Rational Pharmaceutical Management Plus
Meeting of Stakeholders to Discuss the Implementation Plan for the New Drug Policy for Malaria, Accra, Ghana, August 16 – 20, 2004: 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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Contents

Acronyms

ACT	Artemisinin-based Combination Therapies
AED	Academy for Educational Development
AMDP	Anti-malaria Drug Policy
AQ	Amodiaquine
ASU	Artesunate
BCC	Behaviour Change Communication
CDC	US Centers for Disease Control
CEO	Chief Executive Officer
CMS	Central Medical Stores
CQ	Chloroquine
DMIS	Drug Management Information System
DRA	Drug Regulatory Agency
EDM	Essential Drugs and Medicines
FDB	Food and Drugs Board
GAR	Greater Accra Region
GF	Global Fund
GFATM	Global Fund to Fight AIDS, Tuberculosis & Malaria
GHS	Ghana Health Service
GNDP	Ghana National Drugs Program
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HPU	Health Promotion Unit
HRU	Health Research Unit
ICB	International Competitive Bidding
ICP	Inter-country programme
IEC	Information, Education and Communication
IMCI	Integrated Management of Childhood Illness
IPT	Intermittent Preventive Treatment
MAC	Malaria Action Coalition
MAL	Malaria
MMSS	Malaria Medicines Supply Service
MNH	Maternal and Neonatal Health Program
MoH	Ministry of Health
MSH	Management Sciences for Health
NCB	National Competitive Bidding
NMCP	National Malaria Control Program
NMIMR	Noguchi Memorial Institute for Medical Research
PCI	Project Concern International
PHD	Public Health Division
PPME	Policy, Planning, Monitoring & Evaluation
PU	Procurement Unit
RBM	Roll Back Malaria
RDT	Rapid Diagnostic Test
RIII	Round 3

RIV	Round 4
RMS	Regional Medical Stores
RPM Plus	Rational Pharmaceutical Management Plus
SP	Sulphadoxine Pyrimethamine
SSDM	Stores Supplies & Drug Management
TA	Technical Assistance
TB	Tuberculosis
TOR	Terms of Reference
USAID	United States Agency for International Development
WG	Working Groups
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 drug 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), the US Centers for Disease Control (CDC), the Maternal and Neonatal Health Project (MNH) and RPM Plus.

In February 2004, Ghana changed its antimalarial drug policy for the treatment of uncomplicated malaria from chloroquine (CQ) to artemisinin-amodiaquine combination treatment, and submitted a proposal for the Round 4 (RIV) Global Fund (GF) grants to support the implementation of this policy. This proposal was approved and the National Malaria Control Program (NMCP) of the Ghana Health Service (GHS) is preparing for the implementation of this new policy in January 2005. To plan for this implementation, the GHS requested technical support from its partners in the malaria control effort to attend a meeting with all its partners to develop a plan for the transition period. This meeting took place from August 16-20, 2004.

RPM Plus, through the MAC, having been an active partner providing technical support to the NMCP to develop its antimalarial treatment policy and Global Fund RIV Proposal, was invited to participate in the planning of the implementation of the new policy.

Purpose of Trip

Grace Adeya and Gladys Tetteh from RPM Plus traveled to Accra, Ghana from July 14 – 21, 2004 to provide technical support to the Ghana Health Service in preparation for the implementation of the new malaria treatment policy.

Scope of Work

The scope of work for Grace Adeya and Gladys Tetteh on this trip was to:

- Work with the Ghana Health Service, WHO and other RBM partners to develop a plan for the introduction of the new antimalarial treatment policy.
- Provide an arrival briefing and/or departure debriefing to USAID upon request.

Activities

Work with the Ghana Health Service, WHO and other RBM partners to develop a plan for the introduction of the new antimalarial treatment policy.

The 5-day activity started with a formal meeting on August 16, 2004 which involved all major stakeholders for implementation of the ACT policy *(see Annex 1 for program and participant list)*. The subsequent 4 days were dedicated to work planning among the stakeholders.

WHO/AFRO and MSH/RPM Plus provided external technical assistance. RPM plus gave a presentation on the first day *(see Annex 2)* which outlined the steps needed for implementation which are included in the implementation guide that RPM Plus developed in collaboration with WHO, the RBM partnership and the Global Fund.

Below are the main points that were discussed during the 5-day undertaking.

1. **Roll-out of the new policy** – The Ghana Health Service (GHS) had anticipated a national rollout of the new policy in January 2005 but, by the end of the week, it had become clear that a phased implementation would be the most effective method and the start date may have to be postponed. The phased implementation would entail rolling out the policy in districts and the progression would be based on the readiness of districts (as was done for the rolling out of implementation of the IPT policy). A major determinant of when and how to phase-in the implementation is the availability of the drugs (including limited global supplies of ACTs and limited national financial resources for their procurement) and the political and/or ethical issue of continuing to use CQ in some districts given the high resistance levels. These questions were not resolved during the mission, and have to be agreed on soon as it has direct implications on all the procurement and distribution activities.

2. **Drug Registration** – Amodiaquine (AQ) and Artesunate (ASU) are both registered as monotherapy formulations with the Food and Drugs Board (FDB) in Ghana. However the co-packaged AQ-ASU in combination is not registered. There is an abridged registration process for public sector procurements only. This abridged registration process takes approximately two weeks and has to be initiated by the Ghana Health Service (GHS) through the procurement unit to the FDB. However this registration is only valid for the life of the tender to which it applies and the suppliers would still be subject to the full registration process which takes approximately 12 weeks. It was not clear whether any of the WHO pre-approved companies have registered any of their AQ or ASU products in Ghana; however, if the plan is to procure prepackaged products from these suppliers, then it is likely that the initial procurements supported by the GF may have to use the abridged registration process to purchase the drugs for the public sector while awaiting the full registration.

3. **Quantification** – The Ghana Round IV proposal estimated annual malaria episodes at approximately 3.5 million and planned for treatment of 600,000 episodes in Year 1 of implementation of the proposal. These figures are very likely to be underestimates of the real incidence rates and the uptake of the new policy – and based on the experience in Zambia – may lead to shortages of the ACTs once the policy is implemented. The incidence figure was obtained from the national health management information system (HMIS) data which reports data from public health facilities and a few mission facilities. The NMCP estimates that approximately three quarters of the facilities expected to report to the HMIS are providing information as required though we were not able to verify this with the HMIS personnel. The procurement unit determined that they would require TA to undertake a detailed quantification of the national need for AQ/ASU. The challenge will be to get better incidence rates (since there is limited information on the private sector malaria incidence and management) and to model uptake of the new policy in the public health facilities. Determination of rate of uptake of new policy alongside phased implementation would enable system strengthening for AQ/ASU tracking and re-supply.

4. **Procurement**- The procurement unit was under the impression that, although quantification would be done to determine the national requirements for Ghana, there would be two separate tracks for the procurement of ACTs into the country:

   a) According to the Director of Public Health, the GFATM-supported procurements (for 600,000 doses of AQ/ASU) would be handled by the Fund and the RBM secretariat and the role of the procurement unit would be limited to the preparation of the tender documents. This process would then result in receipt of the first batch of ACTs in Ghana in December 2004.
   b) A second track for procurements using MOH resources would be needed (to cover the needs for the remaining malaria episodes in the country) and this would be subject to their normal procurement rules and regulations. The normal procurement process takes at least 8 – 12 months and we estimated that any drugs procured using this process would not be available until Aug - Sep 2005 at the earliest.

Based on later conversations, it appears that the information available to the country on how the GFATM-supported procurements would be done was incorrect. The system established by the RBM secretariat will initially be working essentially as a “broker” between the national procurement authorities and the suppliers (the systems are not yet in place to do more). The national authorities would have to go through their normal procurement process, select a supplier, then submit this information to the RBM secretariat (or the Malaria Medicines Supply Service [MMSS]) to act as the broker between them and the supplier. This was mentioned to the NMCP as it directly impacts their planning, but the functioning of this system definitely needs to be clarified by the GFATM and RBM secretariat and communicated to the national authorities soon.

Additionally, the procurement unit’s list of prequalified suppliers has already been developed and will not be revised until next year. No suppliers of AQ and/or ASU are on this list. Based on

the Ghana regulations, the WHO pre-approved suppliers are not automatically included on this list and will have to apply to the Ghana procurement unit for addition to the prequalification list at its next revision. Initial procurements of the ACTs will have to be done through an open tender system unless specifically limited by the GFATM rules.

4. **Prepackaging** – the GHS, FDB, local manufacturers and other stakeholders have had discussions on the national standards for the ACT combination prepackaging to be used in Ghana. Based on these discussions they have agreed to use pre-packaging with color coded tablets using the following system:

    a) AQ tablets for all age-groups will be yellow (which is the current normal color).
    b) ASU tablets would be colored based on the treatment age-groups
        i) White tablets – for adults (>13 years)
        ii) Blue tablets – for children 7 to 13 years
        iii) Pink tablets – for children 1 – 6 years
        iv) Orange dispersible tablets – for infants (<1 year)

These specifications conflict with the recommendations of a recent WHO consultative meeting on prepackaging of antimalarials. This meeting established global standards for prepackaging of antimalarials – the recommendation being that the tablets for different age-groups should be the same color and the differences should be in the primary or secondary packaging. In Ghana, the GHS and FDB were unaware of this recommendation when developing their standards, and it is unclear how much flexibility they have to change their own specifications given that it is the result of national consultative process. Also unresolved was the extent to which the WHO prequalified suppliers will be able and/or willing to meet the specifications of individual countries given that they participated in the WHO consultative meeting and were part of the process in developing the global standards.

The procurement unit is already working on developing a procurement plan based on their past procurements but this will remain a provisional plan until some of these issues are addressed.

Mission Output

The main output of the 5-day meeting was a draft strategic framework *(Annex 3)* and a draft implementation plan *(Annex 4)* for the new malaria policy. The implementation plan lays out the key actions, technical/operational leads, estimated timelines and resource requirements for seven major areas, namely –

- Financing
- Planning and Coordination
- Drug Regulatory Issues & Quality Assurance
- Malaria Treatment Guidelines/Training
- Advocacy and Communication
- Procurement/Forecasting/Existing Stocks/Distribution/Stock Management
- Monitoring & Evaluation

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

A debriefing meeting was held with Ursula Nadolny, Chief, Health, Population & Nutrition Unit of USAID and Peter Wondergem, HIV/AIDS advisor of USAID on Friday, 20th August 2004. The week's activity was discussed as well as planned RPM Plus FY 2004/5 activities to support the implementation of the malaria policy.

Collaborators and Partners

WHO/AFRO
Dr. Josephine Namboze

WHO/ICP/MAL
Dr. Jackson Sillah

Malaria Consortium
Dr. Joseph Somuah Akuamoah

WHO Country Office, National Professional Officer
Dr. Felicia Owusu-Antwi

Discussions and individual meetings were held with stakeholders including:

- Director, Division of Public Health, GHS
- Manager, National Malaria Control Program, GHS
- Director, Procurement and Supplies Division, MoH
- Head, Procurement Unit, MoH
- Head, Human Resource Division
- Representative, Pharmacovigilance Unit
- Head, Epidemiology Unit, NMIMR & chairman of the AMDP review taskforce
- Representative, Private Sector
- Chairperson, Case Management sub-committee of the AMDP review taskforce
- Representative, Planning, Policy, Monitoring & Evaluation Unit
- Head, Central Medical Stores
- Deputy Chief Executive Officer, Food & Drugs Board
- Representative, Health Promotion Unit

Next Steps

Immediate Follow-up Activities

- Determination of availability of global supplies to meet country ACT (AQ/ASU) requirements
- Collaboration with PU/CMS to determine feasibility, methodology and timing of detailed quantification of national ACT requirements
- Clarification of GFATM/RBM arrangement with countries for procurement of ACTs
- Determination of MAC/AED contribution to Ghana's communication efforts in support of new policy
- Work with NMCP to finalize Strategic and Implementation Plan in order to initiate carrying out of key actions
- Debrief USAID and RPM Plus on outcome of trip

Annex 1

MEETING TO DISCUSS IMPLEMENTATION PLAN FOR NEW ANTI-MALARIA TREATMENT POLICY IN GHANA - PROGRAMME

Arrival/Registration of Participants	
Welcome and Introduction of Chairman *(Dr. Kojo Koram - Chairman of the Anti-malaria Drug Policy Review Task Force)*	**Mrs. Aba Baffoe-Wilmot**
Presentation – Objectives and Expected Outcomes of Meeting	**Dr. George Amofah - Director of Public Health**
Presentation – The New Drug Policy, progress made, proposed timelines for managing change	**Dr. Constance Bart-Plange National Malaria Program Manager**
General Discussion	
Perspectives of the Mission	**WHO Team** **MSH/RPM Plus Team**
General Discussion	
Introduction to Group Work	**Director of Public Health**
Group Work	
Feedback from Group Work	
Summary/Way forward	**Chairman**

NATIONAL MALARIA CONTROL PROGRAMME

REGISTRATION FORM

ACTIVITY: MEETING FOR THE IMPLEMENTATION PLAN OF THE NEW DRUG POLICY

DATE: 16TH AUGUST 2004-08-19

VENUE: MIKLIN HOTEL

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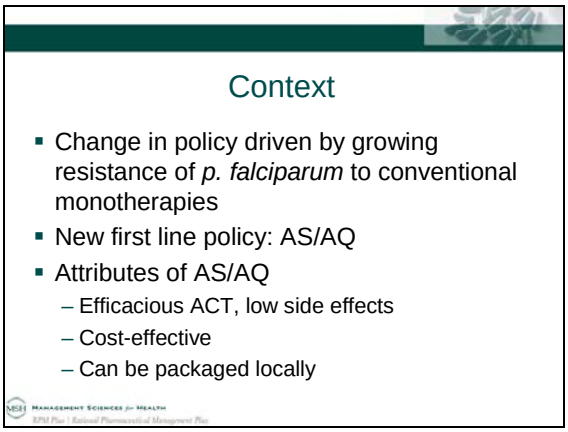
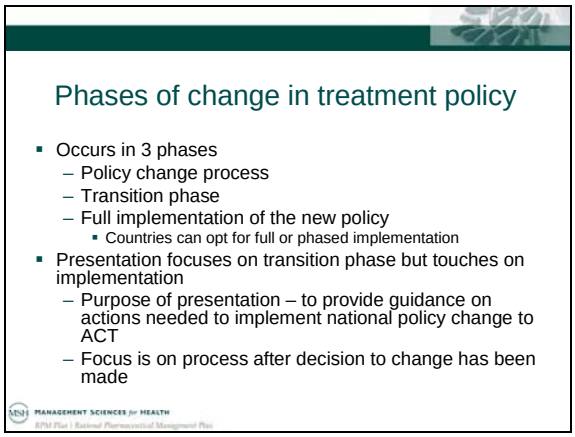
44.	Mr. Kofi Osae	NMCP	0208175828	-
45.	Mr. Emmanuel Twumasi	GHS/NMCP	0208179846	

Annex 2. RPM Plus Presentation on ACT Implementation





Framework for implementation of ACT policy (1)

- Financing
- Planning & coordination
  - Identify stakeholders
  - Establishment of committees
- Technical considerations
  - Drug regulatory considerations
  - Pharmacovigilance
    - Quality Assurance
    - ADR monitoring
  - STGs and other guidelines

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Framework for implementation of ACT policy (2)

- Technical considerations (cont.)
  - Communication
    - IEC/BCC
    - Training

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Framework for implementation of ACT policy (3)

- Operational considerations
  - Procurement
    - Forecasting
  - Prepackaging
  - Distribution
    - Inventory management
  - Phasing out of old drug
  - Private sector access
- Monitoring & Evaluation

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Financing

- Before beginning policy implementation process, critical to ensure that financing issues have been addressed
- Effective transition and implementation likely to require a time-limited investment of additional resources
- Costs should be and in Ghana's case have been budgeted for at the planning stage
  - Commitment from departments within country and from donors need to be sought before beginning the implementation process

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Planning and coordination

- Identify stakeholders
- Determine their roles and responsibilities
- Establish transition committee and other working groups/task forces with responsibilities such as:
  - Program planning
  - Implementation plan development
  - M & E

  and determine persons responsible for execution of implementation plan and M&E plan
- Establish TORs for working groups/ taskforces and develop mode of work and frequency of meetings

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Drug regulatory considerations

- Registration of AS/AQ combination *(shd happen early)*
- Evaluate regulatory enforcement capacity and develop plan for strengthening
- Promulgate regulations for appropriate prescribing and dispensing of AS/AQ
- Promulgate regulations to facilitate phasing out of old drug and/or monotherapies if needed
- Review diagnostic requirements for treatment (clinical, biological (microscopic/RDTs))
- Consider policy for pregnant women (1st trimester)

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Pharmacovigilance

- Quality Assurance systems
  - Develop/review systems for QA during procurement
  - Develop/review systems for violations against drug quality standards
  - Develop review plan for post-marketing product quality surveillance

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Pharmacovigilance

- ADR monitoring
  - Develop/review system for monitoring of adverse events
- Establish mechanism to coordinate the surveillance systems (effectiveness, product quality, ADR)

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National treatment guidelines

- Determine which guidelines need to be revised
  - National malaria treatment guidelines
  - Ghana STG/EDL
  - IMCI/RH
- Determine the process for revision, groups involved, TA needed and timelines
  - New guidelines *vs.* addendum
- Publish and disseminate new guidelines

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Communication

- Training
  - Revise pre-service and in-service training curricula to incorporate new guidelines
  - Develop/review plan for training of health workers on new guidelines
  - Convene training workshops immediately after
- IEC/BCC
  - Develop/review BCC strategies
  - Develop/review IEC strategies
  - Develop/review plan for implementation of BCC strategy

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Procurement

- Develop procurement plan
- Identify source of TA if needed and obtain assistance
- Develop tender documents
- Initiate and manage procurement process
- Monitor supplier performance

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Quantification

- Obtain morbidity and/or consumption data from the field
- Calculate estimated consumption (ACTs have a short shelf-life)
- Adjust quantities based on budget

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Pre-packaging

- Identify manufacturer for pre-packaging of combination
- Develop weight/dosage schedules and appropriate pre-packaging for children
- Determine if same packaging should be used in public and private sectors

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Distribution and inventory management

- Develop/review distribution plan
- Review/develop inventory management systems to improve management of AS/AQ in peripheral health facilities
- Develop/review strategies to prevent leakage to private sector
- Develop/review distribution systems to remove expired stocks
- Develop/review systems to monitor efficiency of distribution system and re-distribution mechanisms

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Phase out old drug

- Determine pipeline for old drug through central and peripheral data collection
- Adjust future procurements of current drugs to avoid accumulation of large pipelines of old drug when new drug is procured
- Develop plan for phase out of current drug from health system as new drug becomes available
- Withdraw old drug using plan developed above when change occurs

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Private sector

- Develop plan for making AS/AQ available in private sector
- Consider appropriate interventions (e.g. accredited private practitioners /pharmacies/ chemical sellers) to enable access
- Train relevant private sector providers

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Monitoring & Evaluation

- Define performance targets
- Define program milestones/indicators
- Identify data needs *(including existing data)*
- Develop/adapt information systems
- Identify and address human and IT resource needs
- Develop schedule for M&E activities
- Implement M&E plan- determine who will be responsible

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Some relevant M & E indicators

- Prompt, effective antimalarial treatment
  - Outputs
    - Number of patients with uncomplicated and severe malaria receiving correct diagnosis and treatment
    - Health facilities with no reported stockouts of antimalarial drugs
  - Outcomes
    - Children under 5 years of age with access to prompt effective treatment
    - Patients with severe malaria receiving correct treatment

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Resources

- **Policy Formulation**
  - WHO/AFRO (2003). Framework for Developing, Implementing and Updating National Antimalaria Treatment Policy: A Guide for Country Malaria Control Programmes. AFR/MAL/03.02.
- **Pharmaceutical Management**
  - Management Sciences for Health and World Health Organization. Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals. 2d ed., rev. and exp. W. Hartford, CT: Kumarian Press, 1997.

MANAGEMENT SCIENCES for HEALTH

Annex 3. Strategic Plan for the Introduction of ACTs in Ghana

INTRODUCTION

Ghana initiated the process of drug policy change in 1998. At that time, the need to collect more data to support the anecdoctal evidence of increasing chloroquine (CQ) and Sulphadoxine / Pyrimethamine (SP) resistance was deemed necessary. By 2002, with the data from drug efficacy studies from 6 sites, the stakeholders recommended that there was sufficient evidence for increasing CQ resistance to support the policy change. However, more information on the appropriate drug combination to be used in the new anti-malarial drug policy was requested and a multidisplinary task force established to collect and collate this information.

Based on their analysis, the multi-disciplinary task force recommended a combination of Artesunate +Amodiaquine to replace chloroquine as first line treatment of choice for uncomplicated malaria managed in the health facilities. This recommendation was endorsed at a General Consensus meeting that was hosted by the national malaria control program (NMCP) and the GHS in April 2004. This decision was based on the ease of implementation of this combination, the possible participation of the private sector in ensuring availability of the combination, and the lower cost of this combination compared to the artemether/lumefantrine combination.

The new malaria drug policy is as follows:
Artesunate+Amodiaquine: First line treatment for uncomplicated malaria
Quinine tablets: Second line treatment for uncomplicated malaria and for treatment failures
Parental quinine: treatment of severe and complicated malaria.

Ghana has already secured funding from Global Fund under the fourth round grants to support part of implementation of the new policy. The current plan is for implementation of the ACT policy to start in January 2005.

Purpose of this document

This document will serve as a guide for implementers at all levels on key actions that need to be undertaken for the smooth implementation of the anti-malarial drug policy change. It mainly focuses on the preparatory phase of policy change and sets up mechanisms that will support actual implementation. It aims at ensuring the achievement of the following objectives:
To review the drug management system to ensure that it supports the change;
To update already existing guidelines and training manuals to include the drug policy change
To come up with a realistic plan that is cost–effective for orientation of all cadres of health staff on the new drug policy;
To review the various communication materials and strategy for creating awareness on the new drug policy change; and
To strengthen monitoring and evaluation system in order to track the process and key technical areas relating to ACTs.

Planning & coordination

As a preliminary step, the Ghana Health Service requested for technical assistance in order to develop a provisional strategic plan that will be followed during the preparatory period. During the planning process, all possible partners to be used during implementation were identified and consulted so that their roles and responsibilities were agreed upon. Also the funding options for some of the processes will be finalized during this period. This will allow for identification of gaps that may require additional resources and work out ways of rapidly addressing these so as not to halt the process. Initial funding of these activities will mainly be from Global Fund.

From the information that is available to the programme, health care is provided from 3 main sources. These are namely: the public sector that caters for about 40% of population, mission facilities – 30% and the private sector 30%. However, these figures only include those that seek care from health facilities (proportion not known)**. It is therefore important that during the planning process, clear strategies for addressing all these actors and particularly the private sector, are worked out.

In order to avoid the likely problems of having two drug policies in place, it was agreed that the process of introduction to achieve national coverage should be expedited. It is proposed that complete coverage be achieved in a period of about 12-18 months. Phased implementation therefore, needs to be adequately planned.

For ease of implementation, and for elaboration of the tasks and key actions, four working groups (WG) were agreed on. These are :

Drug Supply and Management Group (includes drug regulatory, quality assurance, forecasting, procurement& procurement plan, pricing, distribution and inventory management, phasing out old drug)

Case Management Group (revision of treatment guidelines, training manuals, Standard Treatment Guidelines, Essential Drug List, IMCI, curriculum, training plan, plan for dissemination of materials, guidelines)

Advocacy and Communication Group: Review/revise Behavior Change Communication strategies (Review existing materials/documents and develop new ones. Develop/review plan for implementation of BCC strategy)

Monitoring and Evaluation Group:
a. Monitoring the Policy Change (The system)
To develop a plan/ framework for monitoring the implementation of the new drug policy

b. Monitoring technical components on availability, use and Effectiveness of ACT
Areas to be covered include:
Monitoring *Availability* and *Quality* of artesunate-amodiaquine,
Post-market surveillance to eliminate *sub-standard drugs* from the market,
Prescribing and dispensing habits and dosage compliance

Drug Efficacy: Expand 6 sentinel sites to 10 for monitoring artesunate-amodiaquine, sulfadoxine-pyrimethamine and quinine
Pharmacovigilance (adverse drug reaction monitoring).
Develop strategies for incorporating the private sector in all malaria activities
The proposed Terms of reference for each working group and membership are in annex 1.

Proposed method of work

These working groups should be facilitated to rapidly come up with the key strategies that will need elaboration. The proposed ways this can be done is by facilitating a work shop outside Accra that will bring all the key focal persons in each WG to finalize the plan and agree to the strategies outlined in this document. The intended workshop will result in the finalization of the strategic plan and eventual start of the activities. But for this to be successful, those that are key should be encouraged to draft the key documents and present these during the workshop and the subsequent meetings.

A coordinator of each working group will convene the meetings. He with the team will submit a budget of their requirements that will enable them complete the tasks. A total period of 15 working days will be given to each group to finalize their tasks.

The guiding principles will be for these working groups to adapt and adopt existing guidelines, materials and systems rather than developing new ones if these already exist. Cross consultation will be facilitated so that all aspects are adequately planned. At the end of this period, a feedback will be arranged by NMCP and the strategic plan will be finalized.

Coordination of activities

It is proposed that a consultant will be recruited to assist with the preparatory activities. He/she will assist NMCP to coordinate activities and actors involved in the implementation. The consultant will initially be contracted for six months.

Drug supply and management

As part of its' successful GFATM round 4 proposal, Ghana plans to procure sufficient AQ/ASU through the GFATM, to treat approximately 600,000 episodes of malaria in Year 1 of the implementation of the new malaria policy. In 2003 there were an estimated 3.6 million episodes of un-complicated malaria treated at the public health facilities[1], thus the GFATM procurement would represent approximately 20% of the requirements. Additional resources will be required for the procurement of additional AQ/ASU to meet the national requirements; and for the procurement of drugs and commodities required for the management of complicated or severe malaria (including quinine, intravenous kits and solutions, and the laboratory requirements for microscopy). The availability of the AQ/ASU is integral to the success of the implementation of

[1] The number of episodes is based on data from HMIS. The HMIS collects information from public health facilities and some mission health facilities. It is estimated that only 78% of these facilities are providing reports to the HMIS system.

the new policy therefore the issues around related to the management of these drugs must be addressed soon.

Forecasting

Assumptions: Only about 60% of all malaria episodes are treated in some health facility.
Of these about 70% are treated in both the public and missionary facilities
3 Episodes of fever per year for children below 5 years of age
2 Episodes of fever per year for all those above five years

The estimated number of episodes that will be treated in the first year assuming a nation wide coverage is therefore:
Total population: 19,200,000 people
60% of this: 11,520,000 People -Assuming only 70% of these are treated

Age band	Population	Number of episodes a year	Number of doses of anti-malarials per year
Under 1 year	322,560	967,680	967,680
1-5 Years	1,290,240	3,870,720	3,870,720
6-13 Years	3,225,600	6,451,200	6,451,200
Above 14 years	3,225,600	6,451,200	6,451,200
Total	**8,064,000**	**17,740,800**	**17,740,800**

These forecasts give a rough estimate of the potential need for ACTs in the country; however accurate quantification needs to be done for the actual procurement. This is discussed further below.

Drug Regulatory Requirements and Quality Assurance

Drug Registration

Some Artesunate and Amodiaquine products are already registered as individually packaged products by the Food and Drug Board (FDB) of Ghana. All these products are registered as prescription-only-medications. No ACT prepackaged products or fixed dose combinations have been registered in Ghana therefore registration of the AQ/ASU, if procured as a prepackaged product, will be required of the suppliers selected during the procurement process. The regular registration process usually takes approximately 12 weeks from the date of submission of the full registration dossier by the supplier with a registration fee of $1000. An abridged system which takes approximately 2 weeks for a fee of $200 exists for public sector procurements, where the selected product is not already registered. The abridged registration process would need to be initiated by the Ghana Health Services (GHS) through the procurement unit and the resulting registration is valid only for the life of the tender. The supplier would still be subject to the full registration process. The abridged registration will be required for the initial procurements of the AQ/ASU for the implementation of the new malaria policy.

Prepackaging

The GHS, FDB, local manufacturers and other stakeholders have had discussions on the national standards for the ACT combination prepackaging to be used in Ghana. Based on these discussions they have agreed to use the following system:
AQ tablets for all age-groups will all be yellow (which is the current normal color).
ASU tablets would be colored based on the treatment age-groups
White tablets – for adults (>13 years)
Blue tablets – for children 7 to 13 years
Pink tablets – for children 1 – 6 years
Orange dispersible tablets – for infants (<1 year)

Drug Deregulation

The use of ACTs outside of the health facilities (e.g. for community based management of malaria; for sale by chemical sellers) would require the deregulation of ACTs to Over-The-Counter (OTC) products. The decision on how soon to use ACTs at community level is still outstanding. Depending on the availability of data, gazetting of the deregulation will occur in one of the two ways;
Through the development of a legislative instrument that will be submitted to parliament through the Attorney-General. This process can take more than six months and depends on the legislative calendar.
The NMCP can submit a request for deregulation through to the FDB who then advise the Minister of Health. Based on this advice, the minister may issue an administrative instrument to be gazetted through the attorney-general's office. This process takes a shorter time – up to six months.

There is also an interest on the part of the NMCP to deregulate the use of Artesunate and Amodiaquine as monotherapy drugs and thus only register them for use as combination drugs. This requires strengthening of the enforcement capacity of the FDB and the pharmacy council. This raises several complexities particularly with respect to the private sector and the FDB, and should not be the focus in the initial year of implementation of the policy.

It is advised that the method where NMCP submits a request through FDB will be used.

Related to this, there is also a need to start a process with Ghana national Drug Programme (GNDP) for the revision of the scheduling of antimalarial drugs for appropriate levels. This process normally requires agreement of the levels of care to which particular antimalarials should be assigned and subsequently adding an addendum to the essentials drug list.

Drug quality assurance

Systems for assuring the quality of drugs before and after registration with the FDB already exist. The FDB and the Pharmacy Council of Ghana work together to conduct the post-marketing surveillance of products already in the market however there is a need for additional human and financial resources to strengthen the capacity of these organizations. The capacity of the laboratory services of the FDB to test the quality of ACT products also needs to be strengthened. There is a particular need to support the purchasing of the laboratory consumables (e.g. reagents)

and the human resource capacity. As these are strengthened, there is also need to link this up with the drug information center.

Procurement & Quantification

While rough estimates of the initial requirements of AQ/ASU for implementation of the policy have been done, accurate quantification of the drugs and other commodities that will be required to meet the requirements for a nationwide implementation of the new malaria policy still need to be done. Quantification is the first step in the procurement process and thus needs to be completed as soon as possible preferably by the end of October 2004. Adjustments to the estimated quantities will need to be made before the next procurement cycle to take into account any changes in health facility utilization resulting from the availability of new more effective drugs in the public health sector.

Procurement of ACT

A procurement plan will need to be developed as soon as quantification is completed. This plan needs to take into account the two separate tracks that may be needed for the procurement of the ACTs. Initial procurement of ACTs using the grant from the GFATM will be part of a pooled procurement coordinated by the RBM secretariat. At a minimum the GHS will need to prepare the tender documents and submit these documents to the RBM secretariat. The exact details of how this procurement process will work needs to be clarified soon with the GFATM and the RBM secretariat. This would need to be done by the end of October 2004. As noted above, the funds from the GFATM are not enough to meet the ACT requirements for a nationwide roll-out of the new policy but it should be enough to meet the requirements of doing a phased-implementation of the policy.

If a nationwide roll-out of the policy is preferred additional resources for the procurement of ACTs will be required and this procurement would be subject to the Ghana government regulations. These regulations include:

Tenders for goods valued at $50,000 - $400,000 can be conducted using the National Competitive Bidding (NCB) process. This is open only to companies registered in Ghana. Tenders for goods valued at $400,000 - $1,000,000 have to be conducted using the International Competitive Bidding (ICB) process and is thus open to all companies from any part of the world.

Ghana has recently adopted a pre-qualification system[2] for the procurements of public sector drugs, and the list of pre-qualified suppliers for the next two years has been developed (the list will be reviewed every two years to add / remove suppliers from the list). Bidding on tenders for the procurement of drugs will therefore be limited to the list of prequalified suppliers. No supplier of AQ/ASU has been prequalified though it is expected that some suppliers will be added to the list when it next revised. The initial procurement of additional AQ/ASU

[2] At present the WHO prequalified suppliers of ACTs are not automatically included in the list of prequalified suppliers used by the GHS and they will still need to submit an application to the GHS procurement unit to be included in its pre-qualified suppliers list. As the GHS has adopted the specifications developed by the WHO for pre-qualification of suppliers, it is unlikely that there would be any barriers to the inclusion of these suppliers to the GHS list of pre-qualified suppliers.

requirements through the regular procurement process would therefore be a NCB or an ICB depending on the value of the tender.

The regular procurement process can take between 8 – 12 months from initiation of the process to the delivery of the drugs at the CMS. If the process begins in November 2004 after completion of the quantification, then delivery of the ACTs would not be expected to occur before August 2004. A system for monitoring the performance of suppliers exists and a plan needs to be developed for the monitoring of the suppliers of the ACTs. This plan needs to be completed before the contracts with the ACT suppliers are signed.

Distribution and inventory management

Ghana utilizes a tiered 'Pull' system[3] to supply required drugs and commodities to the peripheral health facilities. However this systems depends on the availability of reliable transportation at the peripheral facilities which is not usually the case. A comprehensive distribution strategy and plan (from the perspective of the peripheral health facilities) needs to be developed and strategies for utilizing the private sector to assist in this should also be explored. The distribution plan needs to include a strategy for the re-distribution of soon-to-expire stocks from one health facility to another where they can be used before they expire. Such a strategy is best coordinated by the regional medical stores (RMS) and the central medical stores (CMS). There is also a need to review the inventory management systems to improve store-keeping practices at the health facilities, to reduce diversion of ACTs from the health facilities and to dispose of expired stocks appropriately. All this needs to be done by the end of December 2004.

Phasing out of Chloroquine

There is a sufficient stock of CQ at the CMS to last until September 2005, if the current consumption patterns remain the same. Information on the current stock levels of CQ in the regional medical stores and in the health facilities is not available at this time and this information will need to be obtained by the end of November 2004 in order to properly plan for the phase-out of CQ from the public health system. This phase-out plan would need to be completed by December 2004 and this needs to be coordinated with the distribution plan. A plan for the phasing out of CQ from the private sector is more complex and this may need to be deferred until the completion of the implementation of the new policy in the public health sector.

Case management

Two major activities are planned. These are the updating of various guidelines and training manuals and the orientation of all health workers. This will be for public and private sectors, quasi-governmentt and mission hospitals, pharmacies and chemical sellers.

Private sector

Although the private sector takes care of about 30% of health needs of country, this is mainly in the major urban areas. The private sector can be broadly grouped into three:

[3] The health facilities are responsible for collecting their drugs from the district medical stores (DMS); the DMS is responsible for collecting its drugs from the regional medical store (RMS); and the RMS is responsible for collecting its drugs from the central medical store.

a. Private-sectors hospitals and clinics headed by doctors. Some of these doctors belong to the society of private practitioners. It is easier to deal with the organized groups that are members of the society. They can be approached through the society for the necessary updates

b. Private sectors headed by midwives/nurses: midwifery clinics registered by the nurses and midwifery council.

c. Private sector made up of pharmacies and chemical sellers

All these groups will be individually targeted to ensure that they all benefit from the orientation.

Revision of guidelines and training manuals

There are several documents that will require revision. These include the anti-malarial drug policy document, malaria treatment guidelines and the training manuals for health workers. A different training manual will be developed for the different level health workers thus emphasizing the main areas of focus. As a guide, the training of health workers in referral care facilities will mainly focus on the management of severe malaria and those in primary level facilities, management of uncomplicated malaria using the IMCI approach. It therefore means that the intended revisions will be worked on alongside the updating of the guidelines.

To assist with the training and orientation of different cadres of health workers, job aids too will be developed that will include posters, fact sheets and treatment charts. These will serve as easy take away packages after orientation.

The other materials that will need updating are the IMCI & IPT training manuals, Standard Treatment Guidelines, Essential Drug List, and Standard Operating Procedures for management of pharmaceutical products. The revision of these materials will be undertaken by the members of the case management working group.

Production and dissemination of revised materials

The key ones, especially the job aids will be translated in the key local languages before production. The distribution of these materials is planned to be during orientation of the health workers. All materials produced will take into account the private sector as well.

Plan for orientation of the health workers

Two major sensitizations will be undertaken, one for all key persons expected to facilitate the process and the second is the actual orientation of health workers in both public, including mission facilities and the private providers.

Sensitization of key stakeholders

Key stakeholders will be identified especially those that contribute in one way to proper case management. Among those identified are at national level include the Deans of medical schools, principals of training schools, Chief executives of health institutions and Quasi-government health institutione – University hoepitals, police, mining, GHAPOHA, military, cocoa clinic, etc. This sensitization could be extended to other players: regional representatives drawn from the public and private sector including tutors in the training institutions. After successful completion

of this sensitization, the country could be zoned to facilitate further orientation. Three zones are proposed: northern, middle and southern zones. Key people for each zone will be identified, to become the contact persons. The national level will mainly play the coordination role and training/orientation will depend on availability of drugs and resources.

Orientation of health workers

It is important to point out the need of a comprehensive plan for orientation of all the health personnel in both the public and private sectors. In drawing up this plan different cadres of health workers are recognized. Table 1 below outlines the cadres of health workers that will need orientation and possible areas of orientation.

Generally speaking for the health workers within the public system and mission facilities, orientation will be through the cascade system. This will start with the training of national facilitators; who in turn will train the regional trainers. It is recommended that training should only start within a month from the delivery date of the new drugs. After this training, the regional trainers will draw up a plan for training district trainers. The district trainers will be trained and after the training, they in turn will draw up a plan for orienting all health workers within their catchments area. For quality to be maintained, it is proposed that a national facilitator works with the trainers at the different levels. In order to ensure coverage and adequate support of the process, the unit in-charges will be first given an orientation. The advantage of this is that they will then be able to support the process as health workers are enrolled into the orientation. The orientation will be organized at the nearest level bringing about 20 health workers per session. It is proposed that this can be for 2 days covering the areas in table 1 below. After this orientation, a system of follow – up of those oriented to facilitate uptake of the new behavior will be instituted. The health unit in-charges can be tasked with this responsibility in the initial period. In the long term, supervision will need to be integrated in the already existing system and those undertaking it facilitated to do it properly.

For the private sector, orientation and distribution of materials could be arranged through the medical councils and the department for registration of the health practitioners. Mass communication and other innovative means could also be used in the sensitization of these health workers.

Table 1: Summary of orientation details of health workers

Cadre of staff	Content	Length of time	Who responsible	Materials needed
National facilitators/trainers	New drug policy System of monitoring implementation Treatment schedules by agegroups Establishment of a pharmacovigillance	To be completed by NMCP	To be completed by NMCP	To be completed by NMCP

Cadre of staff	Content	Length of time	Who responsible	Materials needed
	system Roles and responsibilities			
Medical Doctors	As above			
Nurses/health assistants at hospitals	As above			
Nurses/health assistants at health centres	As above			
Laboratory technicians	Microscopy RDTs			
Drug inspectors	New drug policy DMIS Issues related to phasing in of new drug Monitoring for expiry of drugs Roles and responsibilities			
Store keepers	Drug policy Treatment schedules Advise to give			
Dispensers	Treatment schedules of new drug policy			
Pharmacists	Treatment schedules of new drug policy			
Chemical sellers	To be developed			
Community resource persons	As above			
Training institutions	New drug policy System of monitoring implementation Treatment schedules by agegroups Establishment of a pharmacovigillance system			

Cadre of staff	Content	Length of time	Who responsible	Materials needed
	Roles and responsibilities			

Improvement of diagnosis for malaria case management
Rapid, accurate and accessible detection of malaria parasites has an important role in addressing misdiagnosis of malaria, and in promoting more rational use of increasingly costly drugs. Initially, microscopes at the levels with trained microscopist will be provided and orientation given. But for levels below these, and those that treat most cases of uncomplicated malaria, other methods will be used/worked on. Rapid Diagnostic Tests (RDTs) offer potential to provide accurate diagnosis at community level as well as health facilities that lack access to good microscopy services. However, there are still limitations to RDT use in the field. In addressing this, and mainly to curb down the over use of the expensive combination in the treatment of malaria as a result of overdiagnosis, use of RDTs will be introduced in phased manner and piloted as implementation progresses.

Introduction of ACT use at community level
Two research proposals on feasibility, acceptability, compliance and safety use of ACTs has been funded by TDR in Ghana. It is hoped that as the results from these two researches are received, these will be used to input into the process of implementation at community level. After about one year of introduction of ACTs, a phased implementation at community level could be planned on a larger scale. This will be after the de-regularization of ACTs for community use.

Advocacy and Communication

Currently, communication for the first line of treatment of malaria is a chloroquine-based IEC strategy, hence the need to carry out essential activities for the introduction and implementation of the use of ACT (Amodiaquine plus Artesunate). The planned activities for Programme communication, Advocacy and Social mobilisation are discussed below.

Programme communication:
The existing IEC materials should be reviewed and new ones developed if necessary. The following communication/IEC materials should be considered for use for electronic media and print media: Posters, Leaflets, Flyers, Briefing Kits and Promotional products. The current IEC strategies should also be reviewed and a clear dissemination and distributionplan, appropriate for the target population considered. There is need to develop/review the plans for Behavioural change communication strategies.
A mass media campaign should be organized to educate the general public about the new drug for the treatment of uncomplicated malaria. This could be done in the form of a national launching of the programme, production of media materials/adverts, airing of TV and Radio adverts, TV and Radio discussion programmes.

Advocacy:
Advocacy will be conducted to address policy issues that may hinder the successful introduction and implementation of the use of ACT for the treatment of malaria. This should mainly be targeted to the policy and decision makers. Policy issues such as the cost of treatment for the patient should be considered among other things. Advocacy /sensitisation of key stakeholders/partners will be conducted to secure their commitment for the introduction and implementation of the use of ACT. Sensitization of community and opinion leaders on home management of malaria will be carried out for early referral of cases to health facilities for prompt and effective treatment.

Social mobilisation:
Relevant stakeholders/partners will be mobilised to participate in the implementation process of the new treatment policy using ACTs. This could be done through meetings, briefings, joint planning meetings and orientations.

Since there is no RBM advocacy and communication group, there is need to establish this working group by the end of August with clear terms of reference (TORs) and membership

Monitoring and evaluation

This is key, as it will inform the process even as implementation of ACTs is rolled out to cover the country. A system and plan to monitor and evaluate the process of drug policy change is proposed. Although indicators of outcome and impact are already available, those needed to monitor programme implementation will need to be developed. These will compliment the indicators that have been developed under the Global Fund Proposal. In addition for smooth implementation, there will be need to review the already existing systems and data formats to be able to support the process. M&E has been divided into the monitoring of process of policy change and monitoring of effectiveness of ACTs, described below.

Monitoring the process:
There will be a need to come up with a monitoring plan in line with all the key actions agreed upon in each key area. Clear deadlines of reporting will need to be agreed on so that there is feedback on the process and the coordination team advised of any challenges that may need to be addressed.

Technical monitoring:
Under this, several areas are recognized: routine surveillance of malaria data, drug availability, drug quality surveillance (already addressed above), pharmacovigilance, drug efficacy monitoring, acceptability and prescriber and patient compliance and finally the outcome of implementation. Each of these areas deserves special mention.

Routine surveillance of malaria morbidity and mortality data
There is already a system in place in Ghana under Health Management Information System (HMIS). Although this has been in existence for some time, the data that is usually got through this system, is short on accuracy that may be required for it's use. This system needs to be strengthened in order to support implementation. Currently, one of the quality indicators which

is completeness of reporting is about 78%. Strengthening the system will require looking at ways of improving this indicator and ensuring also timeliness in reporting. The following are also proposed: review of data collecting formats to be more useful. Most of the data is presented in two age bands only, under five and over five. With the introduction of ACTs, four formulations are going to be available. These are for children under one, 1-6 year olds, 7-13 years and then 14 years and older. For the quantification of the drug requirements, it is therefore important to review the forms to capture these age categories. It will be useful if this is divided into under one, 1-5 years and above 5. These are the key ones. If too many categories are included, it may cause increased workload for those collecting the data.

Pharmaco-vigilance

Under the Center for Clinical Pharmacology and Tropical Medicine, a system for pharmacovigilance for IPT using SP has been developed. As part of this system, a spontaneous reporting of adverse events following the administration of S-P is undertaken. If there is a report, an in-depth interview of patients (followed-up in homes) is undertaken. Health workers interview patients who have reported any side effects/reactions. Pharmacovigilance unit does random visits to homes of patients. A database has been designed to capture information. DHMTs report to NMCP and pharmacovigilance unit follows-up is organized.

This system however will need to be strengthened. It will involve all the health units reporting on ADR through agreed on formats. These will be for only the severe adverse reactions defined as any reaction leading to death or which is life threatening, resulting in a congenital abnormality, requires or prolongs patient hospitalization or permanent disability or damage after administration of a drug. This will be for any drug not really specific for antimalarial.

So these will be monitored at 3 levels: at peripheral health facilities, where health facility staff will report patients suspected of having SAE spontaneously;
At tertiary health care facilities where SAEs will be investigated;
At antenatal and delivery clinics, where congenital abnormalities associated with the use of anti-malarials will be documented. A standard report will be completed with each SAE. For this to happen, all staff will require a training to introduce this system. As part of clinical practice, staff will inform patients that in case of SAE, they should return to the health facility or go to a tertiary health facility to report. A form will be filled for each suspected case. Those in charge of national Drug Programme will give forms to each unit. A referral should folowevery serious case. A district investigation team will be established to investigate all reported cases. If confirmed, then the report will be forwarded to both the national center established for recording SAEs and the Drug Information Centre. The working group will give details on this system.

Drug efficacy

Six sentinel sites for monitoring drug efficacy have been established by the Noguchi Research Institution and NMCP. With funding from Global Funds, these are going to be extended to ten so that there is a site in every region. These will be used to monitor drug efficacy of the new drug policy annually.

Drug availability

The National Medical Stores has a system in place that tracks the availability of drugs. However, this has not been adequately adhered to. There is therefore need to strengthen this system so that information on drugs can be reported. In order for this to happen, the Drug Management information System (DMIS) will need to be established for all the levels. The working Group will elaborate on how this system will be developed.

Prescribing habits and consumer compliance

As part of Rational Drug Use, a system has been established to monitor prescriber habits. This will be expanded to include the review of the malaria prescriptions in order to determine the compliance to the new drug policy. Teams will be facilitated on a quarterly basis to review these and advise on the process.

For consumer compliance, the routine follow-up of patients will be encouraged as much as possible but in addition, this could be studied in organized surveys.

Conclusion

ANNEX A: TERMS OF REFERENCE FOR CONSULTANT AND WORKING GROUPS

a. FOR THE CONSULTANT

Under the supervision of the Director of Public health, and with technical support from the NMCP, the consultant will be expected to carry out the following:
To coordinate the activities of the working groups
Participate in the working groups' deliberations
Ensure the prompt and timely implementation of planned activities
To consolidate outputs of the working groups and make recommendations for moving process forward
Provide regular feedback on progress to Malaria Program Manager and Director of Public health
Undertake any other duties that are relevant to the smooth implementation of the process

b. TOR for Working Groups

Short-term –
Develop a plan to present to NMCP on how they will implement the key actions listed in the plan. The working group will be responsible for the implementation of all the key actions for which they are the technical / operational lead in the plan.
Provide technical review of documents, materials etc produced as part of the progress on the completion of the key actions
Long-term –
Will not sit indefinitely but will be available for consultation with the NMCP as needed

More specifically

a. Drug Management (Procurement, supply, distribution etc) Group
Ensure registration of AS+AQ and other regulatory concerns with Drug Regulatory Authority (DRA)
Calculate requirements to be procured annually taking into consideration the different dosage forms and propose procurement schedule.
Develop procurement plan including procurement and importation schedule that will ensure no stock-out while minimizing expiration
Propose mechanism for incorporating AS+AQ into existing distribution systems
Propose changes that need to be made in the different drug kits, materials
Propose mechanism for phasing out CQ and reducing SP supplies in all sectors???
Develop training materials on drug management for inclusion in the overall training materials of health workers
Propose a system for monitoring supplies, quality and utilization of drugs in all sectors
Propose alternative financing mechanisms for AS+AQ at the end of current funding

Main output:
Inventory of all the documents to be worked on and the target groups
Draft reviewed/updated documents
Brief description of systems to be put in place
Identification of the key partners and their roles and responsibilities

Detailed costed plan of key actions with a time frame
Procurement plan

Membership:

CHAIR: ***Director SSDM MOH: Mr Sam Boateng (0244-269336);***
CONVENOR: Procurement Unit:*Joycelyn Azeez (020-8176728)/Ms. Allotey NMCP,(Back-up)*

Mrs Edith Andrews-NPO-EDM WHO
Food and Drugs Board: ***Mr Ben Botwe (024-4318126)***
Pharmacovigilance Unit:
National Drugs Program:
Director SSDM GHS: Mr. Addae Donkor
Chief Pharmacist:
Central Medical Stores: Mr. Peter Gyimah (022-204162)
Ghana Pharmaceuticals Manufacturers Association: Mr. Mark Owiredu (022-305448)
Management Sciences for Health (MSH/RPM Plus): Dr.Gladys Tetteh, Dr. Grace Adeya
Drug Information Center:
Engender Health
Mrs Martha Lutterodt
Naa Korkor, NMCP
Dr G. Amofah, Dir PHD

b. Case management

Update the current treatment guidelines for management of malaria
Update the current training manuals to reflect the new drug policy changes
Review and propose an approach for orienting health workers and community resource persons on new drug policy in both public and private sectors
Develop a plan and budget for orienting health workers

Main output:Detailed costed plan of key actions
Inventory of all the documents to be worked on and the target groups
Draft reviewed/updated documents
Plan for orienting health professionals
Strategy for including the private sector

Membership:

CHAIR: ***Dr (Mrs) E. Ofori-Adjei***
CONVENOR: NPO, WHO, ***Dr. Mrs. Felicia Owusu-Antwi***

Dr Srofenyoh
Dr C. Bart-Plange
Dr Aliu Bello, UNICEF

Mr Raymond Tetteh
Dr Felicia Owusu-Antwi
Dr Isabella Sagoe-Moses
Dr H. Odoi-Agyarko
Dir, ICD Dr Awuah Siaw
Dr Cynthia Bannerman
Dr Mary Brantuo
Dr Bamenla Quarm
Private sector: Dr Hanson (021-304325; 020-8119228)
Mr Koku, Rep, Human Resource Development Division of Ghana Health
Dr Irene Agyepong, RDHS
Rep, Pharmaceutical Society Of Ghana
Rep, Pharmacy council
Rep, Dept. of Medicine

c. Advocacy and communication

Update the current IEC materials Management of Malaria
Elaborate a strategy and plan for sensitizing the public and communities on the new policy
Elaborate a strategy and plan for continuous advocacy and consensus building on the new drug policy at different levels of decision making
Develop a communication strategy on the Policy and management of malaria

Main output:
Costed plan of key actions
Inventory of all the documents to be worked on and the target groups
Draft reviewed/updated documents
Updated advocacy and communication strategy

Membership

CHAIR: Head of Health Promotion Unit, Mrs. Mary Arday- Kotei
CONVENOR: Mrs. Aba Baffoe-Wilmot

Health Promotion Unit, Ms. Eleanor Sey
Academy for Education and Development (AED)
Mrs Aba Baffoe-Wilmot, NMCP
Kwame Gakpey
J.K. Ofori-020-8121725; 028-257450
Mrs Ivy Forson
NPO, Health Information and Promotion, Attn: Ms Sophia Twum-Barimah
Rep, PrimeTime Ltd
Iyeme Efeme, PCI
PRO, GHS

d. Monitoring and evaluation

Propose a mechanism for incorporating AS+AQ efficacy into on-going drug efficacy studies
Develop a strategy for regular collection of information on availability, acceptability and compliance of new policy
Develop a pharmacovigilance system for tracking Adverse Reactions associated with deployment of ACTs at health facility and community levels
Develop a system for evaluating the impact of deploying ACTs
Propose indicators for monitoring and evaluation of the new drug policy

Main output:
Detailed costed plan of key actions
Monitoring and evaluation plan
Inventory of all the documents to be updated
Draft reviewed/updated documents
Brief description of systems to be put in place

Membership:

CHAIR: Rep PPME, MOH, Dr Eddie Addai
CONVENOR; Mr. Kofi Osae

Rep, PPME, GHS, Attn. Dr F Nyonator
Dr. K Koram
Rep, NMCP, Mr Kofi Osae
Malaria Consortium, Attn: Dr Joseph Somuah Akumoah
Mr. Emmanuel Twumasi, NMCP
Rep, CHIM
Rep, Surveillance Dr L. Ahadzie
Rep, Food and Drugs Board
Pharmacovigilance
Rep, Central Medical Stores
Dr. Nana Enyimayew
Health Research Unit, Attn Mrs Bertha Garshong

ANNEX B: Issues requiring attention

a) Develop Mechanisms and ways of getting people involved to complete the schedule:
Who constitutes the working group?
Identify leaders
Give T.O.Rs
Groups to budget and submit
Give deadlines/milestones for completion of activities

Involvement of Private Sector
Involve the Registrar of the Private Clinics and Midwives Board

Human Resource Development Division
To be involved planning, organising and evaluation of training

Supervision
Need to revise supervisory checklist of IMCI to incorporate ACT

Pharmacovigilance
There is spontaneous reporting of adverse events following the administration of S-P, in-depth interview of patients (follow-up to homes of patients reporting adverse reactions). Health workers interview patients who have reported with any side effects/reactions. Pharmacovigilance unit does random visits to homes of patients. A database has been designed to capture information. DHMTs report to NMCP and pharmacovigilance complies and follows-up.

Action Points for Pharmacovigilance
Categorisation of reactions required: mild, moderate, severe
Pharmacovigilance unit needs to be strengthened to cope with increased work
Need to clarify: FDB and pharmacovigilance any links?

Quality
How do we ensure quality? A system needs to be developed to capture quality

Leakage of drugs into the private sector from the public sector
How do we minimize leakage from public to the private sector?

Annex 4. Ghana Health Service ACT Implementation Plan

Ghana Health Service
Implementation of the new Ghana Malaria Treatment Policy - Key Actions
Planning and coordination

Key Actions	**Technical /Operational lead**	**Estimated Timeline**	**Resource Requirements**
Identify and commission consultant** to coordinate plan	NMCP / Dir-PHD	31st August 2004	Funds, TOR**
Identify and notify members of the working group	Dir PHD/ NMCP	27th August 2004	Stationery, Fuel
Meet each working group to agree on: Terms of reference Deadline for submission of work-plans	Dir PHD/ NMCP	1st week of September 2004	Fuel, T&T, Snacks
Working groups submit work-plans including budgets	Consultant/Working group chairpersons	2nd week September 2004	Stationery
Budgets released to working groups for tasks to begin	Dir PHD /NMCP	3rd week September 2004	
Working groups complete assignments and submit reports	Consultant/ Chairpersons of working group	Last week October 2004	Funds, stationery
Develop the provisional plan for phasing in implementation of the malaria policy nationwide	NMCP	September 20th, 2004	

Drug Regulatory Issues & Quality Assurance

Key Actions	**Technical /Operational Lead**	**Estimated Timeline**	**Resource Requirements**
Register new drug Regular registration: submit full dossier for registration Abridged registration system as needed: available for public procurements only.	Food and Drugs Board	12 weeks 2 weeks	
Strengthening of laboratory services for quality assurance of ACTs and other anti-malarials:	Food and Drugs Board	Start December 2004	Reagents Human resources
Dossier evaluation training for registration staff			
Evaluate and strengthen regulatory enforcement capacity if needed	FDB / Pharmacy Council	Start December 2004	
De-regulation of ACTs from prescription only drugs as decided in the National Drug Policy	FDB		
Promulgate regulations for appropriate prescribing and dispensing of ACTs and other antimalarials if needed	GNDP / Pharmacy Council	Start December 2004	
Strengthen post-marketing surveillance system: human resource capacity, communication systems, transport systems.	FDB / Pharmacy Council	Start December 2004	
Safety Monitoring/Pharmacovigilance: Design/adapt system and print specific forms for monitoring adverse drug reaction	Food and Drugs Board		Transportation and postage costs.

Malaria Treatment Guidelines/Training

Key Actions	**Technical /Operational Lead**	**Estimated Timeline**	**Resource Requirements**
Revise guidelines and training manuals: Drug policy document Malaria treatment guidelines Malaria training manuals (by level; public and private) Job aids (posters, factsheets, treatment charts) IMCI IPT training manual Standard Treatment Guidelines Essential Drugs List Pharmacy – Standard Operating Procedures (SOP), training manuals. Chemical sellers training manuals	NMCP CMWG CMWG / HRD training unit CMWG IMCI RCH/NMCP NDP NDP Pharmacy Council Pharmaceutical Society	October 30, 2004	
Produce revised guidelines, training manuals and EDL	NMCP / Engenderhealth	December 31, 2004	
Develop plan for distributing new guidelines and EDL to peripheral health facilities	NMCP / Pharmacy council	November 30, 2004	
Develop plan for training / orientation of health workers (private and public sectors) and storekeepers	CMWG / Pharmacy Council / Pharmaceutical society / CMS / HRD training unit	By November 30, 2004	
Organise sensitization meetings for deans, principals, chief executives of health institutions, quasi-government health institutions like university hospitals, police, mining, GHAPOHA, police, military, Cocoa clinic, Trust Hospital	NMCP/Chairman of RBM Coordinating committee	By November 30 2004	
Convene training / orientation workshops soon after procurement of the ACT (public and private sectors).	CMWG / Pharmacy Council / Pharmaceutical society / CMS /HRD training unit	January - December 2005	Registration list of all private practitioners from Private clinics and Maternity Homes Board
Plan and convene continuous medical education sessions	Ghana Medical Association / Pharmacy Council / Society of Private Medical Practitioners	Start January 2006	

Key Actions	**Technical /Operational Lead**	**Estimated Timeline**	**Resource Requirements**
Revise pre-service training curricula to incorporate new guidelines	HRD Training Unit	January – December 2005	T.A required
Develop plan for improving laboratory diagnosis at all levels			Upgrade laboratories
Trial of test Kits with RDTs to support the new drug policy			

Advocacy and Communication

Key Actions	**Technical /Operational Lead**	**Estimated Timeline**	**Resource Requirements**
Program Communication			
Review and Develop educational materials Electronic Media - Radio spots (e.g. He, Ha, Ho); TV spots Print Media – newspapers; billboards Posters, Leaflets, Flyers Briefing kits Promotional products	HPU / AED / PRO unit of GHS / NMCP	Aug -Nov.2004.	Funds Technical Assistance (USAID) and/or Advertising agency
Organize a mass media campaign to educate the general public through: National launch of the programme Production of Media materials / advertisements Airing of TV and Radio advertisements TV and Radio discussion programs Distribution plan of materials	HPU / PRO unit of GHS	 April 2005 Oct-Dec. 2004 Jan - Dec 2005 Start Jan 2005	Technical Assistance required (USAID) Advertising Agency Funds
Advocacy			
Advocacy / Sensitization of key stakeholders to secure their commitment through joint planning meetings, briefings and lobbying Political leaders, Decision makers, RBM Partners Commercial partners Private Medical Practitioners	NMCP HPU PRO unit of GHS	November 2004	Briefing kits Funds Transport
Sensitization of community and opinion leaders on home-based management of malaria	District Health Teams / NMCP	September 2004	Briefing kits Funds Transport
Social Mobilisation			

Key Actions	**Technical /Operational Lead**	**Estimated Timeline**	**Resource Requirements**
Mobilize the relevant stakeholders to ensure their participation in the implementation of the ACT policy e.g.: Drug manufacturers / suppliers Health Institutions and health managers Private Medical practitioners Pharmacists, Chemical sellers, Community Health Volunteers, District Assemblies, NGOs Civil Society groups, Teachers and school-children, Media practitioners, Extension workers, Religious bodies, Women's Organisation, Chiefs and Community leaders Through: Meetings, briefings, joint planning meetings and orientations	NMCP HPU DHMT RHMT	Start August 2004	Funds Briefing kits Leaflets

Procurement/Forecasting/Existing Stocks

Key Actions	Technical /Operational Lead	Estimated Timeline	Resource Requirements
Procurement			
For GFATM funded procurements, follow the steps under GFATM requirements (for 600,000 doses) Letter of notification sent from GFATM and RBM secretariat (Geneva) on pre-qualified companies for AQ/Art sent to MOH MOH response to letter Registration of drug by FDB (abridged system) Initiate procurement process (quantification of needs; Preparation of tender documents) Submission of tender documents or tender award to the RBM secretariat) Delivery of ACTs	SSDM / NMCP	September 15, 2004 October 31, 2004 December 2004	
Develop a procurement plan			
Quantification of drugs and commodities needs (ACTs, SP, Quinine, Paracetamol)	SSDM / NMCP	October 2004	Technical assistance (MSH)
Initiate procurement process (lead-time to delivery 8 -12months. Process begins after the determination of quantities) Develop specifications Develop tender documents Advertise tender Launch tender Evaluation of tender Award Contract Post-qualification Delivery time	Procurement Unit	(Estimated minimum time) 1 week 4 weeks 8 weeks 4 weeks 2 week 8-12 weeks	Financial resources
Supplier performance monitoring Develop plan	Procurement Unit	-	

Key Actions	**Technical /Operational Lead**	**Estimated Timeline**	**Resource Requirements**
Phasing out old drug from the health system			
Determine pipeline chloroquine and adjust future procurements of the current drugs to make sure that large pipelines of chloroquine do not accumulate when the ACT is procured Central level (current stocks to last until September 2005) Regional level Peripheral level Private sector	Procurement unit	November 2004	
Develop a plan for the phase-out of the current drug from the health system as the new drug becomes available Public sector Private sector	Procurement unit / NMCP/ FDB	December 2004	Technical assistance

Distribution/Stock Management

Key Actions	**Technical /Operational Lead**	**Estimated Timeline**	**Resource Requirements**
Develop comprehensive distribution plan (including re-distribution systems of soon-to expire stocks)	Procurement plan / CMS	December 2004	Technical assistance
Review inventory management systems to improve the management of the drugs in the peripheral health facilities	CMS	December 2004	
Develop systems / strategies to manage leakage of stocks	Procurement unit / CMS	December 2004	
Develop / review systems to remove expired stocks	CMS	December 2004	

Monitoring & Evaluation

Key Actions	**Technical /Operational Lead**	**Estimated Timeline**	**Resource Requirements**
M&E of program implementation			
Develop plan to monitor and evaluate the introduction and implementation of the ACT policy	Malaria Consortium / KNUST	September 2004	
Technical Monitoring[4]			
Develop / adapt and implement drug management information systems Monitoring of drug availability (Nat, Reg, Dist, Health facility)	CMS / NMCP	Start October 2004	
Conduct drug efficacy studies at the 10 (6 current sentinel sites and at 4 additional sites) for Artesunate-Amodiaquine and SP	NMIMR and NMCP	Start November 2004	Funds
Ensure that drug quality assurance systems are developed and implemented	Food and Drugs Board		
Strengthen pharmacovigilance systems.	Pharmacovigilance unit/NMCP/DHMT		
Develop and implement a system for the supervision and support of newly oriented / trained health care workers	RHMT / DHMT		
Strengthen HMIS systems to ensure collection of required malaria data	NMCP / Center for Health Information Management / Disease control surveillance		
Identify and address human and IT resource needs	HRD / GHS		

[4] The M&E group will not be responsible for developing the systems and plans for the technical monitoring but will be ensure that the technical working groups develop these systems and plans.

Financing

Key Actions	**Technical /Operational Lead**	**Estimated Timeline**	**Resource Requirements**
Develop a plan for financing of the costs on the implementation of the ACT policy Drugs and other commodities Technical assistance (short/long-term consultancy with the NMCP) Other Key Actions	NMCP		
Financing options for consumers (subsidies, national health insurance)	Director Public Health / PPME		