

Consultative Workshop to Finalize Strategy and Plan of Action by the National Drug Authority in Support of the New Malaria Treatment Policy, October 2 – 6, 2006: Trip Report

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Strategic Objective 5

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About RPM Plus

RPM Plus works in more than 20 developing and transitional 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
AIDS	Acquired Immune Deficiency Syndrome
DRA	Drug Regulatory Authority
GFATM	Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria
HIV	Human Immunodeficiency Virus
JMS	Joint Medical Stores
MOH	Ministry of Health
MSH	Management Sciences for Health
NDA	National Drug Authority
NMCP	National Malaria Control Program
NMS	National Medical Stores
PMI	Presidents Malaria Initiative
PSU	Pharmaceutical Society of Uganda
RBM	Roll Back Malaria
RPM Plus	Rational Pharmaceutical Management Plus
USAID	United States Agency for International Development
WHO	World Health Organization

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 has been working to improve pharmaceutical management for malaria in countries in Africa by identifying and addressing the causes of poor access, ineffective supply, and inappropriate use of antimalarials. RPM Plus has developed and applied tools to assess pharmaceutical management for malaria and has worked to provide technical assistance to countries by working with policymakers, researchers, managers, and providers in the public and private sectors to implement new and proven interventions. Significant among these interventions are Artemisinin-based Combination Therapies (ACTs).

RPM Plus is an Implementing Partner under USAID Uganda's President's Malaria Initiative (PMI) Year One Country Action Plan. Within the FY06 scope of work, RPM Plus is supporting the strengthening of distribution systems for Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria (GFATM) nets to children under 5, pregnant women, and people already experiencing weakened health, such as HIV/AIDS patients. In addition, RPM Plus is providing support to overcome the challenges in the pharmaceutical management system necessary to roll-out ACTs under the direction of the National Malaria Control Program (NMCP). Whilst providing technical assistance to the roll-out process, additional RPM Plus support is aimed at ensuring the rational use of the selected expensive national first-line treatments. Implementation is being achieved under the guidance of a regional technical adviser based in Uganda with support from RPM Plus regional office and headquarters.

Purpose of Trip

Gladys Tetteh, Regional Malaria Adviser for RPM Plus based in Nairobi, Kenya traveled to Kampala Uganda to provide technical support to the development of a phase-out plan for chloroquine and other antimalarial monotherapies in Uganda. Development of the plan was done under the leadership of the Uganda National Drug Authority¹. Using funds from the USAID Uganda country mission, RPM Plus provided financial and technical support for a two-day stakeholder planning workshop held in Entebbe, Uganda on October 4-5, 2006. It was planned that Gladys Tetteh would work with Saul Kidde, Senior Technical Adviser for RPM Plus based in Uganda to implement the planned activity.

¹ The mandate of NDA is to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory health care and safeguarding the appropriate use of drugs.

Scope of Work

The scope of work for Gladys Tetteh was to:

- Work with the RPM Plus Senior Technical Adviser/Uganda, to finalize technical material, prepare templates and arrangements for the planned workshop
- Work with the National Drug Authority to facilitate the planned workshop and share lessons learned from other country programs
- Work with Ministry of Health stakeholders to develop the phase-out plan for antimalarial monotherapies in Uganda's former Malaria Treatment Policy
- Provide an arrival briefing and /or departure debriefing to USAID upon request.

ACTIVITIES

Work with the RPM Plus Senior Technical Advisor/Uganda, to finalize technical material, prepare templates and arrangements for the planned workshop

Gladys Tetteh worked with Saul Kidde to finalize the workshop program in conjunction with the National Drug Authority (*see Annex 1 for Agenda*). The objectives of the workshop and expected outputs were agreed upon and presenters were reminded to highlight the NDA's role within the thematic areas presented. A presentation to be delivered by RPM Plus - *Experience in the Change of Malaria Treatment Policy from Other Countries* – was finalized and a session planned for group work.

Work with the National Drug Authority to facilitate the planned workshop and share lessons learned from other country programs

The workshop was held from October 4 -5, 2006 at the Imperial Resort Beach Hotel in Entebbe, Uganda. The workshop was intended to be a national forum to share and exchange ideas on required regulatory considerations and actions needed in the context of implementing the new malaria treatment policy in public and private sectors of Uganda.

The key objectives of the workshop were to:

- Identify the key mandate of the National Drug Authority and agree on its role in supporting implementation of the new malaria treatment policy
- Identify the key regulatory actions that need to be implemented in Uganda in support of the policy implementation
- Identify common challenges in the NDA support to ACT policy implementation, both technical and managerial from other countries and share experiences and lessons learned from previous and current policy change
- Finalize an agreed upon strategy and implementation plan to include key elements of drug registration, ACT deregulation, scheduling of ACTs for different levels within EDL, local manufacture of ACTs, phasing out of monotherapies, limiting SP for IPT use as well as for strengthening drug regulatory procedures and practices

The workshop was opened by the Executive Secretary & Registrar of the Uganda National Drug Authority, Mr. Apollo Muhairwe and attended by 25 representatives from the following MOH units and partner agencies:

- National Malaria Control Programme, MOH
- Pharmacy Department, MOH
- Malaria Disease Surveillance Unit, MOH
- National Medical Stores (NMS)
- Joint Medical Stores (JMS)
- Butabika Regional Hospital

- Wakiso District Directorate for Health Services
- National Drug Authority (NDA)
 - Registration department
 - Inspectorate department
 - Drug Information department
 - Finance department
- MSH/RPM Plus Uganda
- MSH/RPM Plus Nairobi
- World Health Organization (WHO)
- The Global Fund to Fight AIDS, Tuberculosis & Malaria (GFATM)
- Pharmaceutical Society of Uganda (PSU)
- Malaria Consortium
- Axios

The workshop keynote address was delivered by Mr. Muhairwe. Presentations were delivered to highlight the new antimalarial treatment policy in the context of the country's overall malaria policy, the NDA mandate and key required actions planned in support of the new policy, case studies delineating steps taken by other drug regulatory agencies in support of policy change; lessons learned in Uganda during malaria treatment policy change from use of chloroquine to use of HOMAPAK, existing current role of monotherapies and challenges of procurement and supply of ACTs. Experiences with malaria treatment policy change processes, particularly the steps taken by drug regulatory agencies in other countries in the Africa region, were shared.

At the end of the presentations, a summary of issues was listed under four thematic areas for discussion during group work. The areas and issues were:

- 1. Re-scheduling ACTs for different levels within NDA schedules**
 - a. Key Activities & Responsibilities
 - b. Information Required & from whom
 - c. Financial Requirements
 - d. Timelines
 - e. Deliverables
- 2. Registration of Antimalarials**
 - a. Agreed upon requirements by NDA for registration/de-registration of antimalarials
 - b. Types of Registration (Full/provisional with clauses)
 - c. Process of review for new molecules/formulations and involvement of experts
 - d. Periodicity of publicization of lists of approved drugs and audiences
- 3. Post-marketing activities**
 - a. Key Activities & Responsibilities
 - b. Information Required & From Whom
 - c. Financial Requirements
 - d. Timelines

e. Deliverables

4. Phasing out monotherapies and sub-optimal combination therapies/Increasing access to ACTs in the private sector

- a. Types of monotherapies recommended for phasing out and rationale
- b. Monotherapies to be limited in quantity and rationale
- c. Types of sub-optimal combinations recommended for phasing out and rationale
- d. Processes required for phasing out/limiting quantities (activities, timelines, responsibilities & deliverables)
- e. Activities to increase access to ACTs in the private sector, responsibilities, timelines and deliverables

The objective of the group work session was for experts to brainstorm on the issues listed and to plan activities that needed to be undertaken by the NDA. Presentations were made in a plenary session following group work (*see Annex2 for presentations*).

Work with Ministry of Health stakeholders to develop the phase-out plan for antimalarial monotherapies in Uganda's former Malaria Treatment Policy

RPM Plus is mandated by the MOH and USAID within the PMI country operational plan to work with the NMCP, NMS and NDA to design and implement a strategy for phasing out chloroquine as first line for malaria case management and other mono-therapies. This workshop was an initial step in the process and it has been agreed that the following required activities will be undertaken by the NDA in-conjunction with the NMCP and NMS and with support from RPM Plus.

- Nationwide assessment of the supply chain pipeline for all monotherapies and sub-optimal combination therapies recommended for phasing out/quantity limitation (Oct – Dec 2006)
 - Develop Tracer List of selected antimalarial medicines, their formulation and strength and list active pharmaceutical ingredients (APIs)
 - List facilities to be assessed in both sectors (public/mission and private)
 - Design tools and assemble and train data collection teams
 - Inventory-taking of stocks within the National Medical Stores
 - Inventory-taking of stocks in warehouses of local manufacturers and importers
 - Assessment of stock held in public sector health facilities
- Determine availability of policy recommended of ACTs (Oct – Dec 2006)
 - Stock in-country
 - Pipeline for expected ACT stock (guaranteed funding sources) for next 2 years
- Review of current MOH contracts for monotherapies and planning (Oct – Dec 2006)
- Agree on phase out timelines (Jan 2006 onwards)
- Legal arrangements for phasing out/limiting (Jan 2006 onwards)
 - Restricting importation of monotherapies subject to availability of adequate quantities of ACTs

- Re-scheduling
- De-registration

Provide an arrival briefing and /or departure debriefing to USAID upon request.

Gladys Tetteh did not travel to Kampala and was unable to meet with USAID staff, however, it was agreed that Saul Kidde would update Erik Janowsky and Annie Kabogozza on the outputs of the RPM plus supported workshop and planned next steps for RPM Plus. This has been achieved.

NEXT STEPS

Immediate Follow-up Activities

- RPM Plus support to Uganda phasing out of antimalarial medicines activity
- Continued RPM Plus activity implementation and activity reporting to USAID

ANNEX 1. WORKSHOP AGENDA

PROGRAMME FOR A WORKSHOP ON THE STRATEGIC PLAN FOR IMPLEMENTATION OF THE NEW ANTI-MALARIAL POLICY

Date	Time	Provisional Agenda	Facilitator
Tue. 03/10/06	6.00 p.m.	Arrival of guests	
Day One – Morning Session – Mr. Kidde Saul – Chairman			
Wed.4/10/06	7:00-8:00 a.m.	Breakfast	
	8:30-9:00 a.m.	Registration of participants	
	9:00-9:30 a.m.	Keynote address	<i>Executive Secretary & Registrar (NDA)</i>
	9:30-10:00 a.m.	Highlights of the new anti-malarial policy	<i>Dr. Kato (MCP)</i>
	10:00-10:30 a.m.	Discussion	
	10:30-11:00 a.m.	Coffee Break	
	11:00-11:30 a.m.	Plan of implementation of the new anti-malarial policy by NDA	<i>Chief Inspector of Drugs (NDA)</i>
	11:30-12:00	Discussion	
	12:00-12:30 p.m.	Experience in the change of malaria treatment policy from other countries	<i>Dr. Gladys Tetteh (MSH/RPM Plus)</i>
	12:30-1:00 p.m.	Discussion	
	1:00-2:00 p.m.	Lunch	
Afternoon Session – Dr. Kato - Chairman			
	2:00-2:30 p.m.	Change of malaria treatment policy from Chloroquine as first line to Homapak. What were the lessons learnt	<i>Deo Kimera</i>

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			<i>(Axios)</i>
	2:30-3:00 p.m.	Discussion	
	3:00-3:30 p.m.	Role of monotherapies in the treatment in the treatment of malaria	<i>Dr. Ambrose Talisuna</i>
	3:30-4:00 p.m.	Discussion	
	4:00-4:30	Impact of the new policy on access of anti-malarials in private sector	<i>James Tamale</i>
	4:30 p.m.	Discussion	
	Day Two: Morning Session – Mr. Mubangizi Deus - Chairman		
Thursday, 5/09/06	8:30-9:00 a.m.	The challenges of procurement and supply of ACTs by NMS. What is the impact of the new anti-malarial treatment policy on the activities of NMS	<i>Mr. Tenywa Paul</i>
	9:9:30 a.m.	Discussion	
	9:30-10:00 a.m.	Anti-malarials for Paediatric use in the new treatment policy	<i>Dr. Mworozzi E.</i>
	10:00-10:30 a.m.	Discussion	
	10:30-11:00 a.m.	Coffee Break	
	11:00-11:45 p.m.	Focus group discussions	
	11:45- 12:15 p.m.	Presentation of the results	
	12:15 – 1:00 p.m.	Resolutions and the way forward	
	2:00 p.m.	Departure	

Rapporteur: **Mr. Apollo Angole**
 Ms. Kasweet Beatrice

ANNEX 2. WORKSHOP PRESENTATIONS

Group 1

RESCHEDULING ACTs FOR DIFFERENT LEVELS WITHIN NDA SCHEDULES

Group 1 presentation

MoH and Parliament

- Review of the statutory instrument by MoH Committee on Laws
- Forwarding SI to First Parliamentary Counsel
- FPC presenting SI to Members of Parliament
- Parliament forwarding SI to MoH
- Gazetting
- Dissemination

KEY ACTIVITIES

- A- Sharing of Mid Term Review Results of the Feasibility study of use of ACTs in the community (WHO/NMCP)
- B- Report writing of the MTR results (?)
- C- Drafting of the Statutory Instrument (NDA)
- D- MoH Evaluation of the Statutory Instrument
- E- Parliamentary counsel evaluation of the Statutory Instrument
- F- Parliament Evaluation of the Statutory Instrument
- G- Gazetting of the ACTs

FINANCAL REQUIREMENTS

- Report to Technical Committee of NDA – (F)
- Report to CNF (NDA) – (F)
- Report to NDA Board – (F)
- Review of the statutory instrument by MoH Committee on Laws – (F*)
- First Parliamentary Counsel – (F*)
- Publication of Gazette – (F*)
- Dissemination – (F*)

NDA

- MTR Report to be presented & discussed by Technical Committee of NDA
- Report sent to the Committee on National Formulary of NDA
- Report sent to NDA Board
- Drafting of Statutory Instrument by NDA
- Statutory Instrument sent to MoH

TIME LINE

- Dissemination and sharing of results to stakeholders-Jan 2007
- Report to be discussed by technical Committee of NDA – Jan 2007
- Report to CNF (NDA) Jan 2007
- Report sent to NDA Board Feb 2007
- Drafting of Statutory Instrument by NDA-March 2007
- Review of the statutory instrument by MoH Committee on Laws March 2007
- First Parliamentary Counsel-April 2007
- Presentation to MPs-April 2007
- Signing by the Minister –May 2007
- Publication of Gazette-May 2007
- Dissemination-May 2007

INFORMATION REQUIRED

- Effectiveness of the drugs
- Stability thru the supply chain
- Compliance by distributors/care givers
- Safety Profile of the drug
- Acceptability by the users

INDICATORS

- Draft of mid-term report
- Draft of statutory instrument
- Forwarding letter from the Minister to Parliament
- Report of the first Parliamentary Counsel to the Parliament
- Report of Parliament to the Minister
- Gazette

THANK YOU

Group 2

REGISTRATION OF ANTI-MALARIALS

Recommendations:

- Efficacy studies done in areas with stable malaria transmission intensity
- Safety data should be carried out in groups with similar genetic profiles (including phenotype)
- Companies that do not fully meet the above requirements on efficacy and safety data, could be given provisional registration for a specified period (1year) as they carry out studies .
- For new molecules and formulations the NDA secretariat should seek expertise from relevant experts for an independent scientific opinion on efficacy and safety data. One or two experts with no conflict of interest should be requested to submit a confidential report which can be reviewed by the CNF
- Periodically NDA should publicize a list of the newly registered medicines in the locally available gazettes (for transparency, sensitize the public [health care providers] and help prevent counterfeits entering the country)
- The consultative process highlighted can be used to de-register medicines whose efficacy is failing

Group 3

POST MARKETING ACTIVITIES

- Efficacy studies through Sentinel sites
- Safety through PV
- Quality controls & Post marketing surveillance
- Monitoring distribution and availability through records

1. Efficacy studies through SS

Note: There are 8 SS in Uganda for the MoH
Not all are functioning: Financial constraints

Way forward:

1. Endeavour to do Efficacy every 2-3 years dependant funding
2. However, PVC reports should act as a guide
3. Studies done in the East African region or areas with similar ethos should be valued

In-Put

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Indicators:

Efficacy studies done
Results from SS

2. Safety thru: PV

Note: Inadequate sensitization of both HWs and Consumers

Recommendation:

1. More sensitization of both parties is done
2. HWs should inform and encourage patients to report back to HWs in the event of any ADRs
3. Improve efficiency of reporting thru: technology to capture ADR from patients & HWs e.g cellphones.

Indicators:

Reports received by NDA from HWs and patients

In-put

Manpower

3. Quality Control & Post Marketing Surveillance

Note: That 100% sampling, batch for batch sampling at entry points

Recommendations:

1. Encourage both Hws and Patients to ID any changes in the medicines:
ie. Start from Level I-4 in PV
2. Equip Drug inspectors with hand testing equipment at 2nd level QC method at post marketing points

Indicators:

Tests done on ACTS by NDA Quality Lab.

4. Monitoring & Distribution

Note: Distribution & monitoring issues exist at all levels

Recommendation:

1. Training of current Drug monitors
2. Train HF managers on record keeping & quantification
3. Recruit more drug monitors
4. Advice to NMS to device alternative methods emergency for distribution of malaria commodities. E.g Allow some HF with Mvs to pick their supply whenever they come from up country after informing NMS 3-4 days prior to arrival.

Indicators:

No. of HF mgrs. Trained
No. of current Drug monitors recruited
No. of Drug monitors
Correct Record forms verified

Group 4

Group 4 Phasing out monotherapies and sub-optimal combination therapies

Dr.Kato
Mr. Saul Kidde
Dr. Ambrose Talisuna
Mr. Peter Mbabazi
Ms. Gladys Tetteth
Mr. Apollo Angole

What are we Phasing out Sub-Optimal Combination therapies

- Complete Phase out
 - All combinations with Chloroquine
 - All combinations with SP / Metakelfin

What are we Phasing out Mono-therapies

- Complete Phase out
 - Chloroquine Injection and Syrup
 - SP INJECTION
 - Artemisinin derivatives Tablet and syrup
 - Amodiaquin Tablets and syrup
 - Sulphametopyrazine/P yrimethamine
- Limited Supply
 - Chloroquine tablets for SCD
 - SP TABLETS (FOR IPTp)

Rationale for phasing out Sub-Optimal Combination therapies

- Cannot partner with any drug whose failure is already high.

Rationale for phasing out Mono-therapies

- Unacceptably high failure rate (SP,CQ)
- Protection of combinations where partner drugs exist (delay resistance)
 - Artemisinin derivatives
 - Amodiaquin Tablets and syrup

Processes

Activity	Timelines	Responsibility	Deliverable
<u>Assessing the pipeline for all listed drugs</u> ✦Inventory at the National Medical Stores ✦Inventory of Local manufacturers and Importers; ✦National Stock Taking of tracer drugs and Active Pharmaceutical Ingredient (by brand)	2 Months	NDA	Report
<u>Rescheduling</u> (details from group 1)			
<u>Restricting importation of Mono-therapies subject to availability of adequate quantities of ACTs</u> ✦Determination of what is in the pipeline ✦Survey of availability of ACTs	1 year from introduction of ACT HBMF	MoH/MCP	Report

Processes (cont)

Activity	Timelines	Responsibility	Deliverable
Cont			
❖Guaranteed supplies of ACTs for the next 1 year		MoH/MCP	
❖Restrict Importation of Mono-therapies		NDA	
Review of current contracts		MoH/MCP	Revised agreements

Increasing Access of ACTs in the Private Sector

Activity	Timelines	Responsibility	Deliverable
❖Monitor the developing of ACTs and facilitate their registration;		MoH/MCP/NDA	
❖Advocacy in the Private Sector to re-assure them that free drugs are complementing the need	3 months	MoH/MCP	
❖Transparency in prices - Resume publication of indicator prices	4 months	NDA	Regular production of indicator prices
❖Raise profile of ACTs among the private sector	4 months	MoH/MCP/NDA	Workshop