

## **A Consultative Meeting to Improve Surveillance of Antimalarials in Tanzania: Trip Report**

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July 2006



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Strategic Objective 5

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**

RPM Plus works in more than 20 developing and transitional 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.

## **Abstract**

Amelia Burke, Edmund Rutta, and Dat Tran traveled to Dar es Salaam, Tanzania to facilitate a 2-day consultative meeting between the Tanzania Food and Drugs Authority and key partners, including pharmacovigilance experts from the Centers for Disease Control and Prevention, Ghana, and Mozambique, to improve the surveillance of antimalarials in Tanzania.

## **Recommended Citation**

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Burke, A., Rutta, E. and Tran, D. 2006. *A Consultative Meeting to Improve Surveillance of Antimalarials in Tanzania*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

## **Key Words**

ACTs, ADRs, Pharmacovigilance, PMI, TFDA

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## ACRONYMS

ACT	Artemisinin Combination Therapy
ADDO	Accredited drug dispensing outlet
ADR	Adverse Drug Reaction
AMR	Antimicrobial Resistance
AS	Artesunate
AQ	Amodiaquine
CDC	Centers for Disease Control and Prevention
CIMed	Center for Drug Information
DHMT	District Health Management Team
DIC	Drug Information Center
DRA	Drug Regulatory Authority
DTCs	Drug and Therapeutic Committees
IPTi	Intermittent Preventive Treatment in infants
ISoP	International Society of Pharmacovigilance
LLD	Large Linked Database
MSH	Management Sciences for Health
MoH	Ministry of Health
PMI	Presidential Malaria Initiative
PV	Pharmacovigilance
RPM Plus	Rational Pharmaceutical Management Plus Program
SP	Sulfadoxine-Pyrimethamine
STGs	Standard Treatment Guidelines
TADATIS	Tanzania Drug and Toxicology Information Services
TFDA	Tanzania Food and Drugs Authority
USAID	United States Agency for International Development
WHO	World Health Organization
ZDICs	Zonal Drug Information Centers



## **BACKGROUND**

Recently, USAID Mission in Tanzania, under the Presidential Malaria Initiative (PMI), requested assistance from RPM Plus, Management Sciences for Health (MSH) to support the Tanzanian Food and Drugs Authority (TFDA) monitor adverse drug reaction (ADR) of the antimalarial artemisinin-based combination therapy (ACTs) in pregnant women in Tanzania. Currently, there is limited experience with wide scale use of ACTs and therefore, safety profile in pregnant women is not yet known.

The ability to monitor and report ADRs of ACTs, and medicines in general, requires a functional pharmacovigilance (PV) system. An effective PV system is critical to ensuring that medicines are safe and effective – it does this by monitoring not only ADRs, but also medication errors as well as product quality. Combined, these factors have serious implications in the development of antimicrobial resistance (AMR).

To address this issue, the malaria and AMR programs of RPM Plus/MSH organized a consultative meeting as the first step to assist TFDA gather ideas on how best to develop a cost-effective pharmacovigilance (PV) system to monitor ADR of ACTs in pregnant women by focusing on Tanzania's ADR reporting structure, specifically, its design and management.

The key objectives of the meeting included: (1) share experience and key lessons learned from ADR monitoring of antimalarials in pregnant women in Ghana and Mozambique; (2) identify gaps in ADR monitoring system of ACTs in Tanzania; and (3) identify key elements for the design of a cost-effective PV system to monitor ADR of ACTs in pregnant women (and other medicines in the future).

The meeting consisted of presentations from key partners, followed by small group discussions. RPM Plus facilitated these discussions between TFDA and relevant partners to identify key ADR system components required to effectively monitor the use of ACTs in pregnant women in Tanzania. The meeting discussion drew from TFDA's PV activities and other partners' experience in ADR monitoring of antimalarials: CDC in Tanzania and PV programs of Ghana and Mozambique.

### **Purpose of Trip**

Dat Tran, Senior Program Associate and Amelia Burke, Communications Associate, of RPM Plus traveled to Dar es Salaam to attend and facilitate a 2-day consultative meeting between TFDA and key partners to improve the ADR reporting of ACTs (and other antimalarials) and the overall pharmacovigilance system in Tanzania.

## **Scope of Work**

The scope of work for Dr. Tran on this trip was to:

- Undertake preparatory planning meetings for Pharmacovigilance (part of RPM Plus/PMI work plan)
- Participate and facilitate discussion in a pharmacovigilance consultative meeting between TFDA and other stakeholders (July 21-22, 2006)
- Provide an arrival briefing and/or departure debriefing to USAID upon request

The scope of work for Ms. Burke on this trip was to:

- Attend Pharmacovigilance meeting
- Distill key issues from presentations and discussion and put them down on a paper precisely and concisely
- From this, develop a product to clearly articulate MSH/RPM Plus' approach and what it has to offer in anticipation of the implementation phase and our future strategic position
- Product must ultimately –
  - Consider practical issues for implementation, consistent with available resources and defined objectives
  - Clearly outline the most crucial elements of a PV program and accordingly, define a plan consistent with available resources
- Provide an arrival briefing and/or departure debriefing to USAID upon request

## ACTIVITIES

**Summary of presentations/presenter** (the meeting agenda is included in Annex I)

### Designing Sustainable Pharmacovigilance Systems/Dat Tran

The MSH presentation suggested 2 key considerations for designing a cost-effective PV system, including:

- Assessment of available resources and mechanisms to prioritize use of future resources
- Use of standardized processes and practices to develop a model program, which can be replicated elsewhere

The presentation also focused on the need for a PV system to be built on a solid foundation with clear communication and reporting channels and feedback loops that ultimately leads to an appropriate response by Drug Regulatory Authority or DRA (regulatory, managerial, educational, etc.). In this context, an effective national PV system requires DRA to play a central leadership role to:

- Facilitate and supervise response to adverse events
- Supervise and coordinate activities with national PV and other partners: public health programs, universities, procurement agencies, hospitals, health facilities, therapeutic committees, and media and advocacy groups
- Develop and integrate standardized processes (e.g. use of guidelines, SOPs, etc.) for ADR reporting structure nationally, including those of public health programs

### Pharmacovigilance System in Tanzania/Henry Irunde

In its presentation, TFDA outlined the origin of the country's PV system, followed by its current developments, weaknesses, and challenges.

The national PV system in Tanzania was first established in 1989 as a drug information center (DIC) – known as Tanzania Drug and Toxicology Information Services or TADATIS – in Muhumbili National Hospital. Among the key functions of TADATIS were promoting, reporting, and analyzing ADRs, with reports submitted to WHO. In addition, it also provided drug information and education for the public and healthcare workers about rational use, prescribing, etc. through radio, TV, bulletins, newspapers, etc.

In 1998, TADATIS was incorporated into MOH to be part of TFDA, where a risk analysis section (for PV) was established under the Directorate of Inspection and Surveillance. At the lower level, TFDA has since established 4 zonal drug information centers (ZDICs): Dar es Salaam (Muhumbili); Bugando; Mbeya; and Kilimanjaro.

TFDA has supported ZDIC activities by purchasing computers, as well as providing PV awareness training for healthcare professionals. SOPs for ADR data handling have been developed for these ZDICs and the PV unit within TFDA.

However, under-reporting remains a huge challenge due to the following factors:

- Lack of cooperation from healthcare professionals
- Lack of reporting by pharmaceutical industry (not mandatory)
- Lack of priority setting, within TFDA and public health programs
- Lack of technical and financial resources
- Weak organizational structure, leading to uneven distribution to and collection of ADR forms (“yellow card”) from health facilities

To improve its PV system, TFDA plans to carry out these activities:

- Incorporate PV into healthcare teaching curricula
- Institute mandatory ADR reporting by pharmaceutical industry
- Increase collaboration with public health programs within MOH
- Increase ADR awareness among health professionals
- Make ADR forms (“yellow card”) available to each health facility nation wide
- Establish more zonal DICs

*Monitoring Adverse Drug Reactions in Southern Tanzania*/Prof. David Schellenberg

CDC/IHRDC presented their work under the Intermittent Preventive Treatment in infants or IPTi initiative, which examines the use of sulfadoxine-pyrimethamine (SP) in the Lindi and Mtwara regions. Their activities centered around 2 reporting-related components:

- Yellow card system – design, training, follow up & reports
- Linked database approach

A 2-day training program was designed to: (i) identify “ADR Monitors” from each district health management team (DHMT) and each hospital (day 1) and (ii) train staff from health facilities (1/dispensary; 2/health center). Overall, it took 2 months to train staff from all 135 health facilities.

For post-training follow up, the project ADR coordinator visited the DHMT ADR coordinator at least once every 3 months to check the following:

- Presence of trained person and ADR file
- Confirmation of last ADR identified
- Follow up on any un-reported ADRs
- Discuss with staff to hear comments and problems

After one year of implementation, there have been 47 ADR reports, 5 for age 2 and below with the rest coming from infants over 2 years of age. The key lessons learned thus far include:

- Broad reporting criteria (all drugs, all ages) leads to increased number of reports
- There is a great need in maintaining staff awareness, especially site visits
- There is a need to prioritize follow up responses

The second component of CDC/IHRDC ADR activity, large linked database (LLD), aims to generate safety data through routine collection of health information, e.g. recorded at time of vaccination/IPTi, outpatient attendance, laboratory attendance, etc. by linking databases together. This approach is modeled after those used in the US and UK.

LLD offers some advantages over yellow card, namely it does not depend on:

- Clinician considering and recognizing ADR
- Clinician completing ADR report form

However, it is resource-intensive and it is not clear if it can be applied widely. Furthermore, considerations must be given to statistical approach for ADR signal identification, follow up of signals, and quality (and detail) of clinical data.

### *Pharmacovigilance in Mozambique/Dr. Esperance Sevene*

In Mozambique, the national PV center, located in the center for drug information (CIMed), was implemented in 2003. The center was intended to be a focal point for ADRs of all medicines (by spontaneous reporting using yellow card) and to encourage all health care providers to report.

The key features of the approach used by Mozambique program include:

- Adoption of a step-by-step approach toward implementation, beginning with pilot phase in 2 districts (Namaacha and Mtutuine)
- Formed close collaboration with the malaria control program right from the beginning

Among the specific activities implemented to strengthen the PV are:

- Developing ADR reporting form, using simple language with limited essential questions
- Developing a guidebook, which includes a case study and how to fill out ADR form
- Training health professionals (to date, 10 districts of Maputo Province (capital area) and 6 sentinel sites from malaria control program have received training)
- Providing quality assurance visits at least once a month (to check if staff knows where forms are stored, how to fill out form, flow of information, etc.)

As a result, about 400 health professionals have been trained about ADR reporting. The PV unit has received about 130 reports, mostly from technicians and nurses. The ADRs reported are related to medication errors, rational use, and treatment failure, perhaps product quality.

The challenges for the Mozambique PV program are:

- Flow of information – getting feed back information and reports sent to CIMed remain barriers
- Under-reporting – site visits and the use of PV bulletins have to be emphasized to increase awareness
- Expansion to national level, including collaboration with other public health programs (HIV/AIDS, immunization, etc.)

Some general conclusions about spontaneous reporting can be drawn for Mozambique:

- Health professionals from different levels are able to implement PV system.
- However, implementation has to be adapted to the reality of each district
- Training and supervisory site visits are critical to improve and stimulate reporting
- Collaboration with malaria and other public health programs should be used to expand and sustain PV system

In addition to spontaneous reporting, the Mozambique presentation also touched on recent “active” surveillance or cohort studies to intensely monitor the use of antimalarials for treatment and prophylaxis during pregnancy in Manhica district. Protocols have been developed to monitor specifically, the use of SP + AQ (amodiaquine) combinations. These protocols cover: recruitment of pregnant women during admission; how information about antimalarials and all other medicines used are recorded; assessment of effect of SP + AQ on both mother and baby, where the child is assessed at delivery time, first and twelfth month after delivery.

The current challenge in Mozambique now is to revise the protocols for ACTs, the newly adopted first-line antimalarial. Efforts are also geared toward carrying cohort studies in areas where demographic surveillance is available, for the purpose of follow up.

*Ghana Pharmacovigilance & Progress Indicators* /Dr. Alex Dodoo

In its presentation, Ghana outlined its approach toward PV, key success factors, and challenges. Also discussed were studies to monitor ADRs of antimalarials, including ACTs.

The National Pharmacovigilance Center was established in 1998 and became part of WHO program for International Drug Monitoring in 2001. It is currently located within Department of Clinical Pharmacology & Therapeutics, University of Ghana Medical School. The centre promotes ADR reporting through:

- Distribution of ADR forms to institutions, with proper training
- Use of mass media – TV/radio programs, newspapers. This includes training of reporters to ensure that drug safety information are accurately reported to avoid public confusion
- Participation in national initiatives on rational drug use involving Drug and Therapeutic Committees (DTCs), development of drug formularies and standard treatment guidelines (STGs)
- Active collaboration with WHO (Uppsala Monitoring Center) and participation in National Centres meeting and International Society of Pharmacovigilance (ISoP)

The above mentioned approach has been instrumental in the success of implementing a national PV program. Other important key success factors include:

- Wide consultation and conveyance of a sense of ownership among leaders in medicine, pharmacy, and nursing
- Persistence – repeat PV message anytime, everywhere, and anywhere
- Interaction and collaboration with existing public health programs
- Advocacy with policy makers, academics, and health professionals

Despite a comprehensive approach, there remain many challenging issues, including:

- Establishing a good working relationship with the national drug regulatory agency
- Debate over independent or interdependent status of national PV program
- Lack of financial support
- Managing tension between science and politics
- Lack of legal basis for pharmacovigilance
- A priori determination of what to do with PV findings

- Undue influence of pharmaceutical industry

The Ghana experience indicated that it was important to include PV right from the beginning in any policy review and subsequent policy change. This was the case in Ghana when first-line antimalarial was changed from chloroquine to ACTs (artesunate/amodiaquine or AS/AQ). The need for monitoring was critical in the context of public perception regarding the safety of newly introduced ACTs. To address this issue, the government also conducted media briefing to present an unbiased risk/benefit analysis, including potential side effects of ACTs, for the popular press.

For the monitoring of ACTs, simplified ADR forms were developed in close consultation with district health workers. People were encouraged to report by ADR reporting form or by telephone, which was made available widely through radio and TV. As the result, over 50 cases of ADRs due to AS/AQ have been reported to the national center.

In summary, some key lessons can be drawn from Ghana PV:

- PV must play a key role in policy decision making, especially when introducing new medicines
- Both routine PV (ADR reporting) and intensive monitoring (in selected health facilities, pharmacies) are important for PV
- The National PV program must play a leadership role in conveying the risk/benefit analysis of medicines to the public
- A key component of ADR monitoring must include product quality – the public must have confidence that medicines being used are safe and of good quality

### **Highlights from group discussion**

The 3 breakout groups were asked to address the following key questions:

1. How do we design a PV system that combines both passive and active surveillance to increase ADR reporting in Tanzania?
2. How do we use the existing PV structure (ZDICs, CDC/IHRDC district research projects) to increase ADR reporting at the District level?
3. What strategies should TFDA adopt to increase awareness in drug safety monitoring for both health professionals and lay public?

Some practical considerations emerged from all 3 discussion groups, highlighting the need for the PV program to improve operationally. Taken together, they map out a path for TFDA to address specific needs to improve its ADR reporting system:

- In a resource-limited environment, priority should be to strengthen passive surveillance (spontaneous reporting) for routine PV
- Active surveillance should be used selectively to determine “denominator” drug safety data (i.e. baseline). This is especially crucial when a policy change is considered, e.g. change in STGs
- National PV program needs to network with active surveillance studies in the country – through public health programs, universities, hospitals, research centers, CDC/IHRDC,

- etc. – to leverage technical and operational resources
- The key gap in the ADR reporting structure is the lack of communication and reporting linkage between the district level and central PV unit – the current ZDIC system operates on a voluntary basis, with clear roles and responsibilities defined for ZDIC officers
  - The processes used for the distribution, completion, and collection of ADR forms should be standardized to improve reporting consistency
  - TFDA should consider “training of trainers” approach to build ADR awareness at district level. Use of existing district-level programs, e.g. ADDO, should be considered a mechanism to raise awareness
  - TFDA should use simple language to develop key messages about ADR for both health professionals and lay public, especially through mass media

### **Discussion with TFDA about Proposed partnership and activities**

After the meeting, the RPM Plus team, including Dr. Edmund Rutta and Dr. Peter Risha, both RPM Plus Senior Program Associates, met with Ms. Margareth Sigonda, Director General of TFDA to discuss the general approach and next steps.

The group emphasized the consensus of the participants:

*A key gap in the ADR reporting system is at the district level – there is a lack of well-defined communication/reporting channels between the district (where the majority of ADR reports are expected, i.e. DHMT, health facilities, etc.) and central levels (PV unit of TFDA).*

To address this gap, two major activities are proposed:

1. Strengthening passive surveillance (see ADR reporting scheme in Annex II)

It is proposed that MSH/RPM Plus, TFDA, and CDC/IHDRC form a partnership to develop activities to address the following key objectives:

- Assist TFDA in strengthening its ADR report system at the district level
- Collaborate with CDC/IHDRC to identify ways to improve surveillance methods to monitor ADR of ACTs in pregnant women

To achieve these objectives, it is proposed that the following activities be developed in 2 districts, 1 each in Ruvuma and Morogoro regions, to:

- Improve the ADR reporting system at the district level by focusing on the crucial linkage of: DHMT (especially district pharmacist), health facilities, ADDOs
- Improve the ADR information flow between levels by providing training in guidelines and SOPs for ADR form distribution and collection

2. Strengthen an “active” surveillance network

Currently, there is weak coordination between TFDA and active surveillance research projects throughout the country, e.g. at hospitals, research centers, universities, etc. To take advantage of these existing resources:

- It is proposed that a pharmacovigilance advisory group be formed – or if one already exists, its mission revised to emphasize PV – to advise senior TFDA management and MOH on important policy decisions related to safety of medicines.

#### Expected outcomes

The successful implementation of these activities in the pilot districts will help to define a suitable and cost effective PV model that may be rolled out in into other districts, thus enhancing the oversight capability of TFDA in monitoring safety of medicines in the country.

#### **Collaborators and Partners**

Ms. Margareth Sigonda, Director General, TFDA

Ms. Charyss Ugullum, Director, Laboratory Services, TFDA

Dr. Alex Dodoo, National Pharmacovigilance Center, Ghana

Dr. Esperanca Sevene, National Pharmacovigilance Center, Mozambique

Dr. Peter Risha, MSH Tanzania

Dr. Edmund Rutta, RPM Plus/MSH, USA



## **NEXT STEPS**

### **Immediate Follow-up Activities**

- RPM Plus will provide TFDA with more details about the proposed activities and their timeline

### **Recommendations**

- Pharmacovigilance has increasingly become a high priority for many countries in recent years. The common problem among many countries is the lack of an ADR reporting structure, especially linkage between the district level and the central PV program. Collaboration between partners with specific technical expertise in PV and management system building is crucial for implementing practical and functional PV systems.

### **Agreement or Understandings with Counterparts**

- RPM Plus, CDC/IHDRC, and TFDA will together develop strategies to implement proposed activities to strengthen ADR reporting, including training of health workers at district level on SOPs

### **Important Upcoming Activities or Benchmarks in Program**

- RPM Plus will use the meeting as a spring board to develop a general “how to” guide to assist countries in the region and beyond to develop cost-effective PV systems. The guide will focus on key system management issues, both on technical and operational levels. The guide will also emphasize a regional approach and how countries can best leverage their resources to design a functional PV system.

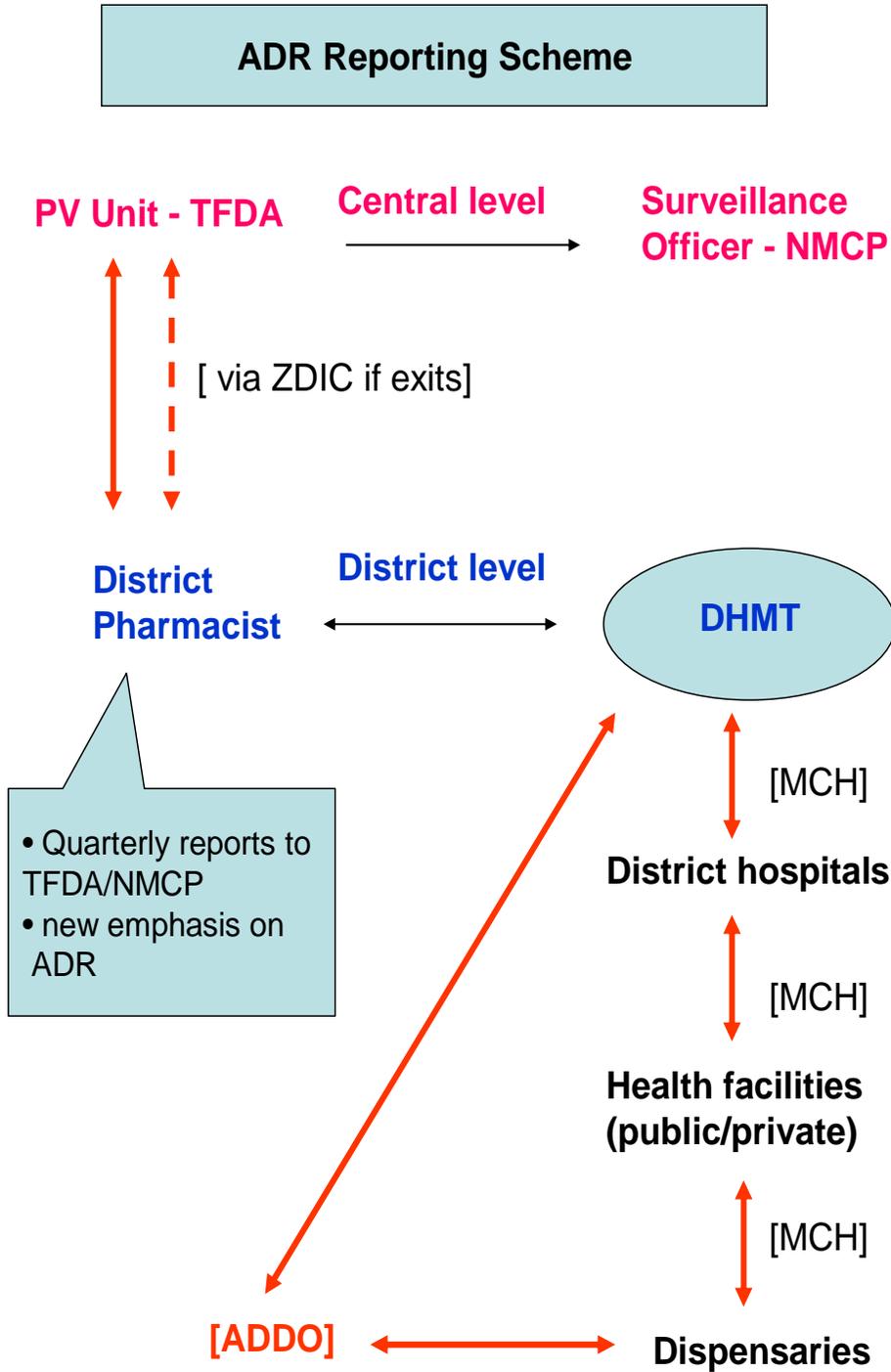


## ANNEX 1. MEETING AGENDA

<b>Day 1</b>		
Time	Topic	Presenter
9:00 – 10:00	Introduction/Opening remarks	<i><b>MOH/NMCP/TFDA</b></i>
10:00 – 10:15	<b>Break</b>	
10:15 – 10:30	<ul style="list-style-type: none"> <li>• Building sustainable pharmacovigilance systems</li> </ul>	<i><b>MSH</b></i>
10:30 – 11:15	<ul style="list-style-type: none"> <li>• Structure and function of Tanzania PV</li> </ul>	<i><b>TFDA/PVP</b></i>
11:15 – 12:00	<ul style="list-style-type: none"> <li>• Review of past and on-going PV activities in Tanzania</li> <li>• Assessment of current ADR reporting of ACTs and other medicines</li> <li>• PV of ACTs and other antimalarials</li> </ul>	<i><b>TFDA consultant</b></i>
12:00 – 12:45	<ul style="list-style-type: none"> <li>• ADR reporting in Tanzania</li> <li>• Key lessons learned from SP/artesunate study</li> </ul>	<i><b>CDC/IHDRC</b></i>
12:45 – 14:00	<b>Lunch</b>	
14:00 – 14:45	Mozambique experience: <ul style="list-style-type: none"> <li>• ADR of antimalarials in pregnant women</li> <li>• Successes and challenges of PV management system</li> </ul>	<i><b>Dr. E. Sevene</b></i>
14:45 – 15:30	Ghana experience: <ul style="list-style-type: none"> <li>• ADR of antimalarials in pregnant women</li> <li>• Successes and challenges of PV management system</li> </ul>	<i><b>Dr. A. Dodoo</b></i>
15:30 – 16:30	<ul style="list-style-type: none"> <li>• Summary of lessons learned</li> <li>• Application of lessons learned to address ADR of ACTs in Tanzania</li> </ul>	<b>All participants</b>

<b>Day 2</b>		
<b>Time</b>	<b>Topic</b>	<b>Presenter</b>
8:30 – 9:00	<ul style="list-style-type: none"> <li>• Critical PVP elements of Tanzania: gaps and key areas of improvement</li> <li>• How to apply lessons learned from other PV programs</li> </ul>	<i>TFDA</i>
9:00 – 11:00	<p>Key elements for designing cost-effective PV system to monitor ADR of ACTs in pregnant women in Tanzania</p> <ul style="list-style-type: none"> <li>• Level of intervention: site and scale</li> <li>• ADR communication and reporting network</li> <li>• Resources</li> <li>• Training</li> </ul>	<p><i>Group facilitators</i></p> <p><u><i>Group I: CDC</i></u>  <u><i>Group II: Ghana</i></u>  <u><i>Group III: Mozambique</i></u></p>
11:00 – 11:15	<b>Break</b>	
11:15 – 12:30	<ul style="list-style-type: none"> <li>• Group I recommendations</li> <li>• Discussion/Q&amp;A</li> </ul>	<i>Group facilitator</i>
12:30 – 13:45	<b>Lunch</b>	
14:00 – 15:15	<ul style="list-style-type: none"> <li>• Group II recommendations</li> <li>• Discussion/Q&amp;A</li> </ul>	<i>Group facilitator</i>
15:15 – 16:30	<ul style="list-style-type: none"> <li>• Group III recommendations</li> <li>• Discussion/Q&amp;A</li> </ul>	<i>Group facilitator</i>
16:30 – 16:45	<b>Break</b>	
16:45 – 18:00	<ul style="list-style-type: none"> <li>• Consensus on critical PV elements for TFDA</li> <li>• Future collaboration areas between partners (human/tech. training)</li> <li>• Wrap Up: final words from TFDA</li> </ul>	<i>All participants</i>

**ANNEX 2. PROPOSED ADR REPORTING SCHEME FOR TFDA**





### ANNEX 3. LIST OF PARTICIPANTS

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