process:

- Selection committees with clear selection protocols
- Update standard treatment guidelines and essential medicine list
- Define clear procurement plans
- Training of personnel
- Dissemination and communication of selection process

To improve the registration bottlenecks, including registration of multiple generics of same products, group 1 proposed the following activities:

- Fast track applications for antimalarials, ARVs and anti-TBs
- Data sharing on the newer ACTs at the regional and international levels
- Refer national requirements for indigenous clinical trials
- Stop issuing/reissuing licenses for obsolete pdts
- Limiting license duration
- Implement retention fees
- Harmonize regional registration system, especially CoArtem

To improve procurement, group 1 proposed the following:

- Fast tracking the logistics
- Streamlining the tendering process
- Create a logistics management information system
- Utilize pooled procurement
- Implement QC along the supply chain
- Involve private sector, NGO's, FBO's, civil society
- Involve healthcare insurance schemes
- Borrow from the vaccine initiative
- Prequalification of suppliers
- Sharing information on prices

For QC/QA, group 1 proposed the following activities:

- Regional GMP inspection group
- Data/reported sharing
- Convene a regional technical committee
- Lobbying for political support
- Implement QC in the distribution system (Minilabs -Stability problems of ACTs Quality
- Improve Management systems (GLP training) & accreditation of NQCL
- Establish regional reference lab for ACT
- Mapping of lab facilities and capacities in the region
- NDRA to contract services
- Secure sources & funding for reference standards

- Strengthen & encourage use of peripheral labs - Incorporate into hospital activities

For post-marketing surveillance, group 1 proposed the following activities:

- Training in PMS
- Expand scope of duties for the sentinel sites
- Communicate & educate on the need for PMS
- Strategies for PMS-why & who
- Mapping of resources-equipment, report forms
- Feeding into the national central system

## Group 2

Group 2 made the following recommendations for different QA areas:

### Selection

- National Medicines policy to define selection
- Use National selection process
  - Robust selection criteria, e.g. based on scientific evidence (local/international)
  - SOPs for selection

### Procurement

- Process to ensure coordination among DOMC, DRA, supply chain system, NQCL (Who to take the lead?)
  - National procurement planning
  - Criteria for selection of suppliers (prequalification to be done by DRA, WHO)
  - Clear specifications for products
  - QA assurance throughout supply chain
- Strengthening logistics management information systems, quantification
- Explore regional pooled procurement

### Registration

- Capacity building on the registration system-Training, drug evaluation software
- Standard Operating Procedures for every process
- Regional harmonization of drug registration

### QC

- Training of staff on QC methods, especially in documentation system-accreditation (fast track WHO accreditation, ISO 17025)
- Regional laboratory networking (Centers of excellence-specialization/reference labs within Africa)
- Identify and utilize technical resource base within the Universities, research institutions, and others
- USP/WHO to develop reference standards (Monographs) where they are lacking

### PMS/Pharmacovigilance

- Continuous quality studies-Mini labs

- product testing that is integrated within the DRA inspectorate/surveillance system
- DRA to facilitate continuous efficacy studies through universities, research institutions, teaching hospital
- *Set up Bioequivalence centers (Long term)*
- Strengthen recall systems (best practice from Madagascar)
- IEC-Awareness among health professionals, public on drug safety reporting
- Study on reasons why ADR reporting is weak among health professionals
- Define scope for PVG e.g. geographical, product, disease, as a starting point
- DRA to play a key role but link within the universities and teaching hospitals to tap expertise in risk assessment and management
- Strengthening drug information so that unbiased information is available to those who need to know, e.g drug alerts, new indications, recalls

#### Performance Indicators

- Documentation and communication of action taken, e.g DRA
- DRA to make drug registration information public

#### How to communicate

- Make a joint report, seek appointment with PS, MOH to discuss the Pharmaceutical Regulatory authority (Zambia, Ethiopia)
- Start a networking process between Regulators, NQCL, DOMC, Universities, Teaching hospitals
- Advocate the use of mini labs.
- Meetings, advocacy to the decision makers, including those outside the health system. Report of this meeting to every participant-present this to the management/ stakeholders in our countries (All)
- Email/informal network (Africa list serve)

#### Group 3

##### Selection

- National Drug List or National Essential Drug List
- Involve the Malaria Control Program and other policy makers to limit number of drugs to be registered for a particular disease

##### Registration

- Use an expert panel in the review of dossiers to reduce the backlog.
- Use available facility in the country e.g. University lab, local manufacturers for quality testing of samples
- Sharing system information with neighboring countries e.g. registration guidelines

##### PMS/pharmacovigilance

- Use existing reporting system to add the ADR component e.g. Consumption data, health statistics
- DRA to consult other experts in the analysis of the data and response to ADRs

- Create incentive for reporting: use mass media campaign to deliver message on health safety (Health radio to reach rural community)
- Designed testing programs based on random sampling
- Limit number of targeted products
- Focus on problem geographical areas and place mini-labs at selective inspection sites
- Use QC labs for confirmation only
- Develop a quality system for NDQCL to achieve accreditation (ISO 17025 / WHO pre-qualification)

#### Group 4 (Francophone countries)

##### Selection

- Choose molecules according to evidence of drug efficacy and quality
- Select prequalified suppliers
- Appoint a technical committee to review choices

##### Procurement

1. Request for applications
  - Consider a technical commission to review the applications
  - Verify all technical specifications according to the specifications of the regulatory authority
2. Quantification
  - Estimate the quantities of ACT to be ordered for countries
  - Arrange a flexible delivery schedule (divide up the deliveries of products)
  - Obtain technical assistance to ensure appropriate medicine management

##### Registration

- Stop registration of monotherapies
- Improve collaboration among the DPL, LNCM, PNLP and PNA for registration of medicines
- Limit the number of registered products of the same medicines according to need

##### Quality Control

- Systematically control all antimalarials at the registration stage

##### Storage and Distribution

- Good stock management
- Destruction of expired medicines
- Training on best practices on storage and distribution

##### Pharmacovigilance

- Establish a management system for monitoring ADRs for the ACTs chosen
- Implement the PV plans proposed by the malaria programs

*Discussion on next steps*

A discussion of the next steps followed.

The activities proposed by all 4 groups to improve key QA priority areas were very similar. Overall, the next steps necessary called for:

- The need to impress the crucial role of QA system on policy makers
- The need to involve private sector players in QA discussion and implementation
- Sharing and/or providing technical assistance in areas of need
- Feedback mechanisms to monitor progress

Toward these ends, the challenge is to:

- Develop a framework for regional collaboration
- Mapping out concrete steps toward that collaboration
- Subsequently, develop a regional communication system for drug quality data and information

It was agreed that the organizers, USP DQI and RPM Plus/MSH, will prepare a draft of a framework for regional collaboration and develop steps for moving forward. The document will then be shared with all participants for input.

*Closing remarks*

Ms. Pamela White, Director of the USAID Mission to Tanzania closed the workshop with some closing remarks. She remarked that poor quality antimalarials is a significant challenge to the battle against malaria. She said this message needs to be conveyed to all involved and this workshop provided a great opportunity for malaria endemic countries to come together, not only to share technical expertise, but more importantly, to raise quality as an important link to effective treatment of malaria. She concluded that the battle against malaria should and will be won.

## **Collaborators and Partners**

See participant list (Annex 2).



## Annex 1. Agenda – Regional Consultative Meeting on Quality of Antimalarials

**14-16 November 2006  
Sea Cliff Hotel, Dar es Salaam, Tanzania**

<b>Day</b>	<b>Time</b>	<b>Activity</b>	<b>Presenter/Facilitator</b>
<b>Day 1</b>	8:30–9:00	Registration	
	9:00–9:15	Welcome remarks Meeting objectives, outcomes and agenda	Rima Shretta (RPM Plus/MSH)
	9:15–9:30	Introduction of presenters and participants	Catherine Wachira (USP DQI)
	9:30-9:45	Malaria and quality assurance in Tanzania: USAID perspective	USAID/Tanzania
	9:45-10:00	Introduction of Guest of Honor from MOH	Alex Mwita (NMCP/MOH)
	10:00-10:15	Official opening	MOH
	10:15	Group Picture	All
	10:15–10:45	<b>Break</b>	
		<b>I. Current malaria trends in Africa</b>	Facilitator: Edmund Rutta (RPM Plus/MSH)
	10:45-11:15	Malaria treatment: ACTs and related policy issues	Issa Sanou (AFRO/WHO)
	11:15-11:45	Quality of antimalarials: pre-qualification and related issues	Clive Ondari (WHO/HQ)
	11:45-12:30	Discussion	All
	12:30–14:00	<b>Lunch</b>	
		<b>II. Quality Assurance Systems</b>	Facilitator: Rima Shretta (RPM Plus/MSH)
	14:00-14:30	Quality Assurance: The backbone of pharmaceutical management	Dat Tran (RPM Plus/MSH)
	14:30-15:00	Development of the national drug policy: Assuring the quality of medicines: case study & lessons learned	Country presentation (Kenya)
	15:00-15:30	Streamlining Registration	Country presentation (Uganda)
	15:30–15:45	<b>Break</b>	
	15:45–16:15	Moderated Discussion: DRA/NMCP coordination: quality, safety, efficacy of antimalarials	Moderator: Dat Tran (RPM Plus/MSH) All
		16:15-17:30	General Discussion
<b>Day 2</b>		<b>III. Laboratory Quality Testing</b>	Facilitator: Catherine Wachira (USP DQI)

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<b>Day</b>	<b>Time</b>	<b>Activity</b>	<b>Presenter/Facilitator</b>
	8:30–9:00	Tiered testing system – role of central QC laboratory	Karim Smine (USP DQI)
	9:00–9:30	Testing at peripheral sites	Country presentation (Senegal)
	9:30-10:00	Inspection network	Country presentation (Tanzania)
	10:00–10:15	<b>Break</b>	
	10:15-10:45	Reports of counterfeit and substandard antimalarials: Examples from Africa, Asia and Latin America	Karim Smine (USP DQI)
	10:45-12:30	Discussion	All
	12:30–14:00	<b>Lunch</b>	
		<b>IV. Common quality-related challenges</b>	Facilitator: Clive Ondari (WHO/HQ)
	14:00-14:30	Technical challenges: testing methods, reference standards, etc.	Karim Smine (USP DQI)
	14:30-15:00	Moderated discussion: Technical challenges	
	15:00–15:15	<b>Break</b>	
	15:15-15:30	Managerial challenges: Monitoring & Evaluation	Rima Shretta (RPM Plus/MSH)
	15:30-15:45	Next steps: What to do with the drug quality data findings (rapid alert systems, enforcement etc)	
	15:45-17:30	Moderated Discussion	
<b>Day 3</b>		<b>V. Regional Approach to improving QA</b>	Facilitator: Dat Tran (RPM Plus/MSH)
	8:30-9:30	Regional Approach to improving QA <ul style="list-style-type: none"> <li>• Leveraging technical resources</li> <li>• Leveraging operational resources</li> <li>• Role of DRA: Coordination &amp; Supervision</li> </ul>	Issa Sanou (WHO/AFRO)
	9:30-10:30	Working groups (4): key elements in designing QA system (regional/country level approaches) <ul style="list-style-type: none"> <li>• Basic testing &amp; inspection at key entry points</li> <li>• Role of central NDQCL: MOH/university/research-based</li> <li>• Role of regional networks</li> </ul>	Working group leader
	10:30–10:45	Break	
	10:45–13:00	Working groups (4): key elements in designing QA system (regional/country level approaches) <ul style="list-style-type: none"> <li>• Information/data sharing and reporting networks</li> <li>• DRA: Making use of DQ data for regulatory response</li> <li>• Role of regional networks</li> </ul>	Working group leader
	13:00–14:00	Lunch	

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<b>Day</b>	<b>Time</b>	<b>Activity</b>	<b>Presenter/Facilitator</b>
	14:00-14:45	Presentation of QA plans <ul style="list-style-type: none"> <li>• Develop framework on what is needed to develop a QA system (regional/country approaches)</li> <li>• Role of regional networks</li> </ul>	Facilitator: Karim Smine (USP DQI) Working Group presentations (4)
	14:45-16:00	Discussion on next steps for development of a generic QA model	Facilitators: RPM Plus/MSH; USP DQI
	16:00–16:15	Break	
	16:15-16:30	Discussion of next steps	RPM Plus/MSH; USP DQI
	16:30-17:00	Closing remarks	Pamela White (USAID/Tanzania)



## Annex 2. Participant List

### Consultative Workshop on Quality of Antimalarials

November 14-16, 2006

Seacliff Hotel, Dar es Salaam

List of Participants		
Country/ Organization	Name	Affiliation/ Contact
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