

Translating ACT Policy Change into Implementation in Kenya:

*Report of the RPM
Plus Program's
Contribution
through the Malaria
Drug Policy
Technical Working
Group November
2003–September
2007*

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Strategic Objective 5

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About RPM Plus

RPM Plus 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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CONTENTS

ACRONYMS	v
ACKNOWLEDGMENTS	vi
EXECUTIVE SUMMARY	7
INTRODUCTION TO THE DRUG POLICY TECHNICAL WORKING GROUP	9
BUILDING A FRAMEWORK FOR POLICY CHANGE.....	11
Reorganizing the DPTWG Structure	11
Creating a Transition Plan	11
Mobilizing Resources	12
Working within the Drug Management Working Group.....	12
SUPPORTING REGULATORY ASPECTS OF THE POLICY CHANGE.....	15
Ensuring Coartem Registration	15
Deregulating Medicines.....	15
Supporting Quality Assurance.....	16
SUPPORTING COMMUNICATION COMPONENTS OF THE POLICY CHANGE	17
Reviewing Treatment Guidelines and the Essential Medicines List	17
Training Health Care Workers	17
MANAGING ANTIMALARIALS UNDER THE NEW POLICY.....	20
Assessing Availability of Antimalarial Medicines in Kenya—Before and After ACTs	20
Supporting Quantification and Procurement	22
Supporting Receipt, Warehousing, and Distribution.....	23
Supporting Inventory Management	23
Developing a Phase-Out Plan	24
Assessing Rational Use of Medicines.....	24
MONITORING AND EVALUATION	26
ADDRESSING CHALLENGES IN TREATMENT POLICY IMPLEMENTATION.....	28
Major Challenges to Policy Adoption	28
Finding Solutions to Implementation Bottlenecks	29
CONCLUSIONS.....	31
DOCUMENTS CONSULTED	33
ANNEX A - Time Lines in Translating ACT Policy Change into Implementation in Kenya: November 2003-September 2007.....	35
ANNEX B - Reorganized DPTWG Structure that Facilitated the Implementation of the New ACT Policy in Kenya.....	36

ACRONYMS

ACT	artemisinin-based combination therapy
CDC	U.S. Centers for Disease Control and Prevention
DfID	Department for International Development (U.K.)
DOMC	Division of Malaria Control
DPTWG	Drug Policy Technical Working Group
GoK	Government of Kenya
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
M&E	Monitoring and Evaluation
MEDS	Mission for Essential Drugs and Supplies
MIAS	Malaria Information Acquisition System
MoH	Ministry of Health
NGO	nongovernmental organization
RPM Plus	Rational Pharmaceutical Plus [Program]
SP	sulfadoxine-pyrimethamine
USAID	U.S. Agency for International Development
WHO	World Health Organization

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EXECUTIVE SUMMARY

By the end of 2003, policy makers in Kenya had agreed that the recommended first-line malaria treatment, sulfadoxine-pyrimethamine, was ineffective and that the best line of defense was an artemisinin-based combination therapy (ACT). As a result, the government of Kenya announced its plan to recommend artemether-lumefantrine as the first-line malaria treatment in April 2004. Changing the treatment policy in Kenya to incorporate ACTs took a concerted effort from a broad range of stakeholders supporting the Division of Malaria Control (DOMC).

The U.S. Agency for International Development funds the Rational Pharmaceutical Management (RPM) Plus Program to improve the supply, quality, management, and use of antimalarials and related supplies in malaria-endemic countries, including Kenya. RPM Plus joined the DOMC's Drug Policy Technical Working Group (DPTWG) in November 2003. The DPTWG comprises multiple stakeholders from the public, private, academic, donor, and nongovernmental sectors and fulfills the following functions—

- Reviews the status of drug resistance sensitivity studies and makes recommendations on implications for treatment policy
- Reviews the quality of antimalarial medicines and manufacturing practices and recommends action as necessary to deal with substandard products
- Monitors the implementation of the existing pharmaceutical policy, identifies problems and recommends solutions, and liaises with the clinical management working group as necessary
- Advises the government on policy related to antimalarial donations
- Reports regularly to the DOMC on relevant aspects of malaria control

This report documents the DPTWG's activities supporting Kenya's introduction of ACTs as the first-line malaria treatment. In particular, the report emphasizes the importance of prioritizing pharmaceutical management in the treatment policy change process and illustrates the RPM Plus Program's significant contribution to planning and implementing the country's transition to ACTs.

Activities that RPM Plus carried out to help build the framework for the policy change transition included reorganizing the DPTWG to make it more efficient and to fast-track the implementation process; creating the *Transition Plan for Implementation of Artemisinin-based Combination Therapy (ACT) Malaria Treatment Policy in Kenya*, which focused on addressing early policy issues and other preparatory steps needed to set up the implementation process; and helping mobilize resources by providing technical support to developing Global Fund to Fight AIDS, Tuberculosis and Malaria grants.

RPM Plus also provided support related to regulatory aspects of the policy change by working with the DPTWG to assure the registration of artemether-lumefantrine in Kenya and support the process of gathering safety data to provide evidence needed to classify it as an over-the-counter rather than prescription only medicine, so it can be more widely distributed at the community level. RPM Plus also contributed to the phase-out plan for obsolete antimalarials.

One of the most important actions the Kenyan government undertook as part of the treatment policy change was to officially revise and distribute national malaria treatment guidelines, standard treatment guidelines, and the essential medicines list, and to coordinate the revisions with the development of behavior change communication and interventions to ensure harmonized messages to health care workers and the public. RPM Plus contributed to training Kenyan health care providers in case management; also, RPM Plus developed the curriculum for pharmaceutical management training for health workers who handle medicines in health facilities. In addition to a training-of-trainers program, over 1,000 health care workers from the most malaria-endemic districts in the country have received training on how to manage antimalarials and supplies.

Procurement, distribution, and inventory management activities have included calculating the amount of artemether-lumefantrine needed to serve public sector needs nationwide for the first two years under the new treatment policy. RPM Plus also helped determine a procurement and importation schedule for Coartem, the current artemether-lumefantrine brand in use, and spearheaded the development and funded the printing and dissemination of a two-year operational plan for receipt, warehousing, packaging distribution, and monitoring and evaluation.

Monitoring and evaluation will be facilitated through a new malaria information acquisition system that RPM Plus is developing with the DOMC to track the implementation of the national malaria strategy by district and by partner in conjunction with the globally recommended Roll Back Malaria Strategy. An interim information system that creates a clear paper trail for the receipt, storage, and issue of artemether-lumefantrine by all government and mission health facilities is serving as a stopgap measure for activity planning, budgeting, and monitoring as work progresses toward introducing the primary system.

An important aspect to RPM Plus's ability to support Kenya's policy transition has been its availability to participate in all the DPTWG meetings in-country and to work closely with the DOMC to respond quickly to issues that may have constrained the successful implementation of ACTs. Throughout the transition and implementation of the new treatment policy, RPM Plus's major contribution to the DPTWG has been to increase national awareness of the crucial role of pharmaceutical management and to incorporate pharmaceutical management issues for malaria medicines into all working groups.

INTRODUCTION TO THE DRUG POLICY TECHNICAL WORKING GROUP

Like many other countries in sub-Saharan Africa where malaria is endemic, Kenya had to change its antimalarial treatment policy because of resistance to previously effective monotherapies such as chloroquine and sulfadoxine-pyrimethamine (SP). By the end of 2003, policy makers agreed that SP was ineffective and that the best line of defense against *Plasmodium falciparum* malaria was an artemisinin-based combination treatment (ACT). In April 2004, the government of Kenya (GoK) announced its plan to recommend an ACT, artemether-lumefantrine, as its first-line malaria treatment. Changing the treatment policy in Kenya to incorporate the use of ACTs took a concerted effort from a broad range of stakeholders supporting the Division of Malaria Control (DOMC) to achieve its goals of reducing malaria morbidity and mortality.

Management Sciences for Health's Rational Pharmaceutical Management (RPM) Plus Program is funded by the U.S. Agency for International Development (USAID) to improve the supply, quality, management, and use of antimalarials and related supplies in malaria-endemic countries, including Kenya. RPM Plus joined the DOMC's Drug Policy Technical Working Group (DPTWG) in November 2003 at the invitation of a long-standing DPTWG member and technical advisor to the Division, Professor Robert Snow of the Kenya Medical Research Institute (KEMRI)/Wellcome Trust Research Programme. Professor Snow recognized the importance of prioritizing pharmaceutical management in the policy change process and advocated to include RPM Plus as a stakeholder. Pharmaceutical management—the core competence of the RPM Plus Program—is defined as a set of practices aimed at ensuring the timely availability and appropriate use of safe, effective, quality medicines, and related products and services in any health care setting. Pharmaceutical management is an important aspect of malaria control, and without it, other efforts to implement a new treatment policy may be futile.

Established in 1996, the DPTWG is one of the many working groups that advises the DOMC and addresses specific components of the National Malaria Strategy¹. The other working groups are the Malaria Clinical Working Group on Insecticide-treated Bed Nets; the Management Working Group; the Malaria Information, Education, and Communication Working Group; the Malaria Research Working Group; the Working Group on Monitoring and Evaluation Methodology for Malaria; and the Working Group on Malaria in Pregnancy. The DPTWG comprises multiple stakeholders from the public, private, academic, donor, and nongovernmental sectors and fulfills the following functions—

- Reviews the status of drug resistance sensitivity studies and makes recommendations on implications for treatment policy
- Reviews the quality of antimalarial medicines and manufacturing practices and recommends action as necessary to deal with substandard products

¹ The strategy embodies four strategic approaches to malaria control in Kenya: (1) case management—guaranteeing access to quick and effective treatment; (2) providing malaria prevention and treatment to pregnant women; (3) ensuring the use of insecticide treated nets and other vector control measures by at-risk communities; and (4) improving malaria epidemic preparedness and response. Strategic approaches are supported by two vital cross-cutting strategies, information education and communication and monitoring evaluation and research.

- Monitors the implementation of the existing pharmaceutical policy, identifies problems and recommends solutions, and liaises with the clinical management working group as necessary
- Advises the government on policy related to antimalarial donations
- Reports regularly to the DOMC on relevant aspects of malaria control

This report documents the DPTWG's activities supporting Kenya's introduction of ACTs as the first-line malaria treatment. In particular, the report emphasizes the importance of prioritizing pharmaceutical management in the treatment policy change process and illustrates the RPM Plus Program's significant contribution in supporting the planning and implementation of the country's transition to ACTs. The timeline of activities and achievements starts *November 2003*, when SP was declared ineffective, to the *April 2004* announcement of the new ACT policy, through *September 2006*, when the President launched the use of ACTs in all of Kenya's public health facilities, and to *September 2007*, a year after the official policy launch.

Throughout the new treatment policy phases of transition and implementation, RPM Plus's major overall contribution to the DPTWG has been to increase national awareness of the crucial role of pharmaceutical management and to incorporate pharmaceutical management issues for malaria medicines into all working groups.

BUILDING A FRAMEWORK FOR POLICY CHANGE

Reorganizing the DPTWG Structure

Following its inaugural meeting on November 6, 2003, the DPTWG had a mandate to meet at least once each quarter; however, the group held many ad hoc meetings in a bid to rapidly institute key actions necessary to effect the policy change. To facilitate the introduction of ACTs, in 2005, RPM Plus proposed a reorganization of the DPTWG structure into four working groups: Drug Management, Case Management, Advocacy and Communication, and Monitoring and Evaluation. The reorganization was proposed on the basis of a seminal document, *Changing Malaria Treatment Policy to Artemisinin-Based Combinations: An Implementation Guide*, which RPM Plus developed in collaboration with the Roll Back Malaria Partnership and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). The guide provides the steps required when rolling out a new treatment policy for national-level implementation of ACTs as first-line malaria treatment. The previous DPTWG working groups had overlaps in their terms of reference and membership, which impeded the implementation of policy actions.

The newly formed DPTWG structure was instrumental in fast-tracking the implementation process, and working groups worked tirelessly to enhance implementation. Annex B illustrates the DPTWG structure with working groups, subcommittees, and their key roles.

Creating a Transition Plan

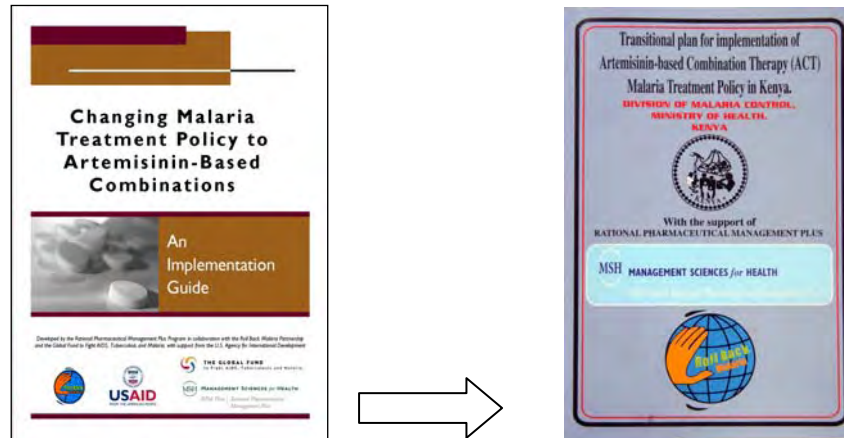
To minimize delays in the transition, the DOMC and RPM Plus developed a draft transition plan as a framework for the DPTWG members to achieve the core technical, operational, and monitoring and evaluation components needed to smoothly implement the new policy. The transition plan, based on the *Changing Malaria Treatment Policy to Artemisinin-Based Combinations* guide, focused on addressing early policy issues and other preparatory steps needed to set up the implementation process. The plan highlighted the terms of reference of the four working groups and described a list of outputs for which they are responsible.

The *Transition Plan for Implementation of Artemisinin-based Combination Therapy (ACT) Malaria Treatment Policy in Kenya* was completed in February 2005 and circulated to DPTWG members for their comments before finalization and printing (see Box 1). The DOMC encouraged all working groups to use the transition plan to make budgets, prioritize activities, and identify funding gaps. RPM Plus provided funding to working groups to help them complete the tasks outlined in their terms of reference, which included adapting and adopting existing guidelines, materials, and systems rather than developing new ones.

In addition to printing 1,000 copies of the transition plan, RPM Plus encouraged the DOMC to distribute it to all stakeholders, and the DOMC used the document to guide partners, donors, and various governmental departments in planning for needed technical assistance and seeking additional funding to cover identified gaps.

Box I: Creating the Transition Plan for Kenya

RPM Plus adapted *Changing Malaria Treatment Policy to Artemisinin-Based Combinations: An Implementation Guide* to the Kenya context, which was a critical initial step in preparing for the new policy implementation. The resulting document, *Transitional Plan for Implementation of Artemisinin-based Combination Therapy (ACT) Malaria Treatment Policy in Kenya* provided a framework of the key components needed to translate policy change into implementation, including details on all the actions that needed to take place at all levels of the health care system.



Mobilizing Resources

From the outset, DPTWG members and stakeholders recognized that effectively implementing the new policy would require resources in addition to the funding needed to procure the new antimalarial medicines. Therefore, throughout the transition and implementation phases of the new policy, RPM Plus and other partners have provided technical input into the development of the GFATM round IV and round VII malaria proposals. The resulting success in securing the round IV grant guaranteed major financial support for the treatment transition. The outcome of the round VII proposal is yet to be announced. In addition to this support, RPM Plus has held two procurement and supply management workshops and worked with the Kenya Ministry of Health (MoH) to help the country prepare adequate procurement and supply management plans to support its Global Fund applications.

Working within the Drug Management Working Group

The Drug Management Working Group, also known as the Drug Management Subcommittee, advises the DPTWG on all pharmaceutical management issues surrounding the new treatment policy and takes responsibility for activities related to ACT procurement, supply, and distribution at all levels in the Kenya health system. RPM Plus is a key member of this working group, which also includes representatives from the DOMC, Kenya Medical Supplies Agency (KEMSA), Mission for Essential Drugs and Supplies (MEDS), National Quality Control Laboratory, Office of the Chief Pharmacist, Pharmacy and Poisons Board, the Procurement and Supply Chain Management Consortium,² and the World Health Organization (WHO).

² The consortium includes representatives of KEMSA, Crown Agents, German Technical Cooperation, and John Snow, Inc. The consortium is contracted through USAID funding to procure all GFATM-funded commodities.

The working group's terms of reference at the beginning of the policy change process was as follows—

Short-term

- Develop a plan for the DOMC on how the working group will implement the key actions and what the costs will be. The working group will be responsible for implementing all the key actions for which they are the technical/operational lead.
- Provide technical review of documents and materials produced as part of the completion of key actions.

Long-term

Within the terms of reference instituted by the DPTWG, the working groups will not sit indefinitely but will be available for consultation with the DOMC as needed during the transition period and after the deployment of the new medicines. The terms of reference include—

- Ensure registration of the six-dose regimen of artemether-lumefantrine and address other regulatory concerns with the Pharmacy and Poisons Board
- Calculate annual requirements of artemether-lumefantrine to be procured, taking into consideration the different dosage forms
- Develop a procurement plan including a procurement and importation schedule that will prevent stock-outs while minimizing expiration
- Propose a mechanism for incorporating artemether-lumefantrine into existing distribution systems
- Propose changes to the different medicine kits
- Propose a mechanism for phasing out SP and reducing amodiaquine supplies in all health sectors
- Develop training materials on pharmaceutical management to include in the overall training materials for health workers
- Propose a system for monitoring supplies, quality assurance, and use of medicines in all health sectors
- Propose alternative financing mechanisms for artemether-lumefantrine at the end of current funding

The main outputs expected under the terms of reference include—

- Inventory of all the documents to be created and their target groups
- Reviewed/updated documents
- Brief description of systems to be put in place
- Identification of the key partners and their roles and responsibilities
- Detailed plan of key actions with costs and time frame
- Procurement plan

As a member of the Drug Management Working Group, RPM Plus has worked within these terms of reference; however, RPM Plus and the rest of the working group have at times worked outside of the mandate to plan for and respond to transition and implementation bottlenecks related to forecasting and procurement; distribution; inventory management issues, such as stock-outs and leakages; pharmacovigilance; and increasing ACT access.

SUPPORTING REGULATORY ASPECTS OF THE POLICY CHANGE

Ensuring Coartem Registration

As a member of the Drug Management Working Group, RPM Plus addressed the registration of artemether-lumefantrine and other regulatory concerns with the Pharmacy and Poisons Board. To date, the only brand of artemether-lumefantrine prequalified by WHO and allowed under major donor funding is Coartem[®], manufactured by Novartis Pharma AG. Coartem is a fixed-dose combination tablet of 20 mg artemether and 120 mg lumefantrine. In March 2006, RPM Plus confirmed the Pharmacy and Poisons Board's re-registration of Coartem 20/120 tablets through an update presented to the DPTWG on behalf of the Drug Management Working Group. A Pharmacy and Poisons Board letter to Novartis dated July 19, 2005 was provided to the DOMC as evidence that the product was registered in-country and could be legally procured and used. At the same DPTWG meeting, RPM Plus confirmed that in a letter dated July 21, 2004, the Pharmacy and Poisons Board had granted Novartis Pharma's request to harmonize the four-dose regimen (circulating in the private sector) to the WHO- recommended six-dose regimen.

Deregulating Medicines

RPM Plus mapped out the process of deregulating artemether-lumefantrine in Kenya in the transition plan. In Years 1 and 2 (2006/2007–2007/2008) of the phase-in plan for ACTs, the DOMC agreed to ensure the supply of Coartem to public sector facilities (GoK and mission hospitals, health centers, and dispensaries), but also agreed to consider the distribution and use of ACTs in the private sector; Year 3 would focus on the private-for-profit health facilities, and Years 4 and 5 on the informal retail sector. In the interim, amodiaquine would be promoted as an alternative to artemether-lumefantrine in the informal retail sector where a substantial number of people seek first treatment for fevers.

Because many Kenyans treat malaria at home and access treatment through the private sector, making artemether-lumefantrine available outside of the public health sector is important to assure wider community access. SP had been readily available at the community level for fever management, and it was unclear how the government would handle community access to ACTs. To expand access to ACTs in the community by offering the medicines for sale at retail shops, artemether-lumefantrine must be scheduled as an over-the-counter medicine; it is currently scheduled as a prescription-only medicine.

The DOMC and its DPTWG must make the decision to change the scheduling of artemether-lumefantrine to over-the-counter status and offer evidence to the Pharmacy and Poisons Board to justify the change. RPM Plus has contributed to technical discussions on this topic, and through its membership in a pharmacovigilance working group hosted by the Pharmacy and Poisons Board, it is supporting the fast-track set-up of an adverse drug reaction reporting system in public-sector health facilities. In addition, RPM Plus is working with other stakeholders in mapping out ways in which additional data can be collected through operational research studies to monitor adverse events associated with the use of artemether-lumefantrine outside of the public sector.

In addition to collecting evidence on the safety of artemether-lumefantrine use in populations outside of the public sector, the DOMC is encouraging pilot projects intended to expand access to antimalarial medicines at the community level and to investigate the feasibility, acceptability, and safety of offering artemether-lumefantrine through community outlets. To evaluate the projects' success, a minimum set of evaluation indicators has been developed on behalf of the DOMC by the KEMRI/Wellcome Trust Research Programme. RPM Plus contributed specifically to the indicators related to medicines availability and management at private sector outlets such as general retail shops.

Based on the results of the pilot studies and the safety data generated from the pharmacovigilance systems, the DOMC will (1) select and implement the most comprehensive strategy to increase ACT access in the community; (2) determine how best to proceed with introducing artemether-lumefantrine responsibly into the private-for-profit sector, informal retail sector, and community; and (3) submit a formal request to the Pharmacy and Poisons Board to allow over-the-counter status for artemether-lumefantrine (Coartem).

Supporting Quality Assurance

The main quality assurance issues that the policy change addresses relate to product efficacy, product safety (pharmacovigilance), and postmarketing product quality surveillance. Related activities are summarized as follows—

- Product efficacy issues were high on the agenda in the first few DPTWG meetings, with the KEMRI/Wellcome Trust Research Programme, the U.S. Centers for Disease Control and Prevention (CDC), the African Medical Research Foundation, the East African Network for Monitoring Antimalarial Treatment and WHO leading the technical support.
- In addition to the country-level pharmacovigilance support described above, RPM Plus sponsored three technical officers from the DOMC, Pharmacy and Poisons Board, and the MoH Division of Pharmacy to attend a regional drug quality workshop organized by WHO and the U.S. Pharmacopeia Drug Quality and Information Program in November 2006.
- The two-year operational plan developed by RPM Plus and other pharmaceutical management partners describes the protocol for quality testing selected batches of artemether-lumefantrine.
- WHO provided support to the DOMC to conduct a baseline antimalarial medicines quality survey in 2006. In addition, RPM Plus is supporting initial plans for the Pharmacy and Poisons Board's institution of a long-term postmarketing surveillance system for antimalarial medicine quality.

Reviewing Treatment Guidelines and the Essential Medicines List

One of the most important actions the Kenyan government undertook as part of the treatment policy change was to officially revise and distribute related guidelines (e.g., national malaria treatment guidelines, standard treatment guidelines, and essential medicines list) and coordinate the revisions with the development of behavior change communication and interventions to ensure that the same messages are communicated to health care workers and the public.

Between February and May 2005, the U.K. Department for International Development (DfID), CDC, and WHO took the lead in providing technical support to develop malaria treatment guidelines under the DOMC's Case Management Working Group. RPM Plus, in consultation with USAID, provided financial support and facilitated two guideline development workshops in Mombasa (May 2005) and Nairobi (July 2005) to finalize the treatment guidelines. During these workshops, RPM Plus provided both a general review and specific technical input on pharmaceutical management issues.

The malaria guidelines were harmonized with other relevant guidelines including integrated management of childhood illness, reproductive health registers, and others. The revised malaria treatment guideline served as the basis for developing all additional policy change communication material.

To ensure cohesiveness in all the requisite guidelines, RPM Plus recommended that the MoH update Kenya's essential medicines list and standard treatment guidelines to include the newly recommended ACTs.

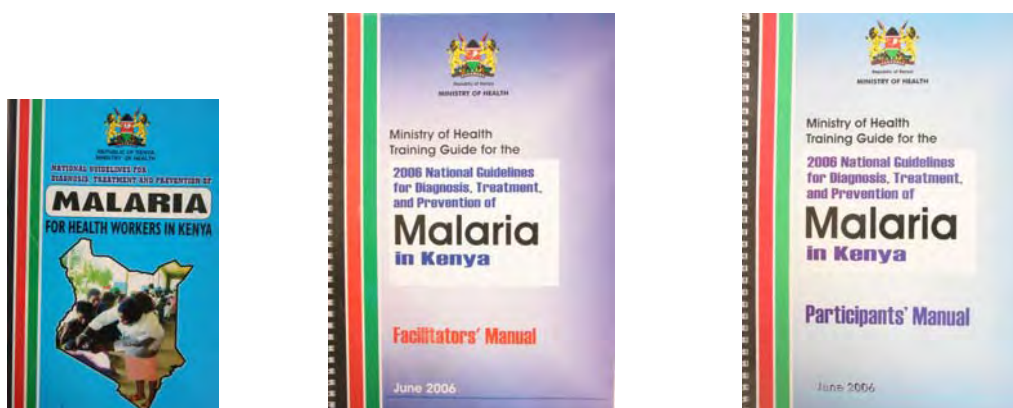
Training Health Care Workers

A major communication component in the policy change involved training health care providers on how to manage malaria cases under the new guidelines and how to prescribe and dispense the new ACT treatments appropriately.

Training Manuals (Facilitator and Participant)

In April 2006, the DOMC developed facilitator and participant case management training materials with technical support from the USAID's Malaria Action Coalition through the CDC. To support this activity, RPM Plus, one of the Coalition partners, reviewed the training manuals and funded the production of 15,000 participant manuals and 1,000 facilitator manuals (see Box 2).

Box 2: Providing Practical Support through the Development of Guidelines: Review and Publication of Training Manuals



Case Management Training Workshops

The DOMC developed a training/sensitization plan for health workers to be carried out at an appropriate time before the introduction of ACTs into health facilities. The DPTWG case management and drug management working groups negotiated to achieve the right timing based on artemether-lumefantrine's expected arrival in-country.

The DOMC recognized that efforts to improve malaria case management must include not only MoH facilities, but also the widely used health services provided by the mission/non-governmental organization (NGO) sector, private-for-profit sector, and academic health facilities. RPM Plus participated in the national dissemination workshop for key malaria stakeholders from public health facilities, NGOs, United Nations agencies, and members of professional bodies. Following this meeting, the first national training of trainers was held in April 2006, a month before artemether-lumefantrine arrived in-country and three months before it was available at health facilities. Public-sector health worker trainings were then rolled out.

To allow the DOMC to provide requisite training to all health facilities implementing the new treatment policy, RPM Plus provided financial support for a set of six 3-day national training of trainers workshops for referral hospitals, private-for-profit health facilities, and NGO institutions between August and October 2006.³ The 236 participants included medical officers, clinical officers, lecturers, nursing officers, public health officers, pharmacists/pharmaceutical technologists, laboratory technologists/technicians, and parasitologists. Members of the DPTWG served as trainers.

³ Participants' institutions included Aga Khan University Hospital, Division of Malaria Control, Equator Hospital, Gertrude's Children Hospital, Kenya Forestry Research Institute, Kenyatta National Hospital, Lumumba Health Center, Mater Hospital, Ministry of Defense, Ministry of Health, Moi Hospital (Voi), Moi Teaching and Referral Hospital, MP Shah Hospital, Nairobi Hospital, Nairobi Women's Hospital, Nazareth Hospital, KEMRI-Walter Reed Project, KEMRI, and the University of Nairobi.

Managing ACTs and other Antimalarial Medicines Workshops

In addition to the case management trainings, the DOMC decided that health workers handling medicines in health facilities should receive parallel training on managing medicines and supplies. This decision was based on the findings of a pharmaceutical management assessment that RPM Plus conducted between March and May 2004 (detailed below), which described poor inventory management practices that might affect the availability and use of antimalarials under the new treatment policy.

RPM Plus developed the related training materials, and in November 2005, in conjunction with the DOMC and other pharmaceutical sector stakeholders, conducted a national training-of-trainers course to update the knowledge and skills of 20 provincial and district-level pharmacists in basic techniques for managing medicines and supplies. Following this workshop, the trainers trained at least one health worker per health facility in the 46 malaria-endemic districts in two-day district workshops conducted between December 2005–May 2006. A total of 1,211 public and mission health facilities sent one health worker⁴ responsible for the management of medicines to the training. Table 1 shows participating health facility types by province.

Table 1. Participating Health Facility Types by Province

Health Facility Type	Coast	Nyanza	Rift Valley	Western	Central	Eastern	North Eastern
Provincial general hospitals	2	0	0	6	1	0	0
District hospitals	10	72	48	59	3	14	3
Subdistrict hospitals	7	30	13	17	4	3	0
Health centers	20	89	76	74	1	23	14
Dispensaries	69	124	202	61	20	98	4
Mission hospitals	5	8	9	3	4	3	0
TOTAL	113	323	348	220	33	141	21

⁴ Health workers trained included pharmacists, pharmaceutical technologists, stores personnel, nurses, public health officers, and clinical officers.

MANAGING ANTIMALARIALS UNDER THE NEW POLICY

Assessing Availability of Antimalarial Medicines in Kenya—Before and After ACTs

To prevent frequent stock-outs of antimalarials, the DOMC recognized that a critical step in implementing the new policy would be to determine how to efficiently distribute artemether-lumefantrine throughout the Government of Kenya and mission sectors. The RPM Plus Program was asked to help assess the procurement and supply chain for antimalarials within these two systems and identify bottlenecks in the flow of medicines, quantify the frequency and extent of medicine stock-outs, identify appropriate points of intervention within the systems, and propose interventions to help roll out the new ACT policy.

RPM Plus carried out a pre-intervention assessment from March to May 2004 (before the treatment policy change) and an assessment in May 2007, seven months after ACTs had been introduced. The 2004 assessment evaluated the antimalarial medicines supply chain based on four basic functions: selection, procurement, distribution, and use, and characterized the extent of stock-outs in the GoK and mission sector health facilities. In 2007, almost a year into policy implementation, a follow-up study documented the availability of artemether-lumefantrine and other antimalarials in 126 GoK and mission facilities in four sentinel districts and identified the strengths and weaknesses of the artemether-lumefantrine and antimalarial supply chain. The assessments were guided by RPM Plus's *Pharmaceutical Management for Malaria* manual.

The 2004 assessment revealed that the GoK pharmaceutical management system was facing challenges that were bound to affect the implementation of the new policy—

- Data on pharmaceuticals and commodities needed to supply health facilities was grossly lacking. In addition, district health facilities did not have the capacity to quantify their antimalarial medicines needs.
- The government health facilities kept poor stock records and had poor availability of antimalarials.
- The government supply organization was an unreliable distributor of pharmaceuticals because of bad roads, poor communication technology, and a lack of money for fuel to transport supplies.
- Most facilities surveyed did not have access to reference materials, such as the national antimalarial treatment guidelines, which are useful tools for prescribers.

In comparison to the 2004 assessment, the 2007 availability of antimalarial medicines in the GoK facilities was comparable; however, the percentage of time out of stock was much lower in 2007 compared to 2004. Availability of antimalarial medicines in mission facilities in 2007 was not as high as in the 2004 assessment, and the percentage of time out of stock was higher in 2007 than 2004.

These findings are illustrated in Figures 1 and 2 below.

Figure 1. Comparison of Antimalarial Medicine Availability in Public Sector Facilities in 2004 and 2007

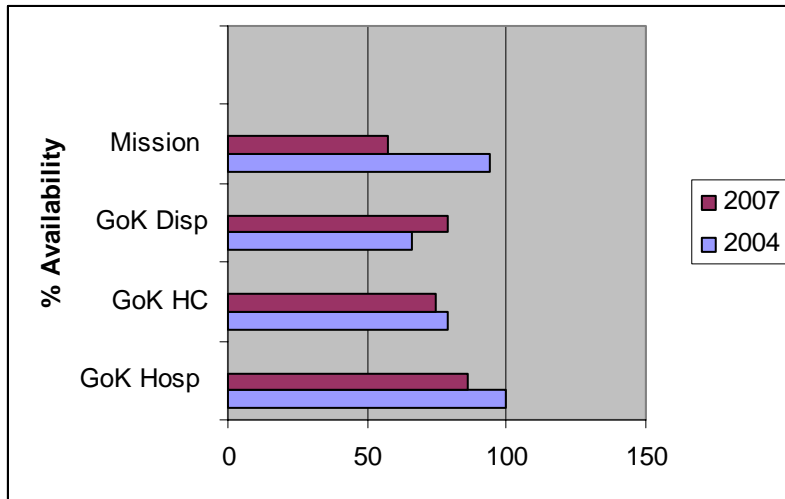
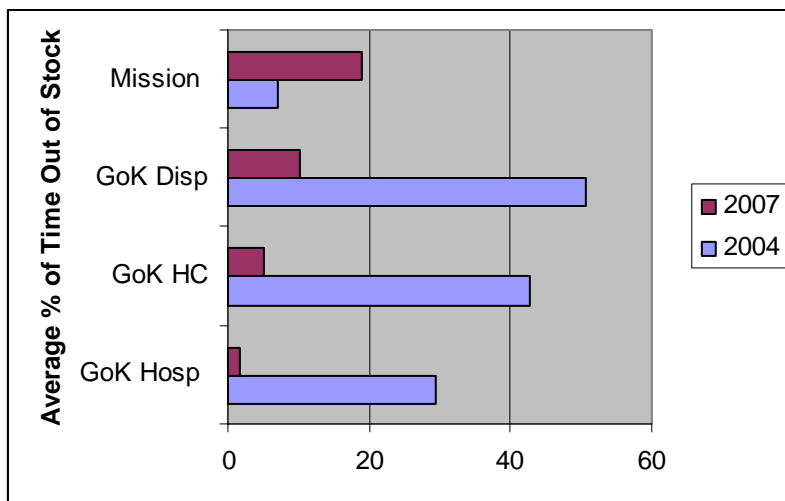


Figure 2. Comparison of Time Out of Stock of Antimalarial Medicines in Public Sector Facilities in 2004 and 2007



In the 2007 assessment, the availability of artemether-lumefantrine treatments, irrespective of dose category, was good in surveyed facilities with an average of 93.8 percent of hospitals, 79.2 percent of MoH health centers, 82.1 percent of MoH dispensaries, and 77.8 percent of mission facilities having artemether-lumefantrine in stock.

Although availability of antimalarials had generally improved in 2007 compared with 2004, the assessors still reported that health facilities were keeping poor records, and that inventory control was weak. The DOMC is continuing to work through the Drug Management Working Group to improve the availability of artemether-lumefantrine and other antimalarial medicines at the facility level.

Supporting Quantification and Procurement

Quantification is the process used to determine how much of a product is required for procurement purposes. Accurate quantification relies on reliable information, which is often based on how much of the medicine has been used in the past. However, with a new treatment policy and no history of the consumption of the new first-line medicine, the quantification process is made more complex. Ensuring an uninterrupted supply of antimalarial medicines, particularly artemether-lumefantrine, to health facilities is crucial to the success of the new malaria treatment policy in Kenya.

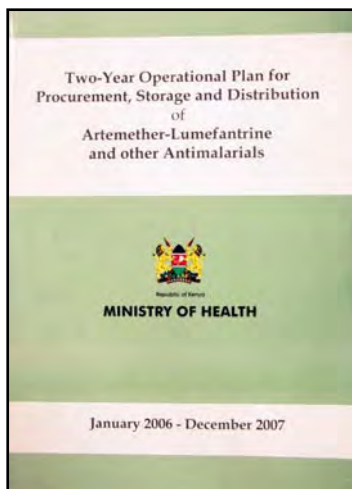
In November 2003, in anticipation of the policy change, RPM Plus and the KEMRI/Wellcome Trust Research Programme helped the DOMC estimate the required national annual quantities and costs of artemether-lumefantrine. In early 2004, with technical support from WHO, the DOMC validated that 10,980,000 treatment doses of artemether-lumefantrine were required to serve public sector needs for the procurement period of July 2006–June 2007. To help build capacity among new DOMC drug management staff, RPM Plus invited the DOMC pharmacist to a regional workshop that provided training in quantification techniques.

In addition to contributing to the national quantification exercise, RPM Plus helped determine a procurement and importation schedule for Coartem and spearheaded the development and funded the printing and dissemination of a two-year operational plan for receipt, warehousing, packaging, distribution, and monitoring and evaluation by the Drug Management Working Group. See Box 3 for a summary of the operational plan.

Box 3: The Operational Plan to Manage ACTs

One of the Drug Management Working Group's key accomplishments is the development of the *Two-Year Operational Plan for Procurement, Storage and Distribution of Artemether-Lumefantrine and other Antimalarials (January 2006 - December 2007)*, which lays out the first two years of procuring, storing, and distributing antimalarial medicines, including Coartem. Components of this plan include selection, procurement, warehousing and distribution, inventory management, monitoring and evaluation, activity costing, and ensuring appropriate use. The plan also covers management support, human resources, and information management, as well as transitional issues relating to the policy change.

One thousand copies of the operational plan were printed and provided to the DOMC for dissemination in 2006 before the arrival of the first shipment of artemether-lumefantrine. The plan will be updated after two years (January 2008) and will provide added details relevant to Years 3, 4, and 5 in order to clearly define the processes that need to be instituted by the major agencies (DOMC, KEMSA, MEDS) involved in procuring, storing, distributing, tracking, and resupplying artemether-lumefantrine and other antimalarial medicines. The plan facilitates the DOMC's monitoring efforts to achieve an uninterrupted supply of antimalarials.



At end of the initial procurement period in July 2007, RPM Plus hosted a one-day quantification workshop to enable the DOMC to quantify artemether-lumefantrine and other antimalarial medicines for Year 2's procurement period, July 2007–June 2008. Workshop participants included members of the Drug Management Working Group. A report of the quantification exercise is available for use by other potential funders for antimalarial medicine procurements.

Before the workshop, however, the head of the DOMC had to submit an order for Year 2 quantities of artemether-lumefantrine in order to meet his GFATM disbursement schedule requirements. The DOMC asked that the quantification workshop proceed anyway, so that the actual artemether-lumefantrine quantities could be determined properly using a methodical approach and data on hand, which had not been possible in the earlier order.

Supporting Receipt, Warehousing, and Distribution

To ensure the smooth receipt and warehousing of artemether-lumefantrine, RPM Plus and the Drug Management Working Group assessed the available warehousing space at KEMSA and recommended to Novartis Pharma that it stagger its deliveries to avoid overwhelming KEMSA's holding capacity.

To ensure the distribution of accurate quantities of ACTs in Year 1, RPM Plus organized and funded a retreat of the Drug Management Working Group and KEMSA's field liaison officers to develop a distribution plan for ACTs to public sector facilities nationwide. The retreat ensured the establishment of mechanisms for incorporating artemether-lumefantrine into existing distribution system before it arrived in-country. Following the retreat, KEMSA distributed the medicines according to set schedules, and MEDS also adhered to the agreements made during the retreat.

The first orders of artemether-lumefantrine were received and distributed to facilities in public and mission health sectors by KEMSA, which had a mandate to distribute 70 percent of artemether-lumefantrine to government health facilities, and MEDS, which supplied faith-based health facilities with the remaining 30 percent. In addition, KEMSA distributed artemether-lumefantrine to other major health service providers, such as government parastatals, universities, and community-access pilot programs run by the Sustainable Healthcare Foundation and USAID's Regional Economic Development Services Office. RPM Plus was invited to KEMSA monitoring meetings to discuss distribution progress.

Supporting Inventory Management

During the RPM Plus-facilitated workshops on pharmaceutical management, health facility staff highlighted a lack of inventory management tools, such as bin cards, as one of their major challenges. At RPM Plus's recommendation, the DOMC distributed bin cards to each health facility receiving its supply of artemether-lumefantrine from KEMSA. In addition to bin cards, RPM Plus provided technical and financial support to develop and distribute artemether-lumefantrine consumption tracking tools with each initial artemether-lumefantrine shipment (Box 4). RPM Plus developed and disseminated an artemether-lumefantrine dispensing register, monthly health facility summary forms, and district summary forms as part of the introduction of an interim national information system on malaria treatment. The system was designed to create a clear paper trail for the receipt, storage, and issue of artemether-lumefantrine by all government and mission health facilities. Staff members dispensing artemether-lumefantrine at the facility level were instructed on how to record the use of the medicines and send the reports to district-level pharmacy staff at the end of every month. District pharmacy staff then forwards the monthly summary forms to the DOMC, where it is analyzed and sent to KEMSA.

RPM Plus's recommended consumption tracking system provides the data that district pharmacy staff needs to monitor stock levels and expiration dates and compare to the average consumption at district health facilities. At the central level, data will be used to (1) advise KEMSA on resupply quantities throughout the year; (2) report on Global Fund indicators; and (3) guide subsequent national quantification exercises.

Box 4: Artemether-Lumefantrine Dispenser's Book

The dispenser's book is used in individual health facilities to—

- Record the name and quantity of the artemether-lumefantrine dispensed each day (needed to monitor item utilization and help detect inappropriate use)
- Calculate consumption of each item over a chosen period (for estimating order requirements)
- Compare dispenser book records with stock (use stock control cards or bin cards and physical inventory checks) to identify discrepancies between medicines issued from stores and those actually dispensed

The data from the dispenser's book is forwarded every month to the district pharmacist to give procurement managers the needed data to accurately estimate quantities of medicines needed for each facility.

Developing a Phase-out Plan

Phasing out the old stock of amodiaquine, which was Kenya's previous second-line treatment, continues to be a challenge. In the early days of the new treatment policy implementation, KEMSA received a delayed delivery of pharmaceutical kits that included amodiaquine. Although the Drug Management Working Group recognized that distributing amodiaquine to health facilities in the kits might complicate the transition to ACTs, removing the amodiaquine from the kits would have been a huge undertaking; in addition, the DOMC wanted to ensure that health facilities would have some antimalarial on hand if ACTs were not distributed in time. KEMSA no longer procures amodiaquine and procures only enough SP to use for intermittent preventive treatment in pregnancy.

Monitoring of health worker behavior showed that because of the large pipelines of amodiaquine and SP in public health facilities, health workers were reluctant to prescribe artemether-lumefantrine until they had depleted their stocks of monotherapy. To maintain the efficacy of the individual components of artemether-lumefantrine, the DOMC, in conjunction with the Pharmacy and Poisons Board, KEMSA, the MoH's Procurement Unit, and with technical assistance from RPM Plus, developed a phase-out plan in March 2007 to guide the withdrawal of antimalarial monotherapies from the market, the limitation of SP for intermittent preventive treatment in pregnancy only, and the registration of optimal combination treatments for malaria only. The DOMC circulated a letter to health facilities requesting that they return amodiaquine to districts.

Assessing Rational Use of Medicines

In April 2006, RPM Plus and the DOMC conducted a rapid assessment to review health worker prescribing and dispensing practices for malaria and to assess the implications of those practices on the proper use of the new combination therapy.

The rapid assessment highlighted some positive findings as well as challenges in the use of antimalarial medicines in the facilities surveyed, which are being addressed. Major challenges included—

Availability of treatment guidelines. Few facilities had even one copy of the national treatment guidelines for malaria available. The DOMC, with DfID support, printed and disseminated 50,000 treatment guidelines and is currently revising and reprinting additional copies for dissemination.

Prescribing practices. In spite of the lack of references in the facilities, approximately three-quarters of prescriptions were for quantities sufficient for a full course of treatment. However, the previously recommended first- and second-line treatments for uncomplicated malaria had a very simple dosage regimen compared with artemether-lumefantrine, so the DOMC emphasizes rational medicine use in case management trainings.

Dispensing practices. Health facilities actually dispensed more than 90 percent of prescribed antimalarial medicines, which illustrates good dispensing practices and reliable availability of the recommended medicines in health facilities. Although more than 80 percent of patients and caregivers could correctly describe how to take or give the prescribed antimalarial, observations of health workers in government health facilities showed that fewer than 50 percent provided information to the patients or caregivers on how to take or give the recommended medicines. This finding showed that the combination of SP and amodiaquine's long-term use, their simple dosage regimen, and general public education had enabled patients and caregivers to learn how to administer the recommended medications rather than rely on instructions from health workers. To date, the DOMC has made major efforts to raise and sustain public awareness about the new first-line treatment.

RPM Plus is poised to support the DOMC's efforts to ensure the effectiveness of the new policy by designing and implementing strategies for the rational prescribing, dispensing, and use of artemether-lumefantrine.

MONITORING AND EVALUATION

The DOMC is responsible for monitoring the success of Kenya's *National Malaria Strategy: 2001–2010*. Monitoring includes ensuring that the resources invested in malaria prevention and treatment are used in the most cost-efficient, effective, and equitable way. Evaluation includes the assessment of progress towards achieving the strategy targets.

In 2005, RPM Plus was selected by USAID to help design and implement a computer-based malaria information acquisition system (MIAS) that will assist monitoring and evaluation (M&E) efforts as well as provide priority information needed to control malaria in Kenya. The system is designed to allow the timely tracking of national malaria strategy implementation by districts and by partners in conjunction with the globally recommended Roll Back Malaria Strategy. Data will be transferred through the system to DOMC managers, who will use the information to meet international reporting requirements for the Millennium Development Goals, GFATM, and Roll Back Malaria.

With funding from the USAID Kenya Mission, RPM Plus undertook a thorough assessment of the existing systems at DOMC, as well as the staff capacity and information needs. The assessment highlighted key priority areas, overall requirements of the MIAS, and some key recommendations.

The basic design principles for the MIAS are that—

- All monitoring of activities and indicators will be based on national malaria strategy targets and outputs, which will be operationalized in a DOMC business plan
- All activities and all indicators will be linked to the DOMC business plan and also linked to National Health Sector Strategic Plan II/Annual Operational Plan/Kenya Essential Package for Health (where applicable)
- All program implementers will need to report to DOMC on a timely basis
- A data warehouse will need to be established at DOMC
- DOMC staff will be trained in using the recommended monitoring tools
- Part of the system design for DOMC will include an M&E dissemination strategy
- Strategic indicators will be monitored by DOMC's M&E unit, together with the M&E technical working group

In the project's first year (October 2006–September 2007), DOMC and RPM Plus made great strides in developing the MIAS. As a result of RPM Plus's technical support, DOMC staff are now proficient in the use of common office applications, modern computer equipment has been acquired, and the network infrastructure improved. An interim MIAS system is in place at DOMC and is serving as a stopgap measure for activity planning, budgeting, and monitoring as

work progresses toward the implementation of the main MIAS system. Key achievements include—

- The endorsement of the workplan and schedule by the DOMC
- Capacity building of DOMC staff in information technology
- The creation of a MIAS implementation work group within the DOMC
- The development of the *Malaria Business Plan* for 2007–2008
- The launch of a new more informative and interactive malaria website (www.nmcp.or.ke)
- The development of a malaria organizations database and collection of data on organizations addressing malaria issues in Kenya
- The development of harmonized health registers in collaboration with the Health Management Information Service

Although the work on the MIAS has been done outside the context of the DPTWG, the results have allowed the DOMC to promptly report to the DPTWG on ongoing activities and achievements related to policy implementation.

ADDRESSING CHALLENGES IN TREATMENT POLICY IMPLEMENTATION

Despite continual support to the DOMC in the policy implementation process by RPM Plus and other partners, the Division and its DPTWG faced some major challenges in adopting the new policy. In collaboration with other partners, RPM Plus provided technical assistance to resolve bottlenecks and facilitate policy acceptance.

Major Challenges to Policy Adoption

Although the policy change was announced in April 2004, the government did not officially adopt the new policy until April 2005 when the Global Fund round IV agreement was signed. The delay resulted from policy makers' concerns about the implications and funding of the new policy. A summary of those issues follows—

- *No alternative antimalarial medicines for first, second, and third line of treatment.* The new policy recommends only artemether-lumefantrine as the first-line treatment with no fall back in the event of stock-outs. The use of quinine as second-line treatment could promote antimalarial resistance, which would leave no other option for treating severe malaria should quinine lose its efficacy.
- *Uncertain financial sustainability of the first-line antimalarial medicines drug policy.* Although the GFATM had been identified as a resource for financing the new policy change, Global Fund support was not guaranteed. Policy makers cited the *Haemophilus influenzae* type B (Hib) vaccine as a negative lesson learned.⁵ In addition, the MoH requested a policy brief outlining the cost of *not* changing the policy before making decisions about budget allocations for the new policy.
- *Delay in GFATM round IV disbursement.* Disbursement of GFATM funds is heavily reliant on performance, and the MoH was reluctant to take chances on funding that would be tied to nationwide health care provider training on updated treatment guidelines.
- *The patent status of artemether-lumefantrine.* Because artemether-lumefantrine (Coartem) was a single-source drug, policy makers and the Pharmaceutical Society of Kenya were concerned about its availability, price, and the inability to produce it locally.
- *Treatment options for malaria during pregnancy.* Little data was available on the safety of ACTs in pregnancy, and failure rates of SP in intermittent presumptive treatment were increasing.
- *Differential pricing in the private versus public sectors.*

⁵ Hib was introduced in Kenya in 2001 with an initial funding commitment from the Global Alliance for Vaccines and Immunization. The MoH initially agreed that at the end of the five-year funding cycle in 2006, it would incorporate Hib into the Expanded Programme for Immunization based on optimistic estimates that the cost of the vaccine would come down substantially. However, when this did not happen, the MoH found itself saddled with an expensive intervention that lacked funding.

The DPTWG members asked the MoH headquarters what additional technical information was needed to advocate for the Government of Kenya's full commitment to the policy change. The DPTWG was asked to put together an advocacy document including the following information—

- Economic analysis of *not* changing the policy
- Written commitment from GFATM that funding for drugs would not be tied to performance
- Analysis of all alternatives for WHO-recommended ACTs
- Analysis of how to reach the private sector as well as MEDS' capacity to provide artemether-lumefantrine to the private sector. The GoK was prepared to apply price controls on the medicine in the private sector
- Guidance on legislative framework for the new policy

Finding Solutions to Implementation Bottlenecks

The DPTWG carefully considered the concerns raised by MoH policy makers, and as a result of considerable deliberations, working group members crafted the following strategies and activities to tackle the issues—

- RPM Plus and DOMC prepared a policy brief addressing the concerns on the choice of artemether-lumefantrine as first-line treatment and circulated it to members of DPTWG for input. The policy brief highlighted the fact that WHO supports the transition to ACTs based on credible antimalarial drug resistance data and evidence of the effectiveness of ACTs. The brief also stressed that DOMC through the DPTWG was working with other stakeholders to prepare clear treatment guidelines for every applicable age group, detailed distribution plans, and a communication strategy with messages targeting health care providers and the public.
- The consistent availability of artemether-lumefantrine could only be assured if the government decided to commit to the treatment change and place an order for ACT with Novartis Pharma. The GoK sought resources from other donors in addition to the Global Fund; for example, the DOMC used DfID funds to procure artemether-lumefantrine to introduce in pilot districts in Kenya. The KEMRI/Wellcome Trust Research Programme, RPM Plus, and DOMC worked together to quantify the number of treatments by regimen that each health facility needed for the artemether-lumefantrine pilot.
- At the DPTWG's request, RPM Plus prepared a briefing paper for the MoH to present to parliament in an effort to promote the need to allocate budget for procuring essential medicines and commodities, including artemether-lumefantrine, in order to reduce donor dependency.
- DPTWG recommended that the DOMC collaborate closely with the Pharmaceutical Society of Kenya regarding the complexities surrounding local manufacturers wanting to

produce artemether-lumefantrine and the challenges of marketing artemether-lumefantrine in the private sector. For example, Novartis produces a commercial Coartem product that is accessible to private wholesalers and is already marketed in Kenya. The subsidized artemether-lumefantrine from WHO is restricted to public-sector use, and has distinct packaging that differentiates it from the commercial version.

- Members of DPTWG asked the DOMC to draft a summary of the DPTWG's recommendations related to differential pricing of first- and second-line antimalarials in different health sectors for the Director of Medical Services to review.

CONCLUSIONS

“The DOMC acknowledges MSH/RPM Plus as a very proactive and responsive partner to work with. RPM Plus has played a very important role in the Drug Policy Technical Working Group, which has enabled Kenya’s efficient transition to the use of ACTs. The relevant, sustained and inclusive nature of RPM Plus technical assistance is commended.”

— Dr. Willis Akhwale, Head, Division of Malaria Control

Because Kenya’s entire policy implementation hinged on the timely availability of artemether-lumefantrine, RPM Plus focused its technical support on pharmaceutical supply and management issues and worked with the DOMC to overcome several implementation bottlenecks. For example, RPM Plus played a critical role in developing the GFATM round IV funding proposal and helped to quantify Kenya’s ACT procurement needs. In addition, RPM Plus built local capacity for pharmaceutical management through its work in health care worker training. In addition, RPM Plus responded immediately to other requests, such as assuring that rational medicine use issues are promoted in the case management trainings. The development of the *Transition Plan for the Implementation of Artemisinin-based Combination Therapy (ACT) Malaria Treatment Policy in Kenya* was one of RPM Plus’s major contributions and served to fast-track the process; the operational plan provided a road map for procuring, distributing, and storing the new medicines.

An important aspect to RPM Plus’s ability to support Kenya’s policy transition is having an in-country presence—being available to participate in all the DPTWG meetings and working closely with the DOMC ensured continuous dialogue and an ability to respond quickly to issues that may have constrained the successful implementation of ACTs. Throughout the transition and implementation process, RPM Plus’s major contribution has been to increase national awareness of the crucial role of pharmaceutical management in treatment policy.

Box 5 lists select tools and resources to which RPM Plus contributed during the planning, transition, and implementation of Kenya’s introduction of ACTs into the public and private health sectors.

Box 5. Tools and Resources

Planning and Coordination

- Changing Malaria Treatment Policy to Artemisinin-Based Combinations: An Implementation Guide
- Transition Plan for Implementation of Artemisinin-based Combination Therapy (ACT) Malaria Treatment Policy in Kenya
- Two-Year Operational Plan for Procurement, Storage and Distribution of Artemether-Lumefantrine and other Antimalarials (January 2006 - December 2007)

Treatment Guidelines & Case Management

- MoH National Guidelines for Diagnosis, Treatment, and Prevention of Malaria in Kenya, 2006
- MoH Training Guide for the 2006 National Guidelines for Diagnosis, Treatment, and Prevention of Malaria in Kenya, Facilitators' Manual
- MoH Training Guide for the 2006 National Guidelines for Diagnosis, Treatment, and Prevention of Malaria in Kenya, Participants' Manual
- RPM Plus Support to Case Management Trainings for Referral Hospitals, Private Health Facilities and Non-Governmental Institutions in Kenya, August – October 2006

Pharmaceutical Management

- Modeling the Anti-malarial Drug Requirements for the Kenyan Government's Formal Health Sector Using Imperfect Data
- Antimalarial Medicines Supply Chain and Stock-Outs at Government and Mission Facilities, Kenya, March–May 2004: Assessment Report
- Training materials for Basic Techniques for Managing Medicines and Supplies Course
- Report of the Workshop on Basic Techniques for Managing Medicines and Supplies (in Support of the ACT Policy Implementation in Kenya): November 23–25, 2005 Nairobi, Kenya
- Transitioning to ACTs: Ensuring Improved Management of Medicines and Supplies in Peripheral Health Facilities in Malaria-Endemic Districts of Kenya December 2005–May 2006
- Assessment of the Use of Antimalarial Medicines in Public and Private Sectors of Kenya: Research Findings for Evidence-Based Strategy Development, April 2006
- Artemether-Lumefantrine Dispenser's Book
- Plan for Phase Out of Antimalarial Monotherapies in Support of the New Artemisinin-Based Combination Therapy Policy, March 2007
- Availability of Antimalarial Medicines in the Kenyan Public Sector during the Initial Period following Policy Change: May 2007
- Quantification of Artemether-Lumefantrine and other Antimalarial Medicine requirements for Kenya: Year 2 of ACT Policy Implementation: July 2007
- RPM Plus Technical Assistance to the Kenya Division of Malaria Control for Establishment of a Malaria Information Acquisition System: MIAS Assessment and Recommendations Report: June 2007
- RPM Plus Support to the Division of Malaria Control for the Malaria Information Acquisition System (MIAS): Annual Report for October 1, 2006–September 30, 2007
- The Division of Malaria Control's Website: www.nmcp.or.ke

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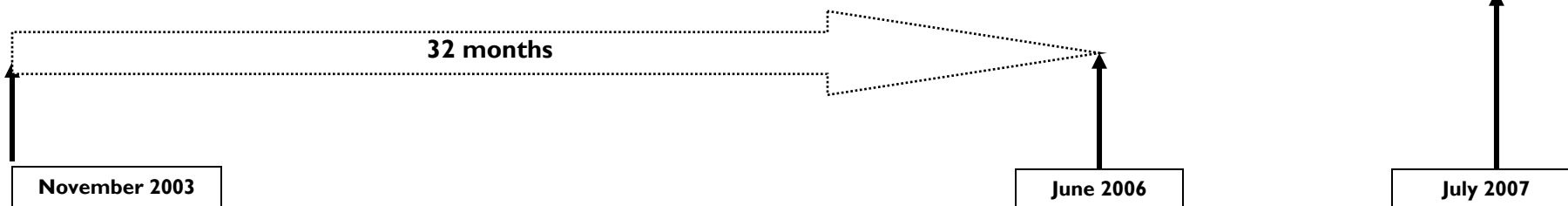
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ANNEX A

Time lines in Translating ACT Policy Change into Implementation in Kenya: November 2003-September 2007

Policy Review and Change Process	Re-organization of Existing DPTWG Structure	Operation and Technical Milestones	One year into ACT Policy Implementation
<ul style="list-style-type: none"> ▪ Inaugurate DPTWG. ▪ Review antimalaria drug efficacy studies and present of evidence for policy change. ▪ DOMC builds stakeholder consensus around new malaria treatment policy change. ▪ DPTWG members agree that Kenya should adopt new treatment for malaria; critical first step in the ACT policy change process. [April 2004] ▪ DOMC asks the DPTWG to draft the policy brief paper to address policy makers' concerns. [August 2005] 	<ul style="list-style-type: none"> ▪ Adopt new DPTWG structure with of four working groups and terms of reference on Case Management, Drug Supply and Management, Advocacy and Communication, and M&E. ▪ Publish the <i>Transition Plan for Implementation of Artemisinin-based Combination Therapy (ACT) Malaria Treatment Policy in Kenya.</i> ▪ Develop the <i>Two -Year Operational Plan for Procurement, Storage and Distribution of Artemether-Lumefantrine and other Antimalarials (January 2006 –December 2007).</i> 	<ul style="list-style-type: none"> ▪ Hold malaria national symposium to discuss malaria treatment policy. ▪ Confirm registration status of Coartem with Pharmacy and Poisons Board. ▪ GFATM round IV grant award; develop Procurement and Supply Management Plan; DOMC submits request to transfer funds to WHO to procure ACTs with GFATM money. ▪ Revise treatment guidelines and training manuals and print 50,000 copies. ▪ Complete first training of trainers and first phase of health care worker training. ▪ Stagger arrival of 12.3 million doses of Coartem and distribute to health facilities nationwide. ▪ Officially launch new treatment policy. 	<ul style="list-style-type: none"> ▪ Continue development of MIAS at DOMC. ▪ Monitor Coartem availability within public health facilities. ▪ Phase out of old amodiaquine stock continues to be challenge. ▪ Institute drug safety monitoring systems, launch pilot access projects, and plan for registration status change of artemether-lumefantrine to over-the-counter to allow greater community access. ▪ Address challenges in inventory management and improve access to first-line antimalarial medicines. ▪ Support the private sector in the transition. ▪ U.S. Government conducts Presidential Malaria Initiative assessment and pledges additional financial support to DOMC.



ANNEX B

Reorganized DPTWG Structure that Facilitated the Implementation of the New ACT Policy in Kenya

