# Rational Pharmaceutical Management Plus
# Assessment of Antimalarial Drug Availability and Quality in the Public and Private Sectors of Ghana: Trip Report

Gladys Tetteh
July 2004

Printed July 2004

Rational Pharmaceutical Management Plus
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203
Phone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmplus@msh.org

This report was made possible through support provided by the U.S. Agency for International Development, under the terms of cooperative agreement number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

## 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.



## Recommended Citation

Tetteh, G. 2004. *Assessment of Antimalarial Drug Availability and Quality in the Public and Private Sectors of Ghana: Trip Report.* Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

# Contents

# Acronyms

| | |
|---|---|
| ACT | Artemisinin-based Combination Therapies |
| AQ | Amodiaquine |
| AS | Artesunate |
| CDC | US Centers for Disease Control |
| CMS | Central Medical Stores |
| DMM | Drug Management for Malaria |
| FDB | Food and Drugs Board |
| GFATM | Global Fund to Fight AIDS, Tuberculosis & Malaria |
| GHS | Ghana Health Service |
| HIV | Human Immunodeficiency Virus |
| IEC | Information, Education and Communication |
| MAC | Malaria Action Coalition |
| MNH | Maternal and Neonatal Health Program |
| MoH | Ministry of Health |
| MSH | Management Sciences for Health |
| NMCP | National Malaria Control Program |
| RBM | Roll Back Malaria |
| REAPING | RBM Essential Actions, Progress, and Investments Gaps |
| RPM Plus | Rational Pharmaceutical Management Plus |
| SP | Sulphadoxine-Pyrimethamine |
| TA | Technical Assistance |
| TB | Tuberculosis |
| USAID | United States Agency for International Development |
| USP | United States Pharmacopoeia |
| WARP | West Africa Regional Project |
| WHO | World Health Organization |

# Background

More than 90% of the clinical cases of malaria each year occur in Africa with much of the burden in children under five years of age. Pregnant women are especially at risk and strategies to decrease the morbidity in this group have been found to be effective. Strategies to address these challenges must be implemented in collaboration with programs aimed at integrated approaches to childhood illness and reproductive health.

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. A key objective of the MAC is to create partnerships and linkages with other Roll Back Malaria (RBM) partners.

Widespread resistance[1] to chloroquine has recently prompted Ghana to revise its antimalarial treatment policy in favor of a more effective combination therapy of artesunate (AS) and amodiaquine(AQ). In line with this, a proposal re-submitted for the fourth round of the Global Fund Proposal to fight AIDS, TB and Malaria had as its first objective – to implement the new antimalarial drug policy in all 110 districts of Ghana. The policy aims to provide AS+AQ at no cost to the beneficiary in public facilities[2] and accredited private facilities[3] using "existing procurement and distribution systems of the GHS/MoH". The Ghana Health Service last year[4] identified the need to define the status of the pharmaceutical management system as it relates to antimalarial drugs used both for treatment and prevention of malaria in pregnancy.

RPM Plus has in the past year provided technical assistance to Ghana to assess the available methods for quantification of sulphadoxine/pyrimethamine (SP) for its IPT program. The major outcomes of this activity were facilitation of the procurement of adequate supplies of SP, the development of an appropriate model for use for future quantification needs by the country as its IPT program moves to national scale, and the building of capacity amongst relevant Ministry of Health (MoH) stakeholders. In addition, RPM Plus worked with the Ghana National Drugs Program to de-regulate SP to ensure its access at the health post level for implementation of the IPT program. In January 2004, RPM Plus participated in the REAPING (RBM Essential Actions, Progress & Investments Gaps) consultative mission to Ghana, which supports the attainment of the Abuja targets, in order to provide technical inputs into drug management issues. In February 2004, RPM Plus worked with other MAC partners to provide support to Ghana to develop and re-submit the successful funded Malaria component of the Round III (RIII) Global Fund proposal.

[1] Drug resistance monitoring in six sentinel sites show resistance to chloroquine ranging from 8.6% to 26.6%.
[2] These include Mission health facilities
[3] In areas where there is no public sector facility, private institutions will be accredited to provide the drug at no cost to the patients (This accreditation process is currently being used by the GHS Anti-retroviral Program). Where both public and private facilities exist, the choice as to which facility to patronize will be left to the patient.
[4] Assessing available methods for quantification of SP for IPT in Ghana – Debriefing workshop Sept 3, 2003

## Purpose of Trip

Gladys Tetteh from RPM Plus traveled to Accra, Ghana from July 12 – 18, 2004 to work using USAID/MAC funds to RPM Plus in collaboration with the Ghana Health Service (GHS), to assess the aspects of the pharmaceutical management system in the public and private sectors that are crucial to ensure the availability and proper use of the new recommended combination therapy. Currently in Ghana, both amodiaquine and artesunate exist as monotherapies within the private sector and although the use of these drugs as monotherapy will not be recommended under this policy, it is as yet not certain how malaria will actually be treated within the non-accredited private sector facilities in the early stages. RPM Plus in collaboration with the United States Pharmacopoeia (USP) also provided support to the GHS to assess antimalarial drug quality in the public and private sectors.

A local consultant was identified to work with the RPM Plus/GHS team. Based on the findings of the assessment, RPM Plus will provide recommendations to the GHS to further strengthen systems of procurement, distribution, availability and quality of antimalarials in the public and private sectors.

## Scope of Work

Gladys Tetteh's scope of work on this trip was to:

- Work with the local consultant and GHS team, using methodology based on the Drug Management for Malaria (DMM) Manual to conduct an assessment of the availability and quality of antimalarials in the public and private sectors.
- In collaboration with USP and the Food & Drugs Board of Ghana, use specific sampling procedures to obtain samples of artesunate, amodiaquine and sulphadoxine-pyrimethamine from the public and private sectors for quality testing.
- Produce a report at the end of the assessment and make recommendations to address any potential problems with an aim to strengthen the pharmaceutical management system in Ghana to support the malaria management program and implementation of the new antimalarial policy.
- Provide an arrival briefing and/or departure debriefing to USAID upon request.

# Activities

**Work with the local consultant and GHS team, using methodology based on the Drug Management for Malaria (DMM) Manual to conduct an assessment of the availability and quality of antimalarials in the public and private sectors**

The first day of the trip consisted of planning, logistic arrangements and meetings with the local consultant and Ghana Health Service, aimed at preparing for a successful assessment.

***Meeting with local consultant - Mr. Peter Gyimah, Head, Central Medical Stores, MoH Ghana***

A meeting held with the local consultant selected coordinators for the assessment, finalized the selection of data collection sites (in conjunction with the NMCP), prepared the tracer list of DMM antimalarial drugs, decided on the selection of data collectors, team leaders and the formation of field teams, and arranged logistics such as timetables, transport, and letters of authorization.

***Meeting with Mr. Samuel Boateng, Director for Procurement and Supply, MoH Ghana***

A meeting was held with the Director of Procurement and Supply for a final review of the data collection tools and to finalize the letters of authorization for signature by the Deputy Minister of Health. Mr. Boateng warned that the GHS had directed that all future assessments should be done in collaboration with the Ghana Health Research Unit. He also advised that the results of the assessment should be disseminated within the GHS before the final assessment report is printed, as was done for the RPM Plus assessment of available methods for quantification of SP for IPT. He expressed his eagerness to see the outcome of the assessment and called for updates during the period of the assessment. Mr. Boateng was thanked by RPM Plus for releasing the Head of CMS, who possessed familiarity with pharmaceutical policy, logistics management, procurement, and budget issues in Ghana, to work as local consultant on the assessment.

***Meeting with Dr. Constance Bart-Plange, Manager – National Malaria Control Program***

This meeting was planned to finalize preparations for the RPM Plus/GHS assessment including the involvement of at least one representative from the NMCP on the field team, to synchronize RPM Plus proposed activities for fiscal year 2004-2005, to inquire about the dates for the planned RBM forecasting workshop in Ghana, and to determine possible needs for the NMCP which could be relevant to other countries in the West Africa region to enable activity planning under USAID/WARP planning.

Dr. Felicia Owusu-Antwi, National Professional Officer, WHO/Ghana Country Office was present for the discussion on the RPM/Plus GHS assessment and expressed keen interest in seeing the outcome of the activity. The involvement of WHO/Ghana was requested by RPM Plus as it is planning a similar drug quality survey in the future.

Dr. Bart-Plange sanctioned the involvement of one of her NMCP staff for the entire duration of training and fieldwork for the assessment.

The discussion of RPM Plus proposed activities realized the synchronization of activities with the immediate needs of the NMCP. Since the MAC workplan was yet to be finalized, the outcome of these discussions was deemed provisional. Activities as discussed included provision of technical assistance to the NMCP for implementation of Ghana's new policy, technical assistance (TA) to the RBM stakeholders for pre-packaging of Artesunate/Amodiaquine (AS/AQ), TA to the National Drug Program for de-regulation of AS/AQ, and assistance to the Ghana drug regulatory agency to strengthen drug regulatory procedures and practices.

Within the *TA to NMCP for implementation of the new policy* – NMCP's particular needs included the development of a transition/implementation plan with firm timelines and TA for case management guideline/training material development. The plan would be to carry out the guideline and training material development by putting together a local team of experts (NMCP would do this) who would be joined by technical experts from MAC (as was done for the IPT guideline/training manual development last year). A third request was support for IEC – it was agreed that the feasibility of support from the Academy for Educational Development (AED) would be explored.

With regards to the activity TA *to the RBM stakeholders for pre-packaging of Artesunate/Amodiaquine (AS/AQ)*, RPM Plus was informed that a task force headed by the Food & Drugs Board was already in place to ensure that standards for pre-packaging would be adhered to. It was advised that RPM Plus provide TA to the ongoing process.

***Training of field team for assessment of availability and quality of antimalarials in the public and private sectors of Ghana***

A three-day training session for assessment coordinators, team leaders and data collectors was held at the Erata Hotel in Accra on July 14 – 16, 2004. This session was facilitated by RPM Plus staff. A total of 20 persons were trained. The three day training gave the data collectors a brief background of the malaria disease and policy situation in Ghana and the purpose of the antimalarial drug availability and quality assessment.

A field test was carried out at the Central Medical Stores in Tema outside Accra. Lessons learned from the field test were used to modify some of the data collection tools. Logistics and administrative matters relevant to field work were dealt with. Four teams of 4-5 data collectors each (including FDB and NMCP staff) would travel out into the field for 2 weeks beginning Monday, July 19, 2004 and return on Saturday, July 31, 2004.

**In collaboration with the United States Pharmacopoeia and the Food & Drugs Board of Ghana, use specific sampling procedures to obtain samples of Artesunate, Amodiaquine and Sulphadoxine-Pyrimethamine from the public and private sectors for quality testing**

Following a conference call with Karim Smine of USP, and the subsequent development by USP of a sampling procedure for the quality assessment, two separate meetings were held with the Directorate of the Food & Drugs Board.

An initial meeting held between Mr. Emmanuel Agyarko, Chief Executive Officer of FDB, Mr. Ben Botwe, Deputy CEO of FDB and Dr. Gladys Tetteh of RPM Plus discussed the rationale for sampling and quality testing of artesunates, amodiaquine and sulphadoxine-pyrimethamine within the public and private sectors. It was agreed that three FDB zonal officers would join the RPM Plus/GHS field team (one representing each sector of the country) and be responsible for obtaining and handling the samples for quality testing. The USP sampling procedure was shared with FDB and with the zonal officers; slight modifications were made to the procedure.

A second meeting with Mr. Ben Botwe and Mr. Eric Karikari Boateng, head of laboratory services at FDB discussed the budget for the sampling process and the cost of quality testing of half the drugs sampled.

**Produce a report at the end of the assessment and make recommendations to address any potential problems with an aim to strengthen the pharmaceutical management system in Ghana to support the malaria management program and implementation of the new antimalarial policy**

Data collection was completed on Saturday, July 31, 2004. Data entry and analysis is planned for the week beginning August 2, 2004 in Ghana and Kenya respectively after which a report of the assessment will be written.

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

An arrival briefing with Dr. Jan Paehler, Child Survival and Infectious Diseases Advisor, USAID Ghana Mission was held on Thursday, July 15, 2004. The planned assessment was discussed as well as the RPM Plus FY 2004/5 workplan.

On the issue of Quality, RPM Plus was informed that one of the recent award by USAID for the upcoming fiscal year was won by Engender Health. USAID commended the collaboration between USP and RPM Plus and suggested that RPM Plus speak with Engender Health to determine how to collaborate on quality of health care issues.

# Next Steps

## Immediate Follow-up Activities

- Monitor field work and activities of the local consultant from Nairobi, Kenya
- Analyze assessment data and write up report to include recommendations
- Debrief USAID, RPM Plus and USP on outcome of trip
- Finalize Ghana workplan on the basis of NMCP priorities
- Determine the possibility of AED involvement in IEC for the new Ghana policy

## Recommendations

Although budgeted under the RPM Plus FY 2004/5 Ghana workplan commencing on 1st October, 2004, the activity – provision of technical assistance to NMCP for implementation of the new antimalarial drug policy – needs to occur now. It is recommended that the MAC workplan be finalized by the end of July, 2004 so that the RPM Plus malaria team can begin working on this activity.

# Annex 1.

## RPM PLUS PROPOSAL FOR ASSESSMENT OF ANTIMALARIAL DRUG AVAILABILITY AND QUALITY IN THE PUBLIC AND PRIVATE SECTORS OF GHANA

### Background

Effective case management requires that the effective and appropriate antimalarials are available and used appropriately in the appropriate formulations and amounts and according to an appropriate regimen.

Widespread resistance[5] to chloroquine has recently prompted Ghana to revise its antimalarial treatment policy in favor of a more effective combination therapy of artesunate and amodiaquine. In line with this, a proposal being re-submitted for the fourth round of the Global Fund Proposal to fight AIDS, TB and Malaria has as its first objective – To implement the new antimalarial drug policy in all 110 districts of Ghana. The policy aims to provide AS/AQ at no cost to the beneficiary in public facilities[6] and accredited private facilities[7] using "existing procurement and distribution systems of the GHS/MoH". However, the Ghana Health Service last year[8] identified the need to define the status of the pharmaceutical management system as it relates to antimalarial drugs used both for treatment and prevention of malaria in pregnancy (SP).

### Proposal

Using USAID/MAC funds RPM Plus in collaboration with the Ghana Health Service, plans to assess the aspects of the pharmaceutical management system in the public and private sectors that are crucial to ensure the availability and proper use of the new recommended combination therapy. Based on the findings of the assessment, RPM Plus will provide recommendations to the GHS to further strengthen systems of procurement, distribution and availability of antimalarials in the public and private sectors.

Activities of the GHS drug policy implementation plan include the sensitization of all key stakeholders at national and regional levels, and others from the Food and Drugs Board, Pharmacy Council and Private pharmacies on use of the new drug policy to assure their compliance and cooperation; training of key health staff from the public and private sectors on the use of new drug policy guidelines; and an IEC programme to educate the general public on

[5] Drug resistance monitoring in six sentinel sites show resistance to chloroquine ranging from 8.6% to 26.6%.
[6] These include Mission health facilities
[7] In areas where there is no public sector facility, private institutions will be accredited to provide the drug at no cost to the patients (This accreditation process is currently being used by the GHS Anti-retroviral Program). Where both public and private facilities exist, the choice as to which facility to patronize will be left to the patient.

[8] Assessing available methods for quantification of SP for IPT in Ghana – Debriefing workshop Sept 3, 2003

the change in drug policy among others. However, currently in Ghana, both Amodiaquine and Artesunate exist as monotherapy within the private sector and though the use of these drugs as monotherapy will not be recommended under this policy, it is as yet not certain how malaria will actually be treated within the non-accredited private sector facilities in the early stages. As such, RPM Plus working with the US Pharmacopoeia will provide support to the GHS to assess antimalarial drug quality in the public and private sectors and make recommendations to address any potential problems identified in this area.

## Methodology

### I - Assessment of Antimalarial Drug Availability in the Public and Private Sectors

The methodology for the initial part of the assessment will be based on the Drug Management for Malaria (DMM) Manual, an indicator-based assessment tool developed by the Rational Pharmaceutical Management (RPM) project, in collaboration with the U.S. Agency for International Development (USAID). The *DMM Manual* is designed to guide the review of drug availability and patterns of use of drugs for malaria treatment in public health facilities of the Ministry of Health (MoH) and in private facilities, pharmacies and drug retail outlets.

The assessment will be built around RPM Plus's Drug Availability Study. The study assesses various aspects of drug management in the public and private sectors. Data collection techniques to be used will include document reviews, structured interviews and physical inventory checks.

#### Selection of Data collection sites

The will collect data from four different settings: National level, Regional level, health facilities (MoH and formal private sector facilities) and formal and informal drug retail outlets within selected districts. Data collection efforts will be dual:

1. Collection of data at the national and regional levels
2. Sample survey of health facilities and drug retail outlets

#### S*ampling:*

This will involve three steps as follows:

1. Selection of the national and regional sites sample
2. Selection of the health facilities sample
3. Selection of the drug retail outlet sample

#### *Selection of National and Regional Sites Sample*

The assessment will be conducted in 4 regions of Ghana. The Greater Accra region will be purposively selected as well as three others; one randomly selected from each of the geographical belts of the country.

National Level Information will be obtained in the Greater Accra region through key informant interviews with important stakeholders (listed below). This aspect of the assessment will aim to collect background information on malaria epidemiology, malaria control, drug resistance, existent malaria policies and review reports relevant to antimalarials and the antimalarial pharmaceutical management system.

In order to obtain a detailed overview of the MoH Pharmaceutical management operations, key informant interviews as well as document reviews will be conducted at the central level as well as the regional levels to identify any major problems that affect the movement of antimalarial drugs through the procurement and distribution system.

Sites to be visited at the National and Regional Levels will include:

National Level –
Stores and Procurement Division, MoH
Central Medical Stores
Office of the Chief Pharmacist
National Drugs Program
National Malaria Control Program
Global Fund Secretariat
Food and Drugs Board
USAID, Health Population & Nutrition Office
WHO country office

Regional Level –
Regional Medical Stores in the 4 regions
Regional Health Administrations in the 4 regions

Preparation of a list of commonly used antimalarial drugs (tracer list) that should be available in the stores, at each level of MoH health facilities, in the private health facilities and in the drug retail outlets is an important step in the assessment preparation process and this can be achieved by obtaining inputs from the RBM program and partners at the national level.

### *Selection of Districts*

Within each of the four regions, two districts will be randomly selected from a list of Roll Back Malaria and GFATM districts for the assessment.

### *Selection of the Public Health Facilities Sample*

The sample size of health facilities to be selected will be 40 public health facilities, 5 from each of the eight selected districts. The rationale for selecting a sample size of at least 20 health facilities is based on previous studies and using methodologies extrapolated from WHO EPI and INRUD studies and the study design factors.

Within each district, the district hospital will be selected as one of the health facilities to be visited. In the event that there is more than one district hospital in the district, one hospital will

be randomly selected. Two health centres will then be selected at random and then for each of these two health facilities, one health post/community health clinic that is geographically close. The result is paired sets of health facilities and health posts within the district.

***Selection of the Private Facilities and Drug Retail Outlet Sample***

For the purposes of the assessment, private health facilities refers to private hospitals, Mission hospitals and clinics, drug retail outlets such as pharmacies and chemical shops.

The sample size to be used here is a total of 40 facilities, five from each of the eight districts selected. From a sample frame of private facilities, a sample of one private/mission hospital or clinic and two pharmacies will be randomly selected. As in the case of the public health facilities, for each of the two pharmacies selected, one chemical shop that is geographically close will be selected. The result is paired sets of pharmacies and chemical shops within the district.

For both the selection of public health and private health facilities, once the initial facilities are selected, a nearby "backup outlet" will be selected for each, which the data collection teams will only visit if the selected outlet is closed. A code will be assigned for each outlet, which data collectors will use on data collection forms to ensure confidentiality of the data source.

**II - Assessment of Antimalarial Quality in the Public and Private Sectors** (*see pages 16-18).*

**Deliverables**

- Assessment Report

**Outcome**

- Strengthened pharmaceutical management system in Ghana to support the malaria management program and implementation of the new antimalarial policy

**Timeline**

July – August 2004

## 1. General considerations

Sampling comprises the operations designed to collect samples of anti-malarial drugs, namely sulfadoxine-pyrimethamine tablets, amodiaquine tablets, and artesunate tablets.
Sample of any combination of the above three drugs (e.g. amodiaquine - artesunate) should also be collected when the two active are presented in one tablet.
Collect samples regardless of their strength.

### 1.1. *Purpose of sampling*

Samples will be tested for establishing antimalarial drug quality baseline in Ghana

### 1.2. *Testing methods and reference standards*

Tests and assays will be carried out according to major pharmacopoeia, USP, BP, EP and IP. The drug will be tested for Identity, dosage, dissolution and uniformity of dosage units. The testing procedures will be developed by USP DQI in collaboration with FBD laboratory.

### *1.3 Definitions*

In this contest a "*sample*" is 50 tablets of a selected drug from **the same lot/batch** (same manufacturer).

*Lot/batch*: a quantity of any drug produced during a given cycle of manufacture, under the same manufacturing conditions.

### 1.4. *Parties involved in sampling operations are ("Sampling Team"):*

- RPM Plus as team leader in addition to:
- FDB should be informed and one FDB staff must take part of the sampling
- An additional staff from the malaria control program

## 2. Sampling method and procedures

*2.1. Sample size*: The size of any sample should be sufficient to carry out all anticipated test procedures as per point 1.2. Samples will be collected in 2 sets (one for USP DQI and one for FDB laboratory). One sample consists of 50 tablets and two samples of each product will be collected, that is 100 tablets total per product from one lot/batch from the same source.

Sample obtained according to this sampling procedure will be packed, transported and stored in such a way to prevent any deterioration, contamination, and adulteration. Samples collected should be stored in accordance with storage instructions for the respective drug; closures and labels should be of such a kind that unauthorized opening can be detected.

Table 1: Drug sample names and size/quantity

| Item | Number of units to be collected (50 units for each lab) |
|---|---|
| Artesunate tablet | 100 |
| SP tablet | 100 |
| Amodiaquine tablet | 100 |

*2.2. Sampling record*: a written record of the sampling operations carried out is shown in Annex 1. This form has to be filled out and signed for each sample collected.

**3. General precautions to be taken during sampling operations**

All operations related to sampling should be performed with care. The "Sampling Team" should have at his or her disposal all the tools needed to open the packages, containers, etc., e.g. knives, pliers, sealable plastic bags and brushes to remove dust, and material to re-close the packages (such as sealing tape), as well as self-adhesive labels to indicate (note book, permanent marker, dark plastic bags) that a part of the contents has been removed from a package or container.

**4. Packaging and labeling of samples**

The container used to store a sample should not interact with the already sampled material nor allow contamination. The samples should be in their original "unit" packaging and labeling, if applicable. It should also protect the sample from light, air, moisture, etc., as required by the storage directions for the material sampled. As a general rule, the container should be sealed and tamperproof. The container must be properly labeled and contain the information as described in Annex 1. Drug samples should be kept at their original packaging. The total number of tablets should be fifty (50) per sample.

Appropriate care will be taken into account for adequate packaging to protect samples during transportation, either by totally filling the container with cotton batting or foam or by filling any residual space with a suitable material. All containers should be sealed and appropriately labeled.

**5. Transportation of samples to USP and FDB laboratories**: Adequate measures will be taken to ensure that samples are transported to the testing labs.

**Annex 1: Sample receipt form** **Serial number: _____**

*Two copies of this form should be produced and one copy to be kept with/attached to each of the sample set prior sealing the plastic bag.*

Name and address of place where sample is taken
……
……
……
……
……

Date of sampling: ……..

Names of the sample collector (s)
1…….
2……..
3…….

Name of the drug product
……
……
Dosage form (tablet, capsule, etc. ) …….
Batch number:……
Registration number (if applicable):……..
Name of the Manufacturer:……
Address of manufacturer: ……
Number of unit per sample……
Expiration date……
Manufacture date (if applicable) ……

Signature of the Sampling Team Leader
……..