# Rational Pharmaceutical Management Plus
# Consultative Meeting for Pharmacovigilance in Tanzania – A Planning Discussion: Trip Report

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Strategic Objective 5

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## About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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## Abstract

Dat Tran traveled to Dar es Salaam on 26 June, 2006 to discuss with the Centers of Disease Control and Prevention, Ifakara Health and Development Research Center, and USAID Mission to discuss the planning of a pharmacovigilance consultative meeting for the Tanzania Food and Drugs Authority.

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## Key Words

PMI, Pharmacovigilance, ADR, ACTs, TFDA

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# ACRONYMS

| | |
|---|---|
| ACT | Artemisinin-based Combination Therapy |
| ADR | Adverse Drug Reaction |
| AMR | Antimicrobial Resistance |
| MSH | Management Sciences for Health |
| QA | Quality Assurance |
| RPM Plus | Rational Pharmaceutical Management Plus |
| TFDA | Tanzania Food and Drugs Authority |
| USAID | United States Agency for International Development |

# BACKGROUND

In February 2006, RPM Plus/MSH received a request from USAID's Presidential Malaria Initiative (PMI) to provide support to the National Malaria Control Program (NMCP) for a number of activities, including pharmacovigilance, under USAID/PMI work plan in Tanzania. Two such activities are *"support to TFDA to undertake ADR monitoring"* and *"establish systems to detect unintentional exposure to artemether-lumefantrine during pregnancy."* Currently, there is limited experience with wide-scale use of this class of antimalarials, known as artemisinin-based combination therapy or ACTs, and therefore, its potential adverse drug reaction (ADR) in pregnant women.

The request for technical assistance from MSH/RPM Plus stems from its close and long-standing working relationship with TFDA, established through activities under the scope of pharmaceutical quality assurance (QA), initially funded through the Bill & Melinda Gates Foundation and now, by USAID core funds (SO5/AMR). This work has played an important role in reducing the circulation of poor quality pharmaceuticals, which can contribute to the threat of antimicrobial resistance (AMR).

As the first step, RPM Plus/MSH plans to organize a consultative meeting to assist TFDA gather ideas on how best to develop a cost-effective pharmacovigilance (PV) system to monitor ADR of ACTs in pregnant women.

RPM Plus/MSH's role will be to facilitate discussion between TFDA and participants to identify key ADR system components required to effectively monitor the use of ACTs in pregnant women in Tanzania. This discussion will draw from the experience of the Centers of Disease Control and Prevention (CDC)/Ifakara Health and Development Research Center (IHDRC), which has conducted pilot projects to monitor ADR of ACTs at the district level in Tanzania. Other key participants will also include PV programs of Ghana and Mozambique, countries with relevant experience in ADR of antimalarials in pregnant women. Specifically, the meeting will focus on issues relevant to ADR management system design

## Purpose of Trip

As a side trip from another trip to discuss QA activities in nearby Zambia, Dat Tran and Peter Risha (MSH Tanzania), both Senior Program Associates, went to Dar es Salaam to meet CDC/IHDRC and USAID Mission to discuss planning details for the upcoming pharmacovigilance consultative meeting in Dar es Salaam.

## Scope of Work

The scope of work for Drs. Tran and Risha on this trip was to:

- Meet with CDC/IHDRC to discuss the planning of the consultative meeting, as well as general pharmacovigilance activities in Tanzania
- Meet with USAID PMI coordinator in Tanzania to discuss the planning of the consultative meeting and implications of pharmacovigilance activities for PMI

Under this scope of work, the specific objectives included:

- To learn about CDC/IHDRC pharmacovigilance activities in Tanzania and explore potential areas of collaboration to address challenges in ADR of ACTs in pregnant women

# ACTIVITIES

## Visit to CDC/IHDRC

Dr. Patrick Kachur

The RPM Plus team met with Dr. Patrick Kachur of CDC/IHDRC to seek his input on the planning of the pharmacovigilance consultative meeting for TFDA. The team also shared with Dr. Kachur the tentative agenda for the meeting.

Specifically, the team discussed with Dr. Kachur his center's pharmacovigilance activities, especially those involving the monitoring of ADR of ACTs in Rufiji district in southern Tanzania. The partners identified several key areas for collaboration, including training of district-level health workers to improve passive and active ADR reporting, as well as developing guidelines and standard operating procedures (SOPs) for ADR information gathering processes.

Overall, Dr. Kachur was fully supportive of the meeting and its approach. He said the meeting would provide momentum for TFDA and partners to discuss pharmacovigilance, especially as it has broad implications for malaria national treatment policy: Tanzania will adopt ACTs as the first-line treatment for malaria starting in October 2006. The key points of the discussion are as follows:

- CDC thinks MSH should play a key role in facilitating and helping TFDA to monitor unintended exposure to ACT, citing a strong working relationship with TFDA as the key reason
- CDC is enthusiastic about partnering with MSH and TFDA to strengthen overall PV programs in Tanzania
- With regard to the planned consultative meeting, CDC agrees with MSH's assessment that TFDA does not need technical help, i.e., TFDA has extensive knowledge of technical issues of PV. Rather, TFDA needs help to build momentum and this meeting would serve that purpose, where TFDA can learn hands-on experience from other countries that have similar challenges
- CDC agrees that Ghana and Mozambique are appropriate participants – they have direct experience in monitoring antimalarials in pregnant women
- CDC also agrees that exposure to ACTs by pregnant women needs to be addressed now and cannot wait until national PV programs are in place. Much is unknown about ADRs of ACTs (e.g. unlike sulfadoxine-pyramethamine or SP with known ADR [Stevens-Johnson syndrome] commonly observed)

Dr. Kachur also shared some key observations from CDC/IHDRC studies in Tanzania:

- During the course of the study, CDC/IHRDC found a lack of ADR forms to be a problem in areas of activities: Rufiji, Kilombero, Ulanga districts and Mtwara and Lindi regions. The forms are not available in the peripheral health facilities (HF) even at regional and district hospitals. There is no functioning system for distribution, collection and transfer to

the TFDA. In addition, majority of the health workers (HW) were not aware on the need and importance of ADR reporting

- To improve ADR reporting, CDC/IHRDC contacted TFDA to obtain the forms and distribute to the districts and HFs and provided a coordinator to the facilities to collect the forms and visited HFs in periphery
- Assist Council Health Management Team (CHMT) to train HW from peripheral health facilities on PV, ADR (especially on sulfadoxine-pyrimethamine) and how to manage ADR cases
- Provided refresher training to the HWs after a 2-year interval
- As a result of this intervention planned by the CDC/IHRDC, TFDA has received much more ADR reports from the study area compared to other regions in the country

**Visit to PMI Coordinator in Tanzania**

Dr. Rene Salgado

The team briefed Dr. Salgado on the planning of the pharmacovigilance meeting. Dr. Salgado emphasized the need to use pharmacovigilance to establish a safety profile for ACT use. He also pointed out the need to put small-scale and feasible intervention in place, with clear and measurable results. The key points drawn from the discussion include:

- USAID Mission agrees that ADR monitoring of ACTs in pregnant women (and PV in general) is a small (budget-wise), but important, project. This is reflected in the fact that PV was added to the PMI work plan – it was not in the original work plan
- Mission is supportive of the meeting being planned and would like more work plan details after the workshop, including list of participants, planned activities, and budget
- Mission agreed with MSH that approach should be on small scale; something achievable within 2 years

## Collaborators and Partners

The key collaborators and partners on this visit were:

- Dr. Peter Risha, MSH Tanzania
- Dr. Patrick Kachur, CDC/IHDRC
- Dr. Rene Salgado, PMI Coordinator, Tanzania

# NEXT STEPS

## Immediate Follow-up Activities

- MSH will finalize the meeting agenda and share it with CDC/IHDRC for input