

Rational Pharmaceutical Management Plus Quantification of ACTs and Development of a Procurement Plan for Mali, December 19-23, 2005: Trip Report

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Strategic Objective 5

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About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen pharmaceutical and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning, and in promoting the appropriate use of health commodities in the public and private sectors.

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ACRONYMS

ACT	artemisinin-based combination therapy
ADR	adverse drug reaction
AFRO	Regional Office for Africa [WHO]
AIDS	acquired immunodeficiency syndrome
AS/AQ	artesunate/amodiaquine
ASC	agent de santé communautaire
ATN	Assistance Technique Nationale
CDC	U.S. Centers for Disease Control and Prevention
CSCom	Centre de Santé Communautaire
DAF	Direction des Affaires Administratives et Financières
DNS	Direction Nationale de la Santé
DPM	Direction de la Pharmacie et du Médicament
DRC	Dépôt Repartiteur de Cercle
EML	essential medicines list
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIPC	heavily indebted poor country
IPT	intermittent preventive treatment
ITN	insecticide-treated net
LNS	Laboratoire National de la Santé
MAC	Malaria Action Coalition
MOH	Ministry of Health
MRTC	Medical Research and Training Center
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
PEV	Programme élargi de Vaccinations
PPM	Pharmacie Populaire du Mali
PNLP	Programme Nationale de Lutte contre le Paludisme
RBM	Roll Back Malaria
RDT	rapid diagnostic test
RPM Plus	Rational Pharmaceutical Management Plus
SP	sulfadoxine/pyrimethamine
STG	standard treatment guidelines
TRP	Technical Review Panel
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
WB	World Bank
WHO	World Health Organization

BACKGROUND

Malaria is the major cause of morbidity and mortality in Mali. According to statistics for 2002, the estimated rate of incidence of malaria for the whole population is 67 percent. Although it is endemic throughout most of the country, the northern regions and large cities have a high epidemic risk. In public health facilities, malaria represents 39 percent of all visits for children under the age of five and 34 percent of total patient visits. Malaria is also a major cause of both low-birth-weight and maternal anemia.

Chloroquine (CQ) resistance is significant in some areas in Mali. As part of its efforts to reduce the public health impact of malaria, the new Ministry of Health (MOH) policy document recommends amodiaquine plus artesunate (AS/AQ) as the first-line treatment for uncomplicated malaria in accordance with the World Health Organization (WHO) recommendations. However, if Coartem[®] (artemether/lumefantrine) becomes more widely available and more affordable, Mali may consider using this option as its first line of treatment. A formal policy document has been drafted (August 2005) and is awaiting the signature of the Minister of Health.

Mali received 2 million U.S. dollars (USD) from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) during its Round 1 funding; however, little was budgeted for procurement of artemisinin-based combination therapies (ACTs). Furthermore, disbursement of Phase II of GFATM's Round 1 funding has been slowed down by a protracted process of implementing Phase I. Subsequent proposals submitted in GFATM's Rounds 4 and 5 were not approved for funding.

In addition, Mali implements the Bamako Initiative, which operates on the principles of cost recovery. ACTs are substantially more expensive than CQ, and in the absence of financing strategies, purchasing them will result in out-of-pocket expenditures of nearly 30 times greater than that of CQ for malaria treatment, potentially making financial access to malaria treatment out of reach for the majority of the population. The *Programme Nationale de Lutte contre le Paludisme* (PNLP) expects to put in place a partial-cost recovery system; however, the (planned) level of subsidization for ACTs is not clear.

Management Sciences for Health's (MSH) Rational Pharmaceutical Management (RPM) Plus Program has received funds from the U.S. Agency for International Development (USAID) to develop strategies to implement malaria policies and to provide technical assistance in pharmaceutical management issues for malaria. RPM Plus is a key technical partner in the USAID Malaria Action Coalition (MAC), which also includes as partners WHO (working primarily through its Regional Office for Africa [AFRO]), the U.S. Centers for Disease Control and Prevention (CDC), and the Access to Clinical and Community Maternal, Neonatal and Women's Health Services (ACCESS) program of JHPIEGO.

RPM Plus has been working to improve pharmaceutical management for malaria in countries in Africa by identifying and addressing the causes of poor access, ineffective supply, and inappropriate use of antimalarials. RPM Plus has developed and applied tools to assess pharmaceutical management for malaria and has worked to provide technical assistance to

countries by working with policymakers, researchers, managers, and providers in the public and private sectors to implement new and proven interventions.

Purpose of Trip

Rima Shretta, Kathleen Webb, and Thidiane Ndoye from RPM Plus traveled to Bamako, Mali, to provide technical assistance in the areas of procurement and quantification of antimalarials.

Scope of Work

- Provide an arrival briefing and/or departure debriefing to USAID upon request
- Provide technical assistance (TA) for quantification of ACTs
- Provide TA for procurement of ACTs (including the development of a procurement plan)
- Plan for follow-up RPM Plus/MAC activities in Mali
- Introduce the new RPM Plus Regional Technical Advisor, Thidiane Ndoye

ACTIVITIES

Provide an Arrival Briefing to USAID

The RPM Plus team was welcomed by USAID/Mali representatives Sixte Zigirumugabé, Christine Sow, and Mahamadou Sissoko. The RPM team then gave a brief summary of the scope of work for the week, which included—

- Quantification of ACTs
- Development of a Procurement Plan
- Discussion and planning of activities from the fiscal year (FY) 2005 workplan

RPM Plus's new Regional Technical Advisor for West Africa to USAID Thidiane Ndoye will be the new focal person for RPM Plus malaria activities in Mali with continued assistance from Ms. Shretta as needed.

The RPM Plus team stated that they wanted to verify the quantification done by PNLP in March 2005. They agreed that they would get malaria morbidity and incidence data from the PNLP to obtain representative data to calculate needs and develop a procurement plan for the country. The RPM Plus team raised the issue of the choice of first-line therapies. According to the national antimalarial policy documents, both artemether/lumefantrine (Coartem) and artesunate plus amodiaquine were chosen as first-line therapies. USAID could not clarify which of the two was the final choice; however, it recommended having the PNLP select one therapy that would then require quantification of only one combination.

The issue of procurement cost was raised, particularly inclusion in the procurement plan. Distribution costs will need to be determined during a later trip. It was agreed that RPM Plus would return to Mali to carry out this determination at the same time as the costing exercise included in the FY 2005 workplan. The issue of the lack of clarity of resources available for procurement of ACTs was raised. Mr. Zigirumugabé suggested that the team move forward with the procurement plan as if resources were in place.

In addition to the meetings already organized, USAID advised the RPM Plus team to meet with Assistance Technique Nationale (ATN), Save the Children, Ciwara Kenya project (CARE), Medical Research and Training Center (MRTC), and Médecins Sans Frontières (MSF). MSF is already implementing ACTs on a small scale in Mali.

Other issues that may directly affect ACT implementation were discussed, including the World Bank (WB) Booster Program and the *Direction de la Pharmacie et du Médicament* (DPM). USAID could not provide details on heavily indebted poor country (HIPC) and WB Booster Program funds and suggested that the team seek clarification on these programs from the MOH and WB. USAID suggested that the status of the National Quality Control Lab be discussed with the DPM.

RPM Plus informed USAID of the upcoming West Africa Regional Training Course on Pharmaceutical Management for Malaria, which is to be held in Dakar the last week of March 2006.

There was also some discussion on Mali's participation in the West Africa Regional Training of Trainers Course held in Accra in August 2005. The team confirmed that Mr. Ndoeye would be available to assist the Mali malaria program with a national-level training that may be planned for 2006.

Meetings with PNLP and Other Stakeholders

1. PNLP—Drs. Georges Dakono and Barasson Diarra

RPM Plus explained the trip's purpose and discussed the scope of work with the PNLP. Dr. Dakono welcomed the team and described the issues faced by the PNLP related to GFATM, specifically quantification of need and the procurement plan. He noted that the RPM Plus mission had come at the right time.

Dr. Dakono gave some history on the choice of the first-line antimalarial therapy. He explained that initially a decision had been made to have both artemether/lumefantrine and AS/AQ as first-line drugs, but stakeholders rejected the decision due to a lack of involvement. Subsequently, a meeting was convened with all stakeholders and two committees were formed (antimalarial drugs committee and implementation committee). AS/AQ was chosen as the first line as a result of this large consultation as Coartem was believed to be unavailable in the short-term. The PNLP informed the team that there may be a possible shift to Coartem should it become more readily available in the future.

Further discussions clarified that the quantification exercise carried out earlier in the year was on the basis of data from Faladie district, an area of high CQ resistance.

As Mali operates under the Bamako Initiative, the MOH plans to implement a partial-cost recovery system for ACTs but the level of subsidization is not yet clear. There are some stakeholders that argue that the price of ACTs should not be greater than the current price of CQ.

The PNLP explained that the *Direction des Affaires Administratives et Financières* (DAF) of the MOH/*Direction Nationale de la Santé* (DNS) manages the HIPC fund portfolio with the WB. Advocacy is needed to make sure that a portion of these funds can be allocated for procuring ACTs. Dr. Dakono did not know much about the WB Booster Program having only learned of it in the previous month.

Dr. Dakono advised that pharmacovigilance issues be discussed with the DPM, National Quality Control Lab, and the MRTC.

Dr. Diarra is responsible for monitoring and evaluation within the PNLP and provided the team with malaria case and incidence data disaggregated by age, region, and *cercle* (district). This

information will be used to quantify the need of ACTs and will inform both the procurement and distribution plans.

RPM Plus informed Dr. Dakono that should there be a GFATM Round 6, they would be available to help develop a malaria proposal.

The PNLP provided RPM Plus with the following documents—

- *Document de Politique Nationale de Santé du Mali*
- *Plan d'achat*—quantification for Faladie
- *Données* health information system (SLIS) 2003

2. Deputy National Director of Health (*Direction Nationale de la Santé*)— Dr. Mountaga Bore

The PNLP coordinator explained the purpose of the mission and expressed his satisfaction with the technical support that MSH/RPM Plus is providing on pharmaceutical management for malaria.

Dr. Bore expressed the MOH's concern of the urgent need to make an uninterrupted supply of ACTs available to the population at affordable prices.

The RPM Plus team asked the National Health Directorate to advocate for DAF to allocate more HIPC funds for malaria control, particularly for ACT procurement. Dr. Bore assured the team that this was already a concern.

3. *Direction de la Pharmacie et du Médicament*—Dr. Minkala Maiga

Dr. Maiga explained the DPM's mission, which is responsible for revising the Essential Medicines List (EML) every two years, based on inputs from the different programs. The current EML is due to be revised in January 2006. The DPM also assists with the determination of medicine needs (quantification) and is involved in the procurement process. It ensures distribution of medicines in the public and private sector and coordinates with the National Health Laboratory [(*Laboratoire National de la Santé*) (LNS)] on quality assurance and quality control issues. The DPM is also responsible for regulation and training and revision of standard treatment guidelines (STGs). The STGs have not yet been revised for the new malaria treatment policy. The DPM and PNLP will work together to revise the STGs based on treatment directives from the PNLP. They will also cooperate to develop case management guidelines, job aids, and treatment algorithms.

Although artemether/lumefantrine and AS/AQ are both registered in Mali, Coartem is the only one of the two on the EML. Additional artemisinin-based monotherapies, such as artemether, artemisinin, and artesunate, are also on the list but are only available in the private sector pharmacies.

The national drug regulatory authority, the DPM, heads the commission for drug registration, which includes the LNS, the faculty of medicine and pharmacy, hospitals, and the DNS. This commission meets quarterly and discussions of drug registration are informed by quality control test results from the LNS and information provided by the applicant in a dossier to the DPM. Medicines sold in the public sector are controlled and their quality is assured; however, substandard medicines are a problem, particularly within the informal private sector. In principle, samples submitted the LNS should be for medicines only on order; often samples received at the LNS for quality control testing are already delivered and waiting to clear customs.

The DPM coordinates and works with the LNS according to clearly defined laws. The LNS, however, lacks resources to analyze samples, particularly for procurement and postmarketing surveillance.

The PNLN has requested assistance from the DPM to train health providers and pharmacists on the new malaria treatment policy and STGs. The DPM will also work with private pharmacists to provide refresher training on the new policy.

The issue of deregulation of the first-line therapy was discussed and whether it was necessary to change the product's legal status so it would be available at the lowest levels of the health care system. The DPM was of the opinion that this was not required.

Mali is not implementing a pharmacovigilance system but there are plans to do so for HIV/AIDS medicines. Surveillance at lower levels of the health system is lacking. This is a priority and the DPM hopes to improve the management of health information. There is a need for training on quality control and technical assistance on pharmacovigilance.

Effective implementation and monitoring of ACTs will require engaging the MOH at the highest levels.

4. National Health Laboratory (*Laboratoire National de la Santé*)— Drs. Amara Cherif Traore and Sindy Berthe

Dr. Traore, Head of the Medicines Quality Control department, explained that LNS does quality control testing for all samples received through international tenders. Testing is done both at the proposal stage and when the product is received in-country. There is a post-marketing surveillance system in place for all classes of medicines, including antimalarials. This surveillance, performed annually, has been financed by WHO in the past. Random samples are collected once a year from all levels of the health system in all regions. However, the findings of these surveys are communicated to the various levels of the system: Regional Directions for the public sector and National Council of the Pharmacists Corporation for the private sector.

Additionally, LNS is responsible for testing and gives advice for authorization of all new products for registration and importation. DPM gives authorization based on test results and “visa” (registration) committee recommendations.

The LNS is a member of the reception committee when products are received by the *Pharmacie Populaire du Mali* (PPM). Discussions and observation identified that—

- Of generics, 3.8 percent do not meet quality and conformity testing.
- Lab instruments are shared among several departments, and many do not work or need to be recalibrated.
- There are some written standard operating procedures on quality testing and procedures for some tests being performed; for other the SOPs are under scrutiny, but not yet validated.

5. WHO/Mali—Dr. Massambou Sacko

Dr. Sacko explained the support that WHO gave to develop the training modules used in training health providers on the new policy. These materials were developed with the input of many partners and addressed both Coartem and AS/AQ. WHO carried out a workshop to sensitize and train head doctors from each region to serve as regional trainers. The plan is for these trainers to carry out cascade trainings with support from the national level. Each region was asked to develop a training plan to train all health service providers, both public and private, from head doctors to nurses in charge of community health centers—Centres de Santé Communautaires (CSCComs). The cascade training should be planned in coordination with the PNLP when it is ready; however, initial trainings should target private sector prescribers as ACTs are already available in private sector pharmacies. Public sector health service providers should be trained when the PNLP has a more clear idea of when ACTs will be available in the public sector. The training should occur immediately preceding implementation to ensure that health workers do not forget key messages.

A formal agreement to provide assistance and support for 2006–2007 exists between WHO and the Malian Government.

6. UNICEF/Mali—Dr. Alpha Telli Diallo

Dr. Diallo explained the Integrated Management of Childhood Illness work that the United Nations Children’s Fund (UNICEF) is doing with the MOH in the regions of Kayes, Koulikoro, Segou, and Mopti. These activities fall under the accelerated strategy for child survival and the interventions are based on the series of child survival articles from *The Lancet* in 2004. They are implementing three packages of integrated services (*Programme élargi de Vaccinations + [PEV+]*, *Consultation Prénatal [CPN+]*, and *Prise en Charge Intégrée des Maladies de l’Enfant + [PCIME +]*). In these four regions, UNICEF is also providing sulfadoxine/pyrimethamine (SP) for intermittent preventive treatment (IPT) of malaria in pregnant women. Their strategy is to provide insecticide-treated nets (ITNs) for all children from 0–1 years and pregnant women for a period of four years, to raise the ITN coverage rates. They have also trained and equipped *Agents de Santé Communautaires* (ASC) or *relais* in each *cercle* to follow up with ITN recipients to ensure their correct use. In the six *cercles* where UNICEF worked this year they attained ITN coverage of 87 percent.

Although UNICEF does not have enough resources to pay for ACTs, they are ready and willing to support the MOH and PNLN on related training and communication activities.

Dr. Diallo advised speaking with the WB to explore the possibility of them considering the procurement of ACTs a priority in cooperation with the Government. He stated that only the GFATM or WB can support the amount needed to procure ACTs.

He also suggested reviewing the GFATM Technical Review Panel (TRP) responses and queries from the Round 5 proposal and to make sure those are taken into account when developing the procurement plan.

7. Assistance Technique Nationale—Ciro Franco, Chief of Party

Assistance Technique Nationale (ATN) is one of two USAID bilateral projects and is managed by Abt Associates. The other, *Ciwara Keneya*, is managed by CARE. ATN works on high impact services including reproductive health, malaria, nutrition, immunization, and health reform.

There was some discussion on the malaria program and challenges with ACTs procurement and implementation. Mr. Franco mentioned that there were some issues associated with effective spending of the GFATM funds from Round 1. He also noted that discussions with the WB should provide a clear and well laid out procurement and implementation plan for ACTs.

8. MSF—Dr. Carlos Recio

MSF works in the *Kangaba cercle* (approximate population 100,000) in the Koulikoro region. They began implementing AS/AQ in August 2005 through the public health system. All CScm and *Reference* (District) Health Center staff members were trained on ACT treatment. ACTs are given free of charge to children under the age of five. Anyone over age five must pay 85 CFA franc (CFA) for a treatment dose. This is the same amount as a treatment dose of CQ. Rapid diagnostic tests [(RDT) (Paracheck)] are used to diagnose all cases of malaria before treatment is given and those who test negative for malaria are tested for other illnesses.

MSF is advocating free treatment with ACTs, especially for children under age five as they believe that the price of medicines at health facilities is part of the reason for low utilization of the public sector.

They are also considering beginning to treat severe malaria cases with artemether monotherapy for five days followed immediately by a course of AS/AQ, although this is not the Mali national malaria control policy.

The *relais* are trained to work with the communities to reinforce behaviors of seeking rapid treatment for malaria symptoms. This has resulted in an increase in health center attendance in the last few months. Although their program was intended to run for one year, it may be extended through the end of December 2006.

9. Pharmacie Populaire du Mali—Drs. Aicha Guindo, Amir Maiga, and Adama Dembele

Dr. Guindo presented the PPM mandate, how it is organized, and its mission. She also explained the role of different governmental bodies (DPM, LNS, DGMP) in the reception commission.

Dr. Guindo was concerned that there had not been a final decision or approved policy for ACTs after nearly two years of discussions, greatly affecting PPM's work as it cannot take any steps toward phasing out CQ or phasing in ACTs until policy and treatment guidelines are in place. Furthermore, PPM did not know what to do with the stock of CQ. About one year ago a public service announcement (developed by PNL) was broadcast on national TV. It explained that CQ should no longer be used for IPT as it is ineffective and should be replaced with SP. She felt that this caused the population to be wary of CQ for treatment as well and hence PPM is not able to sell the stocks of CQ currently on their shelves. Dr. Guindo's opinion was that CQ should continue to be used in areas of low CQ resistance.

PPM conducts procurement once annually through an open international tender. Manufacturers are pre-qualified for a period of three years and all producers and suppliers are given 45 days to respond to the tender request. Their procurement period is six months, which requires them to have six months of stock on hand or in the pipeline, which is challenging.

Dr. Guindo stated that she will not procure non-generic ACTs. She noted that she has had conversations with a number of pharmaceutical manufacturers and knows that they are working on generics as well as a fixed-dose AS/AQ combination.

She explained that a GFATM consultant had come to Mali to assess the procurement and distribution system. Dr. Guindo stated that the consultant did not meet with the PPM and his report (based on a WHO document) focused only on the weakness of the system.

Dr. Guindo also explained that the PPM supplies both the public and private sector. Private sector prices are not regulated at this time; however, a law to regulate this sector, particularly ACTs, is under preparation. The PPM provided a copy of the official decree that outlines the pricing structure and fixed margins between the different levels (Annex 3). Public sector medicine prices are fixed according to a set coefficient. PPM has set price ceilings for the private sector to effectively reduce the number of suppliers.

Dr. Guindo explained the PPM information system and the forecasting tools they use. The system is decentralized and the PPM delivers medicines to regional depots once a month, based on consumption data from these depots. Three months of safety stock is always on hand. Regional hospitals and *dépôts repartiteur de cercle* (*cercle*-level depots)/pharmacies obtain their medicines at the regional depots and are responsible for picking up their stock. The CSCComs in turn obtain their stock from the *cercle*-level depot/pharmacy. The supply chain is described in detail in the official decree regulated by the DPM.

The PPM and health facilities are required to follow this supply chain set by the DPM. Dr. Guindo explained that officially it is the DPM that is responsible for forecasting; however, the

PPM tries to base their orders on previous consumption data. This proves challenging due to problems and a lack of good information on quantities needed. Also, consumption data below the regional level are not available, as the PPM is not responsible for data collection beyond the regional level.

Distribution costs are not available, but transportation is ensured by PPM to the regional level.

When a shipment arrives at the PPM a reception commission is involved and samples are taken to be tested at the LNS. Dr. Guindo noted that the quality control procedures are not effective. Once shipments are approved, they are moved from the receiving warehouse to the appropriate stock warehouse. She also explained that sometimes there are stockouts because of circumstances beyond their control. She specifically noted flooding in Dakar earlier this year, which resulted in a three-week delay in delivery due to problems with the train.

The *Schéma Directeur d'Approvisionnement* is the reference text for PPM which could be obtained from the DPM.

Dr. Guindo said that technical assistance on quantification and logistics would be particularly welcome but in general, all technical assistance would be welcome.

The team was given a tour of the storage facilities.

10. WB—Tonia Marek

Ms. Marek explained that the Mali has HIPC funds totaling about USD 6 million per year but that only a small portion of that goes to malaria. The WB does not manage these funds but they do ensure that the funds are spent on medium-term priority programs.

She noted that there is not enough decentralization of resources and that there is no performance contract for health providers. Too little money goes to the peripheral level and often too late. She has already spoken with the DNS about getting more funds for malaria; however, there are problems with how money is being spent and the MOH and PNLP need to do some investigation to resolve those issues.

Regarding the WB Booster Program, Ms. Marek explained that this program was more about reallocating the existing resources as opposed to providing additional WB resources and funds. She noted that MOH should provide more direction to donors and development partners. Currently, a lack of coordination and direction from the MOH allows partners to develop their own separate agendas which may conflict with each other and be difficult to coordinate. She pointed out that the MOH has PRODESS, a health and social development program which helps partners support the government. There are discussions underway to coordinate partners' procedures.

Ms. Marek explained that the WB has made available CFA 750 million to purchase ITNs but that lack of responsiveness on the part of the MOH and PNLP was jeopardizing these funds.

The annual operational plan is to be validated in January 2006 and this would be a good opportunity for the MOH to define their priorities and decide how funds should be allocated. The WB has little involvement in developing the operational plan and knows few details. Ms. Marek explained that 70 percent of WB funds will be given to the government when they reach agreement on the operational plan. Later in 2006 progress toward achievement of set indicators will be reviewed and depending on performance the remaining funds are transferred to the government. She noted that the funds from WB will keep the government running, as the government budget doesn't come in until July.

She also noted a planned WB appraisal mission is planned for February 2006 and expressed interest in having a USAID malaria expert come and help the government select indicators to be considered in the operational plan for the next five years. RPM Plus will relay this request to USAID.

11. Koulikoro Regional Health Directorate—Dr. Souleymane Sidibe, Division Chief

Dr. Sidibe explained the regional health directorate's *Direction Regional de la Santé* (DRS) mission, which includes technical support to districts, trainings, monitoring and supervision, and health information system management. ACTs are needed at all levels of the health system. The situation is particularly dire because the population has been told that CQ is no longer effective.

Private providers and public providers have participated in some training sessions to sensitize them on the new policy; however the training manuals have since been revised and a formal cascade training to all levels will be planned once ACT procurement has begun. Currently, health providers prescribe ACTs to those who can afford to purchase them through the private sector; for those who cannot afford them, CQ is prescribed in most cases.

The quantification of medicines at the regional level has some limits because of limited data on population and drug management at district and CSCCom levels. Dr. Sidibe also explained that there is a system in place to transfer medicines close to expiration to areas of high need—this depends however on the *cercle*-level team monitoring stock levels. Although this is possible it has only happened a few times because of the lack of information on stock levels.

Dr. Sidibe explained the reporting process from CSCCom to the national level. The process involves CSCCom chiefs compiling data from the consultation register on a monthly basis and sending it to the health district each quarter. The health district then compiles all of the CSCCom data, reviews it, and forwards it to the regional level. The regional level compiles all of the *cercle* data and sends it to the national level quarterly. The national level then analyzes the data and sends results and feedback down through the levels. Dr. Sidibe noted that the data collected at the CSCCom level could be strengthened and that each CSCCom should analyze their own data (i.e., at the operational level) before sending it on to the next level to see how they can improve services.

12. PPM Koulikoro Regional Depot—Dr. Boubacar Koita

Dr. Koita explained how the depot works to supply both public and private sector pharmacies. He explained that the private sector is served directly (not through wholesalers) by the depot and that they have to collect their own medicines. There is not a specific list from which private pharmacies can order and purchase.

CSCComs are served through the *dépôt répartiteur de cercle* or *cercle-level depot (DRC)*. Between the DRC and the CSCCom a fixed price margin is applied. Margins are applied between the various levels. Dr. Koita also noted that although the public sector prices are fixed, the private sector prices are not; the MOH is working on this issue. Bulk packaging is reserved only for public health facilities.

Training was carried out in the Koulikoro on ACT use, but Dr. Koita did not participate in these trainings.

Monthly orders in the public facilities are based on consumption as obtained from records on what the regional depot sells (as opposed to consumption data direct from the DRC and CSCCom level). Average monthly consumption figures are calculated. The team was given a tour of the storage facilities. There were two storage rooms with little room for many additional bulky packages. There was no cool room in the storage area, but there were two refrigerators for cold storage.

Medicine	Strength	Packaging	Price (CFA)
CQ tablets	100 mg	Blister	35/10
		1,000 bulk	1,375/1,000
SP	500 mg/25 mg	Blister	200/3
		1,000 bulk	2725/1,000
Quinine tablets	300 mg	1,000	24,715
Quinine injection	100 mg/ml	2 ml	70
Quinine injection	100 mg/ml	4 ml	90

13. Koulikoro DRC (*Cercle-level depot*)

The pharmacy was closed.

14. CSCom just outside Koulikoro

Prices for antimalarials (CQ, SP, quinine) were collected for comparison.

Medicine	Strength	Packaging	Price (CFA)
CQ tablets	100 mg	<i>Vrac</i> *	5/each
SP	500 mg/25mg	<i>Vrac</i>	110/3
Quinine tablets	300 mg	<i>Vrac</i>	20/each
Glucose infusion	5%		595

* Economy packaging for use only in public sector

The data above illustrate the disparity in the pricing structures, which vary according to when the medicines were bought and from which manufacturer.

15. Malaria Research Training Center—Professor Ogobaro Doumbo

The Malaria Research Training Center (MRTC) is interested in ACT Quality Control and Pharmacovigilance. The MRTC has conducted drug efficacy studies on a variety of ACTs and they have all proven to be more than 98 percent effective. Professor Ogobaro also noted the importance of continued monitoring of efficacy of ACTs and noted that the MRTC is already doing it with a number of ACTs.

He raised concerns that it would be unethical to implement ACTs without a functioning pharmacovigilance system in place. Additionally, he noted that much data are needed before ACTs can be used for pregnant women.

He had great concerns for the level of counterfeit ACTs circulating in Africa (50 percent) and suggested that a system should be in place to control the quality of medicines arriving in countries. He particularly noted that each lot being imported should be tested to confirm the quality of the medicines. He also suggested that medicines should be packaged according to the level at which they will be used in the health system structure.

In Professor Ogobaro's opinion, high subsidies will need to be applied for ACTs for at least five years to prove and establish their efficacy and that the MOH should begin to consider cost recovery options after that time.

There was some discussion on the PNL's choice of having two products as their first-line recommendation. Professor Doumbo said that many medicines can be considered and recommended by the program at the same time. Health providers will need clear information and guidelines on treatment protocols for the different combinations. Professor Ogobaro also noted that RDTs should be used where there are health providers, but that in villages where there is no health provider, treatment based on clinical symptoms should be continued.

16. DNS—Dr. Mamadou Traore

The following topics were reviewed—

- Need to have MOH sign the new policy
- Funding for ACT procurement—HIPC funds
- Issue of two combination therapies listed as first-line treatment
- ITN issue as a bottleneck to the availability of additional funds for malaria

17. Final meeting with PNLP—Dr. Georges Dakono

The team met briefly with Dr. Dakono to collect a few final documents (training materials, GF Technical Review Panel comments on Round 5 proposal and working group Terms of References [TORs]) and to clarify mission follow-up. The team will finalize the trip report in English and then have it translated into French to share with local partners and stakeholders for their review and comment. The team will then work to finalize the quantification of need for ACTs and a procurement plan to inform future discussions on ACT procurement.

The RPM Plus team took the opportunity to express their sincere thanks for the assistance the PNLP accorded the mission.

Visit to Private Pharmacy

The team visited a private pharmacy to determine which antimalarials were available and their prices. The following information was obtained.

Medicine	Strength	Packaging	Price (CFA)
CQ tablets	100 mg	30	250
SP	500 mg/25mg	3	525
Quinine injection	100 mg/ml	2 ml vial	150
Coartem		8	3,500
		16	5,600

ITN Harmonization Workshop (Opening and Initial Session)

The RPM Plus team attended the opening and initial sessions of a harmonization workshop on ITNs. This workshop brought together most partners working with and distributing ITNs throughout Mali and was organized by the DNS/PNLP. The goal of the workshop was to harmonize the ITN distribution system in Mali.

Provide a Departure Debriefing to USAID—Christine Sow and Sixte Zigirumugabé

The RPM Plus mission met with Ms. Sow and Mr. Zigirumugabé on Friday morning for a departure debriefing. After explaining all of the meetings and visits that the team conducted during the week the discussion moved to the quantification and procurement plan.

RPM Plus quantified the ACT needs for the next five years using morbidity and incidence data received from the PNLN through the health information system (SLIS). RPM Plus raised the question of the quality of the data as a number of *cercles* reported zero deaths due to malaria during all of 2004. Mr. Zigirumugabé also mentioned that the issue of underreporting of malaria deaths came up during a meeting in Sikasso earlier in the week. The team provided USAID/Mali with a copy of the quantification of need for ACT for the period 2006–2010 and explained the assumptions made in performing the calculation.

USAID/Mali suggested that the team submit the trip report for review and comment, and use this as a basis for discussion with the Mission on how to design the procurement plan.

RPM Plus explained their concern about the fact that the new malaria control policy has two combination therapies listed as the preferred first-line treatment. Although the issue came up numerous times, it is still not clear why there are two combinations listed and what the actual plan is for their use. The PNLN explained that it was primarily the limited availability of Coartem that resulted in AS/AQ being added to the policy and that AS/AQ will be used in the shorter term because it is more readily available. When the availability of Coartem is stabilized, there will be a transition to it.

The RPM Plus team suggested that the LNS could be strengthened and that there is concern about their capacity to process the number of samples that will come in as a result of ACT procurement. Ms. Sow mentioned that there were funds budgeted from GFATM Round 1 for strengthening the LNS. Although this was in the context of HIV/AIDs, as the facilities are shared this will also impact medicines for malaria control.

On the issue of funding for procurement of ACTs, the team explained that it was the Government of Mali that would ultimately determine the allocation of HIPC funds and the WB is only responsible for ensuring that the HIPC funds are available and spent on priority programs. The team noted that there needs to be advocacy at the highest levels of the MOH and DNS to ensure that HIPC funds are allocated for malaria activities, particularly for ACT procurement. RPM Plus and USAID/Mali discussed the idea that if HIPC funds could be allocated for ACT procurement, even if the funds weren't sufficient to procure the full amount of ACTs needed for nationwide coverage, that this could be a means of leveraging additional funds from other sources.

The team also mentioned the ITN procurement issue and the WB's concerns about the CFA 750 million that had been set aside to purchase ITNs. The concerns are mainly related to weakness on the part of the PNLN in the areas of planning, budgeting, and follow-up implementation. This hinders the advancement of the malaria agenda in Mali particularly with the Ministry of

Economics and Finances. The health sector is perceived by many in the Government as a sector with adequate funding already.

RPM Plus also mentioned the Operational Plan for WB funds that is to be finalized and submitted by the Government in January 2006, the appraisal mission planned for February 2006, and the request to have a USAID malaria expert participate in that mission.

The team discussed the status of the training on the new malaria control policy. A national level training/sensitization has taken place involving Chief Doctors from each region. While visiting the Koulikoro region, the team briefly reviewed the training materials that were developed with the assistance of WHO/AFRO through MAC. USAID/Mali wanted the training materials shared amongst the MAC partnership and comments to be provided before the materials were used again.

Provide TA for Quantification of ACTs

A quantification of ACT need was performed using existing data on incidence from the PNL (Annex 1); however, these figures are a gross underestimate of the actual burden of the disease. Furthermore, they represent incidence in the public sector only. Discussions with regional facility staff confirmed that reporting of cases was poor and presented an inaccurate picture. These figures were therefore not used in the quantification.

Data from 2001 from Sotuba, a peri-urban area, were used to carry out a second quantification to determine how inaccurate the figures were from PNL. The incidence from this area was extrapolated to the rest of Mali and assumed not to increase. The results of this calculation are illustrated in Annex 2 and summarized in Table 1.

If AS/AQ is replaced by Coartem in 2006, the total cost of procuring Coartem will be USD 3,837,475 (in addition, there is a 3 percent WHO handling charge that will be added to the order).

As these figures were obtained using data from one region only, caution must be used when citing these figures widely. To obtain accurate estimates of need, it will be necessary to carry out a national level quantification with a more detailed data collection process.

These figures will be adjusted in the procurement plan after obtaining more accurate incidence figures of children less than five years of age from the MRTC.

RPM Plus will also provide technical assistance for a national level training on quantification of antimalarials.

Table 1. Estimations of need for AS/AQ in Mali

Year	Utilization of the public sector, %	Total number of treatments of AS/AQ needed (for public sector)	Cost (USD)
2006	25	1,846,407	2,013,305
2007	45	3,480,010	3,794,572
2008	55	4,359,942	4,730,427
2009	60	4,841,541	5,279,312
2010	60	4,872,434	5,312,902

Provide TA for Procurement of ACTs (Including the Development of a Procurement Plan)

It was decided during discussions with the USAID/Mali Mission that the procurement plan should be developed after receipt of the trip report. The PNLN will share the recommendations of the trip report with stakeholders in Mali and a joint decision on the framework of the procurement plan would be made.

Plan for Follow-up RPM Plus/MAC Activities in Mali

It was decided with the USAID/Mali Mission that RPM Plus would proceed with the activities in the workplan. A follow-up trip will be made by Mr. Ndoye to begin the costing exercise and other activities.

Collaborators and Partners

See list of persons in Annex 1.

NEXT STEPS

Immediate Follow-up Activities

- Complete trip report
- Complete procurement plan after feedback from PNLP
- Determine with PNLP if a full quantification needs to be done based on limited existing data obtained while in country

Recommendations

For ACTs to be adopted, procured, and implemented effectively, the following steps need to occur:

Selection

- There needs to be one choice for the first-line therapy. Having two choices will create confusion among health workers and at the level of procurement and distribution. Furthermore, beginning implementation with AS/AQ and then moving on to Coartem has the potential to create pipelines of unused medicines leading to a waste of resources. The choice of first-line therapy also affects downstream activities such as pharmacovigilance.
- The AS/AQ combination needs to be added to the EML as soon as possible.
- A decision on the role of RDTs needs to be made. WHO recommends that children under five years of age should continue to be clinically diagnosed and RDTs should only be used to diagnose malaria in adults in areas of stable malaria transmission.
- The new STGs, which are due to be revised in 2006, need to contain the new treatment.

Resource Mobilization

- The issue of resource mobilization has the potential to be a barrier to the ACT policy adoption and implementation. Unless the issues surrounding the lack of movement of funds from Round 1 of the GFATM grant and the appropriate allocation of HIPC funds is addressed, there may be difficulties in advocating for additional funds. First, the procurement of ITNs using the CFA 750 million allocated by the WB needs to begin rapidly. Second, the remaining HIPC funds need to be allocated to programs taking into account the country priorities.

- A concrete plan needs to be developed which outlines the resources needed for ACT implementation (direct procurement and ancillary activities). The portion of existing funds which can be made available for this plan from HIPC and other national level resources should be indicated and the shortfall calculated. This information should then be used to advocate for additional funds through donors such as the WB as the health sector is perceived by many in the Government as already adequately funded. In addition, although Mali is not currently a focus country for the US President's Malaria Initiative, such a planned approach may be used to advocate for funds at this level.
- The DAF needs to be sensitized on ACT issues.
- For the above steps to occur, it is necessary to involve all interested partners and stakeholders. A major problem for the protracted movement towards ACTs in Mali is that there is limited communication between the various MOH structures (PPM, DPM, DNS, PNLP, DAF). Often, the PNLP is not aware of activities that may directly affect the program. Meetings that have been held have not been all-inclusive. A meeting/working group will need to be organized involving the DAF, the PNLP, DNS, and other institutions involved in resource mobilization and ACT implementation.
- The PNLP needs to take on a stronger leadership role particularly in the areas of planning, budgeting, follow-up of implementation, and effective communication among partners in the Ministry of Health and Finance.

Planning

- An ACT implementation committee needs to be set up with representation from the various sectors that will be involved in ACT implementation including the PNLP, DPM, PPM, and WHO. This committee should decide on the sequence and timing of the various steps around ACT implementation including training, shepherd document preparation and formation of working groups, and generally oversee implementation.

Procurement

- Orders for the ACT choice need to be placed with Malaria Medicines and Supplies Service as soon as possible with anticipated implementation start dates.

Quantification

- There is a need to develop a system for the national level to obtain data on consumption by the regions/*cercles*.
- There is a need to train lower levels on appropriate quantification of need. The PNLP mentioned that this was intended, but no date or concrete plan was given.

Storage and Distribution

- A detailed distribution plan needs to be developed in line with the existing MOH Schéma Directeur.
- Storage is a serious issue for ACTs. ACT packages are bulky and need more room for storage than the traditional containers containing 1,000 tablets of CQ. Furthermore, they need a cooler space than the traditional storage areas. In the PPM and the regional stores, there did not seem to be adequate space to accommodate ACTs.¹

Pharmacovigilance

ADR Monitoring

- The DPM (including the LNS) and PNLP need to partner with the MRTC to develop an effective system for monitoring adverse drug reactions (ADR).
- Standard operating procedures for monitoring of ADRs to ACTs need to be developed particularly for accidental dosing by pregnant women.

Quality Control

- The DPM and LNS need to develop appropriate standard operating procedures for carrying out testing of antimalarials which outlines sampling, frequency of collecting samples, and feedback of quality problems to appropriate bodies/institutions.
- A tiered system for monitoring quality needs to be set up which involves carrying out simple color reaction screening at peripheral levels and confirmatory testing at the national level.
- The problem at the national level is not a lack of human resources or skills, as several LNS members had received intensive training on various aspects of pharmacovigilance. Instead, a quality control system with clear direction needs to be set up.

Rational Medicine Use and Training

- Health workers should be trained just before the policy is to be launched and implemented. Training too early will result in health workers forgetting the important points emphasized in the training and training too late will encourage irrational medicines use as the medicine will be available before health workers have been trained on its use. The cascade training planned by WHO should be delayed to occur just before implementation of the new treatment.

¹ One dispenser of Coartem of 6 blisters (144 tabs) measures 160 x 95 x 125 mm. Each box contains 30 dispensers. A container of CQ (1,000 tablets) is in the region of 250 x 125 mm.

- Pharmacists and dispensers will need to be trained in the new therapy.
- Private practitioners and pharmacies need to be sensitized to the new therapy.

Monitoring and Evaluation

- While there seems to be a system for collecting data on the numbers of cases and incidence of malaria in each region, this data demonstrated a gross under-reporting. Furthermore, fever cases are used as proxy indicators for malaria cases and there are no true numbers for the incidence of malaria. Mechanisms to ensure that cases are recorded on a regular basis must be developed to ensure that the numbers provide a true reflection of the incidence in the country.

ANNEX 1. PEOPLE CONSULTED DURING MISSION

Name	Organization	Position
Sindy Berthe	MOH/Laboratoire National de la Santé	Pharmacist in charge of QC testing for medicines
Mountaga Bore	MOH/Direction Nationale de la Santé	Deputy National Director of Health
Georges Dakono	MOH/Programme National de Lutte contre le Paludisme	Director
Adama Dembele	MOH/Pharmacie Populaire du Mali	Procurement Manager
Alpha Telli Diallo	UNICEF/Mali	Project Officer Health - Nutrition
Barasson Diarra	MOH/Programme National de Lutte contre le Paludisme	M&E Focal Point
Ogobaro Doumbo	Malaria Research and Training Center	Director
Ciro Franco	Assistance Technique Nationale (USAID Bilateral)	Chief of Party
Aicha Guindo	MOH/Pharmacie Populaire du Mali	President, General Director
Boubacar Koita	MOH/PPM Koulikoro Regional Depot	Manager
Amir Maiga	MOH/Pharmacie Populaire du Mali	
Minkaila Maiga	MOH/Direction de la Pharmacie et du Médicament	Director
Tonia Marek	World Bank	Lead Public Health Specialist
Carlos Recio	Médecins Sans Frontières - Luxembourg	Medical Coordinator
Massambou Sacko	WHO/Mali	NPO
Souleymane Sidibe	MOH/Koulikoro Regional Health Directorate	Division Chief
Mahamadou Sissoko	MOH/Programme National de Lutte contre le Paludisme - TFGI	Malaria Advisor
Christine Sow	USAID/Mali	Health Team Leader
Amara Cherif Traoré	MOH/Laboratoire National de la Santé	Head of the Quality Control of Medicines Department
Mamadou Soun calo Traoré	MOH/Direction Nationale de la Santé	National Director
Sixte Zigirumugabé	USAID/Mali	Health Activities Manager

ANNEX 2. QUANTIFICATION OF ACT NEEDS IN MALI USING INCIDENCE DATA FROM SOTUBA

(Extrapolating nationally, using 2001 incidence data in children less than five years of age from Sotuba)

Requirements for 2006

Age Group	Episodes per 1,000 Contacts	Past Year Estimated Number of Episodes	Projected No. of Episodes	% Utilization	Drug Product	Basic Unit	Basic Unit per Dose	Basic Units per Episode	Total Basic Units Needed	Lead Times, Safety Stock, etc.*	Adjusted Total Basic Units Needed**	Total no. of Treatment courses Needed†	Cost	Total Cost (USD)
<1	1,056.01	484,101	506,893	25	AS/AQ	Tablet	0.5	3	1,520,679	380,170	475,212	158,404	0.066	31,364
1-6	593.334	1,360,005	1,424,034	25	AS/AQ	Tablet	1	6	8,544,207	2,136,052	2,670,065	445,011	0.066	176,224
7-11	366.282	629,678	659,323	25	AS/AQ	Tablet	2	12	7,911,880	1,977,970	2,472,463	206,039	0.066	163,183
>12	482	3,168,129	3,318,252	25	AS/AQ	Tablet	4	24	79,638,037	19,909,509	24,886,887	1,036,954	0.066	1,642,535
											30,504,626	1,846,407		2,013,305

* Lead time+ safety stock = extra stock to allow for procurement time and buffer stock (3 months)

**Adjusted Total Basic Units Needed = Total Basic Units Needed + Lead Time + Safety Stock

†Total number of treatment courses needed = Adjusted Total Basic Units Needed/Basic Units per Episode

Assumptions

- There are an equal number of children of each age in age groups 1–6 and 7–11 (for adjustment for dosages according to age bands for AS/AQ)
- Five percent of the adult population is pregnant and will not receive ACTs
- Incidence in population over five years is half of that of population under five years
- Percentage of cases in each age group extrapolated from data in Annex 2
- Twenty-five percent of the population will access the public sector for malaria treatment

Requirements for 2007

Age Group	Episodes per 1,000 Contacts	Past Year Estimated No. of Episodes	Projected No. of Episodes	% Utilization	Drug Product	Basic Unit	Basic Unit per Dose	Basic Units per Episode	Total Basic Units Needed	Lead Times, Safety Stock, etc.	Adjusted Total Basic Units Needed	Total No. of Treatments Courses Needed	Cost	Total Cost (USD)
<1	1,077.1261	506,893	530,758	45	AS/AQ	Tablet	0.5	3	1,592,274	398,069	895,654	298,551	0.066	59,113
1-6	605.20068	1,424,034	1,491,080	45	AS/AQ	Tablet	1	6	8,946,480	2,236,620	5,032,395	838,732	0.066	332,138
7-11	373.60764	659,323	690,365	45	AS/AQ	Tablet	2	12	8,284,382	2,071,096	4,659,965	388,330	0.066	307,558
>12	501.10132	3,318,252	3,474,481	45	AS/AQ	Tablet	4	24	83,387,548	20,846,887	46,905,496	1,954,396	0.066	3,095,763
											57,493,510	3,480,010		3,794,572

Assumptions

- There are an equal number of children of each age in age groups 1–6 and 7–11 (for adjustment for dosages according to age bands for AS/AQ)
- Population increases at constant rate
- Incidence remains the same
- Five percent of the adult population is pregnant and will not receive ACTs
- Incidence in population over five years is half of that of population under 5 years
- Percentage of cases in each age group extrapolated from data in Annex 2
- Forty-five percent of the population will access the public sector for malaria treatment

Requirements for 2008

Age Group	Episodes per 1,000 Contacts	Past Year Estimated Number of Episodes	Projected Number of Episodes	% Utilization	Drug Product	Basic Unit	Basic Unit per Dose	Basic Units per Episode	Total Basic Units Needed	Lead Times, Safety Stock, etc.	Adjusted Total Basic Units Needed	Total No. of Treatments Courses Needed	Cost	Total Cost (USD)
<1	1,077.13	530,758	544,850	55	AS/AQ	Tablet	0.5	3	1,634,549	408,637	1,123,753	374,584	0.066	74,168
1-6	605.201	1,491,080	1,530,669	55	AS/AQ	Tablet	1	6	9,184,011	2,296,003	6,314,008	1,052,335	0.066	416,725
7-11	373.608	690,365	746,326	55	AS/AQ	Tablet	2	12	8,955,912	2,238,978	6,157,190	513,099	0.066	406,375
>12	501.619	3,474,481	3,519,890	55	AS/AQ	Tablet	4	24	84,477,366	21,119,342	58,078,189	2,419,925	0.066	3,833,160
											71,673,139	4,359,942		4,730,427

Assumptions

- There are an equal number of children of each age in age groups 1–6 and 7–11 (for adjustment for dosages according to age bands for AS/AQ)
- Population increases at constant rate
- Five percent of the adult population is pregnant and will not receive ACTs
- Incidence in population over 5 years is half of that of population under 5 years
- Percentage of cases in each age group extrapolated from data in Annex 2
- Fifty-five percent of the population will access the public sector for malaria treatment

Requirements for 2009

Age Group	Episodes per 1,000 Contacts	Past Year Estimated No. of Episodes	Projected No. of Episodes	% Utilization	Drug Product	Basic Unit	Basic Unit per Dose	Basic Units per Episode	Total Basic Units Needed	Lead Times, Safety Stock, etc.	Adjusted Total Basic Units Needed	Total No. of Treatments Courses Needed	Cost	Total Cost (USD)
<1	1,066.4615	544,850	553,778	60%	AS/AQ	Tablet	0.5	3	1,661,333	415,333	1,246,000	415,333	0.066	82,236
1-6	599.20859	1,530,669	1,555,750	60%	AS/AQ	Tablet	1	6	9,334,502	2,333,625	7,000,876	1,166,813	0.066	462,058
7-11	369.90855	746,326	720,307	60%	AS/AQ	Tablet	2	12	8,643,685	2,160,921	6,482,764	540,230	0.066	427,862
>12	496.1918	3,519,890	3,625,552	60%	AS/AQ	Tablet	4	24	87,013,258	21,753,314	65,259,943	2,719,164	0.066	4,307,156
											79,989,583	4,841,541		5,279,312

Assumptions

- There are an equal number of children of each age in age groups 1–6 and 7–11 (for adjustment for dosages according to age bands for AS/AQ)
- Population increases at constant rate
- Five percent of the adult population is pregnant and will not receive ACTs
- Incidence in population over 5 years is half of that of population under 5 years
- Percentage of cases in each age group extrapolated from data in Annex 2
- Sixty percent of the population will access the public sector for malaria treatment

Requirements for 2010

Age Group	Episodes per 1,000 Contacts	Past Year Estimated No. of Episodes	Projected No. of Episodes	% Utilization	Drug Product	Basic Unit	Basic Unit per Dose	Basic Units per Episode	Total Basic Units Needed	Lead Times, Safety Stock, etc.	Adjusted Total Basic Units Needed	Total No. of Treatments Courses Needed	Cost	Total Cost (USD)
<1	1,045.55	553,778	557,334	60%	AS/AQ	Tablet	0.5	3	1,672,001	418,000	1,254,001	418,000	0.066	82,764
1-6	587.46	1,555,750	1,565,741	60%	AS/AQ	Tablet	1	6	9,394,444	2,348,611	7,045,833	1,174,305	0.066	465,025
7-11	362.66	720,307	724,932	60%	AS/AQ	Tablet	2	12	8,699,190	2,174,797	6,524,392	543,699	0.066	430,610
>12	486.43	3,625,552	3,648,572	60%	AS/AQ	Tablet	4	24	87,565,725	21,891,431	65,674,294	2,736,429	0.066	4,334,503
											80,498,520	4,872,434		5,312,902

Assumptions

- There are an equal number of children of each age in age groups 1–6 and 7–11 (for adjustment for dosages according to age bands for AS/AQ)
- Population increases at constant rate
- Five percent of the adult population is pregnant and will not receive ACTs
- Incidence in population over five years of age is half of that of population under 5 years
- Percentage of cases in each age group extrapolated from data in Annex 2
- Sixty percent of the population will access the public sector for malaria treatment

ANNEX 3. OFFICIAL MEDICINES PRICING STRUCTURE

PRIMA TURE

REPUBLICQUE DU MALI
UN PEUPLE - UN BUT - UNE FOI

SECRETARIAT GENERAL
DU GOUVERNEMENT

DECRET N°03- 218 /P-RM DU 30 MAI 2003

PORTANT REGLEMENTATION DES PRIX DES MEDICAMENTS EN
DENOMINATION COMMUNE INTERNATIONALE DE LA LISTE
NATIONALE DES MEDICAMENTS ESSENTIELS.

LE PRESIDENT DE LA REPUBLIQUE,

VU la Constitution ;
VU l'Ordonnance N°92-021/P-CTSP du 13 avril 1992, instituant la liberté des prix et de la concurrence ;
VU le Décret N°92-133/P-CTSP du 24 avril 1992 réglementant la liberté des prix et de la concurrence ;
VU le Décret N°02-490/P-RM du 12 octobre 2002 portant nomination du Premier ministre ;
VU le Décret N°02-496/P-RM du 16 octobre 2002 modifié portant nomination des membres du Gouvernement ;
VU le Décret N°02-503/P-RM du 7 novembre 2002 fixant les intérimis des membres du Gouvernement ;

STATUANT EN CONSEIL DES MINISTRES,

DECRETE :

ARTICLE 1ER : Le présent décret régleme les prix des médicaments de la liste nationale des médicaments essentiels en dénomination commune internationale.

ARTICLE 2 : Le prix de cession des médicaments essentiels sous conditionnement hospitalier vendus par la Pharmacie Populaire du Mali est déterminé par l'application d'un coefficient de 1,325 sur le prix CAF (Coût Assurance Fret).

ARTICLE 3 : Le prix de cession des médicaments essentiels sous conditionnement hospitalier au niveau des dépôts répartiteurs de cercle est déterminé par l'application d'un coefficient de 1,15 sur le prix de cession de la Pharmacie Populaire du Mali

ARTICLE 4 : Le prix de vente public des médicaments essentiels sous conditionnement hospitalier au niveau des hôpitaux est déterminé par l'application d'un coefficient de 1,15 sur le prix de cession de la Pharmacie Populaire du Mali.

ARTICLE 5 : Le prix de vente public des médicaments essentiels sous conditionnement hospitalier au niveau des dépôts de vente des centres de santé de commune du District de Bamako et des centres de santé communautaires du District de Bamako est déterminé par l'application d'un coefficient de 1,15 sur le de cession, de la Pharmacie Populaire du Mali.

ARTICLE 6 : Le prix de vente des médicaments essentiels sous conditionnement hospitalier au niveau des dépôts de vente des centres de santé de cercle est déterminé par l'application d'un coefficient de 1,20 sur le prix de cession des dépôts répartiteurs de cercle.

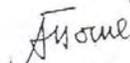
ARTICLE 7 : Le prix de vente maximum au public des médicaments essentiels sous conditionnement hospitalier au niveau des dépôts de vente des centres de santé communautaires en dehors du District de Bamako est déterminé par l'application d'un coefficient de 1,30 sur le prix de cession des dépôts répartiteurs de cercle.

ARTICLE 8 : La liste nationale des médicaments essentiels en Dénomination Commune Internationale est fixée par arrêté du ministre chargé de la Santé. Elle est révisée tous les deux ans après avis d'une commission technique créée par décision du ministre chargé de la santé.

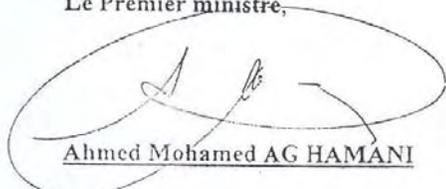
ARTICLE 9 : Le ministre de la Santé, le ministre de l'Economie et des Finances, le ministre de l'Industrie et du Commerce sont chargés, chacun en ce qui le concerne, de l'exécution du présent décret qui sera enregistré et publié au Journal officiel.

Bamako le, 30 MAI 2003

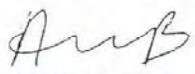
Le Président de la République,


Amadou Toumani TOURE

Le Premier ministre,


Ahmed Mohamed AG HAMANI

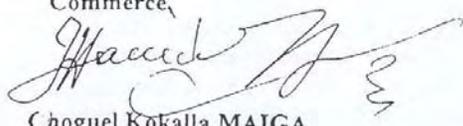
Le ministre de la Promotion de la
Femme, de l'Enfant et de la Famille,
Ministre de la Santé par intérim,


Madame BERTHE Aïssata BENGALY

Le ministre de l'Équipement
et des Transports,
Ministre de l'Economie et des
Finances par intérim,


Ousmane Issoufi MAIGA

Le ministre de l'Industrie et du
Commerce,


Choguel Kokalla MAIGA